Guide to categorising your chemical importation and manufacture

All industrial chemical importers and manufacturers must categorise their chemical introduction. This step-by-step guide takes you through the process of categorisation.

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Version history

Version	Description	Date

2.3	**Step 4.1 and Step 5.1** The draft OECD TG 125 on particle size and particle size distribution on nanomaterials is now final and part of our guidance. We've updated the content related to nanoscale introductions as a result. **Step 6** Clearer instructions on how to use the health and environment risk to work out the introduction category.	30 May 2023
2.2	**Step 3 - Introductions that are in the reported category** Provided more clarity around 3.2 Low-risk flavour and fragrance blend introductions regarding human health hazard characteristics and environmental hazard characteristics requirements.	17 February 2023
2.1	**Step 3 - Introductions that are in the reported category** Added the following 2 chemicals to question 2, part 3.1 Introductions of 10 kg or less in an AICIS registration year. Benzene, 1,2,3,4,5-pentachloro- CAS no. 608-93-5 Benzene, hexachloro- CAS no. 118-74-1	8 February 2023

2.0	**Step 0 - Introductions that are in the listed category** Improvements made to the page around next steps if you have categorised your introduction as listed by adding links to a new page in the guide 'Your obligations after categorisation'. **Step 2 - Introductions that are in the exempted category** Improvements made to the page around next steps if you have categorised your introduction as exempted by adding links to a new page in the guide 'Your obligations after categorisation'. **Step 3 - Introductions that are in the reported category** Criteria added for a new type of low-volume reported introduction of 10 kg or less per year. We've also provided more clarity around next steps depending on the outcome at step 3. This includes adding links to a new page 'Your obligations after categorisation' if an introducer has categorised their introduction as reported at this step. **Step 6 - Complete your categorisation** We've moved some content on this page on reporting and record-keeping obligations to the new page 'Your obligations after categorisation'. **Your obligations after categorisation** This new page gives an overview about reporting and record-keeping obligations for introducers after they've categorised their introduction as one of the following: • listed • exempted • reported	25 November 2022

- assessed

1.4	**Steps 4.1 and 5.1 – Is your chemical a certain chemical at the nanoscale?**	30 March 2022

More options added in a question and answer format to help introducers work out if they are introducing this type of chemical.

Steps 4.1 and 5.1 – Where an introduction is a specified class of introduction

More information added, including when introductions are specified classes, our concerns about them, and that extra information will be required from introducers when submitting an assessment application for a specified class of introduction.

Content has been added under these headings:

- Does your chemical contain a sequence of 4 to 20 fully fluorinated carbon atoms (including per- and poly-fluorinated alkyl substances, known as PFAS)?
- Is your chemical a certain polyhalogenated organic chemical?
- Is your chemical a certain chemical at the nanoscale?
- Is your chemical a certain gas? (step 5.1 only)

Steps 4.5 and 5.5 – Special cases - introductions that cannot have a very low indicative human health risk and introductions that cannot have a very low indicative environment risk

Added this extra point to make it clear this type of chemical cannot have a very low indicative risk for human health or the environment:

'OR

- chemical that is introduced as a solid or a dispersion where there is no information available on its water solubility or its particle size, and the introduction of any nanoscale portion of

the chemical (the part that has a particle size range of 1nm to 100nm) is incidental to the introduction of the non-nanoscale portion'

Step 6 – Next steps: If your introduction is categorised as assessed

Added the next step required if the chemical is on the Inventory. Clarified the outcome when the chemical is not on the Inventory.

1.3	Step 1: added words shown in bold text: '...can not be categorised as an exempted or reported introduction **unless it is both of the following:** 1. **the industrial chemicals are to be introduced solely for use in research or analysis** 2. **the total volume of the industrial chemicals you introduce in a registration year does not exceed 100 kg**' Step 2: clearer explanation of the nanoscale criteria for research and development and chemicals resulting from non-functionalised surface treatment of listed chemicals; removed 'Tylosin, (2R,3R)-2,3-dihydroxybutanedioate (1:1)' with CAS number 74610-55-2 from the comparable chemicals table and improved the instructions on how to use the table. Step 3: clearer explanation of the nanoscale criteria for research and development. Step 5.3: added statement to clarify that a chemical with an end use in an air freshener is not a 'designated kind or release into the environment' **Correction: Environment hazard band A hazard characteristics.** Under bulleted list 'information that demonstrates that all of the following applies to the polymer:...' indented the following paragraphs to correctly align as follows: • information that demonstrates that all of the following applies to the polymer... ○ if it is a polymer that contains polyethylene glycol (PEG) functionalities and has a solubility in water of greater than 200 mg/L - measured data demonstrates that the polymer does not substantially biodegrade, and	23 November 2021

	○ if it is a polymer that contains polypropylene glycol (PPG) functionalities and has a solubility in water of greater than 200 mg/L - measured data demonstrates that the polymer does not substantially biodegrade.	
1.2	• New step : 'Step 0 - Introductions that are in the listed category' • Added 'Who is this guide for' in 'Before you start categorising your introduction' and removed information covered in step 0. • Removal: 'Information you need to work out your introduction category' (covered in Step 0) • Clearer guidance on outcomes and next steps in step 4.1 and 5.1. • More information in step 4.4 including restrictions on use of animal test data. • More information in step 5.4 including restrictions on animal test data. • Replaced references to checking the General Rules with more explanatory text. • More information about water treatment products and designated kind of release to the environment in the context of working out your environment categorisation volume.	28 May 2021
1.1	Replaced references to Categorisation Guidelines in step 4.4 and 5.4 with the details (from the Guidelines) about hazard bands; improvements and more information in 'Before you start categorising your introduction'. Added appendices: acceptable test guidelines for categorisation and in silico predictions for categorisation.	22 December 2020
1	Original	1 July 2020

Drawing on information in the IC Act, General Rules and the Industrial Chemicals Categorisation Guidelines, this practical step-by-step guide with supporting self-guided decision tools helps you categorise your chemical introduction as **listed** or **exempted** or **reported** or **assessed**.

In this guide

Before you start categorising your introduction

This guide does not cover how to categorise your introduction as a **commercial evaluation**. Under this category, you can apply for a time-limited commercial evaluation authorisation for the purpose of testing a chemical's commercial viability in Australia.

An overview of AICIS introduction categories. All introducers must categorise each chemical introduction into one of these categories.

Who is this guide for?

Anyone who plans to manufacture or import industrial chemicals (or products that contain industrial chemicals) into Australia for commercial, research or any business-related purposes.

This guide is designed to help you work out which AICIS introduction category applies to each of your chemical introductions.

Note: you don't need to use this guide or categorise your chemical introductions if it's only for personal or hobby use, or your introduction is a type that doesn't need to be categorised under our laws.

AICIS introduction categories

For mixtures or products containing more than one chemical ingredient, you must work out which of the categories below apply to each chemical introduction.

Listed introductions

A chemical introduction that is categorised as ‘listed’ means it is on our Inventory and already available for industrial use in Australia. Your business must be registered with us and you must meet any terms of the listing for that chemical. You must keep records and submit an annual declaration at the end of each registration year. There's no fee for listed introductions.

Exempted introductions

A chemical introduction that is categorised as ‘exempted’ means it meets a very strict set of criteria that is considered very low risk to both human health and the environment. If your introduction meets the criteria and you're already registered with us, you can introduce the chemical without telling us beforehand. You must keep records and submit an annual declaration at the end of each registration year. Some exempted introductions also require you to submit a once-off post-introduction declaration the first time that you introduce the chemical. There's no fee for exempted introductions.

Reported introductions

A chemical introduction that is categorised as ‘reported’ means it meets our criteria to be considered low risk to human health or the environment. You must be registered with us and submit a once-off pre-introduction report before you start introducing it. You must keep records and submit an annual declaration at the end of each registration year. There's no fee for reported introductions and no fee to submit a pre-introduction report.

Assessed introductions

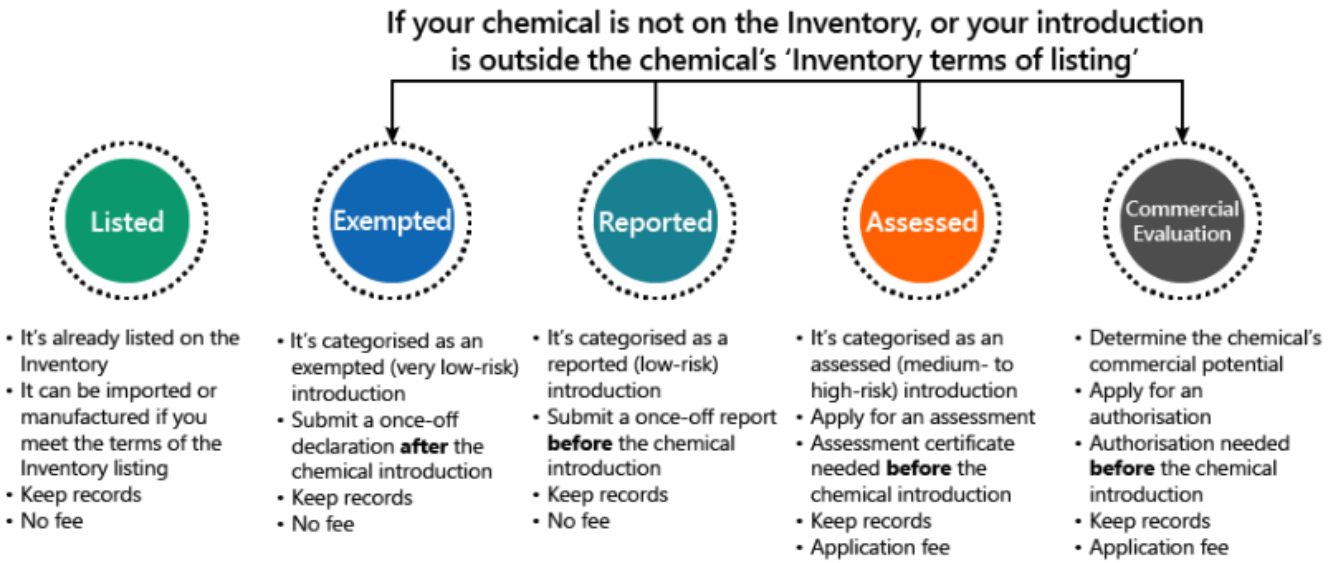
A chemical introduction that is categorised as ‘assessed’ means we consider it to be medium to high risk to human health or the environment. It cannot be in the exempted or reported categories. If the chemical is not on the Inventory, then we must assess your introduction and issue an assessment certificate before you can import or manufacture it. The chemical will be listed on the Inventory 5 years after we issue a certificate.

You must keep records and submit an annual declaration at the end of each registration year. There is a fee to apply for an assessment certificate.

Commercial evaluation

If you meet our commercial evaluation criteria, you can apply for a commercial evaluation authorisation as an alternative option to the exempted, reported or assessed category. The chemical will **not** be listed on the Inventory. You must keep records and submit an annual declaration at the end of each registration year. There is a fee to apply for a commercial evaluation authorisation.

The Minister can also authorise introductions under exceptional circumstances.



Next – Step 0: Introductions that are in the listed category

Step 0: Introductions that are in the listed category

Learn about our introduction categories in 'before you start categorising your introduction'.

Start by searching our Inventory

The Australian Inventory of Industrial Chemicals (Inventory) is an online database of industrial chemicals that are being manufactured or imported into Australia. Start by checking whether your chemical is listed on the Inventory.

If you have a mixture or product that contains more than one chemical, you must search for each one separately.

If you know your chemical's identity

Search the Inventory using your chemical's **CAS number**. If you don't know the CAS number or the chemical does not have an assigned CAS number, search the Inventory using the chemical's **CAS name** (using the keyword search).

Note: Some common names for chemicals are on the Inventory but your results will most likely be a very broad list of candidate chemicals.

If you don't know your chemical's identity

Ask your chemical identity holder (for example, your supplier) to search the Inventory for you. If they find the chemical on the Inventory, you should ask them to tell you if there are any terms or conditions described on the Inventory listing for your chemical.

Search the Inventory

No search results or too many results

Did you search using the chemical's CAS number?

If **no**, then we recommend that you search using the chemical's CAS number. The Inventory rarely contains a trade name, INCI name or product name so this is not the correct way to search for chemicals.

If **yes**, then check if it is one of these reasons:

1. The chemical meets our legal definition of a naturally occurring chemical - chemicals that meet this definition do not need to be on the Inventory.
2. It's a mixture (such as an alloy or hydrate) – the Inventory only contains names of chemicals, not mixtures.
3. You entered an incorrect CAS number or it doesn't match the CAS number format. For example you may have added a space between the numbers or hyphens.
4. You entered an outdated CAS number. Sometimes CAS replaces a chemical's CAS number with a new one, so you need to make sure that you're using the updated CAS number. You can check if you have an up-to-date CAS number for your chemical by searching chemical databases such as ChemIDPlus and SciFinder-n.

Still no result after searching the chemical's CAS number?

You can ask us to check if your chemical is confidentially listed on the Inventory. This is because there are some chemicals that are listed on the Inventory where the CAS name and CAS number are protected as confidential business information (CBI). If it is not confidentially listed on the Inventory, then you must proceed to Step 1 of the Categorisation Guide to work out your chemical introduction category.

Trade names, product names and INCI names

The Inventory is a database of chemicals, not products, mixtures or formulations. Therefore it does not contain product names, trade or marketing names and rarely contains INCI or common chemical names. We recommend finding a CAS number or CAS name for each chemical that you want to search. For example:

 Search using the CAS number or name	 Don’t search using trade or common names
107-21-1 / 1,2-Ethanediol 57-55-6 / 1,2-Propanediol	Antifreeze
144-55-8 / Carbonic acid, monosodium salt	Baking soda
77-92-9 / 1,2,3-Propanetricarboxylic acid, 2-hydroxy-	Citric acid
9005-25-8 / Starch	Corn starch
7487-88-9 / Sulfuric acid magnesium salt (1:1)	Epsom salt
56-81-5 / 1,2,3-Propanetriol	Glycerine
8000-28-0 / Essential oils, lavender	Lavender oil
13463-67-7 / Titanium oxide (TiO2)	Liquid paper

1310-73-2 / Sodium hydroxide (Na(OH))	Lye
68917-75-9 / Oils, wintergreen	Wintergreen oil

Important: These CAS numbers are examples only. It is the introducer's responsibility to correctly identify and know the chemistry of their introductions.

Naturally occurring chemicals

Introductions of naturally occurring chemicals do not need to be on the Inventory. You can import or manufacture naturally occurring chemicals without telling us, as long as they meet our definition of 'naturally occurring'.

Mixture

A mixture contains 2 or more component chemicals that don't react. You need to search the Inventory for each component chemical that make up the mixture, not the mixture itself. You can import or manufacture the mixture as long as their component chemicals are on the Inventory and you follow the regulatory obligations.

If you find your chemical on the Inventory

If you get a match, click on the link to view the chemical identity information and any regulatory obligations associated with that chemical. Take note of the information you see on the listing page and see the descriptions below to find out what to do next.

If your chemical is on the Inventory without specified regulatory obligations

This is when the chemical's 'Inventory terms of listing' only describes chemical identity information like the CAS name and CAS number and does not specify any requirements, conditions or a ‘defined scope of assessment’.

Your introduction is categorised as **listed**. Skip to 'Your obligations after categorisation'.

If your chemical is on the Inventory with a specific information requirement

Your introduction is categorised as **listed** but you must submit information about your introduction under certain circumstances. Skip to 'Your obligations after categorisation' to learn more.

If your chemical is on the Inventory with a defined scope of assessment

If your introduction is within the parameters of the defined scope of assessment, then your introduction is categorised as **listed**. Skip to 'Your obligations after categorisation'.

If your introduction is outside the parameters of the defined scope of assessment, you must do **one of the following** before you can introduce the chemical:

- continue with this guide to work out your introduction category – proceed to Step 1: Introductions that cannot be exempted or reported
- apply to vary the Inventory terms of listing (to change the parameters of the defined scope of assessment for that chemical's listing) and receive approval – fee applies

If your chemical is on the Inventory with a condition of introduction or use

If you plan to introduce the chemical within the boundaries of the specified conditions, then your introduction is categorised as **listed**. Skip to 'Your obligations after categorisation'.

If your introduction does not meet the conditions, you cannot introduce the chemical unless you submit an application and receive approval. **Next step:** apply to vary the Inventory terms of listing (fee applies).

If your chemical is not on the Inventory

If your chemical is not on the Inventory and you have confirmed that it isn't on the list under the heading 'No search results or too many results' then your introduction is **not** in the listed category. Proceed to Step 1: Introductions that cannot be exempted or reported.

Next - Step 1: Introductions that cannot be exempted or reported

Step 1: Introductions that cannot be exempted or reported

Do not continue with this guide if your introduction is in the 'listed' category. To work out if it's a listed introduction, go to step 0.

Some introductions are not eligible for the exempted or reported categories.

Chemicals listed in the Rotterdam Convention or Stockholm Convention

Industrial chemicals that are listed in Annex III to the Rotterdam Convention or Part 1 of Annex A, B or C to the Stockholm Convention can **not** be categorised as an exempted or reported introduction unless it is **both** of the following:

1. the industrial chemicals are to be introduced solely for use in research or analysis
2. the total volume of the industrial chemicals you introduce in a registration year does not exceed 100 kg

If you wish to trade (import or export) a chemical that is listed in Annex III to the Rotterdam Convention and in Section 71 or 73 of the Industrial Chemicals (General) Rules, you must apply in writing and pay a fee. This application process is known as the prior informed consent (PIC) procedure.

If you wish to introduce a chemical that is listed in Annex III to the Rotterdam Convention or Part 1 of Annex A, B or C to the Stockholm Convention but it is not listed in Section 71 of the Industrial Chemicals (General) Rules, your introduction is in the assessed category. You must apply for an assessment before you can introduce this chemical.

Introductions of tetraethyl lead

Tetraethyl lead is a highly toxic fuel additive and examples of use include aviation gasoline or use in the production of aviation gasoline. Although it is listed on the Inventory, the importation and exportation of tetraethyl lead is subject to special conditions.

If you wish to import or export tetraethyl lead, you must contact us before you introduce this chemical.

Chemicals listed on the Inventory but you don't meet the conditions of introduction or use

If your chemical is listed on the Inventory with a condition of introduction or use, you must ensure you can meet the conditions when you introduce the chemical.

An Inventory listing can include a condition about:

- the total annual volume of the chemical that you can introduce
- the location where you can introduce or use the chemical

If your introduction **does not meet** our conditions of introduction or use, it is **not** authorised under our exempted or reported categories. You will need to apply to vary the terms of the Inventory listing.

We must approve your application before you can start introducing the chemical.

If your introduction is not described on this page, go to step 2.

Next - Step 2: Introductions that are categorised as exempted

Step 2: Introductions that are categorised as exempted

Do you meet criteria on this page?

Certain chemical introductions are considered to be ‘very low risk’ to human health and the environment. These are called 'exempted introductions'. If your introduction meets the criteria on this page, it is categorised as exempted and you can stop at this step. You do not need to continue with categorisation steps 3, 4, 5 or 6. Reporting and record-keeping obligations also apply.

Our categorisation decision tool can also help you with step 2

Chemicals that are imported and subsequently exported

Your introduction is categorised as exempted if all of the following apply:

- the entire volume is imported and subsequently exported out of Australia
- the packaging in which your chemical is immediately contained is never opened
- whilst your chemical is in Australia, it remains under the control of either customs (for longer than 25 working days) or the introducer.

Note: if your chemical is under customs controls whilst in Australia and leaves Australia within 25 days, then your introduction is an excluded introduction.

Chemicals that are only used for research and development

Your introduction is categorised as exempted if **all** of the following apply (note that the volume of chemical that you can introduce in a registration year is lower, unless you can demonstrate that the nanoscale criteria do not apply to your introduction):

- you only use your chemical for research and development, or you make it available to another person who only uses it for research and development
- you don't make your chemical available to the public on its own, in combination with other industrial chemicals or as part of an article
- you use control measures to eliminate or minimise any risks to the environment and any risks to the people involved in using the chemical for research and development

and point **1 or 2 or 3** applies:

1. You will introduce up to 250kg of your chemical in a registration year and you can demonstrate that your chemical is not introduced as a solid or in a dispersion. To prove that your chemical is **not** introduced as a solid or in a dispersion, you might have an SDS or product information sheet that indicates the appearance (for example, in liquid form).

2. You will introduce up to 250kg of your chemical in a registration year and you can demonstrate that your chemical does **not** consist of particles in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the particle size range of 1 to 100 nm. To prove that your chemical does not consist of particles in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale, you might have a study report about the particle size distribution of your chemical.

3. You will introduce up to 10 kg of your chemical in a registration year.

Nanoscale criteria for R&D exempted category
If you meet the research and development criteria and your chemical is at the nanoscale, or you had not determined at the time of introduction that it is **not** at the nanoscale, your introduction can only be in the exempted category if you introduce 10kg (or less) in a registration year.

Learn more about categorising chemicals introduced for research and development

Polymers of low concern (PLC)

Your introduction is categorised as exempted if it meets the criteria for a polymer of low concern and it's not a high molecular weight polymer that has lung overloading potential.

Learn about PLC criteria

If you are introducing polymers of low concern, you must submit a once-off exempted introduction declaration by 30 November (following the end of our registration year).

Low-concern biological polymers

Your introduction is categorised as exempted if it's a low-concern biological polymer that meets **all** of the following criteria:

- the chemical is a biological chemical (that is, it's derived from, or produced by, a living or once-living organism)
- the chemical is a polymer
- the polymer meets most of the polymer of low concern criteria, except that it's not stable, meaning that it substantially degrades, decomposes or depolymerises during use into simpler, smaller weight chemicals

Examples of low-concern biological polymers are keratin and collagen. Enzymes are not polymers because of the lack of variability in molecular weight.

If you are introducing low-concern biological polymers, you must submit a once-off exempted introduction declaration by 30 November (following the end of our registration year).

Polymers that are comparable to listed polymers

Your introduction is categorised as exempted if ALL of the following apply:

- your chemical is a polymer
- your polymer contains exactly the same reactants (must have each of the reactants) as another polymer that is already listed on the Inventory
- your polymer contains one or more other reactants (the additional reactants) that the listed polymer does not
- each additional reactant is present at no more than 2% by weight of the polymer

You must also comply with any regulatory requirements associated with the listed polymer.

Chemicals that are comparable to listed chemicals

If you're introducing any of the chemicals in column B of the table below, your introduction could be categorised as exempted.

If your chemical is in the comparable chemicals table

If your chemical is in column B of the table, it means that it has a comparable chemical that is already listed on the Inventory. Go to column C of the same row to find it. Next, search for the comparable chemical on the Inventory using the CAS number in column C to check whether there are any regulatory requirements or obligations for the listed chemical.

If your search results show:

- there are no regulatory requirements for the chemical, your introduction is categorised as exempted
- there are regulatory requirements for the chemical and you can meet these requirements, your introduction is categorised as exempted
- there are regulatory requirements for the chemical, but you cannot meet these requirements and none of the other introductions described on this page apply to you, move onto step 3: Introductions that are categorised as reported.

If your chemical is not in the comparable chemicals table

If your chemical is not in the table below and none of the other introductions described on this page apply to you, move on to step 3: Introductions that are categorised as reported.

A. Item	B. Industrial chemical to be introduced	C. Comparable industrial chemical already listed on the Inventory
1	Aloe barbadensis, extract CAS number: 94349-62-9	Aloe vera, extract CAS number: 85507-69-3

A. Item	B. Industrial chemical to be introduced	C. Comparable industrial chemical already listed on the Inventory
2	Brassica oleracea botrytis, extract CAS number: 223749-36-8	Cabbage, extract CAS number: 89958-13-4
3	Brassica oleracea, extract CAS number: 91771-39-0	Cabbage, extract CAS number: 89958-13-4
4	Brassica oleracea gemmifera, extract CAS number: 1174275-27-4	Cabbage, extract CAS number: 89958-13-4
5	Fatty acids, palm-oil, sodium salts CAS number: 61790-79-2	Fatty acids, C14-18 and C16-18-unsaturated, sodium salts CAS number: 67701-11-5
6	Jojoba, extract CAS number: 90045-98-0	Jojoba oil CAS number: 61789-91-1
7	3,6,9,12,15,18,21,21,24,27-Nonaoxanonatriacontan-1-ol CAS number: 3055-99-0	Poly(oxy 1,2-ethanediyl), α-dodecyl-ω-hydroxy CAS number: 9002-92-0
8	Matricaria recutita, extract CAS number: 84082-60-0	Oils, Chamomile, German CAS number: 8002-66-2

A. Item	B. Industrial chemical to be introduced	C. Comparable industrial chemical already listed on the Inventory
9	Orange, extract CAS number: 84012-28-2	Orange, sweet, extract CAS number: 8028-48-6
10	Pelargonium roseum, extract CAS number: 90082-55-6	Pelargonium graveolens, extract CAS number: 90082-51-2
11	Soya lecithins CAS number: 8030-76-0	Lecithins CAS number: 8002-43-5
12	Soya phospholipids CAS number: 308069-41-2	Phospholipids CAS number: 123465-35-0
13	Spiro[isobenzofuran- 1(3H),9′[9H]xanthen]-3-one, 2′,4′,5′,7′-tetrabromo -4,5,6,7-tetrachloro-3′,6′-dihydroxy-, aluminum salt (3:2) CAS number: 15876-58-1	Spiro[isobenzofuran-1(3H),9′-[9H]xanthen]-3-one, 2′,4′,5′,7′-tetrabromo-4,5,6,7-tetrachloro-3′,6′-dihydroxy-, aluminum salt (3:1) CAS number: 27532-17-8
14	Tridymite CAS number: 15468-32-3	Silica CAS number: 7631-86-9
15	Wheat germ oil CAS number: 313258-61-6	Oils, wheat CAS number: 68917-73-7

Examples

Your proposed introduction:
You plan to introduce ‘fatty acids, palm-oil, sodium salts’ (CAS No. 61790-79-2), which is not on the Inventory, but is in column B of the comparable chemicals table. In column C of the same row you find ‘fatty acids, C14-18 and C16-18-unsaturated, sodium salts’ (CAS No. 67701-11-5), which means this chemical is comparable to your chemical and listed on the Inventory. You search this chemical (CAS No. 67701-11-5) on the Inventory and find there are no regulatory requirements associated with the introduction of this chemical. This means you can introduce your chemical (CAS No. 61790-79-2) as an exempted introduction if you're registered with us.

Your proposed introduction:
You plan to introduce 'soya phospholipids' (CAS No.308069-41-2) in end use products at a concentration level of 30%. Soya phospholipids is in column B of the comparable chemicals table. In column C of the same row, you find 'phospholipids' (CAS No. 123465-35-0) which means this chemical is comparable to your chemical and listed on the Inventory. You search this chemical (CAS No. 123465-35-0) on the Inventory and find there are regulatory conditions under the term ‘defined scope of assessment'. It says 'This chemical has been assessed as a component of dermal cosmetic products at concentrations no more than 20%. This chemical is not to be used in topical products intended for the eye'.

You don't meet this condition because you plan to use your chemical – soya phospholipids – at a concentration of 30% in end use products. This means your introduction is not categorised as exempted. If none of the other introductions described on this page apply to you, go to step 3: Introductions that are categorised as reported.

Chemicals resulting from non-functionalised surface treatment of listed chemicals

Your chemical introduction is categorised as exempted if the chemical is a non-functionalised surface-treated chemical resulting from a reaction of chemicals that are **all** listed on the Inventory. To be an exempted introduction, your chemical must meet **all** of the following criteria:

- it is the result of a reaction between 2 or more chemicals, all of which are listed on the Inventory
- the reaction to produce the chemical occurs at the surface of one of the chemicals (the substrate chemical) and the substrate chemical is listed on the Inventory
- it does not have any reactive functional groups that were not already on the substrate chemical before the reaction occurred
- it is not introduced as a solid or in a dispersion that consist of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the particle size range of 1 to 100 nm.

Your obligations for introducing chemicals in the exempted category

You can introduce an industrial chemical that's categorised as exempted into Australia without telling us about it, as long as you:

- are registered with us
- keep records about the chemical
- submit an annual declaration

You may also need to submit an exempted introduction declaration. This is a once-off post-introduction declaration due after the end of our registration year and only applies if you are introducing:

- polymers of low concern
- low-concern biopolymers

If your introduction is not covered on this page, go to step 3.

Next – Step 3: Introductions that are categorised as reported

Step 3: Introductions that are categorised as reported

On this page:

If your introduction meets criteria for 3.1 or 3.2 or 3.3, then your introduction is categorised as **reported**. This means you can skip to 'Your obligations after categorisation'. Alternatively, you can continue through steps 4, 5 and 6 to see if your introduction can be in the exempted category or can be categorised as another type of reported introduction.

If your introduction is **not covered** on this page or if you **don't meet** the criteria, continue to Step 4 then Step 5 to work out its indicative risk to human health and the environment. Your introduction's category could be exempted or reported or assessed depending on the outcome of steps 4 and 5.

You can also use our Step 3 decision tool to help you complete this step.

3.1: Introductions of 10 kg or less in an AICIS registration year (1 September to 31 August)

Q1. Is the total introduction volume of the chemical 10 kg or less per year?

This is the combined volume of the chemical that you will introduce in an AICIS registration year in all your products that contain the chemical.

If **yes**, go to Q2. If **no**, go to 3.2: low-risk flavour or fragrance blend introductions, or skip to Step 4.

Q2. Is your chemical in this table below?

Chemical name	CAS number
Benzene, 1,1'-(1,2-ethanediyl)bis[2,3,4,5,6-pentabromo- (also known as decabromodiphenylethane or DBDPE)	84852-53-9
Benzene, 1,1'-oxybis-, pentabromo derivative (also known as pentabromodiphenyl ether)	32534-81-9
Benzene, 1,2,3,4,5-pentachloro-	608-93-5
Benzene, hexachloro-	118-74-1

If **no**, go to Q3.

If **yes**, the chemical is not eligible for the reported category - introductions of 10 kg or less. The reason is because the chemical was either removed from the AICIS Inventory, or its certificate was cancelled because risks to human health or the environment could not be managed. Go to 3.2: low-risk flavour or fragrance blend introductions or skip to Step 4.

Q3. Will your chemical have an end use in cosmetics?

Note: if your chemical will be an ingredient in cosmetic products, then answer yes.

If **yes**, go to Q4. If **no**, skip to Q5.

Q4. Is your chemical prohibited or restricted in the EU or USA for use as a cosmetic or in a cosmetic?

Chemicals that are prohibited or restricted in the European Union (EU) or the United States of America (USA):

- Annex II of Regulation 1223/2009/EC on Cosmetic Products (prohibited substances)
- Annex III of Regulation 1223/2009/EC on Cosmetic Products (restricted substances)
- US Federal Food, Drug & Cosmetic Act (prohibited and restricted ingredients in cosmetics)

If your chemical is prohibited or restricted, then answer **yes** even if you will introduce the chemical in accordance with the restrictions.

If **no**, go to Q5. If **yes**, go to 3.2: low-risk flavour or fragrance blend introductions or skip to Step 4.

Q5. As far as you know, is the chemical classified according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as having:

- carcinogenicity?
- germ cell mutagenicity?
- reproductive toxicity?

Note: You could check the SDS, product information sheets, or find out from your supplier.

If **no to all**, go to Q6. If **yes** to one or more, go to 3.2: low-risk flavour or fragrance blend introductions or skip to Step 4.

Q6. As far as you know, will the chemical be introduced as a solid or in a dispersion?

Note: You could find out about the appearance from the SDS, technical data sheet or your supplier. For example, if the SDS indicates that the chemical being introduced is a liquid, answer 'no'.

If **yes or unsure**, go to Q7. If **no**, skip to Q8.

Q7. As far as you know, does the chemical consist of particles, in an unbound state or as an aggregate or agglomerate, any of which have at least one external dimension in the nanoscale (1-100 nm)?

Note: You could check if there are any claims related to the presence of particles at the nanoscale in technical data sheets and commercial labels for the product containing the chemical.

If **no**, go to Q8. If **yes**, go to 3.2: low-risk flavour or fragrance blend introductions or skip to Step 4.

Q8. Does statement A) or B) apply about your chemical?

A) As far as you know, the chemical does not contain fluorine. You could check the chemical name or INCI name to see if it indicates that the chemical contains fluorine (F), or you could check with your supplier.

B) The chemical is an inorganic salt.

If A) or B) or both apply, go to Q9. If neither apply, go to 3.2: low-risk flavour or fragrance blend introductions or skip to Step 4.

Q9. As far as you know, is your chemical persistent, bioaccumulative and toxic (PBT)?

Note: You could check the SDS or find out from your supplier. Further information on the meaning of PBT is in the Industrial Chemicals Categorisation Guidelines.

If **yes**, go to 3.2: low-risk flavour or fragrance blend introductions or skip to Step 4.

If **no**, then your introduction is in the **reported category for introductions that are 10 kg or less**. Skip to 'Your obligations after categorisation'. Alternatively, you can continue through steps 4, 5 and 6 to see if your introduction can be in the exempted category or can be categorised as another type of reported introduction.

3.2 Low-risk flavour or fragrance blend introductions

Flavour blends are mixtures of chemicals that are formulated to impart a taste. Fragrance blends are mixtures of chemicals that are formulated to impart a scent or cover a malodour. Your introduction is categorised as reported if it meets these requirements:

- your chemical is part of a flavour or a fragrance blend and the blend is introduced either on its own, or with other chemicals
- the concentration of your chemical when it is introduced is 1% or less
- the concentration of your chemical in end-use products is 1% or less
- your chemical must not have an end use in a personal vaporiser, such as e-cigarettes

- your chemical does not have any of the hazard characteristics in the highest human health hazard band (hazard band C)
- your chemical does not have any of the hazard characteristics in the highest environment hazard band (hazard band D)
- your chemical must either be on the IFRA Transparency List at the time that your pre-introduction report is submitted, or certain information about its introduction must be given to us before you introduce the chemical, including:
    - the proper name of your chemical and its CAS number (if assigned)
    - information on known hazard characteristics
    - the maximum concentration of the chemical in the blend at introduction and end use
    - the name you use to refer to the blend

Learn more about categorisation of flavour or fragrance blend introductions

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3.3 Chemicals that are used only for research and development

Your introduction is categorised as reported if all of the following apply:

- you only use your chemical for research and development, or make it available to another person who only uses it in research and development
- you don't make your chemical available to the public in any form (whether on its own, in combination with other industrial chemicals or as part of an article)
- you use control measures to eliminate or minimise any risks to the environment and any risks to the people involved in using the chemical for research and development

and point **1 or 2 or 3** applies:

1. you will introduce more than 250 kg of your chemical in a registration year, use of your chemical will be subject to your (the introducer's) control and you can demonstrate that your chemical is **not** introduced as a solid or in a dispersion. To prove that your chemical is not introduced as a solid or in a dispersion, you might have an SDS or product information sheet that indicates the appearance (for example, in liquid form).

2. you will introduce more than 250 kg of your chemical in a registration year, use of your chemical will be subject to your (the introducer's) control and you can demonstrate that your chemical **does not** consist of particles in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size

distribution) of the particles have at least one external dimension in the particle size range of 1 to 100 nm. To prove that your chemical does not consist of particles in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the particle size range of 1 to 100 nm, you might have a study report about the particle size distribution of your chemical.

3. you will introduce more than 10 kg, but not more than 100 kg of your chemical in a registration year.

If your chemical meets our criteria for a chemical at the nanoscale, then your introduction is not point 1 or 2.

Read our extra guidance on categorisation of chemicals introduced for research and development

Step 3 outcome

My introduction meets the criteria on this page

This means that your introduction is in the 'reported' category. Skip to 'Your obligations after categorisation' to learn about your reporting and record-keeping obligations. Alternatively, you can continue through steps 4, 5 and 6 to see if your introduction can be in the exempted category or can be categorised as another type of reported introduction.

My introduction does not meet the criteria on this page

Continue with this guide to work out if your introduction is in the exempted, reported or assessed category. Go to Step 4: Work out your introduction's risk to human health.

Step 4: Work out your introduction's risk to human health

In Step 4, you need to work out the **human health risk** of your introduction - is it medium to high, low or very low? To work this out start at 4.1 and continue as far as you need to through each step.

Once you have your answer for human health, move to step 5 to work out the risk to the environment of your introduction.

At Step 6, you'll combine the human health risk and environment risk for the final category of your introduction.

Step 4.1 Introductions that are always medium to high risk for human health

Start at this step to see if your introduction is of a type that is always medium to high risk for human health.

Step 4.2 Introductions that can be low risk for human health

This step relates to international assessments and how to work out if your introduction can be low risk for human health based on its international assessment.

Step 4.3 Work out your human health exposure band

Part of the process to work out the human health risk of your introduction is to work out its exposure band. There are 4 human health exposure bands - exposure band 1 has the lowest level of human exposure and exposure band 4 the highest level.

Step 4.4 Work out your human health hazard characteristics

A chemical has a human health hazard characteristic if the chemical can cause damage,

harm or adverse effects to humans. Find out what you need to do to establish the human health hazard characteristics of your chemical, including when you can refer to our list of chemicals with high hazards for categorisation.

Step 4.5 Outcome - your human health risk for categorisation

Use the table on this page to confirm the human health risk of your introduction: medium to high, low or very low. After you do this go to step 5 to work out the risk to the environment of your introduction.

To be able to finish your categorisation you need to work out the risks of your introduction to human health and the environment.

Step 4.1 Introductions that are always medium to high risk for human health

You are here because you have already gone through **Steps 0, 1, 2 and 3** of the categorisation process.

Instructions

Go through A, B and C to work out if you are, or are not, introducing any of these types of chemicals. You must keep records of study reports and other information that you used to answer each question.

A. Does your chemical contain a sequence of 4 to 20 fully fluorinated carbon atoms (including per- and poly-fluorinated alkyl substances, known as PFAS).

B. Is your chemical a certain polyhalogenated organic chemical?.

C. Is your chemical a certain chemical at the nanoscale?.

A. Does your chemical contain a sequence of 4 to 20 fully fluorinated carbon atoms (including per- and poly-fluorinated alkyl substances, known as PFAS)?

Fluorinated chemicals contain fluorine atoms and include per- and polyfluorinated chemicals (PFAS). These are commonly used in products to add resistance to heat, other chemicals, and abrasion. They also act as dispersion, wetting or surface treatment agents. We have an increased level of concern for introductions of chemicals that contain a sequence of 4 to 20 fully fluorinated carbon atoms (including PFAS) because these chemicals, or their degradation products, may be persistent in the environment, bioaccumulate and be highly toxic.

No I am not introducing this type of chemical

You must have information about your chemical's identity as proof that you're **not** introducing this type of chemical. You (or the chemical identity holder) need to provide the information if we ask for it.

Next step: Go to 'B. Is your chemical a certain polyhalogenated organic chemical?'.

Yes I am introducing this type of chemical

We have extra guidance on categorisation of fluorinated chemicals

Outcome: Your introduction is medium to high indicative risk to human health and the environment. This means your introduction is in the assessed category and called an '**assessed introduction**'.

- Before you can introduce the chemical, you must apply for an assessment certificate and select 'Health and environment focus' as the application type or apply for a commercial evaluation authorisation (if you meet the strict criteria).

- When you apply for an assessment certificate, you need to answer ‘yes’ when we ask if your introduction is a specified class of introduction. When we receive your application, we’ll contact you to ask for extra information that we need to assess the risks of your introduction.

B. Is your chemical a certain polyhalogenated organic chemical?

Polyhalogenated organic chemicals are carbon-based chemicals that contain more than 1 covalently bonded halogen atom, such as bromine, chlorine, fluorine, or iodine. Polyhalogenated organic chemicals are commonly used as flame retardants in plastics, textiles, and electronic circuitry. They may have long-term effects on human health and the environment. We have an increased level of concern for introductions of chemicals that are polyhalogenated organic chemicals because these chemicals, or their degradation products, may be persistent in the environment, bioaccumulate and be highly toxic.

No I am not introducing this type of chemical

You must have information about your chemical's identity as proof that you're **not** introducing this type of chemical. You (or the chemical identity holder) need to provide the information if we ask for it.

Next step: Go to 'C. Is your chemical a certain chemical at the nanoscale?' below.

Yes I am introducing this type of chemical

☐ We have extra guidance on the categorisation of polyhalogenated organic chemicals

All introductions of polyhalogenated chemicals are specified class of introduction.

If the chemical identity information that you (or the chemical identity holder) have confirms you are introducing this type of chemical, you must consider which of the following circumstances apply to your introduction.

1. Introduced at volumes less than or equal to 100 kg each year

Next step: Go to 'C. Is your chemical a certain chemical at the nanoscale?' below.

2. Introduced at volumes higher than 100 kg each year

You need to have test results about the persistence of your chemical and any of its known environmental degradation products.

- Known environmental degradation products refer to the expected breakdown products of the chemical under environmentally relevant conditions. These breakdown products are ones that have been found in studies or reported in scientific literature.
- A persistent chemical remains intact in the environment for long periods of time. A chemical is persistent if its degradation half-life (T1/2) is greater than or equal to:
    - 2 days in air or
    - 2 months in water or
    - 6 months in soil or
    - 6 months in sediment.

To prove that your chemical and any of its known environmental degradation products **are not** persistent, we accept study results in option 1 or 2.

Option 1

A study conducted following OECD test guideline 301 (Ready Biodegradability) that results in the pass levels being reached within one of the following time periods:

- specified time period – such that the chemical is considered to be readily biodegradable or
- duration of the test – but not within the specified time period for the chemical to be considered readily biodegradable, provided biodegradation has started within the specified time period

If you have this study showing these results, then move on to 'C. Is your chemical a certain chemical at the nanoscale?' below.

Option 2

A study conducted following OECD test guideline 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems) that results in both a degradation half-life of less than 2 months in water and 6 months in sediment.

If you have this study showing these results, then move on to 'C. Is your chemical a certain chemical at the nanoscale?' below.

If you do not have either of the study results described in option 1 or 2

Outcome: Your introduction is medium to high indicative risk to human health and the environment because you cannot prove that your chemical (and any of its known environmental degradation products) are not persistent. This means your introduction is in the assessed category and called an 'assessed introduction'.

- Before you can introduce the chemical, you must apply for an assessment certificate and select 'Health and environment focus' as the application type or apply for a commercial evaluation authorisation (if you meet the strict criteria).
- When you apply for an assessment certificate, you need to answer ‘yes’ when we ask if your introduction is a specified class of introduction. When we receive your application, we’ll contact you to ask for extra information that we need to assess the risks of your introduction.

C. Is your chemical a certain chemical at the nanoscale?

Introductions of chemicals that meet **all 4 criteria below** are medium to high indicative risk to both human health and the environment. We refer to these introductions as 'certain chemicals at the nanoscale'. We have an increased level of concern for chemicals at the nanoscale, because of uncertainty about the risks of some of these chemicals due to their potentially different properties, such as chemical reactivity, relative to the non-nanoscale forms of the chemicals.

1. It is introduced as a solid or is in a dispersion.
2. It consists of particles in an unbound state or as an aggregate or agglomerate. At least 50% (by number size distribution) of the particles have at least 1 external dimension in the particle size range of 1nm to 100nm (ie. the nanoscale). Note that if you meet criteria 1 and 2, and regardless of whether you meet criteria 3 and 4, your introduction is a specified class of introduction.

3. It is not soluble. This means the solubility of the chemical in water is less than 33.3 g/L measured following OECD test guideline 105 or 120 for water solubility; or the dissolution rate of the chemical is not more than 70%.
4. The introduction of the nanoscale portion of the chemical (the part that has a particle size range of 1nm to 100nm) is **not** incidental to the introduction of the non-nanoscale portion. This is the case if **any** of the following apply:

    a. the manufacture of the chemical (in Australia or overseas) at the nanoscale is the result of a deliberate manufacturing decision

    b. the manufacture of the chemical (in Australia or overseas) at the nanoscale is necessary for the manufacture of the non-nanoscale portion of the chemical. This means that to make the non-nanoscale chemical, part of the chemical has to be at the nanoscale

    c. the chemical at the nanoscale has specific technical characteristics that are the intended result of changes in the manufacturing process. For example, if the process of manufacturing the chemical changes in order to change the particle size of the chemical, or its properties at the nanoscale. This could happen by:

        - mechanical actions like milling, grinding, shearing, sieving or sonication
        - chemicals reactions like electrochemical exfoliation, or catalysts
        - other changes such as changes to pressure or temperature or pH or solvent

Yes I am introducing this type of chemical

We have extra guidance on categorising chemicals at the nanoscale

This means that your introduction meets all 4 criteria above and is a 'certain chemical at the nanoscale'.

Outcome: Your introduction has a medium to high indicative risk to both human health and the environment. This means your introduction is in the assessed category and called an ‘assessed introduction’.

- Before you can introduce the chemical, you must apply for an assessment certificate and select 'Health and environment focus' as the application type or apply for a commercial evaluation authorisation (if you meet the strict criteria).
- When you apply for an assessment certificate, you need to answer ‘yes’ when we ask if your introduction is a specified class of introduction. When we receive your application, we’ll contact you to ask for extra information that we need to assess the risks of your introduction.

No I am not introducing this type of chemical

This means that you have information or studies to prove that your chemical does not meet any of the 4 criteria, or it only meets some of the 4 criteria. Answering the questions below will help you prove this. As you go through the questions, we'll tell you the next steps you should take.

Some introductions are always medium to high risk to human health. This means they will be in the assessed introduction category and you need to apply for an assessment certificate.

Open All | Close All

Question 1: Will your chemical be introduced in Australia as a solid or in a dispersion?

For example, information on appearance could be recorded on an SDS or technical data sheet of the chemical or product that will be introduced into Australia.

Note:

- If your information indicates that it's a powder, flakes, granules, pellets or wax, select '**yes**'.
- If your information indicates that it's a liquid, select '**no**'.

Yes

Go to question 2.

I don't know

Go to question 2. Alternatively, contact your chemical supplier and return to this page when you have further information.

No

This means that your introduction is not of a ‘certain chemical at the nanoscale’.

The criteria for ‘certain chemicals at the nanoscale’ are not met for your introduction.

Next step: Go to 'Step 4.2 Introductions that can be low risk for human health' and continue to categorise your introduction.

Question 2: Does the information you have access to indicate that your chemical will be introduced as granules, pellets or as wax?

For example, there is information on the chemical or product’s appearance on an SDS or technical data sheet.

No - the chemical will not be introduced as granules, pellets, or a wax.

Go to question 3.

Yes - the chemical will be introduced as granules, pellets, or a wax.

Note: you must keep a record of this information.

This means that your introduction is not of a ‘certain chemical at the nanoscale’.

Next step: Go to 'Step 4.2 Introductions that can be low risk for human health' and continue to categorise your introduction.

Question 3: Does the information you have access to indicate that your chemical is soluble in water (solubility greater than 33.3 g/L)) or has a high dissolution rate (greater than 70%)?

Examples of when you should answer 'yes'

- Your chemical is imported in an end use product such as laundry or dishwashing powder and it is not known to be an insoluble component of the product. For the product to work the way it should, the chemical must be soluble in water.

- You have a study result from a water solubility study on your chemical that was carried out following the test guideline OECD TG 105.
- You will introduce a polymer and have information on solution/extraction behaviour of the polymer in water (OECD TG 120).
- You have information on the dissolution rate (OECD WPMN Guidance document for the testing of dissolution and dispersion stability of nanomaterials and the use of the data for further environmental testing and assessment strategies; July 2021).

No or don't know - my information does not indicate that the chemical is soluble in water or has a high dissolution rate or I don't have access to information about this

Go to question 4.

Yes - I have access to information that indicates that the chemical is soluble in water or has a high dissolution rate

This means that your introduction is not a 'certain chemical at the nanoscale'. You must keep a record of information you have available. If the information includes a study result and another person holds the study, you must be able to provide the study to us, if we ask for it.

Learn more about your record keeping obligations

If you have information that shows the chemical consists of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale (1-100 nm), the introduction will be a specified class of introduction. Extra reporting obligations apply.

Next step: Go to 'Step 4.2 Introductions that can be low risk for human health' and continue to categorise your introduction.

Question 4: What does your information (if you have any) indicate about the mean particle size of your chemical or the product that will be introduced into Australia? Is it greater than 1000 nm in all dimensions?

For example:

- Information on appearance and mean particle size could be recorded on an SDS or technical data sheet of the chemical or product that will be introduced into Australia.

- You have a study result from a particle size distribution study on your chemical or the product that you will introduce into Australia (conducted according to OECD TG 110).

I don't have access to any information about the mean particle size (all dimensions) / I don't know

Go to question 7.

The information I have access to indicates the mean particle size is less than or equal to 1000 nm in one or more dimensions

Go to question 5.

Yes - information I have access to indicates the mean particle size is greater than 1000 nm in all dimensions

This means that your introduction is not of a 'certain chemical at the nanoscale'.

Next step: Go to 'Step 4.2 Introductions that can be low risk for human health' and continue to categorise your introduction.

Note: you must keep a record of the information you have available.

Question 5: Do you have access to study results that indicate that the mean particle size of your chemical or the product that will be introduced into Australia is greater than 200 nm in all dimensions?

For example: you have a study result from a particle size distribution study on your chemical or the product that you will introduce into Australia (conducted according to OECD TG 110 or 125).

Note the following:

1. For particle size distributions in this range, information only from an SDS/technical data sheet or similar is not enough.
2. OECD TG 110 on Particle Size Distribution/ Fibre Length and Diameter Distributions for insoluble chemicals can be used to measure particle size and distribution to support that a chemical is not at the nanoscale for particles and fibres with sizes above 250 nm.

3. OECD TG 125 on Nanomaterial Particle Size and Size Distribution of Nanomaterials can be used to measure particle size and distribution to support that a chemical is not at the nanoscale for particles and fibres with sizes above 100 nm.
4. If the chemical is in a dispersion, the spectroscopy- and microscopy-based methods such as scanning electron microscopy (SEM) and transmission electron microscopy (TEM) are more appropriate.

No - I don't have access to any study results that indicate this / I don't know

Go to question 6.

Yes - I do have access to study results that indicate the mean particle size is greater than 200 nm in all dimensions

This means that your introduction is not of a 'certain chemical at the nanoscale'.

Next step: Go to 'Step 4.2 Introductions that can be low risk for human health' and continue to categorise your introduction.

Note: you must keep a record of the information you have available. If another person holds the study, you must be able to give it to us, if we ask for it.

Learn more about your record keeping obligations

Question 6: Do you have access to study results that indicate that the mean particle size of your chemical or the product that will be introduced into Australia is less than or equal to 200 nm in one or more dimensions?

For example - you have a study result from a particle size distribution study on your chemical or the product that you will introduce into Australia (conducted according to OECD TG 125).

Note the following:

1. For particle size distributions in this range, information only from an SDS/technical data sheet or similar is not enough.
2. You can use OECD TG 110 to measure particle size and distribution to support that a chemical is not at the nanoscale for particles and fibres with sizes above 250 nm.

3. OECD TG 125 on Nanomaterial Particle Size and Size Distribution of Nanomaterials measures particles and fibres with a diameter of 1 to 1000 nm and fibres with a length up to 20 µm.
4. If the chemical is in a dispersion, the spectroscopy- and microscopy-based methods such as scanning electron microscopy (SEM) and transmission electron microscopy (TEM) are more appropriate.

No - I don't have access to study results that indicate this / I don't know

Go to question 7.

Yes - I have access to study results that indicate the mean particle size is less than or equal to 200 nm in one or more dimensions **and** the chemical consists of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale (1-100 nm)

Go to question 7 - note the introduction will be a specified class of introduction and extra reporting obligations will apply.

Yes - I have access to study results that indicate the mean particle size is less than or equal to 200 nm in one or more dimensions **and** the chemical does **not** consist of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale (1-100 nm):

This means that your introduction is not of a 'certain chemical at the nanoscale'.

Next step: Go to 'Step 4.2 Introductions that can be low risk for human health' and continue to categorise your introduction.

Note: you must keep a record of the information you have available. If the study is held by another person, you must be able to provide it to us, if we ask for it.

Learn more about your record keeping obligations

Question 7: Do you have access to information that indicates that the introduction of any nanoscale portion of the chemical is incidental to the non-nanoscale portion?

For example, you could have a combination of 1 and 2:

1. A declaration from the chemical manufacturer indicating all of the below:
    a. the manufacture of any chemical at the nanoscale is not the result of a deliberate manufacturing decision; and
    b. the manufacture of any chemical at the nanoscale is not necessary for the manufacture of the non-nanoscale portion of the chemical; and
    c. any chemical at the nanoscale does not have specific technical characteristics that are the intended result of changes in the manufacturing process.
2. Information to show that the presence of any nanoscale particles in the chemical is not providing a commercial advantage to the non-nanoscale chemical, such as the absence of claims related to the presence of the nanoscale particles in technical data sheets and commercial product labels on the chemical/introduced product.

Note: in general, the declaration must be from the manufacturer of the chemical in its solid/dispersion form. The declaration must also be held in conjunction with other supporting information.

No - I do not have access to this information / I don't know

You do not have enough information to demonstrate that your introduction is not a ‘certain chemical at the nanoscale’. In the absence of more information from the manufacturer or supplier of your chemical, your introduction has a medium to high indicative risk to both human health and the environment. This means your introduction is in the assessed category and called an 'assessed introduction'. We must assess it before you can introduce. This means your introduction is in the assessed category and called an 'assessed introduction'.

- Before you can introduce the chemical, you must apply for an assessment certificate and select 'Health and environment focus' as the application type or apply for a commercial evaluation authorisation (if you meet the strict criteria).
- When you apply for an assessment certificate, you need to answer ‘yes’ when we ask if your introduction is a specified class of introduction. When we receive your application, we’ll contact you to ask for extra information that we need to assess the risks of your introduction.

Yes - I do have access to this information that indicates this

This means that your introduction is not of a ‘certain chemical at the nanoscale’.

Next step: Go to 'Step 4.2 Introductions that can be low risk for human health' and continue to categorise your introduction.

Note: you must keep a record of the information you have available.

Definition - specified class of introduction

A ‘specified class of introduction’ are introductions that have an increased level of concern to human health or the environment. The reason is due to greater potential for certain hazards or high level of human or environmental exposure. Additional, or different, requirements relating to hazard information, reporting or record keeping apply to specified classes of introductions. These vary depending on whether you have categorised your introduction as exempted, reported or assessed.

If you've followed the guidance on this page and can prove that your introduction is **not** any of these, then continue to step 4.2.

Next – Step 4.2 Introductions that can be low risk for human health

Step 4.2 Introductions that can be low risk for human health

This step relates to introductions that are internationally assessed for human health. These must meet all of the following criteria to be considered ‘low indicative risk’ for human health.

Skip this step if you are not using an internationally assessed chemical.

Note: Your introduction might still be low indicative risk for human health but you will need to complete steps 4.3, 4.4 and 4.5 to work this out.

Step 4.2.1

Refer to our Guide to categorising internationally assessed introductions. It has extra information for introducers using international assessments and covers scenarios and outcomes for chemicals that are internationally assessed for:

- human health only
- the environment only
- both human health and the environment

It also lists the trusted overseas bodies we accept assessments from.

The relevant section to refer to in the guide to help you complete step 4.2 is Internationally assessed for human health only.

Step 4.2.2

Once you've read the guide to categorising internationally assessed introductions, you'll be able to work out whether your introduction either:

- meets our criteria for internationally assessed for human health
- **does not** meet our criteria for internationally assessed for human health

Your introduction meets our criteria for internationally assessed for human health

Option 1

- Keep the outcome you already have — your introduction is **low risk for human health**; and
- Go to step 5 to start categorising your introduction's indicative risk for the environment.

Option 2

Check to see if your introduction can be **very low risk** for human health by completing the rest of step 4:

- Complete Step 4.3 — Work out your introduction's human health exposure band; then
- Complete Step 4.4 — Work out your introduction's human health hazard characteristics

Once you've done this, go to step 4.5 for your final answer.

Your introduction **does not** meet our criteria for internationally assessed for human health

Continue with step 4 to work out your introduction's risk for human health.

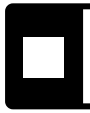
Next:

- Complete Step 4.3 — Work out your introduction's human health exposure band; then
- Complete Step 4.4 — Work out your introduction's human health hazard characteristics

Once you've done this, go to step 4.5 for your final answer.

If you've established your introduction is NOT medium to high risk for human health (Step 4.1), now see if your introduction CAN be low risk for human health.

Step 4.3 Work out your human health exposure band



You can also use our interactive decision tool for this step to work out your human health exposure band.

Why you need to work out your introduction's exposure band?

It is part of the process to identify the indicative human health risk of your introduction. In step 5, you also have to work out your introduction's environment exposure band.

What does a human health exposure band identify about your introduction?

It identifies the likelihood and extent of human exposure to the chemical. This likelihood and extent of exposure increases with each band. Exposure band 4 is the highest exposure band. Introductions in human health exposure band 4 will have the highest level of human exposure.

Information that's used to assign a chemical to its correct exposure band

Need to know your human health categorisation volume?

Follow our guidance on how to work this out

You can also get help to work this out using our online decision tool

The information you need to be able to work out your exposure band can be different depending on the exposure band criteria you will be using. Some of the exposure band criteria mainly depend on human health categorisation volume, while others mainly depend on the concentration of your chemical when it's introduced into Australia and during its end use. This is a full list of the information you might need to be able to work out your human health exposure band:

- Human health categorisation volume (needed for scenario 1 of Exposure Band 2, scenario 1 of Exposure Band 3 and Exposure Band 4)
- Concentration of your chemical at introduction (needed for Exposure Band 1, scenario 2 of Exposure Band 2 and scenario 2 of Exposure Band 3).
- Concentration of your chemical across all end uses (needed for Exposure Band 1, scenario 2 of Exposure Band 2 and scenario 2 of Exposure Band 3).

- If it has an end use in tattoo inks or personal vaporisers (which are always in human health exposure band 4)
- If there are any consumer end uses for the chemical introduction (needed for Exposure Band 1 and scenario 2 of Exposure Band 2 and).

> We define **'consumer end use'** (which we refer to throughout this page) to be where the chemical is made available to the general public, either on its own, with other chemicals or as part of an article.

What's your human health exposure band?

Start with **Exposure Band 1** and work down the page.

Tattoo inks or personal vaporisers: If you're introducing a chemical with an **end use in tattoo inks or personal vaporisers** you are automatically in Exposure Band 4 for human health. If this is your introduction type, go to Step 4.4: Work out your human health hazard characteristics.

Exposure band 1 criteria

To be in exposure band 1, your introduction must meet all of the criteria:

- The concentration of your chemical at introduction IS LESS than 0.1 %
- The concentration IS LESS than 0.1 % across all your introduction's end uses
- The introduction is NOT for any consumer end use

If your introduction meets all criteria, go to Step 4.4 to work out the human health hazard characteristics of your introduction.

If your introduction does not meet all criteria, go to Exposure band 2 criteria.

Exposure band 2 criteria

To be in exposure band 2, your introduction must be at least 1 of these scenarios:

Scenario 1

- The human health categorisation volume for your chemical does not exceed 25kg.

Scenario 2

- The concentration of your chemical at introduction is less than 0.1 % and
- The concentration is less than 0.1 % across all your introduction's end uses and
- The introduction has at least 1 consumer end use

If your introduction meets the criteria, go to Step 4.4 to work out the human health hazard characteristics of your introduction.

If your introduction does not meet the criteria, go to Exposure Band 3 criteria.

Exposure band 3 criteria

To be in exposure band 3, your introduction must be at least 1 of these scenarios:

Scenario 1

- The human health categorisation volume for your chemical does not exceed 100kg.

Scenario 2

- The concentration of your chemical at introduction is less than or equal to 1% and
- The concentration is less than or equal to 1% across all your introduction's end uses

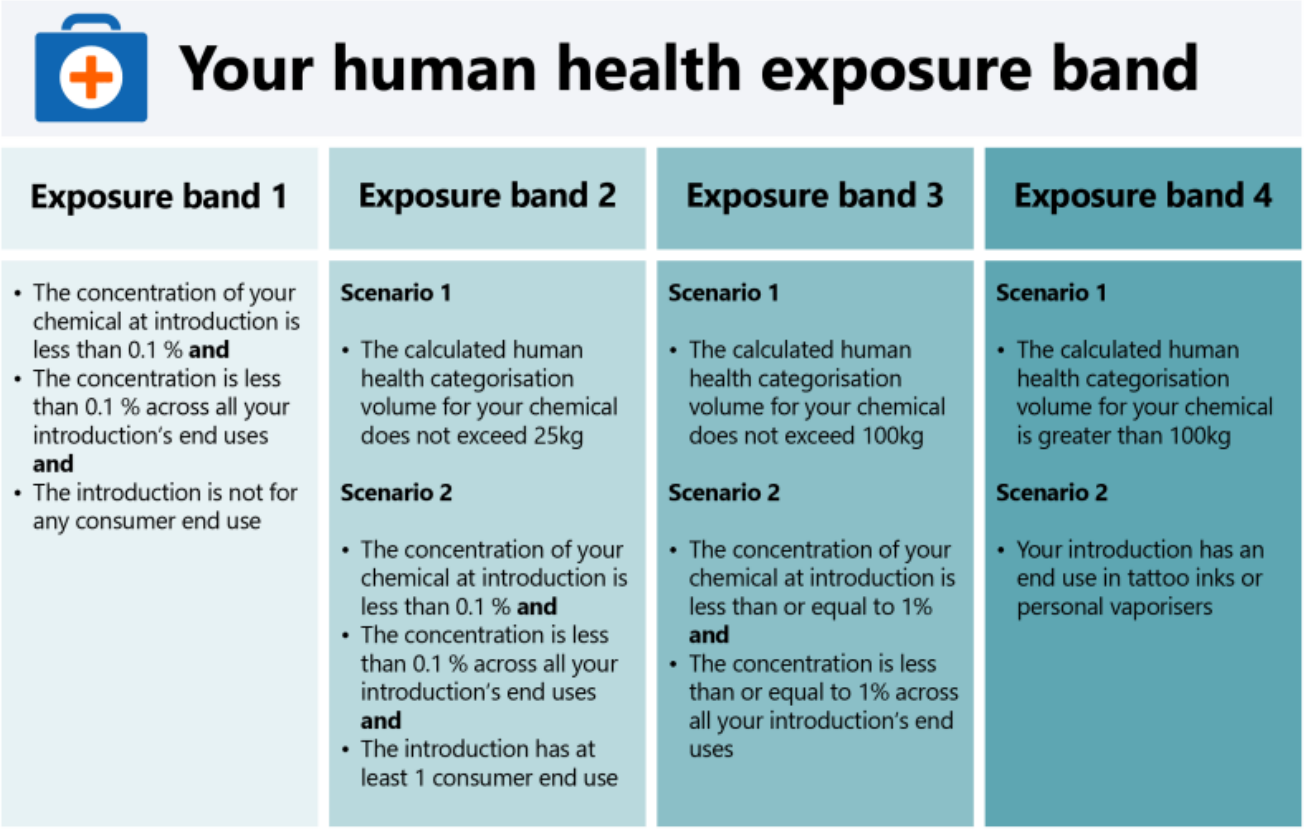
If your introduction meets the criteria, go to Step 4.4 to work out the human health hazard characteristics of your introduction.

If your introduction does not meet the criteria, go to Exposure Band 4 criteria.

Exposure band 4 criteria

Tattoo inks or personal vaporisers: If you're introducing a chemical with an **end use in tattoo inks or personal vaporisers** you are automatically in Exposure Band 4 for human health. If this is your introduction type, go to Step 4.4: Work out your human health hazard characteristics.

If the human health categorisation volume of your introduction is greater than 100kg, your introduction is in exposure band 4. Next, go to Step 4.4: Work out your human health hazard characteristics.



Next: Step 4.4 Work out your human health hazard characteristics

Work out your human health categorisation volume

Explore our categorisation tool for help on this subject

Are you introducing a chemical with an **end use in TATTOO INKS or PERSONAL VAPORISERS?** If you are, your introduction is automatically in **exposure band 4 for human health** — go to Step 4.4: Work out your human health hazard characteristics.

Use this guidance to calculate your introduction's human health categorisation volume.

Instructions

- We've included the equations to use and the options you have to choose from, dependent on the scenarios of your introduction.
- You can adopt a simple method or a more detailed method (which **can result in a lower introduction volume than the simpler method**).
- Once you have worked out your human health categorisation volume, you can complete step 4.3.

When you need to work out a HHCV for your chemical

You need to do this if you want to use an exposure band scenario in step 4.3 that includes HHCV as part of the criteria. This could be if you introduce and use the chemical at relatively high concentrations (> 1%).

When you do not need to work out a HHCV for your chemical

You don’t need to work out a HHCV if:

- you want to use an exposure band scenario in step 4.3 that does not include HHCV as part of the criteria. This could be if the concentration of your chemical when it’s introduced and during its end use is low (concentrations ≤1% or concentrations <0.1%, depending on the exposure band scenario that applies)

- it has an end use in tattoo inks or personal vaporisers

Methods you can use to work out a HHCV for your chemical

There are 2 ways to work out the human health categorisation volume.

Method 1: Simplest approach

Use this method if you want an easy way to work out your human health exposure band.

HHCV calculation for this approach

The HHCV is your chemical's total introduction volume in a registration year for all end uses.

Method 2: More detailed approach

Use this method if you want a more refined human health categorisation volume. Using this method could result in an HHCV that is lower than the total introduction volume in a year. This could mean that your introduction ends up being in a lower human health exposure band than if the total introduction volume (method 1) had been used.

The calculation of the HHCV using method 2 is different depending on whether your chemical introduction has only 1 end use or more than 1 end use.

If your introduction has 1 end use

For a chemical with only 1 end use, calculate the HHCV by multiplying the introduction volume (IV) by the exposure reduction factor (ERF) for your chemical's end use scenario:

Equation (1): HHCV = IV x ERF

The introduction volume you should use in your calculation is the **total introduction volume in a registration year**. Use the exposure reduction factor that applies to your end use scenario (see Table for ERFs for different end uses).

The ERF values range between 0 and 1. A low exposure reduction factor indicates that only a small portion of the introduction volume is likely to contribute to human exposure. A higher exposure reduction factor indicates that a higher proportion of the introduction volume could contribute to human exposure.

Exposure reduction factors (ERFs) for different end use scenarios

Your introduction's end use scenario	**ERF to use**
Chemical imported into Australia; import containers remain closed; then exported for end use overseas	0
Chemical imported into Australia; limited handling of the chemical (such that import containers are opened); then exported for end use overseas	0.05
Chemical manufactured in Australia; exported for end use overseas	0.05
Specified consumer products with end use in Australia*	1
All other end uses in Australia	0.1

Note *Specified consumer products means any of the following products:

- cosmetics
- nasal sprays
- ear sprays
- intimate lubricants
- massage oils and gels
- products applied to the nails to harden, or deter the biting of, nails

Specified consumer products **do not** include tattoo inks and personal vaporisers. If your chemical has an end use in tattoo inks or personal vaporisers, its introduction will be in human health exposure band 4 and you do not need to calculate a HHCV for it.

If your introduction has more than 1 end use

You can choose from 2 options to calculate the HHCV where your chemical has more than one end use

Option 1: Simplest approach

Use this option if:

- you do not know the annual introduction volume of your chemical for each end use
- you want to simplify the process of working out your human health exposure band but still want a more refined human health categorisation volume

HHCV calculation for this approach

Allocate the total introduction volume to the end use scenario that has the highest exposure reduction factor (from the table), and use Equation (1) to calculate the HHCV. Note: do not just use the volume for one of the end uses.

Option 2: More detailed approach

Use option 2 if:

- you know the annual introduction volume of your chemical for each end use
- you are willing to keep track of any changes to your introduction volume for each end use. This is needed to make sure that the indicative human health risk of your introduction does not increase.

HHCV calculation for this approach

Calculate a separate human health categorisation volume for each of your end uses. Use the exposure reduction factor for the end use (from the table), and the volume that you will be introducing for that end use. Do this for all of your end uses and then add them up to get your total human health categorisation volume (use equation (2) below).

HHCV = (IV1 x ERF1) + (IV2 x ERF2) +… + (IVn x ERFn)

Note: IVn = the introduction volume for end use ‘n’

ERFn = the exposure reduction factor (ERF) for end use ‘n’.

Go back to step 4.3

This page accompanies Step 4.3 work out your human health exposure band. You might need to know the human health categorisation volume (HHCV) of your introduction to work out its human health exposure band. Information on this page tells you when you need to work out a HHCV and when you don't.

Step 4.4 Work out your human health hazard characteristics

Important! Your starting point is always hazard band C (the highest hazard band)
Then work your way down the hazard bands as far as you need to get to your outcome (that is, C then B then A). After reading this page, go to human health hazard band C hazard characteristics.

You must have permission to use information that you relied on to demonstrate the absence of hazard characteristics. If we ask you for the information that you relied on to categorise your introduction, you need to provide us with the detailed information, including full study reports, of the kind we specify in this step to demonstrate the absence of the hazard characteristics.

Hazard characteristics in human health hazard bands

A chemical has a human health hazard characteristic if the chemical can cause damage, harm or adverse effects to humans. For example, a chemical that has the 'skin corrosion' hazard characteristic can cause irreversible damage to the skin of humans.

Human health hazard characteristics are split up into hazard bands. Hazard characteristics of most concern are in hazard band C, while those of lower concern are in hazard band A.

Our pages for human health hazard bands C, B and A describe hazard characteristics (eg carcinogenicity and so on) in each hazard band and the information you need to have to prove your chemical does not have a particular hazard characteristic.

Information you need and hazard characteristics you need to consider

This varies depending on your introduction's **human health exposure band.**

If your introduction is in a lower exposure band

Generally, in the lower exposure bands, where the level of exposure to humans is relatively low, as a minimum you have to consider only a few hazard characteristics and you don't need much information on them.

If your introduction is in a higher exposure band

In comparison, in higher exposure bands, where the level of exposure to humans is higher, generally you'll need to consider more hazard characteristics and need more information on them.

Information you need for lower indicative risk

You will need more hazard information to be able to get to lower indicative risk outcomes. Generally, within any given human health exposure band you need:

- less hazard information to get to medium to high risk
- more hazard information to get to low risk
- the most hazard information to get to very low risk

See Step 4.5 for more information about indicative human health risk outcomes

Where to start and when you can stop considering your chemical's hazard characteristics

Starting point — **is always hazard band C**. Always start in the highest hazard band (hazard band C) and work your way down the hazard bands as far as you need to get to your outcome (that is, C then B then A).

You must consider each hazard characteristic in the hazard band you are in (unless there is a reason for you to stop sooner) — does your chemical have that hazard characteristic or not?

When you might not need to consider all of the hazard bands

- **Because your introduction's human health exposure band (which you worked out in step 4.3) doesn't require it.** For example, if your introduction's human health exposure band is 1, you only need to consider the hazards in hazard band C to get to an indicative human health risk of either low or very low.
- **Because the outcome for indicative human health risk that you are trying to get to doesn't require it.** For example, if your introduction's human health exposure band is 3 and you want to get to an indicative human health risk of low, you only need to consider the hazard characteristics in human health hazard band C.

In many cases, you'll only need to consider hazard band C. But in other cases you might need to consider C, B and A, because your introduction is in exposure band 3 or 4 and you are trying to get to very low indicative human health risk.

See step 4.5 for more about indicative human health risk outcomes

When you can stop working through your chemical's human health hazard characteristics

Stop if you:

- determine that your chemical **has** a hazard characteristic in the hazard band (eg carcinogenicity — you are in hazard band C) or
- cannot demonstrate that your chemical does **not** have a certain hazard characteristic in that hazard band. This means that we consider your chemical to have this hazard characteristic or
- get to an indicative human health risk outcome and don't want to go any further — see step 4.5 for more information about human health risk outcomes or
- have demonstrated that your chemical does **not** have any hazard characteristics in hazard bands C, B and A. This would only be needed for human health exposure bands 3 and 4. It means that the indicative human health risk of your introduction is very low.

After you stop, you don't need to consider the remaining hazard characteristics in the hazard band where you stopped, or any of the hazard characteristics in lower hazard bands. Take note of where and why you stopped, then move to step 4.5.

Example: Anna's introduction is in human health exposure band 4. She considers all of the hazard characteristics in human health hazard band C and can demonstrate that her chemical does not have any of these hazards. Anna then moves on to hazard band B. She works through the hazard characteristics in this hazard band in the order that they are shown in the table. When Anna comes to eye damage, she finds that her chemical has the '**eye damage' hazard characteristic**. This means Anna can **stop there**. The indicative human health risk of Anna's introduction is **medium to high**. She does not need to continue further to see if her chemical has any of the other hazard characteristics in hazard band B, like skin sensitisation, or specific target organ toxicity after repeated exposure. Also Anna doesn't need to consider if her chemical has any of the hazard characteristics in hazard band A, such as skin irritation.

How to consider each hazard characteristic

Look at whether your chemical meets the hazard characteristic **definition** based on the information that you have.

If it **does** meet the hazard characteristic definition, stop there and move to step 4.4.

If it **does not** meet the hazard characteristic definition, you'll need to try and **prove** that your chemical **does not** have this hazard characteristic.

Our pages on hazard bands C, B and A describe hazard characteristics and the ways to prove that your chemical does not have a hazard characteristic.

How to prove that your chemical does not have a hazard characteristic

You can read about your options to prove that your chemical does not have a particular hazard characteristic on each human health hazard band page. These options include

- checking if your chemical is on the list of chemicals with high hazards for categorisation
- in silico predictions
- in vitro test results
- in vivo test results
- suitable read-across information in place of information on the chemical itself
- other information about your chemical that means that testing and in silico predictions are not necessary (that is, information waivers)

If you have access to existing information on the chemical or suitable read-across information, you should consider these first. If you need to generate new data to prove the absence of a hazard characteristic, you should **choose non-animal test data when possible**. You should only generate new animal test data as a last resort.

See our section on use of animal test data

If you **can prove** that your chemical does not have the hazard characteristic, move on to the next hazard characteristic in that hazard band, or from the next hazard band down.

If you **cannot prove** that your chemical does not have the hazard characteristic, stop there – your chemical is considered to have this hazard characteristic. Take note of the hazard band that this hazard characteristic is in and move on to step 4.5.

If your chemical is one of these:

- polyhalogenated organic chemical
- UV filter
- is introduced for an end use in a tattoo ink
- is introduced for an end use in a personal vaporiser
- is introduced for an end use in an article that is a children's toy or a children's care product
- is introduced for an end use in an article with food contact

there may be different requirements for you to prove that your chemical does not have certain hazard characteristics.

Human health hazard band C hazard characteristics – using our list of chemicals with high hazards for categorisation

In most cases we do not expect that you will have information about the high level hazard characteristics in human health hazard band C, such as carcinogenicity. Instead, to demonstrate that your chemical does not have these hazard characteristics you can search the list of chemicals with high hazards for categorisation. This is a list that we have compiled directly from trusted international sources, and provides you with a single place to search for your chemical to check if it might be known to have these hazards. Our hazard band pages tell you when you might need to search the high hazards list.

A list of resources to help you with this step

- List of chemicals with high hazards for categorisation

- In silico information- an overview of which human health and environment (step 5.4) characteristics have in silico options and which in silico models are appropriate.
- Acceptable test guidelines for each human health hazard characteristic listed in this step
- Suitable read across information
- **Decision tools for step 4.4** (self-guided tools to help you categorise your introduction):
    - hazard characteristics for human health exposure band 1, hazard characteristics for human health exposure band 2, hazard characteristics for human health exposure band 3, hazard characteristics for human health exposure band 4

Human health hazard bands - what are the hazard characteristics in each hazard band

These pages describe the hazard characteristics in each hazard band and the information you need to have to prove your chemical does not have a particular hazard characteristic. Follow instructions on each of these pages. **Always start with hazard band C.**

To work out the human health hazard characteristics your chemical does and does not have, you must know your human health exposure band (Step 4.3). The information you need to consider hazard characteristics varies depending on your introduction's exposure band.

Human health hazard band C hazard characteristics

Do not start this page unless you have read Step 4.4 Work out your human health hazard characteristics

Human health hazard characteristics are split into hazard bands. Hazard characteristics of most concern are in hazard band C, while those of lower concern are in hazard band A.

Hazard band C has 5 hazard characteristics you need to consider:

- carcinogenicity

- reproductive toxicity
- developmental toxicity
- adverse effects mediated by an endocrine mode of action
- genetic toxicity

Instructions

You must always start at hazard band C. Step 4.4 tells you when you can stop working through your chemical's human health hazard characteristics and when you need to check each of them - ie C, B and A.

Work your way through each hazard characteristic on this page. Look at whether your chemical meets the hazard characteristic definition based on the information that you have.

If it **does** meet the hazard characteristic definition, stop there - your introduction's **human health hazard band is C**. Move on to the next step - step 4.5 Work out your human health risk for categorisation.

If it **does not** meet the hazard characteristic definition, you'll need to try and prove that your chemical **does not** have this hazard characteristic. The information that you need to prove this for each hazard characteristic is shown below. If you **do not** have this information, stop there - your introduction's **human health hazard band is C**. Move onto the next step – step 4.5 Work out your human health risk for categorisation.

If you **do** have this information (so you can prove that the chemical does not have the hazard characteristic), move onto the next hazard characteristic on this page.

After you have considered all the hazard characteristics on this page and have proven that the chemical does not have any of them, decide whether you can stop there or continue to human health hazard band B. This depends on the exposure band of your introduction.

If your introduction is in **human health exposure band 1 or 2**, stop here - you don't need to consider any other hazard characteristics. Next go to step 4.5 to work out your human health risk for categorisation.

If your introduction is in **human health exposure band 3** you can choose to stop (and go to step 4.5 to work out your human health risk for categorisation), or to continue to human health hazard band B and then A.

If your introduction is in **human health exposure band 4**, continue to human health hazard band B.

Carcinogenicity

Carcinogenicity means that any of the following apply to the industrial chemical:

- the chemical is a known, presumed or suspected human carcinogen, as described in chapter 3.6 of the GHS, with the chemical classified as carcinogenicity (category 1 or 2), or
- the chemical (or the chemical of which it is an ester or salt) is on the **list of chemicals with high hazards for categorisation** based on its carcinogenicity, or
- an in vivo study on the chemical conducted following an acceptable test guideline for carcinogenicity, chronic toxicity, subchronic oral toxicity, subchronic dermal toxicity or subchronic inhalation toxicity results in the induction of cancer, or an increase in the incidence of cancer.

Information required to demonstrate the absence of the hazard characteristic, carcinogenicity

- Confirmation that the chemical (or the chemical of which it is an ester or salt) is not on the **list of chemicals with high hazards for categorisation**, based on its carcinogenicity.
- In addition, if the human health **exposure band for the introduction is 4** and the **chemical is a UV filter**, information is required to justify why the chemical would not cause carcinogenicity mediated by exposure to UV light. This may include one or more of the following:
    - the chemical has a molar extinction/absorption coefficient of less than 1,000Lmol-1cm-1 at wavelengths between 290 and 700nm (based on the results of a study following OECD test guideline 101), or
    - results from in vitro phototoxicity studies, or

- results from in vivo carcinogenicity studies where the methods have been modified to include photoactivation.

More information: categorisation of UV filters

This page accompanies step 4.4 Work out your human health hazard characteristics.

Reproductive toxicity

Reproductive toxicity means that any of the following apply to the industrial chemical:

- the chemical is known, presumed or suspected to produce adverse effects on sexual function and fertility, as described in chapter 3.7 of the GHS, with the chemical classified as toxic to reproduction (category 1 or 2), or
- the chemical (or the chemical of which it is an ester or salt) **is on the list of chemicals with high hazards for categorisation** based on its reproductive toxicity, or
- an in vivo study on the chemical conducted following an acceptable test guideline for reproductive toxicity, carcinogenicity, chronic toxicity, subchronic oral toxicity, subchronic dermal toxicity or subchronic inhalation toxicity results in adverse effects on sexual function and fertility, as described in chapter 3.7 of the GHS.

Information required to demonstrate the absence of the hazard characteristic, reproductive toxicity

- If the chemical is a polyhalogenated organic chemical and the human health **exposure band for the introduction is 4** -
  - an in vivo test result on the chemical or suitable read across information conducted following an acceptable test guideline for reproductive toxicity, which results in none of the adverse effects on sexual function or fertility described in chapter 3.7 of the GHS;
- Otherwise –
  - confirmation that the chemical (or the chemical of which it is an ester or salt) is **not on the list of chemicals with high hazards for categorisation**, based on its reproductive toxicity.

Developmental toxicity

Developmental toxicity means that any of the following apply to the industrial chemical:

- the chemical is known, presumed or suspected to produce adverse effects on the development of the offspring or effects on the offspring via lactation, as described in chapter 3.7 of the GHS, with the chemical classified as follows:
    - toxic to reproduction (category 1 or 2), or
    - effects on or via lactation, or
    - the chemical (or the chemical of which it is an ester or salt) **is on the list of chemicals with high hazards for categorisation** based on its developmental toxicity, or
    - an in vivo study on the chemical conducted following an acceptable test guideline for developmental toxicity or reproductive toxicity results in adverse effects on the development of the offspring or effects on the offspring via lactation, as described in chapter 3.7 of the GHS.

Information required to demonstrate the absence of the hazard characteristic, developmental toxicity

- If the chemical is a polyhalogenated organic chemical and the human health **exposure band for the introduction is 4** –
    - an in vivo test result on the chemical or suitable read across information conducted following an acceptable test guideline for developmental toxicity or reproductive toxicity which results in none of the adverse effects on the development of the offspring or effects on the offspring via lactation, as described in chapter 3.7 of the GHS
- Otherwise –
    - confirmation that the chemical (or the chemical of which it is an ester or salt) **is not on the list of chemicals with high hazards for categorisation**, based on its developmental toxicity.

Adverse effects mediated by an endocrine mode of action

Adverse effects of mediated by an endocrine mode of action means that any of the following apply to the industrial chemical:

- the chemical meets all of the following:

- it shows an adverse effect in an intact organism or its progeny, which is a change in the morphology, physiology, growth, development, reproduction or lifespan of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in the susceptibility to other influences, and
- it has an endocrine activity, which is the capacity to alter the function(s) of the endocrine system, and
- the adverse effect is a consequence of the endocrine activity

or

- the chemical (or the chemical of which it is an ester or salt) **is on the list of chemicals with high hazards for categorisation**, based on its adverse effects mediated by an endocrine mode of action or
- the chemical meets all of the following:
  - information is available that is relevant to determining whether the chemical has the hazard characteristic, adverse effects mediated by an endocrine mode of action, and
  - the information has been considered in a weight of evidence analysis based on the following guidance documents:
    - the EU guidance for identifying endocrine disruptors, and
    - the guidance provided in OECD GD 150; and
  - the weight of evidence analysis concludes that the chemical has the hazard characteristic, adverse effects mediated by an endocrine mode of action.

Information required to demonstrate the absence of the hazard characteristic, adverse effects mediated by an endocrine mode of action

- If the chemical has existing information relevant to determining whether it has the hazard characteristic, adverse effects mediated by an endocrine mode of action, information is required to demonstrate that the chemical does not have this hazard characteristic:
  - this must involve a documented weight of evidence analysis based on the EU guidance for identifying endocrine disruptors* and the guidance in OECD GD 150**, and
  - the analysis must conclude that the chemical does not have the hazard characteristic, adverse effects mediated by an endocrine mode of action.
- Otherwise, the information required to demonstrate that a chemical does not have the hazard characteristic, adverse effects mediated by an endocrine mode of action, is confirmation that the chemical (or the chemical of which it is an ester or salt) is **not on the list of chemicals with high hazards** for categorisation, based on its adverse effects mediated by an endocrine mode of action.

*Guidance for the identification of endocrine disruptors in the context of 39 Regulations (EU) No 528/2012 and (EC) No 1107/2009, currently a 2017 consultation draft.

**ENV/JM/MONO(2012)22, OECD Series on Testing and Assessment, No. 150 - Guidance document on standardised test guidelines for evaluating chemicals for endocrine disruption.

Genetic toxicity

Genetic toxicity means that any of the following apply to the industrial chemical:

- the chemical is known to induce or may induce mutations in the germ cells of humans, as described in chapter 3.5 of the GHS, with the chemical classified as germ cell mutagenicity (category 1 or 2), or
- the chemical (or the chemical of which it is an ester or salt) **is on the list of chemicals with high hazards for categorisation**, based on its genetic toxicity, or
- an in vitro study on the chemical:
    - conducted following an acceptable test guideline for gene mutation or chromosomal abnormalities results in the prediction of mutagenic or genotoxic effects, as described in chapter 3.5 of the GHS, and
    - the results of the study have not been negated by in vivo studies conducted on the chemical for gene mutation, chromosomal abnormalities or heritable germ cell mutagenicity, or
    - an in vivo study on the chemical conducted following an acceptable test guideline for gene mutation, chromosomal abnormalities or heritable germ cell mutagenicity results in mutagenic or genotoxic effects, as described by chapter 3.5 of the GHS.

Information required to demonstrate the absence of the hazard characteristic, genetic toxicity

The information required to demonstrate that a chemical does not have the hazard characteristic, genetic toxicity, is:

- if the **human health exposure band for the introduction is 4** - at least one of the following:
    - information to demonstrate that the chemical is included on the Select Committee on GRAS Substances (SCOGS) Database as a Type 1 conclusion, and that the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or

- information to demonstrate that the chemical has been notified to the US FDA GRAS notification program and FDA had no questions about the notifier's conclusion of GRAS status, and that the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
- information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
- information to demonstrate that the chemical is a high molecular weight polymer, and if you are seeking to demonstrate that the introduction meets the criteria for very low risk **and is not one of the 'special cases' mentioned in step 4.5** - test results from an in vitro study on the polymer or from suitable read across information conducted following an acceptable test guideline for gene mutation, which demonstrates the absence of mutagenic effects, or
- test results that demonstrate the absence of mutagenic or genotoxic effects from both:
  - study on the chemical or from suitable read across information conducted following an acceptable test guideline for gene mutation, and
  - study on the chemical or from suitable read across information conducted following an acceptable test guideline for chromosomal abnormalities.

- if the human health **exposure band for the introduction is 3**, and you are seeking to demonstrate that the introduction meets the criteria for very low risk **and is not one of the 'special cases' mentioned in step 4.5** - at least one of the following:
  - inclusion of the chemical in the Select Committee on GRAS Substances (SCOGS) Database as a Type 1 conclusion, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
  - the chemical has been notified to the US FDA GRAS notification program and FDA had no questions about the notifier's conclusion of GRAS status, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
  - information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
  - if the polymer is a high molecular weight polymer, test results from an in vitro study on the polymer or from suitable read across information conducted following an acceptable test guideline for gene mutations, which demonstrates the absence of mutagenic effects, or
  - information that demonstrates the absence of mutagenic or genotoxic effects from both:
    - information on the chemical or from suitable read across information that addresses gene mutations - this could be:
      - a suitable in silico prediction, both with and without metabolic activation, or
      - test results from a study conducted following an acceptable test guideline for gene mutations; and
    - test results from a study on the chemical or from suitable read across information conducted following an acceptable test guideline for chromosomal abnormalities.
- otherwise, the information required to demonstrate that a chemical does not have the hazard characteristic, genetic toxicity, is confirmation that the chemical (or the chemical of which it is an ester or salt) **is not on the list of chemicals with high hazards for categorisation**, based on its genetic toxicity.

- in addition, if the human health **exposure band for the introduction is 4** and the **chemical is a UV filter**, information is required to justify why the chemical would not cause genetic toxicity mediated by UV light. This may include one or more of the following:
    - the chemical has a molar extinction coefficient/absorption coefficient of less than 1,000Lmol-1cm-1 at wavelengths between 290 and 700nm (based on the results of a study following OECD test guideline 101), or
    - results from in vitro phototoxicity studies, or
    - results from in vitro or in vivo genetic toxicity studies where the methods have been modified to include photoactivation.

More information: categorisation of UV filters

Human health hazard band B hazard characteristics

Do not start this page unless you have read Step 4.4 Work out your human health hazard characteristics and human health hazard band C hazard characteristics.

Human health hazard characteristics are split into hazard bands. Hazard characteristics of most concern are in hazard band C, while those of lower concern are in hazard band A. **You must always start at hazard band C.** Step 4.4 tells you when you can stop working through your chemical's human health hazard characteristics and when you need to check each of them - ie C, B and A.

Hazard band B has 9 hazard characteristics you need to consider:

- High molecular weight polymer that is water absorbing
- Respiratory sensitisation

- Corrosive to the respiratory tract
- Specific target organ toxicity and a single exposure (significant toxicity)
- Skin corrosion
- Eye damage
- Skin sensitisation
- Acute toxicity (fatal or toxic)
- Specific target organ toxicity after repeated exposure

Instructions

You must always start at hazard band C.

You only need to work through the hazard characteristics on this page if your introduction is in:

- human health exposure band 3, and you are trying to get to an outcome of very low indicative human health risk or
- human health exposure band 4, and you are trying to get to an outcome of low **or** very low indicative human health risk.

Work your way through each hazard characteristic on this page. Look at whether your chemical meets the hazard characteristic **definition** based on the information that you have.

If it **does** meet the hazard characteristic definition, stop there - your introduction's **human health hazard band is B**. Move on to the next step - step 4.5 Work out your human health risk for categorisation.

If it **does not** meet the hazard characteristic definition, you'll need to try and prove that your chemical **does not** have this hazard characteristic. The information that you need to **prove** this for each hazard characteristic is shown below. If you **do not** have this information, stop there - your introduction's human health hazard band is B. Move onto the next step – step 4.5 Work out your human health risk for categorisation.

If you **do** have this information (so you can prove that the chemical does not have the hazard characteristic), move onto the next hazard characteristic on this page.
After you have considered all the hazard characteristics on this page and have proven that the chemical does not have any of them, decide whether you can stop there or continue to human health hazard band A This depends on the exposure band of your introduction.

If your introduction is in human health exposure band 3, continue to human health hazard band A.

If your introduction is in human health exposure band 4, you can choose to stop (and go to step 4.5 to work out your human health risk for categorisation), or continue to human health hazard band A.

High molecular weight polymer that is water absorbing

High molecular weight polymer that is water absorbing means that all of the following apply to the industrial chemical:

- it is a high molecular weight polymer, and
- it has a number average molecular weight that is greater than or equal to 10,000 g/mol, and
- it is capable of absorbing its own weight, or more, in water, and
- it contains particles with a particle size less than 10 micrometres (microns).

Information required to demonstrate the absence of the hazard characteristic, high molecular weight polymer that is water absorbing

If the chemical is a high molecular weight polymer, the information required to demonstrate that it does not have the hazard characteristic, high molecular weight polymer that is water absorbing, is at least one of:

- molecular weight information that demonstrates the number average molecular weight (NAMW) is less than 10,000 g/mol, or
- information that demonstrates that the polymer is not introduced in a particulate form, or

- particle size information that demonstrates that the particle size is greater than or equal to 10 micrometres (microns), or
- information that demonstrates that the polymer does not absorb its own weight or more in water, such as experiments that show that it does not form a gel in water, or that if it does, the gel dissolves upon addition of more water.

Respiratory sensitisation

Respiratory sensitisation means that any of the following apply to the industrial chemical:

- the chemical is known or presumed to produce hypersensitivity of the airways in humans, as described in chapter 3.4 of the GHS, with the chemical classified as respiratory sensitisation (category 1), or
- the chemical is named:
    - on the EU SVHC Candidate list for authorisation, based on respiratory sensitising properties (https://echa.europa.eu/candidate-list-table), or
    - in the Danish EPA (Q)SAR Database as a predicted respiratory sensitiser (http://qsar.food.dtu.dk/), or
    - the chemical is an enzyme, or
    - the chemical is a polymer that contains one or more free isocyanate groups, or
    - an in vivo study on the chemical indicates hypersensitivity of the airways, as discussed in chapter 3.4 of the GHS, or
    - an in vitro study on the chemical:
        - indicates hypersensitivity of the airways, as discussed in chapter 3.4 of the GHS, and
        - the result of the study has not been negated by in vivo studies conducted on the chemical for hypersensitivity of the airways.

Information required to demonstrate the absence of the hazard characteristic, respiratory sensitisation

There are no information requirements to demonstrate the absence of the hazard characteristic, respiratory sensitisation. If you do not have any information that demonstrates that the chemical has this hazard characteristic then you can assume it does not for the purposes of categorisation.

Corrosive to the respiratory tract

Corrosive to the respiratory tract means that any of the following apply to the industrial chemical:

- the chemical is known to cause destruction of the respiratory tract tissue, as described in chapter 3.1 of the GHS, with the chemical classified as corrosive to the respiratory tract (AUH071 - non-GHS hazard statement), or
- an in vivo study on the chemical conducted following an acceptable test guideline for acute inhalation toxicity, subacute inhalation toxicity or subchronic inhalation toxicity results in destruction of the respiratory tract, as described in chapter 3.1 of the GHS.

Information required to demonstrate the absence of the hazard characteristic, corrosive to the respiratory tract

There are no information requirements to demonstrate the absence of the hazard characteristic, corrosive to the respiratory tract. If you do not have any information that demonstrates that the chemical has this hazard characteristic, then you can assume it does not for the purposes of categorisation.

Specific target organ toxicity after a single exposure (significant toxicity)

Specific target organ toxicity after a single exposure (significant toxicity) means that any of the following apply to the industrial chemical:

- the chemical is known or presumed to produce significant toxicity in humans, as described in chapter 3.8 of the GHS, with the chemical classified as specific target organ toxicity – single exposure (category 1), or
- an in vivo study on the chemical:
    - conducted following an acceptable test guideline for acute oral toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.8 of the GHS, at less than or equal to 300 mg/kg bw, or
    - conducted following an acceptable test guideline for acute dermal toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.8 of the GHS, at less than or equal to 1,000 mg/kg bw, or
    - conducted following an acceptable test guideline for acute inhalation toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.8 of the GHS:
        - gases - less than or equal to 2,500 ppmV/4h, or
        - vapours - less than or equal to mg/L/4h, or

- for dusts/mists/fumes - less than or equal to 1 mg/L/4h.

Information required to demonstrate the absence of the hazard characteristic, specific target organ toxicity after a single exposure (significant toxicity)

There are no information requirements to demonstrate the absence of the hazard characteristic, specific target organ toxicity after a single exposure (significant toxicity). If you do not have any information that demonstrates that the chemical has this hazard characteristic, then you can assume it does not for the purposes of categorisation.

Skin corrosion

Skin corrosion means that any of the following apply to the industrial chemical:

- the chemical is known to produce irreversible damage to the skin, as described in chapter 3.2 of the GHS, with the chemical classified as skin corrosion (category 1), or
- an in vitro study on the chemical conducted following an acceptable test guideline for skin corrosion results in the prediction of skin corrosion effects, or
- an in vivo study on the chemical conducted following an acceptable test guideline for skin irritation results in destruction of skin tissue, as described for skin corrosion in chapter 3.2 of the GHS, or
- the chemical is a pyrophoric liquid or a pyrophoric solid, as described in chapters 2.9 and 2.10 of the GHS respectively.

Information required to demonstrate the absence of the hazard characteristic, skin corrosion

The information required to demonstrate that a chemical does not have the hazard characteristic, skin corrosion, is at least one of the following:

- information that demonstrates that the chemical is a high molecular weight polymer that does not contain any of the following reactive functional groups:
  - anhydride, or
  - epoxide, or
  - sulfonic acid, or
  - amine, or

- information that demonstrates that the chemical is a high molecular weight polymer that contains any of the following reactive functional groups and the polymer has a combined functional group equivalent weight of greater than or equal to 1,000 g/mol:
    - anhydride, or
    - epoxide, or
    - sulfonic acid, or
    - amine, or
- if the **human health exposure band for the introduction is 3** - a suitable in silico prediction indicating that the chemical is not irritating to skin or has no alerting groups for skin irritation, or
- test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for skin corrosion, with a non-corrosive prediction, or
- test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for skin irritation, with a non-irritant prediction, or
- test results from an in vivo study on the chemical or from suitable read across information, conducted following an acceptable test guideline for skin irritation, which does not result in destruction of skin tissue, as described for skin corrosion in chapter 3.2 of the GHS.

Eye damage

Eye damage means that any of the following apply to the industrial chemical:

- the chemical is known to produce serious eye damage, as described in chapter 3.3 of the GHS, with the chemical classified as eye damage (category 1), or
- an in vitro study on the chemical conducted following an acceptable test guideline for eye damage results in the prediction of serious eye damage effects, or
- an in vivo study on the chemical conducted following an acceptable test guideline for eye irritation results in effects on the eye, as described for serious eye damage in chapter 3.3 of the GHS, or
- the chemical is a pyrophoric liquid or a pyrophoric solid, as described in chapters 2.9 and 2.10 of the GHS, respectively.

Information required to demonstrate the absence of the hazard characteristic, eye damage

The information required to demonstrate that a chemical does not have the hazard characteristic, eye damage, is at least one of the following:

- information that demonstrates that the chemical is a high molecular weight polymer that does not contain any of the following reactive functional groups:
    - anhydride, or
    - epoxide, or
    - sulfonic acid, or
    - amine, or
- information that demonstrates that the chemical is a high molecular weight polymer that contains any of the following reactive functional groups with a combined functional group equivalent weight of greater than or equal to 1,000 g/mol:
    - anhydride, or
    - epoxide, or
    - sulfonic acid, or
    - amine, or
- if the **human health exposure band for the introduction is 3** - a suitable in silico prediction indicating that the chemical is not irritating to the eye, or
- test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for eye damage, which predicts the chemical would not induce serious eye damage
- test results from an in vivo study on the chemical or from suitable read across information, conducted following an acceptable test guideline for eye irritation, which does not result in effects on the eye, as described for eye damage in chapter 3.3 of the GHS.

Skin sensitisation

Skin sensitisation means that any of the following apply to the industrial chemical:

- the chemical is known to cause an allergic response following skin contact, as described in chapter 3.4 of the GHS, with the chemical classified as skin sensitisation (category 1), or
- human testing or epidemiological studies on the chemical result in evidence of an allergic response, as described in chapter 3.4 of the GHS, or
- an in vitro study on the chemical:
    - conducted following an acceptable test guideline for skin sensitisation, results in the prediction of skin sensitisation effects, and
    - the results of the study have not been negated by in vivo studies conducted on the chemical for skin sensitisation, or
- an in chemico study on the chemical:
    - conducted following an acceptable test guideline for skin sensitisation, results in the prediction of skin sensitisation effects, and

- the results of the study have not been negated by in vivo studies conducted on the chemical for skin sensitisation, or

- an in vivo study on the chemical conducted following an acceptable test guideline for skin sensitisation, results in the induction of an allergic response, as described in chapter 3.4 of the GHS.

Information required to demonstrate the absence of the hazard characteristic, skin sensitisation

- There are no information requirements to demonstrate the absence of the hazard characteristic, skin sensitisation, if the chemical is corrosive to the skin (GHS category 1) as the in vivo tests cannot be conducted
- otherwise, the information required to demonstrate that a chemical does not have the hazard characteristic, skin sensitisation, is at least one of the following:
    - information that demonstrates that the chemical is a high molecular weight polymer for which at least one of the following:
        - contains only low concern reactive functional groups, or
        - contains only low concern reactive functional groups and unsubstituted positions ortho and para to phenolic hydroxyl groups, or
        - contains only reactive functional groups it contains are unsubstituted positions ortho and para to phenolic hydroxyl groups, or
        - contains only low and moderate concern reactive functional groups , with a combined functional group equivalent weight of greater than or equal to 1000 g/mol, or
        - it contains only moderate concern reactive functional groups, with a combined functional group equivalent weight of greater than or equal to 1000 g/mol, or
        - has a number average molecular weight that is greater than or equal to 10,000 g/mol and both:
            - less than 2% by mass of molecules with molecular weight that is less than 500 g/mol, and
            - less than 5% by mass of molecules with molecular weight that is less than 1,000 g/mol, or
    - information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V, of the REACH Regulation, or
    - if the **human health exposure band is 3** - all of the following:
        - suitable in silico prediction indicating that the chemical and its metabolites (if any) do not cause skin sensitisation, and
        - results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for the 2nd key event in skin sensitisation, with a non-sensitising prediction, and
        - test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for the 3rd key event in skin sensitisation, with a non-sensitising prediction, or
    - all of the following:

        - test results from an in chemico test on the chemical or from suitable read-across information, conducted following an acceptable test guideline for the 1st key event in skin sensitisation, with a non-sensitising prediction, and
        - test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for the 2nd key event in skin sensitisation, with a non-sensitising prediction, and
        - results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for the 3rd key event in skin sensitisation, with a non-sensitising prediction
    - test results from an in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for skin sensitisation, which does not result in induction of an allergic response, as described in chapter 3.4 of the GHS
- in addition, if the **human health exposure band for the introduction is 4** and the **chemical is a UV filter** or is introduced for an end use in a tattoo ink, information is required to justify why the chemical would not cause skin sensitisation mediated by UV light. This may include one or more of the following :
    - the chemical has a molar extinction coefficient/absorption coefficient of less than or equal to 1,000Lmol-^{1}cm-^{1} at wavelengths between 290 and 700nm (based on the results of a study following OECD test guideline 101), or
    - results from in vitro phototoxicity studies, or
    - results from in vitro or in vivo skin sensitisation studies where the methods have been modified to include photoactivation.

Low concern reactive functional groups - see our polymer of low concern criteria page.

Moderate concern reactive functional groups - see our polymer of low concern criteria page.

More information: Categorisation of UV filters

Acute toxicity (fatal or toxic)

Acute toxicity (fatal or toxic) means that any of the following apply to the industrial chemical:

- the chemical is known to exhibit acute toxicity effects, as described in chapter 3.1 of the GHS, with the chemical classified as acute toxicity (category 1 or 2 or 3), or
- an in vitro study on the chemical:
    - conducted following an acceptable test guideline for acute oral toxicity, results in a predicted acute oral toxicity LD50 value of less than or equal to 300 mg/kg bw, and

    - the results of the study have not been negated by in vivo studies conducted on the chemical for acute toxicity, or
- an in vivo study on the chemical:
    - conducted following an acceptable test guideline for acute oral toxicity results in an acute oral LD50 value of less than or equal to 300 mg/kg bw, or
    - conducted following an acceptable test guideline for acute dermal toxicity results in an acute dermal LD50 value of less than or equal to 1,000 mg/kg bw, or
    - conducted following an acceptable test guideline for acute inhalation toxicity results in an acute inhalation LC50 value of:
        - for gases - less than or equal to 2,500 ppmV/4h, or
        - for vapours - less than or equal to 10 mg/L/4h, or
        - for dusts/mists/fumes - less than equal to 1 mg/L/4h , or
- evidence in humans of systemic toxicity after eye contact, with the chemical classified with the non-GHS hazard statement – AUH070, or
- an in vivo study, conducted following an acceptable test guideline for eye irritation, results in overt signs of systemic toxicity or mortality, which is likely to be attributed to absorption of the chemical through the mucous membranes of the eye, with the chemical classified with the non-GHS hazard statement – AUH070.

Information required to demonstrate the absence of the hazard characteristic, acute toxicity (fatal or toxic)

- there are no information requirements to demonstrate the absence of the hazard characteristic, acute toxicity (fatal or toxic), if the chemical is corrosive to the skin (GHS category 1), or likely to be corrosive to the skin (that is, the chemical is a strong acid (pH less than or equal to 2.0) or base (pH greater than or equal to 11.5), and has high buffering capacity (if relevant)), as the in vivo tests cannot be conducted
- if the chemical is for end use in a personal vaporiser - the information required to demonstrate that the chemical does not have the hazard characteristic, acute toxicity (fatal or toxic), is a test result from at least one in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for acute inhalation toxicity with an LC50:
    - for gases - greater than 2,500 ppmV/4h, or
    - for vapours - greater than 10 mg/L/4h, or
    - for dusts/mists/fumes - greater than 1 mg/L/4h, or
- otherwise, the information required to demonstrate that a chemical does not have the hazard characteristic, acute toxicity (fatal or toxic), is at least one of the following:
    - if the **human health exposure band for the introduction is 3** - both of the following:
        - a suitable in silico prediction for acute toxicity (LD50) of the chemical of greater than 2,000 mg/kg bw/day, and

- test results from an in vitro study on the chemical or from suitable read across information for acute toxicity (LD50), conducted following an acceptable test guideline for acute oral toxicity, of greater than 300 mg/kg bw, or

- information that demonstrates that the chemical is a high molecular weight polymer that has:
  - less than 5% by mass of molecules with molecular weight less than 1,000 g/mol, and
  - less than 2% by mass of molecules with molecular weight less than 500 g/mol, or
- inclusion of the chemical in the Select Committee on GRAS Substances (SCOGS) Database as a Type 1 conclusion, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
- the chemical has been notified to the US FDA GRAS notification program and FDA had no questions about the notifier's conclusion of GRAS status, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
- the chemical is permitted to be used as a food additive according to Schedule 15 of the Australia New Zealand Food Standards Code - Standard 1.3.1 - Food Additives, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
- information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
- a test result from at least one in vivo study on the chemical or from suitable read across information, as detailed below, with the administration route dependent on the most relevant route of exposure (or the oral route if information on the most relevant route is not available):
  - conducted following an acceptable test guideline for acute oral toxicity with an LD50 greater than 300 mg/kg bw, or
  - conducted following an acceptable test guideline for acute dermal toxicity with an LD50 greater than 1,000 mg/kg bw, or
  - conducted following an acceptable test guideline for acute inhalation toxicity, with an LC50:
    - for gases - greater than 2,500 ppmV/4h, or
    - for vapours - greater than 10 mg/L/4h, or
    - for dusts/mists/fumes - greater than 1 mg/L/4h, or
- test results from an in vivo study via the oral route on the chemical or from suitable read across information, conducted following an acceptable test guideline for subacute oral toxicity, with a NOAEL greater than or equal to 1,000 mg/kg bw/day.

This page accompanies step 4.4 Work out your human health hazard characteristics

Specific target organ toxicity after repeated exposure

Specific target organ toxicity after repeated exposure means that any of the following apply to the industrial chemical:

- the chemical is known to exhibit significant toxicity or be potentially harmful to human health following repeated exposure, as described in chapter 3.9 of the GHS, with the chemical classified as specific target organ toxicity – repeated exposure (category 1 or 2), or
- an in vivo study on the chemical:
    - conducted following an acceptable test guideline for subacute oral toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, and a NOAEL (oral) value of less than 300 mg/kg bw/day, or
    - conducted following an acceptable test guideline for subchronic oral toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, and a NOAEL (oral) of less than 100 mg/kg bw/day, or
    - conducted following an acceptable test guideline for subacute dermal toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, and a NOAEL (dermal) value of less than 600 mg/kg bw/day, or
    - conducted following an acceptable test guideline for subchronic dermal toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, and a NOAEL (dermal) of less than 200 mg/kg bw/day, or
    - conducted following an acceptable test guideline for subacute inhalation toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, and a NOAEC (inhalation) of:
        - for gases - less than 750 ppmV/6 h/day, or
        - for vapours - less than 3 mg/L/6 h/day, or
        - for dusts/mists/fumes less than 0.6 mg/L/6 h/day, or
    - conducted following an acceptable test guideline for subchronic inhalation toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, and a NOAEC (inhalation) of:
        - for gases - less than 250 ppmV/6 h/day, or
        - for vapours - less than 1 mg/L/6 h/day, or
        - for dusts/mists/fumes less than 0.2 mg/L/6 h/day.

Information required to demonstrate the absence of the hazard characteristic, specific target organ toxicity after repeated exposure

Information is required to demonstrate the absence of the hazard characteristic, specific target organ toxicity after repeated exposure, if:

- the **human health exposure band for the introduction is 4**, and
- you are seeking to demonstrate that the introduction meets the criteria for low risk or very low risk

and any of the following apply:

1. the human health categorisation volume for the introduction is greater than 100 kg and the chemical is introduced for end use in any of the following types of articles:
    - food contact, or
    - children's toys that can be placed in the mouth, or
    - children's care products that can be placed in the mouth, or
2. the human health categorisation volume for the introduction is greater than 1000 kg and the chemical is not introduced for end use in any of the following types of articles:
    - food contact, or
    - children's toys that can be placed in the mouth, or
    - children's care products that can be placed in the mouth, or

3. the chemical is for end use in a personal vaporiser.

See extra guidance on categorisation of chemicals:

- with an end use in articles that are children's toys or care products
- with an end use in articles with food contact
- in e-cigarettes and personal vaporisers

If 1 or 2 apply, the information required to demonstrate that a chemical does not have the hazard characteristic, specific target organ toxicity after repeated exposure, is at least one of the following:

- inclusion of the chemical in the Select Committee on GRAS Substances (SCOGS) Database as a Type 1 conclusion, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
- the chemical has been notified to the US FDA GRAS notification program and FDA had no questions about the notifier's conclusion of GRAS status, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
- the chemical is permitted to be used as a food additive according to Schedule 15 of the Australia New Zealand Food Standards Code - Standard 1.3.1 - Food Additives, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or

- information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
- information that demonstrates that the chemical is a high molecular weight polymer that does not have the hazard characteristic, skin corrosion, or
- a test result from at least one in vivo study on the chemical or from suitable read across information, as detailed below, with the administration route dependent on the most relevant route of exposure (or the oral route if information on the most relevant route is not available):
    - conducted following an acceptable test guideline for subacute oral toxicity, in which the NOAEL (oral) is greater than or equal to 300 mg/kg bw/day or there were no significant toxic effects of relevance to human health (as described in chapter 3.9 of the GHS) produced, or
    - conducted following an acceptable test guideline for subchronic oral toxicity, in which the NOAEL (oral) is greater than or equal to 100 mg/kg bw/day or there were no significant toxic effects of relevance to human health (as described in chapter 3.9 of the GHS) produced, or
    - conducted following an acceptable test guideline for subacute dermal toxicity, in which the NOAEL (dermal) is greater than or equal to 600 mg/kg bw/day or there were no significant toxic effects of relevance to human health (as described in chapter 3.9 of the GHS) produced, or
    - conducted following an acceptable test guideline for subchronic dermal toxicity, in which the NOAEL (dermal) is greater than or equal to 200 mg/kg bw/day or there were no significant toxic effects of relevance to human health (as described in chapter 3.9 of the GHS) produced, or
    - conducted following an acceptable test guideline for subacute inhalation toxicity, in which there were no significant toxic effects of relevance to human health (as described in chapter 3.9 of the GHS) produced, or the NOAEC (inhalation) is:
        - for gases - greater than or equal to 750 ppmV/6 h/day, or
        - for vapours - greater than or equal to 3 mg/L/6 h/day, or
        - for dusts/mists/fumes - greater than or equal to 0.6 mg/L/6 h/day , or
    - conducted following an acceptable test guideline for subchronic inhalation toxicity, in which there were no significant toxic effects of relevance to human health (as described in chapter 3.9 of the GHS) produced, or the NOAEC (inhalation) is:
        - for gases - greater than or equal to 250 ppmV/6 h/day, or
        - for vapours - greater than or equal to 1 mg/L/6 h/day, or
        - for dusts/mists/fumes - greater than or equal to 0.2 mg/L/6 h/day.

If 3 applies (the chemical is for end use in a personal vaporiser), the information required to demonstrate that the chemical does not have the hazard characteristic, specific target organ toxicity after repeated exposure, is a test result from at least one in vivo study on the chemical or from suitable read across information, as detailed below:

- conducted following an acceptable test guideline for subacute inhalation toxicity, in which there were no significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, or the NOAEC (inhalation) is:
    - for gases - greater than or equal to 750 ppmV/6 h/day, or

    - for vapours - greater than or equal to 3 mg/L/6 h/day, or
    - for dusts/mists/fumes - greater than or equal to 0.6 mg/L/6 h/day, or
- conducted following an acceptable test guideline for subchronic inhalation toxicity, in which there were no significant toxic effects of relevance to human health, as discussed in chapter 3.9 of the GHS, or the NOAEC (inhalation) is:
    - for gases - greater than or equal to 250 ppmV/6 h/day, or
    - for vapours - greater than or equal to 1 mg/L/6 h/day, or
    - for dusts/mists/fumes - greater than or equal to 0.2 mg/L/6 h/day.

There are no information requirements to demonstrate the absence of the hazard characteristic, specific target organ toxicity after repeated exposure, if:

- the **human health exposure band for the introduction is 4**, and
- you are seeking to demonstrate that the introduction meets the criteria for low risk or very low risk,

and any of the following apply:

- the human health categorisation volume for the introduction is less than or equal to 100 kg and the chemical is introduced for end use in any of the following types of articles:
    - food contact, or
    - children's toys that can be placed in the mouth, or
    - children's care products that can be placed in the mouth, or
- the human health categorisation volume for the introduction is less than or equal to 1,000 kg and the chemical is not introduced for end use in any of the following types of articles:
    - food contact, or
    - children's toys that can be placed in the mouth, or
    - children's care products that can be placed in the mouth

In these circumstances, if you do not have any information that demonstrates that the chemical has this hazard characteristic then you can assume it does not for the purposes of categorisation.

Human health hazard band A hazard characteristics

Do not start this page unless you have read Step 4.4 Work out your human health hazard characteristics, and human health hazard band C hazard characteristics, and human health hazard band B hazard characteristics

Human health hazard characteristics are split into hazard bands. Hazard characteristics of most concern are in hazard band C, while those of lower concern are in hazard band A.

Hazard band A has 6 hazard characteristics you need to consider:

- High molecular weight polymer that has lung overloading potential
- Aspiration hazard
- Specific target organ toxicity after a single exposure (harmful or transient effects)
- Skin irritation
- Eye irritation
- Acute toxicity (harmful)

Instructions

You must always start at hazard band C. You only need to work through the hazard characteristics on this page if your introduction is in:

- human health exposure band 3, and you are trying to get to an outcome of very low indicative human health risk or
- human health exposure band 4, and you are trying to get to an outcome of very low indicative human health risk.

Work your way through each hazard characteristic on this page. Look at whether your chemical meets the hazard characteristic definition based on the information that you have.

If it does meet the hazard characteristic definition, stop there - your introduction's human health hazard band is A.

Move on to the next step - step 4.5 Work out your human health risk for categorisation.

If it does not meet the hazard characteristic definition, you'll need to try and prove that your chemical does not have this hazard characteristic. The information that you need to prove this for each hazard characteristic is shown below. If you do not have this information, stop there - your introduction's human health hazard band is A.

Move onto the next step – step 4.5 Work out your human health risk for categorisation.

If you do have this information (so you can prove that the chemical does not have the hazard characteristic), move onto the next hazard characteristic on this page.

After you have considered all the hazard characteristics on this page and have proven that the chemical does not have any of them, go to step 4.5 to work out your human health risk for categorisation).

High molecular weight polymer that has lung overloading potential

High molecular weight polymer that has lung overloading potential means that all of the following apply to the industrial chemical:

- it is a polymer, and
- it has a number average molecular weight that is greater than 70,000 g/mol, and
- it has a solubility in water of less than 0.1 mg/L, and
- it becomes aerosolised during end use.

Information required to demonstrate the absence of the hazard characteristic, high molecular weight polymer that has lung overloading potential

If the chemical is a polymer, the information required to demonstrate that a chemical does not have the hazard characteristic, high molecular weight polymer that has lung overloading potential, is at least one of the following:

- molecular weight information that demonstrates that the number average molecular weight is less than or equal to 70,000 g/mol, or
- information that demonstrates that the polymer has a solubility in water that is greater than or equal to 0.1 mg/L measured following an acceptable test guideline for water solubility, or
- information that demonstrates that the polymer does not become aerosolised during end use

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Aspiration hazard

Aspiration hazard means that any of the following apply to the industrial chemical:

- the chemical is known or presumed to cause aspiration toxicity, as described in chapter 3.10 of the GHS, with the chemical classified as may be fatal if swallowed and enters airways (category 1), or
- the chemical is a hydrocarbon that has a kinematic viscosity less than or equal to 20.5 mm2/s, measured at 40°C.

Information required to demonstrate the absence of the hazard characteristic, aspiration hazard

- If the chemical is a hydrocarbon, the information required to demonstrate the absence of the hazard characteristic, aspiration hazard, is a measured kinematic viscosity greater than a20.5 mm2/s, at 40°C
- Otherwise, there are no information requirements to demonstrate the absence of the hazard characteristic, aspiration hazard. If you do not have any information that demonstrates that the chemical has this hazard characteristic, then you can assume it does not for the purposes of categorisation.

Specific target organ toxicity after a single exposure (harmful or transient effects)

Specific target organ toxicity after a single exposure (harmful or transient effects) means that any of the following apply to the industrial chemical:

- the chemical is known or presumed to be harmful to humans or to cause transient target organ effects, as described in chapter 3.8 of the GHS, with the chemical classified as specific target organ toxicity-single exposure (category 2 or 3), or
- an in vivo study on the chemical:
    - conducted following an acceptable test guideline for acute oral toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.8 of the GHS, at greater than 300 but less than or equal to 2,000 mg/kg bw, or
    - conducted following an acceptable test guideline for acute dermal toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.8 of the GHS, at greater than 1,000 but less than or equal to 2,000 mg/kg bw, or
    - conducted following an acceptable test guideline for acute inhalation toxicity results in significant toxic effects of relevance to human health, as discussed in chapter 3.8 of the GHS, at:
        - for gases - greater than 2,500 but less than or equal to 20,000 ppmV/4h, or
        - for vapours - greater than 10 but less than or equal to 20 mg/L/4h, or
        - for dusts/mists/fumes - greater than 1 but less than or equal to 5 mg/L/4h.

Information required to demonstrate the absence of the hazard characteristic, specific target organ toxicity after a single exposure (harmful or transient effects)

There are no information requirements to demonstrate the absence of the hazard characteristic, specific target organ toxicity after a single exposure (harmful or transient effects). If you do not have any information that demonstrates that the chemical has this hazard characteristic, then you can assume it does not for the purposes of categorisation.

Skin irritation

Skin irritation means that any of the following apply to the industrial chemical:

- the chemical is known to produce reversible damage to the skin, as described in chapter 3.2 of the GHS, with the chemical classified as skin irritation (category 2), or
- an in vitro study on the chemical conducted following an acceptable test guideline for skin irritation results in the prediction of skin irritation effects, or
- an in vivo study on the chemical conducted following an acceptable test guideline for skin irritation results in skin reactions, as described for skin irritation (category 2) in chapter 3.2 of the GHS.

Information required to demonstrate the absence of the hazard characteristic, skin irritation

The information required to demonstrate that a chemical does not have the hazard characteristic, skin irritation, is at least one of the following:

- if the **human health exposure band for the introduction is 3** - a suitable in silico prediction indicating that the chemical is not irritating to the skin, or
- test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for skin irritation, with a non-irritant prediction, or
- test results from an in vivo study on the chemical or from suitable read across information, conducted following an acceptable test guideline for skin irritation, which does not result in skin reactions, as described for skin irritation in chapter 3.2 of the GHS, or
- test results from an in vivo study on the chemical or from suitable read across information conducted following an acceptable test guideline for acute dermal toxicity, that when tested at 2,000 mg/kg bw/day is not irritating to the skin.

In addition, if the chemical is introduced for an end use in a tattoo ink, information is required to justify why the chemical would not cause skin irritation mediated by UV light. This may include one or more of the following:

- the chemical has a molar extinction coefficient/absorption coefficient of less than 1,000Lmol^{-1}cm^{-1} at wavelengths between 290 and 700nm (based on the results of a study following OECD test guideline 101), or
- results from in vitro phototoxicity studies, or
- results from in vitro or in vivo irritation studies where the methods have been modified to include photoactivation.

Eye irritation

Eye irritation means that any of the following apply to the industrial chemical:

- the chemical is known to produce changes in the eye, as described in chapter 3.3 of the GHS, with the chemical classified as eye irritation (category 2), or
- an in vitro study on the chemical conducted following an acceptable test guideline for eye irritation results in the prediction of eye irritation effects, or
- an in vivo study on the chemical conducted following an acceptable test guideline for eye irritation results in changes in the eye, as described for eye irritation in chapter 3.3 of the GHS.

Information required to demonstrate the absence of the hazard characteristic, eye irritation

The information required to demonstrate that a chemical does not have the hazard characteristic, eye irritation, is at least one of the following:

- if the **human health exposure band for the introduction is 3** - a suitable in silico prediction indicating that the chemical is not irritating to the eyes, or
- test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for eye damage or eye irritation with a non-irritant prediction, or
- test results from an in vivo study on the chemical or from suitable read across information, conducted following an acceptable test guideline for eye irritation, which does not result in changes in the eyes, as described for eye irritation (category 2) in chapter 3.3 of the GHS.

Acute toxicity (harmful)

Acute toxicity (harmful) means that any of the following apply to the industrial chemical:

- the chemical is known to exhibit acute toxicity effects, as described in chapter 3.1 of the GHS, with the chemical classified as acute toxicity (category 4), or
- an in vitro study on the chemical:
    - conducted following an acceptable test guideline for acute oral toxicity, results in a predicted acute toxicity LD50 value of greater than 300 but less than or equal to 2,000 mg/kg bw, and
    - the results of the study have not been negated by in vivo studies conducted on the chemical for acute toxicity, or
- an in vivo study on the chemical:
    - conducted following an acceptable test guideline for acute oral toxicity results in an acute oral LD50 value of greater than 300 but less than or equal to 2,000 mg/kg bw, or
    - conducted following an acceptable test guideline for acute dermal toxicity results in an acute dermal LD50 value of greater than 1,000 but less than or equal to 2,000 mg/kg bw, or
    - conducted following an acceptable test guideline for acute inhalation toxicity results in an acute inhalation LC50 value of:
        - for gases - greater than 2500 but less than or equal to 20,000 ppmV/4h, or
        - for vapours - greater than 10 but less than or equal to 20 mg/L/4h, or
        - for dusts/mists/fumes - greater than 1 but less than or equal to 5 mg/L/4h.

Information required to demonstrate the absence of the hazard characteristic, acute toxicity (harmful)

- if the chemical is for end use in a personal vaporiser - the information required to demonstrate that the chemical does not have the hazard characteristic, acute toxicity (harmful), is a test result from at least one in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for acute inhalation toxicity with an LC50 of:
    - for gases - greater than 20,000 ppmV/4h, or
    - for vapours - greater than 20 mg/L/4h, or
    - for dusts/mists/fumes - greater than 5 mg/L/4h, or
- otherwise, the information required to demonstrate that a chemical does not have the hazard characteristic, acute toxicity (harmful), is at least one of the following:
    - if the **human health exposure band for the introduction is** 3 - both of the following:
        - a suitable in silico prediction for acute toxicity (LD50) of the chemical of greater than 2,000 mg/kg bw/day, and
        - test results from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for acute oral toxicity, with a predicted LD50 of greater than 2,000 mg/kg bw, or
    - information that demonstrates that the chemical is a high molecular weight polymer that has:
        - less than than 5% by mass of molecules with molecular weight less than 1,000 g/mol, and
        - less than 2% by mass of molecules with molecular weight less than 500 g/mol
    - inclusion of the chemical in the Select Committee on GRAS Substances (SCOGS) Database as a Type 1 conclusion, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
    - the chemical has been notified to the US FDA GRAS notification program and FDA had no questions about the notifier's conclusion of GRAS status, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
    - the chemical is permitted to be used as a food additive according to Schedule 15 of the Australia New Zealand Food Standards Code - Standard 1.3.1 - Food Additives, as long as the human health exposure expected from the industrial use of the chemical is no higher than the human health exposure expected from food use, or
    - information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
    - a test result from at least one in vivo study on the chemical or from suitable read across information, as detailed below, with the administration route dependent on the most relevant route of exposure (or the oral route if information on the most relevant route is not available):
        - conducted following an acceptable test guideline for acute oral toxicity with an LD50 greater than 2,000 mg/kg bw, or
        - conducted following an acceptable test guideline for acute dermal toxicity with an LD50 greater than 2,000 mg/kg bw, or
        - conducted following an acceptable test guideline for acute inhalation toxicity with an LC50:
            - for gases - greater than 20,000 ppmV/4h, or

        - for vapours - greater than 20 mg/L/4h, or
        - for dusts/mists/fumes - greater than 5 mg/L/4h, or
    - test results from an in vivo study on the chemical or from suitable read across information, conducted following an acceptable test guideline for subacute oral toxicity, with a NOAEL greater than or equal to 1,000 mg/kg bw/day.

This page accompanies step 4.4 Work out your human health hazard characteristics.

Step 4.5 Outcome - your human health risk for categorisation

Get help with this step — explore our categorisation decision tools

We explain the table in detail for each human health exposure band that your introduction could be in. This includes what your indicative human health risk outcome will be, depending on which hazard characteristics your chemical does or does not have. Your outcome will be that your introduction has an indicative human health risk of:

- medium to high
- low OR
- very low

Refer back to step 4.4 for information about how to consider the hazard characteristics and where to start and stop when considering hazard characteristics.

Human health risk table

Work out your indicative human health risk	**Human health exposure band**			
	1	2	3	4

Human health hazard band	C	Low risk	Medium to high risk	Medium to high risk	Medium to high risk
	B	Very low risk	Very low risk	Low risk	Medium to high risk
	A	Very low risk	Very low risk	Low risk	Low risk
	Not C, B, A	Very low risk	Very low risk	Very low risk	Very low risk

If your introduction is in human health exposure band 1

If your introduction is in human health exposure band 1, you will need to consider if your chemical has any of the hazard characteristics in human health hazard band C. It's not necessary to consider the hazard characteristics in band B or A.

The indicative human health risk of your introduction will be:

- **low** if your chemical has **1 or more** of the hazard characteristics in human health hazard band C OR
- **very low** if your chemical does **not** have **any** of the hazard characteristics in human health hazard band C

If your introduction is in human health exposure band 2

If your introduction is in human health exposure band 2, you will need to consider if your chemical has any of the hazard characteristics in human health hazard band C.
It's **not** necessary to consider the hazard characteristics in band B or A.

The indicative human health risk of your introduction will be:

- **medium to high** if your chemical has **1 or more** of the hazard characteristics in human health hazard band C OR
- **very low** if your chemical does not have any of the hazard characteristics in human health hazard band C

If your introduction is in human health exposure band 3

If your introduction is in human health exposure band 3, at a minimum, you will need to consider if your chemical has any of the hazard characteristics in human health hazard band C.

The indicative human health risk of your introduction will be:

- **medium to high** if your chemical has **1 or more** of the hazard characteristics in human health hazard band C OR
- low if your chemical does **not** have **any** of the hazard characteristics in human health hazard band C

You can choose to stop if you get to **low** indicative human health risk.

If you want to see if your introduction could have a **very low** indicative human health risk, you will also need to consider if it has any of the hazard characteristics in human health hazard bands B and A.

The indicative human health risk of your introduction will be:

- **low** if your chemical has 1 or more of the hazard characteristics in human health hazard band B or A OR
- **very low** if your chemical does not have any of the hazard characteristics in human health hazard band B or A

If your introduction is in human health exposure band 4

If your introduction is in human health exposure band 4, you will first need to consider if your chemical has any of the hazard characteristics in human health hazard band C. If it does not, then continue on to consider the hazard characteristics in human health hazard band B.

The indicative human health risk of your introduction will be:

- **medium to high** if your chemical has **1 or more** of the hazard characteristics in human health hazard band C or B OR
- low if your chemical does **not** have **any** of the hazard characteristics in human health hazard band C or B

You can choose to stop if you get to low indicative human health risk.

If you want to see if your introduction could have a **very low** indicative human health risk, you will also need to consider if it has any of the hazard characteristics in human health hazard band A.

The indicative human health risk of your introduction will be:

- low if your chemical has 1 or more of the hazard characteristics in human health hazard band A OR
- very low if your chemical does not have any of the hazard characteristics in human health hazard band A

'Special cases' — introductions that CANNOT have a very low indicative human health risk

Your introduction CANNOT have a very low indicative human health risk if it is a:

- UV filter OR
- chemical that is introduced as a solid or a dispersion that is not soluble, that meets the nanoscale particle size criteria, and the introduction of the nanoscale portion of the chemical (the part that has a particle size range of 1nm to 100nm) is incidental to the introduction of the non-nanoscale portion OR
- chemical that is introduced as a solid or a dispersion where there is no information available on its water solubility or its particle size, and the introduction of any nanoscale portion of the chemical (the part that has a particle size range of 1nm to 100nm) is incidental to the introduction of the non-nanoscale portion.

If your introduction is 1 of these, and you got a **very low risk outcome** in this step, you need to CHANGE that outcome to LOW RISK.

This means if your consideration of step 4.5 got you to an outcome of **very low risk**, your **final outcome needs to be changed to low risk**.

Definitions of these 'special cases'

A **UV filter** is a chemical that is intended to protect the skin against ultraviolet radiation in the range of 290nm to 400nm by absorption, reflection, or scattering of ultraviolet radiation.

Nanoscale particle size criteria means that the chemical consists of particles in an unbound state or as an aggregate or agglomerate. At least 50% (by number size distribution) of the particles must have at least 1 external dimension in the particle size range of 1nm to 100nm (i.e. the nanoscale).

Not soluble means the solubility of the chemical in water is less than 33.3 g/L measured following OECD test guidelines 105 or 120 for water solubility; or the dissolution rate of the chemical is not more than 70%.

Next

Go to step 5 to work out the risk to the environment of your introduction

The table on this page shows how you can work out your indicative human health risk by using your human health exposure band and the human health hazard characteristics that your chemical does or does not have.

Step 5: Work out your introduction's risk to the environment

To be able to finish your categorisation you need to work out the risks of your introduction to the **environment**. To work this out start at 5.1 and continue as far as you need to through each step.

Once you have your answer for the risk of your introduction to the environment – medium to high, low or very low – go to Step 6. In Step 6 you'll combine the human health risk and the environment risk for the final category of your introduction.

Step 5.1 Introductions that are always medium to high risk to the environment

Start at this step if your chemical introduction is a type that is always medium to high risk to the environment.

Step 5.2 Introductions that can be low risk to the environment

This step relates to international assessments and how to work out if your introduction can be low risk to the environment based on its international assessment.

Step 5.3 Work out your environment exposure band

Part of the process to work out the risk to the environment of your introduction is to work out its exposure band. There 4 environment exposure bands - Exposure band 1 has the lowest level of environment exposure and exposure band 4 the highest level

Step 5.4 Work out your environment hazard characteristics

A chemical has an environmental hazard characteristic if it can cause damage, harm or adverse effects to the environment. Find out what you need to do to establish the environment hazard characteristics of your chemical.

Step 5.5 Outcome - your environment risk for your categorisation

Use the table on this page to confirm the risk of your introduction: medium to high, low

or very low. After you this, go to step 6 to complete your categorisation.

By now you know the human health risk of your introduction – medium to high, low or very low – which you completed in step 4.

Step 5.1: Introductions that are always medium to high risk to the environment

You are at Step 5.1 because you've ruled out **Steps 0, 1, 2 and 3** and have completed **step 4** of the categorisation process.

Instructions

Go through A, B, C, D and E to work out if you are, or are not, introducing any of these types of chemicals. You must keep records of study reports and other information that you used to answer each question.

A. Is your chemical a certain gas?

B. Is your chemical a certain organotin chemical?.

*C. Does your chemical contain a sequence of 4 to 20 fully fluorinated carbon atoms (including per- and poly-fluorinated alkyl substances, known as PFAS)?.

*D. Is your chemical a certain polyhalogenated organic chemical?.

*E. Is your chemical a certain chemical at the nanoscale?.

*Note, these last 3 types of chemical introductions we describe on this page are the same as the ones that we describe in step 4.1 for human health. This means that they are medium to high indicative risk to the environment and to human health. So if you are introducing one of

these types of chemicals, you should have already worked out that your introduction category is assessed because of its indicative human health risk being medium to high. Also, you now know that it's also assessed because of its indicative environment risk being medium to high.

A. Is your chemical a certain gas?

Your chemical is a gas if it is in the gaseous phase at 20^{O}C and 101.3kPa (ambient conditions).

All introductions of chemicals that are a gas and are persistent in the environment are a specified class of introduction.

No I am not introducing this type of chemical

You must be able prove this. For example, you might have a SDS or product information sheet that indicates the appearance. You also need to be able to provide the information if we ask for it.

Next step: Go to 'B. Is your chemical a certain organotin chemical?'

Yes I am introducing this type of chemical

If you are introducing a gas, you must consider which of the following circumstances apply to your introduction.

1. Introduced at volumes less than 100kg

Next step: Go to 'B. Is your chemical a certain organotin chemical?'.

2. Introduced at volumes higher than 100kg each year

You need to have information about the persistence of your gas. To prove that your gas is not persistent, we'll accept information that shows your gas has a half-life in air of less than 2 days. This could be:

- an in silico prediction using EPI Suite AOPWIN or
- studies that use methods that are well established in published peer-reviewed scientific literature

Next step: If you **do have** the in silico predictions or studies to prove that your gas is **not persistent**, go to 'B. Is your chemical a certain organotin chemical?'.

or

If you **do not** have the required in silico predictions or studies described above, then you **cannot prove** that your gas is not persistent.

Outcome: Your introduction is medium to high indicative risk to the environment. This means your introduction is in the assessed category and called an '**assessed introduction**'.

- Before you can introduce the chemical, you must apply for an assessment certificate and select 'Environment focus' as the application type or apply for a commercial evaluation authorisation (if you meet the strict criteria).
- When you apply for an assessment certificate, you need to answer 'yes' when we ask if your introduction is a specified class of introduction. When we receive your application, we'll contact you to ask for extra information that we need to assess the risks of your introduction.

B. Is your chemical an organotin chemical?

Organotin chemicals are chemicals that contain at least 1 tin atom that is covalently bound to at least one carbon atom. They are widely used as polyvinyl chloride (PVC) stabilisers, biocides, and in antifouling paints.

No I am not introducing this type of chemical

You must be able prove this. You (or the chemical identity holder) need information about the identity of the chemical as proof you are not introducing this type of chemical. You also need to be able to provide the information if we ask for it.

Next step: Go to 'C. Chemicals that contain a sequence of 4 to 20 fully fluorinated carbon atoms (including per- and poly-fluorinated alkyl substances, known as PFAS).

Yes I am introducing this type of chemical

If you are introducing an organotin chemical, you must consider which of the below circumstances apply to your introduction.

1. Introduced at volumes less than or equal to 10kg per year

Next step: Go to 'C. Does your chemical contain a sequence of 4 to 20 fully fluorinated carbon atoms (including per- and poly-fluorinated alkyl substances, known as PFAS)'.

2. Introduced at volumes greater than 10kg per year

Outcome: If this applies to your introduction, it is in the assessed introduction category and is called an 'assessed introduction'. Before you can introduce the chemical, you must apply for an assessment certificate and select 'Environment' focus as the application type or apply for a commercial evaluation authorisation (if you meet the strict criteria).

C. Does your chemical contain a sequence of 4 to 20 fully fluorinated carbon atoms (including per- and poly-fluorinated alkyl substances, known as PFAS)?

Fluorinated chemicals contain fluorine atoms and include per- and polyfluorinated chemicals (PFAS). These are commonly used in products to add resistance to heat, other chemicals, and abrasion. They also act as dispersion, wetting or surface treatment agents. We have an increased level of concern for introductions of chemicals that contain a sequence of 4 to 20 fully fluorinated carbon atoms (including PFAS) because these chemicals, or their degradation products, may be persistent in the environment, bioaccumulate and be highly toxic.

No I am not introducing this type of chemical

You must have information about your chemical's identity as proof that you're **not** introducing this type of chemical. You (or the chemical identity holder) need to provide the information if we ask for it.

Next step: Go to 'D. Is your chemical a certain polyhalogenated organic chemical?' below.

Yes I am introducing this type of chemical

We have extra guidance on categorising fluorinated chemicals

Outcome: Your introduction has a medium to high indicative risk to both human health and the environment. This means your introduction is in the assessed category and called an 'assessed introduction'.

- Before you can introduce the chemical, you must apply for an assessment certificate and select 'Health and environment focus' as the application type or apply for a commercial evaluation authorisation (if you meet the strict criteria).
- When you apply for an assessment certificate, you need to answer ‘yes’ when we ask if your introduction is a specified class of introduction. When we receive your application, we’ll contact you to ask for extra information that we need to assess the risks of your introduction.

D. Is your chemical a polyhalogenated organic chemical?

Polyhalogenated organic chemicals are carbon-based chemicals that contain more than 1 covalently bonded halogen atom, such as bromine, chlorine, fluorine, or iodine. Polyhalogenated organic chemicals are commonly used as flame retardants in plastics, textiles, and electronic circuitry. They may have long-term effects on human health and the environment. We have an increased level of concern for introductions of chemicals that are polyhalogenated organic chemicals because these chemicals, or their degradation products, may be persistent in the environment, bioaccumulate and be highly toxic.

No I am not introducing this type of chemical

You must have information about your chemical's identity as proof that you're **not** introducing this type of chemical. You (or the chemical identity holder) need to provide the information if we ask for it.

Next step: Go to 'E. Is your chemical a certain chemical at the nanoscale?' below.

Yes I am introducing this type of chemical

We have extra guidance on the categorisation of polyhalogenated organic chemicals

All introductions of polyhalogenated chemicals are a specified class of introduction.

If the chemical identity information that you (or the chemical identity holder) have confirms you are introducing this type of chemical, you must consider which of the following circumstances apply to your introduction.

1. Introduced at volumes less than or equal to 100 kg each year

Next step: Go to 'E. Is your chemical a certain chemical at the nanoscale?' below.

2. Introduced at volumes higher than 100 kg each year

You need to have test results about the persistence of your chemical and any of its known environmental degradation products.

- Known environmental degradation products refer to the expected breakdown products of the chemical under environmentally relevant conditions. These breakdown products are ones that have been found in studies or reported in scientific literature.
- A persistent chemical remains intact in the environment for long periods of time. A chemical is persistent if its degradation half-life (T1/2) is greater than or equal to:
    - 2 days in air or
    - 2 months in water or

- 6 months in soil or
- 6 months in sediment.

To prove that your chemical and any of its known environmental degradation products **are not** persistent, we accept study results in option 1 or 2.

Option 1

A study conducted following OECD test guideline 301 (Ready Biodegradability) that results in the pass levels being reached within one of the following time periods:

- specified time period – such that the chemical is considered to be readily biodegradable or
- duration of the test – but not within the specified time period for the chemical to be considered readily biodegradable, provided biodegradation has started within the specified time period

If you have this study showing these results, then move on to 'E. Is your chemical a certain chemical at the nanoscale?' below.

Option 2

A study conducted following OECD test guideline 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems) that results in both a degradation half-life of less than 2 months in water and 6 months in sediment.

If you have this study showing these results, then move on to 'E. Is your chemical a certain chemical at the nanoscale?' below.

If you do not have either of the study results described in option 1 or 2

Outcome: Your introduction is medium to high indicative risk to human health and the environment because you cannot prove that your chemical (and any of its known environmental degradation products) are not persistent. Your introduction is medium to high indicative risk to human health and the environment. This means your introduction is in the assessed category and called an 'assessed introduction'.

- Before you can introduce the chemical, you must apply for an assessment certificate and select 'Health and environment focus' as the application type or apply for a commercial evaluation authorisation (if you meet the strict criteria).
- When you apply for an assessment certificate, you need to answer 'yes' when we ask if your introduction is a specified class of introduction. When we receive your application, we'll contact you to ask for extra information that we need to assess the risks of your introduction.

E. Is your chemical a certain chemical at the nanoscale?

Introductions of chemicals that meet **all 4 criteria below** are medium to high indicative risk to both human health and the environment. We refer to these introductions as 'certain chemicals at the nanoscale'. We have an increased level of concern for chemicals at the nanoscale, because of uncertainty about the risks of some of these chemicals due to their potentially different properties, such as chemical reactivity, relative to the non-nanoscale forms of the chemicals.

1. It is introduced as a solid or is in a dispersion.
2. It consists of particles in an unbound state or as an aggregate or agglomerate. At least 50% (by number size distribution) of the particles have at least 1 external dimension in the particle size range of 1nm to 100nm (ie. the nanoscale). Note that if you meet criteria 1 and 2, and regardless of whether you meet criteria 3 and 4, your introduction is a specified class of introduction.
3. It is not soluble. This means the solubility of the chemical in water is less than 33.3 g/L measured following OECD test guideline 105 or 120 for water solubility; or the dissolution rate of the chemical is not more than 70%.
4. The introduction of the nanoscale portion of the chemical (the part that has a particle size range of 1nm to 100nm) is **not** incidental to the introduction of the non-nanoscale portion. This is the case if **any** of the following apply:

    a. the manufacture of the chemical (in Australia or overseas) at the nanoscale is the result of a deliberate manufacturing decision

    b. the manufacture of the chemical (in Australia or overseas) at the nanoscale is necessary for the manufacture of the non-nanoscale portion of the chemical. This means that to make the non-nanoscale chemical, part of the chemical has to be at the nanoscale

    c. the chemical at the nanoscale has specific technical characteristics that are the intended result of changes in the manufacturing process. For example, if the process of manufacturing the chemical changes in order to change the particle size of the chemical, or its properties at the nanoscale. This could happen by:

        - mechanical actions like milling, grinding, shearing, sieving or sonication
        - chemicals reactions like electrochemical exfoliation, or catalysts
        - other changes such as changes to pressure or temperature or pH or solvent

Yes I am introducing this type of chemical

We have extra guidance on categorising chemicals at the nanoscale

This means that your introduction meets all 4 criteria above and is a 'certain chemical at the nanoscale'.

Outcome: Your introduction has a medium to high indicative risk to both human health and the environment. This means your introduction is in the assessed category and called an ‘assessed introduction’.

- Before you can introduce the chemical, you must apply for an assessment certificate and select 'Health and environment focus' as the application type or apply for a commercial evaluation authorisation (if you meet the strict criteria).
- When you apply for an assessment certificate, you need to answer ‘yes’ when we ask if your introduction is a specified class of introduction. When we receive your application, we’ll contact you to ask for extra information that we need to assess the risks of your introduction.

No I am not introducing this type of chemical

This means that you have information or studies to prove that your chemical does not meet any of the 4 criteria, or it only meets some of the 4 criteria. Answering the questions below will help you prove this. As you go through the questions, we'll tell you the next steps you should take.

Some introductions are always medium to high risk to the environment. This means they will be in the assessed introduction category and you need to apply for an assessment certificate.

Open All Close All

Question 1: Will your chemical be introduced in Australia as a solid or in a dispersion?

For example, information on appearance could be recorded on an SDS or technical data sheet of the chemical or product that will be introduced into Australia.

Note:

- If your information indicates that it's a powder, flakes, granules, pellets, or wax, select '**yes**'.
- If your information indicates that it's a liquid, select '**no**'.

Yes

Go to question 2.

I don't know

Go to question 2. Alternatively, contact your chemical supplier and return to this page when you have further information.

No

This means that your introduction is not of a 'certain chemical at the nanoscale'.

The criteria for 'certain chemicals at the nanoscale' are not met for your introduction.

Next step: Go to 'Step 5.2 Introductions that can be low risk for the environment' and continue to categorise your introduction.

Question 2: Does the information you have access to indicate that your chemical will be introduced as granules, pellets, or as wax?

For example, there is information on the chemical or product's appearance on an SDS or technical data sheet.

No - the chemical will not be introduced as granules, pellets or a wax.

Go to question 3.

Yes - the chemical will be introduced as granules, pellets or a wax.

Note: you must keep a record of this information.

This means that your introduction is not of a 'certain chemical at the nanoscale'.

Next step: Go to 'Step 5.2 Introductions that can be low risk for the environment' and continue to categorise your introduction.

Question 3: Does the information you have access to indicate that your chemical is soluble in water (solubility greater than 33.3 g/L)) or has a high dissolution rate (greater than 70%)?

Examples of when you should answer 'yes'

- Your chemical is imported in an end use product such as laundry or dishwashing powder and it is not known to be an insoluble component of the product. For the product to work the way it should, the chemical must be soluble in water.
- You have a study result from a water solubility study on your chemical that was carried out following the test guideline OECD TG 105.
- You will introduce a polymer and have information on solution/extraction behaviour of the polymer in water (OECD TG 120).
- You have information on the dissolution rate (OECD WPMN Guidance document for the testing of dissolution and dispersion stability of nanomaterials and the use of the data for further environmental testing and assessment strategies; July 2021).

No or don't know - my information does not indicate that the chemical is soluble in water or has a high dissolution rate or I don't have access to information about this

Go to question 4.

Yes - I have access to information that indicates that the chemical is soluble in water or has a high dissolution rate

This means that your introduction is not a 'certain chemical at the nanoscale'. You must keep a record of information you have available. If the information includes a study result and another person holds the study, you must be able to provide the study to us, if we ask for it.

Learn more about your record keeping obligations

If you have information that shows the chemical consists of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale (1-100 nm), the introduction will be a specified class of introduction. Extra reporting obligations apply.

Next step: Go to 'Step 5.2 Introductions that can be low risk for the environment' and continue to categorise your introduction.

Question 4: What does your information (if you have any) indicate about the mean particle size of your chemical or the product that will be introduced into Australia? Is it greater than 1000 nm in all dimensions?

For example:

- Information on appearance and mean particle size could be recorded on an SDS or technical data sheet of the chemical or product that will be introduced into Australia.
- You have a study result from a particle size distribution study on your chemical or the product that you will introduce into Australia (conducted according to OECD TG 110).

I don't have access to any information about the mean particle size (all dimensions) or I don't know the answer to this question

Go to question 7.

The information I have access to indicates the mean particle size is less than or equal to 1000 nm in one or more dimensions

Go to question 5.

Yes - information I have access to indicates the mean particle size is greater than 1000 nm in all dimensions

This means that your introduction is not of a ‘certain chemical at the nanoscale’.

Next step: Go to 'Step 5.2 Introductions that can be low risk for the environment' and continue to categorise your introduction.

Note: you must keep a record of the information you have available.

Question 5: Do you have access to study results that indicate that the mean particle size of your chemical or the product that will be introduced into Australia is greater than 200 nm in all dimensions?

For example: you have a study result from a particle size distribution study on your chemical or the product that you will introduce into Australia (conducted according to OECD TG 110 or 125).

Note the following:

1. For particle size distributions in this range, information only from an SDS/technical data sheet or similar is not enough.
2. OECD TG 110 on Particle Size Distribution/ Fibre Length and Diameter Distributions for insoluble chemicals can be used to measure particle size and distribution to support that a chemical is not at the nanoscale for particles and fibres with sizes above 250 nm.
3. OECD TG 125 on Nanomaterial Particle Size and Size Distribution of Nanomaterials can be used to measure particle size and distribution to support that a chemical is not at the nanoscale for particles and fibres with sizes above 100 nm.
4. If the chemical is in a dispersion, the spectroscopy- and microscopy-based methods such as scanning electron microscopy (SEM) and transmission electron microscopy (TEM) are more appropriate.

No - I don't have access to any study results that indicate this / I don't know

Go to question 6.

Yes - I do have access to study results that indicate the mean particle size is greater than 200 nm in all dimensions

This means that your introduction is not of a 'certain chemical at the nanoscale'.

Next step: Go to 'Step 5.2 Introductions that can be low risk to the environment' and continue to categorise your introduction.

Note: you must keep a record of the information you have available. If another person holds the study, you must be able to give it to us, if we ask for it.

Learn more about your record keeping obligations

Question 6: Do you have access to study results that indicate that the mean particle size of your chemical or the product that will be introduced into Australia is less than or equal to 200 nm in one or more dimensions?

For example - you have a study result from a particle size distribution study on your chemical or the product that you will introduce into Australia (conducted according to OECD TG 125).

Note the following:

1. For particle size distributions in this range, information only from an SDS/technical data sheet or similar is not enough.
2. You can use OECD TG 110 to measure particle size and distribution to support that a chemical is not at the nanoscale for particles and fibres with sizes above 250 nm.
3. OECD TG 125 on Nanomaterial Particle Size and Size Distribution of Nanomaterials measures particles and fibres with a diameter of 1 to 1000 nm and fibres with a length up to 20 µm.
4. If the chemical is in a dispersion, the spectroscopy- and microscopy-based methods such as scanning electron microscopy (SEM) and transmission electron microscopy (TEM) are more appropriate.

No - I don't have access to study results that indicate this / I don't know

Go to question 7.

Yes - I have access to study results that indicate the mean particle size is less than or equal to 200 nm in one or more dimensions **and** the chemical consists of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale (1-100 nm)

Go to question 7 - note the introduction will be a specified class of introduction and extra reporting obligations will apply.

Yes - I have access to study results that indicate the mean particle size is less than or equal to 200 nm in one or more dimensions **and** the chemical does **not** consist of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale (1-100 nm):

This means that your introduction is not of a 'certain chemical at the nanoscale'.

Next step: Go to 'Step 5.2 Introductions that can be low risk for the environment' and continue to categorise your introduction.

Note: you must keep a record of the information you have available. If the study is held by another person, you must be able to provide it to us, if we ask for it.

Learn more about your record keeping obligations

Question 7: Do you have access to information that indicates that the introduction of any nanoscale portion of the chemical is incidental to the non-nanoscale portion?

For example, you could have a combination of 1 and 2:

1. A declaration from the chemical manufacturer indicating all of the below:
    a. the manufacture of any chemical at the nanoscale is not the result of a deliberate manufacturing decision; and
    b. the manufacture of any chemical at the nanoscale is not necessary for the manufacture of the non-nanoscale portion of the chemical; and
    c. any chemical at the nanoscale does not have specific technical characteristics that are the intended result of changes in the manufacturing process.

2. Information to show that the presence of any nanoscale particles in the chemical is not providing a commercial advantage to the non-nanoscale chemical, such as the absence of claims related to the presence of the nanoscale particles in technical data sheets and commercial product labels on the chemical/introduced product.

Note: in general, the declaration must be from the manufacturer of the chemical in its solid/dispersion form. The declaration must also be held in conjunction with other supporting information.

No - I do not have access to this information / I don't know

You do not have enough information to demonstrate that your introduction is not a ‘certain chemical at the nanoscale’. In the absence of more information from the manufacturer or supplier of your chemical, your introduction has a medium to high indicative risk to both human health and the environment. This means your introduction is in the assessed category and called an 'assessed introduction'.

- Before you can introduce the chemical, you must apply for an assessment certificate and select 'Health and environment focus' as the application type or apply for a commercial evaluation authorisation (if you meet the strict criteria).
- When you apply for an assessment certificate, you need to answer ‘yes’ when we ask if your introduction is a specified class of introduction. When we receive your application, we’ll contact you to ask for extra information that we need to assess the risks of your introduction.

Yes - I do have access to this information that indicates this

This means that your introduction is not of a ‘certain chemical at the nanoscale’.

Next step: Go to 'Step 5.2 Introductions that can be low risk for the environment' and continue to categorise your introduction.

Note: you must keep a record of the information you have available.

Definition - specified class of introduction

A ‘specified class of introduction’ are introductions that have an increased level of concern to human health or the environment. The reason is due to greater potential for certain hazards or high level of human or environmental exposure. Additional, or different, requirements relating to hazard information, reporting or record keeping apply to introductions that are a specified class of introduction. These vary depending on whether you have categorised your introduction as exempted, reported or assessed.

If you've followed the guidance on this page and can prove that your introduction is **not** any of these, continue to step 5.2.

Next - Step 5.2 Introductions that can be low risk to the environment

Step 5.2 Introductions that can be low risk for the environment

This step relates to introductions that are internationally assessed for the environment. These must meet all of the following criteria to be considered ‘low indicative risk’ for the environment.

Skip this step if you are not using an internationally assessed chemical.

Note: Your introduction might still be low indicative risk for the environment but you will need to complete steps 5.3, 5.4 and 5.5 to work this out.

Step 5.2.1

Refer to our Guide to categorising internationally assessed introductions. It has extra information for introducers using international assessments and covers scenarios and outcomes for chemicals that are internationally assessed for:

- human health only
- the environment only
- both human health and the environment

It also lists the trusted overseas bodies we accept assessments from.

The relevant section to refer to in the guide to help you complete step 5.2 is Internationally assessed for the environment only.

Step 5.2.2

Once you've read the guide to categorising internationally assessed introductions, you'll be able to work out whether your introduction either:

- meets our criteria for internationally assessed for the environment
- **does not** meet our criteria for internationally assessed for the environment

Your introduction meets our criteria for internationally assessed for the environment

Option 1

- Keep the outcome you already have — your introduction is **low risk for the environment**; and
- Go to step 6 to complete your categorisation.

Option 2

Check to see if your introduction can be **very low risk** for the environment by completing the rest of step 5:

- Complete Step 5.3 — Work out your introduction's environment exposure band; then
- Complete Step 5.4 — Work out your introduction's environment hazard characteristics

Once you've done this, go to step 6 to complete your categorisation.

Your introduction **does not** meet our criteria for internationally assessed for the environment

Continue with step 5 to work out your introduction's risk for the environment.

Next:

- Complete Step 5.3 — Work out your introduction's environment exposure band; then
- Complete Step 5.4 — Work out your introduction's environment hazard characteristics

Once you've done this, go to step 6 to complete your categorisation.

If you've established your introduction is not medium to high risk for the environment (Step 5.1), now see if your introduction can be low risk for the environment.

Step 5.3 Work out your environment exposure band

Why you need to work out your introduction's exposure band

It is part of the process to identify the indicative environment risk of your introduction. In step 4, you also had to work out your introduction's human health exposure band.

What does an environment exposure band identify about your introduction?

It identifies the likelihood and extent of environmental exposure to the chemical. This likelihood and extent of exposure increases with each band. Exposure band 1 is the lowest exposure band, and exposure band 4 the highest. Introductions in environment exposure band 1 will have the lowest level of environmental exposure, and exposure band 4, the highest.

Information used to assign a chemical to its correct exposure band

Environment categorisation volume

Get help with working out your environment categorisation volume

Explore our online decision tool on categorisation volumes

If your chemical has a designated kind of release into the environment

We define **'designated kind of release into the environment'** (which we refer to throughout this page) to be where the chemical is intentionally released during use to land, biota, natural waterways, municipal water supplies or air (unless its only for domestic or personal use, or end use in an air freshener). It also includes any releases to the environment from firefighting end uses and releases into the ocean.

See also:

- Categorisation of chemicals intentionally released to the environment during use
- Categorisation of chemicals with an end use in firefighting
- Categorisation of chemicals with an end use offshore

What's your environment exposure band?

Start with **Exposure Band 1** and work down the page.

Introductions with a designated kind of release into the environment: if you're introducing one of these you are automatically in exposure band 4 for the environment. If this is your introduction type, go to Step 5.4: Work out your environment hazard characteristics.

Exposure band 1 criteria

If the environment categorisation volume for your chemical does not exceed 25kg, then your introduction is in environment exposure band 1. Next, work out the environment hazard characteristics of your introduction (Step 5.4)

If your introduction does not meet this criteria, go to exposure band 2 criteria.

Exposure band 2 criteria

If the environment categorisation volume for your chemical is greater than 25kg, but no more than 1,000kg, then your introduction is in environment exposure band 2. Next, work out the environment hazard characteristics of your introduction (Step 5.4)

If your introduction does not meet this criteria, go to exposure band 3 criteria.

Exposure band 3 criteria

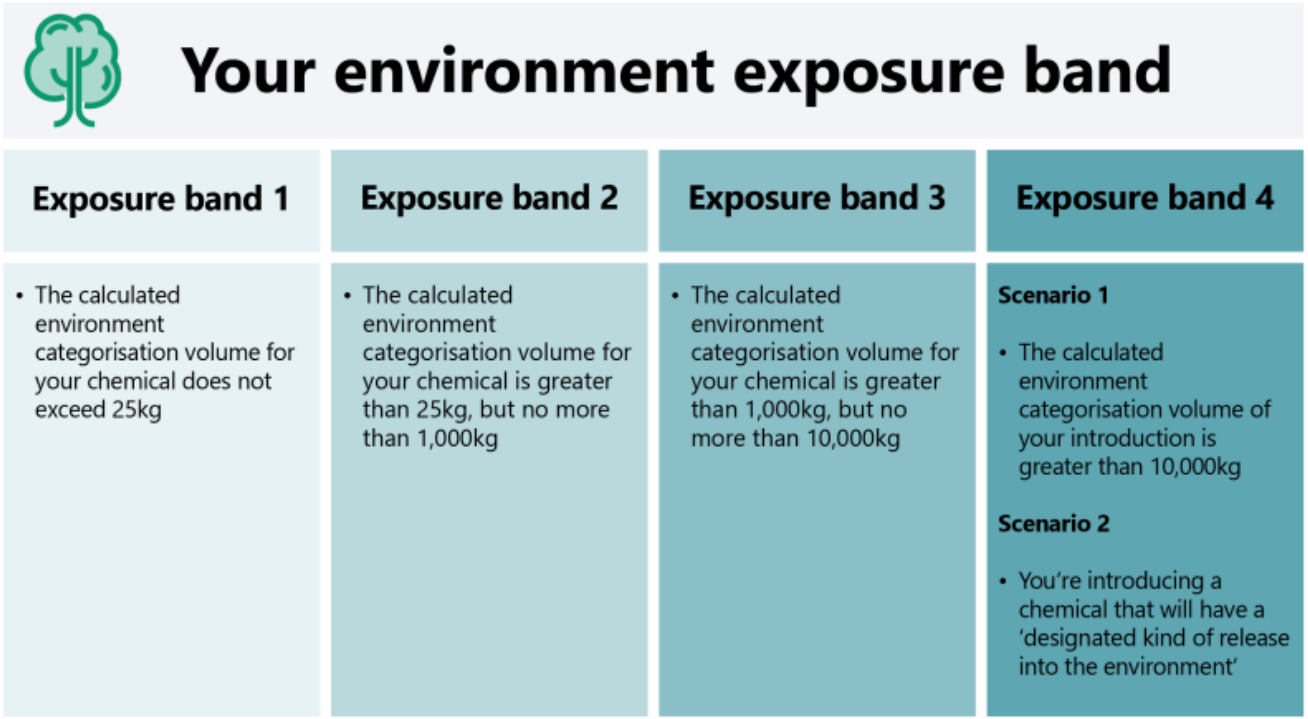
If the environment categorisation volume for your chemical is greater than 1,000kg, but no more than 10,000kg, then your introduction is in environment exposure band 3. Next, work out the environment hazard characteristics of your introduction (Step 5.4).

If you are not in exposure bands 1-3 for the environment, go to exposure band 4 criteria.

Exposure band 4 criteria

Introductions with a designated kind of release into the environment: if you're introducing one of these you are in exposure band 4 for the environment. Next, go to Step 5.4: Work out your environment hazard characteristics.

The environment categorisation volume of your introduction is greater than 10,000kg. Go to Step 5.4: Work out your environment hazard characteristics.



Next: Step 5.4 Work out your environment hazard characteristics

There are 4 environment exposure bands - exposure band 1 has the lowest level of environmental exposure and exposure band 4 the highest level. Follow steps on this page to work out your environment exposure band.

Work out your environment categorisation volume

On this page:

Explore our categorisation tool for help on this subject

Are you introducing a chemical that will have a **designated kind of release into the environment?** If you are, your introduction is automatically in **exposure band 4 for environment** — go to Step 5.4: Work out your environment hazard characteristics.

Instructions

- Use this guidance to calculate your introduction's environment categorisation volume.
- We've included the equations to use and the options you have to choose from, dependent on the scenarios of your introduction.
- You can adopt a simple method or a more detailed method (which **can result in a lower introduction volume than the simpler method**).
- Once you have worked out your environment categorisation volume, you can complete step 5.3.

Methods you can use to work out an ECV for your chemical

There are 2 ways to work out the environment categorisation volume.

Method 1: Simplest approach

Use this method if you want an easy way to work out your environment exposure band.

ECV calculation for this approach

The ECV is your chemical's total introduction volume in a registration year for all end uses.

Method 2: More detailed approach

Use this method if you want a more refined environment categorisation volume. Using this method **could result in an ECV that is lower** than the total introduction volume in a year. This could mean that your introduction ends up being in a **lower environment exposure band** than if the total introduction volume (method 1) had been used.

The calculation of the ECV using method 2 is different depending on whether your chemical introduction has 1 end use or more than 1 end use.

If your introduction has 1 end use

For a chemical with only 1 end use, calculate the ECV by multiplying the introduction volume (IV) by the release reduction factor (RRF) for your chemical's end use scenario:

Equation (1): ECV = IV x RRF

The introduction volume you should use in your calculation is the **total introduction volume in a registration year**. Use the RRF that applies to your end use scenario (refer to our RRF table).

The RRF values range between 0 and 1. A **low RRF** indicates that only a small portion of the introduction volume is likely to contribute to environmental exposure. A **higher RRF** indicates that a higher proportion of the introduction volume could contribute to environmental exposure.

If your introduction has more than 1 end use

You can choose from 2 options to calculate the ECV where your chemical has more than 1 end use.

Option 1: Simplest approach

Use this option if:

- you **do not know** the annual introduction volume of your chemical for each end use
- you want to **simplify the process** of working out your environment exposure band but still want a more refined environment categorisation volume

ECV calculation for this approach

Allocate the total introduction volume to the end use scenario that has the **highest RRF** (refer to our RRF table, and use **Equation (1)** to calculate the ECV. **Note:** do not just use the volume for one of the end uses.

Option 2: More detailed approach

Use option 2 if:

- you **know** the annual introduction volume of your chemical for each end use
- you are willing to **keep track of any changes** to your introduction volume for each end use. This is needed to make sure that the indicative environment risk of your introduction does not increase

Calculate a **separate** environment categorisation volume for **each of your end uses**. Use the RRF for the end use (refer to our RRF table), and the volume that you will be introducing for that end use. Do this for all of your end uses and then add them up to get your total environment categorisation volume (use equation (2) below).

ECV = (IV1 x RRF1) + (IV2 x RRF2) +… + (IVn x RRFn)

Note: IVn = the introduction volume for end use 'n'

RRFn = the release reduction factor (RRF) for end use 'n'.

Table - Release reduction factor (RRF) you need to work out ECV, depending on end use scenario

Note, after this table, we've provided product definitions with examples.

If your introduction's end use scenario is...	**The RRF you need to use is...**
Chemical imported into Australia; import containers remain closed; then exported for end use overseas	0
Chemical imported into Australia; limited handling of the chemical (such that import containers are opened); then exported for end use overseas	0.05
Chemical manufactured in Australia; exported for end use overseas	0.05
Adhesive and sealant products (end use in Australia)	0.05
Apparel and footwear care products (end use in Australia)	0.05
Arts, crafts and hobby products (end use in Australia)	0.05
Explosive products (end use in Australia)	0.05
Fuel, oil, fuel oil additives and related products (end use in Australia)	0.05
Lubricant and grease products (end use in Australia)	0.05
Personal care products - limited environmental release (end use in Australia)	0.05
Tattoo ink products (end use in Australia)	0.05
Paint and coating products (end use in Australia)	0.05
Plastic and polymer products (end use in Australia)	0.05

If your introduction's end use scenario is...	The RRF you need to use is...
Construction products not covered by other end uses (end use in Australia)	0.2
Fabric, textile and leather products not covered by other end uses (end use in Australia)	0.4
Electronic products (end use in Australia)	0.5
Ink, toner and colourant products (end use in Australia)	0.8
Air care products (end use in Australia)	1
Anti-freeze and de-icing products (end use in Australia)	1
Automotive care products (end use in Australia)	1
Cleaning and furniture care products (end use in Australia)	1
Laundry and dishwashing products (end use in Australia)	1
Extractive products not covered by other end uses (end use in Australia)	1
Paper products (end use in Australia)	1
Personal care products not covered by other end use (end use in Australia)	1
Photographic products (end use in Australia)	1
Water treatment products (end use in Australia)	1
Personal vaporiser products (end use in Australia)	1
Any other end use not covered above (end use in Australia)	1

Product definitions and examples from the RRF table

Adhesive and sealant products means an end use to fasten other materials together or stop the passage of liquid or gas. Examples include:

- glues
- binders
- adhesives
- pastes
- sealants
- fillers
- putties
- solder and caulking compounds

Apparel and footwear care products means an end use to care for apparel and footwear products intended for consumer and commercial use. Examples include:

- footwear polishes
- waxes and stains to waterproof and improve appearance and other desirable properties
- apparel surface treatment products for water, stain or flame resistance

Arts, crafts and hobby products means an end use in arts, crafts or hobbies. Examples include:

- crafting paints
- crafting glue
- adhesives (e.g. solder and hot-melt adhesives)
- fixatives
- finishing spray coatings and modelling clay

Explosive products means an end use for producing a sudden expansion, usually accompanied by production of heat and large changes in pressure. Examples include:

- pyrotechnics
- high explosives and propellants
- igniters
- primers
- initiatory
- illuminants
- smoke and decoy flares
- incendiaries

Fuel, oil, fuel oil additives and related products means an end use as:

- liquid fuel in containers used for cooking, heating or for power in vehicles or appliances, or
- a fuel additive to inhibit corrosion, provide lubrication, increase efficiency of use, or decrease production of undesirable by-products.

Examples of liquid fuels include:

- gasoline
- diesel fuels
- kerosene
- lamp oils

Examples of fuel oil additives include:

- stabilisers
- anti-knock agents
- corrosion inhibitors
- detergents
- fuel dyes

- oxygenates
- antioxidants
- odour agents

Lubricant and grease products means an end use in a liquid, paste or spray to reduce friction, heat generation and wear between solid surfaces. Examples include:

- engine oils
- transmission, brake and hydraulic fluids
- gear oils
- calcium, sodium, lithium, and silicone-based greases

Personal care products – limited environmental release means an end use in solid or hardening personal care products (including cosmetics) that are primarily disposed of to landfill. Examples include:

- baby wipes
- facial tissues
- nail care products including nail polish and remover

Tattoo ink products means an end use in a combination of industrial chemicals that contains one or more colouring agents and is applied to the dermal layer of the skin for the purposes of colouring the skin. Examples include:

- pigments
- dyes
- resins

Paint and coating products means an end use to paint or coat substrates intended for consumer or commercial use. Examples include:

- decorative coatings
- automotive coatings

- transportation coatings
- wood finishes
- powder coatings
- coil coatings
- packaging finishes
- general industrial coatings
- automotive refinish
- industrial maintenance and protective coatings
- marine coatings
- thinners
- removers

Plastic and polymer products means an end use in production of plastics or polymers. Examples include:

- monomers
- initiators
- additives

Construction products not covered by other end uses means an end use in construction materials, except where another scenario covers the end use. Examples include:

- additives in cements and dry mortar
- additives to bitumen for road repair
- internal release agents for thermo-set laminating resins
- resins in particle board manufacture
- wood substitutes used to make mouldings
- resins used in the production of composite materials

Fabric, textile and leather products not covered by other end uses means an end use to impart colour and other desirable properties onto fabric, textiles, and leather products that are intended for consumer or commercial use.

These properties include:

- water/soil/stain repellence
- wrinkle resistance
- flame resistance

Examples of this type of product include:

- textile dyes
- textile finishing agents
- leather tanning products
- leather dyes
- leather finishing agents, leather conditioner and surface treatment products

Electronic products means an end use in the production of electronic components. Examples include:

- chemicals in vapour deposition
- electroless plating
- electroplating
- etching
- high vacuum evaporation/sputtering
- laminate processing
- soldering
- photolithography

Ink, toner and colourant products means an end use for:

- writing
- printing
- creating an image on paper and other substrates
- applying to substrates to change their colour or hide images

Examples of this type of product include:

- pigmented liquid
- toners or powders used in copy machines and toner/printer cartridges
- inks used in writing equipment
- inks for stamps and correction fluids and tapes

This category does not include pigments and colourants added to paints and coatings.

Air care products means an end use to odorise or deodorise indoor air in homes, offices, motor vehicles, and enclosed spaces and intended for consumer or commercial use. Examples include:

- aerosol sprays
- liquid/solid/gel diffusers
- air fresheners
- scented candles
- incense

Anti-freeze and de-icing products means an end use:

- as an additive to fluids, especially water, to reduce the freezing point of the mixture, or
- applied to surfaces to melt or prevent build-up of ice

Examples of this type of product include:

- anti-freeze liquids

- de-icing liquids (windshield de-icers, aircraft de-icers)
- de-icing solids (ice melting crystals)
- lock de-icers

Automotive care products means an end use (intended for consumer or commercial use) to clean and care for exterior and interior surfaces of automotive vehicles. Examples include:

- car waxes
- polishes
- waterproofing products for windshield or automotive window glass
- cleaners
- sealers
- car wash solutions
- vinyl/rubber/plastic protectants
- automotive carpet and upholstery cleaners
- wheel and tyre care products
- exterior trim protectants
- touch-up paint products

Cleaning and furniture care products means an end use (intended for consumer or commercial use) to:

- remove dirt, grease, stains, and foreign matter from furniture and furnishings
- cleanse, sanitise, bleach, scour, polish, protect, or improve the appearance of surfaces

Examples include:

- cleaners used on glass, floors, tub and tile, ovens and drains
- scouring powders
- dusting products
- waxes

- polishes
- stain repellent sprays

Laundry and dishwashing products means an end use in liquid, granular, gel or unit dose packets/tablets to:

- remove food residue from dishes
- remove dirt from textiles
- enhance properties of textiles
- remove stains from textiles

Examples include:

- dishwashing detergents and laundry detergents
- stain removers and fabric enhancers
- bleach
- rinse aids
- lime and rust removers
- dry cleaning products used in non-aqueous cleaning processes

Extractive products not covered by other end uses means an end use in:

- mining
- onshore drilling
- related activities such as extraction, cementing, hydraulic fracturing, refining

These scenarios do not include end use in offshore drilling. This end use is a designated kind of release into the environment (for which you do not calculate an ECV).

Paper products means an end use in paper production. Examples include:

- effluent treatment chemicals

- maintenance chemicals
- deposit and cleaning agents
- defoamers
- surfactants
- polymeric retention aids
- coagulants
- clay
- resins

Personal care products not covered by other end uses means an end use for cosmetic use, except those covered under the “personal care products - limited environmental release end use” scenario. Examples include:

- bath and shower products
- make-up products
- hair, oral and skin care products
- secondary sunscreen products
- deodorants
- perfumes

Photographic products means an end use (for consumer or commercial use) to take photographic images, develop and process film, and make photographic prints. Examples include:

- processing solutions (for developing, stopping, and fixing photos)
- chemicals used in the manufacture or processing of film or photographic paper

Water treatment products means an end use to treat water in cooling and heating systems (including industrial heat-exchanger systems) and potable water supplies. Examples include:

- chemicals used in pH buffers
- scale and corrosion inhibitors

- flocculating agents
- ion exchange resins

This scenario does not include end uses to treat municipal water supplies or other large-scale water supplies for human or animal consumptions or irrigation. These end uses involve a designated kind of release into the environment (for which you do not calculate an environment categorisation volume).

Personal vaporiser products means an end use in a device that is intended to produce a vapour or aerosol that is delivered into a person's body when the person inhales through the device. Examples include:

- e-cigarettes
- e-cigars
- e-hookah pens
- e-pens
- e-pipes
- vape pens

Go back to step 5.3

You need to know the environment categorisation volume (ECV) of your introduction to work out its environment exposure band. Information on this page helps you work this out so you can complete Step 5.3.

Step 5.4 Work out your environment hazard characteristics

Important! Your starting point is always hazard band D (the highest hazard band) Then work your way down the hazard bands as far as you need to get to your outcome (that is, D, then C, then B, then A). Our guidance on this page steps you through this. Links on this page take you to hazard characteristics for each hazard band.

You must have permission to use information that you relied on to demonstrate the absence of hazard characteristics. If we ask you for the information that you relied on to categorise your introduction, you need to provide us with the detailed information, including full study reports, of the kind we specify in this step to demonstrate the absence of the hazard characteristics.

Hazard characteristics in environment hazard bands

A chemical has an environment hazard characteristic if the chemical can cause damage, harm or adverse effects to the environment. For example, a chemical that has the 'toxic to any aquatic life' hazard characteristic can cause toxic injury to an organism following short term aquatic exposure.

Environment hazard characteristics are split up into hazard bands. Hazard characteristics of most concern are in hazard band D, while those of lower concern are in hazard band A.

See links below to each of the hazard bands: D, C, B and A.

Our pages for environment hazard bands D, C, B and A describe hazard characteristics (eg toxic to any aquatic life and so on) in each hazard band and the information you need to have to prove your chemical does not have a particular hazard characteristic.

Information you need and hazard characteristics you need to consider

This varies depending on your introduction’s environment exposure band.

If your introduction is in a lower exposure band

Generally, in the lower exposure bands, where the level of exposure to the environment is relatively low, as a minimum you have to consider only a few hazard characteristics and you don’t need much information on them.

If your introduction is in a higher exposure band

In comparison, in higher exposure bands, where the level of exposure to the environment is higher, generally you'll need to consider more hazard characteristics and need more information on them.

Information you need for lower indicative risk

You will need more hazard information to be able to get to lower indicative risk outcomes. Generally, within any given environment exposure band you need:

- less hazard information to get to medium to high risk
- more hazard information to get to low risk
- the most hazard information to get to very low risk

See Step 5.5 for more information about indicative environment risk outcomes

Where to start and when you can stop considering your chemical's hazard characteristics

Starting point — is always hazard band D

Always start in the highest hazard band (hazard band D) and work your way down the hazard bands as far as you need to get to your outcome (that is, D, C then B then A).

You must consider each hazard characteristic in the hazard band you are in (unless there is a reason for you to stop sooner) - does your chemical have that hazard characteristic or not?

When you might not need to consider all of the hazard bands

- **Because your introduction's environment exposure band (which you worked out in step 5.3) doesn't require it.** For example, if your introduction's environment exposure band is 2, you only need to consider the hazards in hazard band D to get to an indicative environment risk of either **medium to high or low**.
- **Because the outcome for indicative environment risk that you are trying to get to doesn't require it.** For example, if your introduction's environment exposure band is 3 and you want to get to an indicative environment risk of low, you only need to consider the hazard characteristics in environment hazard bands D and C.

In many cases, you'll only need to consider hazard band D. But in other cases you might need to consider D, C, B and A because your introduction is in exposure band 3 or 4 and you are trying to get to very low indicative environment risk.

See step 5.5 for more about indicative environment risk outcomes

When you can stop working through your chemical's environment hazard characteristics

Stop if you:

- determine that your chemical **has** a hazard characteristic in the hazard band (e.g. persistent, bioaccumulative and toxic - you are in hazard band D) or
- cannot demonstrate that your chemical does **not** have a certain hazard characteristic in that hazard band . This means that we consider your chemical to have this hazard characteristic or
- get to an indicative environment risk outcome and don't want to go any further - see step 5.5 for more information about environment risk outcomes or
- have demonstrated that your chemical does **not** have any hazard characteristics in hazard bands D, C, B and A . This would only be needed for environment exposure bands 3 and 4. It means that the indicative environment risk of your introduction is very low

After you stop, you don't need to consider the remaining hazard characteristics in the hazard band where you stopped, or any of the hazard characteristics in lower hazard bands. Take note of where and why you stopped and move on to step 5.5.

Example: Rosemary's introduction is in environment exposure band 4. She considers all of the hazard characteristics in environment hazard band D and can demonstrate that her chemical does not have any of these hazards. Rosemary then moves on to hazard band C. She works through the hazard characteristics in this hazard band in the order that they are shown in the table. When Rosemary comes to 'very toxic to any aquatic life', she finds that her chemical **has** this **hazard characteristic**. This means Rosemary can **stop there**. The indicative environment risk of Rosemary's introduction is **medium to high**. She does not need to continue further to see if her chemical has the other hazard characteristic in hazard band C (persistent and bio-accumulative). Also Rosemary doesn't need to consider if her chemical has any of the hazard characteristics in hazard bands B or A.

How to consider each hazard characteristic

Look at whether your chemical meets the hazard characteristic **definition** based on the information that you have.

If it **does** meet the hazard characteristic definition, stop there and move to step 5.5.

If it **does not** meet the hazard characteristic definition, you'll need to try and **prove** that your chemical **does not** have this hazard characteristic.

Our pages on hazard bands D, C, B and A describe hazard characteristics and the ways to prove that your chemical does not have a hazard characteristic.

How to prove that your chemical does not have a hazard characteristic

You can read about your options to prove that your chemical does not have a particular hazard characteristic on each environment hazard band page. These options include:

- checking if your chemical is on the list of chemicals with high hazards for categorisation

- in silico predictions
- in vitro test results
- in vivo test results
- suitable read-across information in place of information on the chemical itself
- other information about your chemical that means that testing and in silico predictions are not necessary (that is, information waivers)

If you have access to existing information on the chemical or suitable read-across information, you should consider these first. If you need to generate new data to prove the absence of a hazard characteristic, you should **choose non-animal test data when possible**. You should only generate new animal test data as a last resort.

See our section on use of animal test data

If you **can prove** that your chemical does not have the hazard characteristic, move on to the next hazard characteristic in that hazard band, or from the next hazard band down.

If you **cannot prove** that your chemical does not have the hazard characteristic, stop there – your chemical is considered to have this hazard characteristic.

Take note of the hazard band that this hazard characteristic is in. If your chemical is one of these:

- highly branched organic chemical
- introduced for an end use as a biocidal active

there may be different requirements for you to prove that your chemical does not have certain hazard characteristics.

Resources to help you with this step

We refer to the following throughout this step:

- List of chemicals with high hazards for categorisation
- In silico information - an overview of which human health (4.4) and environment characteristics have in silico options and which in silico models are appropriate.
  You can also check our glossary for the definition of in silico.
- Acceptable test guidelines for each environment hazard characteristic in this step
- Suitable read across information
- Decision tools for step 5.4 (self-guided tools to help you categorise your introduction)
  - hazard characteristics for environment exposure band 1, hazard characteristics for environment exposure band 2, hazard characteristics for environment exposure band 3, hazard characteristics for environment exposure band 4 - use this tool if your introduction is in this exposure band

To work out the environment characteristics your chemical **does** and **does not** have, you must know your environment exposure band (Step 5.3). The information you need to consider hazard characteristics varies depending on your introduction's exposure band.

Environment hazard band D hazard characteristics

Do not start this page unless you have read Step 5.4: Work out your environment hazard characteristics

Environment hazard characteristics are split into hazard bands. Hazard characteristics of most concern are in hazard band D, while those of lower concern are in hazard band A.

Hazard band D has 5 hazard characteristics you need to consider:

- Contains arsenic, cadmium, lead or mercury
- Ozone depleting chemical
- Synthetic greenhouse gas

- Adverse effects mediated by an endocrine mode of action
- Persistent, bioaccumulative and toxic

Instructions

You must always start at hazard band D. Step 5.4 tells you when you can stop working through your chemical's environment hazard characteristics and when you need to check each of them - ie D, C, B and A.

Work your way through hazard characteristic on this page. Look at whether your chemical meets the hazard characteristic definition based on the information that you have.

If it **does** meet the hazard characteristic definition, stop there - your introduction's **environment hazard band is D**. Move on to the next step - step 5.5 Work out your environment risk for categorisation.

If it **does not** meet the hazard characteristic definition, you'll need to try and **prove** that your chemical **does not** have this hazard characteristic. The information that you need to prove this for each hazard characteristic is shown below. If you do **not** have this information, stop there - your introduction's environment hazard band is D. Move onto the next step – step 5.5 Work out your environment risk for categorisation.

If you **do have** this information (so you can prove that the chemical does not have the hazard characteristic), move onto the next hazard characteristic on this page.

After you have considered all the hazard characteristics on this page and have proven that the chemical does not have any of them, decide whether you can stop there or continue to environment hazard band C. This depends on the exposure band of your introduction.

If your introduction is in environment exposure band 1 or 2, you can choose to stop (and go to step 5.5 to work out your environment risk for categorisation), or to continue to environment hazard band C.

If your introduction is in environment exposure band 3 or 4, continue to environment hazard band C.

Hazard characteristics and required information

Contains arsenic, cadmium, lead or mercury

Contains arsenic, cadmium, lead or mercury means that the industrial chemical contains one or more of the following:

- arsenic
- cadmium
- lead or
- mercury

There are no extra information requirements to prove that the chemical does not have this hazard characteristic.

Ozone depleting chemical

Ozone depleting chemical means that any of the following apply to the industrial chemical:

- the chemical is controlled under the Ozone Protection and Synthetic Greenhouse Gas Management Act 1989, or
- the chemical is controlled under the Montreal Protocol on Substances that Deplete the Ozone Layer.

Synthetic greenhouse gas3>

Synthetic greenhouse gas means that any of the following apply to the industrial chemical:

- the chemical is controlled under the Ozone Protection and Synthetic Greenhouse Gas Management Act 1989, or
- the chemical is listed on the Kyoto Protocol, Synthetic Greenhouse Gases under Annex A, or
- the chemical is controlled under the Montreal Protocol on Substances that Deplete the Ozone Layer.

Adverse effects mediated by an endocrine mode of action

Adverse effects mediated by an endocrine mode of action means that any of the following apply to the industrial chemical:

- the chemical meets all of the following:
  - it shows an adverse effect in an intact organism or its progeny, which is a change in the morphology, physiology, growth, development, reproduction or lifespan of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in the susceptibility to other influences, and
  - it has an endocrine activity, which is the capacity to alter the function(s) of the endocrine system, and
  - the adverse effect is a consequence of the endocrine activity

or

- the chemical (or the chemical of which it is an ester or salt) is on the list of chemicals with high hazards for categorisation, based on its adverse effects mediated by an endocrine mode of action

or

- the chemical meets all of the following:
  - information is available that is relevant to determining whether the chemical has the hazard characteristic, adverse effects mediated by an endocrine mode of action, and
  - the information has been considered in a weight of evidence analysis based on the following guidance documents:
    - the EU guidance for identifying endocrine disruptors , and
    - the guidance provided in OECD GD 150 ; and
  - the weight of evidence analysis concludes that the chemical has the hazard characteristic, adverse effects mediated by an endocrine mode of action.

Information required to demonstrate the absence of the hazard characteristic, adverse effects mediated by an endocrine mode of action

- if the chemical has existing information relevant to determining whether it has the hazard characteristic, adverse effects mediated by an endocrine mode of action, information is required to demonstrate that the chemical does not have this hazard characteristic:
    - this must involve a documented weight of evidence analysis based on the EU guidance for identifying endocrine disruptors and the guidance in OECD GD 1503, and
    - the analysis must conclude that the chemical does not have the hazard characteristic, adverse effects mediated by an endocrine mode of action.
- Otherwise, the information required to demonstrate that a chemical does not have the hazard characteristic, adverse effects mediated by an endocrine mode of action, is confirmation that the chemical (or the chemical of which it is an ester or salt) is not on the list of chemicals with high hazards for categorisation, based on its adverse effects mediated by an endocrine mode of action.

Persistent, bioaccumulative and toxic

Your introduction is in environment hazard band D if any of the following apply to the industrial chemical:

- the chemical (or the chemical of which it is an ester or salt) is on the list of chemicals with high hazards for categorisation, based on it being persistent, bioaccumulative and toxic, or
- all of the following apply:
    - the chemical is persistent (see our glossary definition)
    - the chemical is bioaccumulative, and
    - the chemical has the hazard characteristic, very toxic to any aquatic life

For the purposes of this hazard characteristic, bioaccumulative means any of the following apply to the chemical:

- it has a bioaccumulation factor (BAF) greater than or equal to 2000 for the aquatic compartment, or
- it has a bioconcentration factor (BCF) greater than or equal to 2000 for the aquatic compartment, or
- it has a measured log Kow greater than or equal to 4.2 for the aquatic compartment (unless a measured BAF or BCF is less than 2000), or
- it has a log Koa greater than 6 and log Kow greater than or equal to 2 for the terrestrial compartment, or

- it has a biomagnification factor (BMF) greater than 1.

Information required to demonstrate that a chemical does not have the hazard characteristic, persistent, bioaccumulative and toxic

Confirmation that the chemical (or the chemical of which it is an ester or salt) is not on the list of chemicals with high hazards for categorisation based on it being persistent, bioaccumulative and toxic. In addition, if the environment exposure band for the introduction is 2 (and you are seeking to demonstrate that the introduction meets the criteria for very low risk and it is not the 'special cases' mentioned in step 5.5)**,** or 3, or 4, the information required to demonstrate that a chemical does not have the hazard characteristic, persistent, bioaccumulative and toxic, is at least one of the following:

- information that demonstrates that the chemical is an inorganic chemical, or
- information to demonstrate that the chemical is a biological chemical, or
- information that demonstrates that the chemical has a molecular weight that is greater than 1,000 g/mol, or
- information that demonstrates that the chemical is a high molecular weight polymer with:
    - less than 25% low molecular weight oligomeric species less than 1,000g/mol, and
    - less than 10% low molecular weight oligomeric species less than 500g/mol, or
- information that demonstrates that the chemical has a solubility in water that is greater than 5g/L, measured following an acceptable test guideline for water solubility, or
- information that demonstrates that the chemical is a gas that is not expected to partition to the aquatic compartment, or
- information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
- a suitable in silico prediction for partition coefficient of the chemical itself of log Kow less than 4.2 (that is not negated by a measured log Kow), or
- measured value from a study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for partition coefficient, for which log Kow less than 4.2, or
- if the chemical is not a highly branched organic chemical* – a test result from a study on the chemical or from suitable read across information, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:
    - tests based on dissolved organic carbon (DOC) - greater than or equal to 70% DOC removal, or
    - tests based on carbon dioxide generation - greater than or equal to 60% theoretical carbon dioxide, or
    - tests based on oxygen depletion - greater than or equal to 60% theoretical oxygen demand, or

- a test result from a study on the chemical, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:
    - tests based on dissolved organic carbon (DOC) - greater than or equal to 70% DOC removal, or
    - tests based on carbon dioxide generation - greater than or equal to 60% theoretical carbon dioxide, or
    - tests based on oxygen depletion - greater than or equal to 60% theoretical oxygen demand, or
- if the chemical is not a highly branched organic chemical* – a test result from a study on the chemical or from suitable read across information, conducted following an acceptable test guideline for transformation in aquatic sediment systems, results in both:
    - a degradation half-life in water of less than 2 months, and
    - a degradation half-life in sediment of less than 6 months, or
- a test result from a study on the chemical, conducted following an acceptable test guideline for transformation in aquatic sediment systems, results in both:
    - a degradation half-life in water of less than 2 months, and
    - a degradation half-life in sediment of less than 6 months, or
- if the chemical is not a biocidal active and not a persistent, highly branched organic chemical** – information on aquatic toxicity for all three trophic levels (fish, invertebrates and algae), from suitable in silico predictions on the chemical or in vivo studies on the chemical or from suitable read-across information conducted following acceptable test guidelines for aquatic toxicity, with the following results for all three trophic levels:
    - acute aquatic toxicity greater than 1 mg/L (96h LC50 (fish), or 48h EC50 (invertebrates) or 72 or 96h ErC50 (algae)), or
    - chronic aquatic toxicity NOEC or EC10 greater than 0.1mg/L (for chemicals that are not readily biodegradable), or
- test results for all three trophic levels (fish, invertebrates and algae) from in vivo studies on the chemical or from suitable read-across information, conducted following acceptable test guidelines for chronic aquatic toxicity with a NOEC or EC10 greater than 0.1mg/L for all three trophic levels, or
- a test result from an in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for bioconcentration, for which the BCF less than 2,000, or
- a test result from an in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for bioaccumulation, for which the BAF less than 2,000.

*If the chemical is a highly branched organic chemical, in silico predictions and read across information cannot be used to demonstrate that the chemical does not have the persistence aspect of the persistent, bioaccumulative and toxic hazard characteristic – only studies on the chemical itself, as described in the next dot point, are acceptable

**If the chemical is a biocidal active or a persistent, highly branched organic chemical, in silico predictions cannot be used to demonstrate that the chemical does not have the toxicity aspect of the persistent, bioaccumulative and toxic hazard characteristic – only in vivo chronic aquatic toxicity studies, as described in the next dot point, are acceptable.

This page accompanies step 5.4 Work out environment hazard characteristics.

Environment hazard band C hazard characteristics

Do not start this page unless you have read Step 5.4: Work out your environment hazard characteristics and Environment hazard band D.

Environment hazard characteristics are split into hazard bands. Hazard characteristics of most concern are in hazard band D, while those of lower concern are in hazard band A.

Hazard band C has 2 hazard characteristics you need to consider:

- very toxic to any aquatic life
- persistent and bioaccumlative - environment hazard band C

Instructions

You must always start at hazard band D. Step 5.4 tells you when you can stop working through your chemical's environment hazard characteristics and when you need to check each of them - ie D, C, B and A.. You only need to work through the hazard characteristics on this page is your introduction is in:

- Environment exposure band 1 or 2 and you are trying to get to an outcome of very low indicative environment risk or
- Environment exposure band 3 or 4

Work your way through each hazard characteristic on this page. Look at whether your chemical meets the hazard characteristic **definition** based on the information that you have.

If it **does** meet the hazard characteristic definition, stop there - your introduction's **environment hazard band is C**. Move on to the next step - step 5.5 Work out your environment risk for categorisation.

If it **does not** meet the hazard characteristic definition, you'll need to try and **prove** that your chemical **does not** have this hazard characteristic. The information that you need to prove this for each hazard characteristic is shown below. If you do **not** have this information, stop there - your introduction's environment hazard band is C. Move onto the next step – step 5.5 Work out your environment risk for categorisation.

If you do have this information (so you can prove that the chemical does not have the hazard characteristic), move onto the next hazard characteristic on this page.

After you have considered all the hazard characteristics on this page and have proven that the chemical does not have any of them, decide whether you can stop there or continue to environment hazard band B. This depends on the exposure band of your introduction.

If your introduction is in environment exposure band 1, stop here – you don't need to consider any other hazard characteristics. Next go to step 5.5 to work out your environment risk for categorisation.

If your introduction is in environment exposure band 2, continue to environment hazard band B.

If your introduction is in environment exposure band 3, you can choose to stop here (and go to step 5.5 to work out your environment risk for categorisation, or to continue to environment hazard band B.

If your introduction is in environment exposure band 4, continue to environment hazard band B.

This page accompanies step 5.4 Work out environment hazard characteristics.

Very toxic to any aquatic life

Very toxic to any aquatic life means that any of the following apply to the industrial chemical:

- the chemical is known to cause:
  - toxic injury to an organism following short term aquatic exposure as described in chapter 4.1 of the GHS, with the chemical classified as acute aquatic toxicity (category 1), or
  - adverse effects to an organism during aquatic exposures determined in relation to the life-cycle of the organism, as described in chapter 4.1 of the GHS, with the chemical classified as chronic aquatic toxicity (category 1), or
  - the chemical (or the chemical of which it is an ester or salt) is on the list of chemicals with high hazards for categorisation based on it being very toxic to aquatic life, or
  - an in vivo acute study on the chemical:
    - conducted following an acceptable test guideline for acute toxicity to fish results in a 96h LC50 less than or equal to 1mg/L, or
    - conducted following an acceptable test guideline for acute toxicity to invertebrates results in a 48h EC50 less than or equal to 1mg/L, or
    - conducted following an acceptable test guideline for acute toxicity to algae or other aquatic plants results in a 72 or 96h ErC50 less than or equal to 1mg/L, or
  - an in vivo chronic study on the chemical conducted following an acceptable test guideline for chronic toxicity to fish, chronic toxicity to invertebrates, or chronic toxicity to algae or other aquatic plants results in a:
    - NOEC or EC10 less than equal to 0.1mg/L (for chemicals that are not readily biodegradable), or
    - NOEC or EC10 less than or equal to 0.01mg/L (for chemicals that are readily biodegradable), or
  - a suitable in silico prediction for acute aquatic toxicity results in a prediction of:
    - for fish - 96h LC50 less than or equal to 1mg/L, or
    - for invertebrates - 48h EC50 less than or equal to 1mg/L, or
    - for algae or other aquatic plants - 72 or 96h ErC50 less than or equal to 1mg/L

and the predictions have not been negated by in vivo studies conducted on the chemical for aquatic toxicity.

Information required to demonstrate the absence of the hazard characteristic, very toxic to any aquatic life

The information required to demonstrate that a chemical does not have the hazard characteristic, very toxic to any aquatic life, is:

- if the exposure band for the introduction is 1 - confirmation that the chemical (or the chemical of which it is an ester or salt) is not on the list of chemicals with high hazards for categorisation based on it being very toxic to any aquatic life
- if the environment exposure band for the introduction is 2, 3, or 4, - at least one of the following:
    - information that demonstrates that the chemical has a molecular weight greater than 1,000g/mol and has a low cationic density, or
    - information that demonstrates that the chemical is a high molecular weight polymer that has a low cationic density, or
    - information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
    - if the chemical is not a biocidal active and not a persistent, highly branched organic chemical – information on aquatic toxicity for all three trophic levels (fish, invertebrates and algae), from suitable in silico predictions on the chemical or in vivo studies on the chemical or from suitable read-across information conducted following acceptable test guidelines for aquatic toxicity, with the following results for all three trophic levels:
        - acute aquatic toxicity greater than 1 mg/L (LC50 (fish), or EC50 (invertebrates) or ErC50 (algae)), or
        - chronic aquatic toxicity NOEC or EC_{10} greater than 0.1mg/L (for chemicals that are not readily biodegradable), or
        - chronic aquatic toxicity NOEC or EC_{10} greater than 0.01mg/L (for chemicals that are readily biodegradable), or
    - test results for all three trophic levels (fish, invertebrates and algae) from in vivo studies on the chemical or from suitable read-across information, conducted following acceptable test guidelines for chronic aquatic toxicity with the following results for all three trophic levels:
        - NOEC or EC_{10} greater than 0.1mg/L (for chemicals that are not readily biodegradable), or
        - NOEC or EC_{10} greater than 0.01mg/L (for chemicals that are readily biodegradable).

Persistent and bioaccumulative

Persistent and bioaccumulative means that any of the following apply to the industrial chemical:

- the chemical (or the chemical of which it is an ester or salt) is on the list of chemicals with high hazards for categorisation, based on it being persistent and bioaccumulative, or
- both of the following apply:
    - the chemical is persistent, and
    - the chemical is bioaccumulative.

For the purposes of this hazard characteristic, bioaccumulative means any of the following apply to the chemical:

- it has a bioaccumulation factor (BAF) greater than OR equal to 2000 for the aquatic compartment, or
- it has a bioconcentration factor (BCF) greater than or equal to 2000 for the aquatic compartment, or
- it has a measured log Kow greater than or equal to 4.2 for the aquatic compartment (unless a measured BCF or BAF is less than 2000), or
- it has a log Koa greater than 6 and log Kow greater than or equal to 2 for the terrestrial compartment, or
- it has a biomagnification factor (BMF) greater than 1.

Information required to demonstrate the absence of the hazard characteristic, persistent and bioaccumulative

The information required to demonstrate that a chemical does not have the hazard characteristic, persistent and bioaccumulative, is confirmation that the chemical (or the chemical of which it is an ester or salt) is not on the list of chemicals with high hazards for categorisation based on it being persistent and bioaccumulative. In addition, if the environment exposure band for the introduction is 2 (and you are seeking to demonstrate that the introduction meets the criteria for very low risk and it is not the 'special cases' mentioned in step 5.5), or 3 or 4, the information required to demonstrate that a chemical does not have the hazard characteristic, persistent and bioaccumulative, is at least one of the following:

- information that demonstrates that the chemical is an inorganic chemical, or
- to demonstrate that the chemical is a biological chemical, or
- information that demonstrates that the chemical has a molecular weight that is greater than 1,000 g/mol, or
- information that demonstrates that the chemical is a high molecular weight polymer with:
    - less than 25% low molecular weight oligomeric species less than 1,000g/mol, and
    - less than 10% low molecular weight oligomeric species less than 500g/mol, or
- information that demonstrates that the chemical has a solubility in water that is greater than 5g/L, measured following an acceptable test guideline for water solubility, or
- information that demonstrates that the chemical is a gas that is not expected to partition to the aquatic compartment, or
- a suitable in silico prediction for partition coefficient of the chemical itself of log Kow less than 4.2 (that is not negated by a measured log Kow), or

- a measured value from a study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for partition coefficient, for which log Kow less than 4.2, or
- if the chemical is not a highly branched organic chemical* – a test result from a study on the chemical or from suitable read across information, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:
    - tests based on dissolved organic carbon (DOC) - greater than or equal to 70% DOC removal, or
    - tests based on carbon dioxide generation - greater than or equal to 60% theoretical carbon dioxide, or
    - tests based on oxygen depletion - greater than or equal to 60% theoretical oxygen demand, or
- a test result from a study on the chemical, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:
    - tests based on dissolved organic carbon (DOC) - greater than or equal to 70% DOC removal, or
    - tests based on carbon dioxide generation - greater than or equal to 60% theoretical carbon dioxide, or
    - tests based on oxygen depletion - greater than or equal to 60% theoretical oxygen demand, or
- if the chemical is not a highly branched organic chemical* – a test result from a study on the chemical or from suitable read across information, conducted following an acceptable test guideline for transformation in aquatic sediment systems, results in both:
    - a degradation half-life in water of less than 2 months, and
    - a degradation half-life in sediment of less than 6 months, or
- a test result from the chemical, conducted following an acceptable test guideline for transformation in aquatic sediment systems, results in both:
    - a degradation half-life in water of less than 2 months, and
    - a degradation half-life in sediment of less than 6 months, or
- a test result from an in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for bioconcentration, for which the BCF is less than 2,000, or
- a test result from an in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for bioaccumulation, for which the BAF is less than 2,000.

*If the chemical is a biocidal active or a persistent, highly branched organic chemical, in silico predictions cannot be used to demonstrate that the chemical does not have the very toxic to any aquatic life hazard characteristic – only in vivo chronic aquatic toxicity studies, as described in the next dot point, are acceptable.

Environment hazard band B hazard characteristics

Do not start this page unless you have read Step 5.4: Work out your environment hazard characteristics and environment hazard band D hazard characteristics and environment hazard band C hazard characteristics.

Environment hazard characteristics are split into hazard bands. Hazard characteristics of most concern are in hazard band D, while those of lower concern are in hazard band A.

Hazard band B has 1 hazard characteristic you need to consider - toxic to any aquatic life.

Instructions

You must always start at hazard band D. Step 5.4 tells you when you can stop working through your chemical's environment hazard characteristics and when you need to check each of them - ie D, C, B and A. You only need to work through the hazard characteristics on this page is your introduction is in:

- Environment exposure band 2 or 3 and you are trying to get to an outcome of very low indicative environment risk or
- Environment exposure band 4

Work your way through each hazard characteristic on this page. Look at whether your chemical meets the hazard characteristic definition based on the information that you have.

If it **does** meet the hazard characteristic definition, stop there - your introduction's **environment hazard band is B**. Move on to the next step - step 5.5 Work out your environment risk for categorisation.

If it **does not** meet the hazard characteristic definition, you'll need to try and prove that your chemical does **not** have this hazard characteristic. The information that you need to **prove** this for each hazard characteristic is shown below. If you do not have this information, stop there -

your introduction's **environment hazard band is B**.

Move onto the next step – step 5.5 Work out your environment risk for categorisation.

If you do have this information (so you can prove that the chemical does not have the hazard characteristic), move onto the next hazard characteristic on this page.

After you have considered all the hazard characteristics on this page and have proven that the chemical does not have any of them, decide whether you can stop there or continue to environment hazard band A. This depends on the exposure band of your introduction.

If your introduction is in **environment exposure band 2**, stop here – you don't need to consider any other hazard characteristics. Next go to step 5.5 to work out your environment risk for categorisation.

If your introduction is in **environment exposure band 3**, continue to environment hazard band A.

If your introduction is in **environment exposure band 4**, you can choose to stop here (and go to step 5.5 to work out your environment risk for categorisation, or to continue to environment hazard band A.

Toxic to any aquatic life

Toxic to any aquatic life means that any of the following apply to the industrial chemical:

- the chemical is known to cause:
    - toxic injury to an organism following short term aquatic exposure as described in chapter 4.1 of the GHS, with the chemical classified as acute aquatic toxicity (category 2), or
    - adverse effects to an organism during aquatic exposures determined in relation to the life-cycle of the organism, as described in chapter 4.1 of the GHS, with the chemical classified as chronic aquatic toxicity (category 2), or
- an in vivo acute study on the chemical:

- conducted following an acceptable test guideline for acute toxicity to fish results in a 96h LC50 greater than 1mg/L but less than or equal to 10mg/L, or
- conducted following an acceptable test guideline for acute toxicity to invertebrates results in a 48h EC50 greater than 1mg/L but less than or equal to 10mg/L, or
- conducted following an acceptable test guideline for acute toxicity to algae or other aquatic plants results in a 72 or 96h ErC50 greater than 1mg/L but less than or equal to 10mg/L, or

- an in vivo chronic study on the chemical conducted following an acceptable test guideline for chronic toxicity to fish, chronic toxicity to invertebrates, or chronic toxicity to algae or other aquatic plants results in a:
  - NOEC or EC10 greater than 0.1mg/L but less than or equal to 1mg/L (for chemicals that are not readily biodegradable), or
  - NOEC or EC10 greater than 0.01mg/L but less than or equal to 0.1mg/L (for chemicals that are readily biodegradable), or
- a suitable in silico prediction for acute aquatic toxicity results in a prediction of:
  - for fish - 96h LC50 greater than 1mg/L but less than or equal to 10mg/L, or
  - for invertebrates - 48h EC50 greater than 1mg/L but less than or equal to 10mg/L, or
  - for algae or other aquatic plants - 72 or 96h ErC50 greater than 1mg/L but less than or equal to 10mg/L, or

and the predictions have not been negated by in vivo studies conducted on the chemical for aquatic toxicity.

Information required to demonstrate the absence of the hazard characteristic, toxic to any aquatic life

The information required to demonstrate that a chemical does not have the hazard characteristic, toxic to any aquatic life, is at least one of the following:

- information that demonstrates that the chemical has a molecular weight greater than 1,000gt/mol and has a low cationic density, or
- information that demonstrates that the chemical is a high molecular weight polymer that has a low cationic density, or
- information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
- if the chemical is not a biocidal active and not a persistent, highly branched organic chemical – information on aquatic toxicity for all three trophic levels (fish, invertebrates and algae), from suitable in silico predictions on the chemical or in vivo studies on the chemical or from suitable read-across information conducted following acceptable test guidelines for aquatic toxicity, with the following results for all three trophic levels:
  - acute aquatic toxicity greater than 10 mg/L (LC50 (fish), or EC50 (invertebrates) or ErC50 (algae)), or
  - chronic aquatic toxicity NOEC or EC10 greater than 1mg/L (for chemicals that are not readily biodegradable), or

    - chronic aquatic toxicity NOEC or EC10 greater than 0.1mg/L (for chemicals that are readily biodegradable), or
- test results for all three trophic levels (fish, invertebrates and algae) from in vivo studies on the chemical or from suitable read-across information, conducted following acceptable test guidelines for chronic aquatic toxicity with the following results for all three trophic levels:
    - NOEC or EC10 greater than 1mg/L (for chemicals that are not readily biodegradable), or
    - NOEC or EC10 greater than 0.1mg/L (for chemicals that are readily biodegradable).

This page accompanies step 5.4 Work out environment hazard characteristics.

Environment hazard band A hazard characteristics

Do not start this page unless you have read Step 5.4: Work out your environment hazard characteristics and environment hazard band D hazard characteristics and environment hazard band C hazard characteristics and environment hazard band B hazard characteristics.

Environment hazard characteristics are split into hazard bands. Hazard characteristics of most concern are in hazard band D, while those of lower concern are in hazard band A.

Hazard band A has 6 hazard characteristics you need to consider:

- Contains aluminium, chromium, copper, nickel, selenium, silver or zinc
- Polymer that does not have a low cationic density
- Polymer that is not stable
- Bioaccumulation potential
- Industrial chemical (other than a polymer) that does not meet the criteria for ready biodegradability
- Harmful to any aquatic life

Instructions

You must always start at hazard band D. Step 5.4 tells you when you can stop working through your chemical's environment hazard characteristics and when you need to check each of them - ie D, C, B and A.. You only need to work through the hazard characteristics on this page is your introduction is in:

- Environment exposure band 3 or 4 and you are trying to get to an outcome of very low indicative environment risk

Work your way through each hazard characteristic on this page. Look at whether your chemical meets the hazard characteristic definition based on the information that you have.

If it does meet the hazard characteristic definition, stop there - your introduction's environment hazard band is A. Move on to the next step - step 5.5 Work out your environment risk for categorisation.

If it does not meet the hazard characteristic definition, you'll need to try and prove that your chemical does not have this hazard characteristic. The information that you need to prove this for each hazard characteristic is shown below. If you do not have this information, stop there - your introduction's environment hazard band is A. Move onto the next step – step 5.5 Work out your environment risk for categorisation.

If you do have this information (so you can prove that the chemical does not have the hazard characteristic), move onto the next hazard characteristic on this page.

After you have considered all the hazard characteristics on this page and have proven that the chemical does not have any of them, go to step 5.5 to work out your environment risk for categorisation.

Links to resources to help you with the following:

- Read-across information
- Acceptable test guidelines for categorisation
- In silico predictions for categorisation

Hazard characteristics and required information

Contains aluminium, chromium, copper, nickel, selenium, silver or zinc

Contains aluminium, chromium, copper, nickel, selenium, silver or zinc means that the industrial chemical contains one or more of the following:

- aluminium
- chromium
- copper
- nickel
- selenium
- silver
- zinc

There are no extra information requirements to prove that the chemical does not have this hazard characteristic.

Polymer that does not have a low cationic density

Polymer that does not have a low cationic density means that the industrial chemical is a polymer that does not meet the definition of low cationic density.

There are no extra information requirements to prove that the chemical does not have this hazard characteristic.

Polymer that is not stable

Polymer that is not stable means that all of the following apply to the industrial chemical:

- the chemical is a polymer, and
- the polymer substantially degrades, decomposes or depolymerises during use; that is, the polymer is considerably, meaningfully or to a significantly large extent, changed into simpler, smaller molecular weight chemicals as the result of processes including, but not limited to:
    - oxidation
    - hydrolysis
    - heat
    - sunlight
    - attack by solvents

Information required to demonstrate the absence of the hazard characteristic, polymer that is not stable

The information required to demonstrate that a chemical does not have the hazard characteristic, polymer that is not stable, is at least one of the following:

- information that demonstrates that the polymer is protected from degradation by being encapsulated during use, or
- information that demonstrates that all of the following applies to the polymer:
    - it is not designed to be pyrolysed or burnt, and
    - it is not designed or reasonably anticipated to substantially photodegrade, and
    - it is not designed or reasonably anticipated to substantially biodegrade, and
    - it is not explosive, and
    - it is hydrolytically stable (T½ greater than or equal to 12 hours), and
    - it is not a biological polymer, and
    - it is not a polysaccharide, and
    - if it is a polymer that contains polyethylene glycol (PEG) functionalities and has a solubility in water of greater than 200 mg/L - measured data demonstrates that the polymer does not substantially biodegrade, and
    - if it is a polymer that contains polypropylene glycol (PPG) functionalities and has a solubility in water of greater than 200 mg/L - measured data demonstrates that the polymer does not substantially biodegrade.

Bioaccumulation potential

Bioaccumulation potential means that at least one of the following applies to the industrial chemical:

- it has a bioconcentration factor (BCF) greater than or equal to 500, or
- it has a bioaccumulation factor (BAF) greater than or equal to 500, or
- it has a partition coefficient (log Kow) greater than or equal to 4.0 (unless a measured BAF or BCF is <500).

Information required to demonstrate the absence of the hazard characteristic, bioaccumulation potential

The information required to demonstrate that a chemical does not have the hazard characteristic, bioaccumulation potential, is at least one of the following:

- information that demonstrates that the chemical is an inorganic chemical, or
- information that demonstrates that the chemical has a high molecular weight, or
- information that demonstrates that the chemical is a high molecular weight polymer with:
    - less than 25% low molecular weight oligomeric species less than 1,000g/mol
    - less than 10% low molecular weight oligomeric species less than 500g/mol, or
- information that demonstrates that the chemical has a solubility in water that is greater than 5g/L, measured following an acceptable test guideline for water solubility, or
- information that demonstrates that the chemical is a gas that is not expected to partition to the aquatic compartment, or
- if the chemical is not a highly branched organic chemical* – a test result from a study on the chemical or suitable read across information, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:
    - tests based on dissolved organic carbon (DOC) - greater than or equal to 70% DOC removal, or
    - tests based on carbon dioxide generation - greater than or equal to 60% theoretical carbon dioxide, or
    - tests based on oxygen depletion - greater than or equal to 60% theoretical oxygen demand, or
- a test result from a study on the chemical, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:

    - tests based on dissolved organic carbon (DOC) - greater than or equal to 70% DOC removal, or
    - tests based on carbon dioxide generation - greater than or equal to 60% theoretical carbon dioxide, or
    - tests based on oxygen depletion - greater than or equal to 60% theoretical oxygen demand, or
- a measured value from a study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for partition coefficient, for which log Kow less than 4.0, or
- a suitable in silico prediction for partition coefficient of the chemical using KOWWIN on the chemical for log Kow less than 4.0 (that is not negated by a measured log Kow), or
- a test result from an in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for bioconcentration, for which the BCF less than 500, or
- a test result from an in vivo study on the chemical or from suitable read-across information, conducted following an acceptable test guideline for bioaccumulation, for which the BAF less than 500.

*If the chemical is a highly branched organic chemical, in silico predictions and read across information cannot be used to demonstrate that the chemical does not have the bioaccumulation potential hazard characteristic – only studies on the chemical itself, as described in the next dot point, are acceptable.

Industrial chemical (other than a polymer) that does not meet the criteria for ready biodegradability

Industrial chemical (other than a polymer) that does not meet the criteria for ready biodegradability, means that a study on the chemical, conducted following an acceptable test guideline for ready biodegradability, results in at least one of the following, as relevant to the test method used, and within the period specified in the test method:

- less than or equal to 70% dissolved organic carbon (DOC) removal, or
- less than or equal to 60% theoretical carbon dioxide, or
- less than or equal to 60% theoretical oxygen demand.

Information required to demonstrate the absence of the hazard characteristic, industrial chemical (other than a polymer) that does not meet the criteria for ready biodegradability

The information required to demonstrate that a chemical does not have the hazard characteristic, industrial chemical (other than a polymer) that does not meet the criteria for ready biodegradability, is at least one of the following:

- information that demonstrates that the chemical is highly volatile and it is expected to predominately partition to the air compartment, or
- information that demonstrates that it is an inorganic chemical, or
- information that demonstrates that it is a biological chemical, or
- if the chemical is not a highly branched organic chemical* – a test result from a study on the chemical or suitable read across information, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:
    - tests based on dissolved organic carbon (DOC) - greater than or equal to 70% DOC removal, or
    - tests based on carbon dioxide generation - greater than or equal to 60% theoretical carbon dioxide
    - tests based on oxygen depletion - greater than or equal to 60% theoretical oxygen demand, or
- a test result from a study on the chemical, conducted following an acceptable test guideline for ready biodegradability, which meets at least one of the following degradation pass levels during the period specified in the test method:
    - tests based on dissolved organic carbon (DOC) - greater than or equal to 70% DOC removal, or
    - tests based on carbon dioxide generation - greater than or equal to 60% theoretical carbon dioxide, or
    - tests based on oxygen depletion - greater than or equal to 60% theoretical oxygen demand.

*If the chemical is a highly branched organic chemical, in silico predictions and read across information cannot be used to demonstrate that the chemical does not have the hazard characteristic, industrial chemical (other than a polymer) that does not meet the criteria for ready biodegradability – only studies on the chemical itself, as described in the next dot point, are acceptable.

Harmful to any aquatic life

Harmful to any aquatic life means that any of the following apply to the industrial chemical:

- the chemical is known to cause:

- toxic injury to an organism following short term aquatic exposure , as described in chapter 4.1 of the GHS, with the chemical classified as acute aquatic toxicity (category 3), or
- adverse effects to an organism during aquatic exposures determined in relation to the life-cycle of the organism, as described in chapter 4.1 of the GHS, with the chemical classified as chronic aquatic toxicity (category 3 or 4), or

- an in vivo acute study on the chemical:
  - conducted following an acceptable test guideline for acute toxicity to fish results in a 96h LC50 greater than 10mg/L but less than or equal to 100mg/L, or
  - conducted following an acceptable test guideline for acute toxicity to invertebrates results in a 48h EC50 greater than 10mg/L but less than or equal to 100mg/L, or
  - conducted following an acceptable test guideline for acute toxicity to algae or other aquatic plants results in a 72 or 96h ErC50 greater than 10mg/L but less than or equal to 100mg/L, or
- an in vivo chronic study on the chemical conducted following an acceptable test guideline for chronic toxicity to fish, chronic toxicity to invertebrates, or chronic toxicity to algae or other aquatic plants results in a:
  - NOEC or EC10 greater than 0.1mg/L but less than or equal to 1mg/L (for chemicals that are readily biodegradable), or
- a suitable in silico prediction for acute aquatic toxicity results in a prediction of:
  - for fish - 96h LC50 greater than 10mg/L but less than or equal to 100mg/L, or
  - for invertebrates - 48h EC50 greater than 10mg/L but less than or equal to 100mg/L, or
  - for algae or other aquatic plants - 72 or 96h ErC50 greater than 10mg/L but less than or equal to100mg/L.

and the predictions have not been negated by in vivo studies conducted on the chemical for aquatic toxicity.

Information required to demonstrate that a chemical does not have the hazard characteristic, harmful to any aquatic life

At least one of the following:

- information that demonstrates that the chemical has a molecular weight greater than 1,000g/mol and has a low cationic density, or
- information that demonstrates that the chemical is a high molecular weight polymer that has a low cationic density, or
- information that demonstrates that the chemical is a substance covered by Entry 9 of Annex V of the REACH Regulation, or
- if the chemical is not a biocidal active and not a persistent, highly branched organic chemical – information on aquatic toxicity for all three trophic levels (fish, invertebrates and algae), from suitable in silico predictions on the chemical or in vivo studies on the chemical or from suitable read-across information

conducted following acceptable test guidelines for aquatic toxicity, with the following results for all three trophic levels:

- acute aquatic toxicity greater than 100 mg/L (LC50 (fish), or EC50 (invertebrates) or ErC50 (algae)), or
- chronic aquatic toxicity NOEC or EC10 greater than 1mg/L (for chemicals that are readily biodegradable), or

- test results for all three trophic levels (fish, invertebrates and algae) from in vivo studies on the chemical or from suitable read-across information, conducted following acceptable test guidelines for chronic aquatic toxicity with the following results for all three trophic levels:
  - NOEC or EC10 greater than 1mg/L (for chemicals that are readily biodegradable).

This page accompanies step 5.4 Work out environment hazard characteristics.

Step 5.5 Your environment risk for categorisation

Get help with this step — explore our categorisation decision tools

We explain the table in detail for each environment exposure band that your introduction could be in. This includes what your indicative environment risk outcome will be, depending on which hazard characteristics your chemical does or does not have. Your outcome will be that your introduction has an indicative environment risk of:

- Medium to high
- Low OR
- Very low

Refer back to step 5.4 for information about how to consider the hazard characteristics and where to start and stop when considering hazard characteristics.

Environment risk table

Work out your indicative environment risk	Environment exposure band

		1	2	3	4
Environment hazard band	D	Medium to high risk	Medium to high risk	Medium to high risk	Medium to high risk
	C	Low risk	Low risk	Medium to high risk	Medium to high risk
	B	Very low risk	Low risk	Low risk	Medium to high risk
	A	Very low risk	Very low risk	Low risk	Low risk
	Not A, B, C or D	Very low risk	Very low risk	Very low risk	Very low risk

If your introduction is environment exposure band 1

If your introduction is in environment exposure band 1, at a minimum, you will need to consider if your chemical has any of the hazard characteristics in environment hazard band D.

The indicative environment risk of your introduction will be:

- **Medium to high** if your chemical has **1 or more** of the hazard characteristics in environment hazard bands D OR
- **Low** if your chemical does **not** have **any** of the hazard characteristics in environment hazard band D

You can choose to stop if you get to **low** indicative environment risk.

If you want to see if your introduction could have a **very low** indicative environment risk, you will also need to consider if it has any of the hazard characteristics in environment hazard band C.

The indicative environment risk of your introduction will be:

- **Low** if your chemical has **1 or more** of the hazard characteristics in environment hazard band C OR
- **Very low** if your chemical does **not** have **any** of the hazard characteristics in environment hazard band C

If your introduction is environment exposure band 2

If your introduction is in environment exposure band 2, you will need to consider if your chemical has any of the hazard characteristics in environment hazard band D.

The indicative environment risk of your introduction will be:

- **Medium to high** if your chemical has **1 or more** of the hazard characteristics in environment hazard band D OR
- **Low** if your chemical does not have any of the hazard characteristics in environment hazard band D

You can choose to stop if you get to **low** indicative environment risk.

If you want to see if your introduction could have a **very low** indicative environment risk, you will also need to consider if it has any of the hazard characteristics in environment hazard bands C and B.

The indicative environment risk of your introduction will be:

- **Low** if your chemical has **1 or more** of the hazard characteristics in environment hazard bands C or B OR
- **Very low** if your chemical does **not** have **any** of the hazard characteristics in environment hazard bands C or B

If your introduction is environment exposure band 3

If your introduction is in environment exposure band 3, you will first need to consider if your chemical has any of the hazard characteristics in environment hazard band D. If it does not, then continue on to consider the hazard characteristics in environment hazard band C.

The indicative environment risk of your introduction will be:

- **Medium to high** if your chemical has **1 or more** of the hazard characteristics in environment hazard bands D or C OR
- **Low** if your chemical does **not** have **any** of the hazard characteristics in environment hazard bands D or C

You can choose to stop if you get to **low** indicative environment risk.

If you want to see if your introduction could have a **very low** indicative environment risk, you will also need to consider if it has any of the hazard characteristics in environment hazard bands B and A.

The indicative environment risk of your introduction will be:

- **Low** if your chemical has **1 or more** of the hazard characteristics in environment hazard bands B or A OR
- **Very low** if your chemical does **not** have **any** of the hazard characteristics in environment hazard bands B or A

If your introduction is environment exposure band 4

If your introduction is in environment exposure band 4, you will first need to consider if your chemical has any of the hazard characteristics in environment hazard band D. If it does not, then continue on to consider the hazard characteristics in environment hazard band C. If it does not, then continue on to consider the hazard characteristics in environment hazard band B.

The indicative environment risk of your introduction will be:

- **Medium to high** if your chemical has **1 or more** of the hazard characteristics in environment hazard bands D, C or B OR
- **Low** if your chemical does **not** have **any** of the hazard characteristics in environment hazard bands D, C or B

You can choose to stop if you get to **low** indicative environment risk.

If you want to see if your introduction could have a **very low** indicative environment risk, you will also need to consider if it has any of the hazard characteristics in environment hazard band A.

The indicative environment risk of your introduction will be:

- **Low** if your chemical has **1 or more** of the hazard characteristics in environment hazard band A OR
- **Very low** if your chemical does **not** have **any** of the hazard characteristics in environment hazard band A

'Special cases' - introductions that CANNOT have a very low indicative environment risk

Your introduction CANNOT have a very low indicative environment risk if it is a:

- organotin chemical OR
- polyhalogenated organic chemical OR
- a chemical that has an end use as a biocidal active OR
- a chemical that is introduced as a solid or a dispersion that is not soluble, that meets the nanoscale particle size criteria, and the introduction of the nanoscale portion of the chemical (the part that has a particle size range of 1nm to 100nm) is incidental to the introduction of the non-nanoscale portion OR
- chemical that is introduced as a solid or a dispersion where there is no information available on its water solubility or its particle size, and the introduction of any nanoscale portion of the chemical (the part that has a particle size range of 1nm to 100nm) is incidental to the introduction of the non-nanoscale portion

If your introduction is 1 of these, and you got a **very low risk outcome** in this step, you need to **CHANGE** that outcome to **LOW RISK**.

This means if your consideration of step 5.5 got you to an outcome of **very low risk**, your **final outcome needs to be changed to low risk**.

Definitions of these 'special cases'

Organotin chemicals are chemicals that contain at least 1 tin atom that is covalently bound to at least one carbon atom.

Polyhalogenated organic chemicals are carbon-based chemicals that contain more than 1 covalently bonded halogen atom, such as bromine, chlorine, fluorine or iodine.

Biocidal active is a chemical that is intended to act by chemical means on or against a harmful organism by destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, the harmful organism.

Nanoscale particle size criteria means that the chemical consists of particles in an unbound state or as an aggregate or agglomerate. At least 50% (by number size distribution) of the particles must have at least 1 external dimension in the particle size range of 1nm to 100nm (i.e. the nanoscale).

Not soluble means the solubility of the chemical in water is less than 33.3 g/L measured following OECD test guidelines 105 or 120 for water solubility; or the dissolution rate of the chemical is not more than 70%.

Next – go to step 6 to complete your categorisation

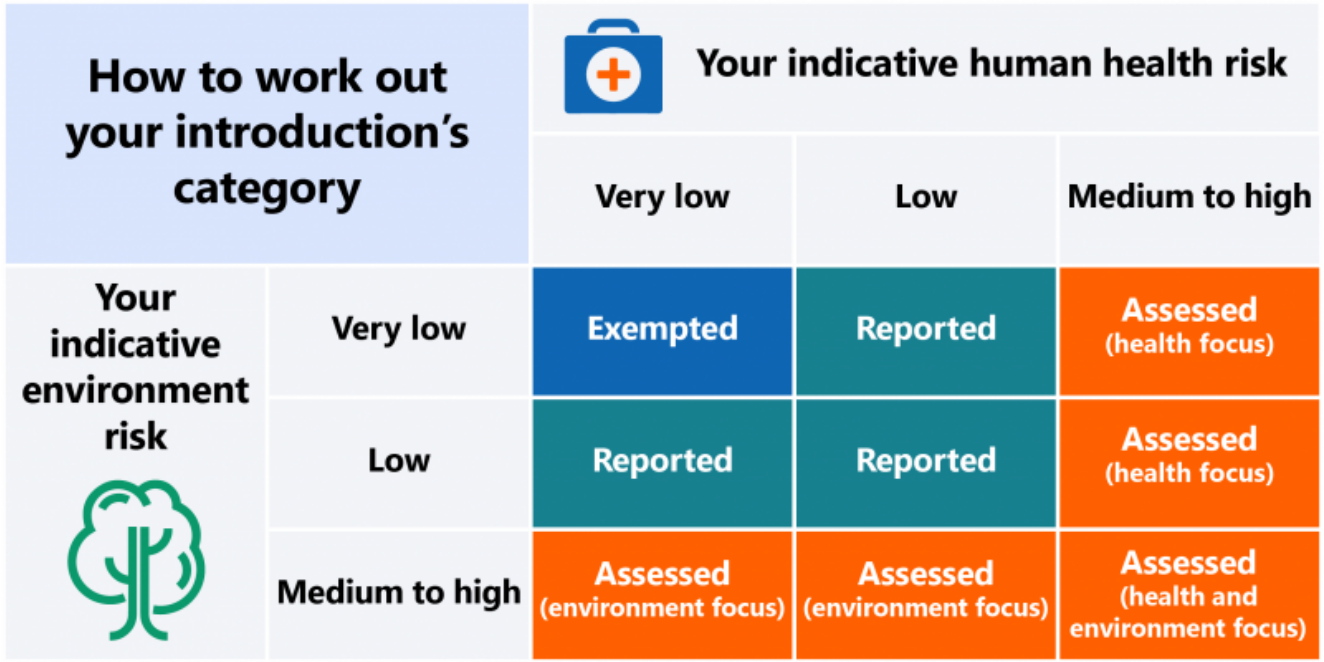
The table on this page shows how you can work out your indicative environment risk by using your environment exposure band (step 5.3) and the environment hazard characteristics (step 5.4) that your chemical does or does not have.

Step 6: Complete your categorisation

What's my introduction's category?

Use our categorisation matrix and your outcome from steps 4.5 and 5.5 to work out if your introduction is in the exempted or reported or assessed category.

1. First, find the column that corresponds with your introduction's **indicative human health risk**, which is either 'very low', 'low' or 'medium to high'.
2. Next, move down the rows until you find your introduction's **indicative environment risk**, which is either 'very low', 'low' or 'medium to high'.
3. Find where these intersect you have your introduction's **category**



How to work out your introduction's category		Your indicative human health risk		
		Very low	Low	Medium to high
Your indicative environment risk	Very low	Exempted	Reported	Assessed (health focus)
	Low	Reported	Reported	Assessed (health focus)
	Medium to high	Assessed (environment focus)	Assessed (environment focus)	Assessed (health and environment focus)

Exempted

Your introduction is in the exempted category if the indicative risk to **both** human health and the environment is **'very low'**.

> Human health risk is **very low** + environment risk **very low** = **exempted introduction**

Reported

Your introduction is in the reported category if the **highest indicative risk** of your introduction to human health or the environment is **'low'**. This means either low risk to both human health and the environment, or low risk for one and very low risk for the other.

Human health risk **very low +** environment risk **low** = reported introduction

Human health risk **low +** environment risk **very low** = reported introduction

Human health risk **low +** environment risk **low** = reported introduction

Assessed

Your introduction is in the assessed category if the **highest indicative risk** of your introduction to human health or the environment is 'medium to high'. This means either medium to high risk to both human health and environment, or, medium to high risk for one and low or very low risk for the other.

Human health risk **very low** + indicative environment risk **medium to high** = assessed introduction (you must apply for an assessment certificate type 'environment focus')

Human health risk **low +** environment risk **medium to high** = assessed introduction (you must apply for an assessment certificate type 'environment focus')

Human health risk **medium to high +** environment risk **very low** = assessed introduction (you must apply for an assessment certificate type 'health focus')

Human health risk **medium to high +** environment risk **low** = assessed introduction (you must apply for an assessment certificate type 'health focus')

Human health risk **medium to high +** indicative environment risk **medium to high** = assessed introduction (you must apply for an assessment certificate type 'health and environment focus')

Example: David has worked through step 4.5 and found that his introduction's indicative human health risk is low. He then worked through step 5.5 and found that the indicative risk to the environment is medium to high. The highest indicative risk for David's introduction is medium to high, therefore his introduction is categorised

as **assessed.**

Final step

Now you know the introduction category, read 'Your obligations after categorisation' to see what you must do next, including records you must keep.

Go to the final step: Your obligations after categorisation

It's time to work out your introduction's category using using the outcome of your introduction's indicative human health risk and environment risk.

Your obligations after categorisation

If your introduction is in the listed category

If you're already registered with us, you are authorised to manufacture or import the chemical into Australia as a **listed introduction** without telling us beforehand.

You must keep records. The records we require you to keep can be different depending on the total introduction volume of chemical in an AICIS registration year (1 September to 31 August). This refers to the combined volume of the chemical that you will introduce in a year across all the products that contain the chemical. You must also submit an annual declaration at the end of the registration year (from August).

If the Inventory listing for your chemical contains a 'specific information requirement', it means that we have assessed this chemical. You're required to submit information to us if the circumstances of your importation or manufacture (introduction) are different to those in our assessment. Learn more about specific information requirements.

If your introduction is in the exempted category

You can introduce your chemical without telling us first, if you are already registered with us. You will need to keep records about the chemical and submit an annual declaration at the end of the registration year (from August). You must also submit a once-off exempted introduction declaration if you are introducing any of the following for the **first time**:

- polymers of low concern
- low-concern biopolymers
- chemicals that you have categorised as **very low risk** for human health and the environment.

If your introduction is in the reported category

You can introduce your chemical into Australia as a reported introduction, as long as you are registered with us and you submit a once-off pre-introduction report before you introduce the chemical.

You must also keep records about the chemical, which varies based on the type of reported introduction. You must also submit an annual declaration at the end of the registration year (from August).

If your introduction is in the assessed category

One of the following applies.

- If your chemical is **not** on the Inventory – you must be registered with us and apply for an assessment certificate. We will assess your chemical introduction. You can start introducing after we issue an assessment certificate.
- If your chemical **is** on the Inventory – and your introduction is outside the parameters of the 'defined scope of assessment' in the Inventory terms of listing for the chemical – you must be registered with us and apply to vary the terms of an Inventory listing.

Appendix - In silico predictions for categorisation

These tables are an overview on which human health and environment hazard characteristics have in silico options, and which in silico options are appropriate.

In silico models for human health hazard characteristics

In silico model	Acute toxicity	Skin irritation / Skin corrosion	Eye damage / Eye irritation	Skin sensitisation	Respiratory sensitisation	Genetic toxicity
OECD QSAR Toolbox	Yes	Yes	Yes	Yes	Yes	Yes
VEGA QSAR	-	-	-	Yes	-	Yes
Danish EPA QSAR Database	Yes	Yes	-	Yes	Yes	Yes
T.E.S.T.	Yes	-	-	-	-	Yes
ToxTree	-	Yes	Yes	Yes	Yes (as protein binding alerts)	Yes
Derek Nexus	-	Yes	Yes	Yes	Yes	Yes
Sarah Nexus	-	-	-	-	-	Yes
OASIS-TIMES	Yes	Yes	Yes	Yes	-	Yes
Chemtunes	Yes	-	-	Yes	-	Yes

In silico model	Acute toxicity	Skin irritation / Skin corrosion	Eye damage / Eye irritation	Skin sensitisation	Respiratory sensitisation	Genetic toxicity
Case ULTRA	Yes	Yes	Yes	Yes	-	Yes
ADMET Predictor	-	-	-	Yes	Yes	Yes
Biovia Discovery Studio (TOPKAT)	Yes	Yes	Yes	Yes	-	Yes
ACD Percepta	Yes	Yes	Yes	-	-	Yes
Hazard Expert	-	-	-	-	-	Yes
Cheminformatics Tool Kit	Yes	Yes	Yes	Yes	-	Yes
Toxread	-	-	-	-	-	Yes
PaDEL-DDPredictor	-	Yes	Yes	-	-	-
Tox21	-	-	-	Yes	-	-

In silico models for environment hazard characteristics

In silico model	Acute aquatic toxicity	Chronic aquatic toxicity	Persistence (as a function of half-life)	Bioaccumulation (as a function of Log Kow)
ECOSAR	Yes	-	-	-
EPI Suite	-	-	Yes	-

In silico model	Acute aquatic toxicity	Chronic aquatic toxicity	Persistence (as a function of half-life)	Bioaccumulation (as a function of Log Kow)
KOWWIN	-	-	-	Yes

Use information on this page to help you complete steps 4.4 and 5.4 to work out the human health hazard characteristics and environment hazard characteristics of your introduction.

Appendix - acceptable test guidelines for categorisation

The acceptable test guidelines for each hazard characteristic and property are set out in the tables below. They include:

- current Organisation for Economic Cooperation and Development (OECD) test guidelines (and their adopted versions if the version shown in the table below is only a draft version)
- deleted and superseded OECD test guidelines if the study was done before the guideline was deleted or superseded
- US EPA OPPT (Office of Prevention, Pesticides and Toxic Substances) test guidelines
- US EPA OCSPP (Office of Chemical Safety and Pollution Prevention) Harmonised Test Guidelines
- test methods for EU REACH, set out in Council Regulation (EC) No 440/2008 (Test Methods Regulation).

Acceptable test guidelines for human health hazard characteristics

Hazard tested	OECD test guidelines	Equivalent test guidelines
Acute dermal toxicity – in vivo	402 or draft 434	EU Annex V test method B.3 OCSPP 870.1200, OPPT 798.110, OPP 81-2
Acute inhalation toxicity – in vivo	403 or 436 or draft 433	EU Annex V test methods B.2 or B.52 OCSPP 870.1300, OPPT 798.1150, OPP 81-3
Acute oral toxicity – in vivo	420, 423, 425 or deleted 401	EU Annex V test methods B.1, B.1 bis, B.1 tris OCSPP 870.1100, OPPT 798.1175, OPP 81-1
Acute oral toxicity – in vitro	129[1]	-
Carcinogenicity – in vivo	451	EU Annex V test method B.32 OCSPP 870.4200, OPPT 798.3300, OPP 83-2
	453	EU Annex V test method B.33 OCSPP 870.4300, OPPT 798.3320, OPP 83-5
Chromosomal abnormalities – in vivo	474	EU Annex V test method B.12 OCSPP 870.5395, OPPT 798.5395, OPP 84-2
	475	EU Annex V test method B.11 OCSPP 870.5385, OPPT 798.5385, OPP 84-2

Hazard tested	OECD test guidelines	Equivalent test guidelines
Chromosomal abnormalities – in vitro	474	EU Annex V test method B.12 OCSPP 870.5395, OPPT 798.5395, OPP 84-2
	475	EU Annex V test method B.11 OCSPP 870.5385, OPPT 798.5385, OPP 84-2
Chromosomal abnormalities – in vitro	473	EU Annex V test method B.10 OCSPP 870.5375, OPPT 798.5375, OPP 84-2
	487	EU Annex V test method B.49
	490	-
Chronic toxicity – in vivo	452	EU Annex V test method B.30 OCSPP 870.4100, OPPT 798.3260, OPP 83-1
	453	EU Annex V test method B.33 OCSPP 870.4300, OPPT 798.3320, OPP 83-5
Developmental toxicity – in vivo	414	EU Annex V test method B.31 OCSPP 870.3700, OPPT 798.4900 or OPP 83-3
	426	OCSPP 870.6300, OPP 83-6
	422[2]	OCSPP 870.3650[2]

Hazard tested	OECD test guidelines	Equivalent test guidelines
Eye damage – in vitro	437	EU Annex V test method B.47 EURL ECVAM DB-ALM protocols No. 98 and 124
	438	EU Annex V test method B.48 EURL ECVAM DB-ALM protocol No. 80
	460	EURL ECVAM DB-ALM protocol No. 71
	491	-
	494	-
Eye irritation – in vitro	492	-
Eye irritation – in vivo	405	EU Annex V test methods B.5 OCSPP 870.2400, OPPT 798.4500 or OPP 81-4
Gene mutation – in vivo	486	EU Annex V test method B.39
	488	EU Annex V test method B.58
	489	-
Gene mutation – in vitro	471	EU Annex V test methods B.13 and B.14 OCSPP 870.5100, OPPT 798.5100, OPPT 798.5265, OPP 84-2

Hazard tested	OECD test guidelines	Equivalent test guidelines
	476	EU Annex V test method B.17 OCSPP 870.5300, OPPT 798.5300, OPP 84-2
Heritable germ cell mutagenicity – in vivo	478	EU Annex V test method B.22 OPPT 798.5450, 870.5450
	485	EU Annex V test method B.25 OPPT 798.5460, 870.5460
Reproductive toxicity – in vivo	421	OCSPP 870.3550
	422[3]	OCSPP 870.3650[3]
	443	EU Annex V test method B.56
	415	EU Annex V test method B.34
	416	EU Annex V test method B.35 OCSPP 870.3800, OPPT 798.4700 or OPP 83-4
Skin corrosion – in vitro	430	EU Annex V test method B.43 EURL ECVAM DB-ALM protocol No.115
	431	EU Annex V test method B.40 EURL ECVAM DB-ALM protocols No.118 and 119

Hazard tested	OECD test guidelines	Equivalent test guidelines
	435	EURL ECVAM DB-ALM protocol No.116
Skin irritation – in vitro	439	EU Annex V test method B.46 EURL ECVAM DB-ALM protocols No.131, 135 and 138
Skin irritation – in vivo	404	EU Annex V test method B.4. OCSPP 870.2500, OPPT 798.4470, OPP 81-5
Skin sensitisation - in vivo	406	EU Annex V test method B.6 OCSPP 870.2600, OPPT 798.4100 or OPP 81-6
	429	EU Annex V test method B.42
	442A	EU Annex V test method B.50
	442B	EU Annex V test method B.51
Skin sensitisation – in chemico (1st key event in skin sensitisation)	442C	EU Annex V test methods B.59 EURL ECVAM DB-ALM protocol No.154
Skin sensitisation – in vitro (2nd key event in skin sensitisation)	442D	EU Annex V test method B.60 EURL ECVAM DB-ALM protocol No.155
Skin sensitisation – in vitro (3rd key event in skin sensitisation)	442E	EURL ECVAM DB-ALM protocol No.158

Hazard tested	OECD test guidelines	Equivalent test guidelines
Skin sensitisation – in vivo	406	EU Annex V test method B.6 OCSPP 870.2600, OPPT 798.4100 or OPP 81-6
	442A	EU Annex V test method B.50
	442B	EU Annex V test method B.51
Subacute dermal toxicity – in vivo	410	EU Annex V test method B.9 OCSPP 870.3200 or OPP 82-2
Subacute inhalation toxicity – in vivo	412	EU Annex V test method B.8
Subacute oral toxicity – in vivo	407	EU Annex V test method B.7 OCSPP 870.3050
Subchronic dermal toxicity – in vivo	411	EU Annex V test method B.28 OCSPP 870.3250, OPPT 798.2250, OPP 82-3
Subchronic inhalation toxicity – in vivo	413	EU Annex V test method B.29 OCSPP 870.3465, OPPT 798.2450, OPP 82-4
Subchronic oral toxicity – in vivo	408	EU Annex V test method B.26 OCSPP 870.3100, OPPT 798.2650, OPP 82-1

Hazard tested	OECD test guidelines	Equivalent test guidelines
	409	EU Annex V test method B.27 OCSPP 870.3150, OPP 82-1

1 – OECD Environment, Health and Safety Publications Series on Testing and Assessment No. 129, Guidance Document on Using Cytotoxicity Tests To Estimate Starting Doses For Acute Oral Systemic Toxicity Tests (2010)

2 – Only for the purposes of the definition of 'developmental toxicity'.

3 – Only for the purposes of the definition of 'reproductive toxicity'.

Acceptable test guidelines for environment hazard characteristics and properties

Hazard or property tested	OECD test guidelines	Equivalent test guidelines
Acute aquatic toxicity – in vivo (fish)	203	ISO 10229 EU Annex V test method C.1 OCSPP 850.1075, OPP 72-1, OPP 72-3
Acute aquatic toxicity – in vivo (invertebrates)	202	ISO 6341 EU Annex V test method C. 2 OCSPP 850.1010 or OPP 72-2

Hazard or property tested	OECD test guidelines	Equivalent test guidelines
Acute aquatic toxicity – in vivo (algae or other aquatic plants)	201	EU Annex V test methods C.3 OCSPP 850.4550, OPPT 797.1050, OPP 122-2, OPP 123-2
Bioaccumulation	315	OCSPP 850.1710
	317	-
Bioconcentration	305	EU Annex V test methods C.13 OCSPP 850.1730 or OPP 72-6
Chronic aquatic toxicity – in vivo (fish)	210	OCSPP 850.1400 EU Annex V test method C.15
Chronic aquatic toxicity – in vivo (invertebrates)	211	OCSPP 850.1300 EU Annex V test method C.20
Chronic aquatic toxicity – in vivo (algae or other aquatic plants)	201	OCSPP 850.4550 OCSPP 850.4500 EU Annex V test method C.3
Partition coefficient	107	EU Annex V test methods A.8 OCSPP 830.7550, OPPT 796.1550, OPP 63-11

Hazard or property tested	OECD test guidelines	Equivalent test guidelines
	117	EU Annex V test methods A.8 OCSPP 830.7570, OPPT 796.1570, OPP 63-11
	123	EU Annex V test methods A.8
Ready biodegradability	301	U Annex V test methods C.4 (A-F) OCSPP 835.3110, OPPT 796.3180, 796.3200, 796.3220, 796.3240, 796.3260
Transformation in aquatic sediment systems	308	-

Acceptable test guidelines for water solubility

Property tested	OECD test guidelines	Equivalent test guidelines
Water solubility – chemicals or polymers	105	OPPTS 830.7840 OPPTS 830.7860
Water solubility - polymers	120	-

Information on this page will help you complete steps 4.4 and 5.4 in working out what the human health characteristics and environment hazard characteristics of your introduction are.