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Order 2025-87-02-01 Amending the **Domestic Substances List: SOR/2025-8**

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CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

Whereas the Minister of the Environment has been provided with information under paragraph 87(5)(a) of the *Canadian Environmental* Protection Act, 1999 ^a in respect of the substance referred to in the annexed Order:

Whereas the period for assessing the information under section 83 of that Act has expired;

And whereas no conditions specified under paragraph 84(1)(a) of that Act in respect of the substance are in effect;

Therefore, the Minister of the Environment makes the annexed Order 2025-87-02-01 Amending the Domestic Substances List under subsection 87(3) $\frac{b}{b}$, paragraph 87(4.1)(a) $\frac{b}{a}$ and subsection 87(5) of the Canadian Environmental Protection Act, 1999 ^a.

Ottawa, January 27, 2025

Steven Guilbeault Minister of the Environment

Order 2025-87-02-01 Amending the Domestic Substances List

Amendments

1 (1) Part 2 of the *Domestic Substances List* $\frac{1}{1}$ is amended by adding the following in numerical order:

Column 1	Column 2
Substance	Significant New Activity for which substance is subject to subsection 81(3) of the Act

1 During the period beginning on the day on which this section 70879-47-9 N-S comes into force and ending on December 7, 2025, the use of the substance phosphoric acid, mixed decyl and octyl esters, potassium salts in the manufacture of a *cosmetic*, as defined in section 2 of the Food and Drugs Act, if it contains the substance at a concentration greater than 1% by weight and the total quantity in all such products during the period is greater than 100 kg. 2 During the period beginning on the day on which this section comes into force and ending on December 7, 2025, the importation of the substance in a *cosmetic*, as defined in section 2 of the Food and Drugs Act, if it contains the substance at a concentration greater than 1% by weight and the total quantity imported in all such products during the period is greater than 100 kg. 3 Despite sections 1 and 2, an activity is not a significant new activity if: (a) the substance is a research and development substance or a site-limited intermediate substance as those terms are defined in subsection 1(1) of the New Substances Notification Regulations (Chemicals and Polymers); or (b) the substance, or the product that contains the substance, is intended only for export. 4 For each proposed significant new activity, the following information must be provided to the Minister at least 90 days before the day on which the activity begins: (a) a description of the significant new activity in relation to the substance; (b) the anticipated annual quantity of the substance to be used or imported; (c) the information specified in paragraphs 7(c) and (d) of Schedule 4 to the New Substances Notification Regulations (Chemicals and Polymers); (d) the information specified in paragraphs 8(f) and (g) of Schedule 5 to those Regulations;

(e) the function of the substance in the product;

(f) information sufficient to assess eye irritation and corrosion at concentrations relevant to the intended end-use of the substance;

(g) information sufficient to assess skin irritation and corrosion at concentrations relevant to the intended end-use of the substance;

(h) information sufficient to assess dermal penetration at concentrations relevant to the intended end-use of the substance;

(i) all other information or test data in respect of the substance that are in the possession of the person proposing the significant new activity, or to which they may reasonably be expected to have access, and that permit the identification of the degree of environmental and public exposure to the substance and the adverse effects that the substance could have on the environment and human health;

(j) the name of every government department or agency, outside or within Canada, to which the person proposing the significant new activity has provided information regarding the use of the substance – and the department's or agency's file number, if known – and the outcome of any assessment by the department or agency and any risk management actions imposed by the department or agency in relation to the substance;

(k) the name, civic and postal addresses, telephone number and, if any, the fax number and email address of the person proposing the significant new activity and, if they are not resident in Canada, of the person resident in Canada who is authorized to act on their behalf; and

(I) a certification that the information is accurate and complete and that is dated and signed by the person proposing the significant new activity if they are resident in Canada or, if not, by the person resident in Canada who is authorized to act on their behalf.

5 Any studies provided under paragraph 4(f), (g) or (h) must be conducted in accordance with the Principles of Good Laboratory Practice set out in Annex II of the *Decision of the Council* concerning the Mutual Acceptance of Data in the Assessment of Chemicals, adopted by the OECD on May 12, 1981, that are current at the time the studies are conducted. 6 The information provided under section 4 is to be assessed within 90 days after the day on which it is received by the Minister.

(2) Sections 1 and 2 in column 2 of Part 2 of the List, opposite the substance "70879-47-9 N-S" in column 1, are replaced by the following:

Column 2

Significant New Activity for which substance is subject to subsection 81(3) of the Act

1 The use of the substance phosphoric acid, mixed decyl and octyl esters, potassium salts in the manufacture of a *cosmetic*, as defined in section 2 of the *Food and Drugs Act*, if it contains the substance at a concentration greater than 1% by weight.

2 The importation of the substance in a *cosmetic*, as defined in section 2 of the *Food and Drugs Act*, if it contains the substance at a concentration greater than 1% by weight and the total quantity imported in all such products in a calendar year is equal to or greater than 10 kg.

2.1 For the purpose of section 2, a calendar year does not include the period beginning on January 1, 2025 and ending on December 7, 2025.

Coming into Force

2 (1) This Order, except subsection 1(2), comes into force on the day on which it is registered.

(2) Subsection 1(2) comes into force on December 8, 2025, but if this Order is registered after that day, that subsection comes into force on the day on which this Order is registered.

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Order.)

Issues

The Minister of the Environment and the Minister of Health (the ministers) assessed information on one chemical, phosphoric acid, mixed decyl and octyl esters, potassium salts (Chemical Abstracts Service [CAS] Registry Number ² 70879-47-9), and determined that it meets the criteria for addition to the *Domestic Substances List*, as set out in the *Canadian Environmental Protection Act, 1999* (CEPA). Therefore, under the authority of section 87 of CEPA, the Minister of the Environment (the Minister) is adding this substance to the *Domestic Substances List*.

The ministers identified potential human health concerns if this substance was to be used in certain new activities. In order to continue addressing these potential human health concerns, the Minister is maintaining the existing requirements under the <u>significant new activity</u> (<u>SNAc</u>) provisions of CEPA applied to this substance.

Background

Assessment of substances new to Canada

Substances that are not on the *Domestic Substances List* are considered new to Canada and are subject to notification and assessment requirements set out in sections 81, 83, 106 and 108 of CEPA, as well as in the <u>New Substances Notification Regulations (Chemicals and Polymers)</u> and the <u>New Substances Notification Regulations (Organisms)</u>. CEPA and these regulations ensure that new substances introduced to the Canadian marketplace are assessed to identify potential risks to the environment and human health, and that appropriate control measures are taken, if deemed necessary.

For more information on the thresholds and scope of these regulations, please see section 1 in the <u>Guidance document for the New Substances</u> <u>Notification Regulations (Chemicals and Polymers)</u> and section 2 of the <u>Guidelines for the Notification and Testing of New Substances: Organisms</u>.

Domestic Substances List

The *Domestic Substances List* (SOR/94-311) provides an <u>inventory of</u> <u>substances</u> in the Canadian marketplace. It was originally published in the *Canada Gazette*, Part II, in 1994 and its current structure was established in 2001 (*Order 2001-87-04-01 Amending the Domestic* <u>Substances List [PDF]</u> [SOR/2001-214]). The *Domestic Substances List* is amended, on average, 14 times per year to add, update or delete substances.

The *Domestic Substances List* includes eight parts defined as follows:

Part 1

Sets out chemicals and polymers, except those referred to in Part 2, 3 or 4 that are identified by their CAS Registry Numbers, or their Substance Identity Numbers assigned by the Department of the Environment and the names of the substances.

Part 2

Sets out chemicals and polymers subject to SNAc requirements that are identified by their CAS Registry Numbers.

Part 3

Sets out chemicals and polymers, except those referred to in Part 4, that are identified by their masked names and their Confidential Accession Numbers (CANs) assigned by the Department of the Environment.

Part 4

Sets out chemicals and polymers subject to SNAc requirements that are identified by their masked names and their CANs.

Part 5

Sets out inanimate biotechnology products and living organisms, except those referred to in Part 6, 7 or 8, that are identified by their American Type Culture Collection (ATCC) numbers, International Union of Biochemistry and Molecular Biology (IUBMB) numbers or specific substance names.

Part 6

Sets out inanimate biotechnology products and living organisms subject to SNAc requirements that are identified by their ATCC numbers, IUBMB numbers or specific substance names.

Part 7

Sets out inanimate biotechnology products and living organisms, except those referred to in Part 8, that are identified by their masked names and their CANs.

Part 8

Sets out inanimate biotechnology products and living organisms subject to SNAc requirements that are identified by their masked names and their CANs.

Adding substances to the Domestic Substances List

A new substance must be added to the *Domestic Substances List* under subsection 87(1), 87(5) or 112(1) of CEPA within 120 days after the following criteria have been met:

- the Minister has been provided with the regulatory information regarding the substance. The information to be provided is set out in the <u>New Substances Notification Regulations (Chemicals and Polymers)</u> and the <u>New Substances Notification Regulations (Organisms)</u>;
- the period prescribed under section 83 or 108 of CEPA for the assessment of the information submitted for the substance has

expired;

- the substance is not subject to any conditions imposed pursuant to paragraph 84(1)(a) or 109(1)(a) of CEPA on its import or manufacture; and
- for additions under subsection 87(1), the ministers are satisfied that the substance has already been manufactured in, or imported into Canada in excess of the prescribed quantity by the person who provided the information; for additions under subsection 112(1), the ministers are satisfied that the substance has already been manufactured in, or imported into Canada by the person who provided the information.

Criteria for adding, varying or rescinding SNAc requirements for substances on the Domestic Substances List

The Minister may amend the *Domestic Substances List* to add, vary or rescind reporting obligations imposed under the SNAc provisions of CEPA. If the ministers assess a substance and available information suggests that certain new activities related to that substance may pose a risk to human health or the environment, the Minister may add that substance to the *Domestic Substances List* with reporting obligations under the SNAc provisions of CEPA (subsection 87(3) or 112(3)). The SNAc provisions of CEPA establish a requirement for any person considering undertaking a significant new activity in relation to the substance to submit a Significant New Activity Notification (SNAN) to the Minister containing certain required information. Upon receipt of the complete information, the ministers would conduct further assessment of the substance and, if necessary, implement risk management measures before the activity is undertaken. To see the substances subject to SNAc provisions of CEPA, please visit the <u>Canada.ca Open Data Portal</u>.

Adding one substance to the Domestic Substances List

The Minister assessed information on one substance new to Canada (CAS Registry Number 70879-47-9) and determined that it meets the criteria for addition to the *Domestic Substances List*, under subsection 87(5) of CEPA. This substance is therefore being added to the *Domestic Substances List* and, as a result, is no longer subject to the *New Substances Notification Regulations (Chemicals and Polymers)*.

The risk assessment of this substance identified potential human health concerns. These include potential ocular, dermal and systemic toxicity concerns if the substance was to be used in certain new activities involving cosmetics. Therefore, the SNAc provisions of CEPA were applied to this substance prior to its addition to the *Domestic Substances List,* pursuant to the *Significant New Activity Notice No. 21862*, published in December 2024.

To continue addressing the potential human health concerns, the SNAc requirements on the substance are being maintained, and are being added with the substance to the *Domestic Substances List*.

Objective

The objective of Order 2025-87-02-01 Amending the Domestic Substances List (the Order) is to add one chemical (CAS Registry Number 70879-47-9) to the Domestic Substances List and to continue contributing to the protection of human health by maintaining the SNAc requirements applied to this substance. The requirement to notify any significant new activity, as defined in the Order, is maintained so that further assessment of the substance is conducted and, if necessary, risk management measures are implemented before the activity is undertaken.

The Order is expected to facilitate access to the substance identified by the CAS Registry Number 70879-47-9 for businesses, as this substance is no longer subject to requirements under subsection 81(1) of CEPA.

Description

The Order is made under subsections 87(3) and 87(5) of CEPA to add one chemical identified by its CAS Registry Number along with SNAc requirements to Part 2 of the *Domestic Substances List*.

The SNAc provisions of CEPA apply to the substance identified by the CAS Registry Number 70879-47-9. It is therefore mandatory to meet the requirements of subsection 81(3) of CEPA before manufacturing, importing or using this substance for a significant new activity, as defined in the Order.

SNAc applicability and reporting requirements

Under the Order, any person wishing to engage in a significant new activity in relation to the substance identified by the CAS Registry Number 70879-47-9 is required to submit a SNAN to the Minister. The SNAN must contain all of the information prescribed in the Order and must be submitted at least 90 days prior to the manufacture, import or use of the substance for the proposed significant new activity. The ministers will use the information submitted to conduct further assessment of the substance and, if necessary, implement risk management measures before the activity is undertaken.

Activities subject to notification requirements

The notification requirements apply to

- the use of the substance phosphoric acid, mixed decyl and octyl esters, potassium salts in the manufacture of a cosmetic, as defined in section 2 of the *Food and Drugs Act*, in which the substance is present in a concentration greater than 1% by weight; and
- the importation of the substance in a quantity that is greater than or equal to 10 kg in a calendar year in a cosmetic, as defined in

section 2 of the *Food and Drugs Act*, in which the substance is present in a concentration that is greater than or equal to 1% by weight.

Transitional provisions

The SNAc provisions of CEPA are applied to the substance with a transitional period phasing in the requirements.

Beginning on the day this Order comes into force and ending on December 7, 2025, the notification requirements apply to

- the use, during this period, of more than 100 kg of the substance in the manufacture of a cosmetic, as defined in section 2 of the <u>Food</u> <u>and Drugs Act</u>, in which the substance is present in a concentration greater than 1% by weight; and
- the importation, during this period, of more than 100 kg or more of the substance in a cosmetic, as defined in section 2 of the *Food and Drugs Act*, in which the substance is present in a concentration that is greater than 1% by weight.

Activities not subject to notification requirements

The notification requirements do not apply to uses of the substance identified by the CAS Registry Number 70879-47-9 that are regulated under any Act of Parliament listed in Schedule 2 of CEPA, including the *Pest Control Products Act*, the *Fertilizers Act* and the *Feeds Act*. Also, the notification requirements do not apply to any transient reaction intermediate, impurity, contaminant, partially unreacted material or incidental reaction product, and under certain circumstances, to mixtures, manufactured items, wastes or substances carried through Canada. For more information on these terms, including definitions, please see section 3.2 of the <u>Guidance document for the *New Substances Notification Regulations (Chemicals and Polymers)*. Please note that individual components of a mixture may be subject to the notification requirements under certain circumstances.</u> Activities involving the use of the substance identified by the CAS Registry Number 70879-47-9 as a research and development substance, site-limited intermediate substances or in the manufacture of an exportonly product are also excluded from notification requirements. For more information on these terms, including definitions, please see section 3.4 of the <u>Guidance document for the New Substances Notification Regulations</u> (<u>Chemicals and Polymers</u>).

Information requirements

The information required under the Order relates to details surrounding the significant new activities, exposure information and toxicity to human health. Some of the information requirements reference the <u>New</u> <u>Substances Notification Regulations (Chemicals and Polymers)</u>.

The information required to complete a SNAN is unique to each substance and is described within the Order. For guidance on preparing a SNAN, please see section 1.3 and section 4 of the <u>Guidance document</u> <u>for the New Substances Notification Regulations (Chemicals and Polymers)</u>.

Regulatory development

Consultation

As CEPA does not prescribe any public comment period before adding a substance to the *Domestic Substances List*, no consultation period for the Order was deemed necessary.

Modern treaty obligations and Indigenous engagement and consultation

The assessment of modern treaty implications made in accordance with the <u>Cabinet Directive on the Federal Approach to Modern Treaty</u> <u>Implementation</u> concluded that orders amending the <u>Domestic Substances</u> List do not introduce any new regulatory requirements and, therefore, do not result in any impact on modern treaty rights or obligations.

Instrument choice

Under CEPA, the Minister is required to add a substance to the *Domestic Substances List* when it is determined to meet the criteria for addition. Orders amending the *Domestic Substances List* are the only regulatory instrument that allows the Minister to comply with these obligations.

Applying the SNAc provisions of CEPA to substances is considered when there is suspicion that new activities may pose a risk to human health or the environment. For more information, please consult the <u>Policy on the</u> <u>Use of Significant New Activity Provisions of the *Canadian Environmental* <u>Protection Act, 1999</u>.</u>

Regulatory analysis

Benefits and costs

Adding one substance to the *Domestic Substances List* is administrative in nature. The Order does not impose any regulatory requirements on businesses and, therefore, does not result in any incremental compliance costs for stakeholders or enforcement costs for the Government of Canada. Adding substances to the *Domestic Substances List* is a federal obligation under section 87 of CEPA that is triggered once a substance meets the criteria for addition.

Maintaining the SNAc requirements for the substance identified by the CAS Registry Number 70879-47-9 continues contributing to the protection of human health by requiring that potential significant new activities involving the substance undergo further assessment and that, if necessary, risk management measures are implemented before the activity is undertaken. The Order does not impose any regulatory requirements (and therefore, any administrative or compliance costs) on businesses related to current activities. The Order will continue to only target significant new activities involving the substance identified by the CAS Registry Number 70879-47-9, should any person choose to pursue such an activity. In the event that any person wishes to use, import or manufacture the substance for a significant new activity, they would be required to submit a SNAN to the Minister containing the complete information referred to in the Order.

While there is no notification fee associated with submitting a SNAN to the Minister in response to the Order, the notifier may incur costs associated with generating data and supplying the required information. Similarly, in the event that a SNAN is received, the Department of the Environment and the Department of Health would incur costs for processing the information and conducting further assessment of the substance to which the SNAN relates. The Department of the Environment will incur negligible costs for conducting compliance promotion and enforcement activities associated with the Order.

Small business lens

The assessment of the <u>small business lens</u> concluded that the Order has no impact on small businesses, as it does not impose any administrative or compliance costs on businesses related to current activities.

One-for-one rule

The assessment of the <u>one-for-one rule</u> concluded that the rule does not apply to the Order, as there is no impact on industry related to current activities.

Regulatory cooperation and alignment

There are no international agreements or obligations directly associated with the Order.

Effects on the environment

In accordance with the <u>Cabinet Directive on Strategic Environmental and</u> <u>Economic Assessment</u>, a preliminary scan of additions to the <u>Domestic</u> <u>Substances List</u> concluded that a strategic environmental assessment is not required for the Order.

Gender-based analysis plus

No gender-based analysis plus (GBA+) impacts have been identified for the Order.

Implementation, compliance and enforcement, and service standards

Implementation

The Order is now in force. Developing an implementation plan is not required when adding substances to the *Domestic Substances List*. The Order does not constitute an endorsement from the Government of Canada of the substance to which it relates, nor an exemption from any other laws or regulations that are in force in Canada and that may apply to this substance or to activities involving it.

Compliance and enforcement

When assessing whether or not a substance is subject to the SNAc provisions of CEPA, a person is expected to make use of information in their possession, or to which they may reasonably be expected to have access. This means information in any of the notifier's offices worldwide or other locations where the notifier can reasonably have access to the information. For example, manufacturers are expected to have access to their formulations, while importers or users of a substance are expected to have access to import records, usage information and the relevant <u>Safety Data Sheet</u> (SDS).

Although an SDS is an important source of information on the composition of a purchased product, it should be noted that the goal of the SDS is to protect the health of workers in the workplace from specific hazards of chemical products, and may not include all the information on these hazards. Therefore, an SDS may not list all product ingredients or substances that may be subject to the SNAc provisions of CEPA. Any person requiring more detailed information on product composition is encouraged to contact their supplier.

If any information becomes available that reasonably supports the conclusion that a substance added to the *Domestic Substances List* through any order is toxic or capable of becoming toxic under section 64 of CEPA, the person who obtains the information and is involved in activities with the substance is obligated, under section 70 of CEPA, to provide that information to the Minister without delay.

A company can submit a SNAN on behalf of its clients. In cases where a person receives possession or control of a substance from another person, they may not be required to submit a SNAN, under certain conditions, if their activities were covered by an original SNAN.

Any person who transfers the physical possession or control of a substance subject to an order to another shall notify that person of their obligation to comply with that order, including the obligation to notify the Minister of any significant new activity and to provide all the required information specified in that order.

A pre-notification consultation (PNC) is recommended for notifiers who wish to consult during the planning or preparation of a SNAN to discuss any questions or concerns they have about the prescribed information and test plans.

Where a person has questions concerning their obligation to comply with an order, believes that they may be out of compliance, or would like to request a PNC, they are encouraged to contact the Substances Management Information Line at <u>substances@ec.gc.ca</u> (email), 1-800-567-1999 (toll-free in Canada) or 819-938-3232 (outside of Canada).

The Order is made under the authority of CEPA, which is enforced in accordance with the <u>Canadian Environmental Protection Act: compliance</u> <u>and enforcement policy</u>. In instances of non-compliance, consideration is given to factors such as the nature of the alleged violation, effectiveness in achieving compliance with CEPA and its regulations, and consistency in enforcement when deciding which enforcement measures to take. Suspected violations can be reported to the Enforcement Branch of the Department of the Environment by email at <u>enviroinfo@ec.gc.ca</u>.

Service standards

In the event that a SNAN is submitted to the Minister in relation to the substance identified by the CAS Registry Number 70879-47-9, the ministers will assess the information after the complete information is received, within the prescribed timelines set out in the Order.

Contact

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Footnotes

- <u>a</u> S.C. 1999, c. 33
- <u>b</u> S.C. 2023, c. 12, s. 26
- <u>1</u> SOR/94-311
- 2 The Chemical Abstracts Service Registry Number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and reports are required by law or administrative policy, is not permitted without the prior written permission of the American Chemical Society.