



COMMISSION IMPLEMENTING REGULATION (EU) 2025/455

of 7 March 2025

granting a Union authorisation for the single biocidal product ‘SatPax® 70/30 IPA’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 13 December 2021, CSI-Ireland submitted an application to the European Chemicals Agency (‘the Agency’) in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a single biocidal product named ‘SatPax® 70/30 IPA’ of product-type 2, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Finland had agreed to evaluate the application. The application was recorded under case number BC-UG072043-42 in the Register for Biocidal Products.
- (2) ‘SatPax® 70/30 IPA’ contains propan-2-ol as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 2.
- (3) On 5 January 2024, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.
- (4) On 27 June 2024, the Agency submitted to the Commission its opinion ⁽²⁾, the draft summary of the biocidal product characteristics (‘SPC’) of ‘SatPax® 70/30 IPA’ and the final assessment report on the single biocidal product, in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘SatPax® 70/30 IPA’ is a single biocidal product within the meaning of Article 3(1), point (r), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) of that Regulation.
- (6) On 15 July 2024, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the single biocidal product ‘SatPax® 70/30 IPA’.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>.

⁽²⁾ ECHA opinion of 30 May 2024 on the Union authorisation of ‘SatPax® 70/30 IPA’ (ECHA/BPC/432/2024), <https://echa.europa.eu/opinions-on-union-authorisation>.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0032869-0000 is granted to CSI-Ireland for the making available on the market and use of the single biocidal product 'SatPax® 70/30 IPA' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 30 March 2025 until 28 February 2035.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 March 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

SatPax® 70/30 IPA

Product type(s)

PT02: Disinfectants and algacides not intended for direct application to humans or animals

Authorisation number: EU-0032869-0000**R4BP asset number:** EU-0032869-0000**1. ADMINISTRATIVE INFORMATION****1.1. Trade name(s) of the product**

Trade name(s)	
	SatPax® 70/30 IPA
	SatPax® Choice® 500
	Sterile SatPax® Choice® 500
	SatPax® 550
	Sterile SatPax® 550
	SatPax® 550 Low Endotoxin
	Sterile SatPax® 550 Low Endotoxin
	SatPax® Choice® 600
	Sterile SatPax® Choice® 600
	SatPax® 670
	Sterile SatPax® 670
	SatPax® 670A
	Sterile SatPax® 670A
	SatPax® 670-R
	Sterile SatPax® 670-R
	SatPax® 3000
	Sterile SatPax® 3000
	SatPax® Choice® 700
	Sterile SatPax® Choice® 700
	SatPax® Choice® 900
	Sterile SatPax® Choice® 900
	SatPax® 1000
	Sterile SatPax® 1000
	SatPax® S1200
	Sterile SatPax® S1200
	SatPax® Choice® SuperSorb
	Sterile SatPax® Choice® SuperSorb
	SatPax® MicroSeal SuperSorb®
	Sterile SatPax® MicroSeal SuperSorb®
	SatPax® Microseal®-VP
	Sterile SatPax® Microseal®-VP
	SatPax® Microseal®-VP Low Endotoxin
	Sterile SatPax® MicroSeal®-VP Low Endotoxin
	SatPax® ValuSeal-HA®
	Sterile SatPax® ValuSeal-HA®
	SatPax® SPSE
	Sterile SatPax® SPSE
	SatPax® SPLWSE
	Sterile SatPax® SPLWSE
	SatPax® SPSWSE
	Sterile SatPax® SPSWSE
	SatPax® ValuSeal® IonX®
	Sterile SatPax® ValuSeal® IonX®

1.2. **Authorisation holder**

Name and address of the authorisation holder	Name	CSI-Ireland
	Address	Block C Ardilaun Court 112-114 St. Stephen's Green D02 TD28 Dublin IE
Authorisation number	EU-0032869-0000	
R4BP asset number	EU-0032869-0000	
Date of the authorisation	30 March 2025	
Expiry date of the authorisation	28 February 2035	

1.3. **Manufacturer(s) of the product**

Name of manufacturer	Berkshire International Ltd
Address of manufacturer	Unit A, The Apex, Farrier Close NR18 0WF Wymondham United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Berkshire International Ltd site 1 Techtex, Units 7 & 8, Rhodes Business Park M24 4NE Middleton United Kingdom of Great Britain and Northern Ireland (the) Berkshire International Ltd site 2 Berkshire Corporation, 6509 Franz Warner Parkway NC 27377 Whitsett United States (the) Berkshire International Ltd site 3 Berkshire International Ltd. Unit A , The Apex, Farrier Close NR18 0WF Wymondham United Kingdom of Great Britain and Northern Ireland (the)

1.4. **Manufacturer(s) of the active substance(s)**

Active substance	Propan-2-ol
Name of manufacturer	Ineos Solvents Germany GmbH
Address of manufacturer	Römerstraße 733 47443 Moers Germany
Location of manufacturing sites	Ineos Solvents Germany GmbH site 1 Römerstraße 733 47443 Moers Germany

Active substance	Propan-2-ol
Name of manufacturer	Exxon Mobil Chemical Europe
Address of manufacturer	Hermeslaan 2 1831 Machelen Belgium
Location of manufacturing sites	Exxon Mobil Chemical Europe site 1 Exxon Mobil Chemical Plant, 4999 Scenic Highway Louisiana 70897 Baton Rouge United States (the)

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		active substance	67-63-0	200-661-7	64,7 % (w/w)

2.2. Type(s) of formulation

RTU wipe pre-saturated with a liquid formulation (AL)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	<p>H225: Highly flammable liquid and vapour.</p> <p>H319: Causes serious eye irritation.</p> <p>H336: May cause drowsiness or dizziness.</p> <p>EUH066: Repeated exposure may cause skin dryness or cracking.</p>
Precautionary statements	<p>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P261: Avoid breathing vapours.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P271: Use only outdoors or in a well-ventilated area.</p> <p>P280: Wear eye protection/face protection.</p> <p>P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P337+P313: If eye irritation persists: Get medical advice.</p> <p>P312: Call a doctor if you feel unwell.</p> <p>P403+P235: Store in a well-ventilated place. Keep cool.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents in accordance with all local, national and international regulations.</p>

4. AUTHORISED USE(S)

4.1. Use description

Table 1

Disinfection of smaller hard surface areas by wiping in cleanrooms and in similar controlled areas within manufacturing and industrial settings (e.g.: work benches in a cleanroom)

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: all Scientific name: no data Common name: Yeasts Development stage: all
Field(s) of use	indoor use Disinfection of smaller hard surface areas by wiping in cleanrooms and in similar controlled areas within manufacturing and industrial settings (e.g.: work benches in a cleanroom)
Application method(s)	Method: wiping Detailed description: Wiping. Direct application onto surfaces with a pre-saturated wipe.
Application rate(s) and frequency	Application rate: 30 - 130 ml/m ² Dilution (%): Not required. Number and timing of application: Ready to use product. Use sufficient wipes in order to maintain a wet surface for a contact time of 1 min. Each wipe contains 3,0 – 56,3 ml of IPA : water 64,7:35,3 w/w% solution (1,6 to 30,9 g active substance). The application rate is depending on the wipe type (see below). 1. 55 % cellulose / 45 % polyester ml of formulated liquid/wipe: 9 - 18 wipes to keep 0,5 m ² wet: 2 ml of formulated liquid/wipe: 6 - 9 wipes to keep 0,5 m ² wet: 3 ml of formulated liquid/wipe: 4,5 - 6 wipes to keep 0,5 m ² wet: 4 ml of formulated liquid/wipe: 4 – 4,5 wipes to keep 0,5 m ² wet: 5

	<p>ml of formulated liquid/wipe: 3 - 4 wipes to keep 0,5 m² wet: 6</p> <p>2. 60 % cellulose / 40 % polyester</p> <p>ml of formulated liquid/wipe: 9 - 15 wipes to keep 0,5 m² wet: 2</p> <p>ml of formulated liquid/wipe: 5,75 - 9 wipes to keep 0,5 m² wet: 3</p> <p>ml of formulated liquid/wipe: 4,5 – 5,75 wipes to keep 0,5 m² wet: 4</p> <p>ml of formulated liquid/wipe: 3,75 – 4,5 wipes to keep 0,5 m² wet: 5</p> <p>ml of formulated liquid/wipe: 3 – 3,75 wipes to keep 0,5 m² wet: 6</p> <p>ml of formulated liquid/wipe: 2 - 3 wipes to keep 0,5 m² wet: 7</p> <p>3. 100 % polypropylene</p> <p>ml of formulated liquid/wipe: 7,5 - 15 wipes to keep 0,5 m² wet: 2</p> <p>ml of formulated liquid/wipe: 5 – 7,5 wipes to keep 0,5 m² wet: 3</p> <p>ml of formulated liquid/wipe: 3,5 - 5 wipes to keep 0,5 m² wet: 4</p> <p>4. 100 % polyester</p> <p>ml of formulated liquid/wipe: 16 - 56 wipes to keep 0,5 m² wet: 1</p> <p>ml of formulated liquid/wipe: 8 - 16 wipes to keep 0,5 m² wet: 2</p> <p>ml of formulated liquid/wipe: 7 - 8 wipes to keep 0,5 m² wet: 3</p> <p>Typical number of applications per day: 10</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>Pre-saturated Wipes – 55% cellulose / 45% polyester</p> <p>Canister/refill pouches 60, 75, 100, 125 wipes Wipe size (cm): 13 × 20, 15 × 23, 30 × 30 Tub material: HDPE (high density polyethylene) Lid material: PP (polypropylene)</p> <p>Pouch 25, 30, 50, 75 or 100 wipes Wipe size (cm): 15 × 23, 18 × 20, 23 × 23, 23 × 28, 30 × 30 Outer layer material: PET (polyethylene terephthalate) Inner Layer material: PE or LLDPE (polyethylene or linear low density polyethylene)</p>

	<p>Pre-saturated Wipes – 60% cellulose / 40% polyester</p> <p>Canister/refill pouch 75, 100, 125 or 150 wipes Wipe size (cm): 13 × 20, 15 × 23, 30 × 30 Tub material: HDPE Lid material: PP</p> <p>Pouch 30, 75, 90 or 100 wipes Wipe size (cm): 15 × 20, 18 × 20, 23 × 23, 23 × 28, 30 × 30 Outer layer material: PET Inner Layer material: PE or LLDPE</p> <p>Pre-saturated Wipes – 100% polypropylene</p> <p>Canister/refill pouch 50, 75, 100, 125 or 150 wipes Wipe size (cm): 15 × 23, 23 × 30 Tub material: HDPE Lid material: PP</p> <p>Pouch 50, 75, 100 or 125 wipes Wipe size (cm): 18 × 28, 23 × 28, 28 × 36 Outer layer material: PET Inner Layer material: PE or LLDPE</p> <p>Pre-saturated Wipes – 100% polyester</p> <p>Pouch 20, 25, 30, 50, 75, 100 wipes Wipe size (cm): 15 × 23, 18 × 20, 23 × 23, 30 × 30 Outer layer material: PET Inner Layer material: PE or LLDPE</p>
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4.1.1. Use-specific instructions

- Use at room temperature.
- Only use on clean surfaces.
- Remove one wipe from pack. Close pack.
- Quarter fold the wiper and refold as needed to use each surface of the wiper.
- Apply pre-saturated wipe directly to the surface to be disinfected.
- Ensure complete wetting of the surface.
- No additional wiping necessary.
- Allow contact time of 1 min for bacteria and yeast.
- Use wipe once.
- Dispose of the wipe immediately after use in a closed container.
- Do not mix with other products.

4.1.2. Use-specific risk mitigation measures

See section 5.2

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See section 5.3

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See section 5.4

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See section 5.5

4.2. Use description

Table 2

Disinfection of larger hard surface areas using wipes and a mop in cleanrooms and in similar controlled areas within manufacturing and industrial settings (e.g.: floors in a cleanroom)

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: all Scientific name: no data Common name: Yeasts Development stage: all
Field(s) of use	indoor use Disinfection of larger hard surface areas using wipes and a mop in cleanrooms and in similar controlled areas within manufacturing and industrial settings (e.g.: floors in a cleanroom)
Application method(s)	Method: mopping Detailed description: Mopping. Attach the pre-saturated wipe to a floor mop for application onto surfaces
Application rate(s) and frequency	Application rate: 17 mL/m ² Dilution (%): Not required. Number and timing of application: Ready to use product. Use sufficient wipes in order to maintain a wet surface for a contact time of 1 min. Each floor wipe contains 22,0 to 24,7 ml of IPA:water 64,7:35,3w/w % solution (12,4 to 13,9 g active substance).

	ml of formulated liquid/per wipe: 25 wipes to keep 25 m ² wet:17 ml of formulated liquid/wipe: 22 wipes to keep 25 m ² wet: 19 Typical number of applications per day: 1
Category(ies) of users	professional
Pack sizes and packaging material	Pre-saturated Wipes – 55% cellulose / 45% polyester Pouch 25, 30, 50, 75 wipes Wipe size (cm): 23 × 58 Product saturation: 60 % Outer layer material: PET (polyethylene terephthalate) Inner Layer material: PE or LLDPE (polyethylene or linear low density polyethylene)

4.2.1. Use-specific instructions

Use at room temperature.

Only use on clean surfaces.

Remove wipe(s) from pack. Close pack.

Attach 4 layers on the mop head and refold or rotate wipers as needed to maintain a wet surface for a contact time of 1 minute.

Apply wipe directly to the surface to be disinfected.

Use sufficient wipes in order to maintain a wet surface for a contact time of 1 min.

No additional wiping necessary.

Allow contact time of 1 min for bacteria and yeast.

Use wipe once.

Dispose of the wipe immediately after use in a closed container.

Do not mix with other products.

4.2.2. Use-specific risk mitigation measures

See section 5.2

4.2.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See section 5.3

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 5.4

4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 5.5

5. GENERAL DIRECTIONS FOR USE⁽¹⁾

5.1. Instructions for use

See section 4.1.1 and 4.2.1

5.2. Risk mitigation measures

Avoid contact with eyes.

Ensure that application is carried out in areas with a minimum ventilation rate of 20 air changes/hour.

Wear protective chemical resistant gloves meeting the requirements of European Standard EN 374 or equivalent during product handling phase (glove material to be specified by the authorisation holder within the product information).

This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

See Section 6 for information on the EN standard and the Council Directive.

Keep in the original container, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid instructions

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

Emergency measures

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Small spill:

Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor

Large spill:

Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach the release from upwind. Prevent entry into sewers, soil, water courses, basements or confined areas. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product.

5.4. Instructions for safe disposal of the product and its packaging

The generation of waste should be avoided or minimised wherever possible. Disposal of this product should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed to the sewer. Do not flush wipes down the toilet. Do not macerate.

Disposal of packaging:

The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Residual alcohol should be emptied prior to disposal of container.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Store in a cool, dry, well-ventilated place in original container.

Keep container tightly closed.

Store at temperatures not exceeding 40 °C. Protect from frost.

Store protected from direct sunlight.

Shelf-life: 2 years

6. OTHER INFORMATION

The product contains wipes of four types of material impregnated with IPA:water (64,7:35,3 % w/w) solution. The materials are cellulose/polyester (55%/45%), cellulose/polyester (60%/40%), polypropylene (100%) and polyester (100%). The sizes of the wipes range from 13 × 20 cm to 23 × 58 cm. More detailed information on the sizes of the wipes is included under the title "Pack sizes and packaging material" in Sections 4.1 and 4.2.

Please be aware of the European reference value of 129,28 mg/m³ for the active substance propan-2-ol (CAS No: 67-63-0) which was used for the risk assessment for this product.

Full titles of EN standards and legislation mentioned in section 5.2:

EN 374 – Protective gloves against dangerous chemicals and micro-organisms.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC).

With respect to the "Category(ies) of users" note: Professionals (including industrial users) means trained professionals if this is required by national legislation.

(¹) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.