Official Journal
of the European Union

EN
L series

2025/2034

10.10.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/2034

of 9 October 2025

amending Implementing Regulation (EU) 2024/2189 as regards administrative changes to the Union authorisation for the single biocidal product 'ClearKlens wipes based on IPA'

(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 50(2) thereof,

Whereas:

(1) On 3 September 2024, Commission Implementing Regulation (EU) 2024/2189 ([2]) granted a Union authorisation, under number EU-0032009-0000, to Diversey Europe Operations B.V. for the making available on the market and use of the single biocidal product 'ClearKlens wipes based on IPA'. The Annex to that Implementing Regulation provides a summary of biocidal product characteristics for that single biocidal product.

(2) On 24 March 2025, Diversey Europe Operations B.V. submitted to the European Chemicals Agency ('the Agency'), in accordance with Article 11(1) of Commission Implementing Regulation (EU) No 354/2013 ([3]), a notification of administrative changes to the Union authorisation for the single biocidal product 'ClearKlens wipes based on IPA', as referred to in Title 1 of the Annex to that Regulation. The notification was recorded in the Register for Biocidal Products ('the Register') under case number BC-KA104994-50. The notified proposed changes to that authorisation concern a change to the address of the authorisation holder and a change to the address of one of the biocidal product manufacturers.

(3) On 11 April 2025, the Agency submitted to the Commission, in accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013, an opinion ([4]) on the notified administrative changes to the Union authorisation for the single biocidal product 'ClearKlens wipes based on IPA'. In the opinion, the Agency concludes that the proposed changes are administrative changes as referred to in Article 50(3), point (a), of Regulation (EU) No 528/2012 and as specified in Title 1, Section 1 and Section 2, of the Annex to Implementing Regulation (EU) No 354/2013, and that after the implementation of the changes, the conditions of Article 19 of Regulation (EU) No 528/2012 will still be met.

(4) On 11 April 2025, the Agency transmitted to the Commission a revised summary of the biocidal product characteristics of the Union authorisation for the single biocidal product 'ClearKlens wipes based on IPA' in all official languages of the Union, covering the administrative changes applied for, in accordance with Article 11(6) of Implementing Regulation (EU) No 354/2013.

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

([2]) Commission Implementing Regulation (EU) 2024/2189 of 3 September 2024 granting a Union authorisation for the single biocidal product ClearKlens wipes based on IPA in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L, 2024/2189, 4.9.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/2189/oj).

([3]) Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p.4, ELI: http://data.europa.eu/eli/reg_impl/2013/354/oj).

([4]) ECHA opinion UAD-C-1816018-33-00/F of 11 April 2025 on administrative changes of the Union authorisation of the single biocidal product 'ClearKlens wipes based on IPA', https://echa.europa.eu/documents/10162/95571017/ua_adc_echa-opinion_bc_ka104994-50_en.pdf/2fbd4613-be26-677d-bd13-126bc0f613f5?t=1744701310955.

(5) The Commission concurs with the opinion of the Agency and therefore considers it appropriate to amend the Union authorisation for the single biocidal product 'ClearKlens wipes based on IPA' to introduce the administrative changes requested by Diversey Europe Operations B.V.

(6) Except for the amendments regarding the administrative changes, all other information included in the summary of the biocidal product characteristics of 'ClearKlens wipes based on IPA' as set out in the Annex to Implementing Regulation (EU) 2024/2189 remains unchanged.

(7) In order to enhance clarity and to ease the access of users and interested parties to the consolidated version of the summary of the biocidal product characteristics which is to be published by the Agency, the Annex to Implementing Regulation (EU) 2024/2189 should be replaced in its entirety. Due to a change in the format used for the generation of the summary of biocidal product characteristics in the Register in February 2024, the summary of biocidal product characteristics in that Annex should also include some minor editorial and layout changes.

(8) Implementing Regulation (EU) 2024/2189 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2024/2189 is replaced by the text set out in the Annex to this Regulation.

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, 9 October 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

ClearKlens wipes based on IPA

Product type(s)

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

Authorisation number: EU-0032009-0000

R4BP asset number: EU-0032009-0000

1. **ADMINISTRATIVE INFORMATION**

1.1. **Trade name(s) of the product**

Trade name(s)	ClearKlens IPA 70 % non sterile WW ClearKlens IPA 70 % v/v wipes ClearKlens IPA 70 % wipes ClearKlens IPA 70 % wipes non sterile ClearKlens IPA 70 % wipes non sterile VH1 ClearKlens IPA 70 % wipes VH1 ClearKlens IPA 70 % WW ClearKlens IPA 70 % WW VH1 ClearKlens IPA 70 % non sterile wipes ClearKlens IPA 70 % non sterile wipes VH1 ClearKlens IPA wipe ClearKlens IPA Wipes ClearKlens IPA WW Divodes IPA WW IPA 70 % v/v WW IPA 70 % wipes IPA 70 % WW IPA 70 % WW VH1 IPA wipes IPA WW Divodes IPA Wipes Soft Care IPA Desinfection Wipes TASKI Sprint IPA Wipes TASKI Sani IPA Wipes TASKI Jontec IPA Wipes TechniSat® DES TexVantage™ DES PolySat® DES AlphaSat™ DES ThermaSat DES TechniScrub™ DES HoneyComb® DES AlphaSat™ 10 DES ClearKlens IPA 70 % v/v WW Suma IPA Wipes Vectra Honeycomb 10 TechniSat DCO TechniSat MDC TexVantage DCO TexVantage MDC PolySat DCO PolySat MDC AlphaSat DCO

	AlphaSat MDC ThermaSat DCO ThermaSat MDC TechniScrub DCO TechniScrub MDC HoneyComb DCO HoneyComb MDC AlphaSat 10 DCO AlphaSat 10 MDC

1.2. **Authorisation holder**

Name and address of the authorisation holder	Name	Diversey Europe Operations B.V.
	Address	De Corridor 4 (Regulatory team) 3621 ZB Breukelen NL
Authorisation number		EU-0032009-0000
R4BP asset number		EU-0032009-0000
Date of the authorisation		24.9.2024
Expiry date of the authorisation		31.8.2034

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

Name of manufacturer	Diversey Europe Operations B.V.
Address of manufacturer	De Corridor 4 (Regulatory team) 3621 ZB Breukelen Netherlands (the)
Location of manufacturing sites	Diversey Europe Operations B.V. site 1 Avenida Conde Duque 5, 7 y 9; Poligono Industrial La Postura 28343 Valdemoro (Madrid) Spain Diversey Europe Operations B.V. site 2 Strada Statale 235 26010 Bagnolo Cremasco (CR) Italy Diversey Europe Operations B.V. site 3 Cotes Park Industrial Estate DE55 4PA Somercotes Alfreton United Kingdom of Great Britain and Northern Ireland (the) Diversey Europe Operations B.V. site 4 Rembrandtlaan 414 7545 ZW Enschede Netherlands (the) Diversey Europe Operations B.V. site 5 Morschheimer Strasse 12 D-67292 Kirchheimbolanden Germany

Name of manufacturer	Flexible Medical Packaging Ltd
Address of manufacturer	Unit 8, Hightown, White Cross Industrial Estate LA1 4XS Lancanter, Lancashire United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Flexible Medical Packaging Ltd site 1 Unit 8, Hightown, White Cross Industrial Estate LA1 4XS Lancanter, Lancashire United Kingdom of Great Britain and Northern Ireland (the)

Name of manufacturer	Ardepharm
Address of manufacturer	Les Iles Ferays 07300 Tournon-sur-Rhône France
Location of manufacturing sites	Ardepharm site 1 Les Iles Ferays 07300 Tournon-sur-Rhône France

Name of manufacturer	Entegris Cleaning Process (ECP) S.A.S
Address of manufacturer	395 rue Louis Lépine 34000 Montpellier France
Location of manufacturing sites	Entegris Cleaning Process (ECP) S.A.S site 1 395 rue Louis Lépine 34000 Montpellier France

Name of manufacturer	Pluswipes Ltd
Address of manufacturer	Pywell Rd, Willowbrook East Industrial Estate NN17 5XJ Corby United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Pluswipes Ltd site 1 Pywell Rd, Willowbrook East Industrial Estate NN17 5XJ Corby United Kingdom of Great Britain and Northern Ireland (the)

Name of manufacturer	ITW Contamination Control BV
Address of manufacturer	Saffierlaan 5 2132 VZ Hoofddorp Netherlands (the)
Location of manufacturing sites	ITW Contamination Control BV site 1 Saffierlaan 5 2132 VZ Hoofddorp Netherlands (the)

Name of manufacturer	ITW Texwipe
Address of manufacturer	1210 South Park Drive 27284 North Caroline Kernersville United States (the)
Location of manufacturing sites	ITW Texwipe site 1 1210 South Park Drive 27284 North Caroline Kernersville United States (the)

Name of manufacturer	ITW Contamination Control (Wujiang) Co., LTD
Address of manufacturer	No. 4660 Pangjin Road Wujiang Economic & Technological Development Zone Suzhou, Jiangsu province 215021 Suzhou China
Location of manufacturing sites	ITW Contamination Control (Wujiang) Co., LTD site 1 No. 4660 Pangjin Road Wujiang Economic & Technological Development Zone Suzhou, Jiangsu province 215021 Suzhou China

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

Active substance	Propan-2-ol
Name of manufacturer	INEOS Solvents Germany GmbH
Address of manufacturer	Anckelmannplatz D-20537 Hamburg Germany
Location of manufacturing sites	INEOS Solvents Germany GmbH site 1 Shamrockstrasse 88 D-44623 Herne Germany INEOS Solvents Germany GmbH site 2 Römerstrasse 733 D-47443 Moers Germany

Active substance	Propan-2-ol
Name of manufacturer	Shell Chemicals Europe B.V.
Address of manufacturer	Postbus 2334 3000 CH Rotterdam Netherlands (the)
Location of manufacturing sites	Shell Chemicals Europe B.V. site 1 Vondelingenweg 601 3196 KK Rotterdam-Pernis Netherlands (the)

Active substance	Propan-2-ol
Name of manufacturer	Exxon Mobil Chemicals
Address of manufacturer	Hermeslaan 2 1831 Machelen Belgium

Location of manufacturing sites	Exxon Mobil Chemicals site 1 4045 Scenic Hailway LA 70805 Baton Rouge United States (the) Exxon Mobil Chemicals site 2 Southampton SO45 1TX Hampshire United States (the)

Active substance	Propan-2-ol
Name of manufacturer	Novapex
Address of manufacturer	21 Chemin de la Sauvegarde 21 Écully Park CS 33167 69134 Écully France
Location of manufacturing sites	Novapex site 1 Rue Gaston Monmousseau 38556 Saint Maurice l'Exil France

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	63,1 % (w/w)

2.2. Type(s) of formulation

xx- presaturated wipes

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P261: Avoid breathing vapours. P271: Use only outdoors or in a well-ventilated area. P280: Wear protective eye protection/face protection. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

	P312: Call a POISON CENTER if you feel unwell. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, ifpresent and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice. P403+P235: Store in a well-ventilated place. Keep cool. P370+P378: In case of fire: Use water to extinguish. P264: Wash hands thoroughly after handling. P501: Dispose of contents to, in accordance with local regulations. P405: Store locked up.

4. **AUTHORISED USE(S)**

4.1. **Use description**

Table 1

Use #1 PT02: Hard surface disinfectant - professionals - wiping

Product type	PT02: Disinfectants and algaecides 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: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Ready-to-use (RTU) pre-saturated wipes for the disinfection of pre-cleaned non-porous hard surfaces in laboratories, cleanrooms and pharmaceutical and cosmetics manufacturing facilities.
Application method(s)	Method: Wiping using RTU pre-saturated wipes Detailed description: -

Application rate(s) and frequency	Application Rate: Use X per 0,5 m^2. Where X is 1 wipe; for wipes with the size 20-46 cm × 38-68 cm 2 wipes; for wipes with the size 15-31 cm × 20-31 cm 3 wipes; for wipes with the size 15 cm × 15 cm 4 wipes; for wipes with the size 10 cm × 10 cm Ready-to-use Number and timing of application: Apply according to disinfection protocols up to 20 times a day Contact time: allow to take effect for at least 5 minutes.
Category(ies) of users	industrial professional
Pack sizes and packaging material	Packaging: Slider bag Polyethylene terephthalate (PET)/ Low-density polyethylene (LDPE)/ High-density polyethylene (HDPE) with co-extruded (COEX) barrier layer Flex pack bag PET/LDPE/ HDPE with COEX barrier layer Bucket - HDPE Tub - HDPE Each package can contain between 5 to 500 wipes, the bucket (HDPE) can contain up to 1000 wipes. Wipes: 100 % Polyester 100 % Polypropylene 50/50 % Polyester/Cellulose or 45/55 % Polyester/Cellulose

4.1.1. *Use-specific instructions for use*

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection. Fold wipe in mid-air into quarter folds. Wipe in one direction with overlapping strokes. Wet the surface completely. Allow to take effect for at least 5 minutes.

Only use wet wipes. Close the package after use.

Dispose used wipes immediately after application into a closed container.

4.1.2. *Use-specific risk mitigation measures*

See general direction for use.

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 general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2. **Use description**

Table 2

Use #2 PT02: Hard surface disinfectant - professionals - mopping

Product type	PT02: Disinfectants and algaecides 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: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Ready to use (RTU) pre-saturated wipes for the disinfection of pre-cleaned non-porous hard surfaces in cleanrooms and pharmaceutical and cosmetics manufacturing facilities.
Application method(s)	Method: mopping using RTU pre-satured wipes Detailed description: -
Application rate(s) and frequency	Application Rate: Use X per 1 m^2. Where X is 1 wipe for wipes with the size 25-38 cm × 38-68 cm; 2 wipes for wipes with the size 20-46 cm × 31-46 cm; 3 wipes for wipes with the size 15-23 cm × 20-28 cm; Ready-to-use Number and timing of application: Apply according to disinfection protocols up to 2 times a day Contact time: allow to take effect for at least 5 minutes.
Category(ies) of users	industrial professional
Pack sizes and packaging material	Packaging: Slider bag Polyethylene terephthalate (PET)/ Low-density polyethylene (LDPE)/ High-density polyethylene (HDPE) with co-extruded (COEX) barrier layer Flex pack bag PET/LDPE/ HDPE with COEX barrier layer Bucket - HDPE Tub - HDPE Each package can contain between 5 to 500 wipes, the bucket (HDPE) can contain up to 1 000 wipes. Wipes: 100 % Polyester 100 % Polypropylene 50/50 % Polyester/Cellulose or 45/55 % Polyester/Cellulose

4.2.1. *Use-specific instructions for use*

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection. Attach wipe onto the mopping tool. Wipe systematically with overlapping strokes. Wet the surface completely. Allow to take effect for at least 5 minutes.

Only use wet wipes.

Close the package after use.

Dispose used wipes immediately after application into a closed container.

4.2.2. *Use-specific risk mitigation measures*

See general direction for use

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 general directions for use.

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

See general directions for use.

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

See general directions for use.

4.3. **Use description**

Table 3

Use #3 PT02: Hard surface disinfectant - professionals – wiping (equipment and small surfaces)

Product type	PT02: Disinfectants and algaecides 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: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Ready-to-use (RTU) pre-saturated wipes for the disinfection of equipment and small non-porous hard surfaces in facilities (including hospitals, nursing homes and medical practices)

Application method(s)	Method: Wiping using RTU pre-saturated wipes Detailed description: -
Application rate(s) and frequency	Application Rate: Use X per 0,5 m^2. Where X is 1 wipe; for wipes with the size 20-46 cm × 38-68 cm 2 wipes; for wipes with the size 15-31 cm × 20-31 cm 3 wipes; for wipes with the size 15 cm × 15 cm 4 wipes; for wipes with the size 10 cm × 10 cm Ready-to-use Number and timing of application: Apply according to disinfection protocols up to 20 times a day Contact time: allow to take effect for at least 5 minutes.
Category(ies) of users	industrial professional
Pack sizes and packaging material	Packaging: Slider bag Polyethylene terephthalate (PET)/ Low-density polyethylene (LDPE)/ High-density polyethylene (HDPE) with co-extruded (COEX) barrier layer Flex pack bag PET/LDPE/ HDPE with COEX barrier layer Bucket - HDPE Tub - HDPE Each package can contain between 5 to 500 wipes, the bucket (HDPE) can contain up to 1 000 wipes. Wipes: 100 % Polyester 100 % Polypropylene 50/50 % Polyester/Cellulose or 45/55 % Polyester/Cellulose

4.3.1. *Use-specific instructions for use*

Thoroughly clean and rinse the surface. Remove excess water from the surface before disinfection. Fold wipe in mid-air into quarter folds and wipe in one direction with overlapping strokes. Wet the surface completely.

Allow to take effect for at least 5 minutes.

Only use wet wipes.

Close the package after use.

Dispose used wipes immediately after application into a closed container

4.3.2. *Use-specific risk mitigation measures*

See general direction for use.

Keep children away from treated surfaces until dried.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE** [1]

5.1. **Instructions for use**

See use-specific instructions for use.

5.2. **Risk mitigation measures**

The product must be applied only in a sufficiently ventilated room. The minimum air change rates required are:

— 8/h in laboratories

— 60/h in pharmaceutical and cosmetics manufacturing facilities

— 20/h in cleanrooms

— 1,5/h in other areas (including hospitals, nursing homes and medical practices)

Wear chemical resistant gloves consistent with 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 of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full references.

Avoid contact with eyes.

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

Inhalation: May cause drowsiness or dizziness.

Eye contact: Causes severe irritation.

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 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.

Environmental precautions

Shall not be released to the ground, watercourses, pipes and sewers. Do not allow to enter the drainage system.

Methods and material for containment and cleaning up. Absorb with liquid-binding material (sand, diatomite, universal binders, sawdust).

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

The product and its container must be disposed of in a safe way, in compliance with any relevant legislation on the disposal of hazardous waste. Perform disposal or incineration in accordance with the local legislation and requirements.

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

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

2 years shelf life.

Keep only in original packaging.

Store away from direct sunlight and below 40 °C.

Store in a closed container

6. **OTHER INFORMATION**

The active substance concentration expressed as percent volume is 70 % v/v.

The full titles of the references in section 5.2 'Risk mitigation measures' are: 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) (OJ L 131, 5.5.1998, p. 11; ELI: http://data.europa.eu/eli/dir/1998/24/oj).