

**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****(Text with EEA relevance)***Article 1*

A Union authorisation with authorisation number EU-0032009-0000 is granted 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' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 24 September 2024 to 31 August 2034.

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.

▼ M2

ANNEX

Summary of product characteristics for a biocidal product

ClearKlens wipes based on IPA

Product type(s)

PT02: Disinfectants and algacides 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 |

▼ **M2**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 | |
| <i>R4BP asset number</i> | 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 | <p>Diversey Europe Operations B.V. site 1 Avenida Conde Duque 5, 7 y 9; Poligono Industrial La Postura 28343 Valdemoro (Madrid) Spain</p> <p>Diversey Europe Operations B.V. site 2 Strada Statale 235 26010 Bagnolo Cremasco (CR) Italy</p> <p>Diversey Europe Operations B.V. site 3 Cotes Park Industrial Estate DE55 4PA Somercotes Alfreton United Kingdom of Great Britain and Northern Ireland (the)</p> <p>Diversey Europe Operations B.V. site 4 Rembrandtlaan 414 7545 ZW Enschede Netherlands (the)</p> <p>Diversey Europe Operations B.V. site 5 Morschheimer Strasse 12 D-67292 Kirchheimbolanden Germany</p> |
| Name of manufacturer | Flexible Medical Packaging Ltd |
| Address of manufacturer | <p>Unit 8, Hightown, White Cross Industrial Estate LA1 4XS Lancanter, Lancashire United Kingdom of Great Britain and Northern Ireland (the)</p> |
| Location of manufacturing sites | <p>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)</p> |

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| | |
|---------------------------------|--|
| 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 Carolina Kernersville United States (the) |
| Location of manufacturing sites | ITW Texwipe site 1 1210 South Park Drive 27284 North Carolina Kernersville United States (the) |

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| | |
|---------------------------------|--|
| 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)**

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|---------------------------------|--|
| 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 ITX Hampshire United States (the) |

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|---------------------------------|---|
| 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, if present 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. |

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|--|---|
| | <p>P370+P378: In case of fire: Use water to extinguish.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P501: Dispose of contents to, in accordance with local regulations.</p> <p>P405: Store locked up.</p> |
|--|---|

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) | <p>Scientific name: no data Common name: Bacteria Development stage: no data</p> <p>Scientific name: no data Common name: Yeasts Development stage: no data</p> |
| Field(s) of use | <p>indoor use</p> <p>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.</p> |
| Application method(s) | <p>Method: Wiping using RTU pre-saturated wipes</p> <p>Detailed description: -</p> |
| Application rate(s) and frequency | <p>Application Rate: Use X per 0,5 m². Where X is</p> <p>1 wipe; for wipes with the size 20-46 cm × 38-68 cm</p> <p>2 wipes; for wipes with the size 15-31 cm × 20-31 cm</p> <p>3 wipes; for wipes with the size 15 cm × 15 cm</p> <p>4 wipes; for wipes with the size 10 cm × 10 cm</p> <p>Ready-to-use</p> <p>Number and timing of application: Apply according to disinfection protocols up to 20 times a day</p> <p>Contact time: allow to take effect for at least 5 minutes.</p> |

▼ M2

| | |
|-----------------------------------|---|
| Category(ies) of users | industrial professional |
| Pack sizes and packaging material | <p>Packaging:</p> <p>Slider bag Polyethylene terephthalate (PET)/ Low-density polyethylene (LDPE)/ High-density polyethylene (HDPE) with co-extruded (COEX) barrier layer</p> <p>Flex pack bag PET/LDPE/ HDPE with COEX barrier layer</p> <p>Bucket - HDPE</p> <p>Tub - HDPE</p> <p>Each package can contain between 5 to 500 wipes, the bucket (HDPE) can contain up to 1000 wipes.</p> <p>Wipes:</p> <p>100 % Polyester</p> <p>100 % Polypropylene</p> <p>50/50 % Polyester/Cellulose or</p> <p>45/55 % Polyester/Cellulose</p> |

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.

▼ **M2**4.2. **Use description**

Table 2

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

| | |
|--|---|
| 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: 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-saturated 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 |

▼ **M2**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 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) | <p>Scientific name: no data Common name: Bacteria Development stage: no data</p> <p>Scientific name: no data Common name: Yeasts Development stage: no data</p> |

▼ M2

| | |
|-----------------------------------|---|
| 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

▼ M24.3.2. *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.

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

▼ M2***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.

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>).