

Summary of product characteristics for a biocidal product

Product name: ClearKlens product based on IPA

Product type(s): PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

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Authorisation number: EU-0022128-0000

R4BP 3 asset reference number: EU-0022128-0000

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Administrative information

1.1. Trade names of the product

ClearKlens IPA
ClearKlens IPA 70%
ClearKlens IPA 70% v/v
ClearKlens IPA VH1
ClearKlens IPA Airless
ClearKlens IPA Pouch
ClearKlens IPA Non Sterile
ClearKlens IPA Non Sterile VH1
ClearKlens IPA SS
ClearKlens IPA SS VH1
ClearKlens IPA RTU
ClearKlens IPA RTU VH1
Texwipe® Sterile 70% Isopropanol
VH01 ClearKlens IPA

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Diversey Europe Operations B.V.
	Address	Regulatory team Maarssebroeksedijk 2 3542 DN Utrecht Netherlands
Authorisation number	EU-0022128-0000	
R4BP 3 asset reference number	EU-0022128-0000	
Date of the authorisation	24/08/2020	
Expiry date of the authorisation	31/07/2030	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Diversey Europe Operations B.V.
Address of the manufacturer	Maarssebroeksedijk 2 3542 DN Utrecht Netherlands
Location of manufacturing sites	Avenida Conde Duque 5, 7 y 9 ; Poligono Industrial La Postura 28343 Valdemoro (Madrid) Spain
	Strada Statale 235 26010 Bagnolo Cremasco (CR) Italy
	Cotes Park Industrial Estate DE55 4PA Somercotes Alfreton United Kingdom
	Rembrandtlaan 414 7545 ZW Enschede Netherlands
	Morschheimer Strasse 12 67292 Kirchheimbolanden Germany

Name of the manufacturer	Multifill BV
Address of the manufacturer	Constructieweg 25a 3640 AJ Mijdrecht Netherlands
Location of manufacturing sites	Constructieweg 25a 3640 AJ Mijdrecht Netherlands

Name of the manufacturer	Flexible Medical Packaging Ltd
Address of the manufacturer	Unit 8, Hightown, White Cross Industrial Estate LA1 4XS Lancaster, Lancashire United Kingdom
Location of manufacturing sites	Unit 8, Hightown, White Cross Industrial Estate LA1 4XS Lancaster, Lancashire United Kingdom

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

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

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

Active substance	1355 - Propan-2-ol
Name of the manufacturer	INEOS Solvents GmbH
Address of the manufacturer	Anckelmannsplatz D-20537 Hamburg Germany
Location of manufacturing sites	Shamrockstrasse 88 D-44623 Herne Germany
	Römerstrasse 733 D-47443 Moers Germany
Active substance	1355 - Propan-2-ol
Name of the manufacturer	Shell Chemicals Europe B.V.
Address of the manufacturer	Postbus 2334 3000 CH Rotterdam Netherlands
Location of manufacturing sites	Vondelingenweg 601 3196 KK Rotterdam-Pernis Netherlands
Active substance	1355 - Propan-2-ol
Name of the manufacturer	Exxon Mobil Chemicals
Address of the manufacturer	Hermeslaan 2 1831 Machelen Belgium
Location of manufacturing sites	4045 Scenic Highway LA 70805 Baton Rouge United States
	Southampton SO45 1TX Hampshire United Kingdom

2. Product composition and formulation

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements

Highly flammable liquid and vapour.
Causes serious eye irritation.
May cause drowsiness or dizziness.
Repeated exposure may cause skin dryness or cracking.

Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.
Avoid breathing spray.
Wash hands thoroughly after handling.
Store in a well-ventilated place.Keep cool.
Dispose of contents to , in accordance with local regulations.
Dispose of container to , in accordance with local regulations.
IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water.
In case of fire:Use alcohol-resistant foam to extinguish.

4. Authorised use(s)

4.1 Use description

Use 1 - PT02: Non-porous hard surface disinfectant - professionals - mopping

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Yeasts Development stage:
Field(s) of use	Indoor Ready to use product for the disinfection of cleaned non-porous hard surfaces in pharmaceutical and cosmetics manufacturing facilities with air change rate of 60 per hour or more and in clean rooms with air change rate of 150 per hour or more.
Application method(s)	Disinfection using a mop - -
Application rate(s) and frequencies	Apply 18.4 mL product /m2 surface. - 0 - -
Category(ies) of users	Professional
Pack sizes and packaging material	Containers (High Density Polyethylene (HDPE), Polypropylene (PP), Polyethylene (PE)): 1 - 20 L.

4.1.1 Use-specific instructions for use

Ready to use product for the disinfection of non-porous hard surfaces.

Clean and dry the surface before disinfection. Wet the mop with the disinfectant and mop the surface. Wet the surface completely. Allow to take effect for at least 30 seconds.
Used mops must be stored in a closed container.

4.1.2 Use-specific risk mitigation measures

Apply the product only in a sufficiently ventilated room. The minimum air change rates required are
- 60/h in pharmaceutical and cosmetics manufacturing facilities;
- 150/h in cleanrooms.

Do not use more than 18.4 mL product/m².

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

Use 2 - PT02: Non-porous hard surface disinfectant - professionals - cloth

Product type

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Where relevant, an exact description of the authorised use

Not relevant

Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Yeasts
Development stage:

Field(s) of use

Indoor

Ready to use product for the disinfection of cleaned non-porous hard surfaces in laboratories with air change rate of 8 per hour or more, in pharmaceutical and cosmetics manufacturing facilities with air change rate of 60 per hour or more and in clean rooms with air change rate of 150 per hour or more.

Application method(s)

Disinfection using a cloth -

-

Application rate(s) and frequencies

Apply 18.4 mL product/m² surface. - 0 -

-

Category(ies) of users

Professional

Pack sizes and packaging material

- Containers (High Density PolyEthylene (HDPE), Polypropylene (PP), Polyethylene (PE)): 1 - 20 L

- Containers (HDPE, PP, PE) with a pump: 200 L (cleanroom only)

- Intermediate bulk containers (IBCs) with a pump (HDPE, PP, PE): 950 and 1000 L (cleanroom only)

4.2.1 Use-specific instructions for use

Ready to use product for the disinfection of non-porous hard surfaces.

Clean and dry the surface before disinfection. Wet the cloth with the disinfectant and wipe the surface. Wet the surface completely. Allow to take effect for at least 30 seconds. In cleanrooms, the exact amount of required product can also be dispensed either using a low flow-rate spray lance or into a bucket via a system of pipes. Used cloths must be disposed of in a closed container.

4.2.2 Use-specific risk mitigation measures

Apply the product 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;
- 150/h in cleanrooms.

Do not use more than 18.4 mL product/m².

The following personal risk mitigation measure can be applied for wiping disinfection unless it can be replaced by technical and / or organisational measures: Wear eye protection during handling of the product.

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

Use 3 - PT02: Non-porous hard surface disinfectant - professionals - spraying

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Yeasts Development stage:
Field(s) of use	Indoor Ready to use product for the disinfection of cleaned non-porous hard surfaces in laboratories with air change rate of 8 per hour or more, in pharmaceutical and cosmetics manufacturing facilities with air change rate of 60 per hour or more and in clean rooms with air change rate of 150 per hour or more.
Application method(s)	Disinfection using a trigger spray - Wiping optional to spread the product.
Application rate(s) and frequencies	Apply 18.4 mL product/ m2 surface. - 0 - -
Category(ies) of users	Professional
Pack sizes and packaging material	- Trigger spray pouch (PE): 0.9 – 20 L - Bag in bottle (multilayer coextruded five-layer Ethylene vinyl acetate (EVA)/EVA/Polyvinylidene dichloride (PVDC)/EVA/EVA bag in a HDPE, PP or PE bottle: 0.9 – 2 L - Trigger Spray bottle (HDPE, PP, PE): 0.5 – 1,5 L - Airless trigger spray bottle (Low-density polyethylene (LDPE)): 0.25 – 1 L

4.3.1 Use-specific instructions for use

Ready to use product for the disinfection of non-porous hard surfaces.

Clean and dry the surface before disinfection. Spray the surface, wipe if necessary to spread the product. Wet the surface completely. Allow to take effect for at least 30 seconds. Used cloths must be disposed in a closed container.

Number of applications per type of packaging, necessary to obtain an application rate of 18,4 mL product / m² surface:

- Trigger spray pouch: apply 19 sprays / m² surface;
- Sterile trigger (bag in bottle): apply 16 sprays / m² surface;
- Trigger spray bottle: apply 14 sprays / m² surface;
- Airless trigger spray bottle: apply 21 sprays / m² surface.

4.3.2 Use-specific risk mitigation measures

Apply the product 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;
- 150/h in cleanrooms

Do not use more than 18.4 mL product/m².

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.

4.4 Use description

Use 4 - PT02: Non-porous glove disinfectant - professionals - non-porous glove disinfection

Product type

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Where relevant, an exact description of the authorised use

Not relevant

Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Yeasts
Development stage:

Field(s) of use

Indoor

Ready to use product for the disinfection of clean non-porous gloves in laboratories with air change rate of 8 per hour or more, in pharmaceutical and cosmetics manufacturing facilities with air change rate of 60 per hour or more and in clean rooms with air change rate of 150 per hour or more.

Application method(s)

Disinfection of non-porous gloves -
-

Application rate(s) and frequencies

Apply 3 mL of the product to gloved hands. - 0 -
-

Category(ies) of users

Professional

Pack sizes and packaging material

Automatic dosing:
-Containers (HDPE, PP, PE): 1 - 20 L
-Containers (HDPE, PP, PE) with a pump: 200 L (cleanrooms only)
-IBCs with a pump (HDPE, PP, PE): 950 and 1000 L (cleanrooms only)
Manual dosing:
-Trigger spray pouch (PE): 0.9 - 20 L
-Bag in bottle (multilayer coextruded five-layer EVA/EVA/PVDC/EVA/EVA bag in a HDPE, PP or PE bottle): 0.9 - 2 L-Trigger Spray bottle (HDPE, PP, PE): 0.5 - 1.5 L
-Airless trigger spray bottle (LDPE): 0.25 - 1 L

4.4.1 Use-specific instructions for use

Ready to use product for the disinfection of non-porous gloves.

Automatic dosing:

Apply 3 mL of the product directly onto clean gloved hands, distribute evenly and make sure to wet the surface completely. Allow to take effect for at least 30 seconds.

Manual dosing:

Spray 3 mL of the product directly onto clean gloved hands, distribute evenly and make sure to wet the surface completely. Allow to take effect for at least 30 seconds.

Number of applications per type of packaging, necessary to apply 3 mL of product onto clean gloved hands:

- Trigger spray pouch: apply 3 sprays of the product on two hands;
- Sterile trigger (bag in bottle): apply 3 sprays of the product on two hands;

- Trigger spray bottle: apply 3 sprays of the product on two hands;
- Airless trigger spray bottle: apply 4 sprays of the product on two hands.

4.4.2 Use-specific risk mitigation measures

Apply the product 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;
- 150/h in cleanrooms.

4.4.3 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.

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

See general directions for use.

4.4.5 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

5.1. Instructions for use

See use specific instructions.

5.2. Risk mitigation measures

Wear new protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

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: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTRE, doctor or physician if you feel unwell.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation occurs and persists, get medical attention.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Get medical attention or advice if you feel unwell.

Environmental precautions:

The product should not reach sewage water or drainage ditch undiluted or unneutralised.

Do not allow the product to enter drainage system, surface or ground water. Dilute with plenty of water.

Methods and material for containment and cleaning up. Absorb the product 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. Dispose of or incinerate in accordance with the local regulations.

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 30°C.

Store in a closed container.

6. Other information

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129.28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.