Summary of product characteristics for a biocidal product

Product name: perform sterile alcohol IPA

 $\mbox{\sc PT02}$ - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) Product type(s):

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

animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Authorisation number: EU-0023656-0000

R4BP 3 asset reference number: EU-0023656-0001

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Administrative information

1.1. Trade names of the product

perform® sterile alcohol IPA
perform® classic alcohol IPA
buraton® IPA
perform® advanced alcohol IPA
arcana® IPA
clear IPA
pure IPA
disinfectant IPA
Surface disinfection liquid classic
sterile IPA
mikrozid® sterile liquid
Surface disinfection liquid sterile
BTS 6000

1.2. Authorisation holder

Name and address of the authorisation holder

Name	Schuelke & Mayr GmbH
Address	Robert-Koch-Str. 2 22851 Norderstedt Germany

Authorisation number

EU-0023656-0000 1-1

R4BP 3 asset reference number

EU-0023656-0001

Date of the authorisation

27/12/2020

Expiry date of the authorisation

30/11/2030

1.3. Manufacturer(s) of the biocidal products

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

Active substance	1355 - Propan-2-ol
Name of the manufacturer	Ineos Solvents Germany GmbH (formerly Sasol)
Address of the manufacturer	Römerstraße 733 47443 Moers Germany
Location of manufacturing sites	Römerstraße 733 47443 Moers Germany
	Shamrockstr. 88 44643 Herne 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	Shell Nederland Raffinaderij B.V., Vondelingenweg 601 3196 KK Rotterdam-Pernis Netherlands

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

Any other liquid (AL), ready-to-use

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.

Keep container tightly closed.

Ground and bond container and receiving equipment.

Use explosion-proof electrical/ventilating/lighting equipment.

Use non-sparking tools.

Take action to prevent static discharges.

Avoid breathing vapours.

Avoid breathing spray.

Use only outdoors or in a well-ventilated area.

Wear eye protection.

IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.

Call a POISON CENTER or doctor if you feel unwell.

If eye irritation persists:Get medical advice.

If eye irritation persists:Get medical attention.

In case of fire:Use alcohol-resistant foam, carbon dioxide or water mist to extinguish.

Store in a well-ventilated place. Keep cool.

Store locked up.

Dispose of contents to /container to an approved waste disposal plant.

4. Authorised use(s)

4.1 Use description

Use 1 - Disinfection of surfaces - 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

animals (Disinfectants)

Target organism(s) (including development stage)

Scientific name: Bacteria Common name: -Development stage: -

Scientific name: Yeast Common name: -Development stage: -

Field(s) of use

Indoor

Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)

Application method(s)

Method: Spraying Detailed description:

Product will be sprayed directly on the surface

Application rate(s) and frequencies

Application Rate: Ready-to-use. Do not apply more than 25 ml/m².

Dilution (%): -

Number and timing of application:

Disinfection after each production and cleaning process or when required according to standard operating procedure (SOP)

Category(ies) of users

Industrial

Professional

Pack sizes and packaging material

Bottle: 250-1000 ml

packaging material: high-density polyethylene (HDPE), surlyn/polypropylene (PP) closure material is either: PP, polyoxymethylene (POM), low-density polyethylene (LDPE), HDPE, polyethylene (PE), ethylene-vinyl acetate (EVA), stainless steel, polybutylene terephthalate (PBT), (LD)PE, exp. polytetrafluoroethylene (PTFE), linear low density polyethylene (LLDPE), expanded PE (EXPPE), Co Polymer PP

canister: 5-10 L

packaging material: HDPE.

closure material is either: HDPE/LDPE

.1.1 Use-specific instruction	ns for use
Spray ready-to-use product on the surfa	ce and allow to take effect at room temperature (20± 2°C) for at least 1 minute.
I.1.2 Use-specific risk mitiga	ation measures
The following personal risk mitigation me organisational measures: Wear eye prot	easure can be applied for refilling procedure unless it can be replaced by technical and/or tection during handling of the product.
<u>-</u>	ise, the particulars of likely direct or indirect effects, first aid measures to protect the environment
See general directions for use.	
1.1.4 Where specific to the u backaging	ise, the instructions for safe disposal of the product and its
.1.5 Where specific to the usinder normal conditions of s	se, the conditions of storage and shelf-life of the product storage
See general directions for use.	
I.2 Use description	
Jse 2 - Disinfection of surfaces	s - wiping
Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact	-

Revolver BAG: 1 L packaging material: EVA

closure material: PP/Silicone/EVA

Scientific name: Bacteria

use

Target organism(s) (including development stage)

Common name: -Development stage: -

Scientific name: Yeast Common name: -Development stage: -

Field(s) of use

Indoor

Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)

Application method(s)

Method: Wiping

Detailed description:

Product will be sprayed or poured on the surface and wiped afterwards or the wipe will be wetted by spraying or pouring with the product and thereafter the product should be wiped on the surface.

Application rate(s) and frequencies

Application Rate: Ready-to-use. Do not apply more than 25 ml/m².

Dilution (%): -

Number and timing of application:

Disinfection after each production and cleaning process or when required according to SOP.

Category(ies) of users

Industrial

Professional

Pack sizes and packaging material

Bottle: 250-1000 ml

packaging material: HDPE, surlyn/PP

closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP.

canister: 5-10 L

packaging material: HDPE.

closure material is either: HDPE/LDPE

Revolver BAG: 1 L packaging material: EVA

closure material: PP/Silicone/EVA.

4.2.1 Use-specific instructions for use

Spray or pour ready-to-use product on the surface and wipe afterwards or wet a wipe with the ready-to-use product by spraying or pouring and thereafter wipe the surface. Allow to take effect for at least 5 minutes at room temperature (20± 2°C).

4.2.2 Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for refilling procedure 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							
4.2.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product storage						
See general directions for use.							
4.3 Use description Use 3 - Disinfection of surfaces	with food and feed contact - spraying						
Product type	PT04 - Food and feed area (Disinfectants)						
Where relevant, an exact description of the authorised use	-						
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: -						
	Scientific name: Yeast Common name: - Development stage: -						
	Scientific name: Viruses Common name: - Development stage: -						
	Indees						
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)						
Application method(s)	Method: Spraying Detailed description: Product will be sprayed directly on the surface.						

Application rate(s) and frequencies

Application Rate: Ready-to-use. Do not apply more than 25 ml/m².

Dilution (%): -

Number and timing of application:

Disinfection after each production and cleaning process or when required according to SOP.

Category(ies) of users

Industrial

Professional

Pack sizes and packaging material

Bottle: 250-1000 ml

packaging material: HDPE, surlyn/PP

closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT,

(LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP.

canister: 5-10 L

packaging material: HDPE.

closure material is either: HDPE/LDPE

Revolver BAG: 1 L packaging material: EVA

closure material: PP/Silicone/EVA.

4.3.1 Use-specific instructions for use

Spray ready-to-use product on the surface and allow to take effect at room temperature (20± 2°C) for at least 1 (bactericidal and yeasticidal activity) or 2 minutes (virucidal activity).

4.3.2 Use-specific risk mitigation measures

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

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

.3.5 Where specific to the us inder normal conditions of s	se, the conditions of storage and shelf-life of the product storage
See general directions for use.	
I.4 Use description	
Jse 4 - Disinfection of surfaces	with food and feed contact - wiping
Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Farget organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: -
	Scientific name: Yeast Common name: - Development stage: -
	Scientific name: Viruses Common name: - Development stage: -
	Indoor
Field(s) of use	Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Method: Wiping Detailed description:
	Product will be sprayed or poured on the surface and wiped afterwards or the wipe will be wetted by spraying or pouring with the product and thereafter the product should be wiped on the surface.
Application rate(s) and requencies	Application Rate: Ready-to-use. Do not apply more than 25 ml/m². Dilution (%): - Number and timing of application:
	Disinfection after each production and cleaning process or when required according to SOP.

Category(ies) of users	Industrial							
	Professional							
Pack sizes and packaging material Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless ste (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP.								
	canister: 5-10 L							
	packaging material: HDPE. closure material is either: HDPE/LDPE							
	Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA.							
4.4.1 Use-specific instruction	ons for use							
Spray ready-to-use product on the surfa	ace and wipe afterwards or wet a wipe with the ready-to-use product by spraying or pouring							
and thereafter wipe the surface. Allow to take effect for at least 5 minutes at room temperature (20± 2°C).								
4.4.2 Use-specific risk mitig	ation measures							
4.4.2 Osc-specific risk filling	ation measures							
	neasure can be applied for disinfection of food processing machinery and for refilling technical and/or organisational measures: Wear eye protection during handling of the							
	use, the particulars of likely direct or indirect effects, first aid y measures to protect the environment							
See general directions for use.								
4.4.4 Where specific to the upackaging	use, the instructions for safe disposal of the product and its							
	ise, 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

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Do not apply more than 25 ml/m2.

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

5.2. Risk mitigation measures

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Apply a funnel for refilling.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

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

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

	5.4.	Inst	truct	tions	for s	safe	dis	posal	l of	tŀ	1e	prod	luct	t and	Ιi	ts	pacl	kag	ing	1
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5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 36 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original 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.