# Summary of product characteristics for a biocidal product family

Family name: Christeyns' Propan-1/2-ol BPF

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

animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

**Authorisation number:** 944-1

**R4BP 3 asset reference number:** DK-0027648-0000

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#### Part I.- First information level

## 1. Administrative information

#### 1.1. Family name

Christeyns' Propan-1/2-ol BPF		

#### 1.2. Product type(s)

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

PT04 - Food and feed area (Disinfectants)

#### 1.3. Authorisation holder

Name and address of the authorisation holder

Name	Christeyns NV
Address	Afrikalaan 182 9000 Gent Belgium
944-1	

**Authorisation number** 

R4BP 3 asset reference number

Date of the authorisation

Expiry date of the authorisation

28/01/2022

25/12/2031

# 1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

Christeyns N.V.

Address of the manufacturer

Afrikalaan 182 9000 Gent Belgium

Location of manufacturing sites

Afrikalaan 182 9000 Gent Belgium

Name of the manufacturer	Christeyns s.r.o.
Address of the manufacturer	Vitovska 453/7 742 35 Odry Czech Republic
Location of manufacturing sites	Christeyns s.r.o. 742 35 Odry Czech Republic
Name of the manufacturer	Christeyns Food Hygiene sas
Address of the manufacturer	ZA Les Farges 24580 Rouffignac St. Cernin France
Location of manufacturing sites	ZA Les Farges 24580 Rouffignac St. Cernin France
Name of the manufacturer	Betelgeux sl
Address of the manufacturer	Poligono Industrial Raconc, Parcelas 2 y 3 CP 46729 Ador - Valencia Spain
Location of manufacturing sites	Poligono Industrial Raconc, Parcelas 2 y 3 CP 46729 Ador - Valencia Spain
Name of the manufacturer	Christeyns France sa
Address of the manufacturer	Rue de la Maladrie 31, PI de la Vertonne 44120 Vertou France
Location of manufacturing sites	Rue de la Maladrie 31, Pl de la Vertonne 44124 Vertou France
Name of the manufacturer	Christeyns Professional Hygiene srl.
Address of the manufacturer	Via Aldo Moro 30 20060 Pessano con Bornago Italy
Location of manufacturing sites	Via Aldo Moro 30 20060 Pessano con Bornago Italy
Name of the manufacturer	Christeyns UK Ltd.
Address of the manufacturer	Rutland Street BD4 7EA Bradford United Kingdom

Rutland Street BD4 7EA Bradford United Kingdom

Location of manufacturing sites

Name of the manufacturer	Christeyns Food Hygiene Ltd.
Address of the manufacturer	2 Cameron Court, Winwick Quay WA2 8RE Warrington United Kingdom
Location of manufacturing sites	2 Cameron Court, Winwick Quay WA2 8RE Warrington United Kingdom

Name of the manufacturer

Clover Chemicals Ltd.

Clover House, Macclesfield Road, Whaley Bridge SK23 7DQ High Peak United Kingdom

Location of manufacturing sites

Clover House, Macclesfield Road, Whaley Bridge SK23 7DQ High Peak United Kingdom

## 1.5. Manufacturer(s) of the active substance(s)

Active substance	1354 - Propan-1-ol
Name of the manufacturer	OQ Chemicals GmbH (Formerly OXEA GmbH)
Address of the manufacturer	Otto-Roelen-Str. 3 46147 Oberhausen Germany
Location of manufacturing sites	Oxea corporation. 2001 FM 3057 TX 77404 Bay City United States
Active substance	1355 - Propan-2-ol
Name of the manufacturer	Brenntag GmbH
Address of the manufacturer	Stinnes Platz 1 45472 Mülhelm an der Ruhr Germany
Location of manufacturing sites	Shell Nederland Raffinaderij BV, Vondelingenweg 601 3196 KK Rotterdam Netherlands
	Exxon Mobil, 4045 Scenic Hwy, Baton Rouge 70805 LA United States

Active substance	1354 - Propan-1-ol
Name of the manufacturer	Sasol Chemie GmbH & Co. KG
Address of the manufacturer	Anckelmannsplatz 1 20537 Hamburg Germany
Location of manufacturing sites	Secunda Chemical Operations, Sasol Place, 50 Katherine streeed 2090 Sandton South Africa
Active substance	1355 - Propan-2-ol
Name of the manufacturer	Alcoholes Montplet S.A.
Address of the manufacturer	NOVAPEX, NOVACAP, Le Carré Joannès, 29 avenue Joannès Masset CS 10619 69258 Lyon Cedex 09 France
Location of manufacturing sites	NOVAPEX, Rue Gaston Monmousseau 38150 Salaise-sur-Sanne France

# 2. Product family composition and formulation

# 2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	24,54 - 49,07
Propan-2-ol		Active Substance	67-63-0	200-661-7	9,77 - 19,54

# 2.2. Type(s) of formulation

AL - Any other liquid

# Part II.- Second information level - meta SPC(s)

#### 1. Meta SPC administrative information

#### 1.1. Meta SPC identifier

Meta SPC 1: Mida San 335 RV

#### 1.2. Suffix to the authorisation number

1-1

#### 1.3 Product type(s)

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

PT04 - Food and feed area (Disinfectants)

# 2. Meta SPC composition

### 2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	24,54 - 24,54
Propan-2-ol		Active Substance	67-63-0	200-661-7	9,77 - 9,77

#### 2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

# 3. Hazard and precautionary statements of the meta SPC

**Hazard statements** 

Flammable liquid and vapour.

Causes serious eye damage.

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.

Avoid breathing vapours.

Wear eye protection.

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

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

Immediately call a POISON CENTER or doctor/physician.

Store in a well-ventilated place. Keep container tightly closed.

Dispose of contents to in accordance with local/regional/national/international regulations..

Dispose of container to in accordance with local/regional/national/international regulations..

Use only outdoors or in a well-ventilated area.

## 4. Authorised use(s) of the meta SPC

#### 4.1 Use description

#### Use 1 - Use 1.1 - PT2 Surface disinfection, trigger 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: bacteria Common name: Bacteria Development stage:

Scientific name: Yeasts Common name: Yeasts Development stage:

#### Field(s) of use

Indoor

Indoors – In Non-food industries, institutions & workplaces. Disinfection of small hard/non-porous surfaces by trigger spraying, with prior cleaning

Α	nn	lication	method	s)
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Method: Trigger Spraying Detailed description:

By trigger spraying.

After trigger spraying & required contact time achieved, the product may be wiped off with a tissue or cloth.

# Application rate(s) and frequencies

Application Rate: 30 ml / m2

Dilution (%): 0%

Number and timing of application:

Active against bacteria & yeasts:

Ready-to-use At room temperature With 5 min contact time Application rate: 30 ml / m<sup>2</sup>

Frequency: daily

#### Category(ies) of users

Industrial

Professional

# Pack sizes and packaging material

1 L flasks with separate trigger spraying device (HDPE)

5, 10, 22, 25 L refill cans (HDPE)

#### 4.1.1 Use-specific instructions for use

Please see general instructions for use.

#### 4.1.2 Use-specific risk mitigation measures

The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be

permanent measures).				
Unspecified rooms: max 1 application per day RPE 4 required during application unprotected bystanders should not be present during application				
Pharmaceutical and cosmetics manufactors RPE 4 required during mixing and loading				
	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment			
Please see general directions for use.				
4.1.4 Where specific to the uspackaging	se, the instructions for safe disposal of the product and its			
Please see general directions for use.				
I.1.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage			
Please see general directions for use.				
4.2 Use description				
Use 2 - Use 1.2 - PT2 Surface di	sinfection, low-pressure 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: bacteria Common name: Bacteria Development stage:			
	Scientific name: Yeasts Common name: Yeasts Development stage:			

#### Field(s) of use

Indoor

Indoors. Non-food industry (e.g. pharmaceutical)

Disinfection of hard/non-porous surfaces by low-pressure spraying, with prior cleaning.

Application method(s)

Method: Low-pressure spraying

Detailed description:

Low-pressure spraying: after low-pressure spraying, the product is left to dry but not

wiped off.

# Application rate(s) and frequencies

Application Rate: 200 ml / m2

Dilution (%): 0%

Number and timing of application:

Active against bacteria & yeasts:

Ready-to-use At room temperature with 5 min contact time Application rate: 200 ml/m<sup>2</sup>

Frequency: daily

#### Category(ies) of users

Industrial

# Pack sizes and packaging material

5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE) 1000 L IBCs (HDPE)

## 4.2.1 Use-specific instructions for use

Please see general instructions for use

# 4.2.2 Use-specific risk mitigation measures

The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures:

Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).

#### **Unspecified rooms:**

1 application per day for a maximum of 8 m<sup>2</sup> RPE 10 required during application unprotected bystanders should not be present during application

#### Cleanrooms:

1 application per day for a maximum of 10 m<sup>2</sup>

RPE 4 and a ventilation rate of 20/h required during application unprotected bystanders should not be present during application

#### Laboratories and biotechnology:

1 application per day for a maximum of 10 m<sup>2</sup> RPE 10 required during application unprotected bystanders should not be present during application

#### Pharmaceutical and cosmetics manufacturing facilities:

1 application per day for a maximum of 10 m<sup>2</sup>

RPE 4 required during application

unprotected bystanders should not be present during application

# 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

please see general directions for use

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

please 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

Please see general directions for us

#### 4.3 Use description

#### Use 3 - Use 1.3 - PT4 Surface disinfection, trigger spraying

## **Product type**

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT04 - Food and feed area (Disinfectants)

not relevant

Scientific name: bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage:

#### Field(s) of use

Indoor

Indoors. Large-scale kitchens, restaurants, food industry:

Disinfection of small hard/non-porous surfaces by trigger spraying with prior cleaning.

## Application method(s)

Method: Trigger Spraying Detailed description:

By trigger spraying: after trigger spraying & required contact time achieved, the product may be wiped off with a tissue or cloth.

#### Application rate(s) and frequencies

Application Rate: 30 ml / m2

Dilution (%): 0%

Number and timing of application:

· Active against bacteria & yeasts : Ready-to-use

At room temperature

With 5 min contact time Application rate: 30 ml / m2

Frequency: daily

## Category(ies) of users

Industrial

Professional

#### Pack sizes and packaging material

1 L flasks with separate trigger spraying device (HDPE) 5, 10, 22, 25 L refill cans (HDPE)

## 4.3.1 Use-specific instructions for use

4.3.1 Use-specific instructions for use
Please see general instructions for use.
4.3.2 Use-specific risk mitigation measures
The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).
Unspecified rooms: max 1 application per day RPE 4 required during application unprotected bystanders should not be present during application
Kitchen and canteens: RPE 4 required during mixing and loading.
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  Please see general directions for use.
4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
Please see general directions for use.
1.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage
Please see general directions for use.

# 4.4 Use description

# **Use 4 - Use 1.4 - PT4 Surface disinfection, low-pressure spraying**

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	not relevant
Target organism(s) (including development stage)	Scientific name: bacteria Common name: Bacteria Development stage:  Scientific name: Yeasts Common name: Yeasts Development stage:
Field(s) of use	Indoor
Field(s) of use	Indoors- In large-scale kitchens, restaurants, food industry: Disinfection of hard/non-porous surfaces by low-pressure spraying, with prior cleaning
Application method(s)	Method: Low-pressure spraying Detailed description: Low-pressure spraying: after low-pressure spraying, the product is left to dry but not wiped off.
Application rate(s) and frequencies	Application Rate: 200 ml / m2 Dilution (%): 0% Number and timing of application:
	Active against bacteria & yeasts : Ready-to-use
	At room temperature
	With 5 min contact time Application rate: 200 ml / m² Frequency: daily
Category(ies) of users	Industrial
Pack sizes and packaging material	5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE) 1000 L IBCs (HDPE)

4.4.1 Use-specific instructions for use	
Please see general instructions for use.	
4.4.2 Use-specific risk mitigation measures	
The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures that and organisational protection measures shall permanent measures).	
Unspecified rooms:  1 application per day for a maximum of 8 m <sup>2</sup> RPE 20 required during application  unprotected bystanders should not be present during application	
Institutional kitchens and canteens:	
1 application per day for a maximum of 10 m <sup>2</sup> RPE 4 required during application unprotected bystanders should not be present during application	
Industrial kitchens: 1 application per day for a maximum of 10 m²	
Industrial production rooms: 1 application per day for a maximum of 10 m <sup>2</sup>	
4.4.3 Where specific to the use, the particulars of likely direct or indirect effects, first instructions and emergency measures to protect the environment	aid
Please see general directions for use.	
4.4.4 Where specific to the use, the instructions for safe disposal of the product and packaging	its
Please 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

Please see general directions for use.	

#### 4.5 Use description

#### Use 5 - Use 1.5 - PT4 Object Disinfection by dipping

## **Product type**

PT04 - Food and feed area (Disinfectants)

Where relevant, an exact description of the authorised use

not relevant

Target organism(s) (including development stage)

Scientific name: bacteria Common name: Bacteria Development stage:

Scientific name: Yeasts Common name: Yeasts Development stage:

Field(s) of use

Indoor

Indoors – In large-scale kitchens, restaurants, food industry: Disinfection of hard/non-porous surfaces (objects) by dipping, with prior cleaning

Application method(s)

Method: Dipping Detailed description:

Disinfection of instruments or equipment by means of dipping (entering objects in a prefilled bath) or filling (filling an empty bath, which already contains the objects). In both cases, objects are completely immersed.

Application rate(s) and frequencies

Application Rate: 25 litres

Dilution (%): 0%

Number and timing of application:

• Active against bacteria & yeasts : Ready-to-use

At room temperature

With 5 min contact time

Frequency: daily

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE) 1000 L IBCs (HDPE)
4.5.1 Use-specific instruction	ns for use
Please see general instructions for use.	
4.5.2 Use-specific risk mitiga	tion measures
Please see general directions for use.	
	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
Please see general directions for use.	
4.5.4 Where specific to the us packaging	se, the instructions for safe disposal of the product and its
Please see general directions for use.	

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

Please see general directions for use.

#### 5. General directions for use of the meta SPC

#### 5.1. Instructions for use

#### - Disinfection procedures by spraying, wiping or dipping:

All the surfaces to be disinfected should be cleaned/rinsed/dried before the disinfection procedure: the user should thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected.

#### - Disinfection cycle:

All the products must be used UNDILUTED.

Please refer to the description of application method related to each use to duly know the required CONTACT TIME and if a FINAL RINSE (with potable water) after disinfection is required.

- <u>- For the disinfection procedures by trigger spraying</u>: Make sure to wet the surfaces completely, allow to take effect for the specified contact time.
- <u>Disinfection procedures</u> **by dipping**: The bath is not intended to be re-used. Use the bath only once a day after work & replace it by a fresh solution daily.

#### 5.2. Risk mitigation measures

Use in well ventilated areas.

Provide adequate ventilation before entering treated rooms.

Not for use in areas accessible for the general public.

Disinfection by trigger spraying:

Wear protective chemical resistant gloves during product handling phase.

The use of eye protection (safety goggles) during handling of the product is mandatory.

Wear a face shield during product handling phase.

Disinfection by low pressure spraying:

Wear protective chemical resistant gloves during product handling phase.

The use of eye protection (full face mask) during handling of the product is mandatory.

A protective coverall which is impermeable for the biocidal product shall be worn.

Disinfection by dipping:

Wear protective chemical resistant gloves during product handling phase.

The use of eye protection (safety goggles) during handling of the product is mandatory.

Wear a face shield during product handling phase.

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

First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing

difficulty persists.

F 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: Immediately rinse with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Most important symptoms and effects, both acute and delayed

Symptoms/injuries: Irritation of the respiratory tract and the other mucous membranes. Risk of serious damage to eyes. Vapours may cause drowsiness and dizziness.

Indication of any immediate medical attention and special treatment needed: Prompt action is critical.

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters

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

Avoid release to the environment. Dispose in a safe manner in accordance with local/national regulations.

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

Technical measures:

Proper grounding procedures to avoid static electricity should be followed.

Storage conditions:

Keep only in the original container in a cool, well ventilated place.

Avoid high temperatures.

Protect from direct sunlight.

Protect from frost.

Incompatible products: Strong acids. Strong bases.

Shelf-life: 2 years

#### 6. Other information

The product contains Propan-2-ol, for which an AEC inhalation for the professional user was agreed and used for the risk assessment of the product.

Bilag 1.1 (Meta-SPC 1) Oplysninger til etiket og brugsanvisning for Christeyns' Propan-1/2-ol BPF, BPR-reg. nr. 944-1-1-x I. Etiketten skal udformes i overensstemmelse med det godkendte resumé af det biocidholdige produkts egenskaber, jf. artikel 69, stk. 1, i biocidforordningen (Forordning (EU) nr. 528/2012), og CLP-Forordningen.

II. Det er udelukkende ansøgers/godkendelsesindehaverens ansvar, at etiket, mærkning og pakning lever op til lovens krav, jf. biocidforordningen artikel 69. Etiket og mærkning skal være på dansk.

Nedstående tekst i afsnit III er bidrag til overholdelsen af reglerne og således kun en del af de krav, som stilles til blandt andet etiketten.

III. Etiketten skal indeholde nedenstående oplysninger. Op-lys-ninger i citationstegn skal angives ordret:

#### 1) I hovedfeltet:

"Desinfektionsmiddel

Må kun anvendes som desinfektionsmiddel til bekæmpelse af bakterier og gær på overflader samt ved dypning af objekter. Kun til erhvervsmæssig brug."

#### 2) I advarselsfeltet:

"FARE

Forårsager alvorlig øjenskade (H318).

Kan forårsage sløvhed eller svimmelhed (H336).

Brandfarlig væske og damp (H226).

Gentagen kontakt kan give tør eller revnet hud.

Undgå indånding af damp/spray.

Brug kun udendørs eller i et rum med god udluftning.

Vask huden grundigt efter brug

Bær øjenbeskyttelse, ansigtsbeskyttelse og kemisk resistente beskyttelseshandsker ved brug af produktet." Handskematerialet og udformning af øjen- og ansigtsbeskyttelse skal angives af godkendelsesindehaveren i produktdatabladet.

"Ved lavtrykssprøjtning skal bæres en beskyttende heldragt som er uigennemtrængelig for det biocidholdige produkt" Heldragtens materiale skal specificeres af indehaveren af godkendelsen i produktinformationen.

"Det er obligatorisk at bruge åndedrætsværn ved brug af produktet i uspecificerede rum, cleanrooms, laboratorier, bioteknologiske faciliteter, farmaceutiske og kosmetiske produktionsfaciliteter og i institutionskøkkener og –kantiner." Beskyttelsesfaktoren skal angives af godkendelsesindehaveren i produktdatabladet).

"Udluft behandlede områder grundigt, inden de tages i brug igen.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes som desinfektionsmiddel til bekæmpelse af bakterier og gær på overflader samt ved dypning af objekter. Kun til erhvervsmæssig brug.

Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.

Holdes væk fra gnister, åben ild og varme overflader. Rygning forbudt.

Må kun anvendes i områder, der er utilgængelige for offentligheden.

Ubeskyttede personer og dyr skal holdes væk fra de behandlede områder under anvendelsen.

Produktet må kun anvendes en gang om dagen.

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Levnedsmidler og foderstoffer må ikke forurenes.

Ved lavtrykssprøjtning må produktet kun anvendes på et område på maksimalt 8  $m^2$  i uspecificerede rum og maksimalt 10  $m^2$  i cleanrooms, laboratorier, bioteknologiske faciliteter, farmaceutiske og kosmetiske produktionsfaciliteter, institutionskøkkener og -kantiner, industrielle køkkener og produktionsrum."

Farepiktogrammerne GHS02, GHS05, og GHS07.

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp, herunder:

VED INDÅNDING: Flyt personen til et sted med frisk luft og sørg for, at vejrtrækningen lettes.

VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let.

Fortsæt skylning.

Ring omgående til en GIFTINFORMATION/læge.

- 3) I deklarationsfeltet:
- a) Teksten "Desinfektionsmiddel, BPR-reg. nr. 944-1-1-x. Aktivstoffer og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)". b) Oplysning om præparattype: "væske" for dette præparat.
- c) Indholdet af aktivstoffer i vægtprocent (% w/w) og g/L ved 20 °C.
- d) Udløbsdatoen skal anføres. Denne dato må højst være to år efter produktionsdatoen. Etikettens dato kan udformes som en hen-visning til en produktionsdato andetsteds på emballagen.
- e) Batchnummer eller betegnelse skal anføres.
- f) Pakningsstørrelse i L
- g) Godkendelsesindehavers navn og adresse.
- 4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Det skal fremgå at produktet kun må anvendes på rene overflader

Følgende retningslinjer gælder i forhold til bortskaffelse.

Der skal mærkes med sikkerhedssætning P501: "Rester og emballage bortskaffes som farligt affald."

Følgende sætning skal anføres under sikkerhedssætning P501: "Ovenstående sætning er Miljøstyrelsens vejledning om affaldshåndtering af dette produkt. Følg altid kommunens affaldsregulativ og forhør dig hos kommunen, hvis du er i tvivl."

#### 7. Third information level: individual products in the meta SPC

## 7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	MIDA SAN 335 RV Market area: DK	
	Form 335	Market area: DK
Authorisation number	DK-0027648-0001 1-1	
(R4BP 3 asset reference number - National Authorisation)	51. 352. 3 . 3 3552 2 2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	24,54

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	9,77

# 1. Meta SPC administrative information

## 1.1. Meta SPC identifier

Meta SPC 2: Mida San 334 MF

#### 1.2. Suffix to the authorisation number

1-2

## 1.3 Product type(s)

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

PT04 - Food and feed area (Disinfectants)

# 2. Meta SPC composition

# 2.1.Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	34,35 - 34,35
Propan-2-ol		Active Substance	67-63-0	200-661-7	13,68 - 13,68

#### 2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

## 3. Hazard and precautionary statements of the meta SPC

#### **Hazard statements**

Flammable liquid and vapour.

Causes serious eye damage.

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.

Avoid breathing vapours.

Wear eye protection.

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

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

Immediately call a POISON CENTER or doctor/physician.

Store in a well-ventilated place. Keep container tightly closed.

Dispose of contents to in accordance with local/regional/national/international regulations..

Dispose of container to in accordance with local/regional/national/international regulations..

Use only outdoors or in a well-ventilated area.

# 4. Authorised use(s) of the meta SPC

#### 4.1 Use description

Use 1 - Use 2.1 - PT2 Surface disinfection, trigger 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: bacteria Common name: Bacteria Development stage: Adults

Scientific name: Yeasts Common name: Yeasts Development stage: Adults

Field(s) of use

Indoor

 $Indoors-In\ Non-food\ industries,\ institutions,\ workplaces,\ ...:$  Disinfection of small hard/non-porous surfaces by trigger spraying, with prior cleaning

Application method(s)

Method: Trigger Spraying Detailed description:

By trigger spraying : after trigger spraying & required contact time achieved, the product may be wiped off with a tissue or cloth.

Application rate(s) and frequencies

Application Rate: 30 ml / m2

Dilution (%): 0%

Number and timing of application:

Active against bacteria & yeasts:

Ready-to-use

At Room Temperature With 5 min contact time Application rate: 30 ml / m<sup>2</sup>

Frequency: daily

Category(ies) of users

Industrial

Professional

Pack sizes and packaging material

1 L flasks with separate trigger spraying device (HDPE)

5, 10, 22, 25 L refill cans (HDPE)

4.1.1 Use-specific instructions for use
Please see general instructions for use.
4.1.2 Use-specific risk mitigation measures
The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).  Unspecified rooms: max 1 application per day RPE 4 required during application unprotected bystanders should not be present during application  Pharmaceutical and cosmetics manufacturing facilities: RPE 4 required during mixing and loading.
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
Please see general directions for use.
4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
Please 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
Please see general directions for use.

# 4.2 Use description

Use 2 - Use 2.2 - PT2 Surface disinfection, low-pressure 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: bacteria Common name: Bacteria Development stage: Adults

Scientific name: Yeasts Common name: Yeasts Development stage: Adults

#### Field(s) of use

Indoor

Indoors – In Non-food industries (e.g. pharmaceutical) : Disinfection of hard/non-porous surfaces by low-pressure spraying, with prior cleaning.

#### Application method(s)

Method: Low-pressure spraying Detailed description:

By Low-pressure spraying : after low-pressure spraying, the product is left to dry but not wiped off.

# Application rate(s) and frequencies

Application Rate: 200 ml / m2

Dilution (%): 0%

Number and timing of application:

Active against bacteria & yeasts:

Ready-to-use

At room temperature

With 5 min contact time Application rate: 200 ml / m<sup>2</sup>

Frequency: daily

#### Category(ies) of users

Industrial

# Pack sizes and packaging material

5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE) 1000 L IBCs (HDPE)

.2.1 Use-specific instruction	is for use
Please see general instructions for use.	
.2.2 Use-specific risk mitiga	tion measures
	s shall be applied unless they can be replaced by technical and/or organisational lal protection measures have to be considered by preference (personal protection isures).
Unspecified rooms: 1 application per day for a maximum of 8 RPE 20 required during application. Unprotected bystanders should not be pro	
Cleanrooms: 1 application per day for a maximum of 10 RPE 4 and a ventilation rate of 20/h requi unprotected bystanders should not be pre	ired during application
Laboratories and biotechnology: 1 application per day for a maximum of 10 RPE 10 required during application unprotected bystanders should not be pre	
Pharmaceutical and cosmetics manufa 1 application per day for a maximum of 10 RPE 4 required during application unprotected bystanders should not be pre	0 m <sup>2</sup>
<u>-</u>	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
Please see general directions for use.	
.2.4 Where specific to the us ackaging	se, the instructions for safe disposal of the product and its
Please 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

Please see general directions for use.		

#### 4.3 Use description

#### Use 3 - Use 2.3 - PT4 Surface disinfection, trigger spraying

Prod	luct	type	
		., ,	

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT04 - Food and feed area (Disinfectants)

not relevant

Scientific name: bacteria Common name: Bacteria Development stage: Adults

Scientific name: Yeasts Common name: Yeasts Development stage: Adults

Field(s) of use

Indoor

Indoors – In large-scale kitchens, restaurants, food industry:

Disinfection of small hard/non-porous surfaces by trigger spraying, with prior cleaning

Application method(s)

Method: Trigger Spraying Detailed description:

By trigger spraying: after trigger spraying & required contact time achieved, the product may be wiped off with a tissue or cloth.

Application rate(s) and frequencies

Application Rate: 30 ml / m2

Dilution (%): 0%

Number and timing of application:

Active against bacteria & yeasts:

Ready-to-use

At room temperature With 5 min contact time

Application rate: 30 ml / m<sup>2</sup>

Frequency: daily

Category(ies) of users

Industrial

Professional

Pack sizes and packaging material	1 L flasks with separate trigger spraying device (HDPE) 5, 10, 22, 25 L refill cans (HDPE)	
4.3.1 Use-specific instruction	ns for use	
Please see general instructions for use		
4.3.2 Use-specific risk mitigation measures		
	nall be applied unless they can be replaced by technical and/or organisational measures: neasures have to be considered by preference (personal protection measures shall not be	
Unspecified rooms: max 1 application per day RPE 4 required during application unprotected bystanders should not be present during application		
Kitchen and canteens:		
RPE 4 required during mixing and loading.		
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		
Please see general directions for use		
4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging		
Please 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

Please see general directions for use		

#### 4.4 Use description

#### Use 4 - Use 2.4 - PT4 Surface disinfection, low-pressure spraying

not relevant

<b>Product</b>	type
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Where relevant, an exact description of the authorised

PT04 - Food and feed area (Disinfectants)

Target organism(s) (including development stage)

Scientific name: bacteria Common name: Bacteria Development stage: Adults

Scientific name: Yeasts Common name: Yeasts Development stage: Adults

Field(s) of use

Indoor

Indoors – In large-scale kitchens, restaurants, food industry: Disinfection of hard/non-porous surfaces by low-pressure spraying, with prior cleaning

Application method(s)

Method: Low-pressure spraying

Detailed description:

By Low-pressure spraying : after low-pressure spraying, the product is left to dry but not wiped off.

Application rate(s) and frequencies

Application Rate: 200 ml / m2

Dilution (%): 0%

Number and timing of application:

Active against bacteria & yeasts: Ready-to-use At room temperature With 5 min contact time Application rate: 200 ml / m<sup>2</sup>

Frequency: daily

# Category(ies) of users Pack sizes and packaging material 5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE) 1000 L IBCs (HDPE)

#### 4.4.1 Use-specific instructions for use

Please see general instructions for use.

## 4.4.2 Use-specific risk mitigation measures

The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).

#### **Unspecified rooms:**

1 application per day for a maximum of 8 m<sup>2</sup> RPE 20 required during application unprotected bystanders should not be present during application

#### Institutional kitchens and canteens:

1 application per day for a maximum of 10 m<sup>2</sup> RPE 4 required during application unprotected bystanders should not be present during application

#### Industrial kitchens:

1 application per day for a maximum of 10 m<sup>2</sup>

#### Industrial production rooms:

1 application per day for a maximum of 10 m<sup>2</sup>

# 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

Please see general directions for use.

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

Please 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

Please see general directions for use.

## 4.5 Use description

#### Use 5 - Use 2.5 - PT4 Object Disinfection by dipping

Product	type
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PT04 - Food and feed area (Disinfectants)

Where relevant, an exact description of the authorised use

not relevant

Target organism(s) (including development stage)

Scientific name: bacteria Common name: Bacteria Development stage: Adults

Scientific name: Yeasts Common name: Yeasts Development stage: Adults

Field(s) of use

Indoor

Indoors – In large-scale kitchens, restaurants, food industry:

Disinfection of hard/non-porous surfaces (objects) by dipping, with prior cleaning

Application method(s)

Method: Dipping
Detailed description:

Disinfection of instruments or equipment by means of dipping (entering objects in a pre-

filled bath) or filling (filling an empty bath, which already contains the objects). In both

cases, objects are completely immersed.

Application rate(s) and frequencies	Application Rate: 25 litres Dilution (%): 0% Number and timing of application: Active against bacteria & yeasts: Ready-to-use At room temperature With 5 min contact time  Frequency: daily	
Category(ies) of users	Industrial Professional	
Pack sizes and packaging material	5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE) 1000 L IBCs (HDPE)	
4.5.1 Use-specific instructions for use		
Please see general instructions for use.		
4.5.2 Use-specific risk mitigation measures		
Please see general directions for use.		
4.5.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment		
Please see general directions for use.		
4.5.4 Where specific to the use, the instructions for safe disposal of the product and its		

packaging

Please see general directions for use.

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

Please see general directions for use.

#### 5. General directions for use of the meta SPC

#### 5.1. Instructions for use

#### - Disinfection procedures by spraying, wiping or dipping :

All the surfaces to be disinfected should be cleaned/rinsed/dried before the disinfection procedure: the user should thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected.

#### - Disinfection cycle:

All the products must be used UNDILUTED.

Please refer to the description of application method related to each use to duly know the required CONTACT TIME and if a FINAL RINSE (with potable water) after disinfection is required.

- <u>- For the disinfection procedures by trigger spraying</u>: Make sure to wet the surfaces completely, allow to take effect for the specified contact time.
- <u>- Disinfection procedures</u> <u>by dipping</u>: The bath is not intended to be re-used. Use the bath only once a day after work & replace it by a fresh solution daily.

#### 5.2. Risk mitigation measures

Use in well ventilated areas.

Provide adequate ventilation before entering treated rooms.

Not for use in areas accessible for the general public.

Disinfection by trigger spraying:

Wear protective chemical resistant gloves during product handling phase.

The use of eye protection (safety goggles) during handling of the product is mandatory.

Wear a face shield during product handling phase.

Disinfection by low pressure spraying:

Wear protective chemical resistant gloves during product handling phase.

The use of eye protection (full face mask) during handling of the product is mandatory.

A protective coverall which is impermeable for the biocidal product shall be worn.

Disinfection by dipping:

Wear protective chemical resistant gloves during product handling phase.

The use of eye protection (safety goggles) during handling of the product is mandatory.

Wear a face shield during product handling phase.

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

First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

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: Immediately rinse with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Most important symptoms and effects, both acute and delayed

Symptoms/injuries: Irritation of the respiratory tract and the other mucous membranes. Risk of serious damage to eyes. Vapours may cause drowsiness and dizziness.

Indication of any immediate medical attention and special treatment needed: Prompt action is critical.

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

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

Avoid release to the environment. Dispose in a safe manner in accordance with local/national regulations.

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

Technical measures:

Proper grounding procedures to avoid static electricity should be followed.

Storage conditions:

Keep only in the original container in a cool, well ventilated place.

Avoid high temperatures.

Protect from direct sunlight.

Protect from frost.

Incompatible products: Strong acids. Strong bases.

Shelf-life: 2 years

#### 6. Other information

The product contains Propan-2-ol, for which an AEC inhalation for the professional user was agreed and used for the risk assessment of the product.

Bilag 1.2 (Meta-SPC 2)

Oplysninger til etiket og brugsanvisning for Christeyns' Propan-1/2-ol BPF, BPR-reg. nr. 944-1-2-x

I. Etiketten skal udformes i overensstemmelse med det godkendte resumé af det biocidholdige produkts egenskaber, jf. artikel 69, stk. 1, i biocidforordningen (Forordning (EU) nr. 528/2012), og CLP-Forordningen.

II. Det er udelukkende ansøgers/godkendelsesindehaverens ansvar, at etiket, mærkning og pakning lever op til lovens krav, jf. biocidforordningen artikel 69. Etiket og mærkning skal være på dansk.

Nedstående tekst i afsnit III er bidrag til overholdelsen af reglerne og således kun en del af de krav, som stilles til blandt andet etiketten.

III. Etiketten skal indeholde nedenstående oplysninger. Op-lys-ninger i citationstegn skal angives ordret:

#### 1) I hovedfeltet:

"Desinfektionsmiddel

Må kun anvendes som desinfektionsmiddel til bekæmpelse af bakterier og gær på overflader samt ved dypning af objekter. Kun til erhvervsmæssig brug."

#### 2) I advarselsfeltet:

"FARE

Forårsager alvorlig øjenskade (H318).

Kan forårsage sløvhed eller svimmelhed (H336).

Brandfarlig væske og damp (H226).

Gentagen kontakt kan give tør eller revnet hud.

Undgå indånding af damp/spray.

Brug kun udendørs eller i et rum med god udluftning.

Vask huden grundigt efter brug.

Bær øjenbeskyttelse, ansigtsbeskyttelse og kemisk resistente beskyttelseshandsker ved brug af produktet."

Handskematerialet og udformning af øjen- og ansigtsbeskyttelse skal angives af godkendelsesindehaveren i produktdatabladet.

"Ved lavtrykssprøjtning skal bæres en beskyttende heldragt som er uigennemtrængelig for det biocidholdige produkt"

Heldragtens materiale skal specificeres af indehaveren af godkendelsen i produktinformationen.

"Det er obligatorisk at bruge åndedrætsværn ved brug af produktet i uspecificerede rum, cleanrooms, laboratorier, bioteknologiske faciliteter, farmaceutiske og kosmetiske produktionsfaciliteter og i institutionskøkkener og –kantiner."

Beskyttelsesfaktoren skal angives af godkendelsesindehaveren i produktdatabladet.

"Udluft behandlede områder grundigt, inden de tages i brug igen.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes som desinfektionsmiddel til bekæmpelse af bakterier og gær på overflader samt ved dypning af objekter. Kun til erhvervsmæssig brug.

Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.

Holdes væk fra gnister, åben ild og varme overflader. Rygning forbudt.

Må kun anvendes i områder, der er utilgængelige for offentligheden.

Ubeskyttede personer og dyr skal holdes væk fra de behandlede områder under anvendelsen.

Produktet må kun anvendes en gang om dagen.

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Levnedsmidler og foderstoffer må ikke forurenes.

Ved lavtrykssprøjtning må produktet kun anvendes på et område på maksimalt 8 m² i uspecificerede rum og maksimalt 10 m² i cleanrooms, laboratorier, bioteknologiske faciliteter, farmaceutiske og kosmetiske produktionsfaciliteter,

#### institutionskøkkener og -kantiner, industrielle køkkener og produktionsrum,

Farepiktogrammerne GHS02, GHS05, og GHS07.

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp, herunder: VED INDÅNDING: Flyt personen til et sted med frisk luft og sørg for, at vejrtrækningen lettes.

VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning.

Ring omgående til en GIFTINFORMATION/læge.

- 3) I deklarationsfeltet:
- a) Teksten "Desinfektionsmiddel, BPR-reg. nr. 944-1-2-x.. Aktivstoffer og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)". b) Oplysning om præparattype: "væske" for dette præparat.
- c) Indholdet af aktivstoffer i vægtprocent (% w/w) og g/L ved 20 °C.
- d) Udløbsdatoen skal anføres. Denne dato må højst være to år efter produktionsdatoen. Etikettens dato kan udformes som en hen-visning til en produktionsdato andetsteds på emballagen.
- e) Batchnummer eller betegnelse skal anføres.
- f) Pakningsstørrelse i L
- g) Godkendelsesindehavers navn og adresse.
- 4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Det skal fremgå at produktet kun må anvendes på rene overflader

Følgende retningslinjer gælder i forhold til bortskaffelse.

Der skal mærkes med sikkerhedssætning P501: "Rester og emballage bortskaffes som farligt affald."

Følgende sætning skal anføres under sikkerhedssætning P501: "Ovenstående sætning er Miljøstyrelsens vejledning om affaldshåndtering af dette produkt. Følg altid kommunens affaldsregulativ og forhør dig hos kommunen, hvis du er i tvivl."

## 7. Third information level: individual products in the meta SPC

## 7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	MIDA SAN 334 MF	Market area: DK
	Form 334	Market area: DK
Authorisation number  (RABP 3 asset reference number - National Authorisation)	DK-0027648-0002 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	34,35
Propan-2-ol		Active Substance	67-63-0	200-661-7	13,68

## 1. Meta SPC administrative information

#### 1.1. Meta SPC identifier

Meta SPC 3: Mida San 311 KZ

#### 1.2. Suffix to the authorisation number

1-3

## 1.3 Product type(s)

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

PT04 - Food and feed area (Disinfectants)

## 2. Meta SPC composition

## 2.1.Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	49,07 - 49,07
Propan-2-ol		Active Substance	67-63-0	200-661-7	19,54 - 19,54

## 2.2. Type(s) of formulation of the meta SPC

#### Formulation(s)

AL - Any other liquid

## 3. Hazard and precautionary statements of the meta SPC

#### **Hazard statements**

Flammable liquid and vapour.

Causes serious eye damage.

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.

Avoid breathing vapours.

Wear eye protection.

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

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

Immediately call a POISON CENTER or doctor/physician.

Store in a well-ventilated place. Keep container tightly closed.

Dispose of contents to in accordance with local/regional/national/international regulations..

Dispose of container to in accordance with local/regional/national/international regulations..

Use only outdoors or in a well-ventilated area.

## 4. Authorised use(s) of the meta SPC

#### 4.1 Use description

#### Use 1 - Use 3.1 - PT2 Surface disinfection, trigger 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: bacteria Common name: Bacteria Development stage:

Scientific name: Yeasts Common name: Yeasts Development stage:

Scientific name: Fungi Common name: Fungi Development stage:

Scientific name: Mycobacteriaceae Common name: Mycobacteria Development stage:

Scientific name: Viruses Common name: Adenovirus Type 5, Murine Norovirus Development stage:

## Field(s) of use

Indoor

Indoors - In Non-food industries, institutions & workplaces:

Disinfection of small hard/non-porous surfaces by trigger spraying, with prior cleaning

## Application method(s)

Method: Trigger Spraying Detailed description:

By trigger spraying: after trigger spraying & required contact time achieved, the product may be wiped off with a tissue or cloth.

#### Application rate(s) and frequencies

Application Rate: 30 ml / m2

Dilution (%): 0%

Number and timing of application:

Ready-to-use At room temperature application rate: 30 ml/m<sup>2</sup>

Active against bacteria, mycobacteria & yeasts: 5 min contact time

Active against bacteria, fungi/yeasts, mycobacteria & viruses: 20 min contact time

#### Category(ies) of users

Industrial

Professional

Pack sizes	and	packaging
material		

750 mL flasks with separate trigger spraying device (HDPE)

1 L flasks with separate trigger spraying device (HDPE) 5, 10, 22, 25 L refill cans (HDPE)

## 4.1.1 Use-specific instructions for use

Please see general instructions for use.

### 4.1.2 Use-specific risk mitigation measures

The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).

Unspecified rooms:

max 1 application per day

RPE 4 required during application

unprotected bystanders should not be present during application

Pharmaceutical and cosmetics manufacturing facilities:

RPE 4 required during mixing and loading.

# 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

Please see general directions for use.

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

Please 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

Please see	general	directions	for	use
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### 4.2 Use description

### Use 2 - Use 3.2 - PT2 Surface disinfection, low-pressure 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: bacteria Common name: Bacteria Development stage:

Scientific name: Yeasts Common name: Yeasts Development stage:

Scientific name: Mycobacteriaceae Common name: Mycobacteria Development stage:

Scientific name: Viruses Common name: Adenovirus type 5, Murine Norovirus Development stage:

Scientific name: Fungi Common name: Fungi Development stage:

#### Field(s) of use

Indoor

Indoors – In Non-food industries (e.g. pharmaceutical) :

Disinfection of hard/non-porous surfaces by by low-pressure spraying, with prior

### Application method(s)

Method: Low-pressure spraying

Detailed description:

By Low-pressure spraying : after low-pressure spraying, the product is left to dry but not

wiped off.

#### Application rate(s) and frequencies

Application Rate: 200 ml/m2

	Dilution (%): 0% Number and timing of application:		
	Ready-to-use		
	At room temperature		
	Application rate: 200 ml/m <sup>2</sup>		
	Active against bacteria, mycobacteria & yeasts: 5 min contact time		
	Active against bacteria, fungi/yeasts, mycobacteria & viruses: 20 min contact time		
Category(ies) of users	Industrial		
category (ics) or ascrs			
Pack sizes and packaging			
material	5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE) 1000 L IBCs (HDPE)		
	1000 2 1000 (1.0.1.2)		
4.2.1 Use-specific instruction	ns for use		
Please see general instructions for use			
4.2.2 Use-specific risk mitiga	ation measures		
The following risk mitigation measure	es shall be applied upless they can be replaced by technical and/or organisational		
The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).			
Unspecified rooms:  1 application per day for a maximum of 8 m <sup>2</sup>			
RPE 20 required during application. Unprotected bystanders should not be present during application			
Originate de discussión de la present during application			

Cleanrooms:

1 application per day for a maximum of 10 m<sup>2</sup>

RPE 4 and a ventilation rate of 20/h required during application

RPE 10 required during application unprotected bystanders should not be properties and cosmetics manufal application per day for a maximum of 1 RPE 4 required during application unprotected bystanders should not be pro-	acturing facilities: 0 m <sup>2</sup>
-	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
Please see general directions for use.	
4.2.4 Where specific to the uspackaging	se, the instructions for safe disposal of the product and its
Please see general directions for use.	
4.2.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage
I loade see general all sellene let ace.	
4.3 Use description	
	isinfection, trigger spraying
4.3 Use description	isinfection, trigger spraying PT04 - Food and feed area (Disinfectants)
4.3 Use description Use 3 - Use 3.3 – PT4 Surface d	
4.3 Use description  Use 3 - Use 3.3 - PT4 Surface di  Product type  Where relevant, an exact description of the authorised	PT04 - Food and feed area (Disinfectants)

Scientific name: Fungi Common name: Fungi Development stage:

Scientific name: Mycobacteriaceae Common name: Mycobacteria Development stage:

Scientific name: Viruses Common name: Adenovirus Type 5, Murine Norovirus Development stage:

#### Field(s) of use

Indoor

Indoors - In large-scale kitchens, restaurants, food industry: Disinfection of small hard/non-porous surfaces by trigger spraying, with prior cleaning

## Application method(s)

Method: Trigger Spraying Detailed description:

By trigger spraying : after trigger spraying & required contact time achieved, the product may be wiped off with a tissue or cloth.

### Application rate(s) and frequencies

Application Rate: 30 ml / m2

Dilution (%): 0%

Number and timing of application:

The product is ready-to-use. At room temperature Application rate: 30 ml / m2

- Active against bacteria, mycobacteria & yeasts : 5 min contact time
- active against bacteria, fungi/yeasts, mycobacteria & viruses: 20 min contact time

#### Category(ies) of users

Industrial

Professional

#### Pack sizes and packaging material

750 mL flasks with separate trigger spraying device (HDPE) 1 L flasks with separate trigger spraying device (HDPE) 5, 10, 22, 25 L refill cans (HDPE)

4.3.1 Use-specific instructions for use
Please see general instructions for use.
4.3.2 Use-specific risk mitigation measures
The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).
Unspecified rooms: max 1 application per day RPE 4 required during application unprotected bystanders should not be present during application
Kitchen and canteens: RPE 4 and gloves (APF 10) required during mixing and loading.
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
Please see general directions for use.
4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
Please 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
Please see general directions for use.

4.4 Use description

Use 4 - Use 3.4 - PT4 Surface disinfection, low-pressure spraying

## PT04 - Food and feed area (Disinfectants) **Product type** Where relevant, an exact description of the authorised use not relevant Scientific name: bacteria Common name: Bacteria Target organism(s) (including development stage) Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Mycobacteriaceae Common name: Mycobacteria Development stage: Scientific name: Viruses Common name: Adenovirus type 5, Murine Norovirus Development stage: Scientific name: Fungi Common name: Fungi Development stage: Indoor Field(s) of use Indoors – In large-scale kitchens, restaurants, food industry: Disinfection of hard/non-porous surfaces by low-pressure spraying, with prior cleaning Method: Low-pressure spraying Application method(s) Detailed description: By Low-pressure spraying: after low-pressure spraying, the product is left to dry but not wiped off. Application Rate: 200 ml/m2 Application rate(s) and Dilution (%): 0% frequencies Number and timing of application: Ready-to-use at room temperature Application rate: 200 ml/m<sup>2</sup> Active against bacteria, mycobacteria & yeasts: 5 min contact time Active against bacteria, fungi/yeasts, mycobacteria & viruses: 20 min contact time

Industrial

Category(ies) of users

Pack	sizes	and	packaging
matei	rial		

5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE) 1000 L IBCs (HDPE)

## 4.4.1 Use-specific instructions for use

Please see general instructions for use.

### 4.4.2 Use-specific risk mitigation measures

The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).

## Unspecified rooms:

1 application per day for a maximum of 8 m<sup>2</sup> RPE 20 required during application unprotected bystanders should not be present during application

#### Institutional kitchens and canteens:

1 application per day for a maximum of 10 m<sup>2</sup> RPE 4 required during application unprotected bystanders should not be present during application

#### Industrial kitchens:

1 application per day for a maximum of 10  $\mbox{m}^2$ 

#### **Industrial production rooms:**

1 application per day for a maximum of 10 m<sup>2</sup>

# 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

Please see general directions for use.		

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

Please 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

Please see general directions for use.

#### 4.5 Use description

#### Use 5 - Use 3.5 - PT2 Object Disinfection by dipping

#### **Product type**

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

## Where relevant, an exact description of the authorised

not relevant

#### Target organism(s) (including development stage)

Scientific name: bacteria Common name: Bacteria Development stage:

Scientific name: yeasts Common name: Yeasts Development stage:

Scientific name: Mycobacteriaceae Common name: Mycobacteria Development stage:

Scientific name: viruses Common name: Adenovirus type 5, Murine Norovirus Development stage:

## Field(s) of use

Indoor

Indoors – In non-food industry:

Disinfection of hard/non-porous surfaces (objects) by dipping, with prior cleaning

#### Application method(s)

Method: Dipping Detailed description:

Disinfection of instruments or equipment by means of dipping (entering objects in a prefilled bath) or filling (filling an empty bath, which already contains the objects). In both cases, objects are completely immersed.

Application rate(s) and frequencies	Application Rate: 25 litres Dilution (%): 0% Number and timing of application:  Ready-to-use At room temperature  • Active against bacteria, mycobacteria & yeasts: 5 min contact time  • Active against bacteria, fungi/yeasts, mycobacteria and viruses: 20 min contact time	
Category(ies) of users	Industrial Professional	
Pack sizes and packaging material	5, 10, 2 2, 25 L cans (HDPE)	
4.5.1 Use-specific instruction	ns for use	
Please see general instructions for use.		
4.5.2 Use-specific risk mitiga	tion measures	
Please see general directions for use.		

<u>-</u>	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
Please see general directions for use.	
4.5.4 Where specific to the u packaging	se, the instructions for safe disposal of the product and its
Please see general directions for use.	
4.5.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product
Please see general directions for use.	
4.6 Use description	
Use 6 - Use 3.6 – PT4 Object Dis	sinfection by dipping
Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	not relevant
Target organism(s) (including development stage)	Scientific name: bacteria Common name: Bacteria Development stage:  Scientific name: Yeasts Common name: Yeasts
	Development stage:  Scientific name: Mycobacteriaceae Common name: Mycobacteria Development stage:
	Scientific name: Viruses Common name: Adenovirus type 5, Murine Norovirus Development stage:

Scientific name: Fungi Common name: Fungi Development stage:

	Field(	(s)	of	use
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Indoor

Disinfection of instruments or equipment by means of dipping (entering objects in a prefilled bath) or filling (filling an empty bath, which already contains the objects). In both cases, objects are completely immersed.

Application method(s)

Method: Dipping Detailed description:

Dipping

## Application rate(s) and frequencies

Application Rate: 25 litres

Dilution (%): 0% Number and timing of application:

Ready-to-use At room temperature

- Active against bacteria, mycobacteria & yeasts : 5 min contact time
- Active against bacteria, fungi/yeasts, mycobacteria and viruses : 20 min contact time

## Category(ies) of users

Industrial

Professional

Pack sizes and packaging material

5, 10, 22, 25 L cans (HDPE)

4.6.1 Ose-specific instructions for use
Please see general intructions for use.
4.6.2 Use-specific risk mitigation measures
Please see general directions for use.
4.6.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
Please see general directions for use.
4.6.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
Please see general directions for use.
4.6.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage
Please see general directions for use.
5. General directions for use of the meta SPC
5.1. Instructions for use
- <u>Disinfection procedures by spraying, wiping or dipping</u> :  All the surfaces to be disinfected should be cleaned/rinsed/dried before the disinfection procedure: the user should thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected.  - <u>Disinfection cycle</u> :

All the products must be used UNDILUTED.

Please refer to the description of application method related to each use to duly know the required CONTACT TIME and if a FINAL RINSE (with potable water) after disinfection is required.

- - For the disinfection procedures by trigger spraying : Make sure to wet the surfaces completely, allow to take effect for the specified contact time.
- <u>Disinfection procedures</u> by dipping: The bath is not intended to be re-used. Use the bath only once a day after work & replace it by a fresh solution daily.

#### 5.2. Risk mitigation measures

Use in well ventilated areas.

Provide adequate ventilation before entering treated rooms.

Not for use in areas accessible for the general public.

Disinfection by trigger spraying:

Wear protective chemical resistant gloves during product handling phase.

The use of eye protection (safety goggles) during handling of the product is mandatory. Wear a face shield during product handling phase.

Disinfection by low pressure spraying:

Wear protective chemical resistant gloves during product handling phase.

The use of eye protection (full face mask) during handling of the product is mandatory.

A protective coverall which is impermeable for the biocidal product shall be worn.

Disinfection by dipping:

Wear protective chemical resistant gloves during product handling phase.

The use of eye protection (safety goggles) during handling of the product is mandatory.

Wear a face shield during product handling phase.

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

First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

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: Immediately rinse with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Most important symptoms and effects, both acute and delayed

Symptoms/injuries: Irritation of the respiratory tract and the other mucous membranes. Risk of serious damage to eyes. Vapours may cause drowsiness and dizziness.

Indication of any immediate medical attention and special treatment needed: Prompt action is critical.

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

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

Avoid release to the environment. Dispose in a safe manner in accordance with local/national regulations.

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

Technical measures:

Proper grounding procedures to avoid static electricity should be followed.

Storage conditions:

Keep only in the original container in a cool, well ventilated place.

Avoid high temperatures.

Protect from direct sunlight.

Protect from frost.

Incompatible products: Strong acids. Strong bases.

Shelf-life: 2 years

#### 6. Other information

The product contains Propan-2-ol, for which an AEC inhalation for the professional user was agreed and used for the risk assessment of the product.

#### Bilag 1.3 (Meta-SPC 3)

Oplysninger til etiket og brugsanvisning for Christeyns' Propan-1/2-ol BPF, BPR-reg. nr. 944-1-3-x

I. Etiketten skal udformes i overensstemmelse med det godkendte resumé af det biocidholdige produkts egenskaber, jf. artikel 69, stk. 1, i biocidforordningen (Forordning (EU) nr. 528/2012), og CLP-Forordningen.

II. Det er udelukkende ansøgers/godkendelsesindehaverens ansvar, at etiket, mærkning og pakning lever op til lovens krav, jf. biocidforordningen artikel 69. Etiket og mærkning skal være på dansk.

Nedstående tekst i afsnit III er bidrag til overholdelsen af reglerne og således kun en del af de krav, som stilles til blandt andet etiketten.

III. Etiketten skal indeholde nedenstående oplysninger. Op-lys-ninger i citationstegn skal angives ordret:

#### 1) I hovedfeltet:

"Desinfektionsmiddel

Må kun anvendes som desinfektionsmiddel til bekæmpelse af bakterier, mykobakterier, gær, svampe og virus på overflader samt ved dypning af objekter. Kun til erhvervsmæssig brug."

2) I advarselsfeltet:

<u>"FARE</u>

Forårsager alvorlig øjenskade (H318).

Kan forårsage sløvhed eller svimmelhed (H336).

Brandfarlig væske og damp (H226).

Gentagen kontakt kan give tør eller revnet hud.

Undgå indånding af damp/spray.

Brug kun udendørs eller i et rum med god udluftning.

Vask huden grundigt efter brug.

Bær øjenbeskyttelse, ansigtsbeskyttelse og kemisk resistente beskyttelseshandsker ved brug af produktet."

Handskematerialet og udformning af øjen- og ansigtsbeskyttelse skal angives af godkendelsesindehaveren i produktdatabladet.

"Ved lavtrykssprøjtning skal bæres en beskyttende heldragt som er uigennemtrængelig for det biocidholdige produkt"

Heldragtens materiale skal specificeres af indehaveren af godkendelsen i produktinformationen.

"Det er obligatorisk at bruge åndedrætsværn ved brug af produktet i uspecificerede rum, cleanrooms, laboratorier, bioteknologiske faciliteter, farmaceutiske og kosmetiske produktionsfaciliteter og i institutionskøkkener og -kantiner."

Beskyttelsesfaktoren skal angives af godkendelsesindehaveren i produktdatabladet).

"Udluft behandlede områder grundigt, inden de tages i brug igen.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes som desinfektionsmiddel til bekæmpelse af bakterier, mykobakterier, gær, svampe og virus på overflader samt ved dypning af objekter. Kun til erhvervsmæssig brug.

Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.

Holdes væk fra gnister, åben ild og varme overflader. Rygning forbudt.

Må kun anvendes i områder, der er utilgængelige for offentligheden.

Ubeskyttede personer og dyr skal holdes væk fra de behandlede områder under anvendelsen.

Produktet må kun anvendes en gang om dagen.

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Levnedsmidler og foderstoffer må ikke forurenes.

Ved lavtrykssprøjtning må produktet kun anvendes på et område på maksimalt 8 m² i uspecificerede rum og maksimalt 10 m² i cleanrooms, laboratorier, bioteknologiske faciliteter, farmaceutiske og kosmetiske produktionsfaciliteter, institutionskøkkener og -kantiner, industrielle køkkener og produktionsrum.'

Farepiktogrammerne GHS02, GHS05, og GHS07,

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp, herunder:

VED INDÅNDING: Flyt personen til et sted med frisk luft og sørg for, at veirtrækningen lettes.

VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning

Ring omgående til en GIFTINFORMATION/læge.

- 3) I deklarationsfeltet:
- a) Teksten "Desinfektionsmiddel, BPR-reg. nr. 944-1-3-x. Aktivstoffer og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)". b) Oplysning om præparattype: "væske" for dette præparat.
- c) Indholdet af aktivstoffer i vægtprocent (% w/w) og g/L ved 20 °C.
- d) Udløbsdatoen skal anføres. Denne dato må højst være to år efter produktionsdatoen. Etikettens dato kan udformes som en hen-visning til en produktionsdato andetsteds på emballagen.
- e) Batchnummer eller betegnelse skal anføres.
- f) Pakningsstørrelse i L
- g) Godkendelsesindehavers navn og adresse.
- 4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Det skal fremgå at produktet kun må anvendes på rene overflader

Følgende retningslinier gælder i forhold til bortskaffelse.

Der skal mærkes med sikkerhedssætning P501: "Rester og emballage bortskaffes som farligt affald."

Følgende sætning skal anføres under sikkerhedssætning P501: "Ovenstående sætning er Miljøstyrelsens vejledning om affaldshåndtering af dette produkt. Følg altid kommunens affaldsregulativ og forhør dig hos kommunen, hvis du er i tvivl."

## 7. Third information level: individual products in the meta SPC

# 7.1 Trade name(s), authorisation number and specific composition of each individual product

## Trade name(s)

Mida San 311 KZ	Market area: DK
Form 311	Market area: DK
DYBACOL LQ	Market area: DK
PROPANOL PLUS	Market area: DK
PROCID-OL	Market area: DK
CID-OL	Market area: DK
ASEPTOL-CID	Market area: DK
Alcoholdes	Market area: DK
Alcoclean	Market area: DK

## **Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

DK-0027648-0003 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	49,07
Propan-2-ol		Active Substance	67-63-0	200-661-7	19,54

#### 1. Meta SPC administrative information

#### 1.1. Meta SPC identifier

Meta SPC 4: Mida San 311 KZ wipes - Saniwipe

#### 1.2. Suffix to the authorisation number

1-4

## 1.3 Product type(s)

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

PT04 - Food and feed area (Disinfectants)

## 2. Meta SPC composition

## 2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	49,07 - 49,07
Propan-2-ol		Active Substance	67-63-0	200-661-7	19,54 - 19,54

## 2.2. Type(s) of formulation of the meta SPC

AL - Any other liquid

## 3. Hazard and precautionary statements of the meta SPC

#### **Hazard statements**

Flammable liquid and vapour.

Causes serious eye damage.

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.

Avoid breathing vapours.

Wear eye protection.

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

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

Immediately call a POISON CENTER or doctor/physician.

Store in a well-ventilated place. Keep container tightly closed.

Dispose of contents to in accordance with local/regional/national/international regulations..

Dispose of container to in accordance with local/regional/national/international regulations..

Use only outdoors or in a well-ventilated area.

## 4. Authorised use(s) of the meta SPC

#### 4.1 Use description

#### Use 1 - Use 4.1 - PT2 Surface disinfection, wet wipes

#### **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: Bacteria Common name: Bacteria Development stage:

Scientific name: Yeasts Common name: Yeasts Development stage:

Scientific name: Fungi Common name: Fungi Development stage:

Scientific name: viruses Common name: Viruses Development stage:

Scientific name: Mycobacteriaceae Common name: Mycobacteria

Development stagé:

#### Field(s) of use

Indoor

 $Indoors-In\ Institutions,\ industry\ \&\ workplaces:$ 

Disinfection of small hard/non-porous surfaces by wiping, with prior cleaning

## Application method(s)

Method: wiping Detailed description:

By wiping with commercial pre-impregnated wipes or with a wipe/cloth dipped in a bucket containing the disinfectant solution.

## Application rate(s) and frequencies

Application Rate: 1 wipe / m2

Dilution (%): 0%

Number and timing of application:

Ready-to-use At room temperature

- · Active against bacteria, mycobacteria & yeasts: 5 min contact time
- Active against bacteria, fungi/yeasts, mycobacteria and viruses : 20 min contact

time

Surface disinfection: 1 wipe / m² Frequency: multiple times per day

#### Category(ies) of users

Industrial

Professional

## Pack sizes and packaging material

150 wipes/pack: opaque white 1L HDPE pack

800 wipes/bucket: opaque white 15L polypropylene bucket 1500 wipes/bucket: opaque white 15L polypropylene bucket

.1.2 Use-specific risk mitigation measures  The following risk mitigation measure shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).  Unspecified rooms: max 1 application per day  1.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid astructions and emergency measures to protect the environment  Please see general directions for use.  1.1.4 Where specific to the use, the instructions for safe disposal of the product and its tackaging		
.1.2 Use-specific risk mitigation measures  The following risk mitigation measure shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).  Unspecified rooms: max 1 application per day  1.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment  Please see general directions for use.  1.4 Where specific to the use, the instructions for safe disposal of the product and its ackaging  Please see general directions for use.		
.1.2 Use-specific risk mitigation measures  The following risk mitigation measure shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).  Unspecified rooms: max 1 application per day  .1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid astructions and emergency measures to protect the environment  Please see general directions for use.  .1.4 Where specific to the use, the instructions for safe disposal of the product and its ackaging  Please see general directions for use.		
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#### 4.2 Use description

### Use 2 - Use 4.2 - PT4 Surface disinfection, wet wipes

#### **Product type**

PT04 - Food and feed area (Disinfectants)

Where relevant, an exact description of the authorised

not relevant

Target organism(s) (including development stage)

Scientific name: Bacteria Common name: Bacteria Development stage:

Scientific name: Yeasts Common name: Yeasts Development stage:

Scientific name: Fungi Common name: Fungi Development stage:

Scientific name: viruses Common name: Viruses Development stage:

Scientific name: Mycobacteriaceae Common name: Mycobacteria Development stage:

#### Field(s) of use

Indoor

Indoors - In Kitchens, restaurants, food industry:

Disinfection of small hard/non-porous surfaces by wiping, with prior cleaning

#### Application method(s)

Method: wiping Detailed description:

By wiping with commercial pre-impregnated wipes or with a wipe/cloth dipped in a bucket containing the disinfectant solution.

## Application rate(s) and frequencies

Application Rate: 1 wipe / m2

Dilution (%): 0%

Number and timing of application:

Ready-to-use At room temperature

- Active against bacteria, mycobacteria & yeasts: 5 min contact time
- Active against bacteria, fungi/yeasts, mycobacteria and viruses: 20 min contact

time

Surface disinfection: 1 wipe / m<sup>2</sup>

Frequency: daily

Category(ies) of users	Industrial				
	Professional				
Pack sizes and packaging material  150 wipes/pack: opaque white 1L HDPE pack 800 wipes/bucket: opaque white 15L polypropylene bucket 1500 wipes/bucket: opaque white 15L polypropylene bucket					
4.2.1 Use-specific instruction	ns for use				
Please see general instructions for use.					
4.2.2 Use-specific risk mitiga	tion measures				
	shall be applied unless they can be replaced by technical and/or organisational hal protection measures have to be considered by preference (personal protection asures).				
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Please see general directions for use.					
4.2.4 Where specific to the uspackaging	se, the instructions for safe disposal of the product and its				

Please 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

Please see general directions for use.

#### 5. General directions for use of the meta SPC

#### 5.1. Instructions for use

• <u>For the disinfection procedures using RTU pre-impregnated wipes</u>: Make sure to wet the surfaces completely, allow to take effect for the specified contact time.

#### 5.2. Risk mitigation measures

Use in well ventilated areas.

 $\label{provide} \mbox{ Provide adequate ventilation before entering treated rooms.}$ 

Not for use in areas accessible for the general public.

Disinfection by RTU wipes: Wear protective chemical resistant gloves during product handling phase.

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

First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

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

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Most important symptoms and effects, both acute and delayed

Symptoms/injuries: Irritation of the respiratory tract and the other mucous membranes. Risk of serious damage to eyes. Vapours may cause drowsiness and dizziness.

Indication of any immediate medical attention and special treatment needed: Prompt action is critical.

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

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

Avoid release to the environment. Dispose in a safe manner in accordance with local/national regulations.

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

Technical measures:

Proper grounding procedures to avoid static electricity should be followed.

Storage conditions:

Keep only in the original container in a cool, well ventilated place.

Avoid high temperatures.

Protect from direct sunlight.

Protect from frost.

Incompatible products: Strong acids. Strong bases.

Shelf-life: 2 years

#### 6. Other information

The product contains Propan-2-ol, for which an AEC inhalation for the professional user was agreed and used for the risk assessment of the product.

#### Bilag 1.4 (Meta-SPC 4)

Oplysninger til etiket og brugsanvisning for Christeyns' Propan-1/2-ol BPF, BPR-reg. nr. 944-1-4-x

I. Etiketten skal udformes i overensstemmelse med det godkendte resumé af det biocidholdige produkts egenskaber, jf. artikel 69, stk. 1, i biocidforordningen (Forordning (EU) nr. 528/2012), og CLP-Forordningen.

II. Det er udelukkende ansøgers/godkendelsesindehaverens ansvar, at etiket, mærkning og pakning lever op til lovens krav, jf. biocidforordningen artikel 69. Etiket og mærkning skal være på dansk.

Nedstående tekst i afsnit III er bidrag til overholdelsen af reglerne og således kun en del af de krav, som stilles til blandt andet etiketten.

III. Etiketten skal indeholde nedenstående oplysninger. Op-lys-ninger i citationstegn skal angives ordret:

1) I hovedfeltet:

"Desinfektionsmiddel

Må kun anvendes som desinfektionsservietter til bekæmpelse af bakterier, mykobakterier, gær, svampe og virus på overflader. Kun til erhvervsmæssig brug."

2) I advarselsfeltet:

"FARE

Forårsager alvorlig øjenskade (H318).

Kan forårsage sløvhed eller svimmelhed (H336).

Brandfarlig væske og damp (H226).

Gentagen kontakt kan give tør eller revnet hud.

Undgå indånding af damp/spray.

Brug kun udendørs eller i et rum med god udluftning.

Vask huden grundigt efter brug.

Bær øjenbeskyttelse og kemisk resistente beskyttelseshandsker ved brug af produktet."

Handskematerialet skal angives af godkendelsesindehaveren i produktdatabladet.

"Udluft behandlede områder grundigt, inden de tages i brug igen.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes som desinfektionsservietter til bekæmpelse af bakterier, mykobakterier, gær, svampe og virus på overflader. Kun til erhvervsmæssig brug.

Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.

Holdes væk fra gnister, åben ild og varme overflader. Rygning forbudt. Må kun anvendes i områder, der er utilgængelige for offentligheden.

Produktet må kun anvendes 1 gang om dagen.

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Levnedsmidler og foderstoffer må ikke forurenes."

Farepiktogrammerne GHS02, GHS05 og GHS07.

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp, herunder: VED INDÅNDING: Flyt personen til et sted med frisk luft og sørg for, at vejrtrækningen lettes.

VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning.

Ring omgående til en GIFTINFORMATION/læge.

- 3) I deklarationsfeltet:
- a) Teksten "Desinfektionsmiddel, BPR-reg. nr. 944-1-4-x [3] . Aktivstoffer og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".
- b) Oplysning om præparattype: "vådservietter" for dette præparat.
- c) Indholdet af aktivstoffer i vægtprocent (% w/w) og g/stk. ved 20 °C.
- d) Udløbsdatoen skal anføres. Denne dato må højst være to år efter produktionsdatoen. Etikettens dato kan udformes som en hen-visning til en produktionsdato andetsteds på emballagen.
- e) Batchnummer eller betegnelse skal anføres.
- f) Pakningsstørrelse i L
- g) Godkendelsesindehavers navn og adresse.
- 4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Det skal fremgå at produktet kun må anvendes på rene overflader

Følgende retningslinjer gælder i forhold til bortskaffelse.

Der skal mærkes med sikkerhedssætning P501: "Rester og emballage bortskaffes som farligt affald."

Følgende sætning skal anføres under sikkerhedssætning P501: "Ovenstående sætning er Miljøstyrelsens vejledning om affaldshåndtering af dette produkt. Følg altid kommunens affaldsregulativ og forhør dig hos kommunen, hvis du er i tvivl."

## 7. Third information level: individual products in the meta SPC

# 7.1 Trade name(s), authorisation number and specific composition of each individual product

## Trade name(s)

Mida San 311 KZ wipes	Market area: DK
Form 311 wipes	Market area: DK
Saniwipe 311	Market area: DK
Saniwipes 311	Market area: DK

## **Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

DK-0027648-0004 1-4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	49,07
Propan-2-ol		Active Substance	67-63-0	200-661-7	19,54