

# Summary of product characteristics for a biocidal product

**Product name:** Antisept A

**Product type(s):** PT01 - Human hygiene (Disinfectants)

PT01 - Human hygiene (Disinfectants)

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

PT04 - Food and feed area (Disinfectants)

**Authorisation number:** DE-0016013-01-02-04

**R4BP 3 asset reference number:** DE-0016013-0000

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## Administrative information

### 1.1. Trade names of the product

Antisept A
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### 1.2. Authorisation holder

<b>Name and address of the authorisation holder</b>	Name	CG Chemikalien GmbH & Co. KG
	Address	Ulmer Str. 1 30880 Laatzen Germany
<b>Authorisation number</b>	DE-0016013-01-02-04	
<b>R4BP 3 asset reference number</b>	DE-0016013-0000	
<b>Date of the authorisation</b>	03/02/2021	
<b>Expiry date of the authorisation</b>	03/02/2031	

### 1.3. Manufacturer(s) of the biocidal products

<b>Name of the manufacturer</b>	CG Chemikalien GmbH & Co KG
<b>Address of the manufacturer</b>	Ulmer Strasse 1 30880 Laatzen Germany
<b>Location of manufacturing sites</b>	Ulmer Strasse 1 30880 Laatzen Germany

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

<b>Active substance</b>	1355 - Propan-2-ol
<b>Name of the manufacturer</b>	Shell Nederland Raffinaderij B.V.
<b>Address of the manufacturer</b>	Vondelingenweg 601 3196 KK Rotterdam Netherlands
<b>Location of manufacturing sites</b>	Vondelingenweg 601 3196 KK Rotterdam Netherlands

## 2. Product composition and formulation

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	64

### 2.2. Type of formulation

AL - Any other liquid
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## 3. Hazard and precautionary statements

<b>Hazard statements</b>	<p>Highly flammable liquid and vapour.</p> <p>Causes serious eye irritation.</p> <p>May cause drowsiness or dizziness.</p> <p>Repeated exposure may cause skin dryness or cracking.</p>
<b>Precautionary statements</b>	<p>If medical advice is needed, have product container or label at hand.</p> <p>Keep out of reach of children.</p> <p>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.</p> <p>Keep cool.</p>

Avoid breathing vapours.

Use only outdoors or in a well-ventilated area.

Wear eye protection/face protection.

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

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

Call a POISON CENTER if you feel unwell.

If eye irritation persists: Get medical attention.

In case of fire: Use alcohol-resistant foam to extinguish.

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

Store locked up.

Dispose of contents to ....

## 4. Authorised use(s)

### 4.1 Use description

#### Use 1 - hand disinfection (professional user)

**Product type**

PT01 - Human hygiene (Disinfectants)

**Where relevant, an exact description of the authorised use**

Ready to use disinfectant for the hygienic and surgical handrub disinfection.

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

Scientific name:  
Common name: Bacteria  
Development stage:

Scientific name:  
Common name: Yeasts  
Development stage:

Scientific name:  
Common name: Enveloped viruses (only for hygienic hand disinfection)  
Development stage:

**Field(s) of use**

Indoor

**Application method(s)**

Method: Hygienic/surgical hand disinfection  
Detailed description:

The ready to use solution is poured into the palms of one hand out of an automatic dispenser. The application should be performed according to EN 1500 (hygienic handrub) and EN 12791 (surgical handrub). Hands have to be kept sufficiently wet and

have to be rubbed firmly and carefully for the required contact time.  
While performing surgical handrub hands have to be kept above elbows. Only use on visibly clean skin.

**Hygienic hand disinfection:**

Contact time for bacteria, yeasts and enveloped viruses: at least 0.5 minutes

**Surgical hand disinfection** (without long term effect according to EN 12791):

Contact time for bacteria, yeasts: at least 1.5 minutes

**Application rate(s) and frequencies**

Application Rate: hygienic hand disinfection : 4 mL, 25 hand rubs/day surgical hand disinfection: 20 mL, 4 rubs/day

Dilution (%):

Number and timing of application:

hygienic hand disinfection :

4 mL, 25 hand rubs/day

surgical hand disinfection:

20 mL, 4 rubs/day

**Category(ies) of users**

Professional

**Pack sizes and packaging material**

bottle (1 L, HDPE), canister ( 5 L and 10 L, HDPE), drums (60 L and 200 L, coated steel), IBC (1000 L, HDPE)

**4.1.1 Use-specific instructions for use**

1. Keep skin sufficiently wet over the whole contact time.
2. Only use on visibly clean skin.

**4.1.2 Use-specific risk mitigation measures**

1. For refilling, a funnel must be applied.
2. The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures:  
For refilling procedure, the use of eye protection during handling of the product is recommended.

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

See chapter 5.3 and precautionary statements in chapter 3

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

See chapter 5.4

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

See chapter 5.5

### 4.2 Use description

#### Use 2 - hand disinfection (non-professional user)

<b>Product type</b>	PT01 - Human hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Ready to use disinfectant for the hygienic handrub disinfection.
<b>Target organism(s) (including development stage)</b>	<p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Yeasts Development stage:</p> <p>Scientific name: Common name: Enveloped viruses Development stage:</p>
<b>Field(s) of use</b>	<p>Indoor</p> <p>Non-professional users will apply alcohol-based hand rubs only occasionally for hygienic reasons when entering/leaving hospitals or for hygiene reasons at home.</p>
<b>Application method(s)</b>	<p>Method: Hygienic hand disinfection Detailed description: Hands have to be rubbed firmly and carefully for at least 30 seconds. It has to be ensured that the hands are kept wet during treatment. Only use on visibly clean skin.</p>

	Contact time for bacteria, yeasts and enveloped viruses: at least 0.5 minutes
<b>Application rate(s) and frequencies</b>	Application Rate: hygienic hand disinfection 4 mL Dilution (%): Number and timing of application:  3 events/day
<b>Category(ies) of users</b>	General public (non-professional)
<b>Pack sizes and packaging material</b>	Bottle (1 L, HDPE)

#### 4.2.1 Use-specific instructions for use

1. Use 4 mL per each application for max. 3 times per day.
2. Keep skin sufficiently wet over the whole contact time.
3. Only use on visibly clean skin.

#### 4.2.2 Use-specific risk mitigation measures

See chapter 5.2

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

See chapter 5.3 and precautionary statements in chapter 3

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

See chapter 5.4

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

See chapter 5.



### 4.3 Use description

#### Use 3 - small surface disinfection (health care sector, institutional area, pharmaceutical and cosmetic industry)

<b>Product type</b>	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Ready to use solution for disinfection of small surfaces in health care sector.
<b>Target organism(s) (including development stage)</b>	Scientific name: Common name: Bacteria (incl. mycobacteria) Development stage:  Scientific name: Common name: Yeasts Development stage:
<b>Field(s) of use</b>	Indoor  Application in health care sector, institutional area, pharmaceutical and cosmetic industry for disinfection of hard non-porous surfaces.
<b>Application method(s)</b>	Method: Spraying / Pouring Detailed description: The biocidal product is applied to the surface by either spraying or pouring (pre-clean roughly where necessary). Make sure to wet surfaces completely. After the required contact time the whole surface is wiped with cloth or tissue (post-rinse where necessary).  In health care, institutional area, pharmaceutical industry (without cosmetic industry): Required contact time for bacteria (incl. mycobacteria) and yeast: at least 5 min at 20°C  In cosmetic industry: Required contact time for bacteria and yeast on dirty surfaces: at least 15 min at 20°C. Required contact time for bacteria (incl. mycobacteria) and yeast on carefully cleaned surfaces: at least 5 min at 20 °C.
<b>Application rate(s) and frequencies</b>	Application Rate: small surface disinfection (0.5 m2 area): 25 mL Dilution (%): Number and timing of application: 4 events/day
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	bottle (1 L, HDPE), canister ( 5 L and 10 L, HDPE), drums (60 L and 200 L, coated steel), IBC (1000 L, HDPE)

### 4.3.1 Use-specific instructions for use

1. Do not apply more than 25 ml per 0.5 m<sup>2</sup>.
2. Make sure to wet surfaces completely.
3. Pre-clean surfaces or post-rinse off, if necessary.
4. Used wipes must be disposed in a closed container.

### 4.3.2 Use-specific risk mitigation measures

1. The product must only be applied for disinfection of small surfaces.
2. For medical practices and small rooms, provide adequate ventilation (industrial ventilation or keeping windows and doors open). The stay in the treated area should be minimised.
3. For refilling, a funnel must be applied.
4. The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures:  
For refilling procedure, the use of eye protection during handling of the product is recommended.

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

See chapter 5.3 and precautionary statements in chapter 3

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

See chapter 5.4

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

See chapter 5.5

## 4.4 Use description

### Use 4 - small surface disinfection (food and feed area)

#### Product type

PT04 - Food and feed area (Disinfectants)

#### Where relevant, an exact description of the authorised use

Ready to use solution for disinfection of small surfaces in food and feed area.

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

Scientific name:  
Common name: Bacteria (incl. mycobacteria)  
Development stage:

Scientific name:  
Common name: Yeasts  
Development stage:

Scientific name:  
Common name: Viruses  
Development stage:

**Field(s) of use**

Indoor  
  
Application in food/feed preparation and handling (kitchen, restaurants grocery shops, butcher etc.) and in food/feed production facilities (alcoholic beverages (e.g. breweries), processed food/feed (meat, vegetables, fruits etc.) (disinfection of hard non-porous surfaces).

**Application method(s)**

Method: Spraying / Pouring  
Detailed description:  
The biocidal product is applied to the surface by either spraying or pouring (pre-clean roughly where necessary). Make sure to wet surfaces completely. After the required contact time the whole surface is wiped with cloth or tissue (post-rinse where necessary).  
  
In food and feed area (including meat industry), dirty surfaces:  
- Required contact time for bacteria (incl. mycobacteria) and yeast: 5 min at 20°C  
  
In Brewery, dirty surfaces:  
- Required contact time for bacteria and yeast: 15 min at 20°C  
  
In food and feed area (including brewery, milk industry, meat industry) with carefully cleaned surfaces:  
- Required contact time for bacteria (incl. mycobacteria) and yeast  
5 min at 20°C  
- Required contact time for viruses: 2 min at 20°C

**Application rate(s) and frequencies**

Application Rate: small surface disinfections (canteens/kitchen, 1 m2 area): 50 mL small surface disinfection in food/feed processing facilities: 50ml/m2  
Dilution (%):  
Number and timing of application:  
4 events/day

**Category(ies) of users**

Professional

**Pack sizes and packaging material**

bottle (1 L, HDPE), canister ( 5 L and 10 L, HDPE), drums (60 L and 200 L, coated steel), IBC (1000 L, HDPE)

**4.4.1 Use-specific instructions for use**

1. Do not apply more than 50 ml per m<sup>2</sup>.
2. Make sure to wet surfaces completely.
3. Pre-clean surfaces or rinse off, if necessary.
4. Used wipes must be disposed in a closed container.

#### 4.4.2 Use-specific risk mitigation measures

1. The product must only be applied for disinfection of small surfaces.
2. For refilling, a funnel must be applied.
3. The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures:  
For disinfection of food processing machinery and refilling procedure, the use of eye protection during handling of the product is recommended.

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

See chapter 5.3 and precautionary statements in chapter 3

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

See chapter 5.4

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

See chapter 5

### 5. General directions for use

#### 5.1. Instructions for use

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#### 5.2. Risk mitigation measures

1. Keep out of reach of children and pets.
2. Avoid contact with eyes.

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

1. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
2. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
3. Call a POISON CENTER or doctor/physician if you feel unwell.
4. If eye irritation persists, get medical advice/attention.

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

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

Shelf-life: 24 month

#### 6. Other information

Please be aware of the European reference value of 129.28 mg/m<sup>3</sup> for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for this product.