

# Summary of product characteristics for a biocidal product

**Product name:** Product

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

**Authorisation number:** EU-0024324-0000

**R4BP 3 asset reference number:** EU-0024324-0001

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## Administrative information

### 1.1. Trade names of the product

ALCOH-WIPE® PROCESS2WIPE® IPA70
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### 1.2. Authorisation holder

<b>Name and address of the authorisation holder</b>	Name	Veltek Associates Inc. Europe
	Address	Rozengaard 1940 8212DT Lelystad Netherlands
<b>Authorisation number</b>	EU-0024324-0000 1-1	
<b>R4BP 3 asset reference number</b>	EU-0024324-0001	
<b>Date of the authorisation</b>	20/04/2021	
<b>Expiry date of the authorisation</b>	31/03/2031	

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

<b>Name of the manufacturer</b>	Veltek Associates, Inc.,
<b>Address of the manufacturer</b>	15 Lee Blvd. PA19355 Malvern United States
<b>Location of manufacturing sites</b>	15 Lee Blvd. PA19355 Malvern United States

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

<b>Active substance</b>	1355 - Propan-2-ol
<b>Name of the manufacturer</b>	Exxon Mobil Chemical Company
<b>Address of the manufacturer</b>	4045 Scenic Hwy, Baton Rouge, LA 70805 Louisiana United States
<b>Location of manufacturing sites</b>	4045 Scenic Hwy, Baton Rouge, LA 70805 Louisiana United States

## 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	65,4

### 2.2. Type of formulation

AL (any other liquid) - RTU wipe
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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>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.</p> <p>Avoid breathing vapours.</p> <p>Wash hands thoroughly after handling.</p> <p>Wear protective gloves.</p>

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.

Call a doctor if you feel unwell.

If eye irritation persists: Get medical advice.

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

Store locked up.

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

Wear eye protection.

## 4. Authorised use(s)

### 4.1 Use description

#### Use 1 - 1.1 Disinfection of hard non-porous surfaces; Wipes (individual wipes and multi-pack 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

-

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

Scientific name:  
Common name: Bacteria  
Development stage: -

Scientific name:  
Common name: yeast  
Development stage: -

##### Field(s) of use

Indoor

Disinfectant wipe for use in cleanrooms of pharmaceutical, biopharmaceutical, medical device and diagnostic product manufacturing facilities for the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs.

##### Application method(s)

Method: Wiping of surfaces  
Detailed description:

-

##### Application rate(s) and frequencies

Application Rate: -  
Dilution (%): RTU  
Number and timing of application:

Product may be used multiple times a day, if required.  
Contact time: 2 min

Individual wipes:  
15.2 cm x 15.2cm wipe - 4 wipes per m<sup>2</sup>  
30.5 cm x 30.5 cm wipe - 1 wipe per m<sup>2</sup>  
45.7 x 45.7cm wipe - 1 wipe per m<sup>2</sup>

Multi pack wipes:  
30.5 cm x 30.5 cm - 1 wipe per m<sup>2</sup>

**Category(ies) of users**

Industrial

**Pack sizes and packaging material**

Pre-saturated 70% v/v propan-2-ol and water for injection (WFI) wipes.

Individual wipes

A wipe is composed of 100% continuous filament polyester fibre. The wipes are packaged in individual heat-sealed plastic bags made of low density polyethylene.

Pack sizes:

15.2 cm x 15.2 cm wipe - 100/case, non- Sterile

15.2 cm x 15.2 cm wipe - 100/case, sterile

30.5 cm x 30.5 cm wipe - 100/case, sterile

45.7 cm x 45.7 cm wipe - 100/case, sterile

Multi pack wipes

A wipe is composed of 100% continuous filament knitted polyester fibre; 20 wipes per pack; folded together in a re-closable bag package.

Pack sizes:

100% polyester 30.5 cm x 30.5 cm wipe - 200/case, non-sterile

100% polyester 30.5 cm x 30.5 cm wipe - 200/case, sterile

#### 4.1.1 Use-specific instructions for use

Use product only in cleanrooms which are classified according to ISO 14644-1 in class 1 to 9 or according to Good Manufacturing Practice (GMP) EU classification in grade A to D.

Clean and dry surfaces prior to disinfection. Only use wet wipes. Remove one or two wipes at a time for individual wipes and one wipe at a time for multipack wipes. Make sure to wet surfaces completely. Allow to take effect for at least 2 minutes. Discard wipe after use in a closed container and for multipack wipes close the package after opening.

Individual wipes:

15.2 cm x 15.2 cm wipe - 4 wipes per m<sup>2</sup>

30.5 cm x 30.5 cm wipe - 1 wipe per m<sup>2</sup>

45.7 cm x 45.7 cm wipe - 1 wipe per m<sup>2</sup>

Multi pack wipes:

30.5 cm x 30.5 cm - 1 wipe per m<sup>2</sup>

#### 4.1.2 Use-specific risk mitigation measures

See general directions for use

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

### 5. General directions for use

#### 5.1. Instructions for use

See use-specific instructions for use.

## 5.2. Risk mitigation measures

Use adequate ventilation with an air change rate of 8 per hour or more.  
Apply away from eyes and face.

Hand protection: Wear chemically resistant protective gloves.  
Eye protection: Wear eye protection.

Avoid contact with eyes.  
Do not breathe vapours.  
Do not eat, drink or smoke when using the product.  
Wash hands thoroughly after handling.

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

Symptoms/injuries after inhalation : May cause drowsiness or dizziness  
Symptoms/injuries after skin contact: Repeated and/or prolonged skin contact may cause irritation, dryness or cracking.  
Symptoms/injuries after eye contact: Causes serious eye irritation  
Symptoms/injuries after ingestion: Symptoms reported in humans are nausea and vomiting due to local irritation and systemic effects like drunkenness, drowsiness, sometimes unconsciousness and low blood sugar (especially in children). Because of the type of formulations (wipes, aerosol and spray) the systemic effects are however less likely.

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

IF INHALED: Move to fresh air and keep at rest in a position that is comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Rinse skin with water/ or shower. Remove all contaminated clothing immediately. Gently wash with plenty of soap and water. If symptoms develop, seek medical attention.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor

IF SWALLOWED: Rinse mouth. Give something to drink if conscious. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

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

Empty containers must be discharged as normal waste or recycled where possible.

Additional information: Handle empty containers with care because residual vapours are flammable.

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

Keep container tightly closed. Keep in a cool, well-ventilated place. Keep away from open flames, hot surfaces and sources of ignition. Store at temperatures below 30°C.

Shelf-life: 2 years

## 6. Other information



The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129.28 mg/m<sup>3</sup> for the professional user was agreed and used for the risk assessment of the product.