

Summary of product characteristics for a biocidal product family

Family name: AGMA IPA product family

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

Authorisation number: IE/BPA 70468

R4BP 3 asset reference number: IE-0026188-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

AGMA IPA product family

1.2. Product type(s)

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

1.3. Authorisation holder

Name and address of the authorisation holder

Name	Agma Europe Limited
Address	Number 2 Geraldus Farrugia Street ZBG 4351 Zebbug Malta

Authorisation number

IE/BPA 70468

R4BP 3 asset reference number

IE-0026188-0000

Date of the authorisation

18/05/2021

Expiry date of the authorisation

18/05/2031

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

AGMA Ltd

Address of the manufacturer

Gemini Works, Haltwhistle NE49 9HA Northumberland United Kingdom

Location of manufacturing sites

Gemini Works, Haltwhistle NE49 9HA Northumberland United Kingdom

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

Active substance	1355 - Propan-2-ol
Name of the manufacturer	Ineos Solvents Germany GmbH
Address of the manufacturer	Römerstraße 733 47443 Moers Germany
Location of manufacturing sites	Römerstraße 733 47443 Moers Germany

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-2-ol		Active Substance	67-63-0	200-661-7	70 - 70

2.2. Type(s) of formulation

AL - Any other liquid impregnated wipes
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Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta-SPC 1

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)

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-2-ol		Active Substance	67-63-0	200-661-7	70 - 70

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

Formulation(s)

impregnated wipes

3. Hazard and precautionary statements of the meta SPC

Hazard statements

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

Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.
Keep container tightly closed.
Wash hands thoroughly after handling.
Wear protective gloves/protective clothing/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 eye irritation persists: Get medical advice.

If eye irritation persists: Get medical attention.

Avoid breathing dust.

Avoid breathing fume.

Avoid breathing gas.

Avoid breathing mist.

Avoid breathing vapours.

Avoid breathing spray.

Use only outdoors or in a well-ventilated area.

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

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

Store in a well-ventilated place. Keep cool.

Store locked up.

Dispose of container to .

Dispose of contents to .

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Ready-to-use wipe for hard surface disinfection in cleanrooms

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfectants and algacides not intended for direct application to humans or animals.
Target organism(s) (including development stage)	<p>Scientific name: bacteria Common name: Bacteria Development stage:</p> <p>Scientific name: yeasts Common name: Yeasts Development stage:</p> <p>Scientific name: fungi Common name: fungi Development stage:</p>

Field(s) of use

Application method(s)	<p>Indoor</p> <p>Disinfection of clean non-porous hard surfaces in cleanrooms</p> <ul style="list-style-type: none"> - for transfer disinfection - as part of the rotational disinfectant regime - as part of a facility general, small and critical areas, and precision cleaning and disinfection regime in accordance with in-house documented, validated procedures <p>Method: wiping Detailed description: -</p>
Application rate(s) and frequencies	<p>Application Rate: 1 wipe for up to 0.1 m². The wipe should be replaced as frequently as needed to ensure complete wetting of the surface and to avoid transferring contaminants to other parts of the surface.</p> <p>Dilution (%): 0</p> <p>Number and timing of application:</p> <p>Disinfection should be performed as and when required in accordance with cleanroom protocols.</p> <p>contact times:</p> <ul style="list-style-type: none"> - 5 min for bacteria and yeast - 15 min for fungi
Category(ies) of users	Professional
Pack sizes and packaging material	White laminate pouch Packaging material: PET/PE

4.1.1 Use-specific instructions for use

Refer to general directions for use.

4.1.2 Use-specific risk mitigation measures

Refer to 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

Refer to general directions for use.

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

Refer to 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

Refer to general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

Only use on clean surfaces.

Make sure to wet surfaces completely.

Wipe the surface to be disinfected using unidirectional, overlapping strokes. Use a different, unused wipe surface area for each stroke (maximum of eight strokes). This can be done by unfolding and refolding the wipe.

Used wipes must be disposed in a closed container.

5.2. Risk mitigation measures

Avoid contact with eyes.
The product must only be applied for disinfection of small surfaces.
A ventilation rate of at least 20/h has to be ensured.

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

FIRST AID

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 The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166), retain the label for reference. if you feel unwell.

If eye irritation persists: Get medical advice/attention.

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

None

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

Shelf life: 24 months.
Storage requirement: Keep cool and away from heat. Keep away from frost.

6. Other information

1. Please be aware of the European reference value of 129.28 mg/m³ for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for this product.
2. All information on the content is given in volume percent (% v/v). The product contains 70% v/v propan-2-ol, which corresponds to 62.7% w/w propan-2-ol.

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)

Sterile IPA 70% in WFI Alcohol Wipes

Market area: IE

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IE-0026188-0001 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta-SPC 2

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)

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-2-ol		Active Substance	67-63-0	200-661-7	70 - 70

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

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

Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.
Keep container tightly closed.
Wash hands thoroughly after handling.
Wear protective gloves/protective clothing/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 eye irritation persists: Get medical .
Avoid breathing dust.
Avoid breathing fume.
Avoid breathing gas.
Avoid breathing mist.
Avoid breathing vapours.
Avoid breathing spray.
Use only outdoors or in a well-ventilated area.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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

Store in a well-ventilated place.Keep cool.

Store locked up.

Dispose of container to .

Dispose of contents to .

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - – Ready-to-use spray for hard surface disinfection in cleanrooms

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	Disinfectants and algaecides not intended for direct application to humans or animals.
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:
Field(s) of use	Indoor Disinfection of clean non-porous hard surfaces in cleanrooms - for transfer disinfection - as part of the rotational disinfectant regime - as part of a facility general, small and critical areas, and precision cleaning and disinfection regime in accordance with in-house documented, validated procedures
Application method(s)	Method: Spraying Detailed description: -
Application rate(s) and frequencies	Application Rate: Disinfection should be performed as and when required in accordance with cleanroom protocols. Apply 5 actuations per 0.1 m ² (to a maximum of 50 ml/m ²) and to allow the disinfectant to work. Dilution (%): 0 Number and timing of application: contact times: - 5 min for bacteria and yeast - 15 min for fungi After contact time, residual moisture may be removed with a sterile, dry cleanroom

wipe. Alternatively, the area may be left to dry naturally before use.

Category(ies) of users

Professional

Pack sizes and packaging material

5L container (HDPE)
1L trigger spray (HDPE)
500ml trigger spray (HDPE)
900 ml trigger spray (HDPE)

4.1.1 Use-specific instructions for use

Refer to general directions for use.

4.1.2 Use-specific risk mitigation measures

Refer to 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

Refer to general directions for use.

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

Refer to 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

Refer to general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

Only use on clean surfaces.

Make sure to wet surfaces completely.

Spray the product onto the surface to be disinfected.

For optimal application, keep container upright and hold at a distance of approximately 10-20 cm from the surface.

Always close the nozzle after use.

Used wipes must be disposed in a closed container.

5.2. Risk mitigation measures

Avoid contact with eyes.

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

For refilling a funnel must be applied.

The following personal risk mitigation measure can be considered for refilling procedure unless it can be replaced by technical and / or organisational measures:
The use of eye protection during refilling of the product is recommended.

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

FIRST AID

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 the National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166), retain the label for reference. if you feel unwell.

If eye irritation persists: Get medical advice/attention.

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

None

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

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

Shelf life: 24 months.
Storage requirement: Keep cool and away from heat. Keep away from frost.

6. Other information

1. Please be aware of the European reference value of 129.28 mg/m³ for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for this product.
2. All information on the content is given in volume percent (% v/v). The product contains 70% v/v propan-2-ol, which corresponds to 62.7% w/w propan-2-ol.

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)	Sterile IPA 70% in WFI Quality Water	Market area: IE
	Non-Sterile IPA 70% in WFI Quality Water	Market area: IE
	Bioburden Reduced Non-Sterile IPA 70% in WFI Quality Water	Market area: IE
	IPA 70% in WFI Quality Water	Market area: IE
Authorisation number (R4BP 3 asset reference number - National Authorisation)	IE-0026188-0002 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	70
