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ANNEX

**SUMMARY OF PRODUCT CHARACTERISTICS
FOR A BIOCIDAL PRODUCT FAMILY**

Azowipe product family

Product type(s)

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

PT04: Food and feed area

Authorisation number IE/BPA 70473

R4BP asset number IE-0021207-0000

Part I.
FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	Azowipe product family
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1.2. Product type(s)

Product type(s)	PT02: Disinfectants and algacides not intended for direct application to humans or animals PT04: Food and feed area
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	Arrow Regulatory (Ireland) Limited acting on behalf of Vernacare Ltd
	Address	The Black Church, St Mary's Place, D07 P4AX Dublin 7 Ireland
Authorisation number	IE/BPA 70473	
<i>R4BP asset number</i>	IE-0021207-0000	
Date of the authorisation	25/07/2019	
Expiry date of the authorisation	10/04/2029	

1.4. Manufacturer(s) of the product

Name of manufacturer	Vernacare Limited
Address of manufacturer	1 Western Avenue PR7 7NB Chorley United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Pywell Road, Willowbrook, East Industrial Estate, Northant NN17 5XJ Corby United Kingdom of Great Britain and Northern Ireland (the) Lawn Road, Carlton-in-Lindrick S81 9LB Worksop, Notts United Kingdom of Great Britain and Northern Ireland (the)

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

Active substance	Propan-2-ol
Name of manufacturer	Brenntag GmbH
Address of manufacturer	Stinnes Platz 1 45472 Mülheim an der Ruhr Germany
Location of manufacturing sites	Shell Chemicals Europe B.V, Haven 3222, Vondelingenweg 601 3196 KK Vondelingenplaat Rotterdam Netherlands (the) Exxon Mobil Chemical Plant, 4999 Scenic Highway Louisiana 70897 Baton Rouge United States (the)

Active substance	Propan-2-ol
Name of manufacturer	Professional Disposables International Ltd.

Address of manufacturer	Aber Park CH6 5EX Flint United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Exxon Mobil Chemical Plant, 4999 Scenic Highway Louisiana 70897 Baton Rouge United States (the)

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 % (w/w)

2.2. Type(s) of formulation

Formulation type(s)	AL Any other liquid liquid impregnated wipe
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Part II.
SECOND INFORMATION LEVEL - META SPC(S)

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	Meta SPC: Meta SPC 1 - Wipe products
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1.2. Suffix to the authorisation number

Number	1-1
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1.3. Product type(s)

Product type(s)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
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2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		active substance	67-63-0	200-661-7	70 - 70 % (w/w)

2.2. Type(s) of formulation of the meta SPC 1

Formulation type(s)	liquid impregnated wipe
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P403+P235: Store in a well-ventilated place. Keep cool. P264: Wash hands thoroughly after handling. P271: Use only outdoors or in a well-ventilated area. P280: Wear protective gloves. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice. P337+P313: If eye irritation persists: Get medical attention. P261: Avoid breathing fume. P261: Avoid breathing spray. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a doctor if you feel unwell. P405: Store locked up. P501: Dispose of contents to local regulations. P501: Dispose of container to local regulations.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1. Use # 1 – Professional - Hard surface disinfectant – for use in manufacturing/ industrial settings (e.g. laboratories, in sanitation areas, in medical practices, and in pharmaceutical, and cosmetic industry) and private/public health (e.g. hospitals and medical practices)

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Ready to use products applied as a disinfectant, for the disinfection of hard non-porous surfaces, inanimate objects and materials and equipment in private, public health and industrial areas within PT2.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: All Scientific name: Yeast Common name: Yeasts Development stage: All
Field(s) of use	indoor use Room temperature.
Application method(s)	Method: Wiping Detailed description: Wiping - direct application onto surface.
Application rate(s) and frequency	Application rate: Three wipes per 0.5 m ² for a contact time of 1 minute. Dilution (%): Not applicable. Number and timing of application: Three wipes to be used consecutively per application; the surface should remain wet for 1 minute.
Category(ies) of users	professional
Pack sizes and packaging material	Wipes contained in a HDPE canister with a HDPE lid: 200 and 250 wipes - Canister dimension: 110 x 240 mm 100 and 150 wipes - Canister dimension: 170 x 80 mm Wipe (60% viscose and 40% polypropylene) dimensions approx. 206 x 203 mm in canisters containing 200 and 250 wipes and 130 x 180 mm in canisters containing 100 and 150 wipes.

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4.1.1. Use-specific instructions

For the Wipe products:

Cleaning prior to disinfection is required.

Disinfection should take place at room temperature (20±2 °C)

The product must only be used for disinfection of small surfaces

Three wipes per 0.5 m² for a contact time of 1 minute (surface should remain wet for 1 minute). Ensure complete coverage of the surfaces.

Leave the surface to dry.

Use recommended cleanroom wiping procedure.

Wipes should be folded so that the entire surface of the wipe can be used.

Typically wipes are quarter folded, and then refolded after every wipe of the surface, to contain and remove the contamination.

In this manner, there are eight different surfaces of the wipe exposed and able to be used for wiping.

Wiping should be done in overlapping linear strokes from clean to dirty or dry to wet. After all eight surfaces have been used, the wipe (and its captured contamination) should be discarded in an appropriate container.

4.1.2. Use-specific risk mitigation measures

For professional use only.

For PT2:

- Ensure adequate ventilation (e.g. open doors) between use where public are present
- Do not apply more than twice within 24 hours in rooms where public are present.
- Do not use the product in areas where children are present.

General measures:

Provide adequate ventilation to avoid build-up of vapours.

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Avoid contact with eyes. Do not breathe vapours.

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

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

Description of first aid measures:

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

Skin Contact: Wash skin with water. Seek medical attention if irritation or symptoms persist.

Inhalation: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical attention if symptoms persist.

Ingestion: If swallowed, rinse mouth with water (only if the person is conscious). Make victim drink plenty of water. Do not induce vomiting. Obtain medical attention.

Medical professionals should contact The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166) for further advice.

Methods and materials for containment and cleaning up:

Allow small spillages to evaporate provided there is adequate ventilation.

Contain and adsorb large spillages onto an inert, non-flammable adsorbent carrier. Transfer to a container for disposal or recovery.

Environmental precautions:

Small spillages: No special measures are required.

Large spillages: Do not discharge waste and/or cleaning water via public sewer system. Avoid release to the environment.

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

The product should be disposed of according to local, state or national legislation.

Towels contaminated with the product / used wipes must be disposed in a closed container.

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

Storage Conditions:

Store in a well ventilated place/Keep container tightly closed. Keep cool.

Do not store in freezing temperature.

Keep away from oxidising agents.

Shelf life:

24-months.

4.2. Use description

Table 2. Use # 1 – Professional - Hard surface disinfectant – for use in preparation of food in industrial settings and canteens - wipes

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	Ready to use products applied as a disinfectant, for the disinfection of hard non-porous surfaces clean surfaces, in food processing areas within PT 4 uses including canteens.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: All Scientific name: Yeast Common name: Yeasts Development stage: All

Field(s) of use	indoor use Room temperature.
Application method(s)	Method: Wiping. Detailed description: Wiping - direct application onto surface.
Application rate(s) and frequency	Application rate: Three wipes per 0.5 m2 for a contact time of 1 minute. Dilution (%): Not applicable. Number and timing of application: Three wipes to be used consecutively per application; the surface should remain wet for 1 minute.
Category(ies) of users	professional
Pack sizes and packaging material	Wipes contained in a HDPE canister with a HDPE lid: 200 and 250 wipes - Canister dimension: 110 x 240 mm 100 and 150 wipes - Canister dimension: 170 x 80 mm Wipe (60% viscose and 40% polypropylene) dimensions approx. 206 x 203 mm in canisters containing 200 and 250 wipes and 130 x 180 mm in canisters containing 100 and 150 wipes.

4.2.1. Use-specific instructions

For the Wipe products:

Cleaning prior to disinfection is required.

Disinfection should take place at room temperature (20±2 °C)

The product must only be used for disinfection of small surfaces

Three wipes per 0.5 m2 for a contact time of 1 minute (surface should remain wet for 1 minute). Ensure complete coverage of the surfaces.

Leave the surface to dry.

Use recommended cleanroom wiping procedure.

Wipes should be folded so that the entire surface of the wipe can be used.

Typically wipes are quarter folded, and then refolded after every wipe of the surface, to contain and remove the contamination.

In this manner, there are eight different surfaces of the wipe exposed and able to be used for wiping.

Wiping should be done in overlapping linear strokes from clean to dirty or dry to wet. After all eight surfaces have been used, the wipe (and its captured contamination) should be discarded in an appropriate container.

4.2.2. Use-specific risk mitigation measures

For professional use only.

For PT2:

- Ensure adequate ventilation (e.g. open doors) between use where public are present
- Do not apply more than twice within 24 hours in rooms where public are present.

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- Do not use the product in areas where children are present.

General measures:

Provide adequate ventilation to avoid build-up of vapours.

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Avoid contact with eyes. Do not breathe vapours.

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

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

Description of first aid measures:

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

Skin Contact: Wash skin with water. Seek medical attention if irritation or symptoms persist.

Inhalation: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical attention if symptoms persist.

Ingestion: If swallowed, rinse mouth with water (only if the person is conscious). Make victim drink plenty of water. Do not induce vomiting. Obtain medical attention.

Medical professionals should contact The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166) for further advice.

Methods and materials for containment and cleaning up:

Allow small spillages to evaporate provided there is adequate ventilation.

Contain and adsorb large spillages onto an inert, non-flammable adsorbent carrier. Transfer to a container for disposal or recovery.

Environmental precautions:

Small spillages: No special measures are required.

Large spillages: Do not discharge waste and/or cleaning water via public sewer system. Avoid release to the environment.

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

The product should be disposed of according to local, state or national legislation.

Towels contaminated with the product / used wipes must be disposed in a closed container.

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

Storage Conditions:

Store in a well ventilated place/Keep container tightly closed. Keep cool.

Do not store in freezing temperature.

Keep away from oxidising agents.

Shelf life:
24-months.

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 1

5.1. Instructions for use

See Authorised uses.

5.2. Risk mitigation measures

See Authorised uses.

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

See Authorised uses.

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

See Authorised uses.

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

See Authorised uses.

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

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

Trade name(s)	Azowipe	Market area: IE
	Azowipe Blue	Market area: IE
	Azowipette	Market area: IE
	Azowipe Sterile	Market area: IE
Authorisation number	IE-0021207-0001 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		active substance	67-63-0	200-661-7	70 % (w/w)

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	Meta SPC: Meta SPC 2 - Spray products
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

Product type(s)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
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2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		active substance	67-63-0	200-661-7	70 - 70 % (w/w)

2.2. Type(s) of formulation of the meta SPC 2

Formulation type(s)	AL Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	<p>H225: Highly flammable liquid and vapour.</p> <p>H319: Causes serious eye irritation.</p> <p>H336: May cause drowsiness or dizziness.</p> <p>EUH066: Repeated exposure may cause skin dryness or cracking.</p>
Precautionary statements	<p>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P403+P233: Store in a well-ventilated place. Keep container tightly closed.</p> <p>P403+P235: Store in a well-ventilated place. Keep cool.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P271: Use only outdoors or in a well-ventilated area.</p> <p>P280: Wear protective gloves.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P337+P313: If eye irritation persists: Get medical advice.</p> <p>P337+P313: If eye irritation persists: Get medical attention.</p> <p>P261: Avoid breathing fume.</p> <p>P261: Avoid breathing spray.</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P312: Call a doctor if you feel unwell.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents to local regulations.</p> <p>P501: Dispose of container to local regulations.</p>

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1. Use # 2 – Professional - Hard surface disinfectant - for use in manufacturing/ industrial settings (e.g. laboratories, in sanitation areas, in medical practices, and in pharmaceutical, and cosmetic industry) and private/public health (e.g. hospitals and medical practices) - spray

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Ready to use products applied as a disinfectant, for the disinfection of hard non-porous surfaces, inanimate objects and materials and equipment in private, public health and industrial areas within PT2.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: All Scientific name: Yeast Common name: Yeasts Development stage: All
Field(s) of use	indoor use Room temperature
Application method(s)	Method: spraying Detailed description: Surface spray
Application rate(s) and frequency	Application rate: 50ml per m2 of surface for a contact time of 1-minute Dilution (%): Not applicable. Number and timing of application: 50ml per m2 of surface for a contact time of 1-minute.
Category(ies) of users	professional
Pack sizes and packaging material	Azospray (500ml bottles): Material: Trigger bottle made of the following materials: PP, PEHD, EVA, Foamed PE and PELD in cardboard cases. Packaging size: 264mmx55mmx98mm. Azospray Sterile (500ml bottles): Material: Trigger bottle made of the following materials: PP, PEHD, EVA, Foamed PE and PELD in cardboard cases. Packaging size: 264mmx55mmx98mm. Safety features: Spray products - The bottles contain an on/off mechanism.

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4.1.1. Use-specific instructions

For the spray products:

Cleaning prior to disinfection is required.

Disinfection should take place at room temperature (20±2 °C).

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

Apply the spray to the surface which required disinfection. Once applied leave wet for a minute and then wipe the surface. Wash hands thoroughly after using.

No waiting period is required between applications, but each application should ensure that the surface remains wet for at least 1 minute.

4.1.2. Use-specific risk mitigation measures

For professional use only.

For PT2:

- Ensure adequate ventilation (e.g. open doors) between use where public are present
- Do not apply more than twice within 24 hours in rooms where public are present.
- Do not use the product in areas where children are present.

General measures:

Provide adequate ventilation to avoid build-up of vapours.

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Keep container tightly closed.

Avoid contact with eyes. Do not breathe mist/vapours/spray.

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

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

Description of first aid measures:

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

Skin Contact: Wash skin with water. Seek medical attention if irritation or symptoms persist.

Inhalation: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical attention if symptoms persist.

Ingestion: If swallowed, rinse mouth with water (only if the person is conscious). Make victim drink plenty of water. Do not induce vomiting. Obtain medical attention.

Medical professionals should contact The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166) for further advice.

Methods and materials for containment and cleaning up:

Allow small spillages to evaporate provided there is adequate ventilation.

Contain and adsorb large spillages onto an inert, non-flammable adsorbent carrier. Transfer to a container for disposal or recovery.

Environmental precautions:

Small spillages: No special measures are required.

Large spillages: Do not discharge waste and/or cleaning water via public sewer system. Avoid release to the environment.

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

The product should be disposed of according to local, state or national legislation.

Towels contaminated with the product must be disposed in a closed container.

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

Storage Conditions:

Store in a well ventilated place/Keep container tightly closed. Keep cool.

Do not store in freezing temperature.

Keep away from oxidising agents.

Shelf life:

24-months.

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 2

5.1. Instructions for use

See Authorised uses.

5.2. Risk mitigation measures

See Authorised uses.

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

See Authorised uses.

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

See Authorised uses.

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

See Authorised uses.

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

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

Trade name(s)	Azospray	Market area: IE
	Azopray	Market area: IE
Authorisation number	IE-0021207-0002 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		active substance	67-63-0	200-661-7	70 % (w/w)