ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Milton Disinfecting Fluid

Product type(s)

PT04: Food and feed area

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

PT05: Drinking water

Authorisation number: 3258-1

R4BP asset number: BG-0026549-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Milton Steri-bac Fluid	
	Milton Antibacterial Fluid	
	Milton Disinfecting Fluid	
	Milton Sterilising Fluid	

1.2. Authorisation holder

	Name	Milton International
Name and address of the authorisation holder	Address	9 Rue Marcel Sembat Immeuble Le Saint- Louis 44100 Nantes France
Authorisation number		3258-1
R4BP asset number		BG-0026549-0000
Date of the authorisation		26/10/2021
Expiry date of the authorisation		13/10/2033

1.3. Manufacturer(s) of the product

Name of manufacturer	Mc Bride
Address of manufacturer	Middleton Way - Middleton M24 4DP Manchester United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Middleton Way - Middleton M24 4DP Manchester United Kingdom of Great Britain and Northern Ireland (the)

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

Active substance	Active chlorine released from sodium hypochlorite
Name of manufacturer	INOVYN ChlorVinyls Limited
Address of manufacturer	Runcorn Site HQ, South Parade, PO Box 9 WA7 4JE Runcorn, Cheshire United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Runcorn Site HQ, South Parade, PO Box 9 WA7 4JE Runcorn, Cheshire United Kingdom of Great Britain and Northern Ireland (the)

2. PRODUCT COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active chlorine		active substance	7681-52-9	231-668-3	1,9
released from sodium					
hypochlorite					

2.2. Type(s) of formulation

SL Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H290: May be corrosive to metals.
	H315: Causes skin irritation.
	H400: Very toxic to aquatic life.
	H411: Toxic to aquatic life with long lasting effects.
	EUH031: Contact with acids liberates toxic gas.
	EUH206: Warning! Do not use together with other products. May release dangerous gases (chlorine).
Precautionary statements	P101: If medical advice is needed, have product container or label at hand.
	P102: Keep out of reach of children.
	P234: Keep only in original packaging.
	P273: Avoid release to the environment.
	P302+P352: IF ON SKIN: Wash with plenty of soap and water.
	P501: Dispose of contents to hazardous waste collection authorized in accordance with local, regional, national and / or international regulations

4. AUTHORISED USE(S)

4.1. Use description

Table 1. 1 - Immersion

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	The product Milton Disinfecting Fluid is a soluble concentrate disinfectant. It is used for disinfection of nursery accessories (feeding bottles, teats,) by immersion (PT04), disinfection of surfaces (floor, working surfaces,) in domestic and healthcare sectors (PT02 and PT04) by wet wiping and disinfection of water of undefined quality (PT05) for small case use.
Target organism(s) (including development stage)	Scientific name: Pseudomonas aeruginosa Common name: - Development stage: -
	Scientific name: Escherichia coli Common name: - Development stage: -
	Scientific name: Staphylococcus aureus Common name: - Development stage: -
	Scientific name: Enterococcus hirae Common name: - Development stage: -
	Scientific name: Candida albicans Common name: yeast Development stage: -
Field(s) of use	indoor use
Application method(s)	Method: open system: immersion
	Detailed description: Soaking in a prepared solution.
Application rate(s) and frequency	Application rate: -
	Dilution (%): 0.6% v/v
	Number and timing of application: The product is used as needed. Once prepared, the prepared solution can be used for 24 hours.
Category(ies) of users	professional; general public (non-professional)
Pack sizes and packaging material	bottle, plastic: HDPE, 500mL
	Opaque HDPE bottle Dimensions: 76.00 mm * 60.00 mm * 214.00 mm CAD volume: 604 ± 15 mL The bottle is hermetically closed with a cap.

bottle, plastic: plastic: HDPE, 1L

Opaque HDPE bottle

Dimensions: 94.05 mm * 70.00 mm * 271.00 mm

CAD volume: $1104 \pm 25 \text{ mL}$

The bottle is hermetically closed with a cap.

jerry can, plastic: plastic: HDPE, 5L

Opaque HDPE jerry can

Dimensions: 134.00 mm * 185.00 mm * 283.00 mm

Capacity: 5300 mL

The bottle is hermetically closed with a cap.

4.1.1. Use-specific instructions

Wash bottles, teats, breastfeeding equipment... in warm soapy water, then rinse in cold water.

Fill the disinfection unit with 5 L of water, add 30 mL of Milton Sterilising Fluid (one cap of the 500 mL or 1 L bottle).

Add the items in the disinfection unit, submerge them under water. Close the lid.

After 15 minutes, the items are ready to use.

Do not rinse with water.

The items can stay in the solution until needed (up to 24 hours after preparation).

Items can be added in the solution (up to 24 hours after preparation).

Renew the disinfecting solution every 24 hours.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

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

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

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

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4.2. Use description

Table 2. 2 - Surface disinfection

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
Where relevant, an exact description of the authorised use	The product Milton Disinfecting Fluid is a soluble concentrate disinfectant. It is used for disinfection of nursery accessories (feeding bottles, teats,) by immersion (PT04), disinfection of surfaces (floor, working surfaces,) in domestic and healthcare sectors (PT02 and PT04) by wet wiping and disinfection of water of undefined quality (PT05) for small scale use.
Target organism(s) (including development stage)	Scientific name: Pseudomonas aeruginosa Common name: - Development stage: -
	Scientific name: Escherichia coli Common name: - Development stage: -
	Scientific name: Staphylococcus aureus Common name: - Development stage: -
	Scientific name: Enterococcus hirae Common name: - Development stage: -
	Scientific name: Candida albicans Common name: yeast Development stage: -
Field(s) of use	indoor use
Application method(s)	Method: manual application
	Detailed description: Application of 30 mL/m ² of the prepared solution, by wet wiping.
Application rate(s) and frequency	Application rate: 30 mL/m2
	Dilution (%): 2.4% v/v
	Number and timing of application: The product is used as needed.
Category(ies) of users	professional; general public (non-professional)
Pack sizes and packaging material	bottle, plastic: HDPE, 500mL
	Opaque HDPE bottle Dimensions: 76.00 mm * 60.00 mm * 214.00 mm CAD volume: 604 ± 15 mL

The bottle is hermetically closed with a cap.

bottle, plastic: plastic: HDPE, 1L

Opaque HDPE bottle

Dimensions: 94.05 mm * 70.00 mm * 271.00 mm

CAD volume: $1104 \pm 25 \text{ mL}$

The bottle is hermetically closed with a cap.

jerry can, plastic: plastic: HDPE, 5L

Opaque HDPE jerry can

Dimensions: 134.00 mm * 185.00 mm * 283.00 mm

Capacity: 5300 mL

The bottle is hermetically closed with a cap.

4.2.1. Use-specific instructions

Prepare the 2.4% v/v solution by adding 120 mL of Milton Sterilising Fluid (4 caps of the 500 mL or 1 L bottle) to 5 L of water.

Use this solution to disinfect clean surfaces (use 30 mL/m²).

Apply by wet wiping. The surfaces must remain wet for at least 15 minutes. It is not necessary to rinse the treated surfaces.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

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

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

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

4.3. Use description

Table 3. 3 - Water disinfection

Product type	PT05: Drinking water
Where relevant, an exact description of the authorised use	The product Milton Disinfecting Fluid is a soluble concentrate disinfectant. It is used for disinfection of nursery accessories (feeding bottles, teats,) by immersion (PT04), disinfection of surfaces (floor, working surfaces,) in domestic and healthcare sectors (PT02 and PT04) by wet wiping and disinfection of water of undefined quality (PT05) for small scale use.
Target organism(s) (including development stage)	Scientific name: Pseudomonas aeruginosa Common name: - Development stage: -
	Scientific name: Escherichia coli Common name: - Development stage: -
	Scientific name: Staphylococcus aureus Common name: - Development stage: -
	Scientific name: Enterococcus hirae Common name: - Development stage: -
	Scientific name: Candida albicans Common name: yeast Development stage: -
Field(s) of use	indoor use
Application method(s)	Method: manual application Detailed description: Disinfect the unknown water by adding 15 mL of Milton Sterilising Fluid into 100 L of clear water. If the water looks dirty, first filter, and then add 30 mL of Milton Sterilising Fluid into 100 L of water. Wait at least 30 minutes before drinking or using the water.
Application rate(s) and frequency	Application rate: 15-30 mL/100 L
	Number and timing of application: The product is used as needed.
Category(ies) of users	professional; general public (non-professional)
Pack sizes and packaging material	bottle, plastic: HDPE , 500mL
	Opaque HDPE bottle Dimensions: 76.00 mm * 60.00 mm * 214.00 mm CAD volume: 604 ± 15 mL The bottle is hermetically closed with a cap.
	bottle, plastic: plastic: HDPE, 1L
	Opaque HDPE bottle

Dimensions: 94.05 mm * 70.00 mm * 271.00 mm

CAD volume: $1104 \pm 25 \text{ mL}$

The bottle is hermetically closed with a cap.

jerry can, plastic: plastic: HDPE, 5L

Opaque HDPE jerry can

Dimensions: 134.00 mm * 185.00 mm * 283.00 mm

Capacity: 5300 mL

The bottle is hermetically closed with a cap.

4.3.1. Use-specific instructions

Disinfect the unknown water by adding 15 mL of Milton Sterilising Fluid into 100 L of clear water.

If the water looks dirty, first filter, and then add 30 mL of Milton Sterilising Fluid into 100 L of water.

Wait at least 30 minutes before drinking or using the water.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

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

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

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

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5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

See specific instructions.

5.2. Risk mitigation measures

Milton Disinfecting Fluid is intended for professional and public uses.

The product must be used in accordance with the label.

Always wash the hands after handling.

Avoid skin contact with this mixture.

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

Do not use on metal. Mixture which by chemical action can corrode and even destroy metals.

Contact with acids liberates toxic gas (chlorine).

Do not use together with other products. May release dangerous gases (chlorine).

Take care not to splash the solution as it may discolour fabric.

- In case of massive inhalation: move the patient to fresh air and keep warm and at rest.
- In case of eye contact: wash thoroughly with soft, clean water for several minutes while holding the eyelids open. Remove contact lenses if present and easy to do. Continue rinsing. If there is any redness, pain or visual impairment, consult an ophthalmologist.
- In case of skin contact: remove contaminated clothing. Watch out for any remaining product between skin and clothing, watches, shoes, etc. Wash the skin thoroughly with soap and water or a recognised cleaner. If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted or the victim transferred to hospital.
- In case of ingestion: do not give the victim anything orally. If the quantity is small (no more than one mouthful), rinse mouth with water. Immediately call a doctor or a poison control center. Show the label.

Do not throw into the drains or water courses.

Contain the discharges and collect them with non-combustible absorbent material (for example: sand, earth, vermiculite, diatomaceous earth) in drums and dispose as waste in compliance with the current legislation. Clean preferably with a detergent, do not use solvents.

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

Dispose of this material and its container at hazardous or special waste collection point in accordance with local/national regulations.

The disposal of this packaging in the environment will be banned.

Do not empty into drains and streams.

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

Always keep in the original packaging.

Keep out of reach of children. Keep away from food, drink and animal feedingstuffs. Store away from heat. Shelf-life: 24 months

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

6. OTHER INFORMATION