Summary of product characteristics for a biocidal product

Product name: Milton Disinfecting Fluid

Product type(s): PT04 - Food and feed area (Disinfectants)

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

animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Authorisation number: IE/BPA 70766

R4BP 3 asset reference number: IE-0026547-0000

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Administrative information

1.1. Trade names of the product

Milton Steri-bac Fluid
Milton Antibacterial Fluid
Milton Disinfecting Fluid
Milton Sterilising Fluid

1.2. Authorisation holder

Name and address of the authorisation holder

Name Milton International

9 Rue Marcel Sembat Immeuble Le Saint-Louis 44100 Nantes France

Authorisation number

IE/BPA 70766

R4BP 3 asset reference number

IE-0026547-0000

Date of the authorisation

10/12/2021

Expiry date of the authorisation

26/11/2031

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

Mc Bride

Address of the manufacturer

Middleton Way - Middleton M24 4DP Manchester United Kingdom

Location of manufacturing sites

Middleton Way - Middleton M24 4DP Manchester United Kingdom

Name of the manufacturer	Easy Cleaning Solutions Limited		
Address of the manufacturer	Brunel Way Thetford IP24 1HF Norfolk United Kingdom		
Location of manufacturing sites	Brunel Way Thetford IP24 1HF Norfolk United Kingdom		

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

Active substance	1391 - Active chlorine released from sodium hypochlorite		
Name of the manufacturer	INOVYN Trade Services SA		
Address of the manufacturer	Avenue des Olympiades 20 1140 Brussels Belgium		
Location of manufacturing sites	Runcorn Site HQ, South Parade, PO Box 9 WA7 4JE Runcorn, Cheshire United Kingdom		
Active substance	1391 - Active chlorine released from sodium hypochlorite		
Name of the manufacturer	Industrial Chemicals Limited		
Address of the manufacturer	Hogg Lane Grays RM17 5DU Essex United Kingdom		
Location of manufacturing sites	Hogg Lane Grays RM17 5DU Essex United Kingdom		

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 (%)
Active chlorine released from sodium hypochlorite		Active Substance			1,9

2.2. Type of formulation

SL - Soluble concentrate

3. Hazard and precautionary statements

Hazard statements

May be corrosive to metals.

Causes skin irritation.

Harmful to aquatic life with long lasting effects.

Contact with acids liberates toxic gas.

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

Precautionary statements

Wear protective gloves.

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

IF ON SKIN: Wash with plenty of soap and water.

Keep only in original packaging.

Absorb spillage to prevent material damage.

Avoid release to the environment.

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

Use 1 - 1 - Immersion

Product type

PT04 - Food and feed area (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: Yeasts Development stage: -

Field(s) of use

Indoor

The product is used for disinfection of nursery accessories (feeding bottles, teats,...) by immersion.

Application method(s)

Method: Open system: immersion Detailed description: Immersion in a prepared solution.

Application rate(s) and frequencies

Application Rate: -

Dilution (%): Dilution to 0.6% v/v in room temperature water

Number and timing of application:

15 min contact time at +20 °C on non-porous surfaces after cleaning/rinsing and excess water removing.

Use as needed. The dilution can be stored at room temperature (should be packaged in an opaque container with a safety screw cap) and used up to 24h. It should be clear for professional users working in paediatrics/neonatology and maternity care units that the product Milton Disinfecting Fluid does not exhibit sterilizing activity (sometimes needed for newborns and babies).

Category(ies) of users

Professional

General public (non-professional)

Pack sizes and packaging material

Bottle (HDPE, opaque with PP Safety screw cap): 500 mL

Bottle (HDPE, opaque with PP Safety screw cap): 1 L

Jerry can (HDPE, opaque with PP Safety screw cap): 5 L

Professionals only.

4.1.1 Use-specific instructions for use

Before the disinfection procedure, it is important that the user should carry out a meticulous visual examination of the items to be disinfected (i.e.rubber teats) in order to detect any crack or suspect discoloration indicating that these items are not in good shape anymore (for disinfection & reuse) and should be discarded immediately.

Wash carefully the equipment in warm soapy water, rinse meticulously in cold water and pay attention to remove excess water from the surfaces.

Fill your 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 in order to submerge them under water. Close the lid.

After 15 minutes, the items are ready to use. The items can stay in the solution until needed (up to 24 hours after preparation).

Washed items can be added in the solution (up to 24 hours after preparation)

Renew the disinfecting solution every 24 hours. The disinfection solution should be thrown out after use.

After disinfection,the items must be rinsed with water.	

4.1.2 Use-specific risk mitigation measures

Please refer to point 5.2 below

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

Please refer to point 5.3 below

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

Please refer to point 5.4 below

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

Please refer to point 5.5 below

4.2 Use description

Use 2 - 2 - Surface disinfection

Product	type	

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

PT04 - Food and feed area (Disinfectants)

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

Scientific name: -Common name: Bacteria Development stage: -

Scientific name: -Common name: Yeasts Development stage: -

Field(s) of use

Indoor

The product is intended to be used for disinfection of surfaces (floor, working surfaces,...) in domestic and healthcare sectors (PT02 and PT04) by wet wiping.

Application method(s)

Method: Manual application

Detailed description: Manual application by wet wiping.

Application rate(s) and frequencies

Application Rate: 30 mL/m2

Dilution (%): 3% v/v in room temperature water

Number and timing of application:

5 min contact time at $\pm 20^{\circ}$ C on hard/non-porous surfaces after cleaning/rinsing and excess water removing. The surfaces must remain wet for at least 5 minutes. The product is used as needed.

Category(ies) of users

Professional

General public (non-professional)

Pack sizes and packaging material

Bottle (HDPE, opaque with PP Safety screw cap): 500 mL

Bottle (HDPE, opaque with PP Safety screw cap): 1 L

Jerry can (HDPE, opaque with PP Safety screw cap): 5 L

Professionals only.

4.2.1 Use-specific instructions for use

Wash carefully the surfaces with warm soapy water, rinse meticulously and pay attention to remove excess water from the surfaces. Prepare in a bucket a 3% v/v solution by adding 150 mL of Milton Sterilising Fluid (5 caps of the 500 mL or 1 L bottle) to 5 L of water. Then, soak the wipes into the solution before disinfecting by wet wiping hard/non-porous surfaces clean surfaces (30 mL/m²). The surfaces must remain wet for at least 5 minutes. Rinse the surfaces after biocidal product application.

4.2.2 Use-specific risk mitigation measures

Please refer to point 5.2 below

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

Please refer to point 5.3 below

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

Please refer to point 5.4 below

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

Please refer to point 5.5 below

5. General directions for use

5.1. Instructions for use

The product **Milton Sterilising 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.

The product is used by amateurs and professionals, after dilution in water.

5.2. Risk mitigation measures

Milton Sterilising Fluid is intended for professional and public uses. The product must be used in accordance with the label. Professional (to be mentioned on the label):

- Wear gloves

Non-professional (to be mentioned on the label):

- Avoid skin contact with this mixture
- A lways wash hands carefully after handling

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

Particulars of likely direct or indirect effects

- 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.

First aid instructions, antidotes:

- If medical advice is needed, have product container or label at hand
- In case of massive inhalation: move the patient to fresh air and keep warm and at rest in a position comfortable for breathing. If any discomfort persist seek medical help.
- 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 recognized 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.

Emergency measures to protect environment in case of accident:

- 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 drum sand 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 and national regulations.

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

Do not empty or wash into drains and streams

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

Shelf-life: 15 months at room temperature.

Store away from heat. Protect from sunlight. Keep only in original container.

Keep out of reach of children.

Keep away from food, drink and animal feeding stuffs.

6. Other information

Do not splash. The product discolours clothing and fabrics.