

Summary of product characteristics for a biocidal product

Product name: IODOL 100

Product type(s): PT03 - Veterinary hygiene (Disinfectants)

PT03 - Veterinary hygiene (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Authorisation number: RO/2020/0278/MRA/ FR-2017-0071

R4BP 3 asset reference number: RO-0027519-0000

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Administrative information

1.1. Trade names of the product

IODOL 100
IODAVIC
AQUACEET IODE

1.2. Authorisation holder

Name and address of the authorisation holder	Name	LABORATOIRE MERIEL S.A.S.
	Address	12 rue de Malacussy 42100 Saint Etienne France
Authorisation number	RO/2020/0278/MRA/ FR-2017-0071	
R4BP 3 asset reference number	RO-0027519-0000	
Date of the authorisation	21/08/2018	
Expiry date of the authorisation	20/08/2028	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	LABORATOIRE MERIEL S.A.S.
Address of the manufacturer	12 rue de Malacussy 42100 Saint Etienne France
Location of manufacturing sites	12 rue de Malacussy 42100 Saint Etienne France

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

Active substance	1319 - Iodine
Name of the manufacturer	HYPRED
Address of the manufacturer	55 boulevard Jules Verger BP10180 35803 Dinard Cedex France
Location of manufacturing sites	55 boulevard Jules Verger BP10180 35803 Dinard Cedex France

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 (%)
Iodine		Active Substance	7553-56-2	231-442-4	1

2.2. Type of formulation

SL - Soluble concentrate

3. Hazard and precautionary statements

Hazard statements	<p>May be corrosive to metals.</p> <p>Causes severe skin burns and eye damage.</p> <p>May cause damage to organs (thyroid) through prolonged or repeated exposure .</p> <p>Harmful to aquatic life with long lasting effects.</p> <p>Corrosive to the respiratory tract.</p>
Precautionary statements	<p>Do not breathe dust.</p> <p>Do not breathe fume.</p> <p>Do not breathe gas.</p> <p>Do not breathe mist.</p>

Do not breathe vapours.

Do not breathe spray.

Wash hands thoroughly after handling.

Avoid release to the environment.

Wear protective gloves.

Wear protective clothing.

Wear eye protection.

Wear face protection.

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

Wash contaminated clothing before reuse.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with shower.

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

Immediately call a POISON CENTER.

Immediately call a doctor.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Store locked up.

Dispose of contents to according to local regulation.

Dispose of container to according local regulation.

Get medical advice if you feel unwell.

Wash contaminated clothing before reuse.

4. Authorised use(s)

4.1 Use description

Use 1 - Disinfection of equipment for animals by soaking

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Disinfection of equipment

Scientific name: Bacteria

Target organism(s) (including development stage)	Common name: Bacteria Development stage:
Field(s) of use	Indoor Indoor use
Application method(s)	Method: Soaking Detailed description: The product is applied by soaking
Application rate(s) and frequencies	Application Rate: - Dilution (%): 2 Number and timing of application: 2.0% v/v dilution at 10°C Contact time: 30 minutes
Category(ies) of users	Professional
Pack sizes and packaging material	Individual HDPE containers : - jerry can of 5 and 20 L and, - drum of 60 L.

4.1.1 Use-specific instructions for use

- Apply only on non-porous surfaces.

4.1.2 Use-specific risk mitigation measures

- During dipping, gloves and coated coverall have to be worn.
- Rinse materiel after treatment. The same PPE than those required during application have to be worn.
- Do not touch material until a total drying.
- If control task is needed, the same PPE as those required during the treatment have to be worn.

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

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

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4.1.5 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

Use 2 - Disinfection of empty breeding buildings and equipment by spraying

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfection of empty breeding buildings and equipment
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage:
Field(s) of use	Indoor Indoor use
Application method(s)	Method: Spraying Detailed description: The product is applied by spraying
Application rate(s) and frequencies	Application Rate: 200 to 400 mL of diluted product per m ² Dilution (%): 2 Number and timing of application: The product IODOL 100 is a soluble concentrate to be diluted in water with caution before use (2.0% v/v dilution). The recommended dose for spray application is 200 to 400 mL of diluted product per m ² .
Category(ies) of users	Professional
Pack sizes and packaging material	Individual HDPE containers : - jerry can of 5 and 20 L and, - drum of 60 L.

4.2.1 Use-specific instructions for use

- Apply only on non-porous surfaces.
- Apply the product with a low-pressure sprayer.

4.2.2 Use-specific risk mitigation measures

- During spraying: gloves, a mask APF 10 and an impermeable coverall have to be worn. During the cleaning of the equipment, impermeable coverall and gloves must be worn.
- Rinse surface or materiel after treatment. The same PPE than during application have to be worn.
- Do not authorise re-entry before total drying of surface.
- If control task is needed, the same PPE as during treatment have to be worn.

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

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

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

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4.3 Use description

Use 3 - Disinfection of drinking water pipes for drinking water for animals

Product type

PT04 - Food and feed area (Disinfectants)

Where relevant, an exact description of the authorised use

Disinfection of drinking water pipe for drinking water for animals

Target organism(s) (including development stage)

Scientific name: Salmonella Typhimurium
Common name: Bacteria
Development stage:

Scientific name: Yeasts
Common name: Yeasts
Development stage:

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

Field(s) of use

Indoor

Indoor use

Application method(s)	<p>Method: Filling Detailed description: The product is applied by filling</p> <p>Method: Cleaning in place Detailed description: The product is applied by cleaning in place</p>
Application rate(s) and frequencies	<p>Application Rate: - Dilution (%): 1.5 Number and timing of application: Filling the drinking water pipe - bacteria and yeasts: 1.5% v/v dilution at 20°C Contact time : 30 minutes</p> <p>Application Rate: - Dilution (%): 0.2 Number and timing of application: Cleaning in place - bacteria and yeasts: 0.2% v/v dilution (residual pH 5 or 9 respectively after acidic or alkaline cleaning) at 10°C Contact time : 60 minutes</p>
Category(ies) of users	Professional
Pack sizes and packaging material	<p>Individual HDPE containers :</p> <ul style="list-style-type: none"> - jerry can of 5 and 20 L and, - drum of 60 L.

4.3.1 Use-specific instructions for use

<ul style="list-style-type: none"> - For the disinfection of drinking water pipes for animals by filling, a minimum temperature of 20°C has to be respected to guarantee the efficacy of the product IODOL 100 - For the disinfection of drinking water for animals by CIP applications before disinfection, residual pH of the surfaces after the cleaning (acidic or alkaline) and rinsing, has to be strictly in compliance with the conditions of uses to guarantee the efficacy of the product IODOL 100.
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4.3.2 Use-specific risk mitigation measures

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4.3.3 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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4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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4.3.5 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 use

5.1. Instructions for use

- Always read the label or leaflet before use and respect follow all the instructions provided.
- Clean carefully the surfaces before application of the product.
- The diluted solution should be used immediately.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder.
- Pour gradually the product into the water while stirring slowly to avoid the formation of too much foam and overflow.

5.2. Risk mitigation measures

During mixing and loading exposure (corrosive product) has to be limited by use of PPE and application of technical and organisational RMM like:

- Minimisation of manual phases;
- Regular cleaning of equipment and work area;
- Avoidance of contact with contaminated tools and objects;
- Training and management of staff on good practice.

PPE:

- Task appropriate gloves;
- Coated coverall with appropriate barrier material based on potential for contact with the chemicals;
- Eye protection.

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

Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Contact poison treatment specialist if symptoms occur.

Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with warm water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.

Mouth contact: Wash out mouth with water. Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities.

Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.

Inhalation: Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.

Keep the container or label available.

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

- Dispose of unused product, its packaging and all other waste in accordance with local regulations.
- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.

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

Shelf-life : 2 years

6. Other information

The final 2 years at ambient temperature storage study should be required in post-authorization.

According to the persistent foaming test, the volume of foam is higher than the acceptable limit. Additional data have been provided following the data requirement of ANSES indicating that the product is not a foaming product in specific conditions. However, the conditions carried out are not considered as representative of the real conditions of uses. Therefore, a report with a photo/video demonstrating that there are no risks for the operator (farmer or livestock service provider) when the product is diluted at the maximum concentrations of use in the appropriate tanks in the field and during the application (for spraying in the livestock buildings and soaking) of the biocidal product in the real conditions should be provided in post-authorization, within a 2 months delay.