

# 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:** 945-1

**R4BP 3 asset reference number:** DK-0021900-0000

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## Administrative information

### 1.1. Trade names of the product

IODOL 100
IODAVIC
AQUACEET IODE

### 1.2. Authorisation holder

<b>Name and address of the authorisation holder</b>	Name	HUVEPHARMA SA
	Address	34, rue Jean Monnet ZI d'Étriché - Segré 49500 Segré-en-Anjou Bleu France
<b>Authorisation number</b>	945-1	
<b>R4BP 3 asset reference number</b>	DK-0021900-0000	
<b>Date of the authorisation</b>	10/08/2020	
<b>Expiry date of the authorisation</b>	20/08/2028	

### 1.3. Manufacturer(s) of the biocidal products

<b>Name of the manufacturer</b>	HUVEPHARMA SA
<b>Address of the manufacturer</b>	34, rue Jean Monnet, Z.I. d'Etriché 49500 Segré-en-Anjou Bleu France
<b>Location of manufacturing sites</b>	12 rue de Malacussy 42100 Saint Etienne France

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

<b>Active substance</b>	1319 - Iodine
<b>Name of the manufacturer</b>	HYPRED
<b>Address of the manufacturer</b>	57 boulevard Jules Verger BP10180 35803 Dinard Cedex France
<b>Location of manufacturing sites</b>	57 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	1,01
Orthophosphoric acid		Non-active substance	7664-38-2	231-633-2	7,55
Alcohols, C12-14, ethoxylated		Non-active substance	68439-50-9	500-213-3	6,75

### 2.2. Type of formulation

SL - Soluble concentrate
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## 3. Hazard and precautionary statements

### Hazard statements

May be corrosive to metals.

Causes severe skin burns and eye damage.

May cause damage to organs (thyroid) through prolonged or repeated exposure .

Harmful to aquatic life with long lasting effects.

Corrosive to the respiratory tract.

Causes serious eye damage.

### Precautionary statements

Do not breathe spray.

Wash thoroughly after handling.

Avoid release to the environment.

Wear .

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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

Wash contaminated clothing before reuse.

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

Immediately call a .

Specific treatment (see on this label).

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 to .

Get medical if you feel unwell.

## 4. Authorised use(s)

### 4.1 Use description

#### Use 1 - Disinfection of equipment for animals by soaking

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Disinfection of equipment
<b>Target organism(s) (including development stage)</b>	Scientific name: Bacteria Common name: Bacteria Development stage:
<b>Field(s) of use</b>	Indoor  Indoor use
<b>Application method(s)</b>	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, protective chemical resistant glove (glove material to be specified by the authorisation holder within the product information) and protective coverall (at least type 6) which is coated (coverall material to be specified by the authorisation holder within the product information) shall 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

<b>Product type</b>	PT03 - Veterinary hygiene (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Disinfection of empty breeding buildings and equipment
<b>Target organism(s) (including development stage)</b>	Scientific name: Bacteria Common name: Bacteria Development stage:
<b>Field(s) of use</b>	Indoor  Indoor use
<b>Application method(s)</b>	Method: Spraying Detailed description: The product is applied by spraying
<b>Application rate(s) and frequencies</b>	Application Rate: 200 to 400 mL of diluted product per m <sup>2</sup> 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) at 10°C. Contact time: 30 minutes  The dose for spray application is 200 to 400 mL of diluted product per m <sup>2</sup> .
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	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: protective chemical resistant glove (glove material to be specified by the authorisation holder within the product information), protective coverall (at least type 4) which is impermeable (coverall material to be specified by the authorisation holder within the product information) and a mask APF 10 shall be worn.
- During the cleaning of the equipment, protective chemical resistant glove (glove material to be specified by the authorisation holder within the product information) and protective coverall (at least type 4) which is impermeable (coverall material to be specified by the authorisation holder within the product information) 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.

- Do not use the b.p. in animal housings where exposure to a STP cannot be prevented.

#### 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

<b>Product type</b>	PT04 - Food and feed area (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	Disinfection of drinking water pipe for drinking water for animals
<b>Target organism(s) (including development stage)</b>	Scientific name: Yeasts Common name: Yeasts Development stage:  Scientific name: bacteria Common name: Bacteria Development stage:
<b>Field(s) of use</b>	Indoor  Indoor use
<b>Application method(s)</b>	Method: Filling Detailed description: The product is applied by filling  Method: Cleaning in place Detailed description: The product is applied by cleaning in place
<b>Application rate(s) and frequencies</b>	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

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

**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.

**4.3.1 Use-specific instructions for use**

- 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.  
 - Rinse drinking water pipes after treatment.

**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.

During handling of the product, the following PPE are mandatory,:

- Protective chemical resistant glove (glove material to be specified by the authorisation holder within the product information)
- Protective coverall (coverall material to be specified by the authorisation holder within the product information);
- 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

Etiketten skal indeholde nedenstående oplysninger. Oplysninger i citationstegn skal angives ordret:

1) I hovedfeltet:  
"Desinfektionsmiddel

Må kun anvendes som desinfektionsmiddel mod bakterier ved sprøjtning af tomme avlsbygninger og udstyr til dyr, samt ved iblødsætning af udstyr til dyr i en 2,0 % v/v fortynding. Må kun anvendes som desinfektionsmiddel mod bakterier og gærsvampe i drikkevandsledninger til dyr ved gennemskylning i en 0,2 % v/v fortynding og ved påfyldning i en 1,5 % v/v fortynding. Produktet er kun til erhvervsmæssigt brug.

2) I advarselsfeltet:

"FARE

Forårsager svære forbrændinger af huden og øjenskader (H314)

Kan forårsage skader på skjoldbruskkirtlen ved længerevarende eller gentagen eksponering (H373)

Skadelig for vandlevende organismer, med langvarige virkninger (H412)

Kan ætse metaller (H290)

Indånd ikke spray.

Undgå udledning til miljøet.

Ætsende for luftvejene.

"Bær beskyttelsestøj, øjenbeskyttelse, ansigtsmaske (ved sprøjtning) samt kemisk resistente beskyttelseshandsker ved brug af produktet. (P280)". Handske og tøjmateriale skal angives af godkendelsesindehaveren i produktdatabladet.

"

Vask huden grundigt efter brug.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes som desinfektionsmiddel mod bakterier ved sprøjtning af tomme avlsbygninger og udstyr til dyr, samt ved iblødsætning af udstyr til dyr i en 2,0 % v/v fortynding. Må kun anvendes som desinfektionsmiddel mod bakterier og gærsvampe i drikkevandsledninger til dyr ved gennemskylning i en 0,2 % v/v fortynding og ved påfyldning i en 1,5 % v/v fortynding. Produktet er kun til erhvervsmæssigt brug.

Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.

Må ikke tømmes i kloak afløb.

Må ikke anvendes hvor der kan ske afledning til kloak afløb.

Opbevares under lås og utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.  
Levnedsmidler og foderstoffer må ikke forurennes."

Farepiktogrammet GHS05.

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp, herunder:

"Hvis der er brug for lægehjælp, medbring da beholderen eller etiketten.

I TILFÆLDE AF INDTAGELSE: Skyl munden. Fremkald IKKE opkastning. Ring omgående til GIFTINFORMATION/læge.

VED KONTAKT MED HUDEN (eller håret): Alt tilsmudset tøj tages straks af. Skyl huden med vand. Ring omgående til GIFTINFORMATION/læge.

Alt tilsmudset tøj skal vaskes inden genanvendelse.

VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning. Ring omgående til GIFTINFORMATION/læge."

3) I deklarationsfeltet:

- a) Teksten "Desinfektionsmiddel BPR-reg. nr. 945-1. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".
- b) Oplysning om præparattype: " flydende koncentrat" for dette præparat.
- c) Indholdet af aktivstof i vægtprocent (% w/w) og g/L ved 20 °C.
- d) Udløbsdatoen skal anføres. Denne dato må højst være 2 år efter produktionsdatoen. Etikettens dato kan udformes som en henvisning til en produktionsdato andetsteds på emballagen.
- e) Batchnummer eller – betegnelse skal anføres.
- f) Pakningsstørrelse i L.
- g) Godkendelsesindehavers navn og adresse.

4) Brugsanvisningen:

Oplysninger om målorganismer, anvendelsesområde og doseringer.

Brugsanvisningen skal rettes til efter effektivitetsvurderingen foretaget af den kompetente myndighed i første godkendelsesland. Denne forefindes i bilag 2 "Product Assessment Report".

Følgende retningslinjer gælder i forhold til bortskaffelse.

Der skal mærkes med sikkerhedssætning P501: "Indholdet/holderen bortskaffes i overensstemmelse med kommunale regler for affaldshåndtering."

Derudover skal mærkningen ske efter retningslinjerne:

"Rester skal afleveres til den kommunale affaldsordning for farligt affald. Tomme beholdere kan bortskaffes med dagrenovationen."