

Summary of product characteristics for a biocidal product

Product name: Ioklene Concentrate

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

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Authorisation number: EU-0020125-0000

R4BP 3 asset reference number: IS-0026281-0001

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Administrative information

1.1. Trade names of the product

Ioklene Concentrate, Coars Dual

1.2. Authorisation holder

Name and address of the authorisation holder

Name	GEA Farm Technologies GmbH
Address	Siemensstraße 25-27 59199 Bönen Germany
Authorisation number	EU-0020125-0000 1-1

R4BP 3 asset reference number

IS-0026281-0001

Date of the authorisation

19/11/2019

Expiry date of the authorisation

31/10/2029

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

GEA Farm Technologies

Address of the manufacturer

Wylve Works BA12 9HT Warminster United Kingdom
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Location of manufacturing sites

Wylve Works, Watery Lane BA12 9HT Warminster United Kingdom

Gewerbestraße 5 5325 Plainfeld Austria
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ul. Olowiana 10 85-461 Bydgoszcz Poland

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

Active substance	1319 - Iodine
Name of the manufacturer	SQM Europe N.V.
Address of the manufacturer	St Pietersvliet 7, bus 8 2000 Antwerp Belgium
Location of manufacturing sites	Sociedad Quimica y Minera SA, Los Militares, Las Condes 4290 Piso 4 Santiago Chile
Active substance	1319 - Iodine
Name of the manufacturer	Nihon Tennen Gas Co., Ltd (Via Mitsui & Co Europe PLC)
Address of the manufacturer	Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun, 299-4205 Chosei-Gun Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun, 299-4205 Chosei-Gun Japan
Active substance	1319 - Iodine
Name of the manufacturer	Norkem Ltd
Address of the manufacturer	Norkem House, Bexton Lane, WA16 9FB Knutsford United Kingdom
Location of manufacturing sites	OFICINA CALA CALA S/N Unknown POZO ALMONTE Chile

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	1,58
C9-11 Alcohol Ethoxylate	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060	Non-active substance	68439-46-3	614-482-0	1,51

2.2. Type of formulation

SL - Soluble concentrate

3. Hazard and precautionary statements

Hazard statements

Causes serious eye irritation.
May cause damage to organs Thyroid gland through prolonged or repeated exposure .
May be corrosive to metals.
Toxic to aquatic life with long lasting effects.

Precautionary statements

Do not breathe vapours.
Wash hands thoroughly after handling.
Wear protective gloves.
Wear protective clothing.
Wear eye protection.
IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.
Get medical attention if you feel unwell.
If eye irritation persists:Get medical advice.
Collect spillage.
Dispose of container to according to local regulations.
Dispose of contents to according to local regulations.

4. Authorised use(s)

4.1 Use description

Use 1 - Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking - Dipping

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

-

Scientific name: Bacteria

Target organism(s) (including development stage)

Common name: Bacteria
Development stage: All

Scientific name: Other: Yeast
Common name: Other: Yeast
Development stage: All

Field(s) of use

Indoor

-

Application method(s)

Method: Open system: dip treatment
Detailed description:

Application via dip Cup: Using a traditional dip cup with non-return valves, dispense diluted product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking

The same solution can be applied to multiple animals during the same milking session. Cups should be refilled with fresh solution before starting new milking session

Application rate(s) and frequencies

Application Rate: Quantity of diluted product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)

Dilution (%): Product to be diluted by the relevant rate stated on the label. Either; 25% (1 part product to 3 parts water) 20 % (1 part product to 4 parts water) 12.5% (1 part product to 7 parts water) In use concentration of products between 0.29 and 0.52% (w/w) iodine.

Number and timing of application:
2 post milking applications per animal, per day

Category(ies) of users

Trained professional

Professional

Pack sizes and packaging material

Drum, Plastic: HDPE , 10 l
Drum, Plastic: HDPE , 20 l
Drum, Plastic: HDPE , 25 l
Drum, Plastic: HDPE , 200 l
IBC (intermediate bulk container), Plastic: HDPE , 1000 l
Drum, Plastic: HDPE , 5 l

All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.

All drums are capped with tamper evident caps or bungs and are UN certified.

4.1.1 Use-specific instructions for use

Dip at least 2/3 of the teat length with diluted product immediately after milking

4.1.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection

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

See general directions for use

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

See general directions for use

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

See general directions for use

4.2 Use description

Use 2 - Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking - Spraying

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

-

Target organism(s) (including development stage)

Scientific name: Bacteria
Common name: Bacteria
Development stage: All

Scientific name: Yeast
Common name: yeast
Development stage: All

Field(s) of use

Indoor
-

Application method(s)

Method: Open system: spray treatment
Detailed description:
Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the diluted product. The diluted product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the diluted product

Application via manual trigger spray: Fill trigger spray bottle with diluted product. Use trigger spray to cover the bottom two thirds of each teat with diluted product

Application rate(s) and frequencies

Application Rate: Quantity of diluted product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)
Dilution (%): Product to be diluted by the relevant rate stated on the label. Either; 25% (1 part product to 3 parts water) 20 % (1 part product to 4 parts water) 12.5% (1 part product to 7 parts water) In use concentration of products between 0.29 and 0.52% (w/w) iodine.
Number and timing of application:
2 post milking applications per animal, per day

Category(ies) of users

Trained professional

Professional

Pack sizes and packaging material

Drum, Plastic: HDPE , 10 l
Drum, Plastic: HDPE , 20 l
Drum, Plastic: HDPE , 25 l
Drum, Plastic: HDPE , 200 l
IBC (intermediate bulk container), Plastic: HDPE , 1000 l
Drum, Plastic: HDPE , 5 l

All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured.
All drums are capped with tamper evident caps or bungs and are UN certified.

4.2.1 Use-specific instructions for use

Spray at least 2/3 of the teat length with diluted product immediately after milking

4.2.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).
Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information)

A protective coverall (at least type 6, EN 13034) shall be worn

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection

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

See general directions for use

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

See general directions for use

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

See general directions for use

4.3 Use description

Use 3 - Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking - Foaming

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

-

Target organism(s) (including development stage)

Scientific name: Bacteria
Common name: Bacteria

Development stage: All

Scientific name: yeast
Common name: yeast
Development stage: All

Field(s) of use

Indoor

-

Application method(s)

Method: Open system: dip treatment
Detailed description:

Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder

The same solution can be applied to multiple animals during the same milking session.

Application rate(s) and frequencies

Application Rate: Quantity of diluted product to be applied per application; - cows and buffaloes: 3 to 10ml (5 ml recommended) - sheep 1.5 to 5 ml (1.5 ml recommended) - goats 2.5 to 6 ml (2.5 ml recommended)

Dilution (%): Product to be diluted by the relevant rate stated on the label. Either; 25% (1 part product to 3 parts water) 20% (1 part product to 4 parts water) 12.5% (1 part product to 7 parts water) In use concentration of products between 0.29 and 0.52% (w/w) iodine.

Number and timing of application:
2 post milking applications per animal, per day

Category(ies) of users

Trained professional

Professional

Pack sizes and packaging material

Drum, Plastic: HDPE , 10 l

Drum, Plastic: HDPE , 20 l

Drum, Plastic: HDPE , 25 l

Drum, Plastic: HDPE , 200 l

IBC (intermediate bulk container), Plastic: HDPE , 1000 l

Drum, Plastic: HDPE , 5 l

All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour.

IBCs are natural coloured.

All drums are capped with tamper evident caps or bungs and are UN certified.

4.3.1 Use-specific instructions for use

Dip at least 2/3 of the teat length with diluted product immediately after milking

4.3.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection

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

See general directions for use

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

See general directions for use

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

See general directions for use

5. General directions for use

5.1. Instructions for use

Keep out of reach of children
Always read the label or leaflet before use and follow all the instructions provided.
The product must be brought to a temperature above 20°C before use.
Dilute product before application according to the ratio specified on the product label

For manual dilution of the concentrate; Add the ratio of concentrate and water, specified on the product label, to a suitably sized container to achieve the required dilution rate. Mix to a uniform solution.
Before attaching the milking cluster, all teat-dip residues should be removed with either a single use towel or re-usable cloth. One cloth should be used per cow

For effective use against bacteria and yeast, product must be left in contact with the skin for at least 60 seconds

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).
Product can be used during the entire lactation period

5.2. Risk mitigation measures

See section 2.1.4.2 of the relevant use

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

Remove and wash contaminated clothing before re-use.
After inhalation: Move to fresh air in case of accidental inhalation of fumes from overheating or combustion.
If you feel unwell, seek medical advice.
After contact with skin: Wash with water and soap as a precaution. Consult a doctor if skin irritation persists.
After contact with eyes: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical treatment by eye specialist.
After ingestion: Rinse out mouth and give plenty of water to drink. Never give anything by mouth to an unconscious person. Consult a physician.

Large spills should be contained using a chemical spill kit, soaked up using absorbent material such as kieselguhr and disposed of as Hazardous waste.

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

At the end of the treatment, dispose of unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual farm based waste water treatment plant.

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

Protect from frost

Do not store at temperatures above 30 °C

Shelf life 12 months

6. Other information

The signal word, hazard- and precautionary statements shall be in Icelandic on the product label.

Signal word:

Varúð

Hazard statements:

- H319** Veldur alvarlegri augnertingu.
- H373** Getur skaðað líffæri (skjaldkirtill) við langvinn eða endurtekin áhrif.
- H290** Getur verið ætandi fyrir málma.
- H411** Eitrað lífi í vatni, hefur langvinn áhrif.

Precautionary statements:

- P260** Andið ekki að ykkur gufu.
- P264** Þvoið hendur vandlega eftir meðhöndlun.
- P280** Notið hlífðarhanska.
- P280** Notið hlífðarfatnað.
- P280** Notið augnhlífur.
- P305 + P351 + P338** BERIST EFNID Í AUGU: Skolið varlega með vatni í nokkrar mínútur. Fjarlægjið snertilinsur ef það er auðvelt. Skolið áfram.
- P314** Leitið lækni ef lasleika verður vart.
- P337 + P313** Ef augnerting er viðvarandi: Leitið lækni.
- P391** Safnið upp því sem hellist niður.
- P501** Fargið ílát í samræmi við staðbundnar reglur.
- P501** Fargið innihaldi í samræmi við staðbundnar reglur.