

Summary of product characteristics for a biocidal product

Product name: Tincture of Iodine 2.5

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

Authorisation number: IE/BPA 70259

R4BP 3 asset reference number: IE-0014569-0000

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Administrative information

1.1. Trade names of the product

Iodine Tincture
Tincture of Iodine 2.5%

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Foran Healthcare Limited
	Address	Goresbridge R95 EKH4 Kilkenny Ireland
Authorisation number	IE/BPA 70259	
R4BP 3 asset reference number	IE-0014569-0000	
Date of the authorisation	06/06/2018	
Expiry date of the authorisation	06/06/2028	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Foran Healthcare Ltd.
Address of the manufacturer	Unit 4, Purcellsinch Industrial Estate, Dublin Road R95 WV80 Kilkenny Ireland
Location of manufacturing sites	2 Cherry Orchard Industrial Estate 10 Dublin 10 Ireland
	Unit 4, Purcellsinch Industrial Estate, Dublin Road R95 WV80 Kilkenny Ireland

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

Active substance	1319 - Iodine
Name of the manufacturer	Norkem Limited
Address of the manufacturer	Norkem House, Bexton Lane, Knutsford, Cheshire WA16 9FB Knutsford United Kingdom
Location of manufacturing sites	S.C.M. Cía. Minera Negreiros N/A 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	2,5
Ethanol	Ethanol	Non-active substance	64-17-5	200-578-6	92,5
Potassium Iodide		Non-active substance	7681-11-0	231-659-4	2,5
Purified Water		Non-active substance	7732-18-5		2,5

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	Highly flammable liquid and vapour. Toxic to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment. Collect spillage. Dispose of container to in accordance with national regulations.. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.

4. Authorised use(s)

4.1 Use description

Use 1 - Bacteriocidal Skin Tincture.

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Hygienic skin solution for the general disinfection of the navel area as part of good hygiene practice following: calving or lambing.
Target organism(s) (including development stage)	Scientific name: Staphylococcus aureus Common name: Bacteria, aerobic Gram-positive Development stage: Scientific name: Pseudomonas aeruginosa Common name: Bacteria, aerobic Gram-negative Development stage: Scientific name: Candida albicans Common name: Fungi/yeasts Development stage:
Field(s) of use	Outdoor Hygienic skin solution for the general disinfection of the navel area as part of good hygiene practice following: calving or lambing.
Application method(s)	Method: Open system: dip treatment Detailed description: Ensure navel area is free from visible debris and dirt. Place 5-10 ml of product in dedicated plastic navel dip container. Immerse navel in dedicated navel dip container and agitate or swirl to ensure complete coverage of the navel area with product.
Application rate(s) and frequencies	Application Rate: 5-10ml once daily for up to 5 days. Dilution (%): N/A Number and timing of application: Product is applied as soon as practically possible after animals birth and once every 24 hours thereafter for upto 5 days.
Category(ies) of users	Professional
Pack sizes and packaging material	Type of packaging - Bottle Size/volume of the packaging - 500ml Material of the packaging - PET Type and material of closure(s) - PET Intended user (e.g. professional, non-professional) - Professional Compatibility of the product with the proposed packaging materials (Yes/No) - Yes Type of packaging - Bottle Size/volume of the packaging - 1L

Material of the packaging - PET
Type and material of closure(s) - PET
Intended user (e.g. professional, non-professional) - Professional
Compatibility of the product with the proposed packaging materials (Yes/No) - Yes

Type of packaging - Bottle
Size/volume of the packaging - 2.5L
Material of the packaging - Brown PE
Type and material of closure(s) - Tamper Evident HDPE
Intended user (e.g. professional, non-professional) - Professional
Compatibility of the product with the proposed packaging materials (Yes/No) - Yes

Type of packaging - Bottle
Size/volume of the packaging - 5L
Material of the packaging - Brown PE
Type and material of closure(s) - Tamper Evident HDPE
Intended user (e.g. professional, non-professional) - Professional
Compatibility of the product with the proposed packaging materials (Yes/No) - Yes

4.1.1 Use-specific instructions for use

Ensure navel area is free from visible debris and dirt.
Place 5-10 ml of product in dedicated plastic navel dip container.
Immerse navel in dedicated navel dip container and agitate or swirl to ensure complete coverage of the navel area with product.
The above steps may be repeated once daily for up to 5 days to ensure complete hygiene control.

4.1.2 Use-specific risk mitigation measures

Avoid contact with skin and eyes. Wear protective gloves and clothing.

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

Do not allow product to enter drains directly.

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

Do not reuse packaging. Dispose of product and packaging in accordance with national waste regulations.

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

Store in a cool, dry, well ventilated area. Keep containers tightly closed. Store upright in original container. Protect from freezing.

5. General directions for use

5.1. Instructions for use

Ensure navel area is free from visible debris and dirt.
Place 5-10 ml of product in dedicated plastic navel dip container.
Immerse navel in dedicated navel dip container and agitate or swirl to ensure complete coverage of the navel area with product.
The above steps may be repeated once daily for up to 5 days to ensure complete hygiene control.

5.2. Risk mitigation measures

Keep away from sources of ignition.
Store in a cool, dry, well ventilated area. Keep containers tightly closed. Store upright in original container. Protect from freezing.

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

Inhalation may cause coughing, tightness of chest and irritation of the respiratory system. Move exposed person to fresh air.
If in eyes: rinse immediately with plenty of water for 15 minutes holding the eyelids open.
If on skin: wash off immediately with plenty of soap and water. Remove contaminated clothing.
Ingesting may cause nausea and vomiting.
Seek medical attention if irritation or symptoms persist.

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

Do not reuse packaging.
Do not allow product to enter drains.
Dispose of product and container in accordance with national waste regulations.

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

Store in a cool, dry, well ventilated area. Keep containers tightly closed. Store upright in original container. Protect from freezing.
Shelf life:
- In amber PET with PET cap - 2 years
- In brown PE with HDPE lid - 2 years

6. Other information

N/A