

Summary of product characteristics for a biocidal product

Product name: Foradine 10

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

Authorisation number: IE/BPA 70254

R4BP 3 asset reference number: IE-0014570-0000

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Administrative information

1.1. Trade names of the product

Foradine 10
Povidone Iodine Solution 10%
Strong Iodine Solution 10%

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 70254	
R4BP 3 asset reference number	IE-0014570-0000	
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 Limited
Address of the manufacturer	Unit 4, Purcellsinch Industrial Estate, Dublin Road R95 WV80 Kilkenny Ireland
Location of manufacturing sites	Unit 2 Cherry Orchard Industrial Estate 10 Dublin 10 Ireland
	Unit 4, Purcellsinch Industrial Estate, Dublin Road, Kilkenny, R95 WV80, Ireland R95 WV80 Kilkenny Ireland

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

Active substance	1349 - Polyvinylpyrrolidone iodine
Name of the manufacturer	Prachi Pharmaceutical Pvt. Ltd.,
Address of the manufacturer	Plot No. E.108, MIDC, Tarapur, Doisar, Dist-Palghar 401506 Maharashtra India
Location of manufacturing sites	Plot No. E.108, MIDC, Tarapur, Doisar, Dist-Palghar 401506 Maharashtra India

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 (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		10
Isopropanol		Non-active substance	67-63-0	200-661-7	51,75
Purified Water		Non-active substance	7732-18-5	231-791-2	38,25

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness.
Precautionary statements	Avoid breathing spray. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. In case of fire: Use water spray to extinguish.

Wear protective gloves.

Wear eye protection.

Wear face protection.

Use only outdoors or in a well-ventilated area.

Call a POISON CENTER if you feel unwell.

Call a doctor if you feel unwell.

If eye irritation persists: Get medical advice.

If eye irritation persists: Get medical attention.

4. Authorised use(s)

4.1 Use description

Use 1 - Bacteriocidal Skin Spray & Dip

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Hygienic ready-to-use skin spray and/or dip for general disinfection of the navel area as part of good hygiene practice following: calving or lambing.
Target organism(s) (including development stage)	<p>Scientific name: Staphylococcus aureus Common name: Bacteria, aerobic Gram-positive Development stage:</p> <p>Scientific name: Pseudomonas aeruginosa Common name: Bacteria, aerobic Gram-negative Development stage:</p> <p>Scientific name: Candida albicans Common name: Fungi/yeasts Development stage: Yeast</p>
Field(s) of use	<p>Other</p> <p>Veterinary hygiene. Corporeal hygiene.</p>
Application method(s)	<p>Method: Open system: spray treatment Detailed description:</p> <p><u>For Spray Application</u> Wipe the area to be disinfected with a clean dry disposable towel before application, to remove any visible dirt and debris. Turn spray nozzle to the open position. Hold the spray 10cm from the area of skin where it is to be applied. Direct nozzle of spray towards the area to be disinfected and spray directly ensuring complete coverage of the area of application.</p> <p>Allow product to dry on skin. The above steps may be repeated once daily for up to 5 days to ensure complete</p>

hygiene control.

For Navel Dip Application
 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.

Application rate(s) and frequencies

Application Rate: Complete coverage of the area of application (For Spray application).
 Place 5-10 ml of product in dedicated plastic navel dip container (For Navel Dip Application).
 Dilution (%): N/A
 Number and timing of application:
 Product may be applied once daily for up to 5 days to ensure complete hygiene control.

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) - Trigger Spray (PP & PE)
 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 Cap (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 Cap (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

For Spray Application

Wipe the area to be disinfected with a clean dry disposable towel before application, to remove any visible dirt and debris.
Turn spray nozzle to the open position.
Hold the spray 10cm from the area of skin where it is to be applied.
Direct nozzle of spray towards the area to be disinfected and spray directly ensuring complete coverage of the area of application.
Allow product to dry on skin.
The above steps may be repeated once daily for up to 5 days to ensure complete hygiene control.

For Navel Dip Application

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. Always wear gloves when using this product. Avoid breathing vapours or spray. Ensure adequate ventilation of work area.

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 container tightly closed. Store upright in original container. Protect from freezing.
Keep out of reach of children.
Product shelf life: 18 months from date of manufacture.

5. General directions for use

5.1. Instructions for use

For Spray Application

Wipe the area to be disinfected with a clean dry disposable towel before application, to remove any visible dirt and debris.
Turn spray nozzle to the open position.
Hold the spray 10cm from the area of skin surrounding the navel.
Direct nozzle of spray towards the area to be disinfected and spray directly ensuring complete coverage of the area of application.
Allow product to dry on skin.
The above steps may be repeated once daily for up to 5 days to ensure complete hygiene control.

For Navel Dip Application

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. Keep out of reach of children. Always wear gloves when using this product. Avoid breathing vapours or spray. Ensure adequate ventilation of work area.

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

Causes serious eye irritation.

May cause drowsiness or dizziness.

Inhalation may cause coughing and tightness of chest. Move exposed person to fresh air.

If in eyes: rinse immediately with plenty of water for 15 minutes.

If on skin: Remove contaminated clothing and wash off immediately with water.

Seek medical attention if irritation or symptoms persist.

In case of fire use water spray for extinction.

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 container tightly closed. Store upright in original container. Protect from freezing.
Keep out of reach of children.
Shelf-life: 18 months.

6. Other information

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