IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10929/001/001**
Case No: 7005448

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Kilco Chemicals (Ire.) Limited

5 Harrington Street, **Dublin 8**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Co-Op Teat Dip

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **09/01/2007**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Co-op Teat Dip

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	Quantitative
Iodine	20 mg/ml

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Teat Dip/Spray Solution.
Brown/Black concentrate.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

As an aid in the prevention of mastitis in lactating dairy cattle.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

Teat dip cups should be emptied after each milking and washed thoroughly before re-use.
Wash and dry udders and teats before next milking.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the product to animals

Do not eat, drink or smoke whilst using the product.
Wash hands after use.
When the product is being applied through spray equipment avoid working in spray mist.
In case of contact with eyes, give prolonged irrigation with clean water and seek medical attention.
In case of ingestion, seek medical attention immediately.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product is a medicinal disinfectant intended as an aid against mastitis. It is designed to be used on lactating dairy cattle.

4.8 Interaction with other medicinal products and other forms of interaction

Do not mix with other products.
Incompatible with Chlorhexidine-based teat dips.

4.9 Amounts to be administered and administration route

For topical application to the teats and udder. This is a concentrated product, dilute before use.

Teat Dipping

Prepare a stock solution of 1 part Co-op Teat Dip to 2 parts water. Mix thoroughly. A fresh stock solution must be prepared daily. Fill a teat dipping cup 2/3rds full and immediately after each cow has been milked dip each teat in the solution ensuring that the entire surface of the teat comes into contact with the solution. Refill the teat cup with the stock solution of Co-op Teat Dip as necessary. Discard soiled teat dip solution. Wash teat cup after use. Wash teats before each milking.

Teat Spraying

Prepare a stock solution of 1 part Co-op Teat Dip to 2 parts water. Mix thoroughly. A fresh solution must be prepared daily. After each milking spray the entire surface of each teat with stock solution of Co-op Teat Dip. Wash teats before each milking.

Udder Washing

Use 25 mls (1 fl. oz.) of Co-op Teat Dip in 8.0 litres (2 gallons) of water to wash the teats and udder of each cow before milking. When mastitis is in the herd use 25 ml of product in 4 litres of clean water. Prepare a fresh solution daily. Use a separate cloth or preferably a disposable paper towel for each cow.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The product is applied externally to the teat surface only.

4.11 Withdrawal Period(s)

Meat and offal: Zero days

Milk: Zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Phamacotherapeutic group: Antiseptics and disinfectants, iodine.
ATCvet code: QD08AG03

5.1 Pharmacodynamic properties

Iodine is a halogen element being a member of Group VIII of the Periodic Table. In common with other members of this group, notably chlorine, it is a broad-spectrum bactericide useful for skin disinfection.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyoxyethylene 9-nonyl phenol
Polyoxyethylene 8-primary C9/C11 alcohol
Polyethylene glycol 75 lanolin
Propane 1.2-diol
Sodium acetate
Deionised water

6.2 Incompatibilities

Do not mix with Chlorhexidine Digluconate.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 1 year.
Use diluted product immediately.

6.4 Special precautions for storage

Store upright, tightly closed in the original container.
Store below 25°C.
Protect from frost.

6.5 Nature and composition of immediate packaging

HDPE containers containing 5, 10 or 25 litres. Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

The product is harmful to fish, care should be taken to ensure that neither waste product nor used containers enter waterways, ponds, ditches etc..
Unused product or empty containers should be disposed of in accordance with guidance from an appropriate waste regulation authority.

7 MARKETING AUTHORISATION HOLDER

Kilco Chemicals Ireland Ltd
1A Trech Road
Mallusk
Newtownabbey
BT36 8TY

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10929/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

9th January 2007

10 DATE OF REVISION OF THE TEXT