#### MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

### 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Evans Vanodine International Plc Brierley Road Walton Summit Preston lancashire PR5 8AH

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

3TX 1:3 2.15% w/v CONCENTRATE FOR TEAT DIP AND TEAT SPRAY SOLUTION

#### 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

3TX 1:3 2.15% w/v concentrate for teat dip and teat spray solution contains 21.5 mg/ml available iodineand 20 mg/ml glycerol and 180 mg/ml sorbitol.

#### 4. PHARMACEUTICAL FORM

Concentrate for teat dip and teat spray solution.

#### 5. PACKAGE SIZE

5,25,60,200,1000 Litres

Additional wording required on 200 and 1000 litre labels:

200 litre label: This container should not be returned for re-filling.

1000 litre label: This container should not be returned for re-filling. Ensure that all equipment and containers used for decanting not more than enough product for use that day, are fit for purpose, clean, emptied after use and washed before re-use.

#### 6. INDICATION(S)

3TX 1:3 2.15% w/v concentrate for teat dip and spray solution is an iodophor-based teat dip and teat spray which has been specially formulated to help reduce the bacterial contaminationthat causes mastitis in dairy herds.

3TX 1:3 2.15% w/v concentrate for teat dip and spray solution reduces the risk of infection by leaving an antiseptic film of iodine adhering to teats which have been treated by dipping or spraying.

3TX 1:3 2.15% w/v concentrate for teat dip and spray solution contains 20 mg/ml Glycerol and 180 mg/ml Sorbitol )5 mg/ml Glycerol and 45 mg/ml Sorbitol when diluted) to help keep the teats soft and supple, and to aid in the prevention and healing of sores and cracks.

#### 7. CONTRAINDICATIONS

None identified.

#### 8. ADVERSE REACTIONS

The product may cause an allergic reaction in some animals. In the rare case of a suspected or proven allergy in the herd, it is recommended to change to a non-iodine teat disinfectant.

#### 9. TARGET SPECIES

Dairy cows.

#### 10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

**TEAT DIP or SPRAY:** (5,000 ppm available lodine)

Dilute one part **3TX 1:3** 2.15% w/v concentrate for teat dip and teat spray solution with three parts clean water and mix well.

**UDDER WASH & CLUSTER DIP:** (40 ppm available lodine)

Dilute one part **3TX 1:3** 2.15% w/v concentrate for teat dip and teat spray solution with 500 parts clean water (20 ml to 10 litres or 1 fl. oz in 3 gall.)

## **Directions for use**

**TEAT DIPPING**: Fill teat cup about two-thirds full with the prepared solution. Dip teats of every cow immediately after each has been milked, making sure that the full length of the teat is immersed. Top up with fresh solution as required. Empty and wash out cups after milking.

**TEAT SPRAYING:** Immediately after milking, spray the entire surface of each teat of every cow with prepared solution.

#### UDDER WASHING AND CLUSTER DIPPING: Dilute 1:500.

To help prevent cross infection, individual cloths or disposable paper towels are strongly recommended. Dry teats before milking. Immerse clusters and agitate for at least half a minute. Rinse in clean water before use. Wash and dry udders and teats before milking.

#### **11. ADVICE ON CORRECT ADMINISTRATION**

#### CONCENTRATE

The following safety phrases relate to the concentrated product only, and do not apply once the product is diluted to the working solution:

Risk of serious damage to eyes. Wear eye/face protection when preparing the dip or spray.

#### DILUTED WORKING SOLUTION

When using as a spray, avoid working in spray mist. Avoid contact with eyes.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed, seek medical advice immediately and show this label. Hands and exposed skin should be washed after using this product.

Do not eat, drink or smoke while using the product.

Keep away from food, drink and animal feedstuffs.

#### 12. WITHDRAWAL PERIOD

Milk: Zero hours. Meat: Zero days.

#### **13. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C. Store in original tightly closed container. Protect from frost. Diluted product should not be stored above 25°C. Protect from light. Once diluted use the product within 3 months. Store diluted product only in glass or plastic containers.

#### 14. SPECIAL WARNING(S)

For animal treatment only. For external use only. Keep out of the sight and reach of children.

Not be used in conjunction with any other teat dip product.

lodine based teat dips are not compatible with chlorhexidine based products, hypochlorite solutions and other oxidising agents and alkaline soaps and detergents. If signs of disease persist or appear, consult your veterinary surgeon.

#### **15. EXPIRY DATE**

# 16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

**HARMFUL TO FISH AND AQUATIC LIFE.** Do not contaminate ponds, waterways or ditches with the product or empty container. Dispose of any unused product and empty containers in accordance with local requirements. To dispose of unused product to land you must have an authorisation under the Groundwater Regulations 2009.

#### 17. DATE ON WHICH THE LABEL WAS LAST APPROVED

July 2015

# 18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

[Distribution category]

AVM-GSL

**19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"** Keep out of the sight and reach of children.

#### 20. MARKETING AUTHORISATION NUMBER(S)

Vm <number>

Amended pages: October 2017 AN: 00294/2017

Vm03940/4098

#### 21. MANUFACTURER'S BATCH NUMBER

#### 22. OTHER INFORMATION>

# Approved: 09/10/2017 Ffrey

