Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
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(Germany)

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Dermastitis Blocker

Date: 08 August 2018

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0180/001/MR
Name, strength and pharmaceutical form	Dermastitis Blocker, 3mg/ml, Teat Dip Solution
Applicant	Ferdinand Eimermacher GmbH & Co.KG Chemische Fabrik Westring 24 48356 Nordwalde Germany
Active substance(s)	Iodine
ATC Vetcode	QD08AG03
Target species	Cattle
Indication for use	Teat disinfection as part of a strategy of reduction in the incidence of mastitis in lactating cattle (mastitis prophylaxis)

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition procedure	28.03.2018
Date product first authorised in the Reference Member State (MRP only)	17.02.2014
Concerned Member States for original procedure	AT, BE, CZ, DK, FR, IT, LU, NL, PL, SK

I. SCIENTIFIC OVERVIEW

The safety and efficacy aspects of this product are identical to the reference product Fink Euter-Dip 3000 (BVL no. 400080.00.00) with one exception. Dermastitis Blocker is indicated only for use in cattle, while the reference product Fink Euter-Dip 3000 has been authorized for usage in cattle, sheep and goats.

The initial application for Fink Euter-Dip 3000 was assessed before there was a requirement to have a public assessment report, therefore, no details in this section are available.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains 3.08 mg Iodine per ml and Macrogol lauryl ether 9, Macrogol lauryl ether 2, C9-11 Pareth-6, Glycerol (85%), Allantoin, Sodium acetate trihydrate, Potassium iodide, (S)-Lactic acid (for pH adjustment), Sodium hydroxide (50%; for pH adjustment) and Purified water as excipients.

The container/closure system:

Canister made of high density polyethylene (HDPE) containing 5kg (4.9 l), 10kg (9.7 l), 20kg (19.5 l) and 25kg (24.3 l) with HDPE closure caps with LDPE-foam sealing material.

Canister made of HDPE containing 60 kg (58.4 l) with HDPE closure cap with EPDM sealing material.

Drum made of HDPE containing 200 kg (194.7 l) with PP closure cap with PE sealing material and container made of HDPE containing 1000 kg (973.2 l) with HDPE closure cap with PE-foam sealing material.

The information to packaging material and the conducted tests meet the requirements.

The choice of the formulation is justified.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

C. Control of Starting Materials

The active substance is Iodine, an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

There are no substances within the scope of the TSE Guideline „Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products“ present or used in the manufacture of this product.

D. Control on intermediate products

Not applicable.

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been

justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmacological and toxicological tests are not required.

The toxicological aspects of this product are identical to the reference product.

User Safety

A user risk assessment was provided in compliance with the relevant guideline which shows that the product is considered to be safe to use when following the data cited on the SPC and product literature.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore the following applicant's user recommendations are appropriate:

- This medicinal product can irritate the eyes and skin. Avoid contact with the eyes. If eye contact does occur, rinse immediately with plenty of clean water and visit your doctor.
- Avoid contact with the skin. It is recommended to wear gloves during application. Wash exposed areas of skin.
- Exposure to iodine can lead to sensitisation. This medicinal product can cause an allergic reaction in persons with a known hypersensitivity to iodine.
- Oral ingestion of this medicinal product can harm health. Drink plenty of water and seek medical advice immediately.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because:
The initial predicted environmental concentration in soil (PECsoil, initial = 91.3 µg/kg) is less than 100 µg/kg.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted. The applicant has provided sufficient bibliographical data.

MRLs

The active ingredient iodine is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions *(according to Article 14(7) of Regulation (EC) No 470/2009)*	Therapeutic Classification
Iodine and iodine inorganic compounds including: — Sodium and potassium-iodide — Sodium and potassium-iodate — Iodophors including polyvi-nylpyr-rolidone-iodine	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY

The excipients, when used in concentrations as in this product, are either allowed substances for which Table 1 of the Annex to Commission Regulation (EU) No 37/2010 indicates that no MRL is required or are considered as not falling within the scope of Regulation (EC) No 470/2009 with regard to residues of veterinary medicinal products in foodstuffs of animal origin.

Withdrawal Periods

A quantitative risk assessment provided by the applicant indicated that the iodine transfer into cow milk resulting from use of the product is unlikely to pose a risk to the consumer. Furthermore, no relevant increase in tissue iodine content is expected from the use of the product.
Based on this, a withdrawal period of zero days for edible tissues and zero days for milk derived from treated cattle are justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13 (3) of Directive 2001/82/EC as amended 2001, and similarity with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product

IV.A Pre-Clinical Studies

Pharmacology

The applicant has provided preclinical data, including an *in-vitro* suspension test for the evaluation of bactericidal, yeasticidal and fungicidal activity in order to show similar efficacy of Dermastitis Blocker and Fink Euter-Dip 3000.

Tolerance in the Target Species of Animals

The applicant has presented data from literature to support the tolerance of the target species to Dermastitis Blocker.
The product literature accurately reflects the type and incidence of adverse effects which might be expected.

Resistance

Data from recent literature did not show any evidence for resistance to iodine or cross-resistance to antibiotics.

IV.B Clinical Studies

Similarity of Dermastitis Blocker and the reference product Fink Euter-Dip 3000 has been demonstrated, therefore, no clinical studies are needed.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

Date	Type of change
28th March 2018	Mutual recognition procedure (new CMS: AT, BE, CZ, DK, FR, IT, LU, NL, PL, SK)
25th October 2016	Change in pack size of the finished product and in packaging material not in contact with the finished product
03rd June 2014	Change in the invented name from Eimü Dip 3000 to Dermastitis Blocker