FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Dectospot 10 mg/ml Pour-on Solution for Cattle and Sheep

French agency for food, environnemental and occupational health safety– French Agency for Veterinary Medicinal Products
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MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0293/001/DC
Name, strength and pharmaceutical form	Dectospot 10 mg/ml Pour-on Solution for Cattle and Sheep
Applicant	Cross Vetpharm Group Ltd. Broomhill Road, Tallaght, Dublin 24
Active substance(s)	Deltamethrin
ATC Vetcode	QP53AC11
Target species	Cattle and sheep
Indication for use	Prevention and treatment of infestations by the following external parasites: On cattle: For the treatment and prevention of infestations by both sucking and biting lice, including *Bovicola bovis, Solenopotes capillatus, Linognathus vituli* and *Haematopinus eurysternus*. Also as an aid in the treatment and prevention of infestations by both biting and nuisance flies including *Haematobia irritans, Stomoxys calcitrans, Musca* species and *Hydrotaea irritans*. On sheep: For the treatment and prevention of infestations by ticks *Ixodes ricinus* and by lice (*Linognathus ovillus, Bovicola ovis*), keds (*Melophagus ovinus*) and established blowfly strike (usually *Lucilia* spp.). On lambs: For the treatment and prevention of infestations by ticks *Ixodes ricinus* and by lice *Bovicola ovis*.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	22 December 2015
Concerned Member States for original procedure	AT, BE, DK, EE, ES, FI, IE, IT, LT, LV, PL, PT, RO, SE

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species; <the slight reactions observed are indicated in the SPC.
The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The efficacy of the product was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains deltamethrin 10 mg/ml and the excipient Triglycerides, medium chain.
The product is packed in flexipacks or flat bottom containers.
The particulars of the containers and controls performed are provided and conform to the regulation.
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 from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is deltamethrin, an established substance described in the British Veterinary 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.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

E. Control on intermediate products

Not applicable.

F. 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 have been provided demonstrating compliance with the specification.

G. 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.
An in-use shelf-life as detailed on the SPC has been supported by appropriate data.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

The test product can be considered bioequivalent with the reference product VERSATRINE. According to the current bioequivalence guideline (EMEA/CVMP/016/00-Rev.2), the exemption of bioequivalence studies can be granted because, the conditions stated in paragraph 7.1.d) are fulfilled.

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been demonstrated, results of pharmacological tests are not required.

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

Toxicological Studies

As this is a generic application according to Article 13 (1) and bioequivalence with a reference product has been demonstrated, results of toxicological tests are not required.

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

User Safety

The applicant has provided a user safety assessment. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that further assessment was required for cattle and sheep on pasture because the product is an ectopararsiticide. A phase II environmental risk assessment was provided.

The assessment concluded that that deltamethrin is toxic to dung insects. aquatic organisms, is persistent in soils and may accumulate in sediments.

As such appropriate warnings are included in the product literature:

iii) Other precautions

Deltamethrin is very toxic to dung, fauna, aquatic organisms and honey bees, is persistent in soils and may accumulate in sediments.

The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of deltamethrin (and other synthetic pyrethroids) in cattle and sheep, e.g. by using only a single treatment per year on the same pasture.
The risk to aquatic ecosystems will be further reduced by preventing treated sheep from entering watercourses for one hour immediately after treatment.

5.1 Environmental properties

Deltamethrin has the potential to adversely affect non-target organisms, both in water and in dung. Following treatment, excretion of potentially toxic levels of deltamethrin may take place over a period of 4 weeks Faeces containing deltamethrin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

Deltamethrin is very toxic to dung fauna, aquatic organisms and honey bees, is persistent in soils and may accumulate in sediments.

6.1 Special precautions for the disposal of unused veterinary medicinal product or waste material derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Do not contaminate surface waters or ditches with the product or used container.
Deltamethrin has been shown to be persistent in soil.

III.B Residues documentation

Residue Studies

No depletion study was performed with the tested product.

MRLs

The active substance is included in table 1 of the MRL regulation 470/2009, as follows:

DELTAMETHRIN						
Marker residue	**Animal Species**	**MRL**	**Target Tissues**	**Other Provisions**	**Therapeutic Classification**	**Regulation**
deltamethrin	All ruminants	10 µg/kg 50 µg/kg 10 µg/kg 10 µg/kg 20 µg/kg	Muscle Fat Liver Kidney Milk	No entry-	Antiparasitic agents/ Agents against ectoparasites	37/2010 of 22.12.2009
	Fin fish	10 µg/kg	Muscle and skin in natural proportions			

b. excipients

The MRL status of excipients of the product is indicated in the following table.

Excipient	MRL status	ADI
Triglycerides, medium chain	Table 1, no MRL required	-

Withdrawal Periods

No residue depletion studies were conducted because the product is generic and has been shown to be bioequivalent to the reference product.
After discussion between the reference and the concerned member states and in order to harmonise the SPC with the text agreed for similar European products, the following withdrawal periods have been decided:

Cattle
Meat and offal – 18 days
Milk – zero hours

Sheep
Meat and offal – 35 days
Milk – 24 hours

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

No tolerance study has been conducted with the test product.

As the composition of the test product is similar to the one of the reference product and bioequivalence with the reference product can be assumed, specific tolerance studies are not required.

The type and incidence of adverse effects presented in the product literature are equivalent as that of the reference product SPC.

IV.B Clinical Studies

As this is a generic application according to Article 13 (1), and bioequivalence 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.

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.