DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

# Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
**(Reference Member State)**

**DECENTRALISED PROCEDURE**

## PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

## SINERGEL PERMETHRIN 715/1430 MG SPOT-ON SOLUTION FOR DOGS

CORREO ELECTRÓNICO

mresvet@aemps.es



C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 54 01
FAX: 91 822 5443

# MODULE 1

## PRODUCT SUMMARY

| | |
|---|---|
| EU Procedure number | ES/V/0387/001- 002/ DC |
| Name, strength and pharmaceutical form | SINERGEL PERMETHRIN 715/1430 MG SPOT-ON SOLUTION FOR DOGS |
| Applicant | SINERGIC CHEMICAL S.L.<br>C/ Velázquez, Nº 64- 4ºIzq.<br>28001 Madrid – Spain |
| Active substance(s) | Permethrin |
| ATC Vetcode | QP53AC04 |
| Target species | Dogs |
| Indication for use | Treatment and prevention of external parasites infestations in dogs caused by fleas (*Ctenocephalides canis, Ctenocephalides felis*) and ticks (*Rhipicephalus sanguineus*). The veterinary medicinal product prevents infestations for up to 4 weeks following administration.<br>One treatment provides an insecticidal effect for 3 weeks against mosquitoes (*Aedes aegypti*).<br>One treatment provides a repellent effect for one week against sand flies (*Phlebotomus perniciosus*). |

# MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

# MODULE 3

## PUBLIC ASSESSMENT REPORT

| | |
|---|---|
| Legal basis of original application | Decentralised application in accordance with Article 13.3 of Directive 2001/82/EC as amended. |
| Date of completion of the original decentralised procedure | 27.01.21 |
| Date product first authorised in the ReferenceMemberState (MRP only) | - |
| Concerned Member States for original procedure | PT |

## I. SCIENTIFIC OVERVIEW

***For public assessment reports for the first authorisation in a range**:*

This is a hybrid application according to article 13 (3) of Directive 2001/82/EC, as amended by Directive 2004/28/EC. SINERGEL PERMETHRIN SPOT-ON SOLUTION FOR DOGS is presented as spot-on solution containing 715 /1430 mg/ml of permethrin as active substance and Propylene glycol monomethyl ether as excipient. The reference veterinary medicinal product is EXSPOT was first authorised in Spain on 1997 on the basis of a full application.

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 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. Qualitative and quantitative particulars*

The product contains 715/1430 mg/ml of permethrin and propylene glycol monomethyl ether as excipient.

The container/closure system is a white opaque spot-on pipette of COEX-High Density Polyethylene-Extrusion material. The fill volume of the pipette is 2 ml.

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 permethrin (cis:trans/40:60), an active substance not described in any 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 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 have been provided demonstrating compliance with the specification.

### *F. Stability*

Stability data on the active substance has 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*

None.

# III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

## III.A Safety Testing

This application has been submitted in accordance with article 13.3 of Directive 2001/82/EC, as amended by Directive 2004/28/EC. SINERGEL PERMETHRIN SOLUTION SPOT-ON FOR DOGS and the reference product are qualitatively and quantitatively identical in terms of active substance, excipients and pharmaceutical form.

Therefore, it can be concluded that the safety aspects of this product are essentially similar to those of the reference product and that both formulations are “clinically equivalent”. Therefore, the omission of safety studies is justified.

### *User Safety*

A user safety assessment has not been submitted either since the risk for the user is expected to be the same as that of the reference product.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

### *Environmental Risk Assessment*

An Environmental Risk Assessment (ERA) has been provided as required. Since the veterinary medicinal product is indicated only for dogs, no Phase II assessment has been performed. SINERGEL PERMETHRIN SOLUTION SPOT-ON FOR DOGS is considered safe for the environment when used as recommended in the SPC.

## *III.B Residues documentation*

Not applicable.

## IV. CLINICAL ASSESSMENT (EFFICACY)

The application is submitted under article 13.3 of Directive 2004/28/EC (hybrid application). The composition of the product is identical to that of the reference product, so efficacy or tolerance studies are not considered necessary.

Therefore, it can be concluded that the efficacy aspects of this product are essentially similar to those of the reference product and that both formulations are “clinically equivalent”. Therefore, the omission of efficacy studies is justified

## 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 veterinary Heads of 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.

None