Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
10117 Berlin
(Germany)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Cylabel 1000 mg/g powder for use in drinking water/milk

Date: 15 November 2017

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0169/001/DC
Name, strength and pharmaceutical form	Cylabel 1000 mg/g powder for use in drinking water/milk
Applicant	Bela-Pharm GmbH & Co.KG Lohner Str. 19 49377 Vechta Germany
Active substance(s)	Sodium salicylate
ATC Vetcode	QN02BA04
Target species	Cattle (calves), Pigs
Indication for use	Calves: Supportive treatment of pyrexia in acute respiratory disease, in combination with appropriate (e.g. anti-infective) therapy if necessary. Pigs: For the treatment of inflammation in combination with a concurrent antibiotic therapy.

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(1) of Directive 2001/82/EC as amended.
Date of completion of the original Decentralised procedure	26 July 2017
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	Austria, Cyprus, Denmark, Estonia, Hungary, Latvia, Lithuania, The Netherlands, Poland, Romania, Slovenia

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 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 safety and efficacy aspects of this product are identical to Na-Salicylaat 100% authorised in The Netherlands.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains sodium salicylate as the active ingredient. The product does not contain any excipients.

Container/closure system: The product is packed in a folding box or a Kard-O-Seal bag.

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.

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 sodium salicylate, 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 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 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(1) of Directive 2001/82/EC as amended., and bioequivalence with a reference product has been demonstrated, results of safety tests are not required.

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

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH Guideline 6 (CVMP/VICH/592/98-FINAL). The environmental risk assessment can stop in phase I, because the active substance is a natural substance, which does not require an in-depth phase II assessment.

Conclusions:

The environmental risk assessment can stop in Phase I. It is not to be expected that the veterinary medicinal product represents an unacceptable risk to the environment if it is used in accordance with the provisions of the SPC.

III.B Residues documentation

Residue Studies

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product can be concluded, residue studies are not required. The withdrawal periods for this product are equivalent to those of the reference product.

MRLs

Sodium salicylate is included in Table 1 of the Annex to Commission Regulation (EU) No. 37/2010 as follows:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Sodium salicylate	NOT APPLICABLE	Bovine, porcine	No MRL required	NOT APPLICABLE	For oral use. Not for use in animals from which milk is produced for human consumption	NO ENTRY
		All food producing species except fin fish	No MRL required	NOT APPLICABLE	For topical use only	
	Salicylic acid	Turkey	400 µg/kg 2500 µg/kg 200 µg/kg 150 µg/kg	Musde Skin and fat Liver Kidney	Not for use in animals producing eggs for human consumption Provisional maximum residue limits shall expire on 1 January 2015	Anti-inflammatory agents/Non-steroidal anti-inflammatory agents

Withdrawal Periods

Meat and offal

Pigs: zero days

Calves: zero days

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13 (1) of Directive 2001/82/EC (as amended), 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.

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.

<None>