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

Solacyl 1000 mg/g powder for use in drinking water for turkeys

Date: 06 November 2017

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0170/001/DC
Name, strength and pharmaceutical form	Solacyl 1000 mg/g powder for use in drinking water for turkeys
Applicant	Eurovet Animal Health B.V Handelsweg 25 NL-5531 AE Bladel
Active substance(s)	Sodium salicylate
ATC Vetcode	QN02BA04
Target species	Turkeys
Indication for use	Symptomatic treatment of inflammatory respiratory diseases, if necessary in combination with an appropriate anti-infective 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	Czech Republic, France, Hungary, Italy, The Netherlands, Poland, Slovakia, Spain and United Kingdom

I. SCIENTIFIC OVERVIEW

This is an application according to Art. 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC. Solacyl 1000 mg/g is a generic to Avicylat 1000 mg/g authorised in Germany since 2011. Reference to this product is acceptable because Avicylat is part of a global marketing authorisation of another sodium salicylate-containing product authorised in Austria in 2007. It is therefore justified to take the latter product for the calculation of the protection period of eight years according to Art. 5 in connection with Art. 13 (1) of Directive 2001/82/EC as amended. Solacyl is concluded to be bioequivalent to the German reference product.

Solacyl 1000 mg/g, powder for use in drinking water for turkeys contains 1000 mg/g sodium salicylate, a non-steroidal anti-inflammatory drug, and is indicated for the symptomatic treatment of inflammatory respiratory diseases in turkeys, if necessary in combination with an appropriate anti-infective therapy.

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 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.

The container/closure system consists of bags made of an outer layer of polyethylene terephthalic acid, middle layers of aluminium and polyamide and an inner layer of polyethylene (PET/ALU/PA/PE).

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 submitted in accordance to Article 13 (1) of Directive 2001/82/EC pharmacological studies and toxicological studies are not required. The safety claims for this product are equivalent to those of the reference product.
In addition, a complete user safety risk assessment has been provided. The proposed user safety warnings are adequate to ensure the safety of the user when the product is used as recommended.

III.A Safety Testing

Pharmacological Studies
Because of the type of application pharmacological studies are not required.

Toxicological Studies
Because of the type of application toxicological studies are not required.

User Safety
The user safety assessment (URA) has been conducted in accordance with the Guideline for User Safety for Pharmaceutical Veterinary Medicinal Products EMEA/CVMP/543/03-FINAL-rev1 (March 2010) including a hazard identification, exposure assessment, risk characterization and a formulation of corresponding warning phrases. The proposed user safety warnings are adequate to ensure user safety when the product is handled as recommended.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH Guideline 6 (CVMP/VICH/592/98-FINAL).

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the active substance is a natural substance, the use of which will not alter the concentration or distribution of the substance in the environment.

Sodium salicylate is a natural substance of plant's secondary metabolism and an ubiquitous compound in vegetated soils. It is biosynthesised by numerous plant species of different botanic orders and can be found either as free salicylic acid but in particular in bound forms including alcohols, esters and glycosides. Salicylic acid is contained in many vegetable food and feed. A relevant ratio remains unchanged and will eventually be excreted and enter the environment. Different bacteria species in soil are capable of degradation and respective microbiological population adapts to changes in salicylic acid level. Therefore salicylic acid is subject to a full biological cycle naturally existing in the environment.

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	Salicylic acid	Turkeys	400 µg/kg 2500 µg/kg 200 µg/kg 150 µg/kg	Muscle Skin and fat* Liver Kidney	Not for use in animals producing eggs for human consumption	Anti-inflammatory agents/Non-steroidal anti-inflammatory agents

Withdrawal Periods

Meat and offal: 2 days.

Not for use in birds producing or intended to produce eggs for human consumption.

IV. CLINICAL ASSESSMENT (EFFICACY)

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

IV.A Pre-Clinical Studies

Because of the type of application preclinical studies are not required.

IV.B Clinical Studies

Because of the type of application preclinical studies are not required.

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>