ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Paramove 49.5% w/w Hydrogen Peroxide Concentrate for Solution for Fish Treatment

PuAR correct as of 26/03/19 when RMS was transferred to NO.
Please contact the RMS for future updates.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0417/001/DC
Name, strength and pharmaceutical form	Paramove 49.5% w/w Hydrogen Peroxide Contrate for Solution for Fish Treatment
Applicant	Solvay Chemical International S.A Rue de Ransbeek 310 B-1120 Brussels Belgium
Active substance	Hydrogen peroxide
ATC Vetcode	QD08AX01
Target species	Salmon
Indication for use	For the treatment of salmon suffering from infestation with motile (pre-adult to adult) sea lice*, Lepeoptheirus salmonis* or *Caligus* spp, Prior to the stage where serious tissue damage occurs.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies (veterinary) (HMA(v)) website (www.hma.eu).

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	26 September 2012
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	Ireland, Norway

I. SCIENTIFIC OVERVIEW

This was a generic application for Interox paramove 50, 49.0 – 49.9% w/w hydrogen peroxide for the bath treatment of fish submitted in accordance with Article 13 (1) of Directive 2001/82/EC as amended. The reference product was Paramove 50, 50% hydrogen peroxide, solution concentrate for bath treatment, authorised in the UK since 1997. The Marketing Authorisation Holder is the same for both product and reference product, and the products are qualitatively and quantitatively identical. There was therefore no requirement for the applicant to provide bioequivalence studies in support of the application.

The product is intended for the treatment of salmon suffering from infestation with pre-adult to adult lice, *Lepeoptherus salmonis* or *Caligus* spp, prior to the occurrence of serious tissue damage.

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.[1] 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 benefit/risk analysis is in favour of granting a marketing authorisation.

[1] SPC – Summary of Product Characteristics.

II. QUALITY ASPECTS

A. Composition

The product contains 49.5% w/w hydrogen peroxide and excipients disodium dihydrogen diphosphate, nitric acid and demineralised water

The container/closure system consists of single use intermediate bulk containers of 1100 kg or reusable steel containers of 22,900 kg or 26,000 kg. The particulars of the containers and controls performed are provided and conform to the regulation. The choice of the formulation and the absence of preservative are 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 from a licensed manufacturing site. Process validation data on the product have been presented in accordance with the relevant European guidelines. The process is controlled by Good Manufacturing Practice, and process validation was performed on three consecutive batches of product in both container types.

C. Control of Starting Materials

The active substance is hydrogen peroxide, an established active substance described in the European Veterinary Pharmacopoeia (Ph. Eur). Comparable specification data for the active substance as compared to the Ph. Eur specification were provided and the product 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. Tests include those for identification, colour, pH, phosphate, nitrate and carbon. Suitable raw material specifications were provided for nitric acid and disodium acid pyrophosphate.

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. Tests include those for identity, appearance, pH, colour, nitrate and carbon.

G. Stability

Data were not provided for the active substance because it is the same material as the finished product. This was acceptable. Production batches of finished product in scaled down containers were subjected to two protocols, over different time periods. Data confirmed the shelf-life as defined in the SPC.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Shelf-life ten months.

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 were not required.

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, the environment and consumers.

III.A Safety Testing

User Safety

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

- Do not attempt to administer the product unless you have been fully trained to handle and use the product, and are fully aware of operational and safety procedures.
- Hydrogen peroxide is corrosive.
- This product is harmful if swallowed or if inhaled and may cause respiratory irritation. Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
- Avoid contact with skin and eyes. This product may cause skin irritation and serious eye damage.
- Wear personal protective equipment whilst handling this product, consisting of chemically resistant headgear, face shield or safety goggles, chemically resistant PVC acid suit / oilskins, chemically resistant PVC gloves (with cuff under suit) and safety rubber wellington boots (with suit over boots).
- Before commencing handling of this product ensure a supply of fresh water and preferably eye wash solutions are available.
- IN CASE OF INHALATION: Remove person to fresh air and keep comfortable for breathing. If you feel unwell SEEK IMMEDIATE MEDICAL ATTENTION by calling a physician or National Poisons Information Centre.
- IN CASE OF ACCIDENTAL EYE CONTACT: Rinse immediately with plenty of clean water for several minutes. SEEK IMMEDIATE MEDICAL ATTENTION by calling a physician or National Poisons Information Centre. Remove any contact lenses, if easy to do so and continue rinsing eyes.
- IN CASE OF ACCIDENTAL SKIN CONTACT: Immediately remove any contaminated clothing. Wash the exposed skin immediately with water and seek medical advice if irritation persists. Thoroughly clean the contaminated clothing by soaking with plenty of water before re-using.
- Always wash hands with soap and water directly after use.

Ecotoxicity

The applicant provided a first and second phase environmental risk assessment in compliance with the relevant guideline which showed that further assessment was required. The assessment concluded that PEC[2] values for appropriate parameters, calculated using the 'BathAuto' model tool, were within acceptable limits. Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

III.B Residues documentation

No residue depletion studies were conducted because the proposed product was identical to the reference product. No further data were required.

Withdrawal Periods

No withdrawal period data were required because the proposed product was identical to the reference product. No further data were required. The withdrawal period remained the same as that of the reference product for fish meat; zero days.

IV CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and the proposed product was identical to the reference product, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

As this is a generic application according to Article 13, and the proposed product was identical to the reference product, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.B Clinical Studies

As this is a generic application according to Article 13, and the proposed product was identical to the reference product, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

[2] PEC – Predicted Environmental Concentration.

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 benefit/risk 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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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