United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY Homeopathic Remedy

Rhus Tox Tablets 2c-MM

Date Created: February 2018

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Rhus Tox Tablets 2c-MM
Applicant	Complements of Scotland Limited (Trading as Freeman's Homeopathic Pharmacy) 20 Main Street Busby Glasgow G76 8DU Scotland
Homeopathic material(s) and potency(ies)	Rhus Tox 2 c to MM
Target species	All non-food animals

MODULE 2

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Homeopathic
Date of conclusion of the procedure	21st May 2007

I. SCIENTIFIC OVERVIEW

This was an application for a homeopathic remedy, Rhus Tox Tablets 2c-MM. The product is authorised for use in any non-food animal. There are no formal indications.

Part 9 of Schedule 1 (Marketing Authorisations of the Veterinary Regulations 2013, paragraph 65 (1)), states that the procedure for registering a homeopathic product is the same procedure as that for granting a marketing authorisation for a non-homeopathic veterinary medicine, as shown in Part 3. However, no proof of efficacy is required.

The overall benefit:risk analysis was in favour of accepting the registration, and the application was approved.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product (a tablet), contains the following:

Stock Name	Specification	Dilution	Scale of Potency
Rhus Tox	HAB 2005	(30c variant) 2 to MM	c

Other Substances Diluents	
Ethanol	BP
Lactose	Ph. Eur

Pharm base **Ingredients (tablet)**

Lactose
Sucrose
Acacia
Hydrogenated castor oil
Hydrogenated vegetable oil

The container/closure system consists of a 10 ml amber, glass, wide-necked bottle with tamper-evident high-density polyethylene cap, containing 100 tablets. The particulars of the containers and controls performed were provided and conformed to the regulation. The choice of the formulation and the absence of preservative were justified.

The product is established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

II.B. Description of the Manufacturing Method

Suitable descriptions were provided of the methods used for potentisation and dispensing of the product.

II.C. Control of Starting Materials

The homeopathic material contained an ingredient described in the German Homeopathic Pharmacopoeia (HAB). The homeopathic materials are manufactured in accordance with the European Pharmacopoeial (Ph. Eur) monograph 'Methods of preparation of homoeopathic stocks and potentisation'. The homeopathic material specifications were considered adequate to control the quality of the material.

Compliance with appropriate quality standards was demonstrated for all the excipients used to manufacture the product. Appropriate certificates of analysis were provided.

The packaging used was supported by satisfactory specifications and technical drawings, accompanied by suitable declarations of conformity with Ph. Eur and food contact use requirements.

II.C.4. Substances of Biological Origin

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

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. Acceptable data from the proposed production sites have been provided.

II.F. Stability

Stability data on the homeopathic material and final product have been provided in accordance with applicable European guidelines, demonstrating their stability when stored under the approved conditions.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

No pharmacological data are required for applications for homeopathic remedies.

User Safety

No user safety data are required when the product is used as intended.

Environmental Safety

No Environmental Risk Assessment is required for homeopathic remedies.

III.B.2 Residues documentation

The applicant has provided proof that all substances included in the homeopathic remedy are suitable for use in food-producing animals under Regulation 37/2010.

Residue Studies

No residues data are required for applications for homeopathic remedies.

IV. CLINICAL DOCUMENTATION

No proof of either efficacy or target species safety are required for applications for homeopathic remedies.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the labelling, the benefit/risk profile of the product is favourable.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

The package leaflet may be updated to include new information on the quality and safety of the veterinary medicinal product.

The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality and safety of the product.

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

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