

Application summary

Application number:	ERMA200085, L2036PR
Application type:	Notified, Importation or manufacture for release, Category A
Applicant contact:	Paulina Rodriguez
Applicant:	Bomac Laboratories Limited Manukau City PO Box 76369 Auckland 2241 New Zealand
Purpose:	To import or manufacture L2036PR as a veterinary medicine for production animals.
Date formally received:	21 August 2009

Application summary prepared by Bomac Laboratories Limited

This application is submitted to gain an approval to import and release L2036PR in New Zealand. L2036PR is formulated for use in farm animals. It will not pose any economic, social or environmental cost. It will however, produce a number of benefits in relation to animal welfare and profitability to sheep farmers among others. The importation of this substance to New Zealand will represent big benefit to farmers given that market pressure decreases prices. Therefore, more animals will be vaccinated and protected against one of the most common diseases present in all farm animals. Similar products have been manufactured over 100 years around the world and the efficacy and safety profile of these products has been established. The anthelmintic is broad spectrum and has been used in NZ and around the world for many years.. There are several similar products already registered by the ACVM and available for purchase in this country and others. The product is to be applied in the anterior half of the neck and injected subcutaneously. The withholding periods for residues in products originating from animals treated with this substance will be granted by the ACVM Group and take into consideration New Zealand's external trade. This will be covered in the assessment of L2036PR by the NZFSA.

Substances containing the ingredients found in L2036PR are already available in New Zealand, however because this particular formulation has not been notified as a toxic substance, an assessment by ERMA under the HSNO Act 1996 is required. The hazard classifications are as follows: 6.1D, 6.3 B, 6.5 B, 6.6 B, 6.9A, 9.2 D, 9.3 C.

L2036PR triggers the threshold for skin irritation and sensitisation, target organ toxicity, ecotoxicity. The main risks attributed to this substance are those associated with inappropriate handling and disposal of the substance. The magnitude of these risks is judged to be minimal as these events are unlikely and, in the event that they did occur, would be localised. In addition, these risks are further minimized and controlled by the instruction on the label of the substance and the fact that this substance is for use only under the authority or prescription of a veterinarian. Therefore, it can be concluded that the risks resulting from this substance will be insignificant. The leaflet will contain information on adequate use of equipment and of the product. Storage conditions are also included in the label. The product should be discarded as follows: Unused product must be discarded within 10 hours of opening.