

Application summary

Application number:	ERMA200123, BM1991RH
Application type:	Notified, Importation or manufacture for release, Category A
Applicant contact:	Rounak Haddadi
Applicant:	Bomac Laboratories Limited Manukau City PO Box 76369 Auckland 2241 New Zealand
Purpose:	To import or manufacture BM1991RH as a veterinary medicine for topical use in cattle.
Date formally received:	16 September 2009

Application summary prepared by Bomac Laboratories Limited

This application is being made to gain approval for *BM1991RH* to be manufactured and released in New Zealand. Products containing the ingredients found in *BM1991RH* are already on the market; however, because this formulation has not been notified as a toxic substance, it requires assessment by ERMA under the HSNO Act 1996. *BM1991RH* triggers the thresholds for toxicity and ecotoxicity (6.1E, 6.3A, 6.4A, 6.8A, 6.8C, 6.9B, 9.1A, 9.2C, 9.3C and 9.4B).

The main risks attributed to this product are those associated with the user if not handled appropriately or to soil and aquatic organisms and terrestrial vertebrates and invertebrates in the case of accidental spillage or inappropriate disposal. The magnitude of these risks are judged to be minimal as these events are unlikely as measures (GMP, ERMA guidelines) will be taken to ensure the proper use / controlled use of this substance and in the event that they did occur would be localized and would be of short duration. In addition, these risks are further minimized and controlled by the instruction on the product label and the selected method of administration. The product should be stored in its original packaging at or below room temperature and away from light. The product should be kept away from children. Disposal of the product is preferably by use, however in case of spillage or excess product; it should be treated so that it is no longer corrosive or toxic and disposed of in an appropriate land fill. The container should be tripled rinsed and the rinsate added to dip wash and burnt in an appropriate incinerator if conditions such as wind direction permit, or crushed and buried in an appropriate landfill. The local and regional council should be contacted regarding preferred disposal regimen. Therefore, it can be concluded that the risks resulting from this product will be insignificant.

BM1991RH is formulated for the treatment and control of internal parasites in ruminants. 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 farmers among others.