

## Application summary

<b>Application number:</b>	ERMA200116, BD1620RH
<b>Application type:</b>	Notified, Importation or manufacture for release, Category A
<b>Applicant contact:</b>	Rounak Haddadi
<b>Applicant:</b>	Bomac Laboratories Limited Manukau City PO Box 76369 Auckland 2241 New Zealand
<b>Purpose:</b>	To import DAI, and manufacture BD1620RH, for use as a veterinary medicine for topical use in cattle.
<b>Date formally received:</b>	14 September 2009

### Application summary prepared by Bomac Laboratories Limited

This application is being made to gain approval for the importation of *The active ingredient found in the substance, BD1620RH* and to manufacture *BD1620RH* and released in New Zealand. Products containing the ingredients found in *BD1620RH* 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. *BD1620RH* triggers the thresholds for toxicity and ecotoxicity (6.3A, 6.4A, 6.8A, 6.8C, 9.1A, 9.2C and 9.4A). *The active ingredient found in the substance* triggers the thresholds for toxicity and ecotoxicity (6.1C, 6.8C, 6.9A, 9.1A, 9.2A, 9.3B, 9.4A).

The main risks attributed to this product and its active ingredient 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. Therefore, it can be concluded that the risks resulting from this product will be insignificant.

*BD1620RH* 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.