

Application summary

Application number:	ERMA200740, JG1122
Application type:	Rapid Assessment, Importation or manufacture for release,
Applicant contact:	Jyoti Gupta
Applicant:	Bomac Laboratories Limited Manukau City PO Box 76369 Manukau 2241 Auckland
Purpose:	To import or manufacture JG1122 as a veterinary medicine for the treatment of infections in all species.
Date formally received:	2 February 2011

Application summary prepared by Bomac Laboratories Limited

This application is being made to gain approval for JG1122, which is a veterinary medicament, to be manufactured and released for sale in New Zealand. Products containing the same active ingredients are already on the market; however this formulation has not been notified as a toxic substance and therefore requires assessment according to the HSNO Act. JG1122 triggers the thresholds for skin irritation (6.3A), eye (6.4A) irritation, and aquatic ecotoxicity (9.1D).

The formulation of JG1122 is based on a combination of known active ingredients, which are already present in New Zealand in products designed for similar purposes, therefore the risks associated with this substance, when used with controls, are insignificant. The main risks associated with this product are those to production workers if not handled appropriately, or to aquatic organisms in the case of accidental spills or inappropriate disposal. The magnitude of these risks are judged to be minimal as these events are highly improbable and in the event that they did occur would be localised and of short duration due to the nature of the final product and packaging.

These risks will be further controlled by the product labelling, which will instruct the end-user on storage, directions for use and disposal of the product. The end user will be instructed to contact the local or regional council regarding disposal options and not to contaminate surface water or drains with substance or used containers. Preferably the product should be disposed of by use, otherwise the product and packaging should be disposed of in an approved landfill or other approved facility. It is unforeseeable that the substance will be used for any other reason and there are no known adverse effects from unintentional use. Therefore the risks resulting from this product will be insignificant.

JG1122 will not pose any economic, social or environmental cost. The introduction of this product to the market will simply increase market choice. This increased choice may translate into cheaper prices and JG1122 will also have a number of benefits in terms of animal health and welfare.

The details of the intended use of the substance are provided in the Appendix.

