ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

Amended under s67A of the HSNO Act on 12 January 2012
20 February 2011

Application code:	ERMA200740
Application type:	Importation or manufacture of a hazardous substance for release under section 28 of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Application sub-type:	Section 28A(2)(c) – reduced hazard
Applicant:	Bomac Laboratories Ltd
Purpose of the application:	To import or manufacture JG1122 as a veterinary medicine for the treatment of infections in all species.
Date application received:	2 February 2011
Consideration date:	18 February 2011
Considered by:	Rob Forlong (Chief Executive, ERMA New Zealand).

1 Summary of decision

1.1 The import or manufacture of JG1122 **is approved** with the controls as set out in Appendix 1. This approval has been given in accordance with the relevant provisions of the Act, the relevant HSNO Regulations, and the HSNO (Methodology) Order 1998 ("the Methodology"), based on the substance being formulated so that 1 or more of its hazardous properties has a lesser degree of hazard than a substance approved under the Act.

1.2 The substance has been given the following unique identifier for the ERMA New Zealand Hazardous Substances Register:

JG1122

2 Legislative criteria for the application

2.1 Unless otherwise stated, references to section numbers in this decision refer to sections of the Act. The application was lodged pursuant to section 28. The decision was determined in accordance with section 28A(2)(c), taking into account the requirements of that section and matters specified under Part 2 of the Act.

2.2 Unless otherwise stated, references to clauses in this decision refer to clauses of the Methodology. Consideration of the application followed the relevant provisions of the Methodology.

3 Application process

3.1 The purpose of this application is to gain approval to import or manufacture JG1122 as a veterinary medicine.

3.2 The application was formally received on 2 February 2011.

3.3 The Department of Labour Workplace Group, the Agricultural Compounds & Veterinary Medicines Group (ACVMG) of the New Zealand Food Safety Authority (NZFSA) and the Ministry of Health were advised of the application (clause 2(2)(e)).

3.3.1 No responses were received.

3.4 Evaluation of the application was undertaken by the ERMA New Zealand project team which comprised the following staff members:

Nicola Gisler	Advisor (Hazardous Substances)
Margaret Keane	Advisor (Hazardous Substances)
Jim Waters	Senior Advisor (Hazardous Substances)
Haydn Murdoch	Advisor (Hazardous Substances).

3.5 Further information was requested from the applicant during the evaluation of the application in accordance with section 52. Consequently the consideration of this application was postponed by two working days.

3.6 The application was considered by the Chief Executive of ERMA New Zealand as provided for by a delegation from the Environmental Risk Management Authority ("the Authority") under section 19(2)(d).

4 Consideration

Sequence of the consideration

4.1 Bomac Laboratories Ltd seeks approval, under section 28, to import and manufacture JG1122 for release in New Zealand as a veterinary medicine.

4.2 A substance can be assessed by rapid assessment procedures, under section 28A(2)(c), if it can be shown that it has been formulated so that one or more of its hazardous properties has a lesser degree of hazard than any substance already approved under the Act.

4.3 The approach adopted when considering this application was:

- to review the information provided;
- to identify the composition and hazardous properties of JG1122 and of a reference substance;
- to determine whether JG1122 has a similar use to the reference substance; and
- to determine whether the reference substance is one that has been approved by the Authority and whether JG1122 has been formulated so that one or

more of its hazardous properties has a lesser degree of hazard than the reference substance.

4.4 And then:

- to consider whether the risks posed by JG1122 are the same as, less than or greater than those posed by the reference substance;
- to consider whether there are any other effects that mean JG1122 should not be approved under section 28A; and
- to consider whether the controls that apply under the Act to the reference substance, modified according to the hazardous properties of JG1122 will adequately prevent or manage the adverse effects of JG1122.

Information review

4.5 The project team has reviewed all the information supplied by Bomac Laboratories Ltd, and considers that the information constitutes an adequate and appropriate basis for assessing the application (clause 8). They also consider that there are no significant uncertainties (ie sufficient to influence decision making) in the scientific and technical information relating to the risks of JG1122 (clauses 29 and 30).

Identification of the proposed substance

4.6 JG1122 is a veterinary medicine formulated as a liquid containing active ingredients, and other components.

Identification of the reference substance

4.7 The applicant identified a reference substance with which they consider JG1122 may be compared.

4.8 This reference substance is considered to be eligible for comparing with JG1122 and has been used as such in this assessment.

Composition of JG1122 compared to that of the reference substance

4.9 JG1122 and the reference substance are both liquids containing the same active ingredients and other components.

4.10 An active ingredient and components C and D are the major hazardous components that confer the hazard classifications on JG1122. An active ingredient and other components are the major hazardous components that confer the hazard classifications on the reference substance.

4.11 The overall proportion of the major hazardous components and active ingredients is slightly higher in the reference substance than in JG1122.

Hazardous properties of JG1122 compared to those of the reference substance

4.12 The project team has determined the hazard profile of JG1122 based on the information provided by the applicant and other available information. The hazard classifications for JG1122 are set out in Table 4.1 for comparison against the reference substance.

Table 4.1: Comparison of hazard classifications

Hazard Endpoint	Proposed Substance	Reference Substance
Skin irritancy	6.3A	6.3A
Eye irritancy/corrosivity	6.4A	8.3A
Contact sensitisation		6.5B
Aquatic ecotoxicity	9.1C	9.1D

4.13 The project team notes that the 9.1D hazard classification of the reference substance, requires amendment to 9.1C under section 67A of the Act.

4.14 The project team notes that JG1122 has a reduced hazard profile when compared with the reference substance in that it has not been classified as contact sensitiser. In addition, the reference substance is classified as an eye corrosive, whereas JG1122 is an eye irritant. The reduced hazard profile is due to the absence of hazardous excipients that are present in the reference substance.

Comparison of the uses of JG1122 and the reference substance

4.15 JG1122 and the reference substance are both proposed for the same use to treat the same condition and applied in the same manner.

4.16 The project team considers that there are no other substantial differences in the lifecycles, uses, purposes and presentations between JG1122 and the reference substance.

Meeting the criteria for rapid assessment under section 28A(2)(c)

4.17 Based on the comparison and assessment detailed above, the project team considers that the criteria for rapid assessment under section 28A(2)(c) have been met through JG1122 being formulated so that one or more of its hazardous properties has a lesser degree of hazard than a substance that has been approved under the Act.

Comparison of the adverse effects of JG1122 and the reference substance

4.18 Given the similarities in lifecycle and use of JG1122 and the reference substance, the project team does not expect an increase in potential exposure to occur. As JG1122 is of reduced hazard, the risks it poses are less than those of the reference substance.

4.19 The project team considers that there are no other matters that would prevent this application from being approved under section 28A.

Controls

4.20 A set of controls was applied to the reference substance when it was approved under the Act. Changes that have been made in legislation subsequent to the approval of the reference substance now also apply to it (section 77(2)(a)).

4.21 The project team notes that the proposed and reference substances have similar use patterns, therefore most of the controls assigned to the reference substance will be applicable to the proposed substance. However, as JG1122 has a reduced hazard profile relative to the reference substance, the project team notes that the following controls assigned to the reference substance are not triggered for JG1122:

Lifecycle Stage	Control
Identification	I2, I10, I17, I18, I22, I30
Packaging	P14, PG3
Emergency Management	EM2

4.22 The project team notes that control E2 (restrictions on use of substances in application areas), have been triggered for JG1122 on the basis of its intrinsic hazards. However, this control was not considered relevant based on the substance's use as a veterinary medicine and has therefore not been listed.

4.23 The following modifications, deletions, additions and combinations applied to the reference substance, as provided for under section 77 and section 77A, and are equally applicable to JG1122:

4.23.1 Setting of exposure limits:

Control	Comment
T1	This control relates to the setting of tolerable exposure limits (TELs) to control hazardous substances entering the environment in quantities sufficient to present a risk to people. As for the reference substance, no tolerable exposure limit (TEL) is set form the substance at this time.
T2	Control T2 relates to the requirement to control exposure in places of work through the setting of WESs. The Agency typically adopts WES values listed in the Workplace Exposure Standards document (Effective from December 2010): http://www.osh.govt.nz/publications/booklets/wes-dec-2010/wes-dec-2010.pdf The project team notes that Department of Labour WES values have been set for Components B1, B2 and I in the proposed substance; however, as the concentrations of Components B1 and B2 are low, the project team considers only the WES value for Component I is applicable to JG1122.
E1	This control relates to the setting of environmental exposure limits (EELs) to control hazardous substances entering the environment in quantities sufficient to present a risk to the environment. As for the reference substance, no environmental exposure limit (EEL) is set for this substance

Control	Comment
	at this time. The default EELs, set under regulation 32 of the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations, are deleted.

4.23.2 Varied Controls:

Controls	Comment
T7	Control T7 relates to restrictions on the carriage of toxic substances on passenger service vehicles. For JG1122, the project team considers that Regulation 10[1] should apply as if the maximum quantity per package of a 6.5B substance is 1.0 L, rather than 0.1 L.

4.23.3 Additional Controls

Controls	Comment
use control	As the proposed substance's assessment of risk has been based on its use as a veterinary medicine, the following use restriction control is added: *JG1122 shall only be used as a veterinary medicine.*
Schedule 8	Addition of controls relating to stationary container systems as set out in Schedule 8[2].
EM12	The following subclauses are proposed for addition after subclause (3) of regulation 36[3]: *(4) For the purposes of this regulation, and regulations 37 to 40, where this substance is contained in pipework that is installed and operated so as to manage any loss of containment in the pipework it—* *(a) is not to be taken into account in determining whether a place is required to have a secondary containment system; and* *(b) is not required to be located in a secondary containment system.* *(5) In this clause, pipework—* *(a) means piping that—* *(i) is connected to a stationary container; and* *(ii) is used to transfer a hazardous substance into or out of the stationary container; and* *(b) includes a process pipeline or a transfer line.*
EM12	The following subclauses are added at the end of regulation 37[2] (control EM12) to take into account any risk of adverse effects posed by pooling hazardous substances: *(2) If pooling substances which do not have class 1 to 5 hazard classifications are held in a place above ground in containers each of which has a capacity of 60 litres or less—* *(a) if the place's total pooling potential is less than*

1 Hazardous Substances (Classes 6, 8 and 9 Controls) Regulations 2001

2 Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004 (Supplement to the New Zealand Gazette, 26 March 2004, No. 35, page 767), as amended

3 Hazardous Substances (Emergency Management) Regulations 2001

Controls	Comment
	20,000 litres, the secondary containment system must have a capacity of at least 25% of that total pooling potential: *(b) if the place's total pooling potential is 20,000 litres or more, the secondary containment system must have a capacity of the greater of—* *(i) 5% of the total pooling potential; or* *(ii) 5,000 litres.* *(3) Pooling substances to which subclause (2) applies must be segregated where appropriate to ensure that leakage of one substance may not adversely affect the container of another substance.*
EM12	The following subclauses are added at the end of regulation 38[1] (control EM12) to take into account any risk of adverse effects posed by pooling hazardous substances: *(2) If pooling substances which do not have class 1 to 5 hazard classifications are held in a place above ground in containers 1 or more of which have a capacity of more than 60 litres but none of which have a capacity of more than 450 litres—* *(a) if the place's total pooling potential is less than 20,000 litres, the secondary containment system must have a capacity of either 25% of that total pooling potential or 110% of the capacity of the largest container, whichever is the greater:* *(b) if the place's total pooling potential is 20,000 litres or more, the secondary containment system must have a capacity of the greater of—* *(i) 5% of the total pooling potential; or* *(ii) 5,000 litres* *(3) Pooling substances to which subclause (2) applies must be segregated where appropriate to ensure that the leakage of one substance may not adversely affect the container of another substance.*

4.24 Taking into account the control modifications and additions detailed above, the proposed controls for JG1122 are detailed in Appendix 1.

5 Environmental user charges

5.1 The project team considers that use of controls on JG1122 is an effective means of managing risks associated with this substance. At this time, no consideration has been given as to whether or not environmental user charges should be applied to this substance as an alternative or additional means of achieving effective risk management. Accordingly, no report has been made to the Minister for the Environment.

1 Hazardous Substances (Emergency Management) Regulations 2001

6 Decision

6.1 Pursuant to section 28A, I have considered this application to import and manufacture a hazardous substance for release made under section 28.

6.2 Having considered the composition, hazardous properties, and proposed use of JG1122, I am satisfied that it meets the criteria for rapid assessment under section 28A(2)(c) in that it has been formulated so that one or more of its hazardous properties has a lesser degree of hazard than an approved reference substance.

6.3 I am satisfied with the hazard classifications identified by the project team in Table 4.1 and confer them accordingly to JG1122.

6.4 As the risks posed by JG1122 are less than the reference substance, I consider that applying the same suite of controls to JG1122 with the variations and additions proposed, in paragraphs 4.21 to 4.23.3 (inclusive), will ensure adequate management of any adverse effects.

6.5 In this consideration, I have also applied the following criteria in the Methodology:

- clause 9 – equivalent of sections 5, 6 and 8;
- clause 12 – risk assessment;
- clause 21 – the decision accords with the requirements of the Act and regulations;
- clause 24 – the use of recognised risk identification, assessment, evaluation and management techniques;
- clause 25 – the evaluation of risks; and
- clause 35 – the costs and benefits of varying the default controls.

6.1 The application to import and manufacture the hazardous substance, JG1122, for release is thus **approved** with controls as detailed in Appendix 1.

Rob Forlong Chief Executive, ERMA New Zealand	Date:

JG1122	
ERMA New Zealand Approval Code:	**HSR100478**

Amendment January 2012

The 6.3 classification in table 4.1 on page 4 was incorrectly listed as 6.3B. This was amended to 6.3A as a correction to a technical error under s67A of the HSNO Act.

Rob Forlong Chief Executive, EPA New Zealand	Date:

JG1122 **EPA New Zealand Amendment Code:**	**APP201207**

Appendix 1: Controls applying to JG1122

The controls imposed are as follows. The regulations cited should be referred to for definitions and exemptions. The ERMA New Zealand publication *User Guide to Control Regulations* provides useful guidance on the controls.

Table A1.1: Controls – codes, regulations and variations

Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001

Code	Regulation	Description	Variation
T1	11 – 27	Limiting exposure to toxic substances through the setting of TELs	No TELs are set for this substance at this time.
T2	29, 30	Controlling exposure in places of work through the setting of WESs.	A WES value is set for Component I at this time.
T4	7	Requirements for equipment used to handle substances	
T5	8	Requirements for protective clothing and equipment	
T7	10	Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles	Regulation 10 applies to this substance as if the item in Schedule 2 of the regulations relating to the 6.5B hazard classification of a liquid was replaced by **1 L**.

Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001

Code	Regulation	Description	Variation
E1	32 – 45	Limiting exposure to ecotoxic substances through the setting of EELs	No EELs are set for this substance at this time and the default EEL values are deleted.
E6	7	Requirements for equipment used to handle substances	

Hazardous Substances (Identification) Regulations 2001

Code	Regulation	Description	Variation
I1	6, 7, 32 – 35, 36(1) – (7)	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability	
I3	9	Priority identifiers for ecotoxic substances	
I9	18	Secondary identifiers for all hazardous substances	
I11	20	Secondary identifiers for ecotoxic substances	
I16	25	Secondary identifiers for toxic substances	
I19	29 – 31	Additional information requirements, including situations where substances are in multiple packaging	
I21	37 – 39, 47 – 50	General documentation requirements	
I23	41	Specific documentation	

		requirements for ecotoxic substances	
I28	46	Specific documentation requirements for toxic substances	
I29	51, 52	Signage requirements	

Hazardous Substances (Packaging) Regulations 2001

Code	Regulation	Description	Variation
P1	5, 6, 7(1), 8	General packaging requirements	
P3	9	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria	
P13	19	Packaging requirements for toxic substances	
PS4	Schedule 4	Packaging requirements as specified in Schedule 4	

Hazardous Substances (Disposal) Regulations 2001

Code	Regulation	Description	Variation
D4	8	Disposal requirements for toxic and corrosive substances	
D5	9	Disposal requirements for ecotoxic substances	
D6	10	Disposal requirements for packages	
D7	11, 12	Information requirements for manufacturers, importers and suppliers, and persons in charge	
D8	13, 14	Documentation requirements for manufacturers, importers and suppliers, and persons in charge	

Hazardous Substances (Emergency Management) Regulations 2001

Code	Regulation	Description	Variation
EM1	6, 7, 9 – 11	Level 1 information requirements for suppliers and persons in charge	
EM6	8(e)	Information requirements for toxic substances	
EM7	8(f)	Information requirements for ecotoxic substances	
EM8	12 – 16, 18 – 20	Level 2 information requirements for suppliers and persons in charge	
EM11	25 – 34	Level 3 emergency management requirements: duties of person in charge, emergency response plans	
EM12	35 – 41	Level 3 emergency management requirements: secondary containment	The following subclauses are added after subclause (3) of regulation 36: *(4) For the purposes of this regulation, and regulations 37 to 40, where this substance is contained in pipework that is installed and operated so as to manage any loss of*

containment in the pipework it—

(a) is not to be taken into account in determining whether a place is required to have a secondary containment system; and

(b) is not required to be located in a secondary containment system.

(5) In this clause, pipework—

(a) means piping that—

(i) is connected to a stationary container; and

(ii) is used to transfer a hazardous substance into or out of the stationary container; and

(b) includes a process pipeline or a transfer line.

The following subclauses are added at the end of regulation 37:

(2) If pooling substances which do not have class 1 to 5 hazard classifications are held in a place above ground in containers each of which has a capacity of 60 litres or less—

(a if the place's total pooling potential is less than 20,000 litres, the secondary containment system must have a capacity of at least 25% of that total pooling potential:

(b) if the place's total pooling potential is 20,000 litres or more, the secondary containment system must have a capacity of the greater of—

(i) 5% of the total pooling potential; or

(ii) 5,000 litres.

(3) Pooling substances to which subclause (2) applies must be segregated where appropriate to ensure that leakage of one substance may not adversely affect the container of another substance.

The following subclauses are added at the end of regulation 38:

(2) If pooling substances which do not have class 1 to 5 hazard classifications are held in a place above ground in containers 1 or more of which have a capacity of more than 60 litres but none of which have a capacity of more than 450 litres—

(a) if the place's total pooling potential is less than 20,000 litres, the secondary containment system must have a capacity of either 25% of that total pooling potential or 110% of the capacity of the largest container, whichever is the greater:

(b) if the place's total pooling potential is 20,000 litres or more, the secondary containment system must have a capacity of

			the greater of— *(i) 5% of the total pooling potential; or* *(ii) 5,000 litres* *(3) Pooling substances to which subclause (2) applies must be segregated where appropriate to ensure that the leakage of one substance may not adversely affect the container of another substance.*
EM13	42	Level 3 emergency management requirements: signage	

Hazardous Substances (Tank Wagon and Transportable Containers) Regulations 2004

Code	Regulation	Description	Variation
Tank Wagon	4 to 43 as applicable	Controls relating to tank wagons and transportable containers.	

Additional controls under s77A

The substance shall only be used as a veterinary medicine.

The controls relating to stationary container systems, as set out in Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004 (Supplement to the New Zealand Gazette, 26 March 2004, No. 35, page 767), as amended, apply to this substance, notwithstanding clause 1(1) of that schedule.

Addition of subclauses after subclause (3) of Regulation 36 of the Hazardous Substances (Emergency Management Controls) Regulations 2001 (control EM12).

Addition of clauses after Regulation 37 of the Hazardous Substances (Emergency Management Controls) Regulations 2001 (control EM12).

Addition of clauses after Regulation 38 of the Hazardous Substances (Emergency Management Controls) Regulations 2001 (control EM12).

Appendix 2: Confidential Information