Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

30 June 2020

Summary

Substance Name	RXI
Application code	APP204021
Application type	To import or manufacture for release any hazardous substance under Section 28 of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Application sub-type	Section 28A(2)(a) – rapid similar – having a similar composition and similar hazardous properties to a substance that has been approved under the Act
Applicant	Randlab Australia Proprietary Limited
Purpose of the application	To import or manufacture RXI for release
Date application formally received	17 June 2020
Consideration date	30 June 2020
Considered by	The Acting General Manager[1] of the Hazardous Substances and New Organisms group of the Environmental Protection Authority ("the EPA")
Decision	**Approved with controls**
Approval code	**HSR101429**
Hazard classifications	6.1D (oral), 6.3A, 6.4A, 6.6B, 6.7B, 6.9B (oral), 9.3C

[1] The Acting General Manager of the HSNO group of the EPA has made the decision on this application under delegated authority in accordance with section 19 of the Act.

1. Substance

1.1. RXI is a veterinary medicine (analgesic, sedative and skeletal muscle relaxant) for horses and deer containing 116.5 g/L (11.65%) of xylazine HCl, which is equivalent to 100 g/L (10%) of the active ingredient xylazine. It is intended to be imported and administrated via injection in doses of 2.9 – 5.0 mL/450 kg bw in horses and 0.2 – 1.6 mL/40 kg bw in deer.

2. Process and consultation

Application receipt

2.1. The application, including the statutory declaration, was formally received on 17 June 2020 under section 28 of the Act.

Information available for consideration

2.2. The information available for the consideration comprised:

- the application form
- the confidential appendices to the application
- the EPA staff advice memorandum.

2.3. There was sufficient information to assess the application.

Notification to government departments

2.4. In line with section 53(4) of the Act, as the application was not publicly notified under section 53(2) of the Act, government departments were equally not notified of the application for RXI.

Legislative criteria for the application

2.5. This application meets the criteria for rapid assessment under section 28A(2)(a) of the Act, as it is considered that a substance having a similar composition and similar hazardous properties has been approved. This is referred to as the reference substance.

2.6. In considering this application, the relevant provisions of the Act, the EPA Notices, the Health and Safety at Work Act 2015 (HSW Act), the Health and Safety at Work (Hazardous Substances) Regulations 2017 (HSW (HS) Regulations) and the Hazardous Substances and New Organisms (Methodology) Order 1998 were taken into account.

3. Comparison of RXI with the reference substance

Identity of reference substance

3.1. The approved substance 'Liquid containing 10 - 15% xylazine', which has the approval code HSR002336 has been identified as a reference substance, which RXI could be compared to as part of a rapid assessment. This reference substance is considered eligible for comparing with RXI.

Hazardous properties

3.2. The hazard classifications of RXI were determined based on the information provided by the applicant and other available information. The hazard classifications are shown in **Table 1** alongside those of the reference substance.

3.3. RXI has the same hazard profile as the reference substance.

Table 1: Hazard classifications of RXI and the reference substance

Hazard	RXI	Liquid containing 10 - 15% xylazine
Acute toxicity (oral)	6.1D	6.1D
Skin irritancy	6.3A	6.3A
Eye irritancy	6.4A	6.4A
Mutagenicity	6.6B	6.6B
Carcinogenicity	6.7B	6.7B
Target organ or systemic toxicity	6.9B	6.9B
Terrestrial vertebrate ecotoxicity	9.3C	9.3C

Use

3.4. RXI and the reference substance are both proposed for use at comparable doses as analgesics, sedatives and skeletal muscle relaxants in horses and deer. There are no substantial differences in the lifecycle, use and purpose of RXI and the reference substance.

4. Rapid assessment of adverse effects

4.1. The rapid risk assessment of adverse effects has taken into account the hazardous properties of the substance, the considerations under Part 2 of the Act, the prescribed controls under the Act and the requirements under other relevant legislation such as the HSW Act 2015, Land Transport Rule 45001, Civil Aviation Act 1990 and Maritime Transport Act 1994.

4.2. The assessment:

- considered the risks posed by RXI compared to those associated with the reference substance

- determined whether any variations or additions to the prescribed controls are required to manage the risks of this substance, and identified controls that may not be applicable or necessary that can, therefore, be deleted.

Assessment of risks to human health

4.3. The risks to human health are similar to those of the reference substance and as such are managed by the suite of controls.

Assessment of risks to the environment

4.4. The risks to the environment from this substance are similar to those of the reference substance and as such are managed by the suite of controls.

Assessment of risks to Māori and their relationship to the environment

4.5. The risks to Maori and their relationship to the environment from this substance are similar to those of the reference substance and as such are managed by the suite of controls.

Assessment of risks to society, the community and the market economy

4.6. No risks to society, communities or the market economy from the approval of RXI have been identified.

New Zealand's international obligations

4.7. No international obligations that may be impacted by the approval of RXI have been identified.

Summary of assessment

4.8. The risks associated with RXI arise from its hazardous properties and its proposed use pattern. These risks are similar to those posed by the reference substance, and the suite of controls applied to the reference (including any modifications and deletions) can be applied to RXI to equally mitigate its risks to human health and the environment, so that these are negligible.

5. Prescribed controls

5.1. The hazard classifications of RXI determine a set of prescribed controls specified by the EPA Notices[2] under section 77 of the HSNO Act. There are also requirements in the HSW (HS) Regulations. Note: the HSW (HS) requirements are not set for the substance under this approval but apply in their own right.

5.2. The prescribed controls set the baseline for how the substance must be managed and include specifications on how the substance is to be packaged, labelled, stored, disposed, transported, handled and used. The prescribed controls also set information requirements (eg Safety Data Sheets), signage and emergency management. These controls form the basis of the controls specified in Appendix A.

5.3. The Labelling, Safety Data Sheet (SDS), Packaging, Disposal and Hazardous Property Controls (HPC) Part 1, Part 3, Part 4A and Part 4B Notices apply to RXI.

[2] There may also be default controls in regulations made under the Act for certain hazardous substances such as fireworks.

Exposure limits

5.4. Under s77B of the Act, the EPA may set a Tolerable Exposure Limit (TEL) and/or an Environmental Exposure Limit (EEL) for a substance with toxic or ecotoxic properties:

- Regulation 13.17 of the HSW (HS) Regulations prohibits the use of a class 6 substance in excess of a TEL
- Clause 49 of the HPC Notice prohibits use of a class 9 substance in excess of an EEL

5.5. No TEL values have been set previously for the active ingredients in RXI because it is considered that exposure to this substance is not likely to result in an appreciable toxic effect to people, provided controls on use are followed.

5.6. No EEL values are set at this time, or have been set previously for the active ingredients in RXI, as the level of risk of adverse effects to the environment has been qualitatively assessed as being negligible, with controls in place.

5.7. There are no Workplace Exposure Standard (WES) nor Prescribed Exposure Standard (PES) values currently set for components of RXI.

5.8. Clause 17 of the Hazardous Substances (Labelling) Notice 2017 and Section 3 of Schedule 1 of the Hazardous Substances (Safety Data Sheets) Notice 2017 require that certain toxic, corrosive or ecotoxic components are identified on the product label and on the SDS, respectively. Section 8 of Schedule 1 of the SDS Notice requires occupational exposure limits to be identified on the SDS.

5.9. The name and concentration of the following components need to be specified on the label and SDS. (Table 2):

Table 2: Components required on the label and SDS

Labelling requirement	SDS requirement
Xylazine HCl (6.1D, 6.6B, 6.7B, 6.9B)	Xylazine HCl (6.1D, 6.3A, 6.4A, 6.6B, 6.7B, 6.9B)

6. Changes to prescribed controls

6.1. The following modifications to the EPA Notice controls apply to RXI, as set out in **Table 3**:

Table 3: Justification for s77 changes to prescribed controls (see Appendix A for the control wordings)

Control	Justification
Information requirements Labelling Notice	A control has been applied that specifies additional information requirements that must accompany RXI. The information requirements are the equivalent of those specified in the *Veterinary Medicine (Limited Pack Size, Finished Dose) Group Standard 2017 Part 1.* These requirements were developed specifically for veterinary medicines and sit alongside the information requirements prescribed under the EPA Labelling Notice.

6.2. The following additional HSNO controls apply to RXI under section 77A of the Act, as set out in **Table 4**:

Table 4: Justification for s77A additional controls (see Appendix A for the control wordings)

Control	Justification
Use restriction	As the risk assessment of the proposed substance has been based on its use as a veterinary medicine, the addition of the following use restriction control is applied to RXI, as it is more effective than the prescribed controls with respect to their effect on the management, use and risks of the substance.
Sale restriction	An additional control has been applied to RXI to restrict the sale to professional veterinarians. This requirements is applied to reduce the potential for adverse effects on human health, especially children's, if the substance were available to the public.

Assessment of changes to controls

6.3. The changes to the prescribed controls in the above section under sections 77 and 77A of the Act fulfil the legislative criteria.

6.4. These controls have been incorporated into Appendix A of this document.

7. Decision

7.1. Having considered the composition, hazardous properties and use of RXI, I am satisfied that it meets the criteria for rapid assessment under section 28A(2)(a) as a substance having a similar composition and similar hazardous properties has been approved under the Act. I consider that there are no other effects of RXI that would prevent this application for RXI being approved under section 28A of the Act.

7.2. I am satisfied with the hazard classifications identified in Table 1 and have applied this classification to RXI.

7.3. I consider that applying the suite of controls to RXI set out in Appendix A will ensure adequate management of the adverse effects of RXI.

7.4. Therefore, the application to import or manufacture of RXI is approved with controls as listed in Appendix A.

Dr Clark Ehlers	Date: 30 June 2020
Acting General Manager, HSNO, EPA	

Appendix A: Controls applying to RXI

EPA Controls

Control code	EPA Notice	Control description
LAB	EPA Labelling Notice 2017	Requirements for labelling of hazardous substances
PKG	EPA Packaging Notice 2017	Requirements for packaging of hazardous substances
SDS	EPA Safety Data Sheet Notice 2017	Requirements for safety data sheets for hazardous substances
DIS	EPA Disposal Notice 2017	Requirements for disposal of hazardous substances
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	Hazardous Property Controls preliminary provisions
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	Hazardous substances in a place other than a workplace
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	Site and storage controls for class 9 substances
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	Use of class 9 substances

HSNO Additional Controls and Modifications to Controls

Control code	HSNO Act	Control
Information requirements	Section 77 variation to Labelling Notice	The information requirements specified in the *Veterinary Medicines (Limited Pack Size, Finished Dose) Group Standard 2017 Part 1* apply to RXI and sit alongside the information requirements prescriped under the EPA Labelling Notice.
Use restriction	Section 77A	This substance must only be used as a veterinary medicine.
Sale restriction	Section 77A	This substance may only be supplied to a workplace under the management and control of a PCBU, or to a professional veterinarian.

HSW HS Requirements

Note: these requirements are triggered by the classification of the substance. They are listed here for information purposes only.

Code	Regulation	Description
HSW2-1	Reg 2.1 - 2.4	Workplace labelling of hazardous substance containers
HSW2-2	Reg 2.5-2.10	Signage
HSW2-3	Reg 2.11	Safety data sheets
HSW2-4	Reg 2.12-2.14	Packaging
HSW3-1	Reg 3.1	Inventory
HSW3-2	Reg 3.2 -3.3	Managing risks associated with hazardous substances
HSW4-2	Reg 4.5-4.6	Information, instruction, training and supervision
HSW5-2	Reg 5.6-5.13	Emergency response plans
HSW13-2	Reg 13.7	Duty of PCBU who directs work using class 6, 8.1, 8.2, or 8.3 substances to ensure equipment is appropriate
HSW13-3	Reg 13.8	Duty of PCBU who directs work using class 6 and 8 substances to ensure personal protective equipment used
HSW13-8	Reg 13.17	Prohibition on use of substance in excess of tolerable exposure limit
HSW13-9	Reg 13.18	Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded
HSW13-14	Reg 13.30 -33	Secondary containment requirements for class 6 and 8 pooling substances
HSW16-1	Part 16	Requirements for tank wagons and transportable containers
HSW17-1	Part 17	Requirements for stationary container systems