Environmental Protection Authority
Te Mana Rauhī Taiao

RAPID SCIENCE MEMO

Summary

Substance	RXI
Application code	APP204021
Application sub-type	Rapid – similar
Applicant	Randlab Australia Proprietary Limited
Purpose of the application	To import or manufacture RXI for release
Date application formally received	17 June 2020

1. Key Points

1.1. RXI is a veterinary medicine (analgesic, sedative and skeletal muscle relaxant) for horses and deer containing 116.5 g/L (11.650%) 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.

1.2. No major issues were identified with this substance.

2. Status Of Substance (SOS) or statutory determination history

2.1. No SOS or statutory determinations were issued for RXI.

3. Identification of substance and reference

3.1. The applicant proposed four reference substances: Calezine 100, Xylazine 100mg/ml, Akorn Anased 10% Injection and Phoenix Xylazine 10% Injection. These were not considered to be suitable by the EPA because one was not present in the HS database and three were assigned to another approval rather than having their own. The EPA considers that 'Liquid containing 10 - 15% xylazine' is a more suitable reference. This has the same active ingredient at the same concentration as RXI and has its own approval (HSR002336) (see Table 1).

Table 1: identified references for the rapid assessment of RXI

	Substance to be approved	Reference
Name	RXI	Liquid containing 10 - 15% xylazine
Substance database ID	50218	9441
HSNO Approval number	-	HSR002336
Substance physical form	Liquid	Liquid
Active ingredient and concentration (%)	Xylazine (10%)	Xylazine (10 – 15%)

4. RAPID assessment criteria

Active ingredient

4.1. This substance meets the active ingredients criteria.

4.2. The concentration of the active ingredient in RXI is similar, within the range (10 - 15%), of that in the reference substance.

Physical form

4.3. RXI is in the same physical form as the reference substance, namely as a liquid.

Use pattern

4.4. This substance meets the use pattern criteria. Both RXI and the reference substance are veterinary medicines used in a similar manner (see Table 2).

Table 2: Use pattern of RXI in comparison to its reference substance

	Substance to be approved	Reference
Target animal	Horses and deer	Horses, deer, cattle, sheep, goats
Use	Analgesic, sedative, skeletal muscle relaxant	Analgesic, sedative, skeletal muscle relaxant
Dose	Horses: 2.9 – 5.0 mL/450 kg bw Deer: 0.2 – 1.6 mL/40 kg bw	Products available on the market that have been assigned to the reference approval HSR002336 have similar doses.
Comment on any differences	The reference substance is also intended for cattle, sheep and goats, which is not proposed for RXI.	
Are the differences insignificant in terms of risk of adverse effects?	It is not expected that there will be a higher risk of adverse effects for RXI as both substances have a similar concentration of the active ingredient and are intended for the same use pattern as veterinary medicines to be administrated via injection.	

Major Hazardous Components

4.5. RXI meets the major hazardous components criteria. The only major hazardous component in RXI is the active ingredient xylazine. This constitutes a lower proportion (10%) than in the reference substance (10 - 15%).

Adverse Effects

4.6. RXI meets the adverse effects criteria, as the hazards of this substance are the same as those of the reference substance (see Table 3).

Table 3: comparison of the respective classifications of RXI and its reference substance

	Classification comparison
Substance	6.1D (oral), 6.3A, 6.4A, 6.6B, 6.7B, 6.9B (oral), 9.3C
Reference	6.1D (oral), 6.3A, 6.4A, 6.6B, 6.7B, 6.9B (oral), 9.3C

Additional comments

4.7. It is likely that RXI would fit the scope of one of the veterinary group standards. The applicant was informed of the existence of these group standards and of the ability for importers to self-assign hazardous substances to these.

5. Controls

EPA Notice controls

5.1. 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.

5.2. The name and concentration of the following components need to be specified on the label and SDS (see Table 4).

Table 4: Components required on the label and SDS of RXI

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)

5.3. No Tolerable Exposure Limit (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.

5.4. No Environmental Exposure Limit (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.

5.5. No maximum application rate is proposed because the substance is intended to be administered via injection.

Controls varied or added under section 77A

Use restriction

5.6. This substance must only be used as a veterinary medicine.

Label

5.7. The substance label must include the following statements:

- For animal treatment only
- Keep out of reach of children
- The use of gloves is recommended

Information requirements

5.8. The information requirements specified in the *Veterinary Medicine (Limited Pack Size, Finished Dose) Group Standard 2017 Part 1* apply to RXI, and sit alongside the information requirements prescribed under the EPA labelling Notice.