



DECISION

30 July 2020

Summary

Substance Name	Rodenthor Gel Rodenticide
Application code	APP204010
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)(c) – rapid reduced hazard – formulated so that one or more hazardous properties has a lesser degree of hazard than a substance that has been approved under the Act
Applicant	Ensystem New Zealand Limited
Purpose of the application	To import or manufacture Rodenthor Gel Rodenticide for release
Date application formally received	16 July 2020
Consideration date	30 July 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	HSR101434
Hazard classifications	6.1E (oral), 6.9B (oral), 9.1D

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. Rodenthor Gel Rodenticide is a vertebrate toxic agent (VTA) containing 0.05 g/kg of the active ingredient brodifacoum. It is intended to be imported and used by professional pest control operators. The ready to use gel formulation is applied via a caulking gun to bait stations and enclosed spaces around industrial, commercial, public services, agricultural and domestic buildings to control rats and mice.

2. Process and consultation

Application receipt

- 2.1. The application, including the statutory declaration, was formally received on 16 July 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 publically notified under section 53(2) of the Act, government departments were equally not notified of the application for Rodenthor Gel Rodenticide.

Legislative criteria for the application

- 2.5. This application meets the criteria for rapid assessment under section 28A(2)(c) of the Act, as it is considered that a substance having a similar composition and greater degree of hazard 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 HSNO (Methodology) Order 1998 were taken into account.

3. Comparison of Rodenthor Gel Rodenticide with the reference substance

Identity of reference substance

3.1. The approved substance Rodenthor Soft Bait, which has the approval code HSR100814 has been identified as a reference substance to which Rodenthor Gel Rodenticide could be compared as part of a rapid assessment. This reference substance is considered eligible for comparing with Rodenthor Gel Rodenticide.

Hazardous properties

3.2. The hazard classifications of Rodenthor Gel Rodenticide 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. Rodenthor Gel Rodenticide has a reduced hazard profile compared to the reference substance in that Rodenthor Gel Rodenticide has no classification for skin sensitisation. This is because:

- the reference substance contains components that are not present in Rodenthor Gel Rodenticide, and;
- the concentrations of major hazardous components are reduced in Rodenthor Gel Rodenticide compared to the reference substance.

Table 1: Hazard classifications of Rodenthor Gel Rodenticide and the reference substance

Hazard	Rodenthor Gel Rodenticide	Reference Substance
Flammable aerosol	NA	ND
Flammable liquid	NA	ND
Acute toxicity (oral)	6.1E	6.1E
Acute toxicity (dermal)	ND	ND
Acute toxicity (inhalation)	ND	ND
Skin irritancy/corrosivity	ND	ND
Eye irritancy/corrosivity	ND	ND
Metal corrosivity	ND	ND
Contact sensitisation	ND	6.5B
Mutagenicity	ND	ND
Carcinogenicity	ND	ND
Reproductive/ developmental toxicity	ND	ND
Reproductive/ developmental toxicity (via lactation)	ND	ND

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Target organ or systemic toxicity	ND	6.9B
Aquatic ecotoxicity	9.1D	9.1D
Soil ecotoxicity	ND	ND
Terrestrial vertebrate ecotoxicity	ND	ND
Terrestrial invertebrate ecotoxicity	ND	ND

Use

3.4. Rodenthor Gel Rodenticide and the reference substance are both proposed for use as a VTA around industrial, commercial, agricultural and domestic buildings to control rats and mice. There are no substantial differences in the lifecycle, use and purpose of Rodenthor Gel Rodenticide 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 Rodenthor Gel Rodenticide 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. Given the nature of the substance as a VTA, additional controls have been suggested to reduce the risks to human health from this substance.

Assessment of risks to the environment

4.4. Given the nature of the substance as a VTA, additional controls have been suggested to reduce the risks to the environment from this substance.

Assessment of risks to Māori and their relationship to the environment

4.5. The risks to Māori and their relationship to the environment from this substance are less than 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 Rodenthor Gel Rodenticide have been identified.

New Zealand's international obligations

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

Summary of assessment

4.8. The risks associated with Rodenthor Gel Rodenticide arise from its hazardous properties and its proposed use pattern. These risks are less than those posed by the reference substance, and the suite of controls applied to the reference (including any modifications and deletions) can be applied to Rodenthor Gel Rodenticide 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 Rodenthor Gel Rodenticide determine a set of prescribed controls specified by the EPA Notices² 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 Rodenthor Gel Rodenticide.

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 ingredient in Rodenthor Gel Rodenticide 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.

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

- 5.6. No EEL values are set at this time, or have been set previously for the active ingredient in Rodenthor Gel Rodenticide, 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 Workplace Exposure Standard (WES) values currently set for components of Rodenthor Gel Rodenticide but, as they are not Prescribed Exposure Standard (PES) values, they are guidance values used for the management of health risk. No PES has been set for any component of Rodenthor Gel Rodenticide.
- 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
-	Starch (WES) Butylated hydroxytoulene (WES) Triethanolamine (WES)

6. Changes to prescribed controls

- 6.1. The following modifications to the EPA Notice controls apply to Rodenthor Gel Rodenticide, as set out in Table 3:

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

Control	Justification
HPC Notice Clauses 53, 56, 57	Given the use of the substance as a vertebrate toxic agent, clauses 53, 56 and 57 apply
Label Labelling Notice Clause 23	Given the use of the substance as a vertebrate toxic agent, the label must include a use restriction, with a statement to the effect that use must be accordance with the restrictions.

6.2. The following additional HSNO controls apply to Rodenthor Gel Rodenticide 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	The use of Rodenthor Gel Rodenticide is restricted to secure bait stations which restricts accessibility to children and non-target terrestrial vertebrates, and which prevents weathering of the bait
Permission	No person may apply or otherwise use this substance on land administered or managed by the Department of Conservation unless the person first obtains a Permission under section 95A of the Act from the Authority
VTA notify	Any changes to the composition or proposed used of the substance must be notified to the Authority in writing before the substance is used

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 Rodenthor Gel Rodenticide, I am satisfied that it meets the criteria for rapid assessment under section 28A(2)(c) as it has one or more hazardous properties with a lesser degree of hazard than a substance that has already been approved under the Act. I consider that there are no other effects of Rodenthor Gel Rodenticide that would prevent this application for Rodenthor Gel Rodenticide 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 Rodenthor Gel Rodenticide.
- 7.3. I consider that applying the suite of controls to Rodenthor Gel Rodenticide set out in Appendix A will ensure adequate management of the adverse effects of Rodenthor Gel Rodenticide.
- 7.4. Therefore, the application to import or manufacture of Rodenthor Gel Rodenticide is approved with controls as listed in Appendix A.



Dr Clark Ehlers

Date: 30 July 2020

Acting General Manager, HSNO, EPA

Appendix A: Controls applying to Rodenthor Gel Rodenticide

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
HPC Notice	Section 77A to HPC Notice clause 53, 56 and 57	Given the use of the substance as a vertebrate toxic agent, clauses 53, 56 and 57 apply
Label	Section 77 variation to Labelling Notice	The equivalent requirement for a class 9.3C substance is applied to Rodenthor Gel Rodenticide due to its use as a VTA, therefore clause 23 also applies. The label must include a use restriction, with a statement to the effect that use must be in accordance with the restrictions
Use restriction	Section 77A	The use of Rodenthor Gel Rodenticide is restricted to secure bait stations which restricts accessibility to children and non-target terrestrial vertebrates, and which prevents weathering of the bait
Permission	Section 77A	No person may apply or otherwise use this substance on land administered or managed by the Department of Conservation unless the person first obtains a Permission under section 95A of the Act from the Authority
VTA notify	Section 77A	Any changes to the composition or proposed use of the proposed substance must be notified to the Authority in writing before the substance is used

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	Extra information
HSW2-1	Reg 2.1 - 2.4	Workplace labelling of hazardous substance containers	
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	
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	The TEL value is not set at this time
HSW13-9	Reg 13.18	Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded	The PES value is not set at this time
HSW13-10	Reg 13.19 - 13.21	Vertebrate toxic agent requirements	
HSW16-1	Part 16	Requirements for tank wagons and transportable containers	
HSW17-1	Part 17	Requirements for stationary container systems	