Environmental Protection Authority
Te Mana Rauhī Taiao

RAPID SCIENCE MEMO

30 JULY 2020

Summary

Substance	Rodenthor Gel Rodenticide
Application code	APP204010
Application sub-type	Rapid-reduced
Applicant	Ensystex New Zealand Limited
Purpose of the application	To import or manufacture Rodenthor Gel Rodenticide for release
Date application formally received	16 July 2020

1. Key Points

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 in and around industrial, commercial, public services, agricultural and domestic buildings or enclosed spaces at rates of up to 30 g bait gel per bait station to control rats and mice.

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 Rodenthor Gel Rodenticide.

3. Identification of substance and reference

3.1. The reference proposed by the applicant and identified by the EPA are the same (see Table 2)

Table 2: identified references for the rapid assessment of Rodenthor Gel Rodenticide

	Substance to be approved	Reference
Name	Rodenthor Gel Rodenticide	Rodenthor Soft Bait
Substance database ID	50225	43855
HSNO Approval number	-	HSR100814
Substance physical form	Ready to use gel bait	Ready to use soft bait
Active ingredient(s) and concentration (g/kg)	0.05 g/kg brodifacoum	0.05 g/kg brodifacoum

4. RAPID assessment criteria

Active ingredient

4.1. This substance meets the active ingredients criteria.
The concentration of the active ingredient in Rodenthor Gel Rodenticide is the same as that of the reference substance.

Physical form

4.2. Rodenthor Gel Rodenticide has a similar physical form to the reference substance. Rodenthor Gel Rodenticide is in the form of a ready to use gel formulation and the reference substance is in the form of a soft bait.

Use pattern

4.3. This substance meets the use pattern criteria. Both Rodenthor Gel Rodenticide and the reference substance are VTAs used in a similar manner (see Table 3).

Table 3: Use pattern of Rodenthor Gel Rodenticide in comparison to its reference substance

	Substance to be approved	Reference
Target area	Industrial, commercial, public services, agricultural and domestic buildings	Industrial, commercial, agricultural and domestic buildings
Target animal	Rats and mice	Rats and mice
Application rate	Up to 30 g bait gel per bait station	Up to 100 g bait per bait station
Comment on any differences	The only difference between Rodenthor Gel Rodenticide and the reference substance is the application rate.	
Are the differences insignificant in terms of risk of adverse effects?	As the only difference between Rodenthor Gel Rodenticide and the reference substance is the application rate, there is no difference in terms of adverse effects associated with use of the substances.	

Major Hazardous Components

4.4. Rodenthor Gel Rodenticide meets the major hazardous components criteria. The major hazardous components in Rodenthor Gel Rodenticide constitute a lower proportion (0.05%) than in the reference substance (0.11%).

Adverse Effects

4.5. Rodenthor Gel Rodenticide meets the adverse effects criteria, as the hazards of this substance are reduced compared to the reference substance (see Table 4). Rodenthor Gel Rodenticide has no classification for skin sensitisation (6.5B).

Table 4: comparison of the respective classifications of Rodenthor Gel Rodenticide and its reference substance

	Classification comparison
Substance	6.1E (oral), 6.9B (oral), 9.1D
Reference	6.1E (oral), **6.5B**, 6.9B (oral), 9.1D

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 Rodenthor Gel Rodenticide.

5.2. The name and concentration of the following components need to be specified on the label and SDS (see Table 5).

Table 5: Components required on the label and SDS of Rodenthor Gel Rodenticide

Labelling requirement	SDS requirement
-	Starch (WES) Butylated hydroxytoulene (WES) Triethanolamine (WES)

5.3. No Tolerable Exposure Limit (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.

5.4. No Environmental Exposure Limit (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.

5.5. No maximum application rate is proposed because the substance is intended to be used in a bait station.

Controls varied or added under section 77A

Labelling and HPC Notices

5.6. Given the use of the substance as a VTA, the relevant requirements for a class 9.3C VTA are applied to Rodenthor Gel Rodenticide.

5.7. The label must include a use restriction (Clause 23 of the Labelling Notice) with a statement to the effect that use must be in accordance with the restrictions.

5.8. Clauses 53 (Adverse effects of class 9.3 substances to be avoided), 56 (Use of class 9.3 pesticide as vertebrate bait) and 57 (Import and manufacture of class 9.3 pesticides as vertebrate bait) of the HPC Notice apply to Rodenthor Gel Rodenticide.

VTA controls

5.9. The following controls are added to all VTAs:

Use restriction

5.10. The use of the substance is restricted to secure bait stations which restricts accessibility to children and non-target terrestrial vertebrates, and which prevents weathering of the bait.

Permission

5.11. 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 notification

5.12. Any changes to the composition or proposed use of this substance must be notified to the Authority in writing before the substance is used. The notification should include the following information, as applicable:

(a) the name of substance and HSNO approval number;

(b) details of the original formulation;

(c) details of the revised formulation clearly identifying the changed ingredients, their function in the bait, and their concentration and CAS number if appropriate;

(d) the physical form, if different from the original;

(e) bait colour;

(f) changes in bait size;

(g) the intended use(s) of the substance (to include target species, method(s) of release);

(h) change in food bait where the substance requires mixing with bait prior to use;

(i) the physical properties of the substance (for example, flashpoint, pH) if different from the original;

(j) the impurity profile and source of the ‘active’ ingredient, if different from the original;

(k) any information on the effect that the formulation change may have on the risk profile of the substance, including the results of any palatability or field trials undertaken on both target and non-target species.