



APPROVAL

Summary

Substance	Bait containing 8 g/kg cholecalciferol (Substance A)
Application type	To reissue an approval for a hazardous substance under clause 4 of Schedule 7 of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Considered by	The Chief Executive ¹ of the Environmental Protection Authority ("the EPA")
Decision	Approved for reissue
Date of reissue	2 December 2021
Approval code	HSR001598
Hazard classification	Reproductive toxicity Category 2, Designed for biocidal action

¹ The Chief Executive of the EPA has made the decision on this application under delegated authority in accordance with section 19 of the Act

Decision

- 1.1. Pursuant to clause 4 of Schedule 7 of the Act, I have considered this approval to reissue.
- 1.2. I have considered the matters raised in sections 4 to 8 of the Act but, given the nature of the reissue is administrative, there are no further considerations required in order to achieve the purpose of the Act.
- 1.3. I consider it appropriate to reissue approval HSR001598 with the controls set out in the Appendix in accordance with clause 4 of Schedule 7 of the Act. Therefore the reissued approval is now made under section 29 of the Act, in accordance with clause 4(5) of Schedule 7, and Schedule 7 no longer applies to the reissued approval. Given the hazard classification system came into effect on the 30 April 2021, this decision will have immediate effect.
- 1.4. The transitional provisions of the Labelling Notice, Safety Data Sheets Notice and Packaging Notice apply to this reissued approval for the transitional period which begins on the date of reissue and ends on 30 April 2025.



Signed by:

Date: 2 December 2021

Dr Allan L Freeth
Chief Executive, EPA

Appendix: Controls applying to HSR001598

Hazardous substances and new organisms (HSNO) default controls

Control code	EPA Notice	Notice / Part description
LAB	Labelling Notice 2017	Requirements for labelling of hazardous substances
PKG	Packaging Notice 2017	Requirements for packaging of hazardous substances
SDS	Safety Data Sheets Notice 2017	Requirements for safety data sheets for hazardous substances
DIS	Disposal Notice 2017	Requirements for disposing hazardous substances
HPC1	Hazardous Property Controls Notice 2017 Part 1	Preliminary provisions
HPC3	Hazardous Property Controls Notice 2017 Part 3	Requirements for hazardous substances in a place other than a workplace
HPC4A	Hazardous Property Controls Notice 2017 Part 4A	Substances that are hazardous to the environment: Site and storage controls
HPC4B	Hazardous Property Controls Notice 2017 Part 4B	Use of substances that are hazardous to the environment
HPC4C	Hazardous Property Controls Notice 2017 Part 4C	Qualifications required for application of substances that are hazardous to the environment

HSNO additional controls and modifications to controls

Control Description	Varied / Additional Control	Control
LAB	Variation to Labelling Notice	Clauses 19 and 23 of the Labelling Notice apply to this substance as if it is an agrichemical with the hazard classification hazardous to terrestrial vertebrates and not the hazard classification designed for biocidal action.
HPC4A	Variation to Hazardous Property Controls Notice Part 4A	For the purposes of clause 43 of the Hazardous Property Controls Notice, any required signage must indicate that this substance has a classification of hazardous to terrestrial vertebrates and not the hazard classification designed for biocidal action.

Approval for Bait containing 8 g/kg cholecalciferol (Substance A) (HSR001598)

Control Description	Varied / Additional Control	Control
HPC4B	Variation to Hazardous Property Controls Notice Part 4B	<p>Clauses 53, 56 and 57 of the Hazardous Property Controls Notice apply to this substance as if it is an agrichemical with the hazard classification hazardous to terrestrial vertebrates.</p> <p>In accordance with clause 56(1)(c) of the Hazardous Property Controls Notice, the Authority has specified that this substance must only be applied by contained ground-based application methods.</p> <p>Contained ground-based application means application of a hazardous substance—</p> <ul style="list-style-type: none"> (a) in a bait station, or bait bag, or other container that is fixed to an object; or (b) so that it is contained in some other way, such as in a pipe or burrow.
Permission	Additional control	<p>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.</p>
Vertebrate toxic agent - formulation change notification	Additional control	<p>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:</p> <ul style="list-style-type: none"> (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.

Health and safety at work (HSW) requirements

Advisory Note: These requirements are not set for the substance under this approval but apply in their own right under the HSW (Hazardous Substances) Regulations 2017 according to the classification of the substance. They are listed here for information purposes only.

Control code	Regulation Part	Description
HSW1	Part 1	Application
HSW2	Part 2	Labelling, signage, safety data sheets, and packaging
HSW3	Part 3	General duties relating to risk management
HSW4	Part 4	Certified handlers and supervision and training of workers
HSW13	Part 13	Class 6 and 8 substances
HSW16	Part 16	Tank wagons and transportable containers