Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

14 May 2020

Summary

Substance Name	Spitfire PAPP paste
Application code	APP203998
Application type	To import or manufacture a hazardous substance in containment under section 31 of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Applicant	Department of Conservation
Purpose of the Application	To manufacture Spitfire PAPP paste in containment
Date application formally received	2 April 2020
Consideration date	14 May 2020
Considered by	The Acting General Manager[1] of the Environmental Protection Authority ("the EPA")
Decision	**Approved with controls**
Expiry date of approval	**14 May 2022**
Approval code	**HSC100237**

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

1. Background

1.1. The Department of Conservation ('the applicant") sought approval under section 32 of the Act to manufacture one hazardous substance ("the substance") in containment.

1.2. The substance is a vertebrate toxic agent (VTA). The substance contains an existing active ingredient that is present in currently approved hazardous substances in New Zealand.

1.3. The active ingredient in this substance is 4'-aminopropiophenone (PAPP).

1.4. The applicant intends to use the substance to carry out cage trials on stoats in order to generate efficacy data that will be used for research and development of the substances and may be used to inform a future application for release.

1.5. The substance is applied via a resetting toxin delivery device known as a Spitfire, which fires 800 mg of paste onto the belly of the stoat as it passes through a tunnel. The stoat then grooms itself and is exposed to the toxin.

2. Process and notification

Application receipt

2.1. The application was formally received on 2 April 2020 under section 31 of the Act.

Information available for consideration

2.2. The information available for the consideration of APP203998 includes:

- the application form
- confidential appendices to the application, and
- the EPA staff containment evaluation report.

2.3. The available information is sufficient to assess the application.

Notification to government departments

2.4. The Ministry of Health were advised of the application and invited to comment. No comments were received.

3. Hazardous properties

3.1. The applicant submitted information on the hazards of the substance for which approval is sought. It is noted that this is an experimental substance, and as such, there is insufficient information available for the hazard classifications of the substance to be determined.

3.2. Based on the available information, this substance may cause adverse effects to human health and the environment. The potential adverse effects are expected to be similar to other VTAs that are already approved under the Act for import or manufacture with controls.

4. Assessment of risks and benefits

4.1. The applicant has proposed a containment system and information on how they intend to address the risks from the following:

- To limit the likelihood of escape of any contained hazardous substance or contamination of the facility by the substance
- To exclude organisms from a facility or to control organisms within a facility
- To exclude unauthorised people from a facility
- To prevent unintended release of the substance by experimenters working with a substance
- To control the effects of an accidental release of the substance
- Inspection and monitoring requirements of the containment facility

4.2. The EPA considered the applicant's assessment and determined that the substance may pose risks such as, but not limited to, those detailed below.

Risks to human health and the environment

4.3. The substance may cause adverse effects to human health and the environment if people or non-target organisms are exposed to the substance.

4.4. The substance could potentially contaminate waterways, groundwater, soil or neighbouring properties. These potential exposures could result from an incident during manufacture, storage, transport, application, or disposal of the substance. The risk of an incident occurring with the proposed controls in place is considered negligible.

4.5. The likely route for human exposure is through oral or dermal contact while handling the substance. However, it is unlikely that people using the substance will be exposed in this way provided that risk mitigation measures are in place. These measures include the use of personal protective equipment (PPE), and qualification requirements for people preparing and handling the substance.

4.6. There is also a risk that members of the public may be exposed to the substance. This is mitigated by controls that limit access to the cage-trial facility to authorised personnel only. The facility does not include land or facilities that the public can legally access without permission.

4.7. Non-target animals may be exposed to the substance via consumption of any uneaten or unused substance and/or treated stoat carcasses. This is mitigated by limiting the use of the substance to cages during the trial period and by adding controls that specify that the substance and stoat carcasses must be disposed of in accordance with the Hazardous Substances (Disposal) Notice 2017 and with the waste management rules for dead animals set by the relevant region, district or city council.

4.8. The approval holder is also required to ensure that non-target species are not adversely affected by the use of the substance.

4.9. With the controls in Appendix A and restrictions under other relevant legislation, the risks to human health and the environment posed by the manufacture of the substance (in containment) are negligible.

4.10. There are also requirements under the Health and Safety at Work Act 2015 and associated regulations. Note: the Health and Safety at Work Requirements are not set under this approval but apply in their own right.

Risks to the relationship of Māori to the environment

4.11. The potential effects of the substance on the relationship of Māori to the environment have been assessed in accordance with sections 5(b), 6(d) and 8 of the Act. Under these sections all persons exercising functions, powers and duties under this Act shall recognise and provide for the maintenance and enhancement of people and communities to provide for their cultural well-being, and; take into account the relationship of Māori and their culture and traditions with their ancestral lands, water, taonga and the principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

4.12. It is highly unlikely that the manufacture of the substance in containment will impact on Māori culture or traditional relationships with the environment.

4.13. If the substance is managed in accordance with the controls in Appendix A, it would be likely to be consistent with the principles of the Treaty of Waitangi, particularly the principle of active protection.

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

4.14. No risks to society, communities or the market economy were identified from the manufacture of the substance in containment.

New Zealand's international obligations

4.15. No international obligations were identified as being impacted by the manufacture of the substance in containment.

5. Assessment of containment

Purpose of the approval

5.1. Under section 32 of the Act, a containment approval may only be granted if the application is for one of the purposes specified in section 30 of the Act.

5.2. The applicant notes that the purpose of this application is to conduct research and development on the substance, in accordance with section 30(b) and section 30(ba) of the Act. The application is therefore eligible for consideration under section 32 of the Act.

Adequacy of containment

5.3. Section 32(1) of the Act requires that the substance can be adequately contained. The potential for this substance to escape from containment was assessed by taking into account the containment system proposed by the applicant and the potential pathways for release of the substance.

5.4. Section 32(2) of the Act specifies that a containment approval for a hazardous substance must include controls for each of the applicable matters specified in Schedule 3. The approval may also include controls that provide for any other matters in order to give effect to the purpose of the Act.

5.5. Applying the Schedule 3 requirements and using the information provided by the applicant, a set of controls was developed to ensure adequate containment of the substance.

5.6. The applicant was provided with the proposed controls and given an opportunity to comment. The applicant had no comments on the controls but asked that, if granted, the approval period be two years.

5.7. Having considered all the applicable matters, the EPA has determined that the substance can be manufactured in containment, provided that the controls in Appendix A are complied with.

6. Decision

6.1. Pursuant to section 32 of the Act, I have considered this application for an approval to manufacture Spitfire PAPP paste in containment. I have applied the relevant sections of the Act and clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998.

6.2. I am satisfied that Spitfire PAPP paste can be adequately contained with the controls in Appendix A.

6.3. Therefore, the application to manufacture the substance in containment is granted until **14 May 2022**.

Environmental Protection Authority
Te Mana Rauhī Taiao

Clark Ehlers	**Date: 14 May 2020**
Acting General Manager, HSNO, EPA	

Appendix A: Controls applying to the manufacture of Spitfire PAPP paste in containment

General

1. In these controls, “approval holder” refers to the Department of Conservation.
2. In these controls, “substance” refers to, and is limited only to, Spitfire PAPP paste.
3. Spitfire PAPP paste consists of one formulation declared with application APP203998. This substance is summarised in confidential Appendix B.

Accountability

4. The approval holder must ensure compliance with all the controls in this approval.

Requirement for containment

5. The substance must be in containment at all stages of its life cycle in New Zealand.

Limitations

6. This approval expires on **14 May 2022**.
7. This approval applies exclusively to substance that is manufactured and studied by, or on behalf of, the approval holder.
8. Spitfire PAPP paste manufactured under this approval must only be used in a secure facility.
9. The approval holder must ensure that the manufacture and laboratory testing of the substance and the nature of the trials are in accordance with the activities proposed in application APP203998, unless otherwise specified by the controls on this approval.
10. Over the term of this approval, the approval holder may manufacture up to 600 g of the substance covered under this approval.
11. The substance under this approval must be manufactured, stored and used in a secure facility.

General requirements

12. The substance must be correctly packaged. The substance is correctly packaged if it is packed in accordance with the relevant sections of the Hazardous Substances (Packaging) Notice 2017 and its packaging complies with the same notice.
13. The substance must be correctly labelled. The substance is correctly labelled if it is packed in a container that is labelled in accordance with the relevant sections of the Hazardous Substances (Labelling) Notice 2017.
14. A safety data sheet (SDS) must accompany the substance at all stages of its life cycle in New Zealand. The SDS must comply with the relevant requirements of the Hazardous Substances (Safety Data Sheets) Notice 2017.

Workplace site and storage requirements

15. The Hazardous Substances (Hazardous Property Controls) Notice 2017 applies to this approval, as if the substance were a class 9 pesticide.

16. The substance must be stored in a locked container when not in use.

Analytical laboratory

17. The approval holder must only conduct analytical studies on the substance at the test facility described by the approval holder in the application. This facility is described as the “analytical laboratory”.

18. Unauthorised persons must be excluded from the analytical laboratory.

19. The analytical laboratory must, as far as is reasonably practical, be managed so as to exclude unwanted organisms.

Manufacturing facility

20. The approval holder must only manufacture the substance at the manufacturing facility described by the approval holder in the application. This facility is described as the “manufacturing facility”.

21. Unauthorised persons must be excluded from the manufacturing facility.

22. The manufacturing facility must, as far as is reasonably practical, be managed so as to exclude unwanted organisms.

23. The manufacturing facility must be a laboratory compliant with Part 18 of the Health and Safety at Work (Hazardous Substances) Regulations 2017.

24. The manufacture of the substance must occur in a facility that is approved to manufacture vertebrate toxic agents under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

Equipment and facility requirements

25. The manufacture, storage and use of the substance must be undertaken in containment within an area specifically designated for the manufacture, storage or use of the substance. This site may be all or part of a facility.

26. The area of a facility used for the manufacture, storage or use of the substance must be able to be readily decontaminated in the event of a spill.

27. All entrances to a facility that manufactures, stores or uses the substance must be secured at all times to prevent access of unauthorised people.

28. Unauthorised people must be excluded from any facility that manufactures, stores or uses the substance.

29. Signs must be displayed at all entrances to a facility that manufactures, stores or uses the substance, and this sign must state:

    a. that the site is subject to the manufacture, storage or trial of a hazardous substance
    b. the general type of hazards of the substance that is being manufactured, stored or trialled
    c. the immediate response action to be taken in an emergency
    d. that unauthorised access to the site is not permitted
    e. a 24-hour emergency contact phone number.

30. The management of the signs referred to in Control 29 must be compliant with regulation 2.5(2) of the Health and Safety at Work (Hazardous Substances) Regulations 2017, as if references to regulation 2.6 in those regulations were references to Control 29 of this approval.

Use

31. The substance must only be used in a workplace.

32. The substance must not be applied directly to, or enter into water or a waterway.

33. The use of the substance must be compliant with clause 46 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substance were a class 9 pesticide.

34. The use of the substance must be compliant with clause 47 of the Hazardous Substances (Hazardous Property Controls) Notice 2017, as if the substances were a class 9 pesticide.

35. The manufacture, storage and use of the substance must not result in exposure of any of the substance to a place in which people or non-target organisms may be significantly adversely affected by the substance.

36. For the duration of the trial, the approval holder must ensure that secure cages which contain the substance are identified with signs that clearly communicate the presence of a hazardous substance.

37. The approval holder must ensure that trials undertaken with the substance occur in secure cages within the secure facility and that the cages are designed and maintained so as to prevent the access of other non-target species into the secure cages.

38. For the duration of the trial, the approval holder must ensure that the paste is checked daily and that any uneaten paste present in the cage of a deceased stoat is recovered and disposed of in accordance with Control 44.

39. Any evidence of the presence of other non-target species must be checked for, and if found, reported to the EPA in accordance with Control 56.

40. At the end of the trial, the approval holder must ensure that all of the substance used in the trial is recovered and disposed of in accordance with Control 44.

41. Any person that handles the substance must use PPE that is designed, constructed, and operated to ensure that the person:

a. does not come in contact with the substance
b. is not exposed to a concentration of the substance that may cause an adverse effect to the person.

42. All reasonable steps must be taken to ensure that non-target species are not adversely affected by the use of the substance.

Transport

43. No person may transport the substance on a passenger service vehicle[2].

Disposal

44. The disposal of the substance must be in compliance with the Hazardous Substances (Disposal) Notice 2017.

45. The approval holder must ensure that any deceased stoat is disposed of in accordance with the waste management rules for dead animals set by the relevant region, district or city council. In addition, disposal of stoat carcasses must not result in secondary poisoning of non-target organisms or contamination of waterways or groundwater.

46. At the expiry of this approval, the substance must:
    a. have been used up, or
    b. have been disposed of, or
    c. be contained in a laboratory compliant with Part 18 of the Health and Safety at Work (Hazardous Substances) Regulations 2017, or
    d. be covered under a new approval.

Personnel Qualifications

47. The qualification for a person that mixes, loads, or otherwise handles the substance in preparation for application must be compliant with the relevant qualification requirements in clauses 61 and 66 of the Hazardous Substances (Hazardous Property Controls) Notice 2017 as if the substance were a class 9.1A, 9.2A, 9.3A, or 9.4A pesticide.

48. Any person entering the manufacturing, storage or trial site must have received sufficient instruction on the containment regime to enable the person to meet their responsibilities under this approval.

Record keeping and Notification

49. Written records must be kept of the amount of the substance manufactured under this approval.

50. Written records must be kept for each time the substance is trialled. These records must include the information specified in clause 48(3) of the Hazardous Substances (Hazardous Property Controls) Notice 2017.

[2] As defined in section 2(1) of the Land Transport Act 1998.

51. All records kept under this approval must be held by the approval holder for not less than three years after the date on which this approval expires.

52. The approval holder must provide any records kept under this approval to the EPA and WorkSafe New Zealand within five working days of a request being received in writing from the EPA or WorkSafe New Zealand.

53. The approval holder must notify the EPA in writing prior to the start of any trial under this approval. The notification must include:

    a. the application number: **APP203998**
    b. the HSNO approval number **HSC100237**
    c. the name and contact information for the person responsible for the trial
    d. the physical address of the trial facility
    e. the date on which the trial will commence and the expected duration of the trial
    f. the name (as given with APP203998) and quantity of the substance that will be applied
    g. details on how the uneaten and unused substance and stoat carcasses will be disposed of.

Emergency management

54. Any spilled substance must be contained and prevented from entering into any waterway. This material must then be disposed of in compliance with the Hazardous Substances (Disposal) Notice 2017.

55. The approval holder must ensure that the trial sites, storage, use, transport and disposal of the substance comply with the emergency management provisions prescribed by the Hazardous Substances (Hazardous Property Controls) Notice 2017 in addition to the Health and Safety at Work (Hazardous Substances) Regulations.

Breach of containment

56. If for any reason a breach of containment occurs, the approval holder must notify the EPA within 24 hours of the incident being detected.

Interpretation

57. Unless defined below, terms used in the controls have the same meaning as defined in the Act or Notices made under the Act.

Term	Definition
Waterway	Includes every river, stream, passage, and channel on or under the ground, whether natural or not, through which water flows, whether continuously or intermittently.