Environmental Protection Authority
Te Mana Rauhī Taiao

APPLICATION FORM

Section 26 Determination

To obtain a determination for a substance

Send to Environmental Protection Authority, preferably by email (HSApplications@epa.govt.nz) or alternatively by post (Private Bag 63002, Wellington 6140)
Payment must accompany application, see our fees and charges schedule for details

Name of substance

Rabbit Haemorrhagic Disease Virus (K5 variant)

Date

23 September 2016

Completing this application form

1. This form is used when you wish to apply for a statutory determination of a substance under section 26 of the Hazardous Substances and New Organisms (HSNO) Act 1996. This form covers statutory determinations for all substances, excluding explosives. If you wish to make a determination of an explosive substance a different form will have to be used.
2. This determination will provide you with information on
   - whether or not a substance is a hazardous substance;
   - if so, the hazard classification; and
   - the approvals that apply or are required to be obtained.
3. It is recommended that you contact an Advisor at the Environmental Protection Authority (EPA) as early in the application process as possible. An Advisor can assist you with any questions you have during the preparation of your application. If you need help to complete the application form, phone the Inbound Customer Services Administrator (0800 HAZ SUBS / 0800 429 7827), or email HSApplications@epa.govt.nz.
4. Unless otherwise indicated, all sections of this form must be completed for the application to be formally received and assessed. If a section is not relevant to your application, please provide a comprehensive explanation why this does not apply. If you choose not to provide the specific information, you will need to apply for a waiver under section 59(3)(a)(ii) of the HSNO Act. This can be done by completing the section on the last page of this form.
5. Any extra material that does not fit in the application form must be clearly labelled and cross-referenced, and included with the application form when it is submitted.
6. Please add extra rows/tables where needed.
7. To be formally received you must sign the final form (the EPA will accept electronically signed forms), and pay the application fee (including GST) unless you are already an approved EPA customer. To be recognised by the EPA as an “approved customer”, you must have submitted more than one application per month over the preceding six months and have no history of delay in making payments at the time of presenting an application.
8. Information about application fees is available on the EPA website.
9. All application communications from the EPA will be sent electronically, unless you specifically request otherwise.

Commercially sensitive information

10. Commercially sensitive information must be included in an appendix to this form and be identified as confidential. If you consider any information to be commercially sensitive, please identify this in the relevant section of this form and cross reference to where that information is located in the confidential appendix.
11. Any information you supply to the EPA prior to formal lodgement of your application will not be publicly released. Following formal lodgement of your application any information in the body of this application form and any non-confidential appendices will become publicly available.

Definitions

Active ingredient	Component of a formulated substance responsible for the pesticidal or veterinary medicinal effect
CAS Number	Chemical Abstracts Service number. This is a unique identifier for a chemical substance
CIPAC Number	Collaborative International Pesticides Analytical Council. The CIPAC code number system is a simple approach for an unambiguous coding of active ingredients and variants used in the area/field of pesticides
Hazardous substance	Hazardous substance means, unless expressly provided otherwise by regulations, any substance— (a) with 1 or more of the following intrinsic properties: (i) explosiveness: (ii) flammability: (iii) a capacity to oxidise: (iv) corrosiveness: (v) toxicity (including chronic toxicity): (vi) ecotoxicity, with or without bioaccumulation; or (b) which on contact with air or water (other than air or water where the temperature or pressure has been artificially increased or decreased) generates a substance with any 1 or more of the properties specified in paragraph (a)
EINECS	European INventory of Existing Commercial chemical Substances
ELINCS	European List of Notified Chemical Substances
IUPAC	International Union of Pure and Applied Chemistry. The world authority on chemical nomenclature
Substance	Substance means— (a) any element, defined mixture of elements, compounds, or defined mixture of compounds, either naturally occurring or produced synthetically, or any mixtures thereof: (b) any isotope, allotrope, isomer, congener, radical, or ion of an element or compound which has been declared by the Authority, by notice in the Gazette, to be a different substance from that element or compound: (c) any mixtures or combinations of any of the above: (d) any manufactured article containing, incorporating, or including any hazardous substance with explosive properties

1. Applicant details

1.1. Applicant

Company Name: Canterbury Regional Council (Environment Canterbury)

Contact Name: Graham Sullivan

Job Title: Regional Manager

Postal Address (provide only if not the same as the physical)**:** PO Box 345, Christchurch 8140

Physical Address: 200 Tuam Street, Christchurch 8140

Phone (office and / or mobile)**:** 03 687 7800

Email: Graham.Sullivan@ecan.govt.nz

1.2. New Zealand agent or consultant (if applicable)

Company Name: Place Group Limited

Contact Name: Angus McKenzie

Job Title: Director

Postal Address (provide only if not the same as the physical)**:** PO BOX 7008, Hamilton East, Hamilton 3216

Physical Address: 14 Anzac Parade, Hamilton Central, Hamilton 3204

Phone (office and / or mobile)**:** 027 607 5005

Email: angus@placegroup.co.nz

1.3. Formal correspondence contact

All formal correspondence will be sent to the contact person for the application identified here

Company Name: Place Group Limited

Contact Name: Angus McKenzie

Job Title: Director

Postal Address (provide only if not the same as the physical)**:** PO BOX 7008, Hamilton East, Hamilton 3216

Physical Address: 14 Anzac Parade, Hamilton Central, Hamilton 3204

Phone (office and / or mobile)**:** 027 607 5005

Email: angus@placegroup.co.nz

1.4. Invoice contact

Only if different from 1.3. Formal correspondence contact - invoice will be sent to the contact person identified here

Company Name: Place Group Limited

Contact Name: As per section 1.3 above.

Job Title:

Postal Address (provide only if not the same as the physical)**:**

Physical Address:

Phone (office and / or mobile)**:**

Fax:

Email:

2. Information about the substance

2.1. Substance name

Rabbit Haemorrhagic Disease Virus (K5 variant)

2.2. Substance description

Please provide a description of the formulated substance (e.g. Soluble Concentrate 350-400 g active ingredient/L)

Active Ingredient:

Rabbit Haemorrhagic Disease Virus (K5 Variant), 08Q712 Strain, >30,000 ID50 units per 10 ml vial of freeze-dried powder containing live RHDV virus for the infection of wild European rabbits (*Oryctolagus cuniculus*).

See Confidential Appendix A, Section 1 for further detail.

2.3. Synonyms

List alternative names for the substance for which you are seeking the determination, including manufacturer's name if different to the commercial name.

Manufacturer's name: RHDV K5.

Alternative names: RHDV1 K5; Rabbit Haemorrhagic Disease Virus (K5 Variant), 08Q712 Strain.

3. Identity of the substance

Any commercially sensitive information may be provided in the confidential appendix of this form
Provide details on the active ingredient(s) as well as the mixture in this section

3.1. Physical and chemical properties of the formulated substance

Provide as much information as possible on the physical and chemical properties of the substance (at 20°C and 1 atmosphere unless otherwise stated)

Appearance (colour, odour, physical state and form):

Rabbit Haemorrhagic Disease Virus (K5 Variant, Lyophilised) is a sterile, cell free, lyophilised (freeze-dried) powder of purified virus particles, plus non-active media constituents, and is supplied in the form of a pink or cream-coloured wettable powder. RHDV is an RNA virus which has been measured in the range of 28-42 nm in diameter.

The reconstituted end use product has:

pH: 7.4

Density (g/mL or kg/L): 1.03 g/L

Vapour pressure (Pa): not available

Boiling/melting point (°C): not available

Solubility in water (mg/L): not available

Water/Octanol partitioning co-efficient: not available

3.2. Composition details of the formulated substance

Unequivocal identification of the substance must be provided to the EPA. This may be included in the confidential appendix.
Please note:

- If your substance contains reaction products of components that are formed once the components are combined (e.g. salts or esters, products of acid/base reactions, polymers components) you also have to provide the full final composition after reaction.
- If you do not have access to the full composition of the substance due to sub-components, you will need to ask your supplier(s) to provide the EPA with the information on those components directly, with an appropriate cover letter to ensure that we can link your application to that information.
- One hundred percent of the composition must be provided. In some cases, if the amount of each component is presented as a range, the total may be greater than 100%.
- If the composition of your substance includes ranges [e.g. 5-10%] for different components, please indicate where possible if some ingredients are optional, or are not always present.

See Confidential Appendix A Section 1 for all further detail on the composition of RHDV1 K5.

4. Supporting information

Any commercially sensitive information may be provided in the confidential appendix of this form

4.1. Safety Data Sheet(s)

It is not a requirement to provide a Safety Data Sheet (SDS) or Material Safety Data Sheet (MSDS) but it may assist us in the determination of your substance. Provision of a Safety Data Sheet is not a substitute for the other information on the form.

You are also recommended to provide SDS for the components (other than water), particularly where these are mixtures.

All SDS provided in support of your application should be up to date (less than five years old).

☐ (M)SDS provided for the substance

☒ (M)SDS not available for the Active Ingredient

☒ (M)SDS provided for the following component(s):

Non- active ingredients: Sucrose, Dipotassium hydrogen phosphate (K_2HPO), Potassium dihydrogen phosphate (KH_2PO_4), Potassium L-glutamate.

See Confidential Appendix A, Section 1 for details of active ingredient and non-active ingredients

See Appendices D for MSDS of non-active ingredients

4.2. Study reports for the substance

If study reports on physicochemical properties, toxicology or ecotoxicology of the substance are available, please provide them (preferably as electronic files).

☒ Study reports available and provided

☐ Study reports not available

Study reports are attached as Confidential Appendices

See:

Appendix B – Australian Quarantine Information for RHDV1 K5 master stock.pdf

- Confidential information
- Includes analyses of tests for potential contaminant organisms (Pgs 21-32)

Appendix E – License to NZLCR to use RHDV1 K5 APVMA registration package 23082016.pdf

- Confidential information
- Approval providing access to information in the Australian APVMA registration package as confidential information

Appendix F for Australian APVMA Full Application RHDV boost confidential.pdf

- Confidential information
- Includes Part 2: Chemistry, manufacture and biological properties
- Part 3 Toxicological information
- Part 7 Environmental studies including Section 7.3 RHDV and non-target species

Appendix G - Additional information to APVMA application OUT16 13883 response to EPBC 24Mar16 confidential .pdf

- Confidential information
- Section A1-A2: RHDV variants physiochemical information and non-target species susceptibility
- Section C7d & C7e: Impact on non-target species and vaccines to protect companion or commercially bred rabbits

Appendix H - Australian RHDV K5 Draft Label.pdf K5.pdf

- Note New Zealand application is for administration by medicated feed only (not by intramuscular injection)

4.3. Intended uses of substance

Provide a draft label if available and/or any commercial information about the use. It is not a requirement to provide a draft label but it may assist us in the determination of your substance.

☒ Draft label provided ☐ Draft label not provided

Appendix C - RHDV K5 label NZ draft

- An updated version of the NZ label has been provided with this application and is based on the existing label for the currently registered product Rabbit Calicivirus Suspension V9308.
- Whilst these products are very similar, the key variations required to label include that the formulation contains the RHDV1 K5 variant as the active ingredient and the product is a freeze-dried (lypholised) powder (see Australian label Appendix H) rather than liquid suspension.

5. Checklist

This checklist is to be completed by the applicant

Application		**Comments/justifications**
All sections of the application form completed or you have requested an information waiver under section 59 of the HSNO Act	☒ Yes ☐ No (If No, please discuss with an HS Advisor to enable your application to be further processed)	
Confidential data as part of a separate, identified appendix	☒ Yes ☐ No	
Supplementary information attached:		
• Copies of study reports	☒ Yes ☐ No	
• Safety Data Sheet (SDS)	☒ Yes ☐ No	Available for non-active ingredients only
• Draft label	☒ Yes ☐ No	Appendix C - NZ draft RHDV1 K5 label.docxl
Administration		
Are you an approved EPA customer?	☐ Yes ☒ No If yes are you an: ☐ Applicant ☐ Agent	
If you are not an approved customer, payment of fee will be by: • Direct credit made to the EPA bank account (preferred method of payment) Date of direct credit: 26 September 2016 • Cheque for application fee sent to EPA	☒ Yes ☐ No ☐ Payment to follow ☐ Yes ☐ No ☐ Payment to follow	
Declaration signed and dated	☒ Yes	

Statutory Declaration

I Graham Sullivan, of Regional Manager of the Canterbury Regional Council, 200 Tuam Street, Christchurch 8140, being the applicant or authorised to do so on behalf of the applicant, verify that the information contained in this application for Rabbit Haemorrhagic Disease Virus (K5 Variant) is true and correct. I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

Signature

Declared at Canterbury Regional Council on this 21 day of ~~August~~ Sept, 2016 before me.

J.E Ward J.P. No 94074

Witness signature

[name] Barrister or Solicitor of the High Court of New Zealand

[or Justice of the Peace, Notary Public, or other person authorised to take a statutory declaration]

Signature of applicant or person authorised to sign on behalf of applicant

☒ I am making this application or I am authorised to sign on behalf of the applicant or applicant organisation.

23 September 2016

Signature **Date**

Request for information waiver under section 59 of the HSNO Act

☒ I request for the Authority to waive any legislative information requirements (i.e. concerning the information that has been supplied in my application) that my application does not meet (tick if applicable).

been supplied in my application) that my application does not meet (tick if applicable).

Please list below which section(s) of this form are relevant to the information waiver request: