Environmental Protection Authority
Te Mana Rauhī Taiao

APPLICATION FORM
Pesticides

To obtain approval to import or manufacture a pesticide

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.

This form should also be used for

- Antifouling paints ☐
- Fumigants ☐
- Plant protection products ☒
- Timber treatments ☐
- Vertebrate Toxic Agents ☐

Name of the substance to be approved

EroMite

Date

28/11/2016

Completing this application form

1. This form has been approved under section 28 of the Hazardous Substances and New Organisms (HSNO) Act 1996. It only covers the import or manufacture of pesticides to be released in New Zealand under section 28 of the HSNO Act. If you wish to make an application for another type of substance (such as a veterinary medicine or industrial chemical) or for another type of application (such as emergency, special emergency or containment), a different form will have to be used. All forms are available on our website.
2. It is recommended that you contact an Applications Advisor at the Environmental Protection Authority (EPA) as early in the application process as possible. An Applications Advisor can assist you with any questions you have during the preparation of your application including advising on any consultation requirements.
3. Before submitting this application, you may make an informal Status of Substance (SOS) advice request to the EPA. Further information on this process is available on our website. Please note that this is not mandatory and an SOS request is only informal advice.
4. This application form may be used to seek approvals for more than one hazardous substance, if the substances and their uses are of a similar nature.
5. Please make sure that you obtain all appropriate permissions for the use of any data that you have used or provided in this application form, if you are not the owner of such data.
6. 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.
7. Any extra material that does not fit in the application form must be clearly labelled, cross-referenced, and included with the application form when it is submitted.
8. Please add extra rows or tables where needed.
9. You must sign the form (the EPA will accept electronically signed forms) and enclose 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.
10. Information about application fees is available on the EPA website. If you wish to claim a fee reduction for a reduced-risk-formulated product the appropriate justification must be submitted at the pre-lodgement stage for consideration.
11. All application communications from the EPA will be provided electronically, unless you specifically request otherwise.

Commercially sensitive information

12. The EPA strongly advises applicants to provide as much information relating to the hazard classification and use of their substance as possible to help inform the EPA's assessment as well as for submitters and decision-makers. We expect this information to be publicly available in the application unless there is a genuine argument for it to be considered as commercially sensitive.
13. Commercially sensitive information may be put in a confidential appendix to this form (also available on our website) and be identified as confidential. If you consider any information to be commercially sensitive, please show this in the relevant section of this form providing your detailed reasons for considering it to be commercially sensitive and cross referencing to where that information is located in the confidential section.
14. Any information you supply to the EPA prior to formal lodgement of your application will not be publicly released, unless it has already been made publicly available as part of the consultation process. Following formal lodgement of your application any information in the body of this application form and any non-confidential appendices will become publicly available.
15. Once you have formally lodged your application with the EPA, any information you have supplied to the EPA about your application is subject to the Official Information Act 1982 (OIA). If a request is made for the release of information that you consider to be confidential, your view will be considered in a manner consistent with the OIA and with section 57 of the HSNO Act. You may be required to provide further justification for your claim of confidentiality.

Definitions

Active ingredient	Component of a formulated substance responsible for the pesticidal 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	Any substance with one or more of the following intrinsic properties: • Explosiveness • Flammability • A capacity to oxidise • Corrosiveness • Toxicity (including chronic toxicity) • Ecotoxicity, with or without bioaccumulation, or • 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 one or more of the properties specified in this definition

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
Pesticide	Substance or mixture of substances intended to be used for preventing, controlling, repelling or mitigating any pest (including vertebrates) in areas such as, but not limited to, agriculture, home and garden, rights of way or industrial areas
Professional and non-professional users	Professional users are using pesticides in the course of their job or business (such as farmers and growers or amenity users). Professional use may include the use of formulated substances in order to deliver services to business or private customers Non-professional users are not using pesticides in the course of their job or business (such as lifestyle block owners, general public using pesticides for domestic use, and so on)
Public register name	Name of the formulated substance to be mentioned in a publicly available register and that can be different from the final marketing name
Relabelling	Action of changing the label of a formulated substance intended to be imported in New Zealand in order to meet the EPA criteria for information content. This action can also occur when the formulated substance is repacked into packaging of different sizes
Repackaging	Movement or transfer of a substance from one container to another without a change in composition of the formulation or the labelling content, for sale or distribution
Status Of Substance (SOS) advice	The advice provided in a SOS advice request will include: • Whether or not a substance is hazardous • Whether the substance is covered or not by an existing approval • The hazard classifications of the substance • The potential relevant approval pathway for the substance
Substance	Any of the following: • Any element, defined mixture of elements, compounds or defined mixture of compounds, either naturally occurring or produced synthetically, or any mixtures thereof; • 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; • Any mixtures or combinations of any of the above; • Any manufactured article containing, incorporating or including any hazardous substance with explosive properties. (section 2(1) HSNO Act)

1. Applicant details

1.1. Applicant

Company Name: Adria New Zealand Limited

Contact Name: Len Stulich

Job Title: Director

Postal Address (provide only if not the same as the physical)**:** PO Box 535 Kumeu, Auckland 0841

Physical Address: 407 S.H.16 Kumeu, RD 2, Auckland

Phone (office and / or mobile)**:** 09 412 9817

Fax: 09 412 9807

Email: len@adria.nz

1.2. New Zealand agent or consultant (if applicable)

Company Name:

Contact Name:

Job Title:

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

Physical Address:

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

Fax:

Email:

1.3. Formal correspondence contact

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

Company Name: Adria New Zealand Limited

Contact Name: Len Stulich

Job Title: Director

Postal Address (provide only if not the same as the physical)**:** PO Box 535 Kumeu, Auckland 0841

Physical Address: 407 S.H.16, RD 2 Kumeu, Auckland

Phone (office and / or mobile)**:** 09 412 9817

Fax: 09 412 9807

Email: len@adria.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:

Contact Name:

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. Purpose statement or executive summary of the application for the public register

No more than 1,100 characters including the description of the formulated substance to be approved, e.g. Soluble Concentrate 350-400 g active ingredient/L

To import EroMite miticide, containing 110g/litre of the active ingredient etoxazole in the form of a suspension concentrate, to control European Red mite and Two-Spotted mite in pipfruit and Six-Spotted mite in avocados.

2.2. Type of application

Tick the box(es) that best describe your application

Has 'Status of Substance (SOS) Advice' been obtained from the EPA?

☒ Yes ☐ No

If yes, show the SOS reference number:

APP203052

If yes, is the formulation of the substance different to that submitted at the SOS stage?

(In either case, please provide the composition to the EPA. This may be provided as part of the confidential appendix)

☐ Yes ☒ No

Is the product a new active ingredient to New Zealand?

☐ Yes ☒ No

Does the product contain any viable new organisms, including GMOs?

☐ Yes ☒ No

Does the product contain an ingredient originating from an organism (plant, animal, etc)?[1]

☐ Yes ☒ No

[1] If you tick 'Yes' and the product is being imported, then include a Biosecurity Clearance from the Ministry for Primary Industries New Zealand. If one has been provided with a previous application and is still valid, this may be referenced.

Does the formulated substance contain any nanomaterial?

☐ Yes ☒ No

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. Identity of the active ingredient(s)

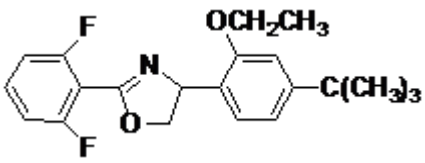
Active ingredient (Common Name): Etoxazole

Chemical name (IUPAC): (*RS*)-5-*tert*-butyl-2-[2-(2,6-difluorophenyl)-4,5-dihydro-1,3-oxazol-4-yl]phenetole

Chemical name (CA): 2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole

Molecular formula: $C_{21}H_{23}F_2NO_2$

Structural formula:



Manufacturer development codes: S-1283 (Sumitomo), YI-5301 (Yashima)

CIPAC No: 623

CAS No: 153233-91-1

EEC No (EINECS or ELINCS): Not allocated

Function:

For plant protection products

☐ Herbicide	☐ Microbial strain	☐ Fungicide
☒ Insecticide	☐ Semiochemical (pheromone, attractant, repellent etc.)	☐ Plant Extracts

☐ Other, eg plant growth regulators (specify):

For timber treatments, Vertebrate Toxic Agents (VTA), anti-fouling paints or fumigants, please describe the function:

FAO Specification (including year of publication): ☒ Yes Year: 2004 ☐ No

Minimum purity of the active ingredient as manufactured (g/kg): 96%

Note: Any impurities must be provided to the EPA. A certificate of analysis may be included in the confidential appendix. See confidential appendix

3.2. Regulatory status of the active ingredient(s)

Jurisdiction	Regulatory status					Comment*
	Never approved	Pending	Approved	Restricted	Not renewed	
Australia	☐	☐	☒	☐	☐	
Canada	☒	☐	☐	☐	☐	
Europe	☐	☐	☒	☐	☐	
Japan	☒	☐	☐	☐	☐	
New Zealand	☐	☐	☒	☐	☐	
USA	☐	☐	☒	☐	☐	
Other jurisdictions (specify in comments)	☐	☒	☐	☐	☐	South Africa

*For instance, specify here under which regulation(s) or directive(s).

When restricted or not renewed, explanations should be provided:

3.3. Identity of the formulated substance

Formulated substance name: EroMite

Manufacturer development codes: Not available

Unique names for public register: EroMite

Active ingredient(s) and content (g/kg or L and % w/w): 110 g/ L 11% % (w/w)

3.4. 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): Cream white liquid, Characteristic odour, SC

pH: 8.2

Density: 1.05 g/L

Vapour pressure: No data available

Boiling/melting point: No data available

Solubility in water: Suspends in water

Water/Octanol partitioning co-efficient: No data available

3.5. Regulatory status of the formulated substance

Jurisdiction	Regulatory status					Comment*
	Never approved	Pending	Approved	Restricted	Not renewed	
Australia	☒	☐	☐	☐	☐	
Canada	☒	☐	☐	☐	☐	
Europe	☒	☐	☐	☐	☐	
Japan	☒	☐	☐	☐	☐	
New Zealand	☐	☒	☐	☐	☐	
USA	☒	☐	☐	☐	☐	
Other jurisdictions	☐	☒	☐	☐	☐	South Africa

(specify in comments)						

*For instance, specify here under which regulation(s) or directive(s).

Has an application been made for an approval under the Agricultural Compounds and Veterinary Medicines Act?

☒ Yes ☐ No

3.6. Composition details of the formulated substance

Full composition details for the substance must be provided to the EPA. These may be included in the confidential appendix

See Confidential attachment.

4. Life cycle of the substance

Manufacturing

Will your formulated substance be manufactured in New Zealand?

☐ Yes ☒ No

Importation

Will your formulated substance be imported into New Zealand by air and/or sea?

☒ Sea ☐ Air

Will your formulated substance be imported in bulk containers or packaged ready for sale?

☐ Bulk Containers ☒ Packaged ready for sale

If your formulated substance will be imported in bulk containers, please describe these containers:

Will repackaging of your formulated substance be carried out in New Zealand?

☐ Yes ☒ No

Will relabelling of your formulated product be carried out in New Zealand?

☐ Yes ☒ No

Please provide any additional relevant information relating to the importation of your formulated substance:

Transport

Will your formulated substance be transported by road, rail, air and/or sea within New Zealand?

☒ Road ☐ Sea ☐ Rail ☐ Air

Please provide any additional information relating to transport of your formulated substance:

UN Number: 3082

UN Transport Hazard Classes: 9

UN Packing Group Number (UN Model Regulations[2]): III

Marine Pollutant? (IMDG Code[3]): Yes

Packaging

Pack sizes: 1L

Type of packaging: HDPE

Type of closure (consider opening size, type of cap, child resistant packaging): 65mm aluminium foil sealed closure with tamper proof screw cap.

Please provide any additional information relating to the packaging of your formulated substance:

Storage

Provide details of how the substance will be stored, and the facilities it will be stored in:

Storage and transport will be through Mainfreight and Chemcouriers. From their logistics store, product will be despatched to resellers throughout New Zealand by approved carriers who will carry the SDS (Safety Data Sheet) and Product Safety Card.
Product will be stored at Mainfreight Logistics – 42 O'Rorke Road, Penrose – in an approved chemical storage facility.

Warehouse storage

[2] UN Model Regulations mean Model Regulations annexed to the most recently revised edition of the Recommendations on the Transport of Dangerous Goods published by the UN
[3] IMDG Code means that International Maritime Dangerous Goods code, as amended

Provide details of how the formulated substance will be stored: As above.

Containment of spillages: As per Mainfreight Logistics Emergency Response Plan.

Decontamination of areas, personnel, vehicles and buildings: As above.

Disposal

Disposal of damaged packaging, contaminated absorbents and other materials: Approved hazardous waste disposal provider.

Detailed instructions for safe disposal of the formulated substance and its packaging: The formulated substance is to be used as per the label recommendations or returned to the supplier. Empty containers must be triple rinsed and then taken to an AgRecovery depot for disposal and recycling.

Methods other than controlled incineration for disposal: As above.

5. Intended uses of the formulated substance

The information you provide here will be used by the EPA to assess the risks posed by the substance and the controls assigned to manage these risks. You must outline either all the proposed uses of the product or the worst-case scenario for each application method (considering both the application rate and the frequency). **Please use table 5.1 for plant protection products or table 5.2 for all other types of pesticides.** Explanatory notes are below each table.

5.1. Intended uses for plant protection products

You must outline either all the proposed uses of the product or the worst case scenario for each application method (considering both the application rate and frequency)

Crop and/or situation (a)	Product Code	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				Type (d-f)	Conc of as (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	Kg as/hL min max	Water L/ha min max	Kg as/ha min max		
Avocados	Miticide	F	Six-Spotted mite	SC	110g/l	High volume broadcast ground-based spraying	Once mite number threshold is reached	1x max	n/a	Min: 0.0039 Max: 0.0039	Min: 750L Max: 3,000L	Min: 0.029 Max: 0.117	14 days	
Apples, Pears	Miticide	F	European Red mite, Two-Spotted mite	SC	110g/l	High volume broadcast ground-based spraying	Once mite number threshold is reached	1x max	n/a	Min: 0.0039 Max: 0.0039	Min: 750L Max: 3,000L	Min: 0.029 Max: 0.117	14 days	

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*eg* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) eg biting and suckling insects, soil born insects, foliar fungi, weeds
(d) eg wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, eg high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, eg overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be described
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: extent of use, economic importance and restrictions

5.2. Intended use for pesticides not used as plant protection products (eg timber treatments, Vertebrate Toxic Agents (VTA), anti-fouling paints or fumigants)

You must outline either all the proposed uses of the product or the worst case scenario for each application method (considering both the application rate and frequency)

User (a)	Area of Use (b)	Pest or group of pests controlled (c)	Application			Application rate per treatment (f)	Remarks (g)
			Method (d)	Number min max (e)	Interval between applications - days (minimum)		

(a) Professional/non professional
(b) Domestic/commercial/industrial
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(e) The minimum and maximum number of applications possible under practical conditions of use must be provided
(f) g/kg and g/l or others
(g) Remarks may include; extent of use, economic importance and restrictions

6. HSNO hazard classifications of the formulated substance

The information you provide here will form the basis of your substance's HSNO classification.

Please consider each of the hazardous properties in the table below and provide information on those properties that trigger any threshold level for your substance. Use the justification column to record the reason for your classification. If your substance is a mixture, you can apply mixture rules to the hazardous components of the mixture. If you do this, you will need to provide information on the hazardous properties of each hazardous component of the mixture, and show your workings. See Assigning A Product to an HSNO Approval on our website for more information.

Please use the following abbreviations if needed.

NA: Not Applicable – For instance when testing is technically not possible: testing for a specific endpoint may be omitted, if it is technically not possible to conduct the study as a consequence of the properties of the substance: eg very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion or the radio-labelling of the substance required in certain studies may not be possible.

ND: No Data or poor quality data (according to Klimisch criteria) – where there is a lack of data.

No: Not Classified based on actual relevant data available for the substance – the data is conclusive and shows the threshold for classification is not triggered.

Hazard Class/Subclass	Formulated substance classification	Justification
Examples	3.1C 6.1D	Flashpoint = 46 deg C (closed cup) Calculated LD50 = 1250 mg/kg (mixture rules)
Class 1 Explosiveness		
Class 2, 3 & 4 Flammability		
Class 5 Oxidisers/Organic Peroxides		
Subclass 8.1 Metallic corrosiveness		
Subclass 6.1 Acute toxicity (oral)		
Subclass 6.1Acute toxicity (dermal)		
Subclass 6.1 Acute toxicity (inhalation)		
Subclass 6.1 Aspiration hazard		
Subclass 6.3/8.2 Skin irritancy/corrosion	6.3B	APP203052

Subclass 6.4/8.3 Eye irritancy/corrosion		
Subclass 6.5A Respiratory sensitisation		
Subclass 6.5B Contact sensitisation		
Subclass 6.6 Mutagenicity		
Subclass 6.7 Carcinogenicity		
Subclass 6.8 Reproductive or developmental toxicity		
Subclass 6.8 Reproductive or developmental toxicity (known, presumed or suspected)		
Subclass 6.8 Reproductive or developmental toxicity (*via* lactation)		
Subclass 6.9 Target organ systemic toxicity[4]	6.9A	APP203052
Subclass 9.1 Aquatic ecotoxicity	9.1A	APP203052
Subclass 9.2 Soil ecotoxicity		
Subclass 9.3 Terrestrial vertebrate ecotoxicity		
Subclass 9.4 Terrestrial invertebrate ecotoxicity		

[4] identify classification for single and/or repeat dose target organ toxicity for oral, dermal or inhalation routes

7. Risks, costs and benefits

These are the positive and adverse effects referred to in the HSNO Act. It is easier to regard risks and costs as being adverse (or negative) and benefits as being positive. In considering risks, cost and benefits, it is important to look at both the likelihood of occurrence (probability) and the potential magnitude of the consequences, and to look at distribution effects (who bears the costs, benefits and risks).

You will need to consider the effects on the environment and human health and welfare, including any social effects.

In each section below, set out the information under the following three sub-headings:

- Costs and benefits which can be stated in monetary (dollar) terms
- Non-monetary risks and costs
- Non-monetary benefits.

You must fully complete this section, referencing supporting material. You will need to provide a description of where the information in the application has been sourced from, e.g. from; in-house research, independent research, technical literature, community or other consultation, and provide that information with this application.

7.1. Identify all of the potential risks, costs and benefits of the substance(s)

Identification is the first step in assessing risks, costs and benefits. It is important to think about the source of the risk, i.e. the way in which the risk is created (the exposure pathway), and then the consequences and likelihood of exposure.

You should try to think as widely as possible about every potential risk, cost and benefit and give a brief description.

EroMite has the following potential toxicity risks:

6.3B: Skin irritant
6.9A (Oral): Target organ systemic toxicant
9.1A: Aquatic ecotoxicant

Potential environmental effects *(Source: FAO):*
Etoxazole degrades rapidly in soil and does not show any potential to bioaccumulate.
However, etoxazole is toxic to many aquatic organisms.

Effects on native flora:
None expected under recommended use patterns.

Effects on human health, applicators, bystanders:
Etoxazole had low acute toxicity in rats, causing no mortality at the limit dose after oral (median lethal dose [LD50] > 5000 mg/kg bw), dermal (LD50 > 2000 mg/kg bw) or inhalation (median lethal concentration [LC50] > 1.09 mg/L air, highest attainable concentration) exposure. Etoxazole was not irritating to the skin or eyes of rabbits and not sensitizing under the conditions of the Magnusson and Kligman maximization test in guinea-pigs.
Following repeated dietary dosing, the liver was the main target organ in mice, rats and dogs. Hepatotoxicity was manifest as increased liver weight, liver enlargement and centrilobular hepatocellular hypertrophy, as well as alterations in clinical chemistry (elevated serum levels of liver

enzymes, cholesterol, triglycerides and protein). In several studies, effects on the liver were mild and considered to be non-adverse, reflecting an adaptive response of the liver rather than overt hepatotoxicity.
Etoxazole is unlikely to be genotoxic or carcinogenic.

Transport/Storage:

At all times, EroMite will be handled, stored, transported and used by persons who are trained and experienced in the handling of pesticides. Warehouse staff, merchants and applicators are required to observe Codes of Practice (GrowSafe or ISO9002) and growers/farmers are also GrowSafe accredited. Stores are provided with Safety Datasheets and Product Safety Cards.

Table 7.1 – Summary of Risk Identification of EroMite

Source of potential risk	Adverse effect/ impact	Likelihood	Distribution of effects (geographic)	Distribution of effects (temporal)	Reversible/ irreversible	Voluntary/ Involuntary	Magnitude	Level of residual risk
Transport accident land	Human health	Unlikely	Localised	Not expected	n/a	n/a	Nil	Insignificant
	Aquatic Environment	Unlikely	Localised	Short term	Reversible	Involuntary	Minor	Insignificant
	Terrestrial Environment	Unlikely	Localised	Not expected	n/a	n/a	Nil	Insignificant
Damage to packaging during storage	Human health	Unlikely	Localised	Not expected	n/a	n/a	Nil	Insignificant
	Aquatic Environment	Unlikely	Localised	Not expected	Reversible	Involuntary	Minimal	Insignificant
	Terrestrial Environment	Unlikely	Localised	Not expected	n/a	n/a	Nil	Insignificant
Substance spillage during use	Human health	Unlikely	Localised	Not expected	n/a	n/a	n/a	Insignificant
	Aquatic Environment	Unlikely	Localised	Short term	Reversible	Involuntary	Minimal	Insignificant
	Terrestrial Environment	Unlikely	Localised	Not expected	n/a	n/a	n/a	Insignificant
Incorrect disposal of surplus substance	Human health	Unlikely	Localised	Not expected	n/a	n/a	n/a	Insignificant
	Aquatic Environment	Unlikely	Localised	Short term	Reversible	Involuntary	Minor	Insignificant
	Terrestrial Environment	Unlikely	Localised	Not expected	n/a	n/a	n/a	Insignificant

7.2. Provide an assessment of those risks, costs, and benefits identified in Section 7.1

This section excludes risks, costs, and benefits which relate specifically to Māori taonga or to international agreements. See Sections 7.3 and 7.4 for those aspects.

A full assessment must be provided of all the risks, costs and benefits identified in Section 7.1.For the risk assessment our preferred format is quantitative, however, you may also provide a qualitative assessment if you can justify this. If you are providing your risk assessment in supporting documentation with this application you can provide a summary of all the risks this in this section.

Please note that if you do not complete a full assessment of all risk, costs and benefits this may result in the EPA requesting further information from you, which will mean that your application takes longer to process.

Costs and Benefits:

EroMite can be harmful if ingested orally and it also poses a risk as a potential skin irritant should contact occur. It is also a target organ systemic toxicant and an aquatic ecotoxicant.

The benefits from using EroMite in apples, pears and avocados as specified are significant and include:

- Highly effective mite control;
- Significantly lower toxicity than most other miticides;
- Low toxicity and very low use rates.

When used according to label directions, there is a limited risk of negative environmental and human effects.

7.3. Provide an assessment of any risks, costs and benefits which arise from the kaitiaki relationship of Māori and their culture to the environment

Please note that consultation with Māori may be appropriate for this application. Please refer to the EPA policy 'Engaging with Māori for applications to the EPA' which can be found on the EPA website (www.epa.govt.nz) or contact the EPA for advice.

An example of the issues to consider include whether the substance poses any risk to native or valued species, or waterways.

EroMite is being introduced to assist pipfruit and avocado growers to improve mite control so that they may achieve higher quality production and yields from their crops. Mite infestations can result in significant yield losses and loss of quality. Adria considers that the application is unlikely to have an impact on the relationship between Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga. However, this substance is likely to carry a 9.1A aquatic ecotoxicity classification, which could impact on aquatic food sources like watercress should there be an accidental release of the substance or spray drift. We believed that the controls to be put in place in the management of the substance would mitigate this risk significantly. The risks are known and understood by Maori by reason of knowledge and experience in the transport, handling and storage of dangerous goods. Those employed by contractors in the use of pesticides would have the appropriate experience and certification of competency to carry out such duties providing the substance is used in accordance with the HSNO controls established for this application and in accordance with any other relevant controls applying under other legislation. The risks costs and benefits associated with them in relation to the Maori culture and traditions are not expected to be any greater than other agricultural chemicals in the marketplace.

7.4. Provide an assessment of any risks, costs or benefits to New Zealand's international obligations

Please show if approving or declining the substance would have any impact upon New Zealand's international obligations

We do not believe that any of New Zealand's international obligations would be affected by the approval of EroMite. The active ingredient in EroMite – etoxazole – is registered and in use throughout much of the world.

7.5. Provide information on the proposed management of the substance

Please outline how the risks of the substance will be managed. This may include default controls triggered by the hazardous property classification(s) and reference to Codes of Practice or to standard operating procedures that will be followed

The overall management of the substance, with respect to transport, storage, use and container disposal will be in compliance with the Code of Practice for the Management of Agrichemicals [NZS 8409:2004]. Documentation to facilitate this will include the ready availability of the container label, Product Safety Card (PSC) and Safety Data Sheet (SDS).

The product will be transported, stored and handled by persons familiar with these types of products. The fungicide presents a low risk to humans and the environment when handled and used correctly. The warnings and precautions set out in the label, SDS and PSC will eliminate or mitigate the toxicity hazards posed by the product.

The following regulations will be adhered to in the management of the formulated product:
Hazardous Substances and New Organisms (HSNO) Act 1996. Relevant Controls specified in the Act and identified in this submission will be implemented.
New Zealand Standard NZS5433:1999, Transport of Dangerous Goods on Land.
Health & Safety in Employment (H&SE) Act (1992)

7.6. Provide an overall evaluation of the combined impact of all of the risks, costs and benefits set out in sections 7.2, 7.3 and 7.4

Please express a view on the relative importance of the different risks, costs and benefits and how they should be brought together in making a decision

The major benefit of EroMite is to help improve mite control in pipfruit and avocados and to increase the respective yields in these crops and harvest quality, enabling the export of high value produce to global markets, as well as local markets.

EroMite is a low toxicity miticide, with minimal risks when used and managed as directed, and negligible risk to users, the environment and others.

8. Pathway determination and rapid assessment

Under the HSNO Act, applications may be processed under different pathways, including a rapid assessment. The pathway for your application will be determined after its formal receipt, based on the data provided in this application form. If you would like your application to be considered for rapid assessment (as per the criteria below), we require you to complete the attached statutory declaration and provide a signed hard copy.

Please note that the EPA will not be able to proceed with the rapid assessment without the statutory declaration.

8.1. Rapid assessment

Under the HSNO Act, a hazardous substance may be approved under a rapid assessment if one of the three following options is satisfied. Please show the section that is relevant to your application.

A substance having a similar composition and similar hazardous properties has been approved	☒ Yes ☐ No If Yes, please give the name of the reference substance: Paramite (HSR100527)
The substance has one or more hazardous properties and each has the least degree of hazard for that property; or	☐ Yes ☒ No
The substance has been formulated so that one or more of its hazardous properties has a lesser degree of hazard than any substance that has been approved under the Act.	☐ Yes ☒ No If Yes, please give the name of the reference substance:

8.2. Statutory Declaration

I Len Stulich, of 87 Joseph Dunstan Drive, Taupaki, Auckland, Director, being the applicant or authorised to do so on behalf of the applicant, verify that the information contained in this application for EroMite 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 Auckland on this 26th day of January, 2017 before me.

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]

9. 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 advisor to enable your application to be further processed)	
Confidential data as part of the confidential form. Please note the EPA strongly encourages applicants to provide as much information as possible in the main body of the application form unless there is a genuine argument that it is commercially sensitive.	☒ Yes ☐ No	
Supplementary optional information attached:		
• Copies of additional references	☐ Yes ☐ No	
• Letter(s) of access	☐ Yes ☐ No	
• Relevant correspondence	☐ Yes ☐ No	
• Draft label	☒ Yes ☐ No	
• Draft Safety Data Sheet (SDS)	☒ Yes ☐ No	
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: • Cheque for application fee enclosed	☐ Yes ☐ No ☐ Payment to follow ☐ Yes ☐ No ☐ Payment to follow	
Electronic signed copy of application e-mailed to the EPA	☒ Yes	

Physical copy of signed statutory declaration sent to the EPA, (rapid assessment only)	☒ Yes	

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

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

☒ I have completed this application to the best of my ability and, as far as I am aware, the information I have provided in this application form is correct.

28/11/2016

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).

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