

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
 NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



FORM HS1

Application for approval to
IMPORT OR MANUFACTURE ANY HAZARDOUS
SUBSTANCE FOR RELEASE

under section 28 of the
Hazardous Substances and New Organisms Act
1996

Name of Substance(s): PYROMITE

Applicant: ADRIA NEW ZEALAND LIMITED

Office use only

Application Code: Date received: ____/____/____

ERMA NZ Contact: _____ Initial Fees Paid: \$

Application Version No: _____.

IMPORTANT

1. Before you fill in this application form, you may find it helpful to consult the *User Guide to Hazardous Substance Applications under the HSNO Act 1996*. This User Guide can either be downloaded from our website or purchased from ERMA New Zealand. The level of information that you need to provide in this application is dependent upon the scale and the significance of the risks and/or whether these risks are well understood and controlled. The User Guide will offer further advice on this.
2. Part B of the User Guide covers applications under Section 28 of the Act and all of the cross references in this application form are to Part B.
3. You can also talk to an applications officer at ERMA New Zealand who can help you scope and prepare your application. We need all relevant information early on in the application process. Quality information up front will speed up the process.
4. This application form may be used to seek approvals for more than one hazardous substance where the substances are related, for example a concentrated compound (active ingredient) and its related formulations or the two parts of an epoxy glue.
5. Any extra material that does not fit in the application form must be clearly labelled, cross-referenced, and included in an Appendix to the application form.
6. Commercially sensitive information must be collated in a separate Appendix.
7. Applicants must sign the form and enclose the correct application fee. The initial application fee can be found in our published *Schedule of Fees and Charges*. Make sure that you have an up to date copy of the Schedule. Please check with ERMA New Zealand staff. We are unable to process applications that do not contain the correct fee.
8. Unless otherwise indicated, all sections of this form must be completed for the application to be progressed. Where an applicant is unable to complete the sections marked optional, this information may be derived by ERMA New Zealand and the costs of doing so will be recovered from the applicant as part of the processing costs.

You can get more information at any time by contacting us. One of our staff members will be able to help you.

ERMA New Zealand

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NEW ZEALAND

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www.ermanz.govt.nz

Section One – Applicant Details

See comments under “Section One of Application Form” in the User Guide for guidance.

1.1 Name and postal address in New Zealand of the organisation making the application:

Name: ADRIA NEW ZEALAND LIMITED
Address: PO BOX 535 KUMEU, AUCKLAND 1250
Phone: 09 4129817
Fax: 09 4129807

1.2 The applicant’s location address in New Zealand (if different from above):

Address: 407 STATE HIGHWAY 16 KUMEU, AUCKLAND

1.3 Name of the contact person for the application:

This person should have sufficient knowledge to respond to queries and either have the authority to make decisions on behalf of the applicant that relate to processing the application, or have the ability to go to the appropriate authority.

Name: LEN STULICH
Position: MANAGING DIRECTOR
Address: PO BOX 535 KUMEU, AUCKLAND
Phone: 09 4129817
Fax: 09 4129807
Email: len@adriacp.co.nz

Section Two – Application Type and Related Approvals Required

This form is only to be used for an application to import and/or manufacture a hazardous substance for ‘release’ and if it does not meet the requirements for rapid assessment. Please note that it is the substance(s) which is approved, and thus the approval covers both import and manufacture.

If you are making the application for some other reason, you will need a different form.

2.1 Is the information in this application relevant to import, manufacture or both:

(See comments under “Section 2.1 of Form” in the User Guide)

- | | |
|--|-----|
| • Import only? | Yes |
| • Manufacture only? | No |
| • Import and manufacture? | No |
| • If import only, indicate whether or not manufacture is likely in New Zealand | No |

2.2 If the information in the application relates to manufacture in New Zealand, provide information on the proposed manufacturing process and any alternatives.

(See comments under “Section 2.2 of Form” in the User Guide)

N/A

2.3 If you have reasons for not providing detailed information in this application, explain what they are and provide some justification.

An example of a reason for not giving detailed information is where an approval has been given by another jurisdiction and information that led to that approval can be referenced or the substance will be used in low risk situations or ways.

(See comments under “Section 2.3 of Form” in the User Guide)

2.4 If this substance(s) needs an approval under any other legislation, has an application for this approval been made?

(Optional) (See comments under “Section 2.4 of Form” in the User Guide)

Name of Approval

Application made

Agricultural Compounds and Veterinary Medicines Act 1997

Yes

Food Act 1981

NA

Medicines Act 1981

NA

Chemical Weapons (Prohibition) Act 1996

NA

Radiation Protection Act 1965

NA

Biosecurity Act 1993

NA

Resource Management Act 1991

NA

Other (please specify):

No

Section Three – Information on the Substance(s)

Note all information that is commercially sensitive must be attached as an Appendix. The application form should be cross-referenced to the Appendix but should be able to be read as a stand-alone document which will be publicly available.

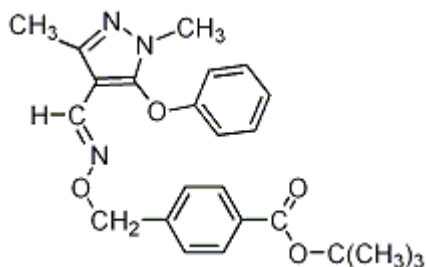
You will need to provide a brief description of where the information in the application has been sourced from, eg from; inhouse data, research, technical literature, etc. See the introductory comments under “Section Three of the Form” in the User Guide for more details.

If approval is being sought for more than one hazardous substance, this section must be completed separately for each hazardous substance.

3.1 State the unequivocal identification of the substance(s).

This section should include all information necessary to unequivocally identify the substance(s) and may include:

- Chemical Name: 1,1-dimethylethyl (*E*)-4-[[[(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl)methylene]amino]oxy]methyl]benzoate
- Common Name: Fenpyroximate
- Synonyms: None
- Trade Names: Fenamite
- CAS Registry Number: 134098-61-6
- Molecular Formula: C₂₄H₂₇N₃O₄
- Structural Formula:



- Significant impurities

tert-butyl 4-(1,1-dichloro-2-(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl)-2-oxoethyl)benzoate 0.2 % Max

4-(chloromethyl) benzoic acid 0.3 % Max

(*E*)-4-(2-(4-tert-butoxycarbonyl)benzyloxyimino) -2-(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl)ethyl)benzoic acid 3.0 % Max

Moisture 0.3 % Max

For mixtures, in addition to the above information being provided on the actual mixture, information is also required on the composition of the mixture ie the chemical name, CAS number, function (eg active ingredient, emulsifier, surfactant, filler) and percentages of **ALL** components of the mixture (including non-hazardous components and impurities) should be provided. This information may be best expressed in tabular form. If the composition is variable, please ensure to state the limits.

If there are commercial reasons for not providing full information in the main part of the form,

alternative approaches must be discussed with and agreed by ERMA New Zealand. These must include the provision of a unique identifier of some kind.

(See comments under “Section 3.1 of Form” in the User Guide

3.2 Provide information on the chemical and physical properties of the substance(s).

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

- Appearance (colour, odour, physical state or form): White liquid
- pH: 7.5
- Density: 1014.83 g/L
- Vapour pressure: 7.4×10^{-3} mPa (25 °C) for fenpyroximate
- Boiling/melting point: > 100 °C
- Solubility in water: Relatively insoluble (1.5×10^{-2} mg/l (25 °C) in water. Disperses in water.
- Water/octanol partitioning co-efficient: $\log P = 5.01$ (20 °C)

For mixtures, information is required on the chemical and physical properties of the mixture itself. However, if this information is not available, you should provide information on the chemical and physical properties of EACH hazardous component of the mixture

(See comments under “Section 3.2 of Form” in the User Guide)

3.3 Provide information on the hazardous properties of the substance(s).

Information should be provided on the hazardous properties of the substance(s) known to the applicant. You must consider each of the six hazardous properties below and provide information on those hazardous properties that trigger any threshold level. If you wish, you may assign the relevant HSNO classification category to each hazardous property that exceeds these threshold levels.

- Explosiveness- Not explosive
- Flammability- Not flammable
- oxidising properties- Not an oxidiser
- corrosiveness- Not corrosive
- toxicity- Oral LD₅₀ > 6 000 mg/kg
Dermal LD₅₀ > 4 000 mg/kg
Inhalation LC₅₀ > 2 000 mg/L
- ecotoxicity- **Birds** LD₅₀ for bobwhite quail and mallard ducks >2000 mg tech/kg. Dietary LD₅₀ (8 d) for bobwhite quail and mallard ducks >5000 ppm. **Fish** LC₅₀ (96 h) for carp 0.0055 mg/l. Daphnia EC₅₀ (48 h) 0.00326 mg/l. **Algae** EC₅₀ (72 h) for *Pseudokirchneriella subcapitata* 9.98 mg/l. **Bees** No adverse effect on honeybees at 250 ppm (5 × recommended dose). Other beneficial spp. Relatively non-toxic to predacious mites. Little adverse effect, at 25–50 ppm, on *Chrysoperla carnea*, *Harmonia axyridis*, *Ephedrus japonicus*, *Misumenops tricuspidatus*, *Lycosa pseudoannulata*, *Orius* sp., *Scolothrips* sp.

If your substance is a mixture and you cannot provide direct information on its hazardous properties, you can apply mixture rules to the hazardous components of the mixture. If you do this, then you will need to provide information on the hazardous properties of each hazardous component of the mixture, and show your workings.

(See comments under “Section 3.3 of Form” in the User Guide).

PROPOSED HAZARD CLASSIFICATIONS: 6.1D, 6.3B, 6.4A, 6.5B, 6.9B, 9.1A, 9.2D, 9.3C

1.1.1

3.4 Identification of the default Controls on the substance(s).

A range of default controls are triggered by the hazardous property classification(s) attached to the substance. If you wish, you can list what these default controls are. If you don't provide this information, ERMA New Zealand will do it for you. Regardless, you need to be aware of what the default controls are so that you can take them into account when assessing risks – see Section 4. **(Optional)** (See comments under “Section 3.4 of Form” in the User Guide)

3.5 Provide information on what will happen to the substance throughout its whole life from its introduction into New Zealand, its uses, through to disposal.

This information is used in the development of exposure scenarios and the assessment of risks, costs and benefits and should therefore be as expansive as possible. (See comments under “Section 3.5 of Form” in the User Guide)

PYROMITE WILL BE USED AS A MITTICIDE FOR CONTROL OF MITES IN PIPFRUIT (APPLES AND PEARS), AS PER LABEL DIRECTIONS. PYROMITE WILL BE APPLIED, USING CONVENTIONAL GROUND-BASED EQUIPMENT, AT A RATE OF 1.0 LITRE PER HECTARE, ONLY ONCE IN A SEASON – AND THIS IS PREDICATED ON CERTAIN THRESHOLDS (I.E. MITE NUMBERS) BEING REACHED. IN MANY SEASONS, FOR EXAMPLE, NO PYROMITE APPLICATIONS WILL BE REQUIRED. APPLICATORS WILL WEAR FULL PROTECTIVE CLOTHING AND SPRAY MASKS. THE APPLICATOR WILL ALSO NEED TO ENSURE THAT THERE ARE NO BYSTANDERS IN THE PROXIMITY.

IMPORTATION AND STORAGE OF PRODUCT

- MODE OF IMPORT: SHIP
- FORECASTED IMPORT QUANTITY: 100 LITRES ANNUALLY
- PRODUCT WILL BE PACKAGED IN UN APPROVED 1 LITRE HDPE BOTTLES.
- PRODUCT WILL BE STORED ON ARRIVAL AND DISTRIBUTED VIA MAINFREIGHT LOGISTICS / CHEMCOURIERS. APPROVED LOGISTICS PROVIDER FOR HAZARDOUS CHEMICALS. DANGEROUS GOODS LICENSE FOR STORAGE AT 42 O'RORKE ROAD, PENROSE, AUCKLAND.
- THE FINAL USER OF THE PRODUCT MUST STORE ANY UNUSED PRODUCT ACCORDING TO INSTRUCTIONS ON THE PRODUCT LABEL AND MSDS. USERS ARE ALSO BOUND TO PROVIDE APPROPRIATE STORAGE FACILITIES ACCORDING TO THEIR LOCAL COUNCIL AND OSH REGULATIONS. KEY ASPECTS OF THESE REGULATIONS STIPULATE SECURE, LOCKED STORAGE WITH BUNDING PROVIDED TO ENSURE ANY SPILLAGES CAN BE CONTAINED AND CLEANED UP WITHOUT ENVIRONMENTAL EXPOSURE.
- PRODUCT WILL BE PRE-LABELLED AT SOURCE OF ORIGIN .



DISTRIBUTION

- PRODUCT WILL BE DISTRIBUTED THROUGH OUR APPROVED NATIONAL DISTRIBUTORS VIA CHEMCOURIERS.
- EMERGENCY RESPONSE INFORMATION IS AVAILABLE VIA ADRIA NZ LTD, OUR DISTRIBUTORS AND THE NATIONAL POISONS CENTRE.
- OUR DISTRIBUTORS WILL HAVE READY ACCESS TO THE PRODUCT'S MSDS (MATERIAL SAFETY DATA SHEET) AND PSC (PRODUCT SAFETY CARD) VIA WWW.ADRIACP.CO.NZ AND ALSO THROUGH ADRIA NZ LTD (POST-REGISTRATION).
-



PRODUCT APPLICATION / DISPOSAL CONSIDERATIONS

- PRODUCT MUST BE APPLIED ACCORDING TO THE DIRECTIONS ON THE LABEL
- THE METHOD OF APPLICATION WILL BE GROUND-BASED APPLICATION VIA MECHANICAL SPRAYING EQUIPMENT.
- STORAGE CONDITIONS: REFER TO DRAFT LABEL FOR DETAILS
- USER SAFETY: APPLICATORS MUST WEAR APPROPRIATE PROTECTIVE CLOTHING, AS LISTED IN THE MATERIAL SAFETY DATA SHEET
- UNUSED PRODUCT SHOULD BE RETURNED TO ADRIA NZ LTD.
CONTAINER DISPOSAL: Triple rinse containers and add residue to spray tank. Return empty containers to an AgRecovery depot for disposal.
- Spills: wear appropriate protective clothing and prevent material from entering waterways. Absorb spills with inert material and place in waste containers. Wash area with water and absorb with further inert material. Dispose of waste safely (such as to a suitable landfill), according to local Council regulations.

Section Four: 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 set out below, it might be easier for you, and most useful for ERMA New Zealand, if the information is set out under the following three sub sections:

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

Complete this section as far as you can. If the analysis provided is incomplete, then it will be completed by ERMA New Zealand. However, the costs of doing this will be chargeable.

You will need to provide a brief description of where the information in the application has been sourced from, eg from; inhouse research, independent research, technical literature, community or other consultation.

(See comments under “Section 4 of Form” in the User Guide)

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

Identification is the first step in assessing risks, costs and benefits. The introductory part of “Section 4 of Form” in the user Guide provides detailed guidance on what kinds of costs, risks and benefits should be thought about. It is important to think about the source of the risk, ie 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. The range of matters that you will need to think about is discussed in the User Guide. You must also decide how significant that risk, cost or benefit is likely to be. If the risk, cost, or benefit is obviously not significant (and you can give reasons), then there is no need to further assess that risk, cost, or benefit.

(See comments under “Section 4.1 of Form” in the User Guide)

Source of significant risk event/incident	Possible reasons for event	Effect/impact	Exposure pathway	Monetary / Non-monetary risks, costs and benefits
Release/spillage of substance (on land or near water)	<ul style="list-style-type: none"> - Transport accident (import, transport) - Accident during use (use) - Theft/vandalism (any stage) - Damaged packaging (any stage) - Warehouse fire (storage) - Failure to follow safety precautions (any stage) - Incorrect disposal (disposal) 	Adverse effect on aquatic environment (fish die) - Low risk	Substance enters waterway	Risk of damage to aquatic organisms and marine life (primary risk during importation via sea).
		Adverse effect on human health -Moderate risk	Ingestion or dermal absorption	Risk of possible adverse effects.
		Adverse effect on terrestrial environment - Moderate risk	Substance absorbed into ground surrounding spillage	Risk of environmental pollution.
Inappropriate/inadvertent use of substance	<ul style="list-style-type: none"> - Wrong dilutions (e.g. over-dosing during use) - Spraying onto wrong crops - Spray-drift onto non-target areas (e.g. neighbouring properties) - Unintended user exposure to spray. - Incorrect disposal of unused substance 	Possible adverse effects on target and non-target crops from excessive or negligent use - Low risk	Substance sprayed onto wrong crops or at excessive rates	Monetary cost of compensation for wrongful application.
		Possible adverse effects from spray-drift, including human exposure to spray. - Moderate to low risk	Dermal absorption or inhalation	Risk of possible adverse effects.
		Adverse effect on terrestrial and aquatic environments - Low risk	Substance applied negligently or spilled carelessly	Risk of environmental pollution.

Benefit Identified	Significant	Reason
One of only 3 possible control options available to apple and pear growers.	Yes	There are very few control options available to apple and pear growers for controlling mites in orchards. These include only 3 different chemical groups. Pyromite offers growers a backup control option when there is an outbreak.
Minimal impact on the environment and applicators	Yes	Pyromite will be applied under controlled conditions. The level and frequency of exposure are therefore minimal.
Employment for New Zealanders	Yes	Adria Crop Protection is a totally NZ owned and operated company and as such employs New Zealanders.

4.2 Provide an assessment of those risks, costs, and benefits identified in Section 4.1 which might be significant.

This section excludes risks, costs, and benefits which relate specifically to Māori taonga or to international agreements. See Sections 4.3 and 4.4 below for those aspects.

Assessments only need to be done for those risks, costs and benefits which Section 4.1 shows might be significant. Section 4.2 in the User Guide provides a detailed explanation of how to do an assessment. Remember that assessments can be qualitative ie based on judgements, if there is no analytical information available. But it is essential that a firm conclusion is drawn about the size and likelihood of the risks, costs or benefits, and also about the certainty of the assessment.

In assessing risks especially, it is important to take account of the extent to which risks will be reduced by the default or other controls (see Section 3.4 above and 4.5 below). (See comments under “Section 4.2 of Form” in the User Guide)

Potentially Significant Risk	Lifecycle	Hazardous Property	Adverse Effect/Impact	Size and Likelihood of Risk
Transport accident causing spillage of substance (over land)	Transport	Toxic Ecotoxic	Human health	Unlikely - localised risk - Short-term risk - Minor magnitude
			Aquatic environment	
			Terrestrial environment	
Damage to packaging causing spillage of substance	Storage	Toxic Ecotoxic	Human health	Unlikely - localised risk - Short-term risk - Minor magnitude
			Aquatic environment	
			Terrestrial environment	
Spillage of substance during use and unintended user exposure during spraying	Use	Toxic Ecotoxic	Human health	Unlikely - localised risk - Short-term risk - Minor magnitude
			Aquatic environment	
			Terrestrial environment	
Incorrect disposal of unused substance	Disposal	Toxic Ecotoxic	Human health	Unlikely - localised risk - Short-term risk - Minor magnitude
			Aquatic environment	
			Terrestrial environment	
Spray-drift onto non-target areas	Use	Toxic Ecotoxic	Human health	Unlikely - Short-term risk - Minor magnitude
			Aquatic environment	
			Terrestrial environment	
Wrong dilutions (e.g. over-dosing)	Use	Toxic Ecotoxic	Terrestrial environment	Unlikely - localised risk - Short-term risk - Minor magnitude

4.3 Provide an assessment of any particular risks, costs and benefits which arise from the relationship of Māori and their culture and traditions with their taonga, or which are, for other reasons, of particular relevance to Māori.

We have asked for a separate response in this area because these requirements are different to other risks, costs and benefits. These are explained in more detail in Section 4.3 of the User Guide. Please note that if there are potentially significant risks in this area, it will almost certainly be necessary to consult with Māori in preparing an assessment. (See comments under “Section 4.3 of Form” in the User Guide)

We do not believe that the substance poses any risks or costs to Maori, as there is a similar substance currently registered which contains the same active ingredient.

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

This is a specialist area which ERMA New Zealand will handle. However, any information you are able to provide on relevant international agreements would help us and save time and cost.

(Optional) (See comments under “Section 4.4 of Form” in the User Guide)

Potentially Significant Risk	Lifecycle	Proposed Risk Management Strategies
Transport accident causing spillage of substance (over land)	Transport	The substance will be exclusively stored and distributed by Chemcouriers who are dedicated transport providers for hazardous chemicals. Refer to www.mainfreight.co.nz/chemcouriers for details relating to certification, risk management and emergency response systems.
Damage to packaging causing spillage of substance	Storage	Refer above
Spillage of substance during use and unintended user exposure during spraying	Use	Refer above. In case of unintended user exposure, the substance label provides First Aid advice. In addition, refer to MSDS.
Incorrect disposal of unused substance	Disposal	As above
Spray-drift onto non-target areas	Use	The product label clearly details the substance directions and recommendations. This issue is also covered in some detail in the Growsafe course and applicators are all knowledgeable about the risk parameters involved and the causes of spray drift, and are educated in practices which minimise the risk.
Wrong dilutions (e.g. over-dosing)	Use	Refer above. In addition, the substance is only available through our approved distributors. They deal with approved users and growers only who are specialist applicators in their field and who are

4.5 Provide information on the proposed management of the substance.

This section should provide information on managing the effects identified and assessed in Sections 4.1 - 4.4 above. The starting point for this is the range of default controls triggered by the hazardous property classification(s) attached to the substance (see Section 3.4). You should describe how these controls would be implemented and indicate other means of managing risks. The information provided must be specific to the substance(s) and cover all areas of intended use. Reference should be made to Codes of Practice or standard operating procedures that will be followed. If changes to the default controls triggered by the substance classification are proposed, the reasons for these changes should be provided.

Please note that you will find it easiest to complete this section in conjunction with section 4.2. That is because the management of risks will influence their residual level. (See comments under "Section 4.5 of Form" in the User Guide)

THE USE OF PYROMITE WILL BE GOVERNED BY THE PRODUCT LABEL (SUBJECT TO ACVM APPROVAL) – SEE LABEL FOR DETAILS. THE LABEL GOVERNS USE RATES, TIMING, APPLICATION METHODS AND WITHHOLDING PERIODS.

THE LEVEL OF ENVIRONMENTAL AND HUMAN EXPOSURE AND THE FREQUENCY WILL MITIGATE ANY POSSIBLE ADVERSE EFFECTS.

APPLICATION WILL GENERALLY BE MADE ONLY ONE OR TWO TIMES A SEASON AND APPLICATORS WILL WEAR FULL PROTECTIVE CLOTHING, AND APPLICATION WILL BE MADE DURING CONDITIONS THAT WILL AVOID SPRAY DRIFT AND EXPOSURE OUTSIDE OF THE TARGET ZONE.

PYROMITE WILL BE STORED AT AN APPROVED DANGEROUS GOODS FACILITY AND TRANSPORTED VIA CHEMCOURIERS TO OUR NATIONAL DISTRIBUTORS – WHO ARE ALL APPROVED HANDLER QUALIFIED. BASED ON CONSULTATION AND REQUIREMENTS THEREOF, PRODUCT WILL BE SOLD TO GROWERS (APPROVED HANDLERS) FOR USE IN THE RESPECTIVE CROP(S). CHEMCOURIERS AND OUR DISTRIBUTORS HAVE EMERGENCY RESPONSE PROCEDURES IN PLACE TO ACTIVATE IN CASE OF SPILLAGE OR OTHER EMERGENCY. THE MSDS AND PRODUCT SAFETY CARD FOR PYROMITE ARE KEPT ON PREMISES AND CARRIED DURING TRANSIT. THEY ARE ALSO AVAILABLE ON OUR WEBSITE www.adriacp.co.nz

BASED ON ALL OF THESE SYSTEMS BEING IN PLACE, WE BELIEVE THAT THE RISKS POSED BY PYROMITE CAN BE MITIGATED TO THE GREATEST POSSIBLE DEGREE.

4.6 Provide an overall evaluation of the combined impact of all of the risks, costs and benefits set out in sections 4.2, 4.3 and 4.4.

Doing this overall evaluation is the main task of the Authority. However, you may wish to 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.

(Optional) (See comments under "Section 4.6 of Form" in the User Guide)

Section Five – International Considerations

- 5.1 ERMA New Zealand is interested in whether this substance (or any of its components) has been considered by any other regulatory authority in New Zealand or by any other country. If you are aware of this, please provide details of the results of such consideration. (Optional) (See comments under “Section 5.1 of Form” in the User Guide)**

Section Six – Miscellaneous

6.1 Provide a glossary of scientific and technical terms used in the application.

(See comments under “Section 6.1 of Form” in the User Guide)

6.2 Provide here any other information you consider relevant to this application not already included.

(See comments under “Section 6.2 of Form” in the User Guide)

Section Seven – Summary of Public Information

The information provided in this section may be used in the Authority’s public register of substances required under Section 20 of the HSNO Act.

This summary information will be used to provide information for those people and agencies (eg Ministry for the Environment, Department of Conservation, Regional Councils, etc), who will be notified of the application, and for potential submitters who request information. This information will also be used to prepare the public notice of the application.

For these reasons, applicants should ensure that this summary information does not contain any commercially sensitive material.

7.1 Name of the substance(s) for the public register:

Please use a maximum of 80 characters.

(See comments under “Section 7.1 of Form” in the User Guide)

PYROMITE

7.2 Purpose of the application for the public register:

This should include (in a maximum of 255 characters) an abstract giving information on the intended use of the substance and why an application is needed based on its hazardous properties.

(See comments under “Section 7.2 of Form” in the User Guide)

“To import or manufacture Pyromite as an insecticide containing the active ingredient fenpyroximate for the control of mites in apples and pears.”

7.3 Use Categories of the substance(s):

ERMA New Zealand has adopted the system of use categories developed by the European Union, which identify various functional uses of substances. This information is pertinent to the assessment of exposure scenarios and the determination of risk and is also useful for building up a profile of the substance. There are three sets of use categories. Within each of these, applicants should state which use categories are relevant to all intended uses of the substance(s).

- Main category: 4
- Industry category: 1
- Function/Use category: 38

(Optional) (See comments under “Section 7.3 of Form” in the User Guide)

7.4 Executive Summary:

In this section, the applicant should provide a summary of information contained in this application, including:

- the identification of the substance, its hazardous properties and intended uses
- an assessment of the risks, costs and benefits
- the methods implemented to manage the risks, particularly in relation to emergency management and disposal.

(See comments under “Section 7.4 of Form” in the User Guide)

PYROMITE IS A MITICIDE FOR THE SPECIFIC CONTROL OF MITES IN APPLES AND PEARS.

PYROMITE CONTAINS THE SAME ACTIVE INGREDIENT (FENPYROXIMATE) AS A SUBSTANCE ALREADY APPROVED FOR USE IN NEW ZEALAND – IN THE SAME CONCENTRATION AND IN THE SAME FORMULATION TYPE (SUSPENSION CONCENTRATE).

THE PRELIMINARY HAZARD CLASSIFICATIONS ARE: 6.1D (ACUTE TOXICANT), 6.3B (SKIN IRRITANT), 6.4A (EYE IRRITANT), 6.5B (CONTACT SENSITISER), 6.9B (TARGET ORGAN SYSTEMIC TOXICANT), 9.1A (AQUATIC ECOTOXICANT), 9.2D (SOIL ECOTOXICANT), 9.3C (VERTEBRATE ECOTOXICANT).

PYROMITE WILL BE APPLIED , USING CONVENTIONAL GROUND-BASED EQUIPMENT, AT A RATE OF 1.0 LITRE PER HECTARE, ONLY ONCE IN A SEASON – AND THIS IS PREDICATED ON CERTAIN THRESHOLDS (I.E. MITE NUMBERS) BEING REACHED. IN MANY SEASONS, FOR EXAMPLE, NO PYROMITE APPLICATIONS WILL BE REQUIRED.

PYROMITE WILL OFFER AN ALTERNATIVE, LOWER-COST MITICIDE CONTROL OPTION IN THE EVENT OF A MITE OUTBREAK. DUE TO THEIR RAPID BREEDING CYCLES, MITES CAN BECOME RESISTANT TO MITICIDES, AND THERE ARE ONLY THREE SPECIFIC CHEMICAL GROUPS REGISTERED TO CONTROL MITES IN APPLES AND PEARS (DOWN FROM 6-7 A DECADE AGO). SO, PYROMITE WILL BE A VALUABLE CONTROL OPTION, IN WHAT IS AN AREA OF DIMINISHING CONTROL OPTIONS AVAILABLE TO GROWERS.

THE SUBSTANCE WILL BE AVAILABLE ONLY TO ERMA APPROVED HANDLERS FOR USE IN SPECIALISED CROP SITUATIONS, UNDER STRICT CONTROLS. THE MAIN TOXICITY HAZARDS RELATING TO ITS HANDLING, USE AND STORAGE, CAN BE MANAGED – WITH COMPREHENSIVE PRECAUTIONARY INFORMATION AND DIRECTIONS ON THE PRODUCT LABEL, MATERIAL SAFETY DATA SHEET, AND THROUGH THE INFORMATION AND ADVICE PROVIDED BY OUR DISTRIBUTORS AND ADRIA. PRODUCT SAFETY CARDS WITH EMERGENCY

MANAGEMENT PROCEDURES WILL BE AVAILABLE ON OUR WEBSITE (WWW.ADRIACP.CO.NZ) AND THROUGH OUR HORTICULTURAL DISTRIBUTORS (PROVIDED WITH ALL PRODUCT DELIVERIES). RINSED AND CLEANED EMPTY PACKAGING (BOTTLES) ARE TO BE RETURNED TO A LOCAL AGRECOVERY DEPOT FOR CORRECT DISPOSAL.

WHEN OUR SYSTEMS AND CONTROLS RELATING TO THE PROPOSED STORAGE, DISTRIBUTION AND APPLICATION ARE TAKEN INTO ACCOUNT, WE BELIEVE THAT THE HUMAN AND ENVIRONMENTAL RISKS POSED BY PYROMITE CAN BE MITIGATED TO A GREAT DEGREE, AND ARE NOT SIGNIFICANTLY DIFFERENT TO OTHER SUBSTANCES THAT ARE ALREADY APPROVED FOR USE IN NEW ZEALAND.

CHECKLIST

Mandatory sections filled out	Yes
Appendices enclosed	Yes
Fees enclosed	Yes
Application signed and dated	Yes

Signed