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

FAE-RTU 398

Date

23rd of September 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: Kiwicare Corporation Ltd

Contact Name: David Colsell

Job Title: Senior Chemist

Postal Address (provide only if not the same as the physical)**:** PO Box 15050, Aranui, Christchurch 8643

Physical Address: 225 Maces Road, Bromley, Christchurch 8062

Phone (office and / or mobile)**:** +64 3 373 8382

Fax: 03 389 0669

Email: davidc@kiwicare.co.nz

1.2. New Zealand agent or consultant (if applicable)

Company Name: Not Applicable

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: Kiwicare Corporation Ltd

Contact Name: David Colsell

Job Title: Senior Chemist

Postal Address (provide only if not the same as the physical)**:** PO Box 15050, Aranui, Christchurch 8643

Physical Address: 225 Maces Road, Bromley, Christchurch 8062

Phone (office and / or mobile)**:** +64 3 373 8382

Fax: 03 389 0669

Email: davidc@kiwicare.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: Kiwicare Corporation Ltd

Contact Name: Mariska Jordaan

Job Title: Accounts Administrator

Postal Address (provide only if not the same as the physical)**:** PO Box 15050, Aranui, Christchurch 8643

Physical Address: 225 Maces Road, Bromley, Christchurch 8062

Phone (office and / or mobile)**:** 03 9400 992

Fax: 03 389 0669

Email: MariskaJ@kiwicare.co.nz

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 manufacture substance 'FAE-RTU 398' as an alternative weed-killer to glyphosate for the control of weeds commonly found in home and gardens.

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:

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

Does the formulated substance contain any nanomaterial?

[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.

☐ 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)

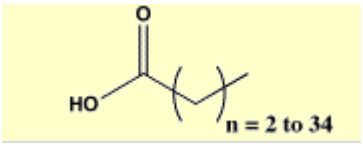
Active ingredient (Common Name): Fatty acids

Chemical name (IUPAC): Fatty acids (please refer to the confidential appendix)

Chemical name (CA): Fatty acids (please refer to the confidential appendix)

Molecular formula: $C_nH_{2n}O_2$ as empirical formula (Please see the confidential appendix)

Structural formula: Generic structure



Manufacturer development codes: None

CIPAC No: (Please see the confidential appendix)

CAS No: (Please see the confidential appendix)

EEC No (EINECS or ELINCS): (Please see the confidential appendix)

Function: Active ingredient

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: ☒ No

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

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

3.2. Regulatory status of the active ingredient(s) Fatty acids

Jurisdiction	Regulatory status					Comment*
	Never approved	Pending	Approved	Restricted	Not renewed	
Australia	☐	☐	☒	☐	☐	APVMA
Canada	☐	☐	☒	☐	☐	PMRA
Europe	☐	☐	☒	☐	☐	EU Directive 91/414/ECC
Japan	☐	☐	☒	☐	☐	Japan Chemical Substances Control Law (CSCL)
New Zealand	☐	☐	☒	☐	☐	HSNO Act
USA	☐	☐	☒	☐	☐	US EPA
Other jurisdictions (specify in comments)	☐	☐	☐	☐	☐	

*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: FAE-RTU 398

Manufacturer development codes: FAE-RTU 398

Unique names for public register: FAE-RTU 398

Active ingredient(s) and content (g/kg or L and % w/w): Fatty acids 70 g/kg or L 7.00% (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): Clear to pale yellow liquid

pH: 7.5 – 8.5

Density: 1.00 kg/L

Vapour pressure: Not known

Boiling/melting point: ~ 100°C

Solubility in water: Soluble

Water/Octanol partitioning co-efficient: Not known

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 (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

Please see confidential appendix.

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?

Not planned at this time

☐ 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: Not applicable

UN Transport Hazard Classes: Not applicable

UN Packing Group Number (UN Model Regulations[2]): Not applicable

Marine Pollutant? (IMDG Code[3]): Not applicable

Packaging

Pack sizes: 100 ml – 10 L, it is our intention initially to market a 1 litre FAE-RTU 398 in 1 litre container size.

Type of packaging: HDPE trigger spray bottle.

Type of closure (consider opening size, type of cap, child resistant packaging): The HDPE trigger spray bottle with child resistance mechanism. Child Resistant packaging is used to reduce the risk of children gaining access to the product.

Please provide any additional information relating to the packaging of your formulated substance: Our initial plan is to fill 1 litre product into 1 litre HDPE trigger spray bottle with child resistant caps.

Storage

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

It is expected that the products would be stored in bulk for short periods in the manufacturing facility and then on retail shelves for periods of up to 3 years before being sold to end users. End users will store these products in cool dry situations until use, and dispose of empty containers and remaining product as per regulations D4, D5, D6, D7, D8.

Warehouse storage

Provide details of how the formulated substance will be stored: Bulk for short periods in GMP manufacturing facility and warehouse and then in packaging on shelves in the manufacturing plant and retailer warehouses.

Containment of spillages: Bulk quantities stored in GMP and HSNO approved manufacturing and warehousing facility, spills and leaks are managed by engineering controls. Spillages of smaller packaged quantities are contained and dealt with by standard spill management protocols.

[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

Decontamination of areas, personnel, vehicles and buildings: Small quantities of contaminated material (<1 L or 1 kg) can be bagged and disposed of in landfill. Users should consult their local council for disposal of larger quantities (>1 L or kg) of any damaged packaging, contaminated absorbents or other materials.

The spillage must be contained at the original site. Prevent the pesticide from entering ditches, storm drains, wells and waterways. A spill pooled on a paved road, or other impermeable surface can be easily removed.

Block the spill from spreading by encircling it using a dike of sand or soil or other absorbent material before being collected for safe disposal.

Disposal

Disposal of damaged packaging, contaminated absorbents and other materials: Small quantities of contaminated material (<1 L or 1 kg) can be bagged and disposed of in landfill. Users should consult their local council for disposal of larger quantities (>1 L or kg) of any damaged packaging, contaminated absorbents or other materials.

Detailed instructions for safe disposal of the formulated substance and its packaging: Landfill disposal without contact with any waterways. Leftover product can be applied in the following season. If disposal of product is an issue, then the user should consult their local Regional Council for advice.

Methods other than controlled incineration for disposal: Landfill - Empty containers will be triple rinsed, and should be taken to a recovery depot for correct disposal.

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		
Non-selective herbicide - Weed control for home	N/A	F	Weeds	SL	70 g/L fatty acids	Small volume trigger sprayer	Any stage post emergent	1-9	3-5 days	7 kg/hL fatty acids	N/A	70 kg/ha fatty acids	N/A	Ready to spray; spot treatment

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		
gardens														

(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	No	None of the components have this classification
Class 2, 3 & 4 Flammability	No	Mixture rules (see attached confidential appendix document 'Ref 1')
Class 5 Oxidisers/Organic Peroxides	No	None of the components have this classification
Subclass 8.1 Metallic corrosiveness	No	1. 2 < Substance PH < 11.5 2. Please also refer to 'Ref 1' about the 8.1 ingredient percentage
Subclass 6.1 Acute toxicity (oral)	No	Mixture rules (see attached

		confidential appendix document 'Ref 1')
Subclass 6.1Acute toxicity (dermal)	No	Mixture rules (see attached confidential appendix document 'Ref 1')
Subclass 6.1 Acute toxicity (inhalation)	No	None of the components have this classification
Subclass 6.1 Aspiration hazard	No	None of the components have this classification
Subclass 6.3/8.2 Skin irritancy/corrosion	6.3A	Mixture rules (see attached confidential appendix document 'Ref 1')
Subclass 6.4/8.3 Eye irritancy/corrosion	6.4A	Mixture rules (see attached confidential appendix document 'Ref 1')
Subclass 6.5A Respiratory sensitisation	No	None of the components have this classification
Subclass 6.5B Contact sensitisation	6.5B	Mixture rules (see attached confidential appendix document 'Ref 1')
Subclass 6.6 Mutagenicity	No	None of the components have this classification
Subclass 6.7 Carcinogenicity	No	None of the components have this classification
Subclass 6.8 Reproductive or developmental toxicity	No	None of the components have this classification
Subclass 6.8 Reproductive or developmental toxicity (known, presumed or suspected)	No	None of the components have this classification
Subclass 6.8 Reproductive or developmental toxicity (*via* lactation)	No	None of the components have this classification
Subclass 6.9 Target organ systemic toxicity[4]	No	None of the components have this classification
Subclass 9.1 Aquatic ecotoxicity	No	Mixture rules (see attached confidential appendix document 'Ref 1')
Subclass 9.2 Soil ecotoxicity	No	None of the components have this classification

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

Subclass 9.3 Terrestrial vertebrate ecotoxicity	No	None of the components have this classification
Subclass 9.4 Terrestrial invertebrate ecotoxicity	No	None of the components have this classification

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.

The applicant is a local New Zealand pesticide manufacturer who has a thorough knowledge of the lifecycle for the proposed substance. The applicant intends to manufacture the substance and supply to the New Zealand market.

Risk to human health:

There is a potential risk that users of these products could be directly exposed to the product through skin contact, eye contact, inhalation and ingestion through spillage, mishandling and misapplication or contact with recently treated surfaces. Bystanders may be indirectly exposed to the spray substance after application.

For users: The consequences of direct exposure are possible skin irritation, eye irritation and skin sensitization. However if the applicant followed the product use instructions; the likelihood to expose to the product could be minimised.

For Bystanders: There is a small degree of likelihood that exposure to the substance may cause skin irritation, eye irritation and skin sensitization.

Risks to the environment:

Potential risks are spillage of the product while storing in bulk in a stainless steel vessel after manufacture in the factory or during transport.

There is no class 9 hazard classification for the substance based on the mixture rule calculations (***Ref 1***). Hence, the risk to the environment is very close to zero in theory. In addition, the product label clearly stated the controls (***Ref 7***) to minimize the potential risk to the aquatic system and other environments.

Costs:

In case of spillage of the product and as a result contamination of vegetation or waterways could result in unforeseen costs which might also be the case if the product were misused (for example label instructions were not followed).

Benefits:

FAE-RTU 398 is formulated to provide effective control of a wide range of weeds. The organic active ingredients act mostly on the surface of the treated weeds by disrupting the cuticle and causing the immediate onset of foliar dehydration (desiccation). A wide range of weeds are controlled, making FAE-RTU 398 a useful tool for weed control, usually effective after a single spot treatment. The formulated herbicidal substance has a natural combination of fatty acids and other organic ingredients. This substance has a high likelihood to obtain an 'Organic' certification after an EPA approval is obtained and to be further used for the organic gardens. In addition the substance has no ecotoxicity (with no class 9 hazard classification), and inactivate in the soil environment.

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.

This substance is a ready to use product for the home and garden market and small commercial use as a combination of fatty acids and other organic ingredients for the control of a wide range of weeds.

Manufacturing / Packing:

Potential risks are spillage of the substance and contact by workers during the manufacturing / packing process. The possible consequences are exposure of workers or the waterways to the substance. However, the likelihood is very low since all the batchers are HSNO approved handlers and all the packing staff are working under an approved handlers' close supervision aligned with the GMP guidance.

Storage / Transport:

Potential risks are spillage of the product while storing in bulk in a stainless steel vessel after manufacture in the factory or during transport. The substance is contained in sealed UN compliant packaging. Kiwicare will only be handling larger volumes in approved factories where spillages can be controlled. The likelihood of a spillage is very low, but if it occurs it can be contained. Kiwicare will only transport the product in small packaging which are again packed in cartons. If through an accident the contents of the transport vehicle fall out, the likelihood of larger spillages (more than 10L) is very low.

Application / after application:

Acute Scenario:

The likelihood of exposure by body contact while applying the substance via the trigger sprayer is low for users not taking label precautions of wearing personal protective equipment and would only be likely with spillage in which case users would be likely to take rapid remedial action of washing off the product. The substance label advises the use of personal protective equipment such as gloves and covering clothing during application.

- During application via a trigger sprayer the likelihood of exposure by eye contact is low because the pressure sprayer will be held in one hand sideways to the body facing the area to be treated.
- There is the low to moderate possibility of contact with the substance on treated weed surfaces right after application before product dried off. However, the residue levels would be presented at a very low on the weed surface and the substance only has a few mild class 6 HSNO classifications.

The likelihood of eye irritation is low:

- The likelihood of exposure by eye contact while applying the substance via the trigger sprayer is low for users not taking label precautions of wearing personal protective equipment and would only be likely with spillage in which case users would be likely to take rapid remedial action of washing off the product. Our label advises the use of personal protective equipment such as eyewear.
- During application via the trigger sprayer the likelihood of exposure by eye contact is very low because the trigger sprayer will be held in one hand sideways to the body facing the area to be treated.
- The ready to use substance (with a few mild class 6 HSNO classifications) is normally applied as a spray mist that could be misdirected or blown by strong winds into user or bystander's eyes. However this is unlikely and would only be expected from the application of the small amount of substance and consequently would have reduced risk of harm when compared to the other concentrated substances.

There is very low likelihood of exposure to the product via ingestion or inhalation.

- The likelihood of exposure to the product via ingestion or inhalation while applying the substance via the trigger sprayer is very low.

- The ready to use substance is normally applied as a spray mist that could be misdirected or blown by strong winds into user or bystander's face and mouth. However, this is unlikely and would only be expected from the application of the ready to use substance and consequently would have reduced risk of harm when compared to the other concentrated substances.

The Hazard Classification (section 6) identifies the hazards of this product in its ready to use form. We believe we have controlled these hazards by providing the right of hazard and precautionary statements in the product label and SDS (***Ref 7, 8***).

The hazard classifications for the substance are relatively mild (please refer to ***Ref 1***, confidential appendix) human health hazards. We believe we have controlled these hazards.

Chronic Scenario:

There is a very low level of risk that chronic exposure to the product as there is no chronic human health hazard classification from calculation (***Ref 1***). The likelihood for this is very low because this would only happen if large regular doses were ingested, or users were exposed to the substance over a long period of time (chronic exposure). Consumers only apply low volumes (spot treatment) occasionally to the home and gardens or other organic gardens. Therefore they would not be exposed over a longer time period. The product is rapidly absorbed by the weed plant and residues remaining on the surfaces are rapidly degraded and/or rinsed off the plant surfaces by watering or rain. Professional users would be using personal protection equipment reducing the risk of exposure even further.

Environmental:

This substance does not have any class 9 hazard classification (***Ref 1***) and hence there is a minimum degree of risk to the aquatic environment and other ecological environments via spillage and/or misapplication or mis-disposal. The consequences of contamination of the aquatic environment should be within control. The consequences of contamination of other ecological environments should be also under the control.

The likelihood of contamination causing ecotoxicity to aquatic environments is minimum because the substance has no ecotoxicity (***Ref 1***) and it will be mainly used in small amounts, the largest risk would be from spillage during transport of the largest size, likely to be 10L, or of many smaller containers. The likelihood of such an occurrence will be very low.

The likelihood of contamination causing ecotoxicity to the soil and terrestrial environments is minimum because the substance has no ecotoxicity (***Ref 1***) and it will be largely used in small amounts, the largest risk would be from spillage during transport of the largest size, likely to be 10L, or of many smaller containers. The likelihood of such an occurrence would be very low.

Disposal:

There is a low level of risk associated to the disposal of FAE-RTU 398 or packaging resulting in exposure of people or the environment to the substance. The likelihood of this happening is low since the substance label provides the correct disposal instructions for both the substance and the empty packaging.

Benefits:

FAE-RTU 398 is formulated to provide effective control of a wide range of weeds. The organic active ingredients act mostly on the surface of the treated weeds by disrupting the cuticle and causing the immediate onset of foliar dehydration (desiccation). A wide range of weeds are controlled, making FAE-RTU 398 a useful tool for weed control, usually effective after a single spot treatment. The formulated herbicidal substance has a natural combination of fatty acids and other organic ingredients. This substance has a high likelihood to obtain an 'Organic' certification after an EPA approval is obtained and to be further used for the organic gardens. In addition the substance has no ecotoxicity (with no class 9 hazard classification), and inactivate in the soil environment.

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.

Risks

The substance FAE-RTU 398 is intended for home & garden use and for small scale organic garden uses. Therefore it is unlikely to be applied to indigenous species. Its release into the greater environment in any significant quantity is very low as the substance will be sold and used in small retail packaged quantities. It is also transported in the same packaging and hence the risk to waterways in the event of a transportation accident is also very low. There is no class 9 hazard classification identified (***Ref 1***) hence there is a minimum chance for a risk to occur on the non-target terrestrial invertebrates. Furthermore, the proposed use pattern, frequency and timing of application should also minimise any potential risk.

Benefits

FAE-RTU 398 is formulated to provide effective control of a wide range of weeds. The organic active ingredients act mostly on the surface of the treated weeds by disrupting the cuticle and causing the immediate onset of foliar dehydration (desiccation). A wide range of weeds are controlled, making FAE-RTU 398 a useful tool for weed control, usually effective after a single spot treatment. The formulated herbicidal substance has a

natural combination of fatty acids and other organic ingredients. This substance has a high likelihood to obtain an 'Organic' certification after an EPA approval is obtained and to be further used for the organic gardens. In addition the substance has no ecotoxicity (with no class 9 hazard classification), and inactivate in the soil environment.

We hope to have provided clear and transparent evidence along with fair cause and justification for this substance so as to allow the Kaitiaki, in their role as active protectors, to find that the risks are minimal, the costs are clear and that the benefits outweigh the both.

Further we believe that if this substance is applied in the prescribed manner it is not likely to breach the principles of the Treaty of Waitangi.

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

There are no negative impacts identified.

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

Manufacturing / Packing:

The substance is to be manufactured in New Zealand by the applicant; all the batchers are HSNO approved handlers and all the packing staff are working under an approved handler's close supervision aligned with the GMP guidance. The substance will be packed in UN compliant high density polyethylene plastic (HDPE) containers with child resistance packaging mechanism. The substance label states safe handling instructions and the disposal information. Our intention initially to market a 1 L FAE-RTU 398 in 1 litre packaging size.

Storage / Transport:

The packed product is kept in UN compliant high density polyethylene plastic (HDPE) containers with CRP. These plastic containers would be further packed in cardboard boxes and the boxes will be distributed to retailers and commercial users. The UN number and the packing group for the transportation regulation is not applicable here as the substance only have mild hazard classifications.

It is expected that the products would be stored on retail shelves for periods of up to 3 years before being sold to end users. End users will store these products in cool dry situations until use, and dispose of empty containers and remaining product as per regulations D4, D5, D6, D7, D8.

Use:

This substance is intended for home use and small scale organic garden uses. This ready to use substance is to be applied by pressure trigger sprayer for the control of a wide range of weeds and provide protection for other non-targeted plants from nutrient deficiency in the garden. The product label provides using instructions (Warning, precautionary statements; active ingredient levels; and first aid of the product).

Disposal:

The disposal instructions are stated in the product label and SDS. (***Ref 7 & 8***)

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

Human health & environment hazards:

Hazard classifications like skin irritation, eye irritation and skin sensitization are identified for this substance. There is no environmental hazard classifications are identified by the mixture rules calculation (***Ref 1***) through spillage or mis-application. In addition, the product label and SDS (***Ref 7 & 8***) supplied the corresponding controls around the existing hazard classifications.

Costs:

The product is a ready to use type which means the application of the substance does not involve any dilution process and hence less equipment required. In this aspect, there will be less costs for the consumers that the customers will avoid purchasing tools for the diluting process for any of the concentrate product. Any unforeseen costs could arise in the case if the product were misused (for example label instructions were not followed) or from any spillage scenario.

Benefits

FAE-RTU 398 is formulated to provide effective control of a wide range of weeds. The organic active ingredients act mostly on the surface of the treated weeds by disrupting the cuticle and causing the immediate onset of foliar dehydration (desiccation). A wide range of weeds are controlled, making FAE-RTU 398 a useful tool for weed control, usually effective after a single spot treatment. The formulated herbicidal substance has a natural combination of fatty acids and other organic ingredients. This substance has a high likelihood to obtain an 'Organic' certification after an EPA approval is obtained and to be further used for the organic gardens. In addition the substance has no ecotoxicity (with no class 9 hazard classification), and inactivate in the soil environment.

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: HSR007704 and HSR100087: Ready to Use liquid containing 50 – 100 g/L fatty acids
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: HSR007704 and HSR100087: Ready to Use liquid containing 50 – 100 g/L fatty acids; HSR000827: Emulsifiable concentrate containing 700 g/L fatty acids.

8.2. Statutory Declaration

I [full name], of [address], [occupation/position], being the applicant or authorised to do so on behalf of the applicant, verify that the information contained in this application for [substance name] 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 on this day of , 20 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	Please see references 1 - 8 in the appendix form
• Letter(s) of access	☐ Yes ☒ No	
• Relevant correspondence	☐ Yes ☒ No	
• Draft label	☒ Yes ☐ No	Ref 7
• Draft Safety Data Sheet (SDS)	☒ Yes ☐ No	Ref 8
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	☐ Yes	

sent to the EPA, (rapid assessment only)		

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.

	23rd 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).

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