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## DECISION

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14 December 2016

### Summary

Substance	F AE-RTU 398
Application code	APP203033
Application type	To import or manufacture for release any hazardous substance under Section 28 of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Applicant	Kiwicare Corporation Limited
Purpose of the application	To manufacture 'FAE-RTU 398' as an alternative weed-killer to glyphosate for the control of weeds commonly found in home and gardens
Date application received	3 November 2016
Consideration date	14 December 2016
Considered by	The Chief Executive <sup>1</sup> of the Environmental Protection Authority ("the EPA")
Decision	<b>Approved with controls</b>
Approval code	<b>HSR101202</b>
Hazard classifications	6.3A, 6.4A, 6.5B, 9.1D

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<sup>1</sup> The Chief Executive of the EPA has made the decision on this application under delegated authority in accordance with section 19 of the Act.

## 1. Substance

- 1.1. FAE-RTU 398 is a soluble concentrate formulation containing 70 g/L fatty acids. It is intended for use as a herbicide for control of weeds in home gardens.

## 2. Process and notification

### Application receipt

- 2.1. The application was formally received on 3 November 2016 under section 28 of the Act.

### Information available for consideration

- 2.2. The information available for the consideration comprised:

- the application form
- confidential appendices to the application
- the EPA staff advice memorandum.

- 2.3. I consider that I have sufficient information to assess the application.

### Public notification

- 2.4. This application was not publicly notified under section 53(2) of the Act because it was unlikely that there would be significant public interest in the application.

### Notification to government departments

- 2.5. In line with section 53(4) of the Act, the following government departments were notified of the application on 7 November 2016: WorkSafe New Zealand, the Ministry for Primary Industries (Agricultural Compounds and Veterinary Medicines Group), and the Ministry of Health. No comments were received.

### Legislative criteria for the application

- 2.6. The application was considered in accordance with section 29 of the Act, taking into account other relevant sections of the Act, the Hazardous Substances Regulations and the Hazardous Substances and New Organisms (Methodology) Order 1998.

## 3. Hazardous properties, prescribed controls and exposure limits

### Hazardous properties

- 3.1. The hazard classification of FAE-RTU 398 was determined based on the information provided by the applicant and other available information.
- 3.2. The classifications that I have applied to this substance are different to those submitted by the applicant (Table 1). The applicant did not classify the substance as having aquatic ecotoxicity (9.1). I concur with this assessment but have applied a 9.1D (biocide) classification due to the intended use of the substance as a herbicide.



**Table 1: Hazard classifications of FAE-RTU 398**

Hazard	Applicant classification	EPA classification
Skin irritancy/corrosivity	6.3A	6.3A
Eye irritancy/corrosivity	6.4A	6.4A
Contact sensitisation	6.5B	6.5B
Aquatic ecotoxicity	No	9.1D

## Prescribed controls

- 3.3. The hazard classifications of FAE-RTU 398 determine a set of prescribed controls specified by the Hazardous Substances Regulations under the Act.
- 3.4. The prescribed controls set the baseline for how the substance must be managed and include specifications on how the substance is to be packaged, labelled, stored, disposed of, transported, handled and used. The prescribed controls also set information requirements (e.g. safety data sheets), signage and emergency management. These controls form the basis of the controls specified in Appendix A.

## Exposure limits

- 3.5. Several prescribed controls allow the EPA to set human health and environmental exposure values.
- 3.6. Control T1 allows the EPA to set ADE (Acceptable Daily Exposure), PDE (Potential Daily Exposure) and TEL (Tolerable Exposure Limit) values. No ADE value has been set for the active ingredient under control T1 previously. No ADE value has been set at this time because I consider that exposure to this substance is not likely to result in an appreciable toxic effect to people. Therefore, the criterion for setting an ADE value under regulation 11(1)(c) of the Hazardous Substances (Classes 6, 8 and 9) Regulations 2001 was not met. As no ADE value has been set, then no PDE or TEL value is required to be set.
- 3.7. Control T2 allows Workplace Exposure Standard (WES) values to be set for any component of a substance to limit the exposure of people to toxic substances in places of work. I have adopted and applied the WES values listed in the WorkSafe New Zealand Standard Workplace Exposure Standards and Biological Exposure Indices 8th Edition<sup>2</sup> for all components of this substance in accordance with regulation 30(1)(a) of the Hazardous Substances (Classes 6,8 and 9) Regulations 2001, where applicable.

<sup>2</sup> Or any subsequent version of this Standard approved or endorsed by the EPA.

## 4. Risk and benefit assessment

### Risk assessment

- 4.1. The risk assessment takes into account the hazardous properties, prescribed controls and other legislation such as the Land Transport Rule 45001, Civil Aviation Act 1990 and Maritime Transport Act 1994.
- 4.2. The risk and benefit assessment:
- considers the risks posed by FAE-RTU 398
  - determines whether the risks are outweighed by the benefits
  - determines whether any variations or additions to the prescribed controls are required to manage the risks of this substance, and identifies controls that may not be applicable or necessary that can, therefore, be deleted.

### Assessment of risks to human health and the environment

- 4.3. I have assessed the human health and environmental risks in accordance with Section 29(1) of the Act. This assessment takes into account the full life cycle of this substance, including import and manufacture, packaging, transport, storage, use and disposal.
- 4.4. I note that FAE-RTU 398 has the same active ingredient at similar concentrations as other home use herbicide substances that are already approved, and is intended to be used in similar ways. Accordingly, the risks to human health and the environment are not likely to be significantly higher from the use of FAE-RTU 398 compared to other approved substances containing the same active ingredient.
- 4.5. I have evaluated the potential of FAE-RTU 398 to cause adverse effects to people and/or the environment during every life cycle stage of the substance.
- 4.6. For import or manufacture, storage, transport, and disposal, I consider that the prescribed controls will manage the human health risks associated with the hazard properties of FAE-RTU 398.
- 4.7. FAE-RTU 398 has the potential to cause skin and eye irritation, and contact sensitisation. It is intended for home use, where it is assumed that people using the substance will not necessarily be using personal protective equipment. There are many approved substances with skin and eye irritancy and sensitising properties available on the home market. These hazards are required to be identified on the labels for these products.
- 4.8. The prescribed controls for FAE-RTU 398 include identification requirements for these hazards, and I consider that such identification requirements are sufficient for FAE-RTU 398, as the product is not intended to be applied to the skin.
- 4.9. I therefore consider that the prescribed controls manage the risks to human health from home use such that these risks are negligible.

4.10. Taking into account the low level of ecotoxicity of this substance, I consider that the risks to the environment are negligible.

### **Assessment of risks to Māori and their relationship to the environment**

4.18 The potential effect of FAE-RTU 398 on the relationship of Māori to the environment has been assessed in accordance with sections 5(b), 6(d) and 8 of the Act. Under these sections all persons exercising functions, powers, and duties under the Act shall:

- recognise and provide for the maintenance and enhancement of people and communities to provide for their cultural well-being, and
- take into account the relationship of Māori and their culture and traditions with their ancestral lands, water, taonga and the principles of The Treaty of Waitangi (Te Tiriti o Waitangi).

4.19 In consideration of these obligations, the following sections address the impact of FAE-RTU 398 on Māori interests including kaitiakitanga (stewardship), taha hauora (human health), taiao (environment), and Te Tiriti o Waitangi.

4.20 I note that FAE-RTU 398 also triggers several hazardous properties that give rise to the potential for cultural risk. Cultural risk includes any negative impacts to taonga species, the environment, and the general health and well-being of individuals and the community. In addition, the introduction and use of hazardous substances has the potential to inhibit the ability of Māori to fulfil their role as kaitiaki.

#### *Taha hauora (human health)*

4.21 I note that FAE-RTU 398 also triggers several hazardous properties that give rise to the potential for cultural risk in relation to taha hauora e.g. skin and eye irritancy, and contact sensitisation. For these reasons, FAE-RTU 398 poses a potential risk to taha hauora, in particular, the dimensions of taha tinana (physical health and well-being) and taha whanaunga (the responsibility to belong, care for and share in the collective, including relationships and social cohesion).

#### *Kupu whakatepe (conclusion)*

4.22 In general, the introduction and use of hazardous substances has the potential to inhibit the ability of Māori to fulfil their role as kaitiaki. This is particularly relevant when considering the guardianship of waterways given the ecotoxic nature of some substances to aquatic species and potential risks to human health under prolonged exposure to some substances.

4.23 Based on the information provided, including the use pattern and the controls proposed to be assigned to FAE-RTU 398, the risks to Māori culture or traditional relationships with the environment are likely to be negligible.

4.24 If FAE-RTU 398 is applied in the proposed manner, I consider that it would not breach the principles of The Treaty of Waitangi, particularly the principle of active protection.

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

4.25 I have not identified any risks to society, communities or the market economy from the approval of FAE-RTU 398.

### New Zealand's international obligations

4.26 I have not identified any international obligations that may be impacted by the approval of FAE-RTU 398.

### The effects of the substance being unavailable

4.27 I have considered the likely effects of the substance being unavailable in accordance with section 29(1) of the Act. I consider that, should this substance not be available, it could lead to less consumer choice.

### Assessment of benefits

4.28 The applicant considers that the approval of FAE-RTU 398 will provide the following benefits:

- An organic formulation
- Effective weed control
- No significant ecotoxicity and it is inactivated in the soil environment

4.29 There is no information available to me in order to corroborate these benefits. However, I am satisfied that the availability of FAE-RTU 398 will provide improved consumer choice and greater market competition.

## 5. Variation and cost-effectiveness of prescribed controls

### Modification of controls under section 77 of the Act

5.1 Section 77 of the Act allows the prescribed controls to be substituted, added and/or deleted where:

- the adverse effects identified for a substance are different from those which would usually be associated with substances with the same hazard classification
- the adverse effects cannot be identified for a substance because of the scientific and technical uncertainty in the available information
- the benefits of the substance are retained without significantly increasing the adverse effects.

5.2 I have varied the prescribed controls, as explained in Table 2.

**Table 2: Justification for the variations to the prescribed controls (see Appendix A for control variations)**

Control	Justification
T1	<p><b>ADE and PDE values</b></p> <p>Control T1 is for limiting hazardous substances from entering the environment in quantities sufficient to present a risk to people through the setting of Acceptable Daily Exposure (ADE)</p>

Control	Justification
	and Potential Daily Exposure (PDE) values. No ADE or PDE values are set at this time as the substance is not likely to result in an appreciable toxic effect.
T7	<p><b>Carriage of toxic or corrosive substances on passenger service vehicles</b></p> <p>This control restricts the carriage of toxic or corrosive substances on passenger service vehicles (e.g. buses, trains). The existing maximum quantities of class 6.5 substances (0.1 L) have been reviewed and an increased maximum quantity of 1 L has been implemented to ensure that any products available in retail outlets can be carried on public transport vehicles.</p>
E1	<p><b>Environmental Exposure Limit (EEL) values</b></p> <p>EEL values can be set to limit hazardous substances from entering the environment in quantities sufficient to present a risk to it. No EEL values are set for any component of this substance at this time as the risk of adverse effects to the environment has been qualitatively assessed as being negligible, after the addition of controls as set out in Appendix A. The default EEL values are deleted.</p>
E2	<p><b>Application rate</b></p> <p>The default controls require the EPA to set an application rate for a class 9 substance that is to be sprayed on an area of land (or air or water) and for which an EEL value has been set. As no EEL value has been set for any component of FAE-RTU 398, a maximum application rate is not set at this time.</p>
EM12	<p><b>Emergency management requirements</b></p> <p>This control specifies the emergency management requirements for secondary containment of liquid hazardous substances (or those likely to liquefy in a fire) and pooling substances. However, this control does not allow for dispensation where it is unnecessary for any pipework associated with the stationary container systems to have secondary containment. I have, therefore, varied the emergency management controls to address this.</p> <p>I consider that the risks associated with the containment of substances which are not class 1 to 5 substances (i.e. do not ignite or explode) are different to those associated with class 1 to 5 substances. Consequently, the secondary containment requirements can be reduced. I consider that these reduced secondary containment measures are adequate to manage the risks of a spillage of FAE-RTU 398, as this substance does not ignite or explode. Therefore, the proposed variation is more cost-effective in terms of managing the risks of the substance.</p>

## Modification of controls under section 77A of the Act

5.3 Section 77A of the Act also allows the EPA to add, vary, substitute, combine or delete controls if such changes are more effective or more cost-effective in terms of managing the use and risks of the substance, or are more likely to achieve their purpose than the prescribed controls.

5.4 I have added the following controls, as set out in Table 3:

**Table 3: Justification for the addition of controls and modification to prescribed controls (see Appendix A for additional controls)**

Control	Justification
Water	The risk assessment for this substance has not evaluated the risks associated with the direct application of FAE-RTU 398 into or onto water. While the substance does not have aquatic ecotoxic properties warranting classification, it is intended to be used as a biocide and so could cause harm if directly



applied to aquatic environments. Accordingly, I consider that it is appropriate to apply an additional control prohibiting the application of this substance into or onto water.

Schedule 8	<p><b>Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004</b></p> <p>The prescribed controls do not address the risks associated with storage or use of substances within stationary container systems (e.g. tanks). These risks include the potential failure of primary containment resulting in a large spill of the substance into the environment. I have added an additional control to mitigate the risk when this substance is stored in bulk without consideration of the equipment.</p>
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## Assessment of control modifications

5.5 I consider that the modifications to the controls under section 77A of the Act fulfil the legislative criteria of being, relative to the prescribed controls:

- more effective with respect to their effect on the management, use, and risks of the substance, or
- more cost-effective in terms of their effect on the management, use, and risks of the substance, or
- more likely to achieve their purpose.

5.6 I have incorporated these controls into Appendix A of this document.

## Review of controls for cost-effectiveness

5.7 The proposed controls, provided they are complied with, are the most cost-effective means of managing the identified potential risks associated with this substance. The applicant was provided with an opportunity to comment on the controls as set out in this decision and no concerns were raised.

## 6. Risk assessment summary

6.1. I consider that the residual level of risk of any potentially significant adverse effects, after taking into account the prescribed controls and any variations to these controls, is negligible.

6.2. I consider that benefits will be derived for some businesses as a result of the approval of FAE-RTU 398.

## 7. Decision

- 7.1 Pursuant to section 29 of the Act, I have considered this application for approval under section 28 of the Act. I have considered the effects of this substance throughout its life cycle, the controls that may be imposed on this substance and the likely effects of this substance being unavailable.
- 7.2 I consider that, with controls in place, the risks to human health and to the environment are negligible, and the benefits associated with the release of this substance will outweigh the adverse effects. Therefore, I consider that FAE-RTU 398 may be approved with controls in accordance with section 29 of the Act and clause 26 of the Hazardous Substances and New Organisms (Methodology) Order 1998.



Environmental  
Protection Authority  
Maha Raupū Tāhū

Dr Allan L Freeth

Date: 14 December 2016

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**Chief Executive, EPA**

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## Appendix A: Controls applying to FAE-RTU 398

Please refer to the Hazardous Substances Regulations<sup>3</sup> for the requirements prescribed for each control.

### Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001

Code	Regulation	Description	Variation
T1	11 – 27	Limiting exposure to toxic substances through the setting of ADE, PDE or TEL values	No ADE or PDE values have been set for any component of this substance at this time
T2	29, 30	Controlling exposure in places of work through the setting of WES values	The EPA adopts as WES values for this substance, and each component of this substance, any applicable value specified in WorkSafe New Zealand's Workplace Exposure Standards and Biological Exposure Indices Document; 8 <sup>th</sup> Edition; June 2016 <sup>4</sup>
T4	7	Requirements for equipment used to handle substances	
T5	8	Requirements for protective clothing and equipment	
T7	10	Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles	The maximum quantity of this substance that can be carried on a passenger service vehicle is 1.0 L per package
E1	32 – 45	Limiting exposure to ecotoxic substances through the setting of EEL values	No EEL values are set for any component of this substance at this time
E2	46 – 48	Restrictions on use of substances in application areas	No maximum application rate has been set for this substance at this time
E6	7	Requirements for equipment used to handle substances	

### Hazardous Substances (Identification) Regulations 2001

Code	Regulation	Description	Variation
I1	6, 7, 32 – 35, 36(1) – (7)	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability	

<sup>3</sup> The regulations can be found on the New Zealand Legislation website; <http://www.legislation.co.nz>

<sup>4</sup> Or any subsequent version of this Standard approved or endorsed by the EPA. The prescribed Regulations permit one or more WES values to be set for a substance, therefore, this note is for informative purposes rather than a variation to the prescribed controls

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Code	Regulation	Description	Variation
I9	18	Secondary identifiers for all hazardous substances	
I11	20	Secondary identifiers for ecotoxic substances	
I16	25	Secondary identifiers for toxic substances	
I17	26	Use of generic names	
I18	27	Requirements for using concentration ranges	
I19	29 – 31	Additional information requirements, including situations where substances are in multiple packaging	
I21	37 – 39, 47 – 50	General documentation requirements	
I28	46	Specific documentation requirements for toxic substances	
I29	51, 52	Signage requirements	

### Hazardous Substances (Packaging) Regulations 2001

Code	Regulation	Description	Variation
P1	5, 6, 7(1), 8	General packaging requirements	
P3	9	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria	
P13	19	Packaging requirements for toxic substances	
PS4	Schedule 4	Packaging requirements as specified in Schedule 4	

### Hazardous Substances (Disposal) Regulations 2001

Code	Regulation	Description	Variation
D4	8	Disposal requirements for toxic and corrosive substances	
D5	9	Disposal requirements for ecotoxic substances	
D6	10	Disposal requirements for packages	
D7	11, 12	Information requirements for manufacturers, importers and suppliers, and persons in charge	

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Code	Regulation	Description	Variation
D8	13, 14	Documentation requirements for manufacturers, importers and suppliers, and persons in charge	

### Hazardous Substances (Emergency Management) Regulations 2001

Code	Regulation	Description	Variation
EM1	6, 7, 9 – 11	Level 1 information requirements for suppliers and persons in charge	
EM6	8(e)	Information requirements for toxic substances	
EM7	8(f)	Information requirements for ecotoxic substances	
EM8	12 – 16, 18 – 20	Level 2 information requirements for suppliers and persons in charge	
EM11	25 – 34	Level 3 emergency management requirements: duties of person in charge, emergency response plans	
EM12	35 – 41	Level 3 emergency management requirements: secondary containment	<p>The following subclauses are added after subclause (3) of regulation 36:</p> <p>(4) <i>For the purposes of this regulation, and regulations 37 to 40, where this substance is contained in pipework that is installed and operated so as to manage any loss of containment in the pipework it—</i></p> <p>(a) <i>is not to be taken into account in determining whether a place is required to have a secondary containment system; and</i></p> <p>(b) <i>is not required to be located in a secondary containment system.</i></p> <p>(5) <i>In this clause, pipework—</i></p> <p>(a) <i>means piping that—</i></p> <p>(i) <i>is connected to a stationary container; and</i></p> <p>(ii) <i>is used to transfer a hazardous substance into or out of the stationary container; and</i></p> <p>(b) <i>includes a process pipeline or a transfer line.</i></p> <p>The following subclauses are added at the end of regulation 37:</p>

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Code	Regulation	Description	Variation
			<p>(2) <i>If pooling substances which do not have class 1 to 5 hazard classifications are held in a place above ground in containers each of which has a capacity of 60 litres or less—</i></p> <p>(a) <i>if the place's total pooling potential is less than 20,000 litres, the secondary containment system must have a capacity of at least 25% of that total pooling potential:</i></p> <p>(b) <i>if the place's total pooling potential is 20,000 litres or more, the secondary containment system must have a capacity of the greater of—</i></p> <p>(i) <i>5% of the total pooling potential; or</i></p> <p>(ii) <i>5,000 litres.</i></p> <p>(3) <i>Pooling substances to which subclause (2) applies must be segregated where appropriate to ensure that leakage of one substance may not adversely affect the container of another substance.</i></p> <p>The following subclauses are added at the end of regulation 38:</p> <p>(2) <i>If pooling substances which do not have class 1 to 5 hazard classifications are held in a place above ground in containers 1 or more of which have a capacity of more than 60 litres but none of which have a capacity of more than 450 litres—</i></p> <p>(a) <i>if the place's total pooling potential is less than 20,000 litres, the secondary containment system must have a capacity of either 25% of that total pooling potential or 110% of the capacity of the largest container, whichever is the greater:</i></p> <p>(b) <i>if the place's total pooling potential is 20,000 litres or more, the secondary containment system must have a capacity of the greater of—</i></p>

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Code	Regulation	Description	Variation
			<p>(i) 5% of the total pooling potential; or</p> <p>(ii) 5,000 litres</p> <p>(3) Pooling substances to which subclause (2) applies must be segregated where appropriate to ensure that the leakage of one substance may not adversely affect the container of another substance.</p>
EM13	42	Level 3 emergency management requirements: signage	

### Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004

Code	Regulation	Description	Variation
Tank Wagon	4 – 43, as applicable	Controls relating to tank wagons and transportable containers	

### Additional controls

Code	Section of the Act	Control
Water	77A	This substance must not be applied into or onto water
Stationary Container Systems	Schedule 8	<p><b>Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004</b></p> <p>This schedule prescribes the controls for stationary container systems. The requirements of this schedule are detailed in the consolidated version of the Hazardous Substances (Dangerous Goods and Schedule Toxic Substances) Transfer Notice 2004, available from <a href="http://www.epa.govt.nz/Publications/Transfer-Notice-35-2004.pdf">http://www.epa.govt.nz/Publications/Transfer-Notice-35-2004.pdf</a></p> <p>The following clause replaces Clause 1 of Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004:</p> <p><i>This Schedule applies to every stationary container system that contains, or is intended to contain the substance</i></p>

## Definitions

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

Term	Definition
Water	Means water in all its physical forms, whether flowing or not, and whether over or under ground, but does not include water in any form while in a pipe, tank or cistern or water used in the dilution of the substance prior to application.