Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

22 August 2019

Summary

Substance	RFC 397 (New Formulation)
Application code	APP203254
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 RFC397 (new formulation) a combination fungicide and insect growth regulator for the control of insect pests and fungi on roses and other ornamental plants including those found in home gardens.
Date application formally received	5 May 2017
Consideration date	22 August 2019 Further information was requested from the application in accordance with section 58 of the Act
Considered by	The Acting General Manager[1] of the Hazardous Substances and New Organisms group of the Environmental Protection Authority (“the EPA”)
Decision	**Declined**
Hazard classifications	6.8B, 6.9B, 9.1A, 9.4B

[1] The Acting General Manager of the HSNO group 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. RFC 397 (New Formulation) is a soluble concentrate containing 5 g/L of pyriproxyfen (an insecticide), 12.6 g/L of boscalid, 6.4 g/L of pyraclostrobin, and 21.5 g/L of tebuconazole (fungicides) as active ingredients. It is intended to be manufactured in New Zealand and used by domestic users to control insect pests and fungi on roses and other ornamental plants. It is also intended to be used in small commercial settings for control and prevention of harm from the insect pests and fungi in roses and other ornamentals.

1.2. The applicant applied for this substance using the substance name RFC 397. This substance is referred to by the EPA in this application as RFC 397 (New Formulation) to avoid confusion with a substance with the same name from an older application (APP202960). The new formulation in this application is a reformulation of the older substance with different active ingredients. The old formulation from APP202960 contained the same three fungicide active ingredients, but contained thiamethoxam as the insecticide active instead of pyriproxyfen. APP202960 was withdrawn after formal receipt of the application but prior to consideration by the EPA.

1.3. Between APP202960 and this current application APP203254, the EPA assessed an application for GPFC 410 (APP203302). GPFC 410 contains the same three fungicide actives as RFC 397 (New Formulation), but does not contain an insecticide active ingredient. It had a similar intended use pattern to RFC 397 (New Formulation), but with additional uses in control of fungi in turf/pasture (non-agricultural). The application for approval of GPFC 410 was declined.

1.4. Consideration of this application for RFC 397 (New Formulation) was postponed while the assessment of GPFC 410 was undertaken.

2. Process and notification

Application receipt

2.1. The application was formally received on 5 May 2017 under section 28 of the Act.

Information available for consideration

2.2. The information available for the consideration comprised the:

- application form
- confidential appendix to the application
- EPA science memorandum.

Public notification

2.3. 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

2.4. The following government departments were notified of the application on 5 May 2017: the Ministry for Primary Industries (Agricultural Compounds and Veterinary Medicines Group), and WorkSafe New

Zealand ("WorkSafe"). No comments were received at that time. WorkSafe were later requested to comment on potential controls to manage risks to workers using RFC 397 (New Formulation), and this comment is discussed below in Section 4.

Legislative criteria for the application

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

3. Hazardous properties of RFC 397 (New Formulation)

3.1. The hazard classifications of RFC 397 (New Formulation), shown on Table 1, were determined by the EPA staff using information on the individual components of RFC 397 (New Formulation) and by mixture rules.

3.2. The classifications that have been applied to RFC 397 (New Formulation) are different to those submitted by the applicant (Table 1).

3.3. The EPA determined that no classification was necessary for skin or eye irritancy based on information available about the irritancy of the components of RFC 397 (New Formulation), and therefore did not apply the irritancy classifications proposed by the applicant.

3.4. The EPA determined that a 6.8B classification for reproductive/developmental toxicity is appropriate for the active ingredient tebuconazole. This classification is also appropriate for RFC 397 (New Formulation). The applicant commented that their classification was based on the classification of tebuconazole and other substances containing tebuconazole not being classified as a reproductive/developmental toxicant.

3.5. The EPA notes that while the approval for tebuconazole has not to date been updated via reassessment to add the 6.8B classification, the EPA has information to justify the 6.8B classification for substances containing tebuconazole, and has applied the 6.8B classification to recent assessments of substances containing tebuconazole.

Table 1: Hazard classifications of RFC 397 (New Formulation)

Hazard	Applicant classification	EPA classification
Skin irritancy/corrosivity	**6.3B**	**No**
Eye irritancy/corrosivity	**6.4A**	**No**
Reproductive/ developmental toxicity	**No**	**6.8B**
Target organ or systemic toxicity (oral/dermal/inhalation)	6.9B	6.9B
Aquatic ecotoxicity	9.1A	9.1A
Terrestrial invertebrate ecotoxicity	9.4B	9.4B

4. Risk and benefit assessment

Risk assessment

4.1. The risk assessment has taken into account the hazardous properties of the substance, the considerations in Part 2 of the Act, the prescribed controls under the Act and the requirements under other relevant legislation such as the HSW Act, the Land Transport Rule 45001, the Civil Aviation Act 1990 and the Maritime Transport Act 1994.

4.2. The risk assessment has taken into account the full life cycle of the substance, including import, packaging, transport, storage, use and disposal.

4.3. While the active ingredients in RFC 397 (New Formulation) are already approved in New Zealand via other substances, RFC 397 (New Formulation) is a new combination of active ingredients and the use pattern is different to existing approved substances containing these ingredients. The EPA staff determined that there is a potential for significant exposures to people and the environment during the use phase of RFC 397 (New Formulation). Therefore, a quantitative assessment was undertaken to estimate human and environmental exposures to the active ingredients in the use patterns intended by the applicant.

4.4. The overall risk and benefit assessment:

- considered the risks posed by RFC 397 (New Formulation)
- determined whether the risks are outweighed by the benefits
- determined 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

4.5. The potential risks to human health from RFC 397 (New Formulation) during its use were assessed by estimating the exposure of operators, re-entry workers and bystanders to the active ingredients. Assessments were made of both commercial and home uses intended by the applicant.

4.6. To assess the risks posed by the substance to human health, the estimated exposure to each active ingredient for each application scenario was compared to an Acceptable Operator Exposure Limit (AOEL) value for each active ingredient and a risk quotient (RQ) is calculated. The AOEL values are derived from toxicological information available on the active ingredients.

4.7. RQ values greater than one (RQ>1) indicate that exposure to the substance could result in significant adverse effects, and that risk mitigating controls should be considered. RQ values less than one (RQ<1) indicate that predicted exposure to the substance is less than the AOEL and such exposure is not expected to result in adverse effects.

Commercial applications

4.8. The risks were assessed for commercial use of RFC 397 (New Formulation) on roses and ornamentals.

4.9. Exposures of operators undertaking mixing, loading, and application activities for applying RFC 397 (New Formulation) were found to be above the AOELs for pyraclostrobin and tebuconazole, even with the use of gloves. Risk quotients for gloves only were 2.2 for tebuconazole and 1.3 for pyraclostrobin. Exposures to operators of boscalid and pyraclostrobin were estimated as being below the respective AOEL values.

4.10. It was determined that full personal protective equipment (without respirator) was necessary for mixing, loading, and application activities in order to reduce exposures of pyraclostrobin and tebuconazole to below levels of concern (RQ < 1).

4.11. Exposures to workers undertaking re-entry work in areas where RFC 397 (New Formulation) has been applied are estimated to be above the AOEL values for each active, where gloves are not used. For tebuconazole and pyraclostrobin the levels of exposure are further above the AOEL (risk quotients 5.9 for tebuconazole; 3.5 for pyraclostrobin) and as a result it is appropriate to recommend a re-entry period for RFC 397 (New Formulation) where full PPE or gloves are needed to reduce exposure to below levels of concern.

4.12. It was determined that for up to 26 days after application it is necessary to use gloves when undertaking re-entry work to ensure that the exposures are below levels of concern. For the first seven days of that re-entry period, it was found that full PPE is necessary to reduce exposure to below levels of concern.

4.13. The main potential source of exposure to the general public from commercial application of RFC 397 (New Formulation) would be exposure to treated surfaces or spray drift from treated areas. The exposure to tebuconazole (the active with the highest risk potential) for bystanders from spray drift after application of RFC 397 (New Formulation) was estimated to be below the AOEL. Overall there are no concerns about bystander exposure from the intended commercial uses of RFC 397 (New Formulation)

Domestic use

4.14. Exposures for home operators using no PPE during mixing, loading, and application of RFC 397 (New Formulation) were also estimated and found to be below levels of concern for all four active ingredients. The risks quotients ranged from 0.13 to 0.72 across the four active ingredients for the highest exposure scenario.

4.15. Although the estimated exposures are expected to be below levels of concern, it is noted that RFC 397 (New Formulation) has both reproductive/developmental and target organ toxic properties. It is considered good practice to use PPE to minimise exposure when handling chemicals with significant hazard properties.

Other phases of the substance lifecycles

4.16. It is considered that there is no significant risk to human health from the manufacture, transport, storage, or disposal phases of the lifecycle of RFC 397 (New Formulation).

Assessment of risks to human health from workplace activities

4.17. The EPA sought advice from WorkSafe under section 58(1)(a) of the Act on whether the HSW requirements are adequate to manage the risks associated with the use of this substance in the workplace. WorkSafe provided a response on whether the risks posed by RFC 397 (New Formulation) to human health (in the workplace) can be adequately managed by HSW requirements.

4.18. WorkSafe considered that compliance with the Hazardous Substances (HSW) and Health and Safety at Work (General Risks and Workplace Management) (GWRM) Regulations will be adequate to reduce the risks associated with the use of this substance in the workplace.

4.19. WorkSafe noted the risk assessment undertaken by the EPA, and proposed that if RFC 397 (New Formulation) is approved, it would set a restricted entry interval (REI) of 26 days for RFC 397 (New Formulation). WorkSafe noted that for the first 7 days of the REI, full PPE as worn for application is required to protect re-entry workers.

Assessment of risks to the environment

4.20. The potential risks posed by RFC 397 (New Formulation) to aquatic and terrestrial environments were assessed for the use patterns proposed by the applicant. The EPA evaluated these use patterns and performed quantitative modelling where appropriate to determine the predicted environmental exposures.

4.21. It was determined that the risks from the formulation with the four active ingredients could be estimated from the results obtained in tests with “pure” active ingredients because there is no evidence that the active ingredients interact with each other or that their combination increases the toxicity compared to the effects expected with each individual active ingredient.

Environmental mobility and persistence

4.22. In water/sediment systems, all four active ingredients are considered relatively persistent.

4.23. Pyraclostrobin and pyriproxyfen are expected to be relatively immobile in soil, while boscalid and tebuconazole are moderately mobile.

4.24. Boscalid, pyraclostrobin and tebuconazole are considered relatively persistent in soil, while pyriproxyfen is not considered persistent in soil.

Assessment of risks to the aquatic environment

4.25. RFC 397 (New Formulation) is highly toxic in aquatic environments, with all four of the active ingredients having a high degree of acute and chronic toxicity to fish, crustaceans and/or algae.

4.26. For some ecotoxicological endpoints, some data were not available. For instance, no information was available regarding the toxicity of boscalid to aquatic plants. However, given the intended use pattern of RFC 397 (New Formulation), these data gaps are not considered significant.

4.27. RFC 397 (New Formulation) is intended for home garden and small-scale commercial uses using hand-held or backpack sprayer. As a result of the limited scale of use, it is considered that the potential for spray drift, runoff, or groundwater contamination will also be limited.

4.28. Overall, the risks to aquatic environments is considered negligible.

Assessment of risks to the terrestrial environment

Soil environments

4.29. Exposures for soil organisms were estimated for each active ingredient, and for an ecotoxicologically significant metabolite of tebuconazole, 1,2,4-triazole.

4.30. The predicted acute exposures of soil organism of the active ingredients and 1,2,4-triazole are all below their respective levels of concern (LOC).

4.31. The predicted chronic exposures to threatened species are above the level of concern in-field for tebuconazole. However, it is considered that it is highly unlikely that threatened species of earthworm would be present in areas where RFC 397 (New Formulation) is expected to be applied.

4.32. Information was not available regarding the chronic toxicity of boscalid, pyraclostrobin, and pyriproxyfen in soil environments.

Plants

4.33. Insufficient information was available regarding toxicity to plants for the EPA to assess any potential risks to plants.

4.34. This data gap is not considered significant as significant adverse effects are considered unlikely.

Birds

4.35. Previous risk assessments undertaken by the EPA have determined that there are significant risks to birds from the use of tebuconazole. In assessing this application, the EPA determined a refined chronic toxicity value for tebuconazole and undertook more detailed assessments taking into account food sources available for birds.

4.36. While risks were identified for tebuconazole, in a refined assessment it was determined that birds were likely to be able to access sufficient uncontaminated food to reduce the exposure of tebuconazole to below levels of concern.

4.37. The risks to birds from the other ingredients are expected to be negligible. However, for pyriproxyfen no chronic data were available to evaluate risks from chronic exposure.

4.38. The data gap for pyriproxyfen is considered a **significant data gap** because the intended use pattern means that significant exposure of birds to pyriproxyfen could occur.

4.39. No risks from secondary poisoning are anticipated.

Pollinators

4.40. The risks from acute exposure of pollinators to boscalid, tebuconazole, and pyraclostrobin are below the level of concern.

4.41. The risks from acute exposure to pyriproxyfen, and the risks from chronic exposure to each the active ingredients, could not be evaluated due to a lack of data on these effects.

4.42. Pyriproxyfen is an insecticide, and it is considered that the lack of data available to the EPA on pyriproxyfen is a **significant data gap**. This is because there is significant potential for pyriproxyfen to cause adverse effects on the health of hives in general, and the development of larvae and pupae in particular.

Non-target arthropods

4.43. Very limited information was available relating the effects of the RFC 397 (New Formulation) or its active ingredients on non-target arthropods. No information was available for several species, and for three of the active ingredients no toxicity information was available at all.

4.44. This lack of information is considered a **significant data gap**. The data gap is particularly important for pyriproxyfen, because pyriproxyfen is an insecticide.

Assessment of risks to Māori and their relationship to the environment

4.35 The potential effect of RFC 397 (New Formulation) 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).

4.36 Findings of the cultural risk assessment (CRA) for RFC 397 (New Formulation) in relation to the above provisions of the Act are summarised below.

Section 5(b) – Recognise and provide for cultural well-being

4.37 This application is not likely to put the cultural well-being of Māori at risk in terms of their cultural beliefs and environmental frameworks.

Section 6(d) – Take into account Māori relationship to the environment

4.38 The CRA for RFC 397 (New Formulation) considered potential risks and impacts on Māori interests including the relationship of Māori to the environment, culturally significant species and resources, and the tikanga (customary values and practices) associated with these taonga. The CRA has identified cultural concerns in relation to taha hauora (human health and well-being), and culturally significant species, and various information gaps. However, potential risks around these issues can be managed,

and therefore the application is not inconsistent with Māori cultural beliefs and environmental frameworks.

Section 8 – Take into account Treaty of Waitangi principles

4.39 For the EPA, as a Crown agency, this includes the duty to actively protect Māori interests, and ensure that EPA decision making is informed by Māori perspectives. The CRA has assessed cultural risk and identified how Māori interests will be protected.

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

4.40 No risks to society, communities or the market economy from the approval of RFC 397 (New Formulation) have been identified.

New Zealand's international obligations

4.41 No international obligations that may be impacted by the approval of RFC 397 (New Formulation) have been identified.

The effects of the substance being unavailable

4.42 The likely effects of the substance being unavailable in accordance with section 29(1) of the Act have been considered. Should this substance not be available, it could lead to less consumer choice.

Risk assessment conclusion

4.45. No formulation data were provided for toxicological or ecotoxicological endpoints for RFC 397 (New Formulation). This leads to a significant degree of uncertainty regarding the magnitude of adverse effects of RFC 397 (New Formulation). The EPA has estimated the effects of the individual active ingredients instead of the formulation as a whole, however, there are significant data gaps in the data available for these actives for this application.

4.46. In particular, information is not available to assess the risks for some environmental endpoints, and in some areas this lack of information is considered significant in terms of its impact on the EPA assessment of the risks associated with RFC 397 (New Formulation).

4.47. The risks to human health from commercial application of RFC 397 (New Formulation) on ornamentals are expected to be managed by controls such that the resulting level of risk is **negligible**. Full personal protective equipment is necessary to reduce exposure to workers in commercial applications to below levels of concern. Additionally, relatively long REI are required in order to reduce the exposures of workers undertaking re-entry work to below levels of concern. The risks to bystanders are considered negligible.

4.48. The risks to human health from the domestic use of RFC 397 (New Formulation) are considered **negligible**.

4.49. The intended uses of RFC 397 (New Formulation) in home gardens and in commercial settings on ornamentals limits the potential exposure to aquatic environments. There are some data gaps in the

information available on the effects of the active ingredients in aquatic environments, but these are not considered significant data gaps. Overall, the risks to aquatic environments are considered **negligible**.

4.50. Potential non-negligible risks to birds from chronic exposure to RFC 397 (New Formulation) have been identified, which are driven by tebuconazole. Based on a refined assessment taking into account dietary exposure, it is considered that the risks to birds from tebuconazole are **negligible**. However, no information on the effects of chronic exposure to pyriproxyfen is available, and taking into account the intended use pattern for RFC 397 (New Formulation), this is considered a **significant data gap**.

4.51. The data gaps relating to the effects on pollinators, in particular the data gaps relating to the effects from exposure to pyriproxyfen, are considered **significant data gaps**.

4.52. The data gaps relating to the effects on non-target arthropods, in particular the data gaps relating to the effects from exposure to pyriproxyfen, are considered **significant data gaps**.

4.53. These significant data gaps combined with the intended use pattern of RFC 397 (New Formulation) give rise to the potential for **non-negligible risk** to pollinators and non-target arthropods. This also gives rise to the potential for **non-negligible** cultural risks arising from potential harm to species and environments of cultural significance.

4.54. Overall, the EPA considers that the **environmental and cultural risks** from the intended use of RFC 397 (New Formulation) in commercial and home garden use on ornamentals are **non-negligible**. Taking into account the significant data gaps, the intended use pattern, and associated uncertainty regarding the adverse effects of RFC 397 (New Formulation), the overall magnitude of impact is considered **low to medium**.

Assessment of costs

4.55. There are not expected to be any significant costs associated with the approval of RFC 397 (New Formulation.

Assessment of benefits

4.43 The applicant in their application noted that the approval of RFC 397 (New Formulation) will provide the following benefits:

- Control of a range of fungal diseases and insects in ornamentals in both domestic and commercial situations
- The fungicide active ingredients are systemic, providing fungal protection throughout treated plants
- Pyriproxyfen is an insect growth regulator that impacts insects in juvenile stages of the life cycle, presenting low risk to mature insects
- The use of three fungicide actives in one formulation minimises the risk of fungicide resistance
- The combination of fungicide and insecticide active means that users only need one product to treat a range of organisms that harm ornamental plants. The combination of actives is a new control option for end-users

- Amenity benefits from the control of organisms that harm ornamental plants

4.44 While the combination fungicide/insecticide formulation is claimed as a benefit by the applicant, it is noted that use of a fungicide/insecticide combination when controlling fungi involves application of an insecticidal active ingredient that is not necessary to implement control of only fungi, and the reverse situation when controlling only insects also involves unnecessary fungicide ingredients. It is considered that since this introduces the potential for unnecessary application of pesticide active ingredients, and the potential for associated unnecessary risks, that this aspect of the formulation does not constitute a benefit.

4.45 It is considered however that overall there would be some benefits associated with the approval of RFC 397 (New Formulation), and that these benefits could range from **negligible to low** in magnitude.

5. Prescribed controls

5.1. The hazard classifications of RFC 397 (New Formulation) determine a set of prescribed controls specified by the EPA Notices under section 77 of the Act. There are also requirements in the HSW (HS) Regulations. Note: the HSW (HS) Regulations requirements are not set for the substance under this approval but apply in their own right.

5.2. The prescribed controls/requirements set the baseline for how the substance must be managed and include specifications on how the substance is to be packaged, labelled, stored, disposed, transported, handled and used. The prescribed controls also set information requirements (eg Safety Data Sheets), signage and emergency management. These controls form the basis of the controls specified in the Appendix.

Exposure limits

5.3. Under s77B of the Act, the EPA may set a Tolerable Exposure Limit (TEL) and/or an Environmental Exposure Limit (EEL) for a substance with toxic or ecotoxic properties.

- Regulation 13.17 of the HSW (HS) Regulations prohibit the use of a class 6 substance in excess of a TEL.
- Clause 49 of the Hazardous Property Controls Notice prohibits use of a class 9 substance in excess of an EEL.

5.4. The EPA has not set any TEL values for any of the active ingredients of RFC 397 (New Formulation) because it is considered that this substance is unlikely to result in environmental concentrations that are likely to result in an appreciable toxic effect to people, provided that any controls set for this substance are complied with.

5.5. While RFC 397 (New Formulation) has the potential to cause environmental exposure that could lead to harm to some organisms in the environment, it is not considered appropriate to set EELs for any component of RFC 397 (New Formulation).

5.6. The EPA may provide ADE (Acceptable Daily Exposure), and Potential Daily Exposure (PDE) values for new active ingredients that may become present in food, to allow the setting of Maximum Residue Levels (MRLs) by the MPI. No ADE and PDE values are provided for any components of RFC 397 (New Formulation) at this time because this substance is not intended to be used on food crops.

5.7. There are Workplace Exposure Standard (WES) values currently set for components of RFC 397 (New Formulation) but, as they are not Prescribed Exposure Standard (PES) values, they are guidance values used for the management of health risk. No PES has been set for any component of RFC 397 (New Formulation)

6. Changes to prescribed controls

6.1. Significant potentially non-negligible risks were identified for RFC 397 (New Formulation). Variations to the prescribed controls and including additional controls were considered for the potential to reduce these non-negligible risks.

6.2. The following modifications to the EPA Notice controls were considered for this substance, as set out in Table 2:

Table 2: Proposed changes to the prescribed controls

Control	Justification
Application restrictions HPC Notice Clause 50	It is considered appropriate to propose a maximum application rate, number of applications and application frequency under clause 50 of the Hazardous Substances (Hazardous Property Controls) Notice 2017 (“HPC Notice”). The proposed maximum application rate is 10 L of formulated product/ha per application, with a maximum of nine applications and a minimum of 14 days between each application. This application rate is equivalent to an application rate per application of 64 g/ha pyraclostrobin, 126 g/ha boscalid, 215 g/ha tebuconazole, and 50 g/ha pyriproxyfen. It is noted that this maximum application rate control is set at the highest application rate and frequency intended by the applicant, in order to prevent additional risks beyond the intended use pattern of the applicant. However, it is noted that this control does not manage the risks of the intended use pattern of RFC 397 (New Formulation).
Label Labelling Notice	Additional labelling requirements are proposed for RFC 397 (New Formulation): - A label statement warning that the substance is not compatible with Integrated Pest Management (IPM) - A label statement detailing the controls to protect beehives and bee nests It is noted that the Labelling Notice and the HPC Notice both contain requirements to put further information on the label, relating to the proposed restrictions on application, controls to protect aquatic organisms, and controls to protect pollinators.

6.3. The following additional HSNO controls were considered for this substance, as set out in Table 3:

Table 3: Proposed additional controls

Control	Justification
Use restriction	RFC 397 (New Formulation) has the potential to cause significant harm to bees and other pollinators. In addition to the requirements of the HPC Notice it is considered appropriate to propose that the substance must not be applied on beehives or bee nests.
Application method	It is proposed that application of the substance be limited to ground-based methods (as intended by the applicant) to prevent the potential for aerial application that could lead to spray drift beyond what is assessed in this application. It is proposed that a restriction on wind speed during application when the substance is applied to an area of greater than 225 m^2 be applied to limit the potential for spray drift.

6.4. It is noted that while additional controls have been proposed that would limit the potential exposure to bees and other beneficial insects, the intended use of the substance as an insecticide to be applied to flowering plants means that there is a significant likelihood of exposure of bees and other beneficial insects to the active ingredients of RFC 397 (New Formulation), even with the proposed additional controls in place.

6.5. The applicant was provided the risk assessment findings and noted that they supported a label requirement stating that the product should not be applied to flowers or when bees are actively foraging. The applicant noted that home gardeners would likely seek to protect their ornamental plants by not applying the product during flowering.

6.6. The applicant was later provided with the proposed controls that were considered for RFC 397 (New Formulation), and invited to comment. The applicant considered that the proposed controls would be comparable to controls applied to similar approved substances. The applicant noted that other substances containing pyriproxyfen are approved under the Act and are also registered under the Agricultural Compounds and Veterinary Medicines Act 1997 for use in a range of crops to control insects such as scale insects and whitefly. The applicant commented that if RFC 397 (New Formulation) was considered by the EPA to present risks to bees, that it could be expected that the risks associated with the commercial crop uses of those substances would be significantly higher than the risks associated with the intended uses of RFC 397 (New Formulation). On this basis the applicant considered there were was no basis to have significant concerns about RFC 397 (New Formulation).

7. Assessment summary

7.1. After taking into account the prescribed controls, and the variations to the controls and the additional controls considered for RFC 397 (New Formulation), it was considered that there remains significant potential for non-negligible risk associated with the use of this substance. This finding is largely as a result of the significant data gaps identified in the risk assessment, that lead to uncertainty regarding

the risks of RFC 397 (New Formulation), and how these risks could potentially be managed by controls.

7.2. The data gaps identified above relating to the potential effects on birds, pollinators, and non-target arthropods are particularly significant, especially as this substance is intended to be used as a combination of three fungicides and one insecticide on ornamental plants where these species could be expected to be exposed to RFC 397 (New Formulation). This increases the potential for adverse effects on the environment, and resulting cultural impacts.

7.3. The EPA is not able to determine the magnitude of all of the potential risks, and considers that overall a **non-negligible** risk could occur as a result of the use of this substance. The risks are considered to be **low to medium** in magnitude.

7.4. There are potential benefits associated with the approval of RFC 397 (New Formulation). It is considered that the level of benefit could be **negligible to low** in magnitude.

7.5. The EPA therefore considers that the risks of RFC 397 (New Formulation) outweigh the benefits.

8. Decision

8.1. 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. I have also taken into account the considerations set out in Part 2 of the Act.

8.2. As required in section 7 in part 2 of the Act, I have exercised caution in assessing the adverse effects of this substance, as there is significant scientific and technical uncertainty about those effects.

8.3. Taking into account all the available information on the substance, and after assessing the potential risks, costs and benefits associated with RFC 397 (New Formulation), I have determined that the potential risks and adverse effects outweigh the potential benefits of this substance.

8.4. Therefore, I consider that this application for approval to import or manufacture RFC 397 (New Formulation) is declined in accordance with section 29 of the Act.

Dr Clark Ehlers	**Date: 22 August 2019**
Acting General Manager, HSNO, EPA	