



Environmental
Protection Authority
Te Mana Rauhi Taiao

EPA STAFF REPORT

Application for approval to import or manufacture Soleto for release

APP203925

DECEMBER 2020



Overview

Substance	Soletto
Application code	APP203925
Application type	To import or manufacture for release any hazardous substance under Section 28 of the Hazardous Substances and New Organisms Act 1996 (“the HSNO Act”)
Applicant	Belchim Crop Protection NV/SA
Purpose of the application	To import or manufacture Soletto for release
Date application lodged	18 September 2019
Date application formally received	13 March 2020
Submission period	24 August 2020 – 5 October 2020
Submissions	No submissions received
Information requests and time waivers	The timeframe for the opening of the public consultation was waived under section 59 of the Act Further information was requested under section 58 of the Act

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1. Executive summary

Background

- 1.1. The applicant, Belchim Crop Protection NV/SA, submitted an application on 18 September 2019 to import or manufacture Soleto for release. Soleto is a pre-emergence herbicide for the control of weeds in potato crops, in the form of a suspension concentrate, containing 500 g/L metobromuron as the active ingredient. It was given application number APP203925 and was formally received on 13 March 2020 as a notified Category C application.
- 1.2. The active ingredient, metobromuron, has not previously been approved in New Zealand. Metobromuron is approved in Europe.
- 1.3. Details on the hazard classifications and risk assessment can be found in the Science Memorandum.

Hazardous properties

- 1.4. The classifications applicable to the active ingredient, metobromuron, are based on toxicological and ecotoxicological studies conducted using the technical grade active ingredient.
- 1.5. The following hazard classifications have been identified as applicable to metobromuron: 6.1E (oral), 6.5B, 6.7B, 6.9B (oral), 9.1A, 9.2A and 9.3C.
- 1.6. Metobromuron is not considered readily biodegradable. Metobromuron is considered persistent in the aquatic environment and in the soil environment. Metobromuron is not considered to be bioaccumulative.
- 1.7. The classifications applicable to Soleto were based on product data, the composition of the substance, and the properties of its components.
- 1.8. The following hazard classifications have been identified as applicable to Soleto: 6.1E (oral), 6.7B, 6.9B (oral), 9.1A and 9.2A.

Public consultation

- 1.9. The application was publicly notified because this substance contained a new active ingredient that has not been approved in New Zealand.
- 1.10. No submissions were received.

Risk assessment

- 1.11. The EPA conducted quantitative human health and environmental risk assessments to determine if the amount of exposure that people and organisms may experience during use of the substance on potatoes is likely to result in adverse effects.

Human health effects

- 1.12. The human health risk assessment results showed that predicted operator exposures to metobromuron during mixing, loading and application of Soleto were below the level of concern provided that full Personal Protective Equipment (PPE) is worn. The risks to re-entry workers and bystanders were deemed below the level of concern without the need for any additional controls.
- 1.13. WorkSafe were notified of the application and have provided comments on whether the Health and Safety at Work (HSW) controls manage the risk to people from workplace activities. WorkSafe comments are provided in section 6.11 of this document and their full advice is available as a separate document.

Environmental effects

- 1.14. A full assessment of the risks for the active ingredient, metobromuron, in accordance with the Good Agricultural Practice (GAP) table for Soleto, was performed as this active ingredient is new to New Zealand.
- 1.15. The aquatic risk assessment indicated risks above the level of concern. To manage these risks, it is proposed to apply controls to reduce spray-drift and runoff into the aquatic environment. Together with prescribed controls, additional various use restrictions will reduce the risks to aquatic organisms below the level of concern. Regarding the risk assessment to groundwater and sediment-dwelling organisms, no risks from the use of Soleto were identified.
- 1.16. Acute and chronic risks to earthworms following the application of the formulated product Soleto are considered below the level of concern. However, chronic risks were identified as potentially above the level of concern for non-threatened species of soil mites and Collembola in-field (further information is available in section 6 of this document). Risks to microorganisms are considered below the level of concern.
- 1.17. The non-target plant risk assessment proposed that a 5 m downwind buffer zone is applied to the product label to protect non-target plants from potential adverse effects. It is also recommended to apply an additional label statement to warn users about the potential for Soleto to cause harm to sensitive terrestrial areas (wetlands, indigenous vegetation habitat areas or reserves which may contain threatened plants), in which case it is recommended to increase the buffer zone to 50 m.
- 1.18. Regarding the birds risk assessment, Soleto is a pre-emergence herbicide, and therefore it is considered that treated fields will have low food availability and provide no protection to predators. Considering this, the conservative nature of the toxicity endpoints, the possibility that birds will forage in other (non-treated) areas, and the limited availability of contaminated

food, the risks identified for birds (threatened and non-threatened) following application of Soleto to pre-emergent potatoes are considered to be below the level of concern.

- 1.19. Risks to pollinators are below the level of concern and any risks are negligible.
- 1.20. Off-field risks to non-target arthropods are below the level of concern. In-field risks were identified for predatory mites when exposed to fresh residues of Soleto, however this exposure is not relevant for the pre-emergence use pattern of Soleto as there will be no foliage in the field during application. A control is proposed to ensure that any weeds, remaining crop or seeds have been mechanically removed before application of Soleto, in order to mitigate the risk of exposure to fresh residues to a negligible level.
- 1.21. It is considered that the risks to the environment from the proposed use of Soleto are below the level of concern with the proposed controls, except for non-threatened species of soil mites and Collembola in-field, for which a low risk was identified.

Summary of the Māori Perspective Report

- 1.22. Kaupapa Kura Taiao (the EPA's Māori Policy and Operations team) has undertaken an assessment to consider potential impacts of Soleto on the economic, social, and cultural well-being of Māori, and the relationship of Māori with the environment, pursuant to sections 5(b), 6(d) and 8 of the HSNO Act.
- 1.23. Soleto is not likely to significantly affect the relationship of Māori and their culture and traditions with their environment and taonga, including culturally significant species, resources, and places, and the customary values, practices and uses associated with these taonga.
- 1.24. Soleto is not likely to significantly affect the ability and capacity of Māori to maintain their economic, social, and cultural well-being.
- 1.25. Ngā Mātāpono o Te Tiriti o Waitangi (the Principles of the Treaty of Waitangi) have been considered in relation to this application – no issues arise in this regard.

Benefit assessment

- 1.26. The applicant considered that the approval and subsequent availability of Soleto would give rise to benefits, such as the early control of broadleaf weeds, the potential to replace the active ingredient 'linuron', improvement of resistance management strategies, low exposure to operators or workers and the environment and the absence of residues on harvested products.
- 1.27. It is considered that the benefits of the substance outweigh the risks of the substance, if used in accordance with the appropriate controls and requirements.

Recommendation

- 1.28. It is considered that there is sufficient information available to assess the application to import or manufacture Soleto for release. With the proposed controls in place, the risks to human health and the environment from the importation, manufacture and use of Soleto are negligible, except for non-threatened species of soil mites and Collembola for which a low risk has been identified. It is considered that the use of Soleto will provide some benefits to farmers.
- 1.29. With the proposed controls in place, it is therefore considered that benefits of the substance, based on the assessment of the information available, outweigh the risks of the substance.
- 1.30. It is therefore recommended that the Committee approves the application to import or manufacture Soleto for release.

2. Background

Use pattern

- 2.1. Soleto is a suspension concentrate (SC) containing 500 g/L metobromuron as the active ingredient, plus other components. It is intended to be used as a pre-emergence herbicide for the control of weeds in potato crops. The applicant seeks to have Soleto approved for ground-based application methods.
- 2.2. Application will be at the rate of 3 L to 4 L of Soleto per hectare, which is equivalent to 1.5 kg to 2 kg of metobromuron per hectare, with one application per crop cycle.

Regulatory status

- 2.3. Metobromuron is a new substance to New Zealand.
- 2.4. Metobromuron is approved in Europe, however it is not approved in Australia, Canada, Japan and the United States.

Impurities

- 2.5. No impurity limits for metobromuron have been identified by the EU.

Life cycle of the substance

- 2.6. The applicant has described the lifecycle of Soleto as follows:
 - Soleto will be imported by sea or air into New Zealand, packaged ready for sale.
 - The substance will be available in 1 L to 15 L High-density Polyethylene (HDPE), Fluorinated-HDPE (HDPE-F), HDPE/Polyamide (HDPE/PA) and HDPE/Ethylene vinyl

alcohol copolymer (HDPE-EVOH) containers (packaging specifications are provided in Appendix A of the application form).

- The substance will be stored in a secure warehouse.
- Damaged packaging, contaminated absorbents and other contaminated materials will be placed into a suitable container and either sent to an approved secure landfill for burial, or to a waste management services provider for incineration.
- Disposal of the formulated substance will be according to label instructions. Packaging will be crushed and sent to a secure approved landfill for burial.

3. Process, consultation, and notification

- 3.1. The application was formally received on 13 March 2020.
- 3.2. It was considered that the application would be of significant public interest. This was because Soleto contains a new active ingredient that has not previously been assessed under the Act and it was considered there would be public interest in its intended use; as such, the application was publicly notified.
- 3.3. The Ministry for the Environment, the Ministry of Health, the Agricultural Compounds and Veterinary Medicines (ACVM) group of the Ministry for Primary Industries and the Department of Conservation were notified of the submission period. No comments were received.
- 3.4. WorkSafe New Zealand (WorkSafe) was also notified of this application in order to receive their assessment on aspects of this application related to the Health and Safety at Work Act 2015 (HSW Act) and Health and Safety at Work (Hazardous Substances) Regulations 2017 (HSW HS Regulations). The feedback from WorkSafe is provided in section 6.
- 3.5. The timeframe for the opening of the public consultation was waived under section 59 of the Act to allow preparation of the draft Science Memorandum, which contains the EPA risk assessment, in order to allow any potential submitter to have this document at their disposal for making an informed submission.
- 3.6. Prior to public notification of the application, further information regarding the effect of the substance to soil macro-organisms and non-target arthropods was requested under section 58 of the Act.
- 3.7. The application was open for submissions from 24 August 2020 to 5 October 2020.
- 3.8. In preparing this report, the following documents and information were taken into account:
 - the application form

- confidential material submitted by the applicant with the application form, including toxicological, ecotoxicological and environmental fate studies on metobromuron and Soletto.
- information received from WorkSafe
- the science memorandum
- the cultural assessment
- other available information.

4. Hazardous properties

- 4.1. The hazard classifications of metobromuron determined by the EPA are shown in Table 1. Physico-chemical, mammalian toxicology and ecotoxicology studies were provided for technical grade metobromuron. Information from these studies was used to classify the substance.

Table 1: Hazard classification of metobromuron

Hazard	Classification
Acute toxicity (oral)	6.1E
Contact sensitisation	6.5B
Carcinogenicity	6.7B
Target organ systemic toxicity (oral)	6.9B
Aquatic ecotoxicity	9.1A
Soil ecotoxicity	9.2A
Terrestrial vertebrate ecotoxicity	9.3C

- 4.2. Metobromuron is of relatively low acute toxicity in mammals and should be classified 6.1E for acute oral toxicity. It is not a skin or eye irritant, but is a contact sensitiser and is classified as 6.5B. Metobromuron was not found to be genotoxic, but should be classified as a suspected human carcinogen (6.7B). It does not cause reproductive or developmental toxicity. Results of repeated dose oral toxicity studies in laboratory animals indicate it should be classified for systemic organ toxicity (6.9B, oral).
- 4.3. Metobromuron is very ecotoxic to the aquatic and soil environment (9.1A, 9.2A), and harmful to terrestrial vertebrates (9.3C). However, it is not toxic to terrestrial invertebrates.
- 4.4. Metobromuron is considered persistent in the aquatic environment ($DT_{50} = 34.5$ days; criterion is $16 \text{ days} < DT_{50} < 60 \text{ days}$) and in the soil environment ($DT_{50} = 42.2 \text{ days} - 73.3 \text{ days}$; criterion is $30 \text{ days} < DT_{50} < 6 \text{ months}$). Metobromuron is considered to have high mobility in

soil ($K_{oc} = 114 \text{ mL/g}$; criterion is $100 \text{ mL/g} < K_{oc} < 150 \text{ mL/g}$). Metobromuron is not considered bioaccumulative (based on the $\text{Log } K_{ow}$ of 2.48; criterion is $\text{Log } K_{ow} < 4$).

- 4.5. The hazard classifications of Soleto were determined based on the information provided by the applicant (including toxicity and ecotoxicity studies), information on the individual components of Soleto (mixture rules) and other available information on the active ingredients (Table 2).

Table 2: Hazard classification of Soleto

Hazard	EPA classification
Acute toxicity (oral)	6.1E
Carcinogenicity	6.7B
Target organ or systemic (oral)	6.9B
Aquatic ecotoxicity	9.1A
Soil ecotoxicity	9.2A

- 4.6. Mammalian toxicity studies with Soleto indicate that this substance has relatively low acute toxicity in mammals and should be classified 6.1E for acute oral toxicity. It is not a skin or eye irritant, or a contact sensitiser. Based on mixture rules, it should be classified for suspected human carcinogenicity (6.7B) and target organ systemic toxicity (6.9B, oral).
- 4.7. Based on test data for the formulation, Soleto is very ecotoxic to the aquatic and soil environment (9.1A, 9.2A), but is not toxic to terrestrial vertebrates or invertebrates.

5. Submissions

- 5.1. No submissions were received for this application.

6. Risk assessment

- 6.1. During the importation, manufacture, transportation, storage, and disposal of this substance, it is expected that exposure is unlikely to occur and that the proposed controls and other legislative requirements will sufficiently mitigate the risks associated with these stages of the substance lifecycle to a negligible level. These include the existing Hazardous Substances Notices around packaging, identification, emergency management and disposal of hazardous substances, the Land Transport Rule 45001, Civil Aviation Act 1990, Maritime Transport Act 1994 and New Zealand's health and safety at work requirements.
- 6.2. In contrast, it is considered that there is the potential for exposure to humans and the environment to occur during the use phase of the substance. Therefore, a human health and environmental risk assessment was carried out. In this assessment, the above controls and

legislative requirements were taken into account when identifying controls to mitigate risks associated with use of the substance.

Use pattern

- 6.3. Soleto is a suspension concentrate (SC) containing 500 g/L metobromuron as the active ingredient, which is intended to be used as a pre-emergence herbicide for the control of weeds in potato crops. Soleto is intended for ground-based application only.
- 6.4. Application will be at the rate of 3 L to 4 L of Soleto per hectare, which is equivalent to 1.5 kg to 2 kg of metobromuron per hectare, with one application per crop cycle.

Human health effects

- 6.5. Soleto is intended to be supplied to the professional market. Users are expected to apply the substance by ground-based methods. It is likely that users will be exposed to the substance during the application stages of the substance.
- 6.6. The potential risks posed by Soleto to human health were assessed by estimating the exposure of operators, re-entry workers and bystanders to the active ingredient, metobromuron.
- 6.7. To assess the risks posed by the substance to human health, the estimated exposure to metobromuron for each application scenario was compared to an Acceptable Operator Exposure Limit (AOEL) value for this active ingredient and a risk quotient was calculated. The AOEL used for metobromuron is 0.03 mg/kg bw/day. This AOEL was based on a one year toxicity study on rats and mice.
- 6.8. The estimated exposures of the operator to metobromuron when mixing, loading and applying Soleto by spray boom are below the AOEL provided full PPE is worn.
- 6.9. For risks to persons re-entering the treated area, the EPA notes that Soleto is proposed to be used early in the plant growth cycle (pre-emergence) in potatoes. Entry exposure risks based on activities such as reach, pick or cereal scouting for vegetables is inappropriate in these circumstances as the model assumes the re-entry worker is exposed to foliar residue. Therefore, as there would be minimal need for worker re-entry following use of Soleto, the EPA concluded on the basis of a qualitative assessment that the re-entry exposures are below the level of concern.
- 6.10. To assess potential risks to the general population or bystanders from use of Soleto, predicted exposures to metobromuron in different use scenarios (different boom heights and droplet sizes) were compared to an acceptable threshold level. The estimated risks to bystanders are also below the level of concern and no buffer zones are proposed to mitigate risks to human health.

WorkSafe's assessment

- 6.11. WorkSafe were notified of the application on 13 March 2020 and have provided the following comment on whether the HSW controls manage the risk to people from workplace activities:

“WorkSafe has assessed the available information for APP203794 (SOLETO) and considers that compliance with the Health and Safety at Work (Hazardous Substances) Regulations and Health and Safety at work (General Risk and Workplace Management (GRWM) Regulations will be adequate to reduce the risks associated with the use of this substance in the workplace. While the regulations cover standard risk mitigation measures, occupational exposure in the workplace needs to be assessed at each site and appropriate controls put in place to mitigate the identified risks.”

“When using substances that have human health risks the PCBU must minimise the risks so far as reasonably practicable by applying the hierarchy of controls set out in Regulation 6 of the General Risk and Workplace Management Regulations 2016 (GRWM).”

“Regulation 13.8 of the HSW (Hazardous Substances) Regulations requires that personal protective equipment (PPE) must be worn when working with this substance to minimise the risks to the health and safety of workers.”

“However, PPE should only be used as a control measure to minimise risk when other control measures alone cannot adequately do so. PPE should not be the first or only control considered, WorkSafe expects PCBUs to give preference to other controls that protect multiple at-risk workers at once.”

“Under Sections 39 - 42 of the Health and Safety at Work Act 2015 (HSWA) manufacturers/importers/suppliers have a duty to ensure substances manufactured, imported or supplied are without risk so far as is reasonably practicable.”

“WorkSafe would like to see PCBUs aware of their upstream duties and applying them during the substance design process and formulating substances that are without risk to human health.”

“WorkSafe notes that Soleto contains a new herbicide active and may reasonably be expected to not have significant human health hazards. A recent review of the new herbicide actives approved in New Zealand over a 5 year period showed that 3 of 6 new herbicide actives had no human health hazards, one was classified as a skin sensitiser and only two had chronic health hazards. This new herbicide active has been classified by the EPA as a 6.7B (carcinogenic) and 6.9B (target organ toxicity).”

“WorkSafe has identified that the PCBU may not have gone so far as is reasonably practicable (SFARP) to ensure it is without risk. It is WorkSafe's advice that for this substance the duties under sections 39-42 may not have been met.”

Environmental effects

- 6.12. It is noted that the applicant provided studies in regard to the environmental fate and ecotoxicity of metobromuron (and metabolites), as well as a number of studies on the formulated substance. The risks to a range of environmental receptors, including plant, invertebrate and vertebrate species living in aquatic, groundwater, sediment and terrestrial environments from the use of metobromuron are considered as a proxy for the risks from Soleto. Full details can be found in the Science Memorandum.

Risks to aquatic organisms

- 6.13. Users are expected to apply Soleto by ground-based application methods in the pre-emergence stage of the plant growth cycle of potatoes. Therefore, it is likely that aquatic species may be exposed to Soleto through spray drift or runoff.
- 6.14. Risks above the level of concern were identified and further modelling was performed to consider whether buffer zones may be able to mitigate risks from spray drift and runoff. It was determined that with spray nozzles delivering a minimum of a medium droplet size, a buffer zone of 5 metres was sufficient to mitigate risks from spray drift and runoff. Together with prescribed controls and various additional use restrictions, the risks to aquatic organisms are reduced to below the level of concern.
- 6.15. The following controls are proposed to reduce exposures to below the level of concern:
- The maximum application rate of Soleto is 4 L/ha (equivalent to 2 kg metobromuron/ha), with a maximum frequency of one application per year.
 - When applied using ground-based methods, the nozzle must be set to a medium droplet quality spray, at a minimum, as defined by the American Society of Agricultural and Biological Engineers ASABE Standard (S572) or the British Crop Production Council guideline.
 - A label statement: "**DO NOT** apply when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site."
 - To mitigate risks from spray drift and runoff the substance should not be applied within 5 m of any waterbody.
- 6.16. Regarding the risk assessment to groundwater and sediment-dwelling organisms, risks were calculated as being below the level of concern.

Risks to soil organisms

Risks to earthworms

- 6.17. Users are expected to apply Soleto by ground-based methods on potatoes, therefore, it is likely that soil organisms will be exposed to the substance through the substance reaching the soil.
- 6.18. Acute and chronic risks above the level of concern were identified for threatened species of earthworms in-field from the use of metobromuron.
- 6.19. It is considered that threatened earthworm species are unlikely to be present in-field as it is noted that there are 179 taxa of earthworms in New Zealand with only one species reported as “at risk - declining” (*Deinodrilus gorgon*) and 31 reported as “at risk - naturally uncommon”¹. Despite a potentially large distribution area for this earthworm species on the West Coast, the best documented natural habitat is not threatened by agriculture but rather by on-going and future mining activities on the Stockton and Denniston Plateaus¹. Furthermore, *Deinodrilus gorgon* is reported to have a total area of occupancy ≤ 1000 ha (10 km²) in New Zealand. The other 31 species ranked as “naturally uncommon” are predominantly endemic to New Zealand. These 32 earthworm species are confined to specific forestry areas or occur within naturally small and widely scattered populations, where this distribution is not the result of human disturbance.
- 6.20. Therefore, risks are considered below the level of concern for both non-threatened and threatened earthworms.

Risks to soil mites and Collembola

- 6.21. Chronic risks above the level of concern were identified for both non-threatened and threatened species of soil mites and Collembola:
- For non-threatened species, the risk would need to be 1.1x lower to be considered as below the level of concern.
 - For threatened species, the risk would need to be 11.3x lower to be considered as below the level of concern. However, the EPA notes that no threatened species of soil mite or

¹ Buckley, T.R.; Boyer, S.; Bartlam, S.; Hitchmough, R.; Rolfe, J.; Stringer, I. (2015). ‘*Conservation status of New Zealand earthworms, 2014*’. New Zealand Threat Classification Series 10. Department of Conservation, Wellington. 10 p.

Collembola² have been identified in New Zealand, therefore, this is not considered to be an issue.

- 6.22. These risks were only associated to the in-field scenario as no risks above the level of concern were identified to these organisms off-field.
- 6.23. While non-threatened species in-field have been identified as being at risk, this risk is considered to be low (TER = 4.44 < 5 = level of concern).

Risks to soil micro organisms

- 6.24. Risks to microorganisms are considered below the level of concern.

Risks to non-target plants

- 6.25. Risks to non-target plants were identified for both non-threatened and threatened species. A level of risk to non-target plants is expected as Solecto is a herbicide.
- 6.26. The following controls are proposed to reduce exposures to below the level of concern:
- A label statement: "**WARNING**, very toxic to some plant species. Certain plants may be damaged or killed from contact with this product. The substance should not be applied within 5 m of a downwind area containing any non-target plants."
 - A label statement: "Before application users should check with the regional authority to establish if there are wetlands, indigenous vegetation habitat areas or reserves which may contain threatened plants adjacent to the application area, in which case it is recommended to increase the buffer zone to 50 m."
 - A label statement: "**DO NOT** apply when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site."

Risks to birds

- 6.27. The bird screening risk assessment identified acute risks below the level of concern and chronic risks above the level of concern for both non-threatened and threatened species.
- 6.28. After refinement at Tier 1, potential chronic risks were still above the level of concern for both non-threatened and threatened species.
- 6.29. It is considered that the risks identified at Tier 1 may be overestimated because:
- The chronic avian endpoint used in the risk assessment is considered conservative.

² Townsend, A.J.; de Lange, P.J.; Duffy, C.A.J.; Miskelly, C.M.; Molloy, J.; Norton, D.A. (2008) 'New Zealand Threat Classification System manual'. Department of Conservation, Wellington. 35 p.

- For the focal bird species used in the bare soil scenarios, it is assumed that 100% of their diet is obtained from the treated field, and that 100% of their diet is contaminated. This is considered highly conservative as birds are also likely to forage in other (non-treated) areas.
- Food availability on treated fields is very limited. The soils of the potato fields are depleted of potential food items for birds as previously harvested crops are incorporated into the soil. Therefore, plant matter, including weed seeds, are not easily accessible to birds. The availability of insects is also limited due to the low availability of food resources and the missing habitat structure for insects on the bare soil.

6.30. After refinement and consideration of the conservative toxicity endpoint, the possibility that birds will forage in other (non-treated) areas, and limited availability of contaminated food, the risks identified for birds (threatened and non-threatened species) following application of Solecto to pre-emergent potatoes are therefore considered to be negligible.

Risks to pollinators

6.31. Risks to pollinators are considered below the level of concern

Risks non-target arthropods

6.32. Off-field risks to non-target arthropods are below the level of concern.

6.33. The Tier 1 assessment indicated that in-field risks were above the level of concern for the predatory mite. After refinement at Tier 2, in-field risks to predatory mites were still above the level of concern when exposed to fresh residues on apple leaves.

6.34. It is considered that exposure to fresh residues is not relevant for the pre-emergence use pattern of Solecto as there will be no foliage in the field during application. It is proposed to apply the following control to reduce exposures to below the level of concern:

- A label statement: "Ensure mechanical removal of weeds, remaining crop and seeds has taken place before application. The substance should only be used after planting and before crop emergence."

Summary of the Cultural Risk Assessment

Executive summary

6.35. Kaupapa Kura Taiao (the EPA's Māori Policy and Operations team) has undertaken an assessment to consider potential impacts of Solecto on the economic, social, and cultural well-being of Māori, and the relationship of Māori with the environment, pursuant to sections 5(b), 6(d) and 8 of the HSNO Act.

- 6.36. Soleto is not likely to significantly affect the relationship of Māori and their culture and traditions with their environment and taonga, including culturally significant species, resources, and places, and the customary values, practices and uses associated with these taonga.
- 6.37. Soleto is not likely to significantly affect the ability and capacity of Māori to maintain their economic, social, and cultural well-being.
- 6.38. Ngā Mātāpono o Te Tiriti o Waitangi (the Principles of the Treaty of Waitangi) have been considered in relation to this application – no issues arise in this regard.

Impact on Papatūānuku (Land and soils)

- 6.39. Soleto is not likely to have a significant impact on Papatūānuku (land and soils) including important species within the domain of Te Aitanga a Punga (soil dwelling organisms). The controls proposed to be assigned to Soleto should be sufficient for managing potential adverse effects on these receptors.

Impact on Ngā otaota (Plants)

- 6.40. Soleto has potential to harm culturally important species of otaota (plants) around the periphery of the target area including the iconic species harakeke (New Zealand flax), pūhā (sowthistle), and kawakawa (New Zealand pepper tree). The controls proposed to be assigned to Soleto should be sufficient for managing potential adverse effects on these receptors.

Impact on Ngā manu, me ngā ngārara (Birds and reptiles)

- 6.41. Soleto is not likely to have a significant impact on culturally important species of manu (birds). There is an information gap in respect of potential harm to ngārara (reptiles). The controls proposed to be assigned to Soleto should be sufficient for managing potential adverse effects on manu.

Impact on Te Aitanga Pepeke (Arthropods)

- 6.42. Soleto is not likely to have a significant impact on culturally important species of pepeke (arthropods). The controls proposed to be assigned to Soleto should be sufficient for managing potential adverse effects on these receptors.

Impact on Ngā wai koiora (Aquatic habitats)

- 6.43. If Soleto enters waterways it has potential to harm culturally significant species of ika (fish), mawhiti (crustaceans), kaiwhao (molluscs), pūkohu wai (algae), and otaota wai (aquatic plants) including the food species tuna (freshwater eels), īnanga (whitebait), kōura (freshwater crayfish), kākahi (freshwater mussels), and kowhitiwhiti (watercress). The controls proposed

to be assigned to Soletto should be sufficient for managing potential adverse effects on these receptors.

Impact on Taha hauora (Human health and well-being)

- 6.44. Soletto is classified as being acutely toxic if ingested and may be harmful to human organs and body systems, and is a suspected human carcinogen. It is noted that Māori have a significantly higher registration rates than non-Māori for cancer-related diseases. Māori working with crops where Soletto is used may potentially be a vulnerable group in view of the classifications associated with this substance. As such, Māori may be disproportionately affected by this substance as a demographic group.
- 6.45. However, the use pattern and controls proposed to be assigned to Soletto should be sufficient for managing potential adverse effects on taha hauora. Therefore, Soletto is not likely to have a significant impact on taha hauora.

Impact on kaitiakitanga and manaakitanga (environmental guardianship and due care)

- 6.46. Soletto is not likely to have a significant impact on the ability of Māori to exercise kaitiakitanga and manaakitanga (environmental guardianship and due care). The controls proposed to be assigned to Soletto should be sufficient for managing potential adverse effects on these practices.

Ngā hua (Benefits)

- 6.47. Using Soletto as a pre-emergence herbicide for controlling broadleaf weeds in potatoes will produce economic and operational benefits for those working with these crops, some of whom are Māori, in terms of yield, quality, and profitability of their crops. Māori growers and operators most likely to benefit from Soletto are those in Pukekohe, Manawatū, Horowhenua, and Waitaha (Canterbury), as these are the main production areas in New Zealand for these crops.
- 6.48. Soletto provides an option that potato growers and spraying contractors can consider as an alternative to more harmful herbicide products that are currently available, and thus help to phase out these products. It may also help to address the issue of resistance to other herbicides.

Analysis of impact

- 6.49. The benefits to Māori associated with this application are unlikely to outweigh any detrimental impacts to Māori.
- 6.50. The controls proposed to be assigned to Soletto should be sufficient for managing the impact of any effects on Māori.

- 6.51. The overall impact on the relationship Māori have with their environment and taonga is not likely to significant and is unlikely to adversely affect the ability of Māori to exercise kaitiakitanga.
- 6.52. The overall impact on Māori economic wellbeing (arising from the impact on the environment and taonga) is not likely to significant.
- 6.53. The overall impact on Māori social wellbeing (arising from the impact on the environment and taonga) is not likely to significant. This includes impacts on Māori ways of life and taha hauora (human health and well-being).
- 6.54. The overall impact on Māori cultural wellbeing (arising from the impact on the environment and taonga) is likely to be negligible. This includes potential impacts Māori may experience in relation to their customary practices, traditions, beliefs, institutions, and lore.

Te Tiriti o Waitangi (Treaty of Waitangi)

- 6.55. The Principles of the Treaty of Waitangi have been considered in relation to this application and no concerns arise under the Treaty Principles, as summarised below.
- 6.56. Māori interests are being actively protected in relation to this application.
- 6.57. The decision makers on this application are making a decision informed by a Māori perspective.
- 6.58. The EPA considers it is acting in good faith, and is acting reasonably and fairly, in respect of this application. Mātauranga Māori and tikanga Māori are being respected.

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

- 7.1. No risks to society, communities or the market economy from the approval of Soleto have been identified.

8. New Zealand's international obligations

- 8.1. No international obligations that may be impacted by the approval of Soleto have been identified.

9. Assessment of benefits

Early control of broadleaf weeds in potato

- 9.1. The applicant explained that *“the use of herbicides, especially in the early stages of crop emergence, is of high importance to obtain acceptable yields. Soleto can be used to control redroot and fathen, which are important weeds in New Zealand.”*

- 9.2. The EPA considers that an efficacious product would be a significant benefit, however, efficacy data is assessed by ACVM. Therefore, the level of this benefit is undetermined.

Potential to replace the active substance linuron

- 9.3. The applicant explained that *“metobromuron has the potential to replace the active linuron as a pre-emergence herbicide. Both actives have a comparable structure, the same mode of action (inhibition of the photosynthesis) and are used as pre-emergence herbicides in potatoes. Linuron presents the industry with a range of issues, market access issues (banned in Europe), a high toxicological potential (endocrine disruptor) and a negative impact on terrestrial vertebrates. Metobromuron (approved in Europe since 2014) has a comparable efficacy potential but is less hazardous as Linuron”*. The applicant provided more information as well as figures regarding this benefit in the application form.
- 9.4. The EPA notes that there are currently two active ingredients approved under the HSNO Act which, along with metobromuron, belong to the chemical family of Ureas, and are also used as pre-emergence herbicides in potatoes. Those are linuron (HSR003248) and methabenzthiazuron (HSR003524). The EPA notes that there are currently seven ACVM-approved substances containing linuron as the active ingredient and one ACVM-approved substance containing methabenzthiazuron as the active ingredient, with a use pattern similar to Soletto. Table 3 provides a comparison of the HSNO classifications for metobromuron, linuron and methabenzthiazuron, whereas Table 4 provides a comparison of the EU classifications.

Table 3: Comparison of the HSNO classifications of metobromuron, linuron and methabenzthiazuron

Hazard	Metobromuron	Linuron	Methabenzthiazuron
Acute toxicity (oral)	6.1E	6.1D	No classification
Eye irritation	No	6.4A	6.4A
Contact sensitisation	6.5B	No	Not determined
Carcinogenicity	6.7B	Not determined	Not determined
Reproductive/developmental toxicity	No classification	6.8B	No classification
Target organ systemic toxicity (oral)	6.9B	6.9A	Not determined
Aquatic ecotoxicity	9.1A	9.1A	9.1A
Soil ecotoxicity	9.2A	9.2A	9.2A
Terrestrial vertebrate ecotoxicity	9.3C	9.3B	No classification

Table 4: Comparison of the EU classifications of metobromuron, linuron and methabenzthiazuron

Hazard	Metobromuron	Linuron	Methabenzthiazuron
Acute toxicity	Category 4 (oral)	Category 4 (oral)	-
Skin sensitisation	Category 1	-	-
Reproductive toxicity	-	Category 1B	-
Carcinogenicity	Category 2	Category 2	-
Specific target organ systemic toxicity (repeated exposure)	Category 2	Category 2	-
Aquatic acute	Category 1	Category 1	Category 1
Aquatic chronic	Category 1	Category 1	Category 1

- : No classification

Note: The classifications of linuron and methabenzthiazuron are those referred to in Regulation (EC) No 1272/2008. Metobromuron is currently not listed in Annex VI of Regulation (EC) No 1272/2008 and the classification of metobromuron in Table 4 is the classification proposed by the Rapporteur Member State (RMS) in the context of the evaluation procedure under Regulation (EC) No 1107/2009.

Note: Linuron and methabenzthiazuron are not approved in Europe

- 9.5. Based on information available, the EPA has identified ten HSNO-approved active ingredients for the pre-emergence control of weeds in potatoes (Table 5).

Table 5: HSNO approved herbicide active ingredients used on potatoes (pre-emergence)

Active ingredient	HSNO Classification	Overseas approval status
Metobromuron (APP203925)	6.1E (oral), 6.5B, 6.7B, 6.9B (oral), 9.1A, 9.2A, 9.3C	Europe
Linuron (HSR003248)	6.1D (oral), 6.4A, 6.8B, 6.9A (oral), 9.1A, 9.2A, 9.3A	Australia, USA, Canada, Japan
Methabenzthiazuron (HSR003524)	6.4A, 9.1A, 9.2A	Australia
Sulfentrazone (no individual approval)	6.1E (oral), 6.4A, 6.8B, 6.9B (oral), 9.1A, 9.2A	USA, Canada
Prosulfocarb (no individual approval)	6.1D (oral), 6.5B, 6.9B, 9.1A, 9.2A, 9.3C	Europe, Australia, Japan
S-metolachlor (HSR003363)	6.1E (oral, dermal), 6.1D (inhalation), 6.3B, 6.4A, 6.5B, 9.1A, 9.2A	Europe, Australia, USA, Canada, Japan
Clomazone (HSR003423)	3.1D, 6.1D (oral, inhalation), 9.1B, 9.2A, 9.3C	Europe, Australia, USA, Canada
Cyanazine (HSR003361)	6.1D (oral), 6.1D (dermal), 6.8B, 6.9A (oral), 9.1A, 9.3B	Australia, Japan
Metribuzin (HSR003028)	6.1C (oral), 6.9B (oral, inhalation), 9.1A, 9.2A, 9.3B	Europe, Australia, USA, Canada, Japan
Flufenacet (no individual approval)	6.1D (oral), 6.1E (inhalation), 6.5B, 6.9B (oral), 9.1A, 9.2A, 9.3C	Europe, USA, Canada, Japan

Note: metobromuron, linuron and methabenzthiazuron belong to the same chemical family of Ureas.

Improvement of the resistance management strategy

- 9.6. The applicant explained that *“weed resistance is a well know problem in agriculture. Moreover, it's a problem with an unknown impact on the environment, to prevent resistance, it is recommended to apply a variety of chemicals, combine different chemical classes and avoid repetition of the same product year after year. Metobromuron, a new active substance, is part of the Urea family (HRAC group C2, WSSA group 7). In New Zealand, only 5 (out of 18) active substance of the Urea family are registered. Furthermore, some of the approved active substances are under discussion worldwide (e.g. Linuron, banned in Europe). It would be a benefit for the resistance management to add a new pre-emergence active substance to the Urea chemical family”*.
- 9.7. The EPA notes that resistance management is a matter assessed by ACVM, and therefore, the level of this benefit is undetermined.
- 9.8. Nevertheless, the EPA notes that Soletto contains a new active ingredient which could provide for an additional tool for farmers, therefore this is considered a significant benefit.

Low exposure to operators, workers and the environment

- 9.9. The applicant explained that *“a low risk is also expected for operators, workers, bystanders and residents. According to the GAP, Soletto will be applied once during a growing season as a pre-emergence herbicide on bare soil. This results in a minimum exposure to Soletto for the operator, resident and bystander in comparison with multiple applications per season. The potential exposure for workers is practically non-existent, there is no need for either re-entry shortly after application or for further operations with the treated soil. In order to control the efficacy of the product, a simple visual inspection is sufficient without touching the soil by hand. In addition, it can reasonably be expected that a worker would wear shoes and trousers. This means, that there is practically no contact of any treated material with the skin, accordingly there is no dermal contact”*.
- 9.10. The EPA notes that the human health risk assessment results showed that predicted operator exposures to metobromuron during mixing, loading and application of Soletto were below the level of concern provided that full PPE is worn. The risks to re-entry workers were deemed below the level of concern without additional controls.

No residues on harvested products

- 9.11. The applicant explained that *“no residues (<LOQ) are found in harvested commodities when Metobromuron is applied according to the Good Agricultural Practice (GAP). This results in a low risk potential to consumers”*.

- 9.12. The EPA notes that residues is a matter assessed by ACVM, and therefore, the level of this benefit is undetermined.

10. Controls

- 10.1. The hazard classifications of Soleto determine a set of prescribed controls specified by the EPA Notices. There are also requirements in the Health and Safety at Work (Hazardous Substance, HSW (HS)) Regulations under the HSW Act.
- 10.2. The prescribed controls set the baseline for how the substance should 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 (eg Safety Data Sheets), signage and emergency management.
- 10.3. The Hazardous Substances Labelling, Safety Data Sheet (SDS), Packaging, Disposal and Hazardous Property Controls (HPC) Notices Part 1, Part 3, Part 4A, Part 4B and Part 4C 2017 apply to Soleto.

Exposure limits

- 10.4. The EPA has not set a Tolerable Exposure Limit (TEL) for Soleto, or any element or compound in the substance. This is because it is not considered that exposure is likely to result in an appreciable toxic effect based on the quantitative risk assessment. However, the Acceptable Daily Exposure (ADE) and Potential Daily Exposure (PDE) shown below are proposed by the EPA as health-based exposure guidance values that can be used to inform risk assessments as well as the setting of controls, such as Maximum Residue Levels (MRLs) under the Agricultural Compounds and Veterinary Medicines Act 1997.
- 10.5. The following values have been provided for metobromuron:
- ADE = 0.03 mg/kg bw/day
 - PDE (food) = 0.021 mg/kg bw/day
 - PDE (drinking water) = 0.006 mg/kg bw/day
 - PDE (other) = 0.003 mg/kg bw/day
- 10.6. No Environmental Exposure Limit (EEL) values are proposed for metobromuron at this time. This is because it is not considered that, with controls in place, environmental exposure is likely to result in an appreciable ecotoxic effect based on the quantitative risk assessment.

Addition and variation of controls to manage risk

- 10.7. The following modified and additional controls are proposed under section 77 and 77A of the Act to manage the risks of use of Soleto.

Maximum application rate

- 10.8. The environmental risk assessment was based on the application rates proposed by the applicant, therefore it is considered necessary to propose a maximum application rate, number of applications and frequency.
- 10.9. The maximum application rate of Soleto is 4 L/ha (equivalent to 2 kg metobromuron/ha), with a maximum frequency of one application per year.

Application method

- 10.10. The environmental risk assessment was based on the application methods specified by the applicant. The restriction to apply Soleto via ground-based methods only, the restriction to a medium droplet size, and the restriction to favourable wind conditions are key factors in minimizing exposure to aquatic environments.
- 10.11. Soleto can only be applied by ground-based methods.
- 10.12. When Soleto is applied using ground-based methods, the nozzle must be set to a medium droplet quality spray, at a minimum, as defined by the American Society of Agricultural and Biological Engineers ASABE Standard (S572) or the British Crop Production Council guideline
- 10.13. Soleto must not be applied when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site.

Buffer zone

- 10.14. To mitigate risks from spray drift and runoff the substance should not be applied within 5 m of any waterbody.

Additional label statements

- 10.15. To mitigate risks to non-target arthropods, the label must include the following statement:
“Ensure mechanical removal of weeds, remaining crop and seeds has taken place before application. The substance should only be used after planting and before crop emergence.”
- 10.16. To mitigate risks to non-target plants, the label must include the following statements:
“**WARNING**, very toxic to some plant species. Certain plants may be damaged or killed from contact with this product. The substance should not be applied within 5 m of a downwind area containing any non-target plants.”
“Before application users should check with the regional authority to establish if there are wetlands, indigenous vegetation habitat areas or reserves which may contain threatened plants adjacent to the application area, in which case it is recommended to increase the buffer zone to 50 m.”

10.17. In order to limit off-target exposure, the label must include the following statements:

“**DO NOT** apply when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site.”

11. Overall evaluation and recommendation

11.1. The proposed use of Soleto results in negligible risks to human health and the environment, except for non-threatened species of soil mites and Collembola for which a low risk has been identified.

11.2. The potential benefits of using Soleto have been assessed as significant.

11.3. Therefore, it is considered that benefits of the substance, based on the assessment of the information available, outweigh the risks of the substance.

11.4. It is recommended that the Committee approves the application to import or manufacture Soleto for release.

Appendix A: Proposed controls for Soletto

EPA Controls

Control code	Regulation	Control description
LAB	EPA Labelling Notice 2017	Requirements for labelling of hazardous substances
PKG	EPA Packaging Notice 2017	Requirements for packaging of hazardous substances
SDS	EPA Safety Data Sheet Notice 2017	Requirements for safety data sheets for hazardous substances
DIS	EPA Disposal Notice 2017	Requirements for disposal of hazardous substances
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	Hazardous Property Controls preliminary provisions
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	Hazardous substances in a place other than a workplace
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	Site and storage controls for class 9 substances
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	Use of class 9 substances
HPC-4C	EPA Hazardous Property Controls Notice 2017 Part 4C	Qualifications required for application of class 9 pesticides

HSNO Additional Controls and Modifications to Controls

Code	HSNO Act	Control
Application rate	Section 77A	The maximum application rate of Soleto is 4 L/ha (equivalent to 2 kg metobromuron/ha), with a maximum frequency of one application per year.
Application method	Section 77A	<p>Soleto can only be applied by ground-based methods.</p> <p>When applied using ground-based methods, the nozzle must be set to a medium droplet quality spray, at a minimum, as defined by the American Society of Agricultural and Biological Engineers ASABE Standard (S572) or the British Crop Production Council guideline.</p> <p>Soleto must not be applied when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site.</p>
Buffer zone	Section 77 variation to HPC notice clause 51	To mitigate risks from spray drift and runoff the substance should not be applied within 5 m of any waterbody.
Label	Section 77 variation to Labelling Notice	<p>The substance label must include the following statement, or words to the same effect:</p> <ul style="list-style-type: none"> • <i>“Ensure mechanical removal of weeds, remaining crop and seeds has taken place before application. The substance should only be used after planting and before crop emergence.”</i> • “WARNING, <i>very toxic to some plant species. Certain plants may be damaged or killed from contact with this product. The substance should not be applied within 5 m of a downwind area containing any non-target plants.”</i> • <i>“Before application users should check with the regional authority to establish if there are wetlands, indigenous vegetation habitat areas or reserves which may contain threatened plants adjacent to the application area, in which case it is recommended to increase the buffer zone to 50 m.”</i> • “DO NOT <i>apply when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site.”</i>

HSW Controls

Note: these controls are not set for the substance under this approval but apply in their own right under the HSW legislation according to the classification of the substance. They are listed here for information purposes only.

Control code	Regulation	Control description
HSW2-1	Reg 2.1 - 2.4	Workplace labelling of hazardous substance containers
HSW2-3	Reg 2.11	Safety data sheets
HSW2-4	Reg 2.12 - 2.14	Packaging
HSW3-1	Reg 3.1	Inventory
HSW3-2	Reg 3.2 - 3.3	Managing risks associated with hazardous substances
HSW4-2	Reg 4.5 - 4.6	Information, instruction, training and supervision
HSW5-2	Reg 5.6 - 5.13	Emergency response plans
HSW13-2	Reg 13.7	Duty of PCBU who directs work using class 6, 8.1, 8.2, or 8.3 substances to ensure equipment is appropriate
HSW13-3	Reg 13.8	Duty of PCBU who directs work using class 6 and 8 substances to ensure personal protective equipment used
HSW13-8	Reg 13.17	Prohibition on use of substance in excess of tolerable exposure limit
HSW13-9	Reg 13.18	Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded
HSW13-14	Reg 13.30	Secondary containment requirements for class 6 and 8 pooling substances
HSW16-1	Part 16	Requirements for tank wagons and transportable containers
HSW17-1	Part 17	Requirements for stationary container systems