Environmental Protection Authority
Te Mana Rauhī Taiao

# Summary of HS application **APP203925** and Submission guidance

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| **Date Submissions Open:** | 24 August 2020 |
| **Date Submissions Close:** | 5 October 2020 |
| **Application number:** | APP203925 |
| **Purpose:** | To import or manufacture Soleto for release |
| **Applicant:** | Belchim Crop Protection NV/SA |
| **Application Lead:** | Régis Lapage |

# Purpose of this document

On 13 March 2020, the Environmental Protection Authority (EPA) formally received an application from Belchim Crop Protection NV/SA to import or manufacture for release Soleto. This substance is intended to be used as a pre-emergence herbicide for the control of weeds in potato crops. Soleto contains metobromuron, which is a new active ingredient to New Zealand.

This application is being publicly notified to enable the public to comment and to put all relevant information before the decision makers.

The purpose of this document is to summarise the application and to provide guidance on the submission process.

## Application summary

**This document has been prepared by EPA staff as a summary of the information provided in the application only, to aid submitters in preparing a submission. It is not the risk assessment produced by EPA staff. The EPA staff risk assessment will be completed at a later date using information from the application, submissions and other relevant sources.**

## Submission process

This document also provides guidance to the submission process. The EPA encourages all submissions. The submission period for this application will start on 24 August 2020 and will end on 5 October 2020 at 5pm.

In a submission you can provide information, make comments and raise issues. In this way, you contribute to the EPA decision making process on specific applications. We are particularly interested in hearing from you on the following matters:

- Adverse effects, especially adverse effects not identified in the application[1]; and
- Positive effects, especially positive effects not identified in the application[2].

Further information on the purpose of submissions is available from the EPA website using the link below:

https://www.epa.govt.nz/public-consultations/

## If you have any questions, you can contact:

- The applicant directly for any question you may have on the technical information in the application or the information provided to the EPA. The applicant representative, Annelies Noyez, can be contacted by e-mail (Annelies.Noyez@belchim.com) or by phone (+32 (0)52 31 59 41).
- The EPA for any question on the application and/or submission process. The Application Lead, Régis Lapage, can be contacted by e-mail (Regis.Lapage@epa.govt.nz) or by phone (+64 4 474 5511).

[1] Adverse effects can include any risks and costs associated with release of the substance.
[2] Positive effects can include any benefits associated with release of the substance.

# Application summary

1. Belchim Crop Protection NV/SA applied to import or manufacture for release Soleto, a suspension concentrate (SC) formulation containing 500 g/L metobromuron for the control of broadleaf weeds in potato crops.

## Intended uses

2. Soleto is a herbicide intended for one application per season, prior to the emergence of the crop (potatoes), by ground-based spray application. The intended application rate is 3 – 4 L of Soleto per hectare (ha), which is equivalent to 1.5 – 2 kg of metobromuron/ha.

3. Soleto is intended for professional use.

## Regulatory history

4. The active ingredient metobromuron is a new active ingredient in New Zealand. It is approved in the European Union (EU).

5. The Soleto formulation is registered in the EU.

## Hazardous properties

6. The applicant has submitted more than 150 studies and documents to support their application, which were evaluated by the EPA in preparing the draft Science Memorandum for this application.

7. The EPA determined the following hazard classifications for Soleto:

| Hazard class/subclass | HSNO Classification | Comment |
|---|---|---|
| Acute toxicity (oral) | 6.1E | Although the $LD_{50}$ was >2000 mg/kg bw animals showed signs of toxicity |
| Carcinogenicity | 6.7B | Triggered by metobromuron |
| Target organ systemic toxicity (oral) | 6.9B | Triggered by metobromuron |
| Aquatic ecotoxicity | 9.1A | 7-day $ErC_{50}$ 0.73 mg formulation/L, duckweed *Lemna gibba* |
| Soil ecotoxicity | 9.2A | Seedling emergence $EC_{50}$ of 0.11 L formulation/ha, equivalent to 0.177 mg |

| Hazard class/subclass | HSNO Classification | Comment |
|---|---|---|
| | | formulation/kg dw, for onion, *Allium cepa* |

## Risk assessment

8. An assessment of the risks to human health and the environment from the use of metobromuron and Soleto was undertaken and full details can be found in the draft Science Memorandum. The overall conclusions of this risk assessment are presented below.

### Human health effects

9. It is considered that the risks to human health from the proposed use of Soleto are acceptable with the use of appropriate Personal Protective Equipment (PPE). No Restricted Entry Intervals (REI) or buffer zones are recommended. The expected concentration in groundwater is well below the level of concern in relation to human drinking water consumption.

### Environmental effects

10. 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 based on the available data for all areas except for non-target soil macro-organisms (mites, collembolan) for which a risk above the level of concern was identified.

## Controls

### Prescribed controls

11. 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.

12. 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.

13. 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.

### Additions and variations to prescribed controls

14. The following additional controls or modifications to the EPA notices are proposed under section 77 and 77A of the Act to manage the risks of use of Soleto.

#### *Maximum application rate*

15. The maximum application rate for Soleto is 4 L/ha (equivalent to 2 kg metobromuron/ha) with a maximum of one application per year.

#### *Application method*

16. Soleto must be applied with ground-based equipment and minimum medium droplets, as defined by the American Society of Agricultural and Biological Engineers ASABE Standard (S572) or the British Crop Production Council guideline.

17. 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 zones*

18. To mitigate risks from spray drift and runoff, when applied to bare soil, the substance should not be applied within 5 m of any waterbody.

#### *Label statements*

19. *"**WARNING**, might impact non-target plants, the substance should not be applied within 10 m downwind of an area containing non-target plants. Additional care is required when sprayed near sensitive terrestrial areas (eg areas with threatened plants or of higher ecological value)"*.

20. *"**WARNING**, exposure to SOLETO may injure or kill susceptible agricultural crops and native vegetation. Care should be taken avoid spray to neighbouring vegetation, it is recommended to conduct a site specific risk assessment that considers the potential movement of spray drift downwind to sensitive areas. This includes assessment of the weather conditions, application equipment, topography and species of plants downwind"*.

21. *"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"*.

## Benefits

22. The following is a summary of the benefits identified by the applicant in the application form:

- Early control of broadleaved weeds in potato;
- Potential to replace the active substance Linuron;

- Improvement of the resistance management strategy;
- Low exposure to operators/workers and environment;
- No residues on harvested products: low risk to consumers.

23. For greater detail, please refer to the application form.

***Please let us know whether you consider that there are additional adverse effects that we should be aware of or additional information related to the described effects.***

When identifying adverse effects it is important that you provide us with reasons as to:

- What other adverse effects are ***likely*** to be caused by the use of Soleto
- How ***likely*** these adverse effects are and their potential scale
- How you think the adverse effects could happen (i.e. the series of events that would have to happen for the adverse effects to occur)
- Options and proposals for managing the adverse effects
- Any uncertainty you have on the scope of the information we will use to assess the adverse effects.

***Please let us know whether you consider that there are additional positive/beneficial effects that we should be aware of or additional information related to the described effects.***

When identifying positive/beneficial effects, it is important that you provide us with information on:

- Other positive effects ***likely*** to be caused by the use of Soleto
- How ***likely*** these positive/beneficial effects are and their potential scale
- How you think the positive/beneficial effects could happen (i.e. the series of events that would have to happen for the positive/beneficial effects to occur)
- Options and proposals for ensuring the positive/beneficial effects occur, and
- Any uncertainty you have on the scope of the information used to assess the positive/beneficial effects.

## Other information

24. If there is other information you wish us to be aware of, please also include this in your submission.

## Draft Science Memorandum

25. Interested parties can view the draft Science Memorandum to inform their submission on this application. The draft Science Memorandum outlines the detailed environmental and human health risk assessment of Soleto, carried out by the EPA.

26. The draft Science Memorandum will be finalised after the public consultation, if required.

# Making a submission

## What is a submission?

We encourage anyone to make a submission, regardless of how much detail you are able to put in to it. In your submission, you can also request a hearing if you would like to strengthen your views in person before the Decision-making Committee. Further information on submissions for a hazardous substance application is available from the EPA website using the link below:

http://www.epa.govt.nz/about-us/have-your-say/Pages/what-is-submission.aspx

Submissions are publicly available and will be displayed on the application web page after submissions close. If you have confidential information you wish to provide, please contact the Application Lead, Régis Lapage, by e-mail (Regis.Lapage@epa.govt.nz) or by phone (+64 4 474 5511).

## How to make a submission?

The EPA website provides guidance on how to make a submission. This is preferably done via the EPA submission form but may be sent as a letter or email to the EPA. This information and the submission form can be accessed from the EPA website using the link below:

http://www.epa.govt.nz/about-us/have-your-say/Pages/make-submission.aspx

## What happens after you make a submission?

When the submission period closes, all submissions will be summarised and made available to the Decision-making Committee together with the EPA Staff Assessment Report.

You are entitled to bring witnesses who may speak to your submission at a hearing. If you choose this option, you should provide the EPA with a list of the witnesses, their areas of expertise, and the elements of the submission or application they will talk to.

You are also entitled to speak at the hearing in one of the three official languages of New Zealand: English, Māori or New Zealand Sign Language. Please advise the Application Lead at least two weeks prior the hearing in order for the EPA to organise for an interpreter. The Application Lead, Régis Lapage, can be contacted by e-mail (Regis.Lapage@epa.govt.nz) or by phone (+64 4 474 5511).

At least two weeks prior to the hearing, both the applicant and submitter(s) need to provide the EPA with copies of any information they intend to present at the hearing.

A decision will be made by the Decision-making Committee at the end of the consideration period. This will be made public on the EPA website.