Environmental Protection Authority
Te Mana Rauhī Taiao

Decision

Lustre 120SC

11 April 2022

Summary

Substance	Lustre 120SC
Application code	APP204304
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	Adria New Zealand Limited
Purpose of the application	Import or manufacture Lustre 120SC for release
Date application formally received	7 March 2022
Consideration date	11 April 2022
Considered by	The General Manager[1] of the Hazardous Substances and New Organisms group of the Environmental Protection Authority ("the EPA")
Decision	Approved with controls
Approval code	HSR101530
Hazard classifications	Eye irritation Category 2 Specific target organ toxicity – repeated exposure Category 2 Hazardous to the aquatic environment acute Category 1 Hazardous to the aquatic environment chronic Category 1 Hazardous to terrestrial invertebrates

[1] The 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 Lustre 120SC is a suspension concentrate containing spinosad at 120 g/L as the active ingredient, plus other components. It is intended for professional use for the control of pests in fruit, vines, vegetables, and fodder brassicas. Lustre 120SC is intended to be applied using ground-based methods.

2. Process and consultation

Application receipt

2.1 The application was formally received on 7 March 2022 under section 28 of the Act.

Information available for consideration

2.2 The information available for the consideration comprised:

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

2.3 There was sufficient information to assess the application.

Public notification

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

Notification to government departments

2.5 In line with section 53(4) of the Act, as the application was not publicly notified under section 53(2) of the Act, government departments were equally not notified of the application for Lustre 120SC.

Legislative criteria for the application

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

3. Hazardous properties of Lustre 120SC

3.1 The hazard classifications of Lustre 120SC were determined based on the information provided by the applicant, information on the individual components of Lustre 120SC and mixture rules.

3.2 The classifications that have been applied to Lustre 120SC are different to those submitted by the applicant (Table 1). The EPA has classified the substance as an eye irritant Category 2, while the applicant has not.

Table 1: Hazard classifications of Lustre 120SC

Hazard Class	Applicant classification	EPA classification
Serious eye damage/eye irritation	-	**eye irritation Category 2**
Specific target organ toxicity – repeated exposure	6.9B (HSNO classification)	specific target organ toxicity – repeated exposure Category 2
Hazardous to the aquatic environment	9.1A (HSNO classification)	hazardous to the aquatic environment acute Category 1 hazardous to the aquatic environment chronic Category 1
Hazardous to the terrestrial environment	9.4A (HSNO classification)	hazardous to terrestrial invertebrates

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, Land Transport Rule 45001, Civil Aviation Act 1990 and Maritime Transport Act 1994.

4.2 The human health and environmental risks have been assessed in accordance with Section 29(1) of the Act. This assessment takes into account the full life cycle of this substance, including import and manufacture, packaging, transport, storage, use and disposal.

4.3 The EPA determined that there is a potential for significant exposures to people and the environment during the use phase of Lustre 120SC.

4.4 Lustre 120SC has the same formulation type, namely as a suspension concentrate, and same active ingredient at a similar concentration as another insecticide that is already approved and is intended to be used in similar ways. However, Lustre 120SC has a higher hazard classification. The risks to human health and the environment are not likely to be significantly higher from the use of Lustre 120SC compared to the other approved substance containing the same active ingredient. Therefore, the assessment of risks to human health and the environment for Lustre 120SC has been limited to a qualitative assessment.

4.5 The risk and benefit assessment:

- considered the risks posed by Lustre 120SC
- determined whether the risks are outweighed by the benefits
- determined whether any variations, additions to or deletion of the prescribed controls are required to manage the risks of the substance.

Assessment of risks to human health

4.6 Lustre 120SC is intended to be supplied to the professional market. Users are expected to dilute the substance in water and apply the substance using high volume ground-based spraying equipment. It is likely that users will be exposed to the substance during the mixing, loading and application stages of the substance.

4.7 The active ingredient in Lustre 120SC is not new and is approved in several other substances. These substances are used as insecticides on various crops, as well as veterinary medicines.

Eye irritation (Category 2)

4.8 It is **likely** that eye exposure will occur during the use of this substance, with any effect expected to be **moderate and reversible**. The substance will only be used by professional users who have prescribed requirements set under the HSW (HS)

Regulations 2017 for the use of personal protective equipment (PPE) when working with class 6 or 8 substances to limit exposure to the substance. As such, the risk from the eye irritancy hazard is considered **negligible**.

Specific target organ toxicity (repeated exposure Category 2)

4.9 Given the use pattern, any long-term effects will require multiple exposures to this product over a time period which is **unlikely**. In the event of repeated exposure via the oral route, the adverse effects are expected to be **moderate**. The prescribed controls include requirements for PPE for professional users, and as such, the risk from the specific target organ toxicity hazard is assessed as **negligible**.

Assessment of risks to the environment

4.10 Lustre 120SC is an insecticide that will be used for the control of pests in fruit, vines, vegetables, and fodder brassicas. Therefore, given its hazard classification, it has the potential to affect aquatic organisms and terrestrial invertebrates if significant exposure occurs.

Hazardous to the aquatic environment (acute Category 1, chronic Category 1)

4.11 It is **likely** that aquatic organisms will be exposed to Lustre 120SC as application may result in spray drift or run off that causes the substance to enter waterways.

4.12 Lustre 120SC is classified as hazardous to the aquatic environment acute Category 1 and hazardous to the aquatic environment chronic Category 1, and as such, it is expected that exposure may result in **major** effects to organisms.

4.13 The hazard classification triggers prescribed controls that will mitigate risks of the substance to the environment, including a restriction forbidding the application of the substance into or onto water (clause 52 of the Hazardous Property Controls Notice 2017 and clause 20 of the Labelling Notice 2017). However, the prescribed controls do not fully mitigate this risk. It is therefore necessary to apply additional controls to minimise the likelihood of Lustre 120SC entering waterways, and thus mitigate the risks to aquatic organisms to a **negligible** level.

4.14 Additional controls, including maximum application rates and wind speed restrictions, are proposed for Lustre 120SC.

Hazardous to terrestrial invertebrates

4.15 It is **likely** that non-target terrestrial invertebrates will be exposed during the spraying phase of Lustre 120SC given its use pattern, this includes the proposed application during post-crop emergence in the summer months when invertebrate pollinators are likely to forage. As such, it is expected that exposure may result in **major** effects to non-target terrestrial invertebrates.

4.16 The hazard classification of the substance triggers prescribed controls that will mitigate some risks of the substance to terrestrial invertebrates, including protecting invertebrate pollinators (clause 58 of the Hazardous Property Controls Notice 2017 and clause 24 of the Labelling Notice 2017), however, the prescribed controls do not fully mitigate these risks. It is therefore necessary to apply additional controls to minimise the likelihood of Lustre 120SC affecting terrestrial invertebrates to a **negligible** level.

4.17 Additional controls, including maximum application rates and frequencies and wind speed restrictions, are proposed for Lustre 120SC.

Māori impact assessment

4.18 A Māori impact assessment has been undertaken by the EPA to consider potential impacts of the application 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. The Māori impact assessment includes tangible and intangible taonga, such as culturally significant species, resources, and places, and the customary values, practices and uses associated with these taonga. Key findings of the assessment are outlined below.

Impact on the relationship of Māori and their culture and traditions with their environment and taonga

4.19 This application 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.

Impact on the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural well-being

4.20 This application is not likely to significantly affect the ability and capacity of Māori to maintain their economic, social, and cultural well-being.

Treaty of Waitangi principles

4.21 The Principles of the Treaty of Waitangi have been considered in relation to this application, as summarised below.

The active protection principle: the Crown has a duty to actively protect Māori interests

4.22 No issues arise.

The informed decision-making principle: the Crown has a duty to make informed decisions

4.23 No issues arise.

The partnership principle: to act fairly, reasonably, and in good faith

4.24 No issues arise.

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

4.25 No risks to society, communities, or the market economy from the approval of Lustre 120SC have been identified.

New Zealand's international obligations

4.26 No international obligations that may be impacted by the approval of Lustre 120SC have been identified.

The effects of the substance being unavailable

4.27 The likely effects of Lustre 120SC being unavailable have been considered. Should Lustre 120SC not be available, it could lead to less consumer choice.

5. Prescribed controls

5.1 The hazard classifications of Lustre 120SC 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) requirements are not set for the substance under this approval but apply in their own right.

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

Exposure limits

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

- Regulation 13.17 of the HSW (HS) Regulations prohibits the use of a class 6 substance (ie a substance with a hazard classification in the hazard grouping health hazards) in excess of a TEL.
- Clause 49 of the Hazardous Property Controls Notice prohibits use of a substance with a hazard classification in the hazard grouping environmental hazards in excess of an EEL.

5.4 The EPA has not provided ADE (Acceptable Daily Exposure) and PDE (Potential Daily Exposure) values for any components in this substance. Therefore, a TEL for Lustre 120SC, or any element or compound in the substance, is also not set as exposure to this substance is not likely to result in an appreciable toxic effect to people, provided controls on use are followed.

5.5 No EEL values are set at this time or have been set previously for spinosad, the active ingredient in Lustre 120SC, as the level of risk of adverse effects to the environment has been qualitatively assessed as being negligible, with controls in place.

5.6 There are Workplace Exposure Standard (WES) values currently set for components of Lustre 120SC 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 Lustre 120SC.

6. Changes to prescribed controls

6.1 The following modifications to the EPA Notice controls apply to Lustre 120SC, as set out in Table 2.

Table 2: Justification for section 77 changes to the prescribed controls (see Appendix A of the Approval document for control wordings)

Control	Justification
Application restrictions HPC Notice Clause 50	Significant human health and environmental risks may occur from the use of this substance, due to the hazards posed by spinosad, the active ingredient in Lustre 120SC. Therefore, it is considered necessary to set a maximum application rate, number of applications and frequency under clause 50 of the HPC Notice. For this substance, the following application restrictions apply: • When applied to avocado, the maximum application rate of 800 mL of Lustre 120SC per hectare (equivalent to 0.096 kg spinosad/ha), with a maximum frequency of four applications per year and a minimum interval period of 21 days is set for this substance. • When applied to fodder brassicas, the maximum application rate of 200 mL of Lustre 120SC per hectare (equivalent to 0.024 kg spinosad/ha), with a maximum frequency of four applications per year and a minimum interval period of 14 days is set for this substance. • When applied to vegetable brassicas and field tomatoes, the maximum application rate of 400 mL of Lustre 120SC per hectare (equivalent to 0.048 kg spinosad/ha), with a maximum frequency of four applications per year and a minimum interval period of seven days is set for this substance. • When applied to citrus, the maximum application rate of 800 mL of Lustre 120SC per hectare (equivalent to 0.096 kg spinosad/ha), with a maximum frequency of four applications per year and a minimum interval period of 7 days is set for this substance. • When applied to grapes, the maximum application rate of 400 mL of Lustre 120SC per hectare (equivalent to 0.048 kg spinosad/ha), with a maximum frequency of four applications per year and a minimum interval period of 21 days is set for this substance. • When applied to potatoes, the maximum application rate of 400 mL of Lustre 120SC per hectare (equivalent to 0.048 kg spinosad/ha), with a maximum frequency of four applications per

Control	Justification
	year and a minimum interval period of 14 days is set for this substance.
Label Labelling Notice	The label must include information on the use restrictions. The information about the maximum application rate and frequency and minimum application interval must be included on the label, according to clause 25 of the EPA Labelling Notice 2017.

6.2 The following additional HSNO controls apply to Lustre 120SC under section 77A of the Act, as set out in Table 3:

Table 3: Justification for the section 77A additional controls (see Appendix A of the Approval document for the control wordings)

Control	Justification
Use restriction	The human health and environmental risk assessments indicate that restrictions on the application method of this substance are necessary to mitigate the risk of death or adverse effects that it could present to people and organisms in the environment. Accordingly, it is considered that the application of controls addressing these potential risks will be more effective than the prescribed controls with respect to their effects on the management, application, and risks of this substance. The method of application of the substance shall be limited to ground-based applications only. The substance 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.

Assessment of changes to controls

6.3 The changes to the prescribed controls in the above section under sections 77 and 77A of the Act fulfil the legislative criteria.

6.4 These controls have been incorporated into the Appendix A of the Approval document.

6.5 The applicant was provided an opportunity to comment on the controls as set out in this decision and no concerns were raised.

7. Summary

7.1 After taking into account the prescribed controls and any variations to these controls, it was concluded that the residual level of risk of any potentially significant adverse effects, is negligible.

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 I consider that, with controls in place, the risks to human health and to the environment are negligible, and the benefits associated with the release of this substance will outweigh the adverse effects. Therefore, I consider that the application to import or manufacture Lustre 120SC for release is approved with controls in accordance with section 29 of the Act and clause 26 of the Hazardous Substances and New Organisms (Methodology) Order 1998.

Name and signature	Date
Dr Christopher Hill General Manager, HSNO, EPA	11 April 2022

Definitions

Terms used in the controls have the same meaning as defined in the Act, EPA Notices or regulations made under the Act. In addition, the following definitions apply:

Term	Definition
a.i.	Active ingredient - the biologically active chemical in a pesticide product
Ground-based application	Ground-based methods of applying pesticides include, but are not limited to, application by ground boom, airblast or knapsack, and do not include aerial application methods.
Likely	Good chance that it may occur under normal operating conditions.
Major	A descriptor used to describe the magnitude of the effect of a substance. This descriptor is used when one or more of the following impacts are met: • significant irreversible adverse health effects affecting individuals and requiring hospitalisation and/or reversible adverse health effects reaching beyond the immediate community • long term/irreversible damage to localised ecosystem but no species loss • measurable adverse effect on GDP, some long-term (more than five years) job losses • social disruption to surrounding community, including some evacuations.
Minor	A descriptor used to describe the magnitude of the effect of a substance. This descriptor is used when one or more of the following impacts are met: • mild reversible short-term adverse health effects to identified and isolated groups • localised and contained reversible environmental impact, some local plant or animal communities temporarily damaged, no discernible ecosystem impact or species damage • regional adverse economic effects on small organisations (businesses, individuals) lasting less than six months, temporary job losses • potential social disruption (community placed on alert).
Moderate	A descriptor used to describe the magnitude of the effect of a substance. This descriptor is used when one or more of the following impacts are met:

Term	Definition
	• minor irreversible health effects to individuals and/or reversible medium-term adverse health effects to larger (but surrounding) community (requiring hospitalisation) • measurable long-term damage to local plant and animal communities, but no obvious spread beyond defined boundaries, medium term individual ecosystem damage, no species damage • medium term (one to five years) regional adverse economic effects with some national implications, medium term job losses • some social disruption (for example, people delayed).
Very likely	Almost certain or expected to occur if all conditions met.
Water	Has the meaning provided in the HPC Notice.
Water body	Includes all natural and modified/artificial water courses such as reservoirs, irrigation canals, water-supply races, canals for the supply of water for electricity generation or farm drainage, ditches, streams, rivers, ponds, and lakes. For clarity, it excludes fully covered pipes, tanks or other enclosed structures, puddles or groundwater.
Watercourse or Waterway	Includes every river, stream, passage, and channel on or under the ground, whether natural or not, through which water flows, whether continuously or intermittently.
Wide dispersive	Refers to activities which deliver uncontrolled exposure.