Environmental Protection Authority
Te Mana Rauhī Taiao

Decision

REVYLUTION Fungicide

May 2022

Summary

Substance name	REVYLUTION Fungicide
Application code	APP204273
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")
Application sub-type	Section 28A(2)(a) – rapid similar – having a similar composition and similar hazardous properties to a substance that has been approved under the Act
Applicant	BASF New Zealand Limited
Purpose of the application	To import or manufacture REVYLUTION Fungicide for release
Date application formally received	5 May 2022
Consideration date	13 May 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	HSR101534
Hazard classifications	acute inhalation toxicity Category 4 skin irritation Category 2 specific target organ toxicity – single exposure Category 3 specific target organ toxicity – repeated exposure Category 2 hazardous to the aquatic environment chronic Category 1

1. Substance

1.1 REVYLUTION Fungicide is an emulsifiable concentrate containing 100 g/L mefentrifluconazole as the active ingredient. It is intended to be imported and applied using ground-based and aerial application methods at rates of up to 150 g mefentrifluconazole/ha to control diseases in cereal and grass seed crops.

2. Process and consultation

Application receipt

2.1 The application, including the statutory declaration, was formally received on 5 May 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.

2.3 There was sufficient information to assess the application.

Notification to government departments

2.4 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 REVYLUTION Fungicide.

Legislative criteria for the application

2.5 This application meets the criteria for rapid assessment under section 28A(2)(a) of the Act, as it is considered that a substance having a similar composition and similar hazardous properties has been approved. This is referred to as the reference substance.

2.6 In considering this application, the relevant provisions of the Act, the EPA Notices, the Health and Safety at Work Act 2015 (HSW Act), the Health and Safety at Work (Hazardous Substances) Regulations 2017 (HSW (HS) Regulations) and the HSNO (Methodology) Order 1998 were taken into account.

3. Comparison of REVYLUTION Fungicide with the reference substance

Identity of reference substance

3.1 The approved substance, Revystar® Fungicide, which has the approval code HSR101415, has been identified as a reference substance which REVYLUTION Fungicide could be compared to as part of a rapid assessment. This reference substance is considered eligible for comparing with REVYLUTION Fungicide based on it's similar composition and similar hazardous properties

Hazardous properties

3.2 The hazard classifications of REVYLUTION Fungicide were determined based on the information provided by the applicant and other available information. The hazard classifications are shown in Table 1 alongside those of the reference substance.

3.3 REVYLUTION Fungicide has an overall reduced hazard profile compared to the reference substance, however, REVYLUTION Fungicide triggers a specific target organ toxicity (single exposure) Category 3 classification that is not present in the classification of Revystar® Fungicide. This is due to a solvent that is present in both substances but is at a higher concentration in REVYLUTION Fungicide, thereby triggering the classification. This classification difference does not generate any additional HSNO or HSW controls and is expected to be minor in effect.

Table 1: Hazard classifications of REVYLUTION Fungicide and the reference substance

Hazard class		REVYLUTION Fungicide	Revystar® Fungicide
Acute toxicity	Oral	**No**	**acute oral toxicity Category 4**
	Inhalation	acute inhalation toxicity Category 4	acute inhalation toxicity Category 4
Skin corrosion/irritation		skin irritation Category 2	skin irritation Category 2
Serious eye damage/eye irritation		**No**	**eye irritation Category 2**
Respiratory or skin sensitisation		**No**	**skin sensitisation Category 1**
Specific target organ toxicity – single exposure		**specific target organ toxicity – single exposure Category 3**	**No**
Specific target organ toxicity – repeated exposure		specific target organ toxicity – repeated exposure Category 2	specific target organ toxicity – repeated exposure Category 2

Hazard class	REVYLUTION Fungicide	Revystar® Fungicide
Hazardous to the aquatic environment	hazardous to the aquatic environment chronic Category 1	hazardous to the aquatic environment chronic Category 1
Hazardous to the terrestrial environment	**No**	**hazardous to terrestrial vertebrates**

Use

3.4 REVYLUTION Fungicide and the reference substance are both proposed for use as a fungicide on cereals and grass seed crops, using comparable application methods (ground based and aerial application) and rate (150 g ai/ha). There are no substantial differences in the lifecycle, use and purpose of REVYLUTION Fungicide and the reference substance.

4. Rapid assessment of adverse effects

4.1 The rapid risk assessment of adverse effects has taken into account the hazardous properties of the substance, the considerations under Part 2 of the Act, the prescribed controls under the Act and the requirements under other relevant legislation such as the HSW Act 2015, Land Transport Rule 45001, Civil Aviation Act 1990 and Maritime Transport Act 1994.

4.2 The assessment:

- considered the risks posed by REVYLUTION Fungicide compared to those associated with the reference substance
- determined whether any variations or additions to the prescribed controls were required to manage the risks of this substance and identified controls that may not have been applicable or necessary that could, therefore, be deleted.

Assessment of risks to human health

4.3 The risks to human health are similar to those of the reference substance and as such are managed by the suite of controls.

Assessment of risks to the environment

4.4 The risks to the environment from this substance are similar to those of the reference substance and as such are managed by the suite of controls.

Assessment of risks to Māori and their relationship to the environment

4.5 The risks to Māori and their relationship to the environment from this substance are similar to those of the reference substance and as such are managed by the suite of controls.

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

4.6 No risks to society, communities, or the market economy from the approval of REVYLUTION Fungicide have been identified.

New Zealand's international obligations

4.7 No international obligations that may be impacted by the approval of REVYLUTION Fungicide have been identified.

Summary of assessment

4.8 The risks associated with REVYLUTION Fungicide arise from its hazardous properties and its proposed use pattern. These risks are similar to those posed by the reference substance, and the suite of controls applied to the reference (including any modifications and deletions) can be applied to REVYLUTION Fungicide to equally mitigate its risks to human health and the environment, so that these are negligible.

5. Prescribed controls

5.1 The hazard classifications of REVYLUTION Fungicide determine a set of prescribed controls specified by the EPA Notices under section 77 of the HSNO 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.

5.3 The Labelling, Safety Data Sheet (SDS), Packaging, Disposal and Hazardous Property Controls (HPC) Part 1, Part 3, Part 4A, Part 4B and Part 4C Notices apply to REVYLUTION Fungicide.

Exposure limits

5.4 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 HPC Notice prohibits use of a substance with a hazard classification in the hazard grouping environmental hazards in excess of an EEL

5.5 No TEL values have been set previously for the active ingredient in REVYLUTION Fungicide because it is considered that exposure to this substance is not likely to result in an appreciable toxic effect to people, provided controls on use are followed.

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

5.7 There are Workplace Exposure Standard (WES) values currently set for components of REVYLUTION Fungicide 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 REVYLUTION Fungicide.

5.8 Clause 17 of the Hazardous Substances (Labelling) Notice 2017 and Section 3 of the Schedule in the Hazardous Substances (Safety Data Sheets) Notice 2017 require that certain toxic, corrosive or ecotoxic components are identified on the product label and on the SDS, respectively. Section 8 of the Schedule in the SDS Notice requires occupational exposure limits to be identified on the SDS.

6. Changes to prescribed controls

6.1 The following modifications to the EPA Notice controls apply to REVYLUTION Fungicide, as set out in Table 2

Table 2: Justification for s77 changes to prescribed controls (see Appendix A of the Approval document for the 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 mefentrifluconazole, the active ingredient in REVYLUTION Fungicide. Therefore, it is considered necessary to set a maximum application rate, number of applications and frequency under clause 50 of the HPC Notice. The maximum application rate is 1.5 L of REVYLUTION Fungicide/ha (equating to 150 g mefentrifluconazole/ha), with a maximum of two applications per year and a minimum interval of 21 days between applications.
Label Labelling Notice	The information about the application method must be stated on the label.

6.2 The following additional HSNO controls apply to REVYLUTION Fungicide under section 77A of the Act, as set out in Table 3**:**

Table 3: Justification for s77A additional controls (see Appendix A of the Approval document for the control wordings)

Control	Justification
Restriction on impurity	The active ingredient in REVYLUTION Fungicide, mefentrifluconazole, is associated with toxicologically significant impurities, *N,N*-dimethylformamide (DMF), toluene, and 1,2,4-(1H)-triazole. When present in high enough concentrations, these impurities can cause adverse effects to people and the environment. Imposing a maximum impurity restriction on mefentrifluconazole will prevent these impurities from being present in concentrations sufficient to cause adverse effects to people or the environment. Accordingly, it is considered that the application of an additional control to address this concern will be more effective than the prescribed controls with respect to its effect on the management, use and risks of the substance.
Application method	The environmental risk assessment indicates that restrictions on the application method of this substance are necessary to mitigate the risk of death or adverse effects that could present to organisms in the environment. Accordingly, it is considered that the application of controls addressing these

Control	Justification
	potential risks will be more effective than the prescribed controls with respect to their effects on the management, application, and risks of this substance.

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 Appendix A of the Approval document.

7. Decision

7.1 Having considered the composition, hazardous properties and use of REVYLUTION Fungicide, I am satisfied that it meets the criteria for rapid assessment under section 28A(2)(a) as a substance having a similar composition and similar hazardous properties has been approved under the Act. I consider that there are no other effects of REVYLUTION Fungicide that would prevent this application for REVYLUTION Fungicide being approved under section 28A of the Act.

7.2 I am satisfied with the hazard classifications identified in Table 1 and have applied this classification to REVYLUTION Fungicide.

7.3 I consider that applying the suite of controls to REVYLUTION Fungicide set out in Appendix A of the Approval document will ensure adequate management of the adverse effects of REVYLUTION Fungicide.

7.4 Therefore, the application to import or manufacture of REVYLUTION Fungicide is approved with controls as listed in Appendix A of the Approval document.

Name and signature	Date
Dr Christopher Hill **General Manager, HSNO, EPA**	13 May 2022