



DECISION

11 February 2019

Summary

Substance Name	Vitaflo
Application code	APP203408
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	Nufarm Limited
Purpose of the application	To seek approval for the seed treatment product Vitaflo. Vitaflo contains 200 g/L carboxin and 200 g/L thiram, for the treatment of wheat, barley, oats and maize
Date application formally received	25 January 2019
Consideration date	11 February 2019
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	HSR101337
Hazard classifications	6.1D (oral), 6.1D (inhalation), 6.4A, 6.5B, 6.8B, 6.9A (oral), 9.1A, 9.3C

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. Vitaflo is a fungicide containing 200 g/L of the active ingredient carboxin and 200 g/L of the active ingredient thiram. It is intended to be imported and applied as a seed treatment at rates of up to 500 mL/100 kg of seed, to control a variety of fungal diseases of wheat, barley, oats, and maize. A maximum seed sowing rate will be set at 200 kg of seed/ha, equating to a maximum of 200 g carboxin/ha and 200 g thiram/ha.
- 1.2. The applicant (Nufarm Limited) currently advertises on its website a similar substance to Vitaflo under the trade name Vitaflo 200. It is approved under the approval number HSR000476 and contains the same active ingredients, has the same intended use and formulation type as Vitaflo.

2. Process and consultation

Application receipt

- 2.1. The application, including the statutory declaration, was formally received on 25 January, 2019 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. The following government departments were notified of the application on 25 January 2019: the Ministry for Primary Industries (Agricultural Compounds and Veterinary Medicines Group) and the Department of Conservation. No comments were received.

Legislative criteria for the application

- 2.1. 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.
- 2.2. In considering this application, the relevant provisions of the Act, the EPA Notices, the Health and Safety at Work Act 2015 (HSW Act) and 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 Vitaflo with the reference substance

Identity of reference substance

- 3.1. The approved substance 'Suspension concentrate containing 200 g/litre carboxin and 200 g/litre thiram', which has the approval code HSR000476 has been identified as the reference substance which Vitaflo could be compared to as part of a rapid assessment. This reference substance is considered eligible for comparing with Vitaflo.

Hazardous properties

- 3.2. The hazard classifications of Vitaflo 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. Vitaflo has a similar hazard profile as the reference substance.

Table 1: Hazard classifications of Vitaflo and the reference substance

Hazard	Vitaflo	Reference Substance
Acute toxicity (oral)	6.1D	6.1D
Acute toxicity (inhalation)	6.1D	6.1D
Eye irritancy	6.4A	6.4A
Contact sensitisation	6.5B	6.5B
Reproductive/ developmental toxicity	6.8B	6.8B
Target organ or systemic toxicity	6.9A	6.9B
Aquatic ecotoxicity	9.1A	9.1A
Terrestrial vertebrate ecotoxicity	9.3C	9.3C

Use

- 3.4. Vitaflo and the reference substance are both proposed for use at comparable rates as fungicides on wheat, barley, oats, and maize, using comparable application methods and rates. There are no substantial differences in the use and purpose of Vitaflo 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 Vitaflo compared to those associated with the reference substance
- determined whether any variations or additions to the prescribed controls are required to manage the risks of this substance, and identifies controls that may not be applicable or necessary that can, therefore, be deleted.

Assessment of risks to human health

4.3. The risks to human health are higher than those of the reference substance. The substance does not generate any additional HSNO controls when compared to the reference substance, however, two additional HSW controls (5-2 and 13-14) are triggered. The risks to human health can be 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 Maori 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. The risks to society, communities or the market economy from this substance are similar to those of the reference substance and as such are managed by the suite of controls.

New Zealand's international obligations

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

Summary of assessment

4.8. The risks associated with Vitaflo 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 Vitaflo 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 Vitaflo determine a set of prescribed controls specified by the EPA Notices² under section 77 of the HSNO Act. There are also requirements in the HSW (HS)

² There may also be default controls in regulations made under the Act for certain hazardous substances such as fireworks.

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. These controls form the basis of the controls specified in Appendix A.
- 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 Vitaflo.
- 5.4. As Vitaflo is a seed treatment, Clause 21 of the Labelling Notice specifically applies stating seeds are not to be used for human or animal consumption and seeds must not be accessible to birds. Clause 54 of the HPC Notice specifically applies to Vitaflo, stating treated seeds must be coloured so they are distinguishable from non-treated seeds, seeds must be completely covered with soil when sown and birds must be prevented from accessing and foraging on sites where the application of treated seeds has occurred.
- 5.5. Clause 17 of the Hazardous Substances (Labelling) Notice 2017 and Section 3 of Schedule 1 of 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 Schedule 1 of the SDS Notice requires occupational exposure limits to be identified on the SDS.
- 5.6. The name and concentration of the following components need to be specified on the label and SDS. (Table 2):

Table 2: Components required on the label and SDS

Labelling requirement	SDS requirement
Thiram (6.1D, 6.5B, 6.8B)	Thiram (6.1D, 6.4A, 6.5B, 6.8B, 9.1A, TEL, WES)
1,2-Ethanediol (ethylene glycol) (6.9A)	1,2-Ethanediol (ethylene glycol) (6.1D, 6.4A, 6.9A, WES)
	Carboxin (6.4A, 9.1D)
	1-Butanol (WES)

Exposure limits

- 5.7. Under s77B of the Act, the EPA may set a Tolerable Exposure Limit (TEL) and/or an Environmental Exposure Limit (EEL) for a substance with toxic or ecotoxic properties.
 - Regulation 13.17 of the HSW (HS) Regulations prohibits the use of a class 6 substance in excess of a TEL
 - Clause 49 of the HPC Notice prohibits use of a class 9 substance in excess of an EEL

- 5.8. No TEL values have been set previously for the active ingredient carboxin in Vitaflo 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.
- 5.9. The following TEL value has been set previously for the active ingredient thiram: $TEL_{air} = 0.002 \text{ mg/m}^3$. This value must be stated on the SDS.
- 5.10. An EEL value had been set previously for thiram; however, the EEL value is deleted for Vitaflo, as the level of risk of adverse effects to the environment has been qualitatively assessed as being negligible, with controls in place.
- 5.11. There are Workplace Exposure Standard (WES) values currently set for components of Vitaflo 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 Vitaflo.

6. Changes to prescribed controls

- 6.1. The following modifications to the EPA Notice controls apply to Vitaflo, as set out in Table 3:

Table 3: Justification for s77 changes to prescribed controls (see Appendix A for the control wordings)

Control	Justification
Application rate HPC Notice Clause 50	Significant human health and environmental risks may occur from the use of this substance, due to the hazards posed by carboxin and thiram, the active ingredients in Vitaflo. Therefore, it is considered necessary to set a maximum application rate under clause 50 of the HPC Notice.
Disposal Disposal Notice	Significant environmental risks may occur if the seeds treated with this substance are not disposed of appropriately. Therefore, it is considered necessary to apply an additional disposal control to ensure treated seeds are disposed of appropriately.
Label Labelling Notice	The substance label and the label on packages containing seeds treated with this substance must specify the personal protective equipment that users must wear when handling the substance, seeds treated with the substance, and equipment that has been used with the substance or with seeds treated by the substance.
Seed information Labelling notice	Information must be provided with the seeds treated with this substance to indicate the substance that the seeds have been treated with, its hazardous properties and the precautions to be taken when handling the seeds.

- 6.2. The following additional HSNO controls apply to Vitaflo under section 77A of the Act, as set out in Table 4:

Table 4: Justification for s77A additional controls (see Appendix A for the control wordings)

Control	Justification
Application method	<p>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 potential risks will be more effective than the prescribed controls with respect to their effects on the management, application and risks of this substance.</p> <p>Appropriate personal protective equipment (PPE) must be worn when handling this substance, the seeds treated with this substance and the equipment used with this substance or with the seeds treated by this substance.</p>
Use restriction	<p>As the risk assessment of the proposed substance has been based on its use as a seed treatment, the addition of a use restriction control is applied to this substance, as it is more effective than the prescribed controls with respect to their effect on the management, use, and risks of the substance.</p>
Seed coating	<p>Any person treating seeds with this substance must ensure that the seeds are film coated at the time of treatment to prevent adverse effects to people and the environment from dust.</p>

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 this document.

7. Decision

- 7.1. Having considered the composition, hazardous properties and use of Vitaflo, 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 Vitaflo that would prevent this application for Vitaflo 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 Vitaflo.
- 7.3. I consider that applying the suite of controls to Vitaflo set out in Appendix A will ensure adequate management of the adverse effects of Vitaflo.
- 7.4. Therefore, the import or manufacture of Vitaflo is approved with controls as listed in Appendix A.



Environmental Protection Authority
Te Mana Rauhi Taiao

Dr Fiona Thomson-Carter

Date: 11/02/2019

General Manager, HSNO, EPA

Appendix A: Controls applying to Vitaflo

EPA Controls

Control code	EPA Notice	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

Control code	HSNO Act	Control
Application rate	Section 77 variation to HPC Notice clause 50	The maximum application rate for this substance is 500 mL Vitaflo/100 kg bare seed, with a maximum seed sowing rate of 200 kg of treated seed/ha (equating to 200 g carboxin/ha and 200 g thiram/ha).
Disposal	Section 77 variation to Disposal Notice	The controls specified under the Hazardous Substances (Disposal) Notice 2017 for this substance are applied to seeds treated with this substance as though the seeds have the same hazard classification as this substance.
Label	Section 77 variation to Labelling Notice	<p>The substance label and the label on packages containing seeds treated with this substance must specify the personal protective equipment that users must wear when handling the substance, seeds treated with the substance, and equipment that has been used with the substance or with seeds treated by the substance.</p> <p>The substance label must include the following statement (or words to this effect) – This substance must only be applied as a seed treatment.</p> <p>The substance label must include the following statement (or words to this effect) – This substance may only be applied to seeds in a purpose-built seed coating machine, in a treatment plant.</p> <p>The following statement (or words to this effect) must be included on the substance label, and information provided with seeds treated with this substance – Seeds treated with this substance must be disposed of in accordance with the disposal requirements for toxic and ecotoxic substances as specified under the Hazardous Substances (Disposal) Notice 2017.</p> <p>The label of packages containing seeds treated with this substance must include the following statement (or words to this effect) – Seeds must be completely covered with soil once sown.</p> <p>The following statement (or words to this effect) must be included on the substance label, and information provided with seeds treated with this substance – The maximum application rate for this substance is 500 mL Vitaflo/100 kg bare seed, with a maximum seed sowing rate of 200 kg of treated seed/ha (equating to 200 g carboxin/ha and 200 g thiram/ha).</p>

Decision on application for approval to import or manufacture Vitaflo for release (APP203408)

Seed Information	Section 77 variation to Labelling notice	Information must be provided with the seeds treated with this substance to indicate the substance that the seeds have been treated with, its hazardous properties and the precautions to be taken when handling the seeds.
Application method	Section 77A	This substance may only be applied to seeds in a purpose-built seed coating machine, in a treatment plant. Appropriate personal protective equipment (PPE) must be worn when handling this substance, the seeds treated with this substance and the equipment used with this substance or with the seeds treated by this substance.
Use restriction	Section 77A	This substance must be applied as a seed treatment only.
Seed coating	Section 77A	Any person treating seeds with this substance must ensure that the seeds are film coated at the time of treatment.

HSW HS Requirements

Note: these requirements are triggered by the classification of the substance. They are listed here for information purposes only.

Control code	Regulation	Control description	Extra information
HSW2-1	Reg 2.1 - 2.4	Workplace labelling of hazardous substance containers	
HSW2-2	Reg 2.5-2.10	Signage	
HSW2-3	Reg 2.11	Safety data sheets	
HSW2-4	Reg 2.12-12.14	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	
HSW13-7	Reg 13.14 - 13.16	Transportation of certain class 6 and 8 substances	
HSW13-8	Reg 13.17	Prohibition on use of substance in excess of tolerable exposure limit	TEL _{air} = 0.002 mg/m ³ is set for this substance.
HSW13-9	Reg 13.18	Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded	No PES limit is set at this time.
HSW13-14	Reg 13.30 -33	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	