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## RAPID SCIENCE MEMO

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03 FEBRUARY 2022

### Summary

Substance	Vitaflo
Application code	APP203408
Application sub-type	Similar hazard
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
Date application formally received	25 January 2019

## 1. Key Points

- 1.1. Vitaflo is a fungicide containing 200 g/L of the active ingredient carboxin and 200 g/L of the active ingredient thiram. Vitaflo 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. Status Of Substance (SOS) or statutory determination history

- 2.1. History or SOS/statutory determination for Vitaflo is given in Table 1 below

**Table 1: SOS/statutory determination history for Vitaflo**

SOS or statutory determination number (if any)	SOS1003434 (under the name Vitavax 200FF Seed Treatment)
Has the formulation changed since the SOS or statutory determination advice?	Yes

## 3. Identification of substance and reference

- 3.1. The reference proposed by the applicant and identified by the EPA are the same (see Table 2)

**Table 2: identified reference for the rapid assessment of Vitaflo**

	Substance to be approved	Reference
Name	Vitaflo	Suspension concentrate containing 200 g/litre carboxin and 200 g/litre thiram
Substance database ID	49095	5250
HSNO Approval number	-	HSR000476
Substance physical form	Liquid – suspension concentrate	Liquid – suspension concentrate
Active ingredient(s) and concentration (g/L)	Carboxin – 200 g/L Thiram – 200 g/L	Carboxin – 200 g/L Thiram – 200 g/L

## 4. RAPID assessment criteria

### Active ingredient

- 4.1. This substance meets the active ingredients criteria. The concentration of the active ingredients in Vitaflo is the same as that of the reference substance.

### Physical form

- 4.2. Vitaflo is in the same physical form as the reference substance, namely as a suspension concentrate.

### Use pattern

- 4.3. This substance meets the use pattern criteria. Both Vitaflo and the reference substance are fungicides used in a similar manner (see Table 3)

**Table 3: Use pattern of Vitaflo in comparison to its reference substance**

	Substance to be approved	Reference
Target pest / condition	Fungal diseases	Fungal diseases
Target animal / crop	Wheat, barley, oats, maize	Wheat, barley, oats, maize
Application rate (kg a.i./ha)	Seed coating rate (max): 500 mL Vitaflo/100 kg of bare seed  Seed sowing rate (max): 200 kg treated seed/ha  Application rate (max): 200 g carboxin/ha 200 g thiram/ha	Seed coating rate: 500 mL Vitaflo/100 kg of bare seed  Seed sowing rate: 200 kg treated seed/ha  Application rate: 200 g carboxin/ha 200 g thiram/ha
Comment on any differences	The reference substance is a transfer approval. Details of the application rate for the reference substance comes from the label provided to the ACVM under its synonym Vitaflo® 200 (ACVM No. P002694). Vitaflo and the reference substance share the same application rates for use on the same crops. Vitaflo and the reference substance are similar products from the same company, Nufarm Limited.	
Are the differences insignificant in terms of risk of adverse effects?	There are no significant differences in the use pattern between Vitaflo and the reference substance.	

## Major Hazardous Components

- 4.4. The major hazardous components in Vitaflo are at a higher proportion (44.67%) than in the reference substance (40.99%). The major hazardous components of Vitaflo are increased by 9%, which is less than the 10% threshold, meeting the major hazardous components criteria.

## Adverse Effects

- 4.5. Vitaflo does not meet the adverse effects criteria, as the hazards of this substance are not reduced compared to the reference substance (see Table 4). Vitaflo contains ethylene glycol at a concentration of [REDACTED], while the reference substance contains [REDACTED]. This gives Vitaflo a 6.9A classification for target organ toxicity (oral), while the reference substance has a 6.9B classification. A 6.9B classification would have been triggered for Vitaflo had the concentration of ethylene glycol been below 10%.

**Table 4: comparison of the respective classifications of Vitaflo and its reference substance**

Classification comparison	
Substance	6.1D (oral), 6.1D (inhalation), 6.4A, 6.5B, 6.8B, <b>6.9A (oral)</b> , 9.1A, 9.3C
Reference	6.1D (oral), 6.1D (inhalation), 6.4A, 6.5B, 6.8B, 6.9B, 9.1A, 9.3C

## Additional comments

- 4.6. Vitaflo contains ethylene glycol at a concentration of [REDACTED] triggering a 6.9A classification. [REDACTED]  
[REDACTED] The higher classification (6.9A) of Vitaflo 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. Ethylene glycol, the component responsible for the 6.9A classification, has a Workplace Exposure Standard (WES) value for vapour and mist (ceiling 50 ppm (127 mg/m<sup>3</sup>)), therefore any workplace exposure risks can be managed by the suite of controls.
- 4.7. The reference substance is a transfer approval with no quantitative risk assessment available, and as such, no risk assessment could be performed.

## 5. Controls

### EPA Notice controls

- 5.1. The Labelling, Safety Data Sheet (SDS), Packaging, Disposal and Hazardous Property Controls (HPC) Part 1, Part 2, Part 3, Part 4A, Part 4B and Part 4C Notices apply to Vitaflo.
- 5.2. 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.

- 5.3. 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.
- 5.4. The name and concentration of the following components need to be specified on the label and SDS (see Table 5).

**Table 5: Components required on the label and SDS of Vitaflo**

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)

- 5.5. No Tolerable Exposure Limit (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.
- 5.6. 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.
- 5.7. 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.

## Controls varied or added under section 77A

### Application restrictions

- 5.8. Vitaflo must only be applied as a seed treatment.
- 5.9. Any person treating seeds with Vitaflo must ensure that the seeds are film-coated at the time of treatment.
- 5.10. The maximum application proposed for Vitaflo is 500 mL/100 kg bare seed with a seed sowing rate of 200 kg of seed/ha (equating to 200 g thiram/ha and 200 g carboxin/ha) as stated in the application.

### Application methods

- 5.11. Vitaflo may only be applied to seeds in a purpose-built seed coating machine, in a treatment plant.
- 5.12. Appropriate personal protective equipment (PPE) must be worn when handling Vitaflo, the seeds treated with this substance and the equipment used with this substance or with the seeds treated by this substance.

## Disposal

- 5.13. 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. 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

- 5.14. The application methods, the requirement to colour the treated seed and to cover the treated seed with soil must be stated on the label.
- 5.15. The label for Vitaflo must include the following statements or words to this effect: "This substance may only be applied in a purpose-built seed coating machine, in a treatment plant".
- 5.16. An additional label statement is required to alert users to the disposal requirements for treated seeds. The controls specified under the Hazardous Substances (Disposal) Notice 2017 for Vitaflo are applied to seeds treated with this substance as though the seeds have the same hazard classification as this substance.
- 5.17. The label of packages containing seeds treated with Vitaflo must include a statement to alert users to the application rate restrictions, and their obligations under the Hazardous Substances (Hazardous Property Control) Notice 2017.
- 5.18. The label of this substance and the label of seeds treated with this substance must specify the personal protective equipment that users must wear when handling: i) the substance, ii) the seeds treated with the substance and iii) the equipment that has been used with the substance or the seeds treated with the substance.

## Information requirement

- 5.19. An additional information requirement control is proposed for this substance. Any person supplying seeds treated with this substance must ensure that packages of treated seeds are accompanied by information that identifies: i) the substance that the seeds have been treated with, ii) its hazardous properties and iii) the precautions to be taken in handling the seeds.