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## DECISION

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6 August 2018

### Summary

Substance	Kestrel
Application code	APP203363
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	Bayer New Zealand Limited
Purpose of the application	To import for release Kestrel into New Zealand as a co-formulated emulsifiable concentrate delivering 160g/L prothioconazole and 80 g/L tebuconazole for use on cereals
Date application received	12 September 2017
Consideration date	20 July – 6 August 2018 Further information was requested from the applicant during the evaluation and review of the application in accordance with section 58 of the Act and consequently the consideration was postponed in line with section 59 of the Act
Considered by	The General Manager <sup>1</sup> of the Hazardous Substances and New Organisms group of the Environmental Protection Authority (“the EPA”)
Decision	<b>Approved with controls</b>
Approval code	<b>HSR101293</b>
Hazard classifications	6.1E (oral), 6.1E (inhalation), 6.3A, 6.4A, 6.8B, 6.9B (oral), 9.1A, 9.3C

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<sup>1</sup> 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. Kestrel is an emulsifiable concentrate containing 160 g/L of prothioconazole and 80 g/L of tebuconazole as the active ingredients, plus other components. It is intended to be imported and used by professional users as a fungicide to control various fungal diseases in cereal crops including wheat, barley and ryegrass seed crops. Kestrel is intended to be applied using ground-based and aerial application methods.

## 2. Process and consultation

### Application receipt

- 2.1. The application was formally received on 12 September 2017 under section 28 of the Act.
- 2.2. Additional information was requested from the applicant in accordance with section 58 of the Act. Consequently, the consideration of the application was postponed in line with section 59 of the Act.

### Information available for consideration

- 2.3. The information available for the consideration comprised the:
  - application form
  - confidential appendices to the application
  - EPA staff advice memorandum.
- 2.4. There was sufficient information to assess the application.

### Public notification

- 2.5. 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

- 2.6. The following government departments were notified of the application on 12 September 2017: the Ministry for Primary Industries (Agricultural Compounds and Veterinary Medicines group), the Ministry of Health and the Department of Conservation. No comments were received from these agencies.
- 2.7. WorkSafe New Zealand (“WorkSafe”) is the agency responsible for administering the Health and Safety at Work Act 2015 (HSW Act) and the Health and Safety at Work (Hazardous Substances) Regulations 2017 (HSW (HS) Regulations). Therefore, advice was sought from WorkSafe on whether the prescribed HSW requirements are adequate to manage the risks associated with the use of this substance in the workplace. WorkSafe was notified of the application and provided with the appropriate documents in March 2018 to allow them to provide this advice. Their response is in section 4.

## Legislative criteria for the application

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

## 3. Hazardous properties, prescribed controls and exposure limits

### Hazardous properties

- 3.1. The hazard classifications of Kestrel were determined by the EPA using information provided by the applicant (including bridging the results from studies conducted on a similar substance), information on the individual components of Kestrel and by mixture rules.
- 3.2. The classifications that have been applied to this substance are different to those submitted by the applicant (Table 1).

Table 1: Hazard classifications of Kestrel

Hazard	Applicant classification	EPA classification
Acute toxicity (oral)	6.1E	6.1E
Acute toxicity (inhalation)	No	6.1E
Skin irritancy	6.3B	6.3A
Eye irritancy	6.4A	6.4A
Reproductive/ developmental toxicity	ND <sup>2</sup>	6.8B
Target organ or systemic toxicity (oral)	6.9B	6.9B
Aquatic ecotoxicity	9.1B	9.1A
Terrestrial vertebrate ecotoxicity	ND	9.3C

### Prescribed controls

- 3.3. The hazard classifications of Kestrel determine a set of prescribed controls, which are specified in the EPA Notices. There are also requirements in the HSW (HS) Regulations, but these are not set for the substance under this approval as they apply in their own right.
- 3.4. 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 the Appendix.
- 3.5. 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

<sup>2</sup> ND: Not Determined

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.

- 3.6. The name and concentration of the following components need to be specified on the label and SDS (Table 2):

Table 2 List of components requiring identification

Label	SDS
Prothioconazole (6.9B)	Prothioconazole (6.9B, 9.1B)
Tebuconazole (6.8B)	Tebuconazole (6.8B, 6.9B, 9.1A)
Decanamide, N,N-dimethyl- (6.1C, 6.9B)	Decanamide, N,N-dimethyl- (6.1C, 6.3A, 6.4A, 6.9B, 9.1D)
	Glycerin (WES)
	Sodium hydroxide (WES)
	Glutaraldehyde (WES)

## Exposure limits

- 3.7. Under section 77B 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 Hazardous Substances (Hazardous Property Controls) Notice 2017 (HPC Notice) prohibits the use of a class 9 substance in excess of an EEL.
- 3.8. No ADE (Acceptable Daily Exposure) or PDE (Potential Daily Exposure) values had previously been provided to set TELs for the active ingredients in Kestrel. ADE and PDE values for both active ingredients and the metabolite prothioconazole-desthio in Kestrel are provided below but no TEL has been set 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.
- 3.9. The ADE and PDE shown below are proposed by the EPA as health-based exposure guidance values that can be used to inform risk assessments as well as the setting of controls, such as Maximum Residue Levels under the Agricultural Compounds and Veterinary Medicines Act 1997.
- 3.10. Prothioconazole:
- ADE = 0.01 mg/kg b.w./day
  - PDE<sub>(food)</sub> = 0.007 mg/kg b.w./day
  - PDE<sub>(drinking water)</sub> = 0.002 mg/kg b.w./day
  - PDE<sub>(other)</sub> = 0.001 mg/kg b.w./day
  - Acute reference dose (ARfD) = 0.2 mg/kg b.w./day
- 3.11. Prothioconazole-desthio:
- ADE = 0.01 mg/kg b.w./day
  - PDE<sub>(food)</sub> = 0.007 mg/kg b.w./day

- $PDE_{(\text{drinking water})} = 0.002 \text{ mg/kg b.w./day}$
- $PDE_{(\text{other})} = 0.001 \text{ mg/kg b.w./day}$
- $ARfD = 0.01 \text{ mg/kg b.w./day}$

3.12. Tebuconazole:

- $ADE = 0.03 \text{ mg/kg b.w./day}$
- $PDE_{(\text{food})} = 0.02 \text{ mg/kg b.w./day}$
- $PDE_{(\text{drinking water})} = 0.006 \text{ mg/kg b.w./day}$
- $PDE_{(\text{other})} = 0.002 \text{ mg/kg b.w./day}$
- $ARfD = 0.03 \text{ mg/kg b.w./day}$

3.13. An EEL value for fresh water has been set previously for one of the active ingredients in Kestrel. It is considered that this value is not applicable to this substance because the quantitative risk assessment concluded that with proposed controls in place, adverse effects to the environment have been assessed as being negligible.

3.14. There are Workplace Exposure Standard (WES) values for components of Kestrel, but, as they are not PES values, they are guidance values used for the management of health risk. No PES has been set for any component of Kestrel.

## 4. Risk and benefit assessment

4.1. The risk assessment 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 risk assessment has taken into account the full life cycle of the substance, including import, 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 Kestrel. Therefore, a quantitative assessment was undertaken to determine the likely routes of exposure to the substance under the use pattern proposed by the applicant.

4.4. The overall risk and benefit assessment:

- considered the risks posed by Kestrel
- 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

4.5. Kestrel is intended to be supplied to the professional market, and users are expected to apply the substance using ground-boom or aerial application methods. It is likely that users may be exposed to the substance during the mixing, loading and application stages of the substance.

- 4.6. The potential risks posed by Kestrel to human health were assessed by estimating the exposure of operators, re-entry workers and bystanders to the active ingredients, as well as to prothioconazole-desthio, a toxicologically relevant metabolite of prothioconazole. The estimated exposure to prothioconazole, prothioconazole-desthio and tebuconazole were then compared to an Acceptable Operator Exposure Limit (AOEL) value for each component.
- 4.7. The risk assessment determined that the estimated operator exposures to prothioconazole are below the AOEL for ground-boom application, even without the use of Personal Protective Equipment (PPE) during mixing, loading, and application.
- 4.8. Estimated operator exposures to prothioconazole-desthio and tebuconazole are below their AOELs for ground-boom application only if full PPE (gloves, hood/visor, coveralls, and heavy boots without a respirator) is worn during mixing, loading, and application.
- 4.9. There are prescribed requirements under the HSW (HS) Regulations to use PPE to minimise risks to the health and safety of workers when working with class 6 or 8 substances. Given the hazard classifications of Kestrel, regulation 13.8 of the HSW (HS) Regulations requires that PPE is to be used when carrying out work using the substance. Any person conducting a business or undertaking (PCBU) must provide PPE to workers and ensure that the PPE provided is selected to minimise risks to health and safety to meet their obligations under regulation 13.8 of the HSW (HS) Regulations and regulations 15 to 20 of the Health and Safety at Work (General Risk and Workplace Management (HSW (GRWM))) Regulations 2016. The EPA advises that full PPE (gloves, hood/visor, coveralls, and heavy boots without a respirator) is appropriate when using Kestrel. Any PCBU should select and provide full PPE for workers using Kestrel in order to meet their obligations under regulation 13.8 of the HSW (HS) Regulations. This information about personal protection, including identification of the specific type of PPE appropriate for Kestrel, must be included in the SDS in accordance with Sections 7 and 8 of Schedule 1 of the SDS Notice 2017.
- 4.10. Estimated operator systemic exposures to prothioconazole, prothioconazole-desthio and tebuconazole during mixing, loading and application of Kestrel are below the AOELs when applied by aircraft, even without the use of PPE. Therefore, the operator exposure is not expected to result in adverse health effects from the aerial use of Kestrel.
- 4.11. Estimated exposures for workers re-entering and working in areas where Kestrel has been applied are below the AOELs. No re-entry interval is therefore necessary, however it is recommended that PPE is used when entering a sprayed crop because of the other hazard classifications of Kestrel.
- 4.12. Kestrel is also irritating to the skin and eyes (6.3B and 6.4A). It is **likely** that exposure may occur during contact with the treated crops, and the effects are expected to be **moderate**. The prescribed requirements under HSW include requirements for PPE. As a result, the residual risk from the skin and eye irritancy hazards has been assessed as being **negligible**.
- 4.13. There is a risk of groundwater contamination by the metabolite 1,2,4-triazole, however the EPA staff did not identify a risk for drinking water.

- 4.14. With these controls and requirements in place and provided the appropriate PPE is worn for each application method, the residual level of risk to human health during the use phase of Kestrel is considered **negligible**.

#### **Risks to human health in a workplace**

- 4.15. The EPA sought advice from WorkSafe on whether the HSW requirements are adequate to manage the risk associated with the use of this substance in the workplace. WorkSafe provided a response on whether the risks posed by Kestrel to human health (in the workplace) can be managed by the HSW requirements.
- 4.16. WorkSafe noted that they assessed the available information of APP203363 and considers that compliance with the HSW (HS) and HSW (General Risk and Workplace Management (GRWM)) Regulations will be adequate to reduce the risks associated with the use of this substance in the workplace. WorkSafe also noted that while the regulations cover standard risk mitigation measures, occupational exposure in the workplace needs to be assessed at each site and appropriate controls put in place to mitigate the identified risks.

#### **Assessment of risks to the environment**

- 4.17. The potential risks posed by Kestrel to the aquatic and terrestrial environments were assessed for the use patterns proposed by the applicant. The EPA evaluated these use patterns and performed quantitative modelling to determine the predicted environmental exposures.
- 4.18. It was determined that the risks from the formulation could be estimated from the results obtained in tests with “pure” active ingredients and with the main metabolite prothioconazole-desthio.
- 4.19. Tebuconazole is considered moderately mobile and is not rapidly degradable in both the soil and aquatic environments. Tebuconazole breaks down into 1,2,4-triazole, which is considered mobile. Prothioconazole is considered slightly mobile and rapidly degradable, it breaks down into the metabolites 1,2,4-triazole and prothioconazole-desthio. Prothioconazole-desthio is considered moderately mobile. Risks from the metabolites prothioconazole-desthio and 1,2,4-triazole were evaluated and included in the risk assessment when considered relevant, based on their environmental-fate characteristics and ecotoxicology.
- 4.20. Prothioconazole and tebuconazole are not considered to be bioaccumulative.

#### *Assessment of risks to the aquatic environment*

- 4.21. The main potential source for aquatic organisms to be exposed to Kestrel is by spray drift or surface-water runoff after the substance is applied.
- 4.22. The predicted exposures to tebuconazole and prothioconazole-desthio were above the level of concern for threatened aquatic species. Therefore, further modelling was performed to determine the buffer zones necessary to mitigate risks to downwind water bodies from spray drift.
- 4.23. The modelling, which took into account the two intended methods of application (ground-based application with high boom and fine or medium sized droplets or aerial application with fine or medium

droplets), determined that the risks to threatened species could be managed through the specification of droplet size and the application of buffer zones. The aerial application with fine droplet size resulted in buffer zones too big to be practicable and therefore an additional control is required to set the droplet to be of a minimum medium size for this application method.

- 4.24. As the size of the buffer zones was calculated based on the two specific application scenarios, restrictions on application methods (droplet size in particular) as well as a maximum application rate of 1.25 L of Kestrel per hectare twice per calendar year have also been set as controls when using this substance.
- 4.25. A risk for potential groundwater contamination by 1,2,4-triazole was identified. The risk to the groundwater community and the aquatic environment is considered **low**, however this risk cannot be mitigated.
- 4.26. Clause 25 of the Labelling Notice requires the application methods (including droplet size), application restrictions (maximum application rate) and associated buffer zones to be stated on the label. With the buffer zones, application restrictions and other prescribed controls, the residual risks to the aquatic environment are assessed as being **low**.

#### *Assessment of risks to the terrestrial environment*

- 4.27. No risks were identified for non-target plants and pollinators.
- 4.28. Risks to earthworms and other soil organisms were above the level of concern in-field; risks were also identified for threatened species off-field. However, the treated fields can be recolonized when concentrations decrease and threatened species are unlikely to be present in agricultural areas, therefore the risks to earthworms and soil organisms were considered **low**.
- 4.29. A low risk was identified for threatened birds when Kestrel is used on cereals late after emergence, however this risk is mitigated because threatened birds are unlikely to be found on arable land and are unlikely to obtain their diet only from a treated area.
- 4.30. Risks to non-target arthropods (in particular predatory mites, parasitic wasps and spiders) were above the level of concern for the in-field situation. The applicant provided additional data to refine this risk assessment. The EPA staff agreed that the data provided support the conclusion that residual risks to non-target arthropods in-field were below the level of concern.
- 4.31. Risks to non-target arthropods from spray drift when fine droplets are used were also above the level of concern for the off-field situation. With a restriction on application method and in particular of the droplet size, the residual risks to non-target arthropods off-field were below the level of concern.
- 4.32. With the buffer zones, application restrictions and other prescribed controls, the residual risks to the terrestrial environment were assessed as being **low**.

### **Assessment of risks to Māori and their relationship to the environment**

4.33. The potential effect of Kestrel on the relationship of Māori to the environment has been assessed in accordance with sections 5(b), 6(d) and 8 of the Act. Under these sections all persons exercising functions, powers, and duties under the Act shall:

- recognise and provide for the maintenance and enhancement of people and communities to provide for their cultural well-being, and
- take into account the relationship of Māori and their culture and traditions with their ancestral lands, water, taonga and the principles of the Treaty of Waitangi (Te Tiriti o Waitangi).

4.34. Findings of the cultural risk assessment (CRA) for Kestrel in relation to the above provisions of the Act are summarised below.

#### *Section 5(b) – Recognise and provide for cultural well-being*

4.35. This application is not likely to put the cultural well-being of Māori at risk in terms of their cultural beliefs and environmental frameworks.

#### *Section 6(d) – Take into account Māori relationship to the environment*

4.36. The CRA for Kestrel considered potential risks and impacts on Māori interests including the relationship of Māori to the environment, culturally significant species and resources, and the tikanga (customary values and practices) associated with these taonga. The CRA has identified cultural concerns in relation to taha hauora (human health and well-being) and culturally significant species, in particular food species. However, potential risks around these issues can be managed, therefore the application is not inconsistent with Māori cultural beliefs and environmental frameworks.

#### *Section 8 – Take into account Treaty of Waitangi principles*

4.37. For the EPA, as a Crown agency, this includes the duty to actively protect Māori interests, and ensure that EPA decision making is informed by Māori perspectives. The CRA has assessed cultural risk and identified how Māori interests will be protected.

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

4.38. No risks to society, communities or the market economy from the approval of Kestrel have been identified.

### **New Zealand's international obligations**

4.39. No international obligations that may be impacted by the approval of Kestrel have been identified.

### **The effects of the substance being unavailable**

4.40. The likely effects of the substance being unavailable in accordance with section 29(1) of the Act have been considered. Should this substance not be available, it could lead to less consumer choice.

## Assessment of benefits

- 4.41. The applicant considers that the approval of Kestrel will provide an alternative to products currently registered for controlling fungal diseases in cereals, thereby providing an important tool for farmers.
- 4.42. There is a large number of products (10-30) registered under ACVM for the treatment of stripe rust, powdery mildew, speckled leaf blotch and glume blotch on wheat, for the treatment of scald, net blotch, ramularia leaf spot and leaf rust on barley and for the treatment of crown rust, stem rust and blind seed disease on ryegrass seed crops.
- 4.43. There are limited options (less than 10) for the treatment of tan spot and ear disease complex on wheat and for the treatment of ear disease complex on barley. There are only two other products containing both tebuconazole and prothioconazole registered in ACVM as fungicides for cereal crops.
- 4.44. The EPA considers that the availability of a fungicide with a new concentration of active ingredients for cereal crops where there is currently at small number of products registered under the Agricultural Compounds and Veterinary Medicines Act 1997 for this use pattern is a significant benefit.
- 4.45. Furthermore, it is considered that the availability of Kestrel will provide beneficial economic effects for some businesses with the potential for flow-on effects to local communities and the New Zealand economy, including improved consumer choice and greater market competition.

## 5. Changes to prescribed controls

- 5.1. The following additional HSNO controls apply to this substance under section 77A of the Act, as set out in Table 3:

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

Control	Justification
Buffer zone HPC Notice Clause 51	HPC Clause 51 allows the EPA to set buffer zone distances as an additional control for a class 9 substance. Buffer zone distances are necessary to mitigate the risks from Kestrel to sensitive areas from spray drift.
Application method	The environmental risk assessment indicates that restrictions on the application methods of this substance are necessary to mitigate the risk of death or adverse effects from spray drift that Kestrel could present to organisms in the environment. Accordingly, it is considered that specifying the application method and in particular the droplet size will be more effective than the prescribed controls with respect to their effects on the management, application and risks of this substance.
Application restrictions HPC Notice Clause 50	Significant environmental risks may occur from the use of this substance, due to the hazards posed by tebuconazole and prothioconazole, the active ingredients in Kestrel. Therefore, it is considered necessary to set a maximum application rate, number of applications and frequency under clause 50 of the HPC Notice.
Restriction on impurity	One active ingredient in Kestrel, prothioconazole, is associated with the toxicologically significant impurities toluene and prothioconazole-desthio. When present in high enough concentrations, these impurities can cause adverse effects to people or the

Control	Justification
	environment. Imposing a restriction on the maximum amount of impurities in prothioconazole will prevent them from occurring 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.

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

## 6. Risk assessment summary

- 6.1. 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.

## 7. Decision

- 7.1. 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.
- 7.2. 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 have decided that Kestrel 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.

 Environmental Protection Authority  
Te Mana Rauhi Taiao

Dr Fiona Thomson-Carter

Date: 06 August 2018

General Manager, HSNO, EPA

## Appendix: Controls applying to Kestrel

### EPA Controls

Control code	Notice	Control description
LAB	EPA Labelling Notice 2017	<a href="#">Requirements for labelling of hazardous substances</a>
PKG	EPA Packaging Notice 2017	<a href="#">Requirements for packaging of hazardous substances</a>
SDS	EPA Safety Data Sheet Notice 2017	<a href="#">Requirements for safety data sheets for hazardous substances</a>
DIS	EPA Disposal Notice 2017	<a href="#">Requirements for disposal of hazardous substances</a>
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	<a href="#">Hazardous Property Controls preliminary provisions</a>
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	<a href="#">Hazardous substances in a place other than a workplace</a>
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	<a href="#">Site and storage controls for class 9 substances</a>
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	<a href="#">Use of class 9 substances</a>
HPC-4C	EPA Hazardous Property Controls Notice 2017 Part 4C	<a href="#">Qualifications required for application of class 9 pesticides</a>

### HSNO Additional Controls and Modifications to Controls

Code	HSNO Act	Control									
Application restrictions	Section 77	<p>The maximum application rate of this substance is 1.25 L of substance/ha (equivalent to 200 g prothioconazole/ha and 100 g tebuconazole/ha)</p> <p>The maximum application frequency of this substance must not be more than twice per calendar year, with a minimum interval period of 21 days.</p>									
Buffer zone	Section 77A	<p>For this substance the following buffer zones apply, according to the relevant application method and scenario:</p> <table border="1"> <thead> <tr> <th>Application method</th> <th>Sensitive area</th> <th>Buffer zone (metres)</th> </tr> </thead> <tbody> <tr> <td>Ground-based</td> <td>Downwind water body</td> <td>2</td> </tr> <tr> <td>Aerial</td> <td>Downwind water body</td> <td>50</td> </tr> </tbody> </table>	Application method	Sensitive area	Buffer zone (metres)	Ground-based	Downwind water body	2	Aerial	Downwind water body	50
Application method	Sensitive area	Buffer zone (metres)									
Ground-based	Downwind water body	2									
Aerial	Downwind water body	50									
Application method	Section 77A	<p>When applied using ground-based or aerial application methods, the nozzle must be set to medium or coarse droplet quality spray, as defined by the American Society of Agricultural and Biological Engineers ASABE Standard (S572) or the British Crop Production Council guideline.</p>									

		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.
Maximum impurity	Section 77A	<p>The following limits are set for toxicologically relevant impurities in the active ingredient prothioconazole used to manufacture this substance:</p> <ul style="list-style-type: none"> <li>• Toluene (CAS 108-88-3): 5 g/kg maximum</li> <li>• Prothioconazole-desthio (2-(1-chlorocyclopropyl)1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol): 0.5 g/kg maximum</li> </ul>

## HSW Requirements

Note: these requirements are not set for the substance under this approval but apply in their own right under the HSW Act and HSW (HS) Regulations according to the classification of the substance. They are listed here for information purposes only.

Code	Regulation	Description	Extra information
HSW2-1	Reg 2.1 - 2.4	<a href="#">Workplace labelling of hazardous substance containers</a>	
HSW2-3	Reg 2.11	<a href="#">Safety data sheets</a>	
HSW2-4	Reg 2.12 - 2.14	<a href="#">Packaging</a>	
HSW3-1	Reg 3.1	<a href="#">Inventory</a>	
HSW3-2	Reg 3.2 - 3.3	<a href="#">Managing risks associated with hazardous substances</a>	
HSW4-2	Reg 4.5 - 4.6	<a href="#">Information, instruction, training and supervision</a>	
HSW13-2	Reg 13.7	<a href="#">Duty of PCBU who directs work using class 6, 8.1, 8.2, or 8.3 substances to ensure equipment is appropriate</a>	
HSW13-3	Reg 13.8	<a href="#">Duty of PCBU who directs work using class 6 and 8 substances to ensure personal protective equipment used</a>	
HSW13-8	Reg 13.17	<a href="#">Prohibition on use of substance in excess of tolerable exposure limit</a>	
HSW13-9	Reg 13.18	<a href="#">Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded</a>	
HSW16-1	Part 16	<a href="#">Requirements for tank wagons and transportable containers</a>	
HSW17-1	Part 17	<a href="#">Requirements for stationary container systems</a>	

## Definitions

Terms used in the controls have the same meaning as defined in the Act, the 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
Coarse spray	Coarse spray, as classified by the American Society of Agricultural & Biological Engineers (ASABE) droplet size classification scheme.
Downwind	Downwind refers to a location in a direction to where the wind blows away from the application area.
Ground-based application	Ground-based methods of applying pesticides include, but are not limited to, application by ground boom, air blast or knapsack, and do not include aerial application methods.
Likely	Good chance that it may occur under normal operating conditions.
Medium spray	Medium spray, as classified by the American Society of Agricultural & Biological Engineers (ASABE) droplet size classification scheme.
Moderate	<p>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:</p> <ul style="list-style-type: none"> <li>• minor irreversible health effects to individuals and/or reversible medium-term adverse health effects to larger (but surrounding) community (requiring hospitalisation)</li> <li>• 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</li> <li>• medium term (one to five years) regional adverse economic effects with some national implications, medium term job losses</li> <li>• some social disruption (for example, people delayed).</li> </ul>
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.