Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

21 February 2017

Summary

Substance	Miravis Fungicide
Application code	APP203072
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	Syngenta Crop Protection Limited
Purpose of the application	To import Miravis Fungicide, a fungicide that contains 200 g/L pydiflumetofen in the form of a suspension concentrate, for the control of powdery mildew in grapevines and early blight in potatoes
Date application received	13 December 2016
Consideration date	21 February 2017
Considered by	The Chief Executive[1] of the Environmental Protection Authority (“the EPA”)
Decision	**Approved with controls**
Approval code	**HSR101223**
Hazard classifications	6.1E (oral), 6.1D (inhalation), 6.9B (oral), 9.1B

[1] The Chief Executive of the EPA has made the decision on this application under delegated authority in accordance with section 19 of the Act.

1. Background

1.1. Miravis Fungicide is a suspension concentrate containing the active ingredient pydiflumetofen, plus other components. It is intended to be used as a fungicide for the control of powdery mildew in grapevines and early blight in potatoes. Pydiflumetofen is a broad-spectrum succinate dehydrogenase inhibitor (SDHI) fungicide. The target enzyme is succinate dehydrogenase (complex II in the mitochondrial respiration chain). The active ingredient is new to New Zealand and a full evaluation of the active ingredient and of the risks and benefits of Miravis Fungicide has been undertaken.

1.2. Miravis Fungicide will be manufactured overseas and imported into New Zealand by sea and air. The substance will arrive packaged and ready for sale.

1.3. At the time of the application, the active ingredient and the substance had not been approved overseas. The applicant seeks approval from several other regulatory authorities including those in Canada, the USA and Europe.

2. Process and notification

Application receipt

2.1. The application was formally received on 13 December 2016 under section 28 of the Act. It was determined to be unlikely that there would be significant public interest in this application. Therefore, this application was not publicly notified in accordance with section 53(2) of the Act.

Information available for consideration

2.2. The information available for consideration includes the application form, confidential appendices to the application, and the EPA staff science memo. I consider that this information is sufficient to assess the application.

Notification to government departments

2.3. Pursuant to section 53(4) of the Act, WorkSafe New Zealand, the Agricultural Compounds and Veterinary Medicines group of the Ministry for Primary Industries, and the Department of Conservation were notified of this application and were invited to comment. No comments were received.

Legislative criteria for the application

2.4. I have considered this application under section 29 of the HSNO Act and have taken into account other relevant sections of the Act, the Hazardous Substances Regulations, and the Hazardous Substances and New Organisms (Methodology) Order 1998.

3. Hazardous properties

3.1. The hazard classifications for Miravis Fungicide, as shown in Table 1, were determined by the EPA staff using data submitted by the applicant and information on the effects of the individual components of Miravis Fungicide, and by mixture rules.

Table 1: Hazard classifications assigned to Miravis Fungicide by the EPA

Hazard	Miravis Fungicide
Acute Toxicity	6.1E (oral), 6.1D (inhalation)
Target organ systemic toxicity	6.9B (oral)
Aquatic ecotoxicity	9.1B

3.2. The EPA staff determined that Miravis Fungicide has a 6.9B (oral) classification while the applicant indicated that there was no data available to assess this hazard. The EPA staff determined that pydiflumetofen triggers this classification based on mixture rules. I consider that the 6.9B classification for Miravis Fungicide applies.

3.3. The EPA staff determined a 9.1B classification for Miravis Fungicide. The applicant suggested that this classification could be downgraded to a 9.1C based on the small portion of the non-readily biodegradable active ingredient, pydiflumetofen, in the substance. No information on the degradation of Miravis Fungicide was available. I consider that it is inappropriate to downgrade the classification of the mixture since it cannot be assumed that the mixture is readily biodegradable without appropriate testing.

4. Assessment of risks and benefits

4.1. I note that the applicant intends to import Miravis Fungicide packaged and ready for sale, and that approval of this substance will also permit manufacture in New Zealand. I consider that the risks posed to human health and the environment during importation, manufacture, transportation, storage and disposal of this substance are negligible with the prescribed controls in place and under obligations imposed by other legislations. These other regulations include the Land Transport Rule 45001, Civil Aviation Act 1990, Maritime Transport Act 1994 and the Health and Safety at Work Act 2015.

4.2. I consider that there is potential for significant exposure to people and the environment during the use phase of Miravis Fungicide. Therefore, a quantitative risk assessment for both human health and the environment was undertaken to determine the likely exposure to the substance under the conditions of use proposed by the applicant.

4.3. The application method for use of Miravis Fungicide on grapes is air blast at an application rate of 0.080 kg pydiflumetofen/ha and an application frequency of two applications per year with a minimum interval of seven days. The applicant indicated that Miravis Fungicide may be applied to potatoes according to several use patterns. Of these, the quantitative risk assessment assessed the highest application rate; 0.075 kg pydiflumetofen/ha with a frequency of three applications per year and a minimum interval of seven days. The other use patterns for potatoes have a lower application rate and/or a longer interval between applications, and result in a lower environmental exposure concentration compared to the assessed method.

Risks to human health

4.4. The potential risks posed by Miravis Fungicide to human health were assessed by estimating the exposure of operators, re-entry workers and bystanders to pydiflumetofen. These exposures were assessed for the ground-based application of Miravis Fungicide on grapes and potatoes using the maximum application rates and frequencies proposed by the applicant.

4.5. I note that the quantitative human health risk assessment determined that the risks to operators, bystanders and re-entry workers are negligible, as modelling of the proposed uses of Miravis Fungicide determined that the risk quotients are below the acceptable operator exposure level (AOEL). The AOEL used for pydiflumetofen is 0.2 mg/kg bw/day.

4.6. The risk assessment also concluded that the estimated operator exposure from mixing, loading and applying Miravis Fungicide is below the AOEL for pydiflumetofen, even without the use of personal protective equipment (PPE). I note that this risk assessment accounts for chronic exposure to pydiflumetofen and that PPE, as triggered by the prescribed controls, is still required to protect users from acute exposure to the substance.

4.7. I note that no risks for re-entry workers were identified in the risk assessment. I therefore consider that it is not necessary to apply a re-entry control as there are negligible risks for re-entry workers after the application of Miravis Fungicide.

4.8. The main pathway through which the general public may be exposed to Miravis Fungicide (other than via food residues which are under the jurisdiction of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997), is via spray drift during application of the substance. To identify the risks associated with potential bystander exposure, modelling was conducted with toddlers as the test population as they are regarded as the most sensitive subpopulation. The modelling determined that bystander exposure to pydiflumetofen is below the AOEL. Therefore, I consider that there are negligible risks to the public and to bystanders who may be exposed to Miravis Fungicide via spray drift.

Risks to the environment

4.9. I note that the EPA staff conducted a quantitative risk assessment to evaluate the potential risks of Miravis Fungicide to the aquatic and terrestrial environments.

4.10. The risk assessment determined that the acute and chronic risks of pydiflumetofen to aquatic organisms, sediment-dwelling organisms, soil-organisms, terrestrial vertebrates (birds) and terrestrial invertebrates are negligible. I note that EPA staff considered that a secondary poisoning risk assessment for birds was not necessary as the substance is not bioaccumulative.

4.11. The applicant also provided an environmental risk assessment. I have evaluated their findings and conclude that the risk assessment and conclusions are similar to those noted above.

4.12. I therefore consider that the use of Miravis Fungicide will pose negligible risks to the environment when used according to the proposed and assessed use pattern.

Persistence of the active ingredient

4.13. Pydiflumetofen is persistent in both the aquatic and terrestrial environments. The risk assessment conducted for Miravis Fungicide indicated that overall the risks that arise from use of the substance for one year at the maximum application rate are negligible. However, I note that there is potential for the substance to accumulate in the environment over time and that the extent of this potential risk could not be determined. I have taken this uncertainty into account during my consideration.

Metabolites

4.14. Insufficient information was available to predict the environmental exposure concentration of two metabolites of pydiflumetofen (SYN545547 and SYN4826) in the aquatic environment. Accordingly, a full assessment could not be undertaken. However, as both metabolites have lower toxicity to fish and crustaceans than pydiflumetofen, and SYN48261 has lower toxicity to algae, these risks are expected to be negligible (assuming the metabolites are not more persistent than the parent). SYN545547 has higher toxicity to algae than pydiflumetofen and therefore there is uncertainty around the level of risks to algae as these depend on the amount of environmental exposure to this metabolite. I have taken this uncertainty into account during my consideration.

4.15. SYN545547 is also a major metabolite in sediment. Insufficient information was available to predict the environmental exposure concentration (EEC) of SYN545547 in the sediment, however this was able to be estimated. This metabolite is more toxic compared with pydiflumetofen and therefore there is

uncertainty around the risks to sediment dwelling organisms. However, I note that the estimated EEC indicates that the level of risk is comparable to that of pydiflumetofen. I have taken this into account during my consideration.

Risks to the relationship of Māori to the environment

Kupu arataki (context)

4.16. The potential effects of Miravis Fungicide on the relationship of Māori to the environment have 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 this 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).

4.17. I note that Miravis Fungicide triggers a number of hazardous properties giving rise to the potential for cultural risk e.g. aquatic ecotoxicity. Cultural risk includes any negative impacts to treasured flora and fauna species, the environment, and the general health and well-being of individuals and the community.

4.18. In general, the introduction and use of hazardous substances has the potential to inhibit the ability of Māori to fulfil their role as kaitiaki. This is particularly relevant when considering the guardianship of land and waterways given the ecotoxic nature of Miravis to Te Marae o Maru (freshwater ecosystems), in particular species associated with mahinga kai (food resources).

Ngā here whakapapa (Genealogical obligations)

4.19. According to Māori creation traditions, Tāne-mahuta (deity of humans, forests and forest-dwelling species) procreated birds, insects, trees, plants and humans. As progeny of Tāne, all of these organisms share whakapapa (genealogy) with one another and are closely related. Since birds, insects, trees and plants were created before humans, the former have tuākana (senior sibling) status in relation to humans who are teina (junior siblings). This tuākana – teina relationship dictates that careful consideration of potential risks and impacts on plants and animals is required because these receptors are our senior relatives.

4.20. Humans are also closely related to fish life. This is because fish and other aquatic species are descendants of Tangaroa (deity of the sea and water-dwelling species), who is a teina i.e. younger brother of Tāne. Many of Tangaroa's descendants live in the domain of Maru (tutelary guardian of fresh water). Again, whakapapa obliges us to ensure that the best interests of these 'relatives' are taken care of.

4.21. Any use of, or effects on, organisms and natural resources need to be contemplated within this fundamental construct. Compelling justification is required for any detrimental impacts.

Ngā rauropi wai (Aquatic organisms)

4.22. In respect of Te Marae o Maru, if Miravis Fungicide enters waterways there is potential for this substance to adversely affect culturally significant food species such as tuna (freshwater eels),

piharau (lamprey), mohoao (black flounder), īnanga (whitebait) and kōura / kēwai (freshwater crayfish).

4.23. The potential for Miravis Fungicide to enter waterbodies also raises concerns regarding other culturally significant species that spend all or part of their lifecycle in waterbodies, for example kōuraura (shrimp), pāpaka (freshwater crab), pūpū wai māori (water snails), piriwai (mayfly), pūrerehua (caddisfly), pūene (dobsonfly), kapowai (dragonflies), hoehoe (water boatman), hoe tuarā (backswimmer) and tātaka ruku (diving beetles). The foregoing species are prey for taonga food species such as tuna (freshwater eels), kōura / kēwai (freshwater crayfish), pūtangitangi (paradise shelduck), pārera (grey duck) and rakiraki (mallard duck), as well as culturally significant non-food species including kōkopu (galaxiids), toitoi (bullies), kotare (kingfishers), kawau (shags), tara (gulls) and matuku (herons).

4.24. Any substance that poses risk to the web of life, and the plants and creatures within it, is an issue for Māori. The importance to Māori of ensuring that taonga species flourish cannot be overstated historically or contemporarily. In former times mahinga kai (food resources) were critical for sustaining Māori communities and whānau. Aquatic species were a critical part of the food supply. Taonga species remain essential for continuing customary practices and meeting cultural obligations, especially in respect of showing manaaki (hospitality) to guests on the marae and providing whānau with traditional kai.

Taha hauora (Human health)

4.25. Miravis Fungicide is acutely toxic when inhaled or ingested, and is classified as being harmful to human organs or systems. For these reasons, Miravis Fungicide poses a risk to taha hauora (human health) particularly the dimensions of taha wairua (spiritual health and well-being obtained through the maintenance of a balance with nature and the protection of mauri) and taha tinana (physical health and well-being).

4.26. Exposure to Miravis Fungicide may inhibit taha whanaunga – the responsibility to belong, care for and share in the collective, including relationships and social cohesion. There is a risk that using this substance may compromise the ability of people to protect co-workers and others where it is being used. Ensuring the collective welfare and fostering a sense of well-being and safety amongst all involved is important for maintaining taha whanaunga. Potential risk to taha hauora of those applying Miravis can be managed by wearing appropriate Personal Protective Equipment.

4.27. Māori living in areas or working with crops where the Miravis Fungicide is used may potentially be a vulnerable group, as Māori have a significantly higher registration rates than non-Māori for a range of diseases and medical conditions relating to human organs including heart, lungs, liver and kidney.

Ētahi atu mea (Other matters)

4.28. Controlling powdery mildew in grapevines and early blight in potatoes with Miravis will produce economic benefits for those growing or working with these crops and the associated supply chains, some of whom are Māori.

4.29. Miravis Fungicide provides an option that agrichemical users can consider as an alternative to more harmful products that are currently available, and thus help to phase out these products.

4.30. Miravis Fungicide may enhance the ability of Māori to produce grapes and potatoes for whānau from their own māra kāinga (domestic cultivations). This is important for fostering manaakitanga (caring for others), whanaungatanga (connectedness), rangatiratanga (self-reliance) and enhances the taha whānaunga dimension of taha hauora.

He whakangāwari (Mitigation)

4.31. Some of the before-mentioned risks to environmental and human health can be mitigated by applying controls such as: maximum rates and frequency of spray applications; limiting use to ground applications; not spraying over or near water, and; stipulating use of PPE.

Kupu whakatepe (Conclusion)

4.32. Based on the information provided, including the use pattern and the controls proposed to be assigned to Miravis Fungicide, as well as taking into consideration information gaps regarding matters of interest to Māori, the potential risks to Māori culture or traditional relationships with the environment should be negligible.

4.33. If Miravis Fungicide is applied in the prescribed manner it is considered that it is not likely to breach the principles of the Treaty of Waitangi, particularly the principle of active protection.

Other risks

Risks to society, communities and the market economy

4.34. I have not identified any risks to society, communities or the market economy from the approval of Miravis Fungicide.

New Zealand's international obligations

4.35. I have not identified any international obligations that may be impacted by the approval of Miravis Fungicide.

The effects of the substance being unavailable

4.36. I consider that if Miravis Fungicide is not available, this would lead to reduced consumer choice as other fungicides are available on the market for the control of powdery mildew and early blight disease in grapes and potatoes.

Benefits assessment

4.37. The applicant referred to several benefits of the substance in the application and provided additional information to support some of these. The benefits presented by the applicant include:

- Highly efficacious (preventative) control of powdery mildew disease in grapevines, resulting in healthier vine growth, better quality, untainted grapes and maximised yield potential.

- Highly efficacious (preventative) control of early blight disease in potatoes, resulting in a higher yield potential.
- Miravis Fungicide has a higher potency compared to other similar fungicides
- Rapid leaf uptake and rain-fastness and long residual control allowing wide spray application window and greater application flexibility compared to other products
- Additional tool for effective fungicide resistance management in grapes and potatoes with excellent potency
- With higher yields, the farmers' profit is likely to increase with flow-on enhancement of rural and national economies

4.38. I have considered all of the available information and have determined that for some claims no additional information was available to support these. In particular I note that the claim that Miravis Fungicide has a higher efficacy compared to other similar fungicides should be supported by additional information. The applicant provided a study summary of the efficacy report in confidence to the EPA. The report shows that the product is effective but I do not consider that it shows that the product performs better than all other similar fungicides on the market. This is the only information provided regarding the efficacy compared to other products. I consider that this information is insufficient to support this benefit claim.

4.39. No information was provided regarding the leaf uptake and rain–fastness of Miravis Fungicide as well as the long duration of pest control and therefore I cannot evaluate whether this claim is justified.

4.40. The applicant has provided a study summary of the efficacy report which concluded that Miravis Fungicide is efficacious at controlling powdery mildew in grapes and early blight in potatoes during trials performed in New Zealand. I used this summary to determine whether the benefit claims are justified. I consider that the summary is reliable and thus recognise the benefits of the substance to successfully control these diseases. I also note that Miravis Fungicide can contribute to higher crop yields which may have a positive flow-on effect in rural and national economies.

4.41. I am satisfied that the availability of Miravis Fungicide will provide beneficial economic effects for some businesses, with the potential for flow-on effects to local communities and the New Zealand economy, including greater consumer choice.

4.42. I therefore consider that there are some benefits related to the approval of Miravis Fungicide, and the benefits are likely to be non-negligible.

5. Controls

5.1. The hazard classifications for Miravis Fungicide determine a set of prescribed controls as specified by the Hazardous Substances Regulations under the Act. These prescribed controls (as detailed in Appendix A) form the basis for how the substance should be managed throughout its lifecycle in New Zealand.

Exposure limits

5.2. Several prescribed controls allow the EPA to set human health and environmental exposure values to limit exposure to hazardous substances to quantities that are unlikely to present a risk of adverse effects.

5.3. Tolerable Exposure Limits (TELs), Acceptable Daily Exposures (ADEs) and Potential Daily Exposures (PDEs) can be set to limit hazardous substances from entering the environment in quantities sufficient to present a risk to people. No TEL values have been set for any component of Miravis Fungicide at this time as the risk of adverse effects to human health has been qualitatively assessed as negligible, provided users demonstrate compliance with the controls as set out in Appendix A. The EPA is however, required to set ADE and PDE values for new active ingredients that may become present in food. The following ADE, PDE values are set for pydiflumetofen:

- ADE: 0.09 mg/kg bw/d
- $PDE_{(food)}$: 0.06 mg/kg bw/d
- $PDE_{(drinking\ water)}$: 0.02 mg/kg bw/d
- $PDE_{(other)}$: 0.01 mg/kg bw/d

5.4. Control T2 allows Workplace Exposure Standard (WES) values to be set for any component of a substance to limit the exposure of people to toxic substances in places of work. I have adopted and applied the WES values listed in the WorkSafe New Zealand Standard *Workplace Exposure Standards and Biological Exposure Indices 8th Edition (June 2016)*[2] for all components of this substance in Miravis Fungicide, where applicable.

5.5. Control E1 allows the EPA to set Environmental Exposure Limit (EEL) values to limit hazardous substances from entering the environment in quantities sufficient to present a risk to it. No EEL values are set for any component of this substance at this time as the risk of adverse effects to the environment has been assessed as being low with the controls applied to this approval. This control has been varied under s 77A of the Act. An EEL might be determined in the future.

[2] Or any subsequent version of this Standard approved or endorsed by the EPA.

Substitution, addition and deletion of prescribed controls

5.2 Section 77 of the Act makes provisions for the EPA to substitute, add or delete any controls prescribed for any classification for a hazardous substance where the adverse effects are different from those usually associated with that classification; or where the adverse effects cannot be accurately identified; or where it is determined that the availability of the substance should be restricted; or where it is determined that such variation is required to retain the benefits of the substance without significantly increasing the adverse effect.

5.3 I have not made any modifications to the prescribed controls under s 77 of the Act.

Additional controls and variation of prescribed controls

5.4 Section 77A of the Act allows the EPA to add, vary, substitute, combine or delete any specified control if such change is more effective or more cost-effective in terms of its effect on the management, use, and risks of the substance; or is more likely to achieve its purpose than the prescribed controls.

5.5 I have added controls and varied the prescribed controls for Miravis Fungicide as set out in Table 2 and Table 3.

Table 2: Justifications for variation of the prescribed controls for Miravis Fungicide

Control	Justification
E1	Environmental Exposure Limit values (EEL) can be set to limit hazardous substances from entering the environment in quantities sufficient to present a risk to it. No EEL values are set for any component of Miravis Fungicide at this time as the risk of adverse effects to the environment has been assessed as being negligible, provided that users comply with the controls, as set out in Appendix A. The default EEL values are deleted.
EM12	**Emergency management requirements** The prescribed EM12 controls include requirements in regulations 35 – 41 of the Hazardous Substances (Emergency Management) Regulations 2001 for secondary containment of pooling substances. However, these prescribed controls do not allow for exemptions where it is unnecessary for pipework associated with a stationary container-system to have secondary containment. Accordingly, I have varied the EM12 control, as detailed in Appendix A, to note that any quantities of this substance contained within pipework are not required to be taken into account when determining whether a place is required to have a secondary containment system. I have also varied the EM12 control to reduce the secondary containment requirements for this substance as I consider that these reduced containment measures are adequate to manage the risks of a spill of this substance.
Schedule 8	**Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004** The prescribed controls do not address the risks associated with storage or use of substances within stationary container systems (e.g. tanks). These risks include the potential failure of primary containment system resulting in a large spill of the substance into the environment. To mitigate against the risk that this substance will be stored in bulk without consideration of the equipment it is contained in, or the location of that equipment, I have imposed this additional control.

Table 3: Justifications for addition of controls for Miravis Fungicide

Control(s)	Justification
Application method Water	The risks associated with applying the substance using other methods than those proposed by the applicant were not determined. Therefore, I consider it appropriate to apply controls to limit the application methods of this substance to the methods that were assessed. I have added controls to prevent the application of this substance onto or into water, and to limit the application method to only ground-based equipment.
Application rate	The risks associated with using this substance at higher application rates and frequencies than those proposed by the applicant were not assessed. I note that significant environmental exposure to Miravis Fungicide and subsequent harm to the environment may occur if the substance is used outside the assessed application rates. Therefore, I consider it appropriate to apply controls to limit the application of this substance to the maximum application rate and frequency that were assessed..
Label	I have imposed a label control to specify information that must be conveyed to users of Miravis Fungicide so that users are aware of the restrictions imposed on this substance, and can take the necessary precautions to minimise adverse effects to human health and the environment.
Purity	I have imposed a purity control on the active ingredient since impurities can increase toxicity of the substance. Furthermore, the control includes that the isomer ratio is 50:50 since a deviation of this ratio can result in a different toxicity and efficacy profile of the active ingredient.

6. Summary

6.1. I consider that the modifications and additions to the prescribed controls fulfil the legislative criteria of being, relative to the prescribed controls, more effective in terms of their effect on the management, use, and risks of Miravis Fungicide.

6.2. Having taken into account all the available information, and after assessing the potential risks of using Miravis Fungicide at the proposed application rates and frequencies, I consider that the overall risks posed by this substance to human health and the environment are negligible with the controls applied to this approval. I also consider that the risks posed by this substance to Māori culture or traditional relationships with the environment are negligible with the controls applied to this approval.

6.3. I have taken into consideration the persistent nature of this active ingredient, the potential for accumulation in the environment and the uncertainty around the effects of pydiflumetofen metabolites. I consider these risks to be low, but I do not consider them to be negligible.

6.4. I acknowledge that the approval of the substance will have benefits that will apply to several parties. I therefore consider that the benefits are non-negligible.

7. Decision

7.1. Pursuant to section 29 of the Act, I have considered this application to import a hazardous substance for release, made under section 28 of the Act. In doing so, I have applied the relevant sections of the Act and clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998.

7.2. I have determined that with the controls specified in Appendix A, the positive effects of this substance outweigh any adverse effects. Therefore, the import and manufacture of Miravis Fungicide is approved with controls, in accordance with section 29 of the Act and clause 27 of the Hazardous Substances and New Organisms (Methodology) Order 1998.

Dr Allan L Freeth	**Date: 21 February 2017**
Chief Executive, EPA	

Appendix A: Controls applying to Miravis Fungicide

Please refer to the Hazardous Substances Regulations[3] for the requirements prescribed for each control.

Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001

Code	Regulation	Description	Variation
T1	11 – 27	Limiting exposure to toxic substances through the setting of ADE, PDE or TEL values	No TEL values are set for any component of this substance at this time.
T2	29, 30	Controlling exposure in places of work through the setting of WES values	*Note: The EPA adopts as WES values for this substance, and each component of this substance, any applicable value specified in WorkSafe New Zealand's Workplace Exposure Standards and Biological Exposure Indices Document; 8th Edition; June 2016*[4]
T4	7	Requirements for equipment used to handle substances	
T5	8	Requirements for protective clothing and equipment	
T7	10	Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles	
E1	32 – 45	Limiting exposure to ecotoxic substances through the setting of EEL values	No EEL values are set at this time and the default EEL values are deleted
E2[5]	46 – 48	Restrictions on use of substances in application areas	See additional controls set under section 77A of the Act
E6	7	Requirements for equipment used to handle substances	

Hazardous Substances (Identification) Regulations 2001

Code	Regulation	Description	Variation
I1	6, 7, 32 – 35, 36(1) – (7)	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability	
I3	9	Priority identifiers for ecotoxic substances	

[3] The regulations can be found on the New Zealand Legislation website: http://www.legislation.co.nz

[4] Or any subsequent version of this Standard approved or endorsed by the EPA. The prescribed Regulations permit one or more WES values to be set for a substance, therefore, this note is for informative purposes rather than a variation to the prescribed controls

[5] This note is for informative purposes rather than a variation to the prescribed controls.

Code	Regulation	Description	Variation
I8	14	Priority identifiers for toxic substances	
I9	18	Secondary identifiers for all hazardous substances	
I11	20	Secondary identifiers for ecotoxic substances	
I16	25	Secondary identifiers for toxic substances	
I17	26	Use of generic names	
I18	27	Requirements for using concentration ranges	
I19	29 – 31	Additional information requirements, including situations where substances are in multiple packaging	
I20	36(8)	Durability of information for class 6.1 substances	
I21	37 – 39, 47 – 50	General documentation requirements	
I23	41	Specific documentation requirements for ecotoxic substances	
I28	46	Specific documentation requirements for toxic substances	
I29	51, 52	Signage requirements	
I30	53	Advertising corrosive and toxic substances	

Hazardous Substances (Packaging) Regulations 2001

Code	Regulation	Description	Variation
P1	5, 6, 7(1), 8	General packaging requirements	
P3	9	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria	
P13	19	Packaging requirements for toxic substances	
P15	21	Packaging requirements for ecotoxic substances	
PG3	Schedule 3	Packaging requirements equivalent to UN Packing Group III	

Code	Regulation	Description	Variation
PS4	Schedule 4	Packaging requirements as specified in Schedule 4	

Hazardous Substances (Disposal) Regulations 2001

Code	Regulation	Description	Variation
D4	8	Disposal requirements for toxic and corrosive substances	
D5	9	Disposal requirements for ecotoxic substances	
D6	10	Disposal requirements for packages	
D7	11, 12	Information requirements for manufacturers, importers and suppliers, and persons in charge	
D8	13, 14	Documentation requirements for manufacturers, importers and suppliers, and persons in charge	

Hazardous Substances (Emergency Management) Regulations 2001

Code	Regulation	Description	Variation
EM1	6, 7, 9 – 11	Level 1 information requirements for suppliers and persons in charge	
EM6	8(e)	Information requirements for toxic substances	
EM7	8(f)	Information requirements for ecotoxic substances	
EM8	12 – 16, 18 – 20	Level 2 information requirements for suppliers and persons in charge	
EM11	25 – 34	Level 3 emergency management requirements: duties of person in charge, emergency response plans	
EM12	35 – 41	Level 3 emergency management requirements: secondary containment	The following subclauses are added after subclause (3) of regulation 36: *(4) For the purposes of this regulation, and regulations 37 to 40, where this substance is contained in pipework that is installed and operated so as to manage any loss of containment in the pipework it—* *(a) is not to be taken into account in determining whether a place is*

Code	Regulation	Description	Variation
			required to have a secondary containment system; and *(b) is not required to be located in a secondary containment system.* *(5) In this clause, pipework—* *(a) means piping that—* *(i) is connected to a stationary container; and* *(ii) is used to transfer a hazardous substance into or out of the stationary container; and* *(b) includes a process pipeline or a transfer line.* The following subclauses are added at the end of regulation 37: *(2) If pooling substances which do not have class 1 to 5 hazard classifications are held in a place above ground in containers each of which has a capacity of 60 litres or less—* *(a) if the place's total pooling potential is less than 20,000 litres, the secondary containment system must have a capacity of at least 25% of that total pooling potential:* *(b) if the place's total pooling potential is 20,000 litres or more, the secondary containment system must have a capacity of the greater of—* *(i) 5% of the total pooling potential; or* *(ii) 5,000 litres.* *(3) Pooling substances to which subclause (2) applies must be segregated where appropriate to ensure that leakage of one substance may not adversely affect the container of another substance.* The following subclauses are added at the end of regulation 38: *(2) If pooling substances which do not have class 1 to 5 hazard classifications are held in a place above ground in containers 1 or more of which have a*

Code	Regulation	Description	Variation
			capacity of more than 60 litres but none of which have a capacity of more than 450 litres— *(a) if the place's total pooling potential is less than 20,000 litres, the secondary containment system must have a capacity of either 25% of that total pooling potential or 110% of the capacity of the largest container, whichever is the greater:* *(b) if the place's total pooling potential is 20,000 litres or more, the secondary containment system must have a capacity of the greater of—* *(i) 5% of the total pooling potential; or* *(ii) 5,000 litres* *(3) Pooling substances to which subclause (2) applies must be segregated where appropriate to ensure that the leakage of one substance may not adversely affect the container of another substance.*
EM13	42	Level 3 emergency management requirements: signage	

Hazardous Substances (Tank Wagons and Transportable Containers) Regulations 2004

Code	Regulation	Description
Tank Wagon	Regs 4 – 43 as applicable	Controls relating to tank wagons and transportable containers

Controls added under section 77A of the Act

Code	Control
Water	This substance must not be applied into or onto water
Application Method	This substance must be applied using ground-based methods only
Application rate	Maximum application rates apply to this substance: 1) When applied using airblast the substance must not be applied at rates exceeding 400 mL of formulated product/ha per application (equivalent to 80 g active ingredient/ha); and the substance

	must not be applied to the same area more than 2 times in any 365 day period; an interval of at least 7 full days must be observed before the substance is reapplied to the same area. 2) When applied using ground boom or knapsack, the substance must not be applied at rates exceeding 375 mL of formulated product/ha per application (equivalent to 75 g active ingredient/ha); and the substance must not be applied to the same area more than 3 times in any 365 day period; an interval of at least 7 full days must be observed before the substance is reapplied to the same area.
Purity	The purity of the active ingredient, pydiflumetofen, used to manufacture this substance must be 980 g/kg or greater in a 50:50 race mix.
Label	The following information, or words to the same effect, must appear on the product label and documentation supplied with this substance: • This substance must not be applied into or onto water • This substance must only be applied using ground-based methods • The maximum application rates, frequencies and intervals between applications • Do not apply when wind speeds are less than 3 km/hr or more than 20 km/hr as measured at the application site
Stationary Container Systems	**Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004** This schedule prescribes the controls for stationary container systems. The requirements of this schedule are detailed in the consolidated version of the Hazardous Substances (Dangerous Goods and Schedule Toxic Substances) Transfer Notice 2004. The following clause replaces Clause 1 of Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004: *This Schedule applies to every stationary container system that contains, or is intended to contain the substance*

Definitions

Unless defined below, terms used in the controls have the same meaning as defined in the Act or regulations made under the Act.

Term	Definition
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.
Water	Means water in all its physical forms, whether flowing or not, and whether over or under ground, but does not include water in any form while in a pipe, tank or cistern or water used in the dilution of the substance prior to application.