## DECISION

14 April 2016

<table>
<thead>
<tr>
<th>Substance</th>
<th>DUPONT ZORVEC® ENICADE® FUNGICIDE</th>
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</thead>
<tbody>
<tr>
<td>Application code</td>
<td>APP202567</td>
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<td>Application type</td>
<td>To import or manufacture for release any hazardous substance under Section 28 of the Hazardous Substances and New Organisms Act 1996 (“the Act”)</td>
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<tr>
<td>Applicant</td>
<td>DuPont (New Zealand) Limited</td>
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<tr>
<td>Purpose of the application</td>
<td>To import for release into New Zealand the substance DuPont Zorvec® Enicade® Fungicide containing 100 g/L oxathiapiprolin as an oil dispersion formulation. The substance is to be used as a foliar applied fungicide for control of downy mildew in onions.</td>
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<tr>
<td>Date application received</td>
<td>9 July 2015</td>
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<td>Hearing and Consideration date</td>
<td>9 March 2016</td>
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<tr>
<td>Considered by</td>
<td>Dr Kerry Laing – Chair</td>
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<td></td>
<td>Dr Louise Malone</td>
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<td>Dr Kevin Thompson</td>
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<td>Decision</td>
<td>Approved with controls</td>
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<tr>
<td>Approval code</td>
<td>HSR101125</td>
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<tr>
<td>Hazard classifications</td>
<td>6.3B, 6.5B, 9.1D</td>
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1. Executive summary

1.1. This application is for approval to import for release into New Zealand the substance DuPont Zorvec® Enicade® Fungicide (Zorvec Enicade) containing 100 g/litre oxathiapiprolin as an oil dispersion formulation. Oxathiapiprolin is a new active in New Zealand. The substance is used as a foliar applied fungicide for control of downy mildew in onions. The Applicant has proposed an application rate of 350 mL formulated product/ha (equivalent to 35 g oxathiapiprolin/ha), by foliar boom spray. One to two applications are intended, with a minimum interval between applications of ten days.

1.2. Zorvec Enicade will be manufactured overseas and imported into New Zealand by sea and air freight. The substance will be packaged ready for sale in 1 to 5 litre PE/EVOH containers. Repackaging or relabelling of the product in New Zealand is not intended. The product will be used by contractors who are familiar with the safe practices for storing and handling fungicides. Domestic or home use by untrained users is not anticipated. It is to be used together with other previously registered fungicide products in a tank mix diluted with water.

1.3. During the submission period, five submissions were received on the application. Ngāti Whātua Ōrākei (NWŌ) stated that they did not oppose the application if their concerns were taken into account. Ngati Huarere ki Whangapoua Trust, Te Rūnanga o Ngāi Tahu, and the Ngāpuhi HSNO Komiti, all opposed the application. Beef + Lamb New Zealand Limited neither supported nor opposed the application.

1.4. After considering all relevant information, the Decision Making Committee (the Committee) decided that it had sufficient information to make a decision on this application.

1.5. With the suite of controls listed in Appendix A in place, the Committee assessed the risks posed by Zorvec Enicade to be negligible. The Committee assessed the level of benefits associated with Zorvec Enicade to be non-negligible. The Committee decided to approve the application to import or manufacture Zorvec Enicade with controls.
2. Application process

Formal receipt and notification

2.1. The application from DuPont (New Zealand) Limited was formally received by the Environmental Protection Authority (EPA) on 9 July 2015. The application was publicly notified and opened for submissions on 23 July 2015. The submission period closed on 3 September 2015.

2.2. The Minister for the Environment was advised of the application in writing on 23 July 2015, in accordance with section 53(4) of the Act.

2.3. The Ministry for the Environment, WorkSafe New Zealand, the Ministry of Health, the Department of Conservation, and the Agricultural Compounds and Veterinary Medicines (ACVM) group of the Ministry for Primary Industries were advised of the application and notified of the submission period. No comments or submissions on the application were received from these parties.

Additional information provided

2.4. Commercially sensitive information was provided to the EPA in a confidential appendix of the application form.

2.5. An overview of the application was distributed to the forum for Māori environmental and resource managers, Te Herenga, by the EPA on behalf of DuPont (New Zealand) Limited.

Submissions received

2.6. Five submissions were received on the application.

2.7. Three submissions opposed the application: these were from Te Rūnanga o Ngāi Tahu, and the Ngāpuhi HSNO Komiti and both requested to speak at the Hearing. Ngāti Huarere ki Whangapoua Trust opposed the application, but did not wish to speak at the Hearing.

2.8. The Ngāti Whātua Ōrākei (NWŌ) advocates for a more holistic approach to eradicating unwanted pests and weeds that does not require the use of herbicides and pesticides. NWO recommended the use of natural alternative methods to eradicate and control downy mildew. NWO concluded that they would not oppose the application, if the issues they had raised were given weight in the consideration.

2.9. Concerns made in the submissions from the four Māori organisations covered the use, management and delivery of chemical and toxic sprays. These organisations are concerned about the impact that such chemicals have their native biodiversity and ecological systems and their cultural values. Their issues ranged from labelling, to current industry practice of tank mixing multiple pesticide actives, and the simultaneous application of multiple pesticide actives.

2.10. Beef + Lamb New Zealand Ltd neither supported nor opposed the application. Their concerns were about risks to human health or economic risks arising from residues in food products.
3. The Evaluation and Review Report (Staff Report) and additional information

3.1. The Evaluation and Review Report (the Staff Report) is the EPA Staff’s review of the application and available data, and provides information to assist the Committee’s decision-making.

3.2. The Staff conducted quantitative human health and ecotoxicological risk assessments based on DuPont™ Zorvec® Enicade® fungicide use pattern. Based on all the available information, the staff assessed the potential risks that the substance may pose to the environment, human health, the relationship of Māori to the environment, society, community, and to the market economy.

3.3. The public submissions and their content were analysed and addressed in detail within the Staff Report.

3.4. The Staff identified and recommended some changes to the default controls and several additional controls based on their assessments and the hazard classifications of Zorvec Enicade. The Staff Report considered that these additional controls will be more effective than the default controls in managing potential risks posed by the use of the product.

3.5. These recommended variations, additions, and deletions of controls were in accordance with Sections 77 and 77A of the Act.

3.6. The Staff considered that there will be financial benefits to some companies associated with the approval of Zorvec Enicade fungicide. The EPA concurred with the Applicant that the product will contribute benefits such as:

- An additional fungicide active with a different mode of action to existing fungicides;
- improved crop performance;
- a useful option for pre-harvest disease control and resistance management.

3.7. The Staff Report concluded that with the default controls, the proposed variations to these controls, and the additional controls, the risks to human health and the environment would be negligible. The Staff recommended to the Committee that with proposed controls in place, the overall level of benefit provided by the availability of the Zorvec Enicade would outweigh the overall risk.

3.8. The Staff recommended that the application be approved with controls

4. The Consideration Process

Hearing

4.1. On 1 March 2016, a Hearing was held at the Willeston Conference Centre in Wellington. Andrew Dyson presented for DuPont (the Applicant), Dr Ivy Robinson presented on behalf of the EPA staff. Oliver Sutherland and Gerry Te Kapa Coates presented on behalf of Te Rūnanga o Ngāi Tahu.
Applicant’s presentation

4.2. Andrew Dyson acknowledged the EPA Evaluation and Review Report was an accurate assessment of DuPont™ Zorvec® Enicade® fungicide. The only difference being EPA’s higher assessment of skin sensitivity compared with the application, but accepted the EPA’s classifications.

4.3. Downy mildew fungicide affects the crop by producing smaller onions and severely limiting storage life. Growers have a continued need for new fungicides. This is due to disease resistance, loss of older products on the market, and the emergence of new diseases. The Applicant said it was increasingly difficult to find a new product and that on average; more than 140,000 compounds must be evaluated in order to find one new product. Discovery to development of such a new product takes 8-10 years.

4.4. Mr Dyson stated that the Zorvec Enicade is an oil dispersible formulation containing a brand new active, oxathiapiprolin. The only proposed use for the product is on onions, targeting the fungicide downy mildew. The application rate is 350 mL/hectare (or 35 g active ingredient/ha), with the requirement of a protectant fungicide in a tank mix. There is a maximum of two applications used from early in the crop to up to ten days before harvest.

4.5. Zorvec Enicade is to be applied by ground boom, although aerial application may be applied for in the future. Oxathiapiprolin has a new, site-specific mode of action involving binding of the Zorvec Enicade molecule in the Oxysterol Binding Protein (OSBP) domain, and is highly selective against downy mildew. It delivers effective control and has a favourable environmental profile with no cross resistance.

4.6. Mr Dyson highlighted the advantages of reliable control, even under challenging environmental conditions. Zorvec Enicade was rain fast in 20 minutes of spray drying. It provided excellent disease control at low rates, crop safety and protected treated leaves as they grow and expand with no spread of disease. It also had compatibility with a wide range of products, and has a lower hazard classification than many existing fungicides.

4.7. Mr Dyson offered the apologies of Onions New Zealand Inc., who were unable to attend the Hearing, but delivered a letter of support. The DuPont presentation included the following quote: ‘While crop rotation and other cultural management techniques can assist in reducing the incidence of some major diseases and crops, this is not the case for downy mildew, considered the most invasive foliar disease of the crop.’ (DuPont emphasis)

4.8. The New Zealand onion industry has an export value of around $100 million and is the third equal largest fresh horticulture export crop. Approximately 5,000 ha are planted predominantly in Canterbury, Waikato and Hawke’s Bay. Onions comprise approximately 10% of the horticultural outdoor cropping area. Approximately 85% of New Zealand’s onion production is exported to 24 markets around the world. Mr Dyson highlighted that there would be reduced trade issues for exports as ten days’ post-application; the residues of Zorvec Enicade would be below the limit of qualification.

4.9. The Committee clarified the terminology of the product use as a protectant, not as an eradicant. The Applicant confirmed that the product is used early in the crop for better control and efficacy, prior to the
disease appearing and the germination of spores. After application, the product acted as an ongoing foliage protectant.

4.10. The Committee considered whether the product would be mixed with other products (tank mixes) and what the combined effects might be. Mr Dyson stated that the product’s mode of action means it is to be used with an accompanying protectant fungicide. He stated ‘on the label there is a compatibility section to include the tank mix partner when spraying and on page 4 of the label, with the warnings. Sequence is very important in tank mixing, powders first then liquids, which is clearly labelled.’

4.11. The Committee enquired about the impact of tank mixtures on aquatic toxicity. Mr Dyson said that none were expected. As with all mixtures and tank mixes with oxathiapiprolin, the aquatic toxicity will be driven by the mix partner. Consistent with the principle that synergy is not expected, synergy has not been observed with any oxathiapiprolin mixtures, such as famoxadone, dimethomorph, and folpet. Accordingly, aquatic effects will be consistent with those seen for the protectant fungicide being tank mixed.

4.12. The Committee enquired about the product’s approval status in other countries. Mr Dyson advised the product is registered in the USA, Canada, Mexico, Singapore, Australia, and South Korea. The registration in Japan is pending.

4.13. The Committee clarified from Mr Dyson that mancozeb would be the most common protectant fungicide used with Zorvec Enicade in the tank mix by New Zealand growers. It is dominant in the market as it is a cost effective protectant. As mancozeb has a higher hazardous substance classification than Zorvec Enicade, this was of concern to the Committee, as the presentation showed that over 1500 g ai/ha mancozeb versus 35 g ai/ha Zorvec Enicade was used. Mr Dyson stated that the Zorvec Enicade’s effective mode of action early in the growing season could beneficially see the need for less mancozeb later in the season.

4.14. Dr Sutherland queried the amount of chemical build up that occurs from Zorvec Enicade. Mr Dyson explained that because such low amounts were used per hectare and the majority of the product falls on the onions, any residues in the soil would be very small.

4.15. Mr Gerry Coates asked for an explanation of cross resistance. Mr Dyson said it is when a disease causing fungus has resistance to multiple compounds, each with a different mode of action, Mr Dyson said that he was aware that downy mildew in New Zealand had resistance to one substance and that there is anecdotal evidence of resistance to others, but there was no evidence that it was cross resistant to more than one substance at the same time.

Staff presentation

4.16. Dr Ivy Robinson addressed the Hearing confirming that DuPont™ Zorvec® Enicade® fungicide is to be used on downy mildew in onions and contains a new active to New Zealand, oxathiapiprolin. The Applicant will import the product in 1-5 litre containers. It will be transported by sea, rail and road, and stored in accordance with New Zealand Standard 8409:2004 Management of Agrichemicals.
4.17. Dr Robinson provided an overview of the Staff Report, which detailed the summary of the human health and environmental risk assessment, including a cultural assessment of the potential risks to Māori. Specifically, the Staff undertook quantitative modelling of risks to aquatic organisms and terrestrial flora and fauna. The results indicated that anticipated exposures are below levels that would cause adverse effects.

4.18. The Staff considered that adverse effects on Māori mahinga kai (traditional food sources) species are not expected. Further, they considered that there will not be any significant impact on culturally important Māori taonga species.

4.19. It is intended that the Zorvec Enicade be used by commercial growers and contractors familiar with safe practices for storing and handling pesticides. The Applicant intends that there would not be domestic or home use of the product by untrained users.

4.20. The human health risk assessment showed that risks to operators, re-entry workers, and bystanders would be negligible. The EPA Report stated that no personal protective equipment (PPE) was identified being required to reduce risks to an acceptable level. However, the EPA considers it appropriate to retain PPE requirements, due to the skin irritancy and contact sensitising properties of Zorvec Enicade.

4.21. Based on studies provided for the Zorvec Enicade fungicide formulation and the active ingredient oxathiapiprolin, the EPA determined that the skin irritancy classification should be 6.3A and not 6.3B proposed by the Applicant. Evidence of persistent desquamation (shedding of the outer layers of skin) was observed in a skin irritation study of the Zorvec Enicade fungicide.

4.22. The environmental risk assessment of the proposed use pattern of the product showed that acute and chronic risks to aquatic organisms, earthworms, sediment dwelling organisms, birds, bees and non-target arthropods, as well as the risk to ground water, are all below the levels of concern.

4.23. The Staff acknowledged that there may be uncertainty with respect to synergistic or antagonistic effects as a result of tank mixing pesticide formulations. The use of combinations of pesticide actives is standard agricultural practice used to minimise the total number of applications of substances. This practice is an aid in the management of pest resistance to pesticide actives. Pesticide actives are divided into compatibility groups to avoid known issues in tank mixes such as: loss of efficacy, physical effects, actives that are prone to developing cross resistance, or increase toxicity.

4.24. Dr Robinson stated that there was no information available that indicated that there is a risk to be managed from tank mixing that would not be covered by controls on Zorvec Enicade and the controls on the other substances included in tank mixes. It was pointed out that it may not be feasible or practicable to obtain data on all possible permutations and combinations of pesticides applied together in tank mixes.

4.25. Dr Robinson outlined that EPA staff considered that with their proposed controls the risks to human health and the environment were negligible. Default controls are triggered by the substance’s hazard
classifications and variations proposed to the default controls include setting the acceptable daily exposure (ADE) and potential daily exposure (PDE) values.

4.26. Additional controls were proposed under section 77A of the Hazardous Substances and New Organisms (HSNO) Act to provide better management of the risks of the substance. These additional controls are:

- maximum application rate of 350 mL formulated product/ha (equivalent to 35g oxathiapiprolin/ha), a maximum of two applications per growing season, and a minimum interval between applications of 10 full days
- restriction to ground-based application methods only and restriction against application onto or into water
- re-entry interval where PPE is required until the spray has dried
- label information to communicate these control requirements to users of the substance
- an impurity control on the level of methanol in the technical grade of oxathiapiprolin.

4.27. The Staff accepted that there will be financial benefits to some companies associated with the approval of Zorvec Enicade fungicide. The Staff concur with the Applicant the product will contribute benefits to growers and New Zealand trade.

4.28. Dr Oliver Sutherland queried whether the use pattern of use of Zorvec Enicade included assessment of tank mixes. Dr Robinson confirmed that they assessed how the product is applied, but not the other products used in the tank mix. Dr Robinson pointed out that under the HSNO Act for this approval the assessment cannot take into account tank mix additives or other actives.

4.29. Dr Sutherland added the concern that the ‘wider’ use pattern would include chemicals such as mancozeb as the protectant in the tank mix. He registered Ngāi Tahu’s primary concern that there had been no evaluation of the other substances to be included in tank mixes with Zorvec Enicade.

4.30. Dr Robinson stated that there is no information available in the application about potential effects from tank mixing Zorvec Enicade with other pesticide formulations. Further that there was no indication that there is a risk to be managed from tank mixing that would not be covered by controls on Zorvec Enicade and the controls of the other substances included in tank mixes.

Presentation provided by Te Rūnanga o Ngāi Tahu (Ngāi Tahu)

4.31. Dr Oliver Sutherland, presenting for Ngāi Tahu, stated they were concerned that the combinations of hazardous substances that were delivered by tank mix would cumulatively increase the risks on the environment. While Dr Sutherland conceded that Zorvec Enicade appeared to have low risk, its labelling did not specify which other hazardous substances were in the tank mixes, such as mancozeb.

4.32. He stated that as with other hazardous substance applications under the Act where he has submitted, there is a gap in the policy around tank mixes and that they are in need of better regulation. Dr Sutherland stated that the US EPA and Health Canada both had policies on tank mixes. He urged the Committee to look into this issue.
4.33. The Committee enquired whether the EPA Staff were aware of the US and Canadian policies and requested that Dr Sutherland table these to the Hearing.

Consideration

4.34. The following information was considered by the Committee:

- the application
- the submissions
- the Staff Report, including confidential information provided in the application
- information presented at the Hearing.

4.35. The Committee considered that it had received sufficient information to proceed with its consideration of the application. Further comments on different aspects of this information can be found in the sections following.

Hazard classifications

4.36. The Committee adopted the hazard classifications for the Zorvec Enicade as recommended by the Staff, based on the information provided by the Applicant and on other available information as documented in the Staff Report. This information included study data, as well as mixture rules calculations.

Table 1: Hazard classification of Zorvec Enicade fungicide

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<th>Hazard Endpoint</th>
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<tbody>
<tr>
<td>Skin irritation</td>
<td>6.3A</td>
</tr>
<tr>
<td>Contact sensitisation</td>
<td>6.5B</td>
</tr>
<tr>
<td>Biocidal action</td>
<td>9.1D</td>
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Identification of controls

4.37. The suite of controls proposed by the staff, and considered by the Committee was detailed in full in the Staff Report. The control suite included:

- default controls i.e. those triggered by the aquatic ecotoxicity hazard classification of Zorvec Enicade
- deletions, variations and additions to the default controls.

Staff risk assessment of Zorvec Enicade

4.38. The Committee took into account the Staff's risk assessment for Zorvec Enicade as detailed in the Staff Report.
Risks during use

Human health and environmental effects

4.39. The Committee noted that the Staff Report's human health risk assessments of Zorvec Enicade. The Staff's recommended re-entry controls, proposed to protect against activities that could lead to skin irritancy or sensitisation and which would make the risk acceptable were accepted by the Committee.

4.40. The Committee also noted that the Staff Report's environmental risk assessment results of the product are below levels of concern, and negligible.

Risks during other parts of the lifecycle

4.41. The Committee noted the Staff Report's risk assessments and that with the controls recommended in place, the level of risk would be negligible during the manufacture, packaging, importation, transport, storage, and disposal of the substance.

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

4.42. The Committee considered the overall level of risk, to society, the community and the market economy after taking into account the controls, would be negligible.

Review of additional controls and variations to default controls

4.43. The Committee considered that each of the additional controls and variations to default controls mentioned are either:

   a) more effective in terms of their effect on the management, use and risk of the substance; or
   b) more cost-effective in terms of their effect on the management, use, and risks of the substance; or
   c) more likely to achieve their purpose.

4.44. The full suite of controls, including variations, can be found in Appendix A of this document.

4.45. At the hearing the Applicant was given an opportunity to comment on the proposed controls as set out in the Staff Report. The Applicant agreed with the controls.

Assessment of benefits

4.46. The Applicant referred to several benefits of the substance in the application and elaborated on these at the hearing. The EPA staff also provided some information to support these claims. These benefits included the following:

   • The active ingredient in Zorvec Enicade has a different mode of action to currently available products for fungicide control.
   • The product is a useful additional option for resistance management.
   • Zorvec Enicade will provide a benefit to growers by improved crop performance and better storage life.

4.47. After considering the information that was presented, the Committee considered that there are benefits that will be derived for New Zealand by approving the use of Zorvec Enicade.
Other relevant matters to be taken into account

Retrospectively imposing controls on existing approvals

4.48. The Committee noted during the Hearing that other hazardous substances would be used in combination with Zorvec Enicade. The approvals of some older substances mentioned predate the Act. Consequently, there is limited ability able to impose controls on prior substance approvals particularly as part of this application process. This can only be done via application and re-approval assessments, or through a change of legislation.

Tank Mixes and Labelling

4.49. The Committee acknowledged that standard agricultural practices use combinations of pesticide actives. Fewer applications are driven by the growers need to minimise costs for maximum efficiency and minimal environmental profile.

4.50. The Committee acknowledged the issue of tank mixes and labelling with multiple substances is a known potential risk, and an area in which more clarity on control and process could be beneficial. They agree that there is a gap in the policy framework and the issues are complex, especially with numerous chemical substance combinations.

4.51. The Committee recommends that the EPA Staff review the Canadian and US tank mix label policies (tabled at the Hearing by Oliver Sutherland) and assess whether the EPA should develop a similar policy and report their findings to the HSNO Committee.

Relationship of Māori to the Environment

4.52. The Committee was satisfied that the risk assessment undertaken by EPA staff was robust, based on best available information and was consistent with international standards.

4.53. Based on the information provided, including the use patterns, and the proposed changes in controls as recommended in Appendix A, the Committee considered the impact of Zorvec Enicade on the relationship of Māori to the environment will be negligible. With this assessment in mind the Committee considered that the application is consistent with the principles of the Treaty of Waitangi.

New Zealand’s international obligations

4.54. The Committee did not identify any international obligations that may be impacted by the approval of Zorvec Enicade.

5. Conclusion

5.1. Taking into account the assessment of the potential risks and benefits associated with Zorvec Enicade, the Committee considered that, with all of the controls in place:

- the overall risks to human health and the environment arising from the hazardous properties and the use of Zorvec Enicade are negligible.
• significant adverse impacts on the social or economic environment from the use of Zorvec Enicade are not anticipated.
• significant impacts on Māori culture or traditional relationships with valued flora and fauna that will breach the principles of the Te Tiriti o Waitangi/Treaty of Waitangi are not anticipated
• benefits will be derived for New Zealand by allowing the use of Zorvec Enicade.

6. Recommendation

6.1 The Committee recommends that the EPA Staff review the Canadian and US tank mix label policies and assess whether the EPA should develop a similar policy and report their findings to the HSNO Committee.

7. Decision

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

7.2. The Committee was satisfied with the hazard classifications identified in Table 1 and has applied these classifications to Zorvec Enicade fungicide.

7.3. The Committee considered that, with controls in place, the overall risks associated with the use of Zorvec Enicade are negligible. The Committee considered that the benefits associated with the use of Zorvec Enicade are non-negligible and are considered to outweigh the negligible risks presented by Zorvec Enicade.

7.4. Therefore, the Committee approved the application for importation and manufacture of the hazardous substance Zorvec Enicade with the controls as listed in Appendix A.

Dr Kerry Laing
Date: 14 April 2016
Chair, Decision Making Committee
Environmental Protection Authority
Appendix A: Controls applying to Zorvec® Enicade® fungicide

Please refer to the Hazardous Substances Regulations\(^1\) for the requirements prescribed for each control.

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

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<thead>
<tr>
<th>Code</th>
<th>Regulation</th>
<th>Description</th>
<th>Variation</th>
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</table>
| T1   | 11-27      | Limiting exposure to toxic substances through the setting of TELs | No TEL values are set for any component of this substance at this time. The following ADE and PDE values have been set for oxathiapiprolin:  
ADE = 1.04 mg/kg bw/d  
PDE(food) = 0.728 mg/kg bw/d  
PDE(drinking water) = 0.208 mg/kg bw/d  
PDE(other) = 0.104 mg/kg bw/d |
| T2   | 29,30      | Controlling exposure in places of work through the setting of WESs | No WES values have been set for any component of this substance at this time. |
| 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 | The maximum quantity of the substance that can be carried on a passenger service vehicle is 1 L per package |
| E1   | 32-45      | Limiting exposure to ecotoxic substances through the setting of EELs | No EEL values are set for this substance at this time and the default EELs are deleted |
| E6   | 7          | Requirements for equipment used to handle substances | |

### Hazardous Substances (Identification) Regulations 2001

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<th>Code</th>
<th>Regulation</th>
<th>Description</th>
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<td>I1</td>
<td>6, 7, 32-35, 36(1) – (7)</td>
<td>Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability</td>
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\(^1\) The regulations can be found on the New Zealand Legislation website: [http://www.legislation.co.nz](http://www.legislation.co.nz)
### Decision on application for approval to import or manufacture DuPont Zorvec Enicade Fungicide (APP202567)

<table>
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<th>Description</th>
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<td>Use of generic names</td>
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<td>27</td>
<td>Requirements for using concentration ranges</td>
<td></td>
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<tr>
<td>I19</td>
<td>29-31</td>
<td>Additional information requirements, including situations where substances are in multiple packaging</td>
<td></td>
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<tr>
<td>I21</td>
<td>37-39, 47-50</td>
<td>General documentation requirements</td>
<td></td>
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<td>I28</td>
<td>46</td>
<td>Specific documentation requirements for toxic substances</td>
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<tr>
<td>I29</td>
<td>51-52</td>
<td>Signage requirements</td>
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</table>

### Hazardous Substances (Packaging) Regulations 2001

<table>
<thead>
<tr>
<th>Code</th>
<th>Regulation</th>
<th>Description</th>
<th>Variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>5-7(1),8</td>
<td>General packaging requirements</td>
<td></td>
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<tr>
<td>P3</td>
<td>9</td>
<td>Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria</td>
<td></td>
</tr>
<tr>
<td>P13</td>
<td>19</td>
<td>Packaging requirements for toxic substances</td>
<td></td>
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<tr>
<td>PS4</td>
<td>Schedule 4</td>
<td>Packaging requirements as specified in Schedule 4</td>
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### Hazardous Substances (Disposal) Regulations 2001

<table>
<thead>
<tr>
<th>Code</th>
<th>Regulation</th>
<th>Description</th>
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</tr>
</thead>
<tbody>
<tr>
<td>D4</td>
<td>8</td>
<td>Disposal requirements for toxic and corrosive substances</td>
<td></td>
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<tr>
<td>D5</td>
<td>9</td>
<td>Disposal requirements for ecotoxic substances</td>
<td></td>
</tr>
<tr>
<td>D6</td>
<td>10</td>
<td>Disposal requirements for packages</td>
<td></td>
</tr>
<tr>
<td>D7</td>
<td>11.12</td>
<td>Information requirements for manufacturers, importers and suppliers, and persons in charge</td>
<td></td>
</tr>
<tr>
<td>D8</td>
<td>13,14</td>
<td>Documentation</td>
<td></td>
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</tbody>
</table>
### Decision on application for approval to import or manufacture DuPont Zorvec Enicade Fungicide (APP202567)

April 2016

<table>
<thead>
<tr>
<th>Code</th>
<th>Regulation</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>requirements for manufacturers, importers and suppliers, and persons in charge</td>
</tr>
</tbody>
</table>

### Hazardous Substances (Emergency Management) Regulations 2001

<table>
<thead>
<tr>
<th>Code</th>
<th>Regulation</th>
<th>Description</th>
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<tbody>
<tr>
<td>EM1</td>
<td>6, 7, 9 – 11</td>
<td>Level 1 information requirements for suppliers and persons in charge</td>
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<tr>
<td>EM6</td>
<td>8(e)</td>
<td>Information requirements for toxic substances</td>
</tr>
<tr>
<td>EM7</td>
<td>8(f)</td>
<td>Information requirements for ecotoxic substances</td>
</tr>
<tr>
<td>EM8</td>
<td>12 – 16, 18 – 20</td>
<td>Level 2 information requirements for suppliers and persons in charge</td>
</tr>
<tr>
<td>EM11</td>
<td>25 – 34</td>
<td>Level 3 emergency management requirements: duties of person in charge, emergency response plans</td>
</tr>
<tr>
<td>EM12</td>
<td>35 – 41</td>
<td>Level 3 emergency management requirements: secondary containment</td>
</tr>
</tbody>
</table>

The following sub clauses are added after sub clause (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 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
The following sub clauses 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 sub clause (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 sub clauses 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 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.
Decision on a Application for approval to import or manufacture DuPont Zorvec Enicade Fungicide (APP202567)

<table>
<thead>
<tr>
<th>Code</th>
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<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(3) Pooling substances to which sub clause (2) applies must be segregated where appropriate to ensure that the leakage of one substance may not adversely affect the container of another substance.</td>
</tr>
</tbody>
</table>

EM13 42 Level 3 emergency management requirements: signage

Hazardous Substances (Tank Wagon and Transportable Containers) Regulations 2004

<table>
<thead>
<tr>
<th>Code</th>
<th>Regulation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tank Wagon</td>
<td>4 to 43 as applicable</td>
<td>Controls relating to tank wagons and transportable containers</td>
</tr>
</tbody>
</table>

Additional controls

<table>
<thead>
<tr>
<th>Code</th>
<th>Section of the Act</th>
<th>Description</th>
<th>Variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Section 77A</td>
<td>The substance must not be applied into or onto water</td>
<td>This substance must not be applied into or onto water.³</td>
</tr>
</tbody>
</table>

application rate | Section 77A | A maximum application rate is set for this substance | The person in charge of the application of this substance, and any person applying the substance, must ensure that the application is carried out in accordance with the following restrictions:  
- the substance must not be applied at rates exceeding 350 mL of formulated product/ha per application (equivalent to 0.035 kg oxathiapiprolin /ha); and  
- the substance must not be applied to the same area more than two times per year; and  
- an interval of at least 10 full days must be observed before the substance is reapplied to the same area. |

Method | Section 77A | The method of application of the substance shall be limited to ground based application only | The application of this substance is limited to ground-based⁴ application methods only. |

Re-entry | Section 77A | Restrictions on re-entry to the treated area have been specified | The person in charge of the application must ensure that no person enters a treated area after the application of this substance until the spray has dried, unless the person entering the application area is wearing personal protective equipment. |
### Decision on Application for Approval to Import or Manufacture DuPont Zorvec Enicade Fungicide (APP202567)

#### Label

<table>
<thead>
<tr>
<th>Code</th>
<th>Section of the Act</th>
<th>Description</th>
<th>Variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Label</td>
<td>Section 77A</td>
<td>Additional label information has been specified</td>
<td>The label for this substance must contain information about the following:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- The maximum application rate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- The maximum number of applications</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- The minimum interval between applications</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- The restriction to ground-based application methods</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- The restriction against application to water</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- The re-entry period</td>
</tr>
</tbody>
</table>

#### Impurity

<table>
<thead>
<tr>
<th>Code</th>
<th>Section of the Act</th>
<th>Description</th>
<th>Variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impurity</td>
<td>Section 77A</td>
<td>A maximum level of an impurity has been set for the technical grade active ingredient of this substance</td>
<td>The maximum level of methanol in the oxathiapiprolin component of DuPont Zorvec Enicade Fungicide is set at 1 g/kg.</td>
</tr>
</tbody>
</table>

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3 where '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 or water used to rinse the container after use.

4 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.