

Decision

April 2021

Item	Detail
Substance	Tebuconazole and Propiconazole
Request number	APP204030
Request type	To decide whether there are grounds for reassessment under the Hazardous Substances and New Organisms Act 1996 (“the Act”/“the HSNO Act”)
Applicant	Environmental Protection Authority
Purpose of the request	To assess whether grounds exist for a reassessment of tebuconazole and propiconazole
Date request received	8 March 2021
Consideration Date	15 - 26 April 2021
Considered by	A Decision-making Committee of the Environmental Protection Authority (“EPA”)
Decision	Grounds exist for the reassessment of tebuconazole and propiconazole

1. Background

The hazardous substances, tebuconazole and propiconazole (“the substances”) are active ingredients used as fungicides. They both belong to the same family, the triazole group, and were approved under the HSNO Act on 1 July 2006 via the Hazardous Substances (Chemicals) Transfer Notice 2006. They have the Hazardous Substances and New Organisms (HSNO) Approval Numbers HSR002879 and HSR003109 respectively.

Currently 104 substances containing tebuconazole are approved under the HSNO Act. Most products containing tebuconazole are used as timber treatments, however, 26 trade name products corresponding to 22 HSNO approved substances are currently registered with the Ministry for Primary Industries’ Agricultural Compounds and Veterinary Medicines group (ACVM). Products registered with ACVM are used on cereals (barley, wheat, oat, rye, corn, triticale), pasture and ryegrass, pome and stone fruits, kiwifruit, grapes, onion, pea and ornamental plants.

Currently 79 substances containing propiconazole are approved under the HSNO Act. Most products containing propiconazole are timber treatments, however, six trade name products corresponding to five HSNO approved substances are currently registered with ACVM. These registered products are used on cereals (barley, wheat, oat), pasture and ryegrass, pome fruits, olive, kiwifruit, avocado, and turf.

Details of all currently approved substances that contain tebuconazole and propiconazole are listed in Table 1 and 2 respectively, including details of corresponding products registered with ACVM. Any future reassessment application will include full details of the scope of the reassessment and which substances are included. The reassessment may cover all or some of the substances listed in Tables 1 and 2, as well as any other substances containing tebuconazole and/or propiconazole, including those that are approved in the interim period between this grounds application and receipt of the reassessment application.

Table 1: Products containing tebuconazole

Chemical Name	HSNO Approval Number	ACVM Registered Product Name (if applicable)	ACVM Registrant (if applicable)
Protim Optimum	HSR000006	-	-
Vacsol Azure	HSR000007	-	-
TimTech AZ	HSR000093	-	-
Copper Naphthenate Formulation Type 3	HSR000128	-	-

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Chemical Name	HSNO Approval Number	ACVM Registered Product Name (if applicable)	ACVM Registrant (if applicable)
Copper Naphthenate Formulation Type 4	HSR000129	-	-
TimTech AZUS	HSR000132	-	-
Water dispersible granule containing 250 g/kg tebuconazole	HSR000511	-	-
Suspension containing 10 g/litre tebuconazole	HSR000519	PruneTec, Vistaseal	Max Stanton Moore, TRS BIO Limited
Flowable concentrate containing 25 g/litre tebuconazole	HSR000520	RAXIL	Bayer New Zealand Limited
Emulsion or suspension concentrate containing 250 - 430 g/litre tebuconazole	HSR000751	FOLICUR SC, Orius Fungicide, Orius Fungicide	Bayer New Zealand Limited, Adama New Zealand Limited, Kenso Corporation (M) Sdn Bhd
Emulsifiable concentrate containing 292 g/litre copper carbonate, 64 g/litre boric acid and 6.4 g/litre tebuconazole	HSR000853	-	-
Emulsifiable concentrate containing 8.65 g/litre tebuconazole and 465 g/litre didecyl dimethyl ammonium chloride	HSR000863	-	-
Emulsifiable concentrate containing 279 g/litre propiconazole and 279 g/litre tebuconazole	HSR000882	-	-
J57.10A	HSR000945	-	-
J57.10B	HSR000955	-	-

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Chemical Name	HSNO Approval Number	ACVM Registered Product Name (if applicable)	ACVM Registrant (if applicable)
J57.10C	HSR000974	-	-
Taratek 1995	HSR001762	-	-
Protim Optimum II	HSR002441	-	-
Protim Optimum III	HSR002442	-	-
TF3 Substance A	HSR002459	-	-
TF3 Substance B	HSR002460	-	-
J57.23A	HSR007640	-	-
J57.23B	HSR007641	-	-
J57.23C	HSR007642	-	-
J57.23D	HSR007643	-	-
J57.23E	HSR007644	-	-
J57.23F	HSR007645	-	-
J57.23G	HSR007646	-	-
J57.23H	HSR007647	-	-
J57.23I	HSR007648	-	-
J57.23J	HSR007649	-	-
J57.23K	HSR007650	-	-
J57.23L	HSR007651	-	-
Hornet 430SC	HSR007675	Hornet 430SC, Compass, AGPRO Tebuconazole 430 SC, SILVZOLE	Nufarm Limited, Agsin Pte Ltd, Agpro (NZ) Ltd, Shandong Rainbow International Co., Ltd.

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Chemical Name	HSNO Approval Number	ACVM Registered Product Name (if applicable)	ACVM Registrant (if applicable)
Liquid containing 70 - 120 g/litre boric acid, 140 - 180 g/litre copper carbonate and 1 - 10 g/litre tebuconazole	HSR007733	-	-
Axis Gold	HSR007767	Axis Gold	Lonza NZ Limited
Wocosen ME-3WP	HSR007772	-	-
Protim Aquazole Concentrate	HSR007777	-	-
PROTIM Aquazole Ready-to-use	HSR007778	-	-
Myco-RF	HSR007810	MYCO-RF	Donaghys Limited
Prosaro	HSR007871	Prosaro	Bayer New Zealand Limited
Folicur WG	HSR007887	Folicur WG	Bayer New Zealand Limited
GELSEAL	HSR007920	-	-
TNL2436	HSR007948	-	-
ORD-X370 plus TEB EC25 - Option 1	HSR007958	-	-
ORD-X370 plus TEB EC25 - Option 2	HSR007959	-	-
ORD-X370 plus TEB EC25 - Option 3	HSR007960	-	-
TEB EC25	HSR007961	-	-
Eurogel	HSR100023	-	-
Preventol A20-CT30	HSR100041	-	-

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Chemical Name	HSNO Approval Number	ACVM Registered Product Name (if applicable)	ACVM Registrant (if applicable)
Preventol A20	HSR100042	-	-
IV 64 WB Timber Concentrate	HSR100111	-	-
Tebuconazole emulsifiable concentrate 50g/kg	HSR100128	-	-
Greenseal Ultra	HSR100149	Greenseal Ultra	PGG Wrightson Limited
Premix B	HSR100274	-	-
Premix BR	HSR100275	-	-
J57.41	HSR100280	-	-
StemCap KF-2	HSR100345	-	-
Envy	HSR100365	Envy	Agpro (NZ) Ltd
Falcon	HSR100368	-	-
J57.47	HSR100405	-	-
J57.52	HSR100482	POLYRAM DF, MetiGro	BASF New Zealand Ltd, Grosafe Chemicals Ltd
J57.48A Concentrate	HSR100503	-	-
J57.48B-RTU	HSR100504	-	-
J57.55	HSR100582	-	-
XYLA Concentrate	HSR100591	-	-
J57.56	HSR100617	-	-
WBA Concentrate	HSR100640	-	-
J57.58A	HSR100656	-	-

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Chemical Name	HSNO Approval Number	ACVM Registered Product Name (if applicable)	ACVM Registrant (if applicable)
J57.58B	HSR100657	-	-
J57.59	HSR100689	-	-
J57.65A	HSR100749	-	-
J57.65B	HSR100750	-	-
J57.63	HSR100802	-	-
ORD-X170 revised	HSR100809	-	-
Capri	HSR100862	Capri	Agsin Pte Ltd
J57.67	HSR100930	-	-
Osmose Protim Aquazole	HSR100940	-	-
Raxil Ultra	HSR100943	Raxil Ultra	Bayer New Zealand Limited
Protim Optimum CA	HSR100985	-	-
Tnl 3215	HSR100987	-	-
Gelseal Ultra	HSR101006	Gelseal Ultra Spray-On	PGG Wrightson Limited
Elito	HSR101009	Elito, GENFARM TEBUCONAZOLE 430 FUNGICIDE	Global Agrichem Limited, LANDMARK OPERATIONS LIMITED
J57.74	HSR101046	-	-
ORD-X170S	HSR101093	-	-
Raxil Star	HSR101132	Raxil Star	Bayer New Zealand Limited
Unicorn	HSR101162	-	-

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Chemical Name	HSNO Approval Number	ACVM Registered Product Name (if applicable)	ACVM Registrant (if applicable)
Soluble Copper Azole	HSR101208	-	-
Protim Optimum HF 0.6%	HSR101265	-	-
ORD-X46P	HSR101272	-	-
ORD-X46S	HSR101275	-	-
Kestrel	HSR101293	Kestrel	Bayer New Zealand Limited
Protim Optimum HFII	HSR101305	-	-
Protim Optimum HFII 2.0%	HSR101307	-	-
Prune Seal (new formulation)	HSR101311	Prune Seal	Adria New Zealand Ltd
BUZZ ULTRA 750 WG FUNGICIDE	HSR101335	VISTA	Agsin PTE Ltd
J57.81	HSR101394	-	-
GPFC-RTU 424	HSR101395	-	-
Protim Optimum LO 0.6%	HSR101403	-	-
Protim Optimum LO 2.0%	HSR101404	-	-
Protim Optimum PTB 0.6%	HSR101405	-	-
Protim Optimum PTB 2%	HSR101406	-	-
Custodia	HSR101411	Custodia	Adama New Zealand Limited

Table 2: Products containing propiconazole

Chemical Name	HSNO Approval Number	ACVM Registered Product Name (if applicable)	ACVM Registrant (if applicable)
Soluble concentrate containing 500 g/litre benzalkonium chloride, 50 g/litre iodocarb and 50 g/litre propiconazole	HSR000876	-	-
Emulsifiable concentrate containing 279 g/litre propiconazole and 279 g/litre tebuconazole	HSR000882	-	-
Soluble concentrate containing 500 g/litre benzalkonium chloride, 50 g/litre guazatine and 50 g/litre propiconazole	HSR000884	-	-
Emulsifiable concentrate containing 100 g/litre propiconazole	HSR000894	-	-
Emulsifiable concentrate containing 240 g/litre didecyl dimethyl ammonium chloride and 48 g/litre propiconazole	HSR000895	-	-
Soluble concentrate containing 86 g/litre boric acid, 50.5 g/litre fenpropimorph and 24.8 g/litre propiconazole	HSR000896	-	-
Protim Optimum	HSR000006	-	-
Vacsol Azure	HSR000007	-	-
Emulsifiable concentrate containing 250 g/litre propiconazole. Also contains hydrocarbon liquids (Substance B)	HSR000580	TILT EC	Syngenta Crop Protection Ltd

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Chemical Name	HSNO Approval Number	ACVM Registered Product Name (if applicable)	ACVM Registrant (if applicable)
Emulsifiable concentrate containing 250 g/litre propiconazole (Substance A)	HSR000596	Aurora Fungicide	Adama New Zealand Limited
Emulsifiable concentrate containing 250 g/litre propiconazole. Also contains hydrocarbon liquids (Substance A)	HSR000597	-	-
Emulsifiable concentrate containing 250 g/litre propiconazole. Also contains toluene	HSR000601	Pro-P	Orion Agriscience Limited
Emulsifiable concentrate containing 250 g/litre propiconazole (Substance B)	HSR000721	-	-
Liquid containing 450 - 550 g/litre propiconazole	HSR100339	-	-
Bazooka	HSR000117	-	-
TimTech AZUS	HSR000132	-	-
TimTech AZ	HSR000093	-	-
J57.10A	HSR000945	-	-
J57.10B	HSR000955	-	-
J57.10C	HSR000974	-	-
TF3 Substance A	HSR002459	-	-
Taratek 1995	HSR001762	-	-
Procure	HSR001740	-	-
TF3 Substance B	HSR002460	-	-

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Chemical Name	HSNO Approval Number	ACVM Registered Product Name (if applicable)	ACVM Registrant (if applicable)
STEMSHOT KF-1	HSR002471	-	-
Protim Optimum II	HSR002441	-	-
Protim Optimum III	HSR002442	-	-
Spotless	HSR007857	Spotless	PGG Wrightson Limited
Wocosen 15TK	HSR100007	-	-
Wocosen ME-3WP	HSR007772	-	-
Protim Aquazole Concentrate	HSR007777	-	-
PROTIM Aquazole Ready-to-use	HSR007778	-	-
J57.23A	HSR007640	-	-
J57.23B	HSR007641	-	-
J57.23C	HSR007642	-	-
J57.23D	HSR007643	-	-
J57.23E	HSR007644	-	-
J57.23F	HSR007645	-	-
J57.23G	HSR007646	-	-
J57.23H	HSR007647	-	-
J57.23I	HSR007648	-	-
J57.23J	HSR007649	-	-
J57.23K	HSR007650	-	-

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Chemical Name	HSNO Approval Number	ACVM Registered Product Name (if applicable)	ACVM Registrant (if applicable)
J57.23L	HSR007651	-	-
TNL2436	HSR007948	-	-
IV 64 WB Timber Concentrate	HSR100111	-	-
J57.41	HSR100280	-	-
Headway	HSR100366	-	-
Instrata	HSR100388	-	-
Premix B	HSR100274	-	-
Premix BR	HSR100275	-	-
J57.47	HSR100405	-	-
J57.48A Concentrate	HSR100503	-	-
J57.48B-RTU	HSR100504	-	-
J57.52	HSR100482	-	-
RotStop	HSR100605	-	-
J57.55	HSR100582	-	-
J57.56	HSR100617	-	-
WBA Concentrate	HSR100640	-	-
J57.58A	HSR100656	-	-
J57.58B	HSR100657	-	-
J57.59	HSR100689	-	-
J57.63	HSR100802	-	-

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Chemical Name	HSNO Approval Number	ACVM Registered Product Name (if applicable)	ACVM Registrant (if applicable)
Osmose Protim Aquazole	HSR100940	-	-
Tnl 3215	HSR100987	-	-
Protim Optimum CA	HSR100985	-	-
Prozole	HSR101041	PROZOLE, Condor	Shandong Rainbow International Co., Ltd., Agri Solutions Ltd
J57.74	HSR101046	-	-
Hylite NCF	HSR101201	-	-
Protim Optimum HF 0.6%	HSR101265	-	-
Propistrong	HSR101283	-	-
Protim Optimum HFII	HSR101305	-	-
Protim Optimum HFII 2.0%	HSR101307	-	-
J57.81	HSR101394	-	-
Protim Optimum LO 0.6%	HSR101403	-	-
Protim Optimum LO 2.0%	HSR101404	-	-
Protim Optimum PTB 0.6%	HSR101405	-	-
Protim Optimum PTB 2%	HSR101406	-	-

The EPA has applied for grounds to reassess tebuconazole and propiconazole in order to update the classifications of the substances.

The purpose of this request is to decide whether there are grounds for the reassessment of the substances.

2. Request process

The request was formally received by the EPA on 8 March 2021 and the information supplied evaluated by EPA staff.

The request was considered on 23 April 2021 by a Decision-making Committee (the “Committee”) of the EPA.

3. Legislative Criteria

The Act specifies a number of factors that the EPA has to take into account when considering whether grounds exist for a reassessment. At least one of these factors must be present before the EPA can use its discretion to determine whether there are grounds for a reassessment.

Significant new information relating to the effects of the substance has become available (section 62(2)(a))

The EPA provided details of recent reports from key international regulatory agencies. These reports include European Food Safety Authority (EFSA) pesticide risk assessments and the European Chemicals Agency (ECHA) Committee for Risk Assessment (RAC) harmonised classification opinions. Key information on the type of hazards identified and the regulatory outcome is highlighted in the grounds for reassessment request. The reports were published between 2007 and 2017.

The information is contained in the following regulatory reports:

Tebuconazole

- European Food Safety Authority (EFSA). (2014). *Conclusion on the peer review of the pesticide risk assessment of the active substance tebuconazole*¹
- European Chemicals Agency Risk Assessment Committee (ECHA RAC). (2013). *Opinion: Proposing harmonised classification and labelling at EU level of tebuconazole*²
- Environmental Protection Authority (EPA). (2017). *Science Memorandum: App203305 – Scorpio Ornamental Fungicide*³

Propiconazole

- European Food Safety Authority (EFSA). (2016). *Peer review of the pesticide risk assessment of the active substance propiconazole*⁴
- European Chemicals Agency Risk Assessment Committee (ECHA RAC). (2016). *Opinion: Proposing harmonised classification and labelling at EU level of propiconazole (ISO)*;

¹ <https://www.efsa.europa.eu/en/efsajournal/pub/3485>

² <https://echa.europa.eu/documents/10162/41e9d7aa-4559-f904-9cb5-0a0d5f0d6445>

³ [APP203305-Science-Memorandum.pdf \(epa.govt.nz\)](https://www.epa.govt.nz/APP203305-Science-Memorandum.pdf)

⁴ <https://www.efsa.europa.eu/en/efsajournal/pub/4887>

(2RS,4RS;2RS,4SR)-1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole⁵

The EFSA risk assessment documents contain reviews of both the toxicological and ecotoxicological properties of tebuconazole and propiconazole.

The ECHA RAC documents contain information relating to the updating of classifications for propiconazole and tebuconazole, including toxicological and ecotoxicological properties.

The EPA Science Memorandum summarises the data supplied to the EPA in regards to the reasoning behind the addition of a reproductive toxicity classification for tebuconazole. Details of these summaries are discussed in Appendix C of the memorandum.

The Committee considered that the information provided is “significant” because it contains information on the toxicological and ecotoxicological effects of the substances, including the reproductive toxicity of both tebuconazole and propiconazole, and skin sensitisation of propiconazole.

The Committee also noted that the information supplied was published during 2007 to 2017 and was therefore not available during the initial approval of the substance. Therefore the Committee considered it to be “new” information.

A change in controls under the Health and Safety at Work Act 2015 (section 62(2)(aa))

This factor is not relevant to this request.

Another substance with similar or improved beneficial effects and reduced adverse effects has become available (section 62(2)(b))

This factor is not relevant to this request.

Information showing a significant change of use, or a significant change in the quantity manufactured, imported, or developed has become available (section 62(2)(c))

This factor is not relevant to this request.

Other reasons for requesting a reassessment under section 62(2)

This factor is not relevant to this request.

4. Achieving the purpose of the Act

The Committee has considered all relevant matters in Part 2 of the Act in the context of determining whether there are grounds to reassess this substance. In particular, the following considerations from sections 6, 7 and 8 have been taken into account.

- a) the sustainability of all native and valued introduced flora and fauna
- b) the intrinsic value of ecosystems

⁵ <https://echa.europa.eu/documents/10162/723fe08d-2ec7-105b-51aa-05064bd91ac3>

- c) public health
- d) the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna, and other taonga
- e) the economic and related benefits and costs of using a particular hazardous substance or new organism
- f) New Zealand's international obligations
- g) the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects; and
- h) the principles of the Treaty of Waitangi (Te Tiriti o Waitangi)

The Committee noted that, if this request is approved and a subsequent reassessment is applied for, these matters will also be considered in the context of that application.

5. Consideration

The Committee considered that there is significant new information relating to the effects of the substance in view of the reviews undertaken by competent authorities in the EU and their published reports.

Taking that into account, the Committee considered that grounds exist under section 62 of the Act for the reassessment of Tebuconazole and Propiconazole, on the basis that significant new information about the effects of the substance has become available (section 62(2)(a)).

<i>Signed by:</i>	Date: 26 April 2021
Tipene Wilson Chair, Decision-making Committee Environmental Protection Authority	