Application for a Reassessment

Under section 63 and 63A of the Hazardous Substances and New Organisms Act 1996

November 2021

To apply for an EPA Reassessment of a hazardous substance: to reassess its approval for use in New Zealand, to modify its controls and/or to change the official description of the substance

Send to Environmental Protection Authority, preferably by email (reassessments@epa.govt.nz) or alternatively by post (Private Bag 63002, Wellington 6140)

We will send an invoice once we have assessed whether a full or modified reassessment is required - see our Fees and Charges schedule for details of the fees for full and modified reassessments.

Completing this application form

Getting advice

1. Contact an Advisor at the Environmental Protection Authority (EPA) as early as possible. We can help you with any questions during the preparation of your application, including assisting with on any consultation requirements. Please contact reassessments@epa.govt.nz for assistance.

Do you have the right form?

2. Before you can apply for a reassessment, there must be a formal decision from the EPA that grounds for reassessment ('grounds') exist. If grounds have not been established, please complete and submit the Grounds for Reassessment application form on our website - we will contact you if we need more information.
3. If the proposed change to the approval is minor in effect or corrects a technical error, please complete the Minor Amendment request form on our website.

Types of reassessment and notifying the public and other parties

4. A reassessment can be a 'full' reassessment (under section 63 of the HSNO Act) or a 'modified' reassessment (under section 63A of the HSNO Act). This form covers both types. We will determine which type of reassessment is most appropriate for the change that you wish to make after we receive your application and before we contact you to let you know that your application is formally received.
5. We may decide to process your application as a modified reassessment if we consider that a full reassessment of the hazardous substance is not appropriate. We generally make this decision if the reassessment will only involve a specific aspect of the substance's existing approval.
6. Applications for reassessments of hazardous substances are usually publicly notified – this means we let the public know that we have received an application for the reassessment of a hazardous substance and they will be given a chance to submit relevant information for consideration during the decision-making process[1].
7. We may opt for targeted notification if we are satisfied that your application meets the criteria under section 63A(5) of the HSNO Act, and if this is more practical and/or cost-effective than publicly notifying the application. During targeted notifications, we identify and consult with all affected parties and give them a reasonable opportunity to supply relevant information for consideration during the decision-making process.

[1] An application for a full reassessment (i.e. submitted under section 63 of the HSNO Act 1996) will be publicly notified, as is required under section 53 of the HSNO Act. An application for a modified reassessment (i.e. submitted under section 63A of the HSNO Act) will be publicly notified unless we are satisfied that it meets the criteria for targeted notification under section 63A(5).

Completing this form

8. The EPA will use the information you provide in this form to consider your application for a reassessment, as covered by section 63 and 63A of the Hazardous Substances and New Organisms Act 1996.
9. If you are supplying information or data with this application that does not belong to you, please ensure that you have permission from the owner of the information or data.
10. Please complete all sections of this form, unless we indicate that they are optional. We cannot formally receive or process your application unless you provide all of the information requested in the mandatory sections of this form. If a section is not relevant to your application, please provide a comprehensive explanation why this does not apply. If you choose not to provide the requested information, you must apply for a waiver[2] by completing the section on the last page of this form.
11. This form is designed to gather the information needed to understand and assess your application, and for interested parties to understand the purpose of the application and how their interests may be affected. We may ask for additional information to help us understand the proposed change and the potential effects of the change. We will endeavour to identify these further information requirements before the application is formally received and publicly notified. Please note that we may request additional information from you or any other source at any time during the application process.
12. You must sign this application form (the EPA will accept electronically signed forms) and send it to us preferably by email (reassessments@epa.govt.nz) or alternatively by post (Private Bag 63002, Wellington 6140).
13. Once we have received your application, we will send you an acknowledgement by email with your assigned application number. We will then decide whether your application will proceed as a modified or full reassessment, and issue an invoice for the appropriate fee. Information about application fees is available on the EPA website.
14. We will email when we need to contact you about your application unless you ask otherwise.

Privacy

15. You have the right to access and correct any personal information in connection with your application under the Privacy Act 1993.
16. Information provided as part of this application is collected by the EPA for the purpose of administering the application for a reassessment. This includes informing the public of applications. We may also contact you for feedback on the application process using a third party provider.

[2] Section 59(3)(a)(ii) of the HSNO Act allows applicants to apply for the EPA to waive the need to supply information.

Commercially sensitive information

17. We strongly advise applicants to provide as much information as possible about the substance and its use. This information helps our assessment and informs the decision-makers.
18. To prevent delays in processing the application, all available information on the substance and active ingredient/s must be provided with your application form. We expect this information will be made publicly available with the application unless there is a genuine reason for it to be considered commercially sensitive.
19. Where scientific studies or other reports are provided and deemed commercially sensitive, a summary of each study or report, its methods and results should be provided as publicly-available information.
20. Commercially-sensitive information may be identified as confidential by placing it in an approved EPA Confidential Appendix form that is separate to this form (also available on our website). Show this in the relevant section of this form by giving your detailed reasons for considering it to be commercially sensitive and cross referencing to where that information is located in an appended Confidential Appendix form. We will review the information you provide as confidential or commercially sensitive and assess whether it meets the criteria in section 57 of the HSNO Act. If we decide it does not, the information provided will be made publicly available with the rest of your application.
21. We will not release any information that you supply to us before the formal lodgement of your application (the date a completed application form is submitted) unless it has already been made publicly available as part of a consultation process. Following formal lodgement of your application, any information in the body of this application form and any non-confidential appendices will become publicly available.
22. After you have formally lodged your application with the EPA, any information that you have supplied to the EPA regarding your application is subject to the Official Information Act 1982 (OIA). If a request is made for the release of information that you consider to be confidential, your view will be considered in a manner consistent with the OIA and with section 57 of the HSNO Act. You may be required to provide further justification for your claim of confidentiality. Please see the guide on our website: Supplying confidential information to the EPA - your rights and our obligations. Further information on the OIA is available at www.ombudsman.parliament.nz/.

Section 1: Applicant details

1.1 Name and postal address of the organisation or person making the application:

Legal name of organisation or person:	Environmental Protection Authority
NZBN:	9429041901977
Postal Address:	EPA, Level 10, 215 Lambton Quay, Private Bag 63002, Wellington 6140
Contact person and role:	Allan Freeth, Chief Executive
Phone:	04 474 5403
Email:	Allan.Freeth@epa.govt.nz
Email for our invoice, if different:	

1.2 Applicant's contact details in New Zealand, if different from 1.1:

Legal name of organisation or person:	Environmental Protection Authority
NZBN:	9429041901977
Postal Address:	EPA, Level 10, 215 Lambton Quay, Private Bag 63002, Wellington 6140
Contact person and role:	Christopher Hill, General Manager Hazardous Substances and New Organisms
Phone	04 474 5403
Email:	christopher.hill@epa.govt.nz

Section 2: Summary of the application

2.1 Name for the reassessment:
Name of the substance(s) or generic name of the class of chemicals or products to be reassessed.

Tebuconazole and propiconazole: A reassessment of a range of mixtures containing the active ingredients tebuconazole and propiconazole for which new information was obtained.

2.2 Purpose statement of the application for the public register:
Please summarise the reason for this application in one concise sentence. You should include the description of the hazardous substance and/or HSNO approval(s) to be reassessed and the proposed change(s)
For example: 'To reassess the active ingredient [name of active ingredient] and its formulations to increase the application rate from X to Y.'

To reassess the classifications and controls of tebuconazole and propiconazole and the mixtures containing them.

2.3 Executive summary of the application for the public register:
Please provide a clear and comprehensive summary of your application, including the specific amendments that you propose for this substance

Significant new information was obtained for tebuconazole and propiconazole, suggesting an update in classification and associated controls of the substances is required.

This significant new information for tebuconazole was identified during the assessment of Scorpio (APP203305, application declined in 2019), where the applicant provided toxicological studies on reproductive toxicity. The EPA determined tebuconazole should be classified as suspected reproductive toxicity Category 2 based on its review of the study data. Classification changes for tebuconazole are also proposed for specific target organ toxicity.

Significant new information for propiconazole was identified in the non-renewal decision made by the European Union on 9 December 2016 which also adopted the classification for known or presumed reproductive toxicity Category 1 in addition to the existing classifications for the substance. Other classification changes regarding contact sensitization had been raised by applicants/enquiries to the EPA. Upon review of classifications in other regulatory agencies, other classification changes are also proposed for eye irritancy and specific target organ toxicity.

2.4 Grounds to conduct a reassessment
Tell us the application number (APPXXXXXX) of the Grounds for Reassessment application for this substance.
Note: grounds for reassessment must be obtained before you can use this form to apply for a reassessment. If you have not obtained grounds please complete and submit the Grounds for Reassessment application form first. This form is available on our website.

Grounds for reassessment have been established as part of the grounds for reassessment application, APP204030. A Decision-making Committee determined that grounds exist to reassess these substances, and mixtures containing those substances.

2.5 Under which criteria were grounds for reassessment granted?

To reassess the hazardous substance(s) because of (tick all that apply):

☒ significant new information becoming available

☐ another substance with similar or improved beneficial effects and reduced adverse effects has become available

☐ information showing a significant change of use, or a significant change in the quantity manufactured, imported, or developed has become available

Section 3: Substance(s) to be reassessed

3.1 Which hazardous substance(s) approval(s) do you want to be reassessed?

It is proposed that the substances, tebuconazole and propiconazole, be reassessed to update their current hazard classifications and associated controls and ensure they align with the most recent information. Approved products which contain these substances are included in the scope of this application and their hazard classifications and controls will also be updated to reflect the proposed classifications for the tebuconazole and propiconazole components. Full details can be found in Appendix 1.

Some approvals included in the scope of the reassessment contain synthetic pyrethroid components which have had their classifications reviewed during the preparatory work on another reassessment application following the same process. Those mixtures which have been affected by this are described in the footnotes of Appendix 2.

It is also important to note that some identification names of substances have changed recently. These changes were implemented on 1 May 2021 when the EPA changed hazard classifications systems to the globally harmonised system (GHS). Those mixtures which have been affected by this are described in the footnotes of Appendix 2.

3.2 Have any of the substance(s) or any of their components: been restricted, had their registrations not renewed, or their approvals revoked overseas?

Overseas restrictions

☒	Yes
☐	No

The European Union decided to not renew the approval for pesticides containing the fungicide propiconazole as an active ingredient as the approval criteria were not considered to be fulfilled (March 2019). The applicant for the approval in Europe was requested to provide information to support the renewal of the substance that showed the risks from the substance were negligible, it is essential for use, and it will not have a negative impact on society. The date at which this approval expires has been postponed until 31 December 2021 due to the applicant not providing sufficient data to carry out the evaluation.

3.3 Use profile of the substance(s)

Where is the substance intended to be used?

☒	Is this substance used in workplaces e.g. on commercial farms or by contractors?
☐	Is this substance sold to or available to the general public e.g. for domestic or household use?

What is the intended use of the substance?

☐	Herbicide	☒	Timber treatment
☒	Fungicide	☐	Vertebrate poison
☐	Insecticide	☒	Antifouling paint
☐	Plant growth regulator	☐	Fumigant
☒	Seed treatment	☐	Industrial chemical
☐	Urban pest control	☐	Other: Please describe

3.4 What is the current use pattern of the substance?

Please use Table 1 and/or 2 below, as appropriate, for identifying the current use(s) of the substance(s) to be reassessed. You may use the same line for multiple substances or crops if the use pattern is the same. If this application is for multiple substances, you may substitute this section for a publicly-available appendix containing the relevant GAP table information and reference that appendix here.

Tebuconazole and propiconazole are active ingredients used as fungicides.

Currently 22 substances containing tebuconazole are approved for use under the HSNO act. Most products containing tebuconazole are used as timber treatments. However, 26 trade name products used as agricultural fungicides and 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 used as agricultural fungicides and 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.

3.5 What is the proposed new use pattern of the substance?

Please use Table 3 and/or 4 below, as appropriate, for identifying the proposed new use(s) of the substance(s) to be reassessed. You may use the same line for multiple substances or crops if the use pattern is the same. If this application is for multiple substances you may substitute this section for a publicly available appendix containing the relevant GAP table information and reference that appendix here.

The use pattern of the substances is not the subject of the proposed reassessment.

Section 4: Your reassessment proposal

4.1 Would you like the Environmental Protection Authority to change the description(s) of the substance(s)? If yes, describe the change, evidence, and reason to support the change.

Identify the aspect of the substance description to be changed (substance name, formulation details, hazard classification, or any other aspect). Provide the reasons and evidence to support this proposed change.

The hazard classifications of the substances listed in Appendix 1 are proposed to be updated to reflect their hazardous properties more accurately, based on new information (provided below). Therefore, controls on some substances need to be updated to manage the apparent risks as shown in Appendix 2.

Reasons for changes in classification:

Tebuconazole: Classification changes for tebuconazole are proposed based on toxicological studies provided to the EPA as part of application APP203305, which was declined in 2019. In the studies reviewed, tebuconazole was shown to have an impact on reproductive potential and was determined that it should be classified as reproductive toxicity Category 2.

Toxicological evaluations (Appendix 3) also found that for the classification specific target organ toxicity (repeated exposure) Category 2, of the toxicity studies reported, there was no significant or severe toxicities

observed. Therefore, it should no longer be classified as specific target organ toxicity (repeated exposure) Category 2.

Propiconazole: Based on information from the European Food Safety Authority (EFSA 2017) and EU (review report), the fungicide propiconazole should be classified as toxic for reproduction Category 1B.
The EFSA document states that propiconazole should be classified as toxic for reproduction Category 1B due to observations of toxic effects to endocrine organs. Given this, it is suggested that the classification of toxic for reproduction Category 1B is added.

Toxicological evaluations (Appendix 3) conducted by the EPA determined that a contact sensitisation Category 1 should be applied to this substance as sensitisation was observed during a maximisation test. Toxicological evaluations also determined that propiconazole should no longer be classified as specific target organ toxicity (repeated exposure) Category 2 or eye irritation Category 2. It was noted for specific target organ toxicity (repeated exposure) Category 2 that the observed effects were not considered indicative of toxicologically relevant disturbances. It was also noted for eye irritation Category 2 that European studies suggested that it was a weak irritant, and no classification was required.

Based on ecotoxicological evaluations conducted by the EPA, it was determined that propiconazole should also be classified as hazardous to soil organisms. This is based on the lowest endpoint obtained from a seedling emergence study reviewed by ECHA in their assessment report of propiconazole (Regulation (EU) No. 528/2012).

4.2 Would you like the Environmental Protection Authority to consider revoking the approval(s) of this substances(s)? If yes, provide evidence to support this proposal.

Identify this evidence and the reason for this proposed revoking of the approval(s).

(Note: If the Authority decides to undertake a full reassessment it can consider revoking any approval included in the reassessment, whether it is part of the applicant's proposal or not)

NA

4.3 Would you like the Environmental Protection Authority to review or change one or more of the control(s) attached to this substance(s)? *If yes, identify the control(s) to be changed, describe what needs to be changed or reviewed and the reasons and evidence to support the proposed change or review. Where practical, include the text of the control showing the proposed change. Supporting information, risk assessments, study reports or other supporting information or evidence can be included in an appendix and referenced in this section.*

Yes, see table 4.

4.4 List and describe any other controls or aspects that may be affected by the proposed change(s). *For example, increasing the application rate of a pesticide may affect the size or need for a buffer zone, or personal protective equipment.*

NA

4.5 Is there reasonable cause to believe that there is actual or imminent danger to human health or safety or the environment from the continued use of the substance(s)? *If yes, please provide a description and evidence to support this claim.*

No

Section 5: Effects of the reassessment

Please provide a comprehensive assessment of the potential effects of the proposed change to the controls or the approval (an "effects assessment"). The size, scope and level of detail provided should be appropriate to the significance of the change proposed, and the effects or issues related to that change.

You may provide an effects assessment as a separate report: if you do, please provide an executive summary below. Your assessment should consider both positive effects (including a reduction in negative effects) and negative effects.

An effect is defined as:

- any potential or probable effect; and
- any temporary or permanent effect; and
- any past, present, or future effects; and
- any acute or chronic effect; and
- any cumulative effect which arises over time or in combination with other effects

The effects assessment should consider covering the following aspects (if there is no effect or the aspect is not relevant then your assessment should describe why this is the case):

- Effects on human health including worker and public health
- Environmental effects including impacts on native or valued species and/or ecosystems
- Economic benefits or costs of the proposed change
- Effects on the relationship of Māori and their culture and traditions with their ancestral lands, waters, historical sites, wāhi tapu, valued flora and fauna, and other taonga
- Effects on, or implications for, New Zealand's International Obligations

You must complete this section, referencing all supporting material used. You must describe the source of the information in this application, e.g. from in-house research, independent research, technical literature, community or other consultation, and provide that information with this application. Details of information sources can be listed in section 8 of this form.

The EPA conducted an assessment of the toxicological and ecotoxicological hazards of the substances. The outcome of this assessment can be found in Appendix 3. This identifies a number of changes that are required to the hazard classifications of the substances included in this reassessment application. Correctly identifying the hazards on product labels and documentation ensures that users are fully informed and appropriate measures are taken to protect human health and the environment.

The EPA considers that any potential costs to the industry of making changes to their labelling, packaging, and Safety Data Sheets to reflect the classification changes could be mitigated by providing a sufficient period of time to update the documentation related to the substances. The EPA noted that although we have recently undergone the adoption of a new hazard classification system (GHS), substances with an individual approval issued after 30 April 2021 must comply with the new classifications and notices immediately. Therefore, an implementation period of one year shall be recommended.

The EPA did not identify any further effects on society, the community, or the market economy associated with the change to the hazard classifications of the substances. The EPA therefore did not consider this further.

The EPA considers that there will be no change to the effects of the substances on the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, wāhi tapu, valued flora and fauna and other taonga, and therefore these risks will be unchanged from those identified when the substances were originally approved. The Māori impact assessment can be found in Appendix 4.

The EPA considers that there are some positive effects on New Zealand's international obligations associated with the proposed change to the hazard classifications of the substances in terms of harmonising chemical classifications with other major jurisdictions. No other effects on any other international obligations were identified.

Taking into account the effects identified above, the EPA considered that there was an overall positive effect in making the change to the hazard classifications of the approvals and noted that the classifications will more accurately represent the hazards of the substances compared to those identified in the current approvals.

Section 6: Best practice considerations

6.1 What are the industry or best New Zealand practices for the safe management of the substance(s)?

NA

6.2 Are there New Zealand standards or Codes of Practice that apply to the management of the substance(s)?

NA

6.3 What are the international standards for the safe management of the substance(s)?

NA

Section 7: Additional Information (optional)

7.1 Provide any additional information to support the proposal to change the approval here and indicate how or why it is relevant.

For example, a letter of support from industry to indicate the need for the substance or proposed change.

NA

Section 8: Source of supporting information

8.1 Please provide an index of your supporting information.

Please list the documents, scientific articles and other information referenced in your application. These are considered as evidence to support your proposal. Please ensure that the supporting information listed here is discussed in one of the completed sections in this application form.

If you are seeking that a document be treated as confidential or commercially sensitive, please ensure that you indicate that in your reference list. If the reference is publicly available, e.g. an article in a scientific journal, then please provide a link or reference that allows external stakeholders to access the document. A copy of all supporting information must be supplied to the EPA with the application. You may provide this information in a separate appendix or a different format provided that you include the information specified in Table 5.

Table 5. Index of supporting information or references

	Name or reference number of report, study or supporting information	Description *(e.g. acute oral toxicity study for bees)*	Source	Confidential information (Y/N)
1	Tebuconazole	European Food Safety Authority (EFSA). (2014). Conclusion on the peer review of the pesticide risk assessment of the active substance tebuconazole	https://www.efsa.europa.eu/en/efsajournal/pub/3485	N
2	Tebuconazole	European Chemicals Agency Risk Assessment Committee (ECHA RAC). (2013). Opinion: Proposing harmonised classification and labelling at EU level of tebuconazole	https://echa.europa.eu/documents/10162/41e9d7aa-4559-f904-9cb5-0a0d5f0d6445	N
3	Tebuconazole	Environmental Protection Authority (EPA). (2017). Science Memorandum: App203305 – Scorpio Ornamental Fungicide	APP203305-Science-Memorandum.pdf (epa.govt.nz)	N
4	Propiconazole	European Food Safety Authority (EFSA). (2016). Peer review of the pesticide risk assessment of the active substance propiconazole	https://www.efsa.europa.eu/en/efsajournal/pub/4887	N
5	Propiconazole	European Chemicals Agency Risk Assessment Committee (ECHA RAC). (2016). Opinion: Proposing harmonised classification and labelling at EU level of propiconazole (ISO); (2RS,4RS;2RS,4SR)-1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1H-1,2,4-triazole	https://echa.europa.eu/documents/10162/723fe08d-2ec7-105b-51aa-05064bd91ac3	N

Section 9: Before you submit: checklist

Please ensure that your application is complete

Application		Comments/justifications
All mandatory sections of the application form completed, or you have requested an information waiver under section 59 of the HSNO Act	☒ Yes ☐ No (If No, please contact us before you submit your application)	Enter here
Any confidential or commercially sensitive data formatted into the Confidential Appendix template and appended. Please note the EPA strongly encourages applicants to provide as much information as possible in the main body of the application form unless there is a genuine reason for it to be considered confidential or commercially sensitive.	☐ Yes ☒ No	Enter here
Supplementary optional information attached:		
• Copies of additional references	☐ Yes ☒ No	Enter here
• Letter(s) of access	☐ Yes ☒ No	Enter here
• Relevant correspondence	☐ Yes ☒ No	Enter here
• Draft label	☐ Yes ☒ No	Enter here
• Draft Safety Data Sheet (SDS)	☐ Yes ☒ No	Enter here

Request for information waiver under section 59 of the HSNO Act

☐ I request for the Authority to waive any legislative information requirements (i.e. concerning the information that has been supplied in my application) that my application does not meet (tick if you are choosing to omit any mandatory information).

Please list below which section(s) of this form are relevant to the information waiver request:

NA

Signature of applicant or person authorised to sign on behalf of applicant

☒ I am making this application, or am authorised to sign on behalf of the applicant or applicant organisation.

☐ I have completed this reassessment application to the best of my ability and, as far as I am aware, the information I have provided in this application form is correct.

3/11/2021

Signature | Date

To submit an application for a reassessment, send to the EPA Hazardous Substances Reassessments team:

- preferably by email to: reassessments@epa.govt.nz
- or by post to: Environmental Protection Authority, Private Bag 63002, Wellington 6140

You will be invoiced once the reassessment application pathway is determined.

See our website for information about fees and charges.

For assistance with preparing your application, contact one of our Hazardous Substances Advisors:

- by email: reassessments@epa.govt.nz
- Freephone (within New Zealand): 0800 429 7827 (0800 HAZSUBS)

Definitions

Active ingredient	Component of a formulated substance responsible for the pesticidal effect or veterinary medicinal therapeutic effect
CAS Number	Chemical Abstracts Service number. This is a unique identifier for a chemical substance
Hazardous properties	This relates to the hazard classification of a substance and the properties that trigger any threshold level for the substance to be hazardous
Hazardous substance	Any substance with one or more of the following intrinsic properties: • Explosiveness • Flammability • A capacity to oxidise • Corrosiveness • Toxicity (including chronic toxicity) • Ecotoxicity, with or without bioaccumulation, or which on contact with air or water (other than air or water where the temperature or pressure has been artificially increased or decreased) generates a substance with any one or more of the properties specified in this definition
Pesticide	Substance or mixture of substances intended to be used for preventing, controlling, repelling, or mitigating any pest (including vertebrates) in areas such as, but not limited to, agriculture, home and garden, rights of way or industrial areas
Professional and non-professional users	Professional users are using pesticides in the course of their job or business (such as farmers and growers or amenity users). Professional use may include the use of formulated substances in order to deliver services to business or private customers Non-professional users are not using pesticides in the course of their job or business (such as lifestyle block owners, general public using pesticides for domestic use, and so on)
Substance	Any of the following: • Any element, defined mixture of elements, compounds or defined mixture of compounds, either naturally occurring or produced synthetically, or any mixtures thereof; • Any isotope, allotrope, isomer, congener, radical or ion of an element or compound which has been declared by the Authority, by notice in the Gazette, to be a different substance from that element or compound; • Any mixtures or combinations of any of the above; • Any manufactured article containing, incorporating, or including any hazardous substance with explosive properties. (section 2(1) HSNO Act)

Appendix 1. Individual components to be reassessed and the list of affected substances containing them

Table 1. List of individual components to be reassessed.

Approval name	Approval Number (e.g. HSRXXXXXX)	CAS Number	Current Classification
Tebuconazole	HSR002879	107534-96-3	Acute oral toxicity Category 4, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1
Propiconazole	HSR003109	60207-90-1	Acute oral toxicity Category 4, Eye irritation Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1

Table 2. List of affected substances containing either tebuconazole or propiconazole

Active Ingredient	**CAS Number**	**Approval Name**	**Approval Number (e.g. HSRXXXXXX)**
Tebuconazole	**107534-96-3**	Water dispersible granule containing 250 g/kg tebuconazole	HSR000511
		Suspension containing 10 g/litre tebuconazole	HSR000519
		Flowable concentrate containing 25 g/litre tebuconazole	HSR000520
		Emulsion or suspension concentrate containing 250 - 430 g/litre tebuconazole	HSR000751
		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
		Hornet 430SC	HSR007675
		Liquid containing 70 - 120 g/litre bi oric acid, 140 - 180 g/litre copper carbonate and 1 - 10 g/litre tebuconazole	HSR007733
		Axis Gold	HSR007767
		Myco-RF	HSR007810
		Prosaro	HSR007871
		Folicur WG	HSR007887
		GELSEAL	HSR007920
		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

Active Ingredient	CAS Number	Approval Name	Approval Number (e.g. HSRXXXXXX)
Tebuconazole	**107534-96-3**	Preventol A20	HSR100042
		Tebuconazole emulsifiable concentrate 50g/kg	HSR100128
		Greenseal Ultra	HSR100149
		StemCap KF-2	HSR100345
		Envy	HSR100365
		Falcon	HSR100368
		J57.65A	HSR100749
		J57.65B	HSR100750
		ORD-X170 revised	HSR100809
		Capri	HSR100862
		J57.67	HSR100930
		Raxil Ultra	HSR100943
		Gelseal Ultra	HSR101006
		Elito	HSR101009
		ORD-X170S	HSR101093
		Raxil Star	HSR101132
		Unicorn	HSR101162
		Soluble Copper Azole	HSR101208
		ORD-X46P	HSR101272
		ORD-X46S	HSR101275
		Kestrel	HSR101293
		Prune Seal (new formulation)	HSR101311
		BUZZ ULTRA 750 WG FUNGICIDE	HSR101335
		GPFC-RTU 424	HSR101395
		Custodia	HSR101411
		Copper Naphthenate Formulation Type 3	HSR000128
		Copper Naphthenate Formulation Type 4	HSR000129
Propiconazole	**60207-90-1**	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
		Emulsifiable concentrate containing 250 g/litre propiconazole (Substance B)	HSR000721
		Soluble concentrate containing 500 g/litre benzalkonium chloride, 50 g/litre iodocarb and 50 g/litre propiconazole	HSR000876
		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
		Procure	HSR001740
		STEMSHOT KF-1	HSR002471
		Spotless	HSR007857
		Wocosen 15TK	HSR100007

Active Ingredient	CAS Number	Approval Name	Approval Number (e.g. HSRXXXXXX)
Propiconazole	**60207-90-1**	Emulsifiable concentrate containing 250 g/litre propiconazole. Also contains hydrocarbon liquids (Substance B)	HSR000580
		Emulsifiable concentrate containing 250 g/litre propiconazole (Substance A)	HSR000596
		Liquid containing 450 - 550 g/litre propiconazole	HSR100339
		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
		Headway	HSR100366
		RotStop	HSR100605
		Prozole	HSR101041
		Hylite NCF	HSR101201
		Propistrong	HSR101283

Table 3: List of affected substances containing both tebuconazole and propiconazole

Approval name	Approval Number (e.g. HSRXXXXXX)
Emulsifiable concentrate containing 279 g/litre propiconazole and 279 g/litre tebuconazole	HSR000882
TF3 Substance A	HSR002459
TF3 Substance B	HSR002460
J57.59	HSR100689
J57.63	HSR100802
Tnl 3215	HSR100987
Protim Optimum	HSR000006
Vacsol Azure	HSR000007
TimTech AZ	HSR000093
TimTech AZUS	HSR000132
J57.10A	HSR000945
J57.10B	HSR000955
J57.10C	HSR000974
Taratek 1995	HSR001762
Protim Optimum II	HSR002441
Protim Optimum III	HSR002442
J57.23I	HSR007648
J57.23K	HSR007650
Wocosen ME-3WP	HSR007772
Protim Aquazole Concentrate	HSR007777
PROTIM Aquazole Ready-to-use	HSR007778
TNL2436	HSR007948
IV 64 WB Timber Concentrate	HSR100111
Premix B	HSR100274
Premix BR	HSR100275

Approval name	Approval Number (e.g. HSRXXXXXX)
J57.41	HSR100280
J57.47	HSR100405
J57.52	HSR100482
J57.48A Concentrate	HSR100503
J57.48B-RTU	HSR100504
J57.55	HSR100582
XYLA Concentrate	HSR100591
J57.56	HSR100617
WBA Concentrate	HSR100640
J57.58A	HSR100656
J57.58B	HSR100657
Osmose Protim Aquazole	HSR100940
Protim Optimum CA	HSR100985
J57.74	HSR101046
Protim Optimum HF 0.6%	HSR101265
Protim Optimum HFII 0.6%	HSR101305
Protim Optimum HFII 2.0%	HSR101307
Protim Optimum LO 0.6% and Protim Optimum LO 1.2%	HSR101403
Protim Optimum LO 2.0%	HSR101404
J57.81	HSR101394
Protim Optimum PTB 0.6% and Protim Optimum PTB 1.2%	HSR101405
Protim Optimum PTB 2%	HSR101406
J57.23A	HSR007640
J57.23B	HSR007641
J57.23C	HSR007642
J57.23D	HSR007643
J57.23E	HSR007644
J57.23F	HSR007645
J57.23G	HSR007646
J57.23H	HSR007647
J57.23J	HSR007649
J57.23L	HSR007651
Protim Optimum HF Premix	HSR101473

Appendix 2. Approved substances with proposed changes

Justifications for changes are included in the footnotes.

Table 4. Approved substances with proposed changes to classifications and associated controls

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
Tebuconazole	HSR002879	Acute oral toxicity Category 4, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Acute oral toxicity Category 4, Reproductive toxicity Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[3]	No changes
Propiconazole	HSR003109	Acute oral toxicity Category 4, Eye irritation Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Acute oral toxicity Category 4, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to soil organisms, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[4]	No changes
Bazooka	HSR000117	Flammable liquid Category 4, Acute dermal toxicity Category 4, Acute inhalation toxicity Category 4, Skin irritation Category 2, Serious eye damage Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Aspiration hazard Category 1, Flammable liquid Category 4, Acute inhalation toxicity Category 4, Skin irritation Category 2, Serious eye damage Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[5]	Controls removed: HPC4C

[3] Classification changes for tebuconazole are proposed based on toxicological studies provided to the EPA as part of application APP203305. Tebuconazole was shown to have an impact on reproductive potential and was determined that it should be classified as reproductive toxicity Category 2.

[4] The EFSA document states that propiconazole should be classified as toxic for reproduction Category 1B due to observations of toxic effects to endocrine organs. Toxicological evaluations conducted by the EPA determined that a contact sensitisation Category 1 should be applied to this substance as sensitization was observed during a maximisation test. Propiconazole should also be classified as hazardous to soil organisms. This is based on the lowest endpoint obtained from a seedling emergence study conducted by ECHA in their assessment report of propiconazole (Regulation (EU) No. 528/2012).

[5] Changes based on changes to propiconazole. Some classifications usually triggered by aromatic hydrocarbon solvents have not been included in this proposed classification due to the unknown proportions of naphthalene in the solvent.

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
Water dispersible granule containing 250 g/kg tebuconazole	HSR000511	Skin sensitisation Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Skin sensitisation Category 1, Reproductive toxicity Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[6]	No changes
Suspension containing 10 g/litre tebuconazole	HSR000519	Hazardous to the aquatic environment chronic Category 3	Reproductive toxicity Category 2, Hazardous to the aquatic environment chronic Category 3[7]	Controls added: HSW1, HSW2, HSW3, HSW4, HSW13, HSW16, HSW17
Flowable concentrate containing 25 g/litre tebuconazole	HSR000520	Skin sensitisation Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment chronic Category 3	Skin corrosion Category 1B, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment chronic Category 3[8]	No changes
Emulsifiable concentrate containing 250 g/litre propiconazole. Also contains hydrocarbon liquids (Substance B)	HSR000580	Flammable liquid Category 4, Aspiration hazard Category 1, Eye irritation Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Aspiration hazard Category 1, Flammable liquid Category 4, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to soil organisms, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[9]	Controls removed: HSW17
Emulsifiable concentrate containing 250 g/litre propiconazole (Substance A)	HSR000596	Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Skin sensitisation Category 1, Reproductive toxicity Category 1,Hazardous to soil organisms, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1,[10]	No changes
Emulsifiable concentrate containing 250 g/litre propiconazole. Also	HSR000597	Flammable liquid Category 4, Acute oral toxicity Category 4, Aspiration hazard Category 1, Skin irritation Category 2, Eye irritation Category 2, Skin sensitisation Category 1, Specific target organ	Aspiration hazard Category 1, Flammable liquid Category 4, Skin irritation Category 2, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1,Hazardous to soil	No changes

[6] Changes based on changes to tebuconazole

[7] Changes based on changes to tebuconazole

[8] Changes based on changes to tebuconazole and mixture rules

[9] Changes based on changes to propiconazole and mixture rules

[10] Changes based on changes to propiconazole

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
contains hydrocarbon liquids (Substance A)		toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment chronic Category 2	organisms, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[11]	
Emulsifiable concentrate containing 250 g/litre propiconazole. Also contains toluene	HSR000601	Flammable liquid Category 2, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Skin irritation Category 2, Eye irritation Category 2, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Flammable liquid Category 2, Acute oral toxicity Category 4, Skin irritation Category 2, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to soil organisms, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[12]	No changes
Emulsifiable concentrate containing 250 g/litre propiconazole (Substance B)	HSR000721	Acute oral toxicity Category 4, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Acute oral toxicity Category 4, Reproductive toxicity Category 1, Hazardous to soil organisms, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[13]	No changes
Emulsion or suspension concentrate containing 250 - 430 g/litre tebuconazole	HSR000751	Acute oral toxicity Category 4, Eye irritation Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Eye irritation Category 2, Reproductive toxicity Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[14]	No changes
Emulsifiable concentrate containing 292 g/litre copper carbonate, 64 g/litre boric acid and 6.4 g/litre tebuconazole	HSR000853	Flammable liquid Category 4, Corrosive to metals Category 1, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute	Flammable liquid Category 4, Corrosive to metals Category 1, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Specific target organ toxicity (single exposure) Category 3 respiratory irritation, Hazardous to the aquatic environment acute	No changes

[11] Changes based on changes to propiconazole. Some classifications usually triggered by aromatic hydrocarbon solvents have not been included in this proposed classification due to the unknown proportions of naphthalene in the solvent.

[12] Changes based on changes to propiconazole and mixture rules

[13] Changes based on changes to propiconazole and mixture rules

[14] Changes based on changes to tebuconazole

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
		Category 1, Hazardous to the aquatic environment chronic Category 1	Category 1, Hazardous to the aquatic environment chronic Category 1[15]	
Emulsifiable concentrate containing 8.65 g/litre tebuconazole and 465 g/litre didecyl dimethyl ammonium chloride	HSR000863	Flammable liquid Category 3, Acute oral toxicity Category 3, Skin corrosion Category 1B, Serious eye damage Category 1, Skin sensitisation Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 3	Flammable liquid Category 3, Acute oral toxicity Category 3, Skin corrosion Category 1B, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 3[16]	Controls removed: HPC4C
Soluble concentrate containing 500 g/litre benzalkonium chloride, 50 g/litre iodocarb and 50 g/litre propiconazole	HSR000876	Acute oral toxicity Category 4, Acute dermal toxicity Category 4, Skin corrosion Category 1B, Serious eye damage Category 1, Skin sensitisation Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Acute dermal toxicity Category 4, Acute oral toxicity Category 4, Skin corrosion Category 1B, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[17]	No changes
Emulsifiable concentrate containing 279 g/litre propiconazole and 279 g/litre tebuconazole	HSR000882	Flammable liquid Category 4, Acute oral toxicity Category 4, Skin irritation Category 2, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Flammable liquid Category 4, Skin irritation Category 2, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (single exposure) Category 3 respiratory irritation, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[18]	Controls removed: HPC4C
Soluble concentrate containing 500 g/litre benzalkonium chloride, 50 g/litre guazatine and 50 g/litre propiconazole	HSR000884	Acute oral toxicity Category 4, Acute dermal toxicity Category 4, Acute inhalation toxicity Category 4, Skin corrosion Category 1B, Serious eye damage Category 1, Skin sensitisation Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Acute dermal toxicity Category 4, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Skin corrosion Category 1B, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[19]	No changes

[15] Changes based on changes to tebuconazole and mixture rules

[16] Changes based on changes to tebuconazole

[17] Changes based on changes to tebuconazole

[18] Changes based on changes to tebuconazole and propiconazole and mixture rules

[19] Changes based on changes to propiconazole

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
Emulsifiable concentrate containing 100 g/litre propiconazole	HSR000894	Flammable liquid Category 4, Eye irritation Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Flammable liquid Category 4, Respiratory sensitisation, Category 1, Reproductive toxicity Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[20]	Controls removed: HPC4C
Emulsifiable concentrate containing 240 g/litre didecyl dimethyl ammonium chloride and 48 g/litre propiconazole	HSR000895	Flammable liquid Category 3, Corrosive to metals Category 1, Acute oral toxicity Category 4, Acute inhalation toxicity Category 2, Skin corrosion Category 1C, Serious eye damage Category 1, Skin sensitisation Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment chronic Category 1	Flammable liquid Category 3, Corrosive to metals Category 1, Acute oral toxicity Category 4, Acute inhalation toxicity Category 2, Skin corrosion Category 1B, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to the aquatic environment chronic Category 1[21]	Controls removed: HPC4C HSW7
Soluble concentrate containing 86 g/litre boric acid, 50.5 g/litre fenpropimorph and 24.8 g/litre propiconazole	HSR000896	Acute inhalation toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[22]	Controls removed: HPC4C
Procure	HSR001740	Eye irritation Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to soil organisms, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[23]	Controls added: HSW5
TF3 Substance A	HSR002459	Flammable liquid Category 4, Acute oral toxicity Category 3, Skin corrosion Category 1C, Serious eye damage Category 1, Respiratory sensitisation Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute	Acute dermal toxicity Category 4, Flammable liquid Category 4, Acute oral toxicity Category 4, Skin corrosion Category 1B, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic	Controls removed: HPC2

[20] Changes based on changes to propiconazole

[21] Changes based on changes to propiconazole and mixture rules

[22] Changes based on changes to propiconazole and mixture rules

[23] Changes based on changes to propiconazole

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
		Category 1, Hazardous to the aquatic environment chronic Category 1	environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[24]	
TF3 Substance B	HSR002460	Flammable liquid Category 4, Acute oral toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Respiratory sensitisation Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Flammable liquid Category 4, Acute oral toxicity Category 4, Skin corrosion Category 1B, Serious eye damage Category 1, Respiratory sensitisation Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[25]	No changes
STEMSHOT KF-1	HSR002471	Skin irritation Category 2, Serious eye damage Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Skin irritation Category 2, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1,[26]	Controls added: HSW5
Hornet 430SC	HSR007675	Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[27]	No changes
Liquid containing 70 - 120 g/litre boric acid, 140 - 180 g/litre copper carbonate and 1 - 10 g/litre tebuconazole	HSR007733	Flammable liquid Category 4, Corrosive to metals Category 1, Acute oral toxicity Category 4, Acute dermal toxicity Category 4, Acute inhalation toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Acute dermal toxicity Category 4, Flammable liquid Category 4, Corrosive to metals Category 1, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[28]	No changes

[24] Changes based on changes to tebuconazole and propiconazole and mixture rules

[25] Changes based on Benzalkonium chloride

[26] Changes based on changes to propiconazole

[27] Changes based on changes to tebuconazole

[28] Changes based on Di-s-octyl phthalate

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
Axis Gold	HSR007767	Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[29]	No changes
Myco-RF	HSR007810	Acute oral toxicity Category 4, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Acute oral toxicity Category 4, Eye irritation Category 2, Reproductive toxicity Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1,[30]	No changes
Spotless	HSR007857	Skin irritation Category 2, Serious eye damage Category 1, Skin sensitisation Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Skin irritation Category 2, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[31]	No changes
Prosaro	HSR007871	Eye irritation Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment chronic Category 2	Eye irritation Category 2, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment chronic Category 2[32]	No changes
Folicur WG	HSR007887	Eye irritation Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Eye irritation Category 2, Reproductive toxicity Category 2, Hazardous to terrestrial invertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[33]	No changes

[29] Changes based on changes to tebuconazole

[30] Changes based on changes to tebuconazole

[31] Changes based on changes to propiconazole

[32] Changes based on changes to tebuconazole

[33] Changes based on changes to tebuconazole

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
GELSEAL	HSR007920	Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment chronic Category 3	Skin sensitisation Category 1, Germ cell mutagenicity Category 2, Reproductive toxicity Category 2, Hazardous to the aquatic environment chronic Category 3[34]	Controls added: HSW5
ORD-X370 plus TEB EC25 - Option 1	HSR007958	Hazardous to the aquatic environment chronic Category 2	Hazardous to the aquatic environment chronic Category 2	No changes
ORD-X370 plus TEB EC25 - Option 2	HSR007959	Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	No changes
ORD-X370 plus TEB EC25 - Option 3	HSR007960	Eye irritation Category 2, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Eye irritation Category 2, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	No changes
TEB EC25	HSR007961	Acute oral toxicity Category 4, Acute dermal toxicity Category 4, Skin irritation Category 2, Eye irritation Category 2, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment chronic Category 2	Acute oral toxicity Category 4, Acute dermal toxicity Category 4, Skin irritation Category 2, Eye irritation Category 2, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment chronic Category 2	No changes
Wocosen 15TK	HSR100007	Eye irritation Category 2, Respiratory sensitisation Category 1, Skin sensitisation Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Acute oral toxicity Category 4, Acute inhalation toxicity Category 3, Skin corrosion Category 1B, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[35]	Controls removed: HPC4C
Eurogel	HSR100023	Skin irritation Category 2, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment chronic Category 2	Skin irritation Category 2, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated	Controls removed: HPC4C

[34] Changes based on mixture rules

[35] Changes based on changes to propiconazole

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
			exposure) Category 2, Hazardous to the aquatic environment chronic Category 2[36]	
Preventol A20-CT30	HSR100041	Acute oral toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment chronic Category 2	Acute oral toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment chronic Category 2	No changes
Preventol A20	HSR100042	Acute oral toxicity Category 4, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Acute oral toxicity Category 4, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	No changes
Tebuconazole emulsifiable concentrate 50g/kg	HSR100128	Skin irritation Category 2, Eye irritation Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment chronic Category 2	Skin irritation Category 2, Eye irritation Category 2, Reproductive toxicity Category 2, Hazardous to the aquatic environment chronic Category 2[37]	Controls removed: HPC4C
Greenseal Ultra	HSR100149	Skin irritation Category 2, Eye irritation Category 2, Skin sensitisation Category 1, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment chronic Category 2	Skin irritation Category 2, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[38]	Controls removed: HPC4C
Liquid containing 450 - 550 g/litre propiconazole	HSR100339	Flammable liquid Category 4, Acute oral toxicity Category 4, Serious eye damage Category 1, Skin sensitisation Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1,	Flammable liquid Category 4, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to soil organisms, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[39]	No changes

[36] Changes based on changes to tebuconazole and Decanamide, N,N-dimethyl-

[37] Changes based on changes to tebuconazole

[38] Changes based on changes to tebuconazole and mixture rules

[39] Changes based on changes to propiconazole and mixture rules

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
		Hazardous to the aquatic environment chronic Category 1		
StemCap KF-2	HSR100345	Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Reproductive toxicity Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[40]	No changes
Envy	HSR100365	Flammable liquid Category 3, Aspiration hazard Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment chronic Category 1	Flammable liquid Category 3, Reproductive toxicity Category 1, Hazardous to the aquatic environment chronic Category 2[41]	Controls removed: HPC4C
Headway	HSR100366	Flammable liquid Category 4, Acute oral toxicity Category 4, Eye irritation Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Flammable liquid Category 4, Acute oral toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to soil organisms, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[42]	No changes
Falcon	HSR100368	Acute oral toxicity Category 4, Acute dermal toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Acute dermal toxicity Category 4, Acute oral toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 1, Specific target organ toxicity (single exposure) Category 3 respiratory irritation, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[43]	No changes
RotStop	HSR100605	Eye irritation Category 2, Respiratory sensitisation Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 2, Specific target	Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1,	Controls removed: HPC4C

[40] Changes based on changes to tebuconazole

[41] Changes based on mixture rules

[42] Changes based on changes to propiconazole

[43] Changes based on changes to tebuconazole and Decanamide, N,N-dimethyl-

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
		organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[44]	
J57.59	HSR100689	Flammable liquid Category 3, Eye irritation Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Aspiration hazard Category 1, Flammable liquid Category 3, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (single exposure) Category 3 narcotic effects, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[45]	Controls removed: HPC4C
J57.65A	HSR100749	Corrosive to metals Category 1, Acute oral toxicity Category 4, Acute dermal toxicity Category 4, Acute inhalation toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Acute dermal toxicity Category 4, Corrosive to metals Category 1, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Specific target organ toxicity (single exposure) Category 3 respiratory irritation, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[46]	Controls removed: HPC4C
J57.65B	HSR100750	Corrosive to metals Category 1, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Corrosive to metals Category 1, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Specific target organ toxicity (single exposure) Category 3 respiratory irritation, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[47]	No changes

[44] Changes based on changes to propiconazole

[45] Changes based on changes to propiconazole, tebuconazole and mixture rules

[46] Changes based on changes to tebuconazole and mixture rules

[47] Changes based on changes to tebuconazole and mixture rules

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
J57.63	HSR100802	Skin irritation Category 2, Eye irritation Category 2, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Skin irritation Category 2, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[48]	No changes
ORD-X170 revised	HSR100809	Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1, [49]	No changes
Capri	HSR100862	Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment chronic Category 3	Reproductive toxicity Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[50]	No changes
J57.67	HSR100930	Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Germ cell mutagenicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Germ cell mutagenicity Category 2, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[51]	No changes
Raxil Ultra	HSR100943	Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment chronic Category 2	Skin sensitisation Category 1, Reproductive toxicity Category 2, Hazardous to the aquatic environment chronic Category 2[52]	Control added: HSW5
Tnl 3215	HSR100987	Acute inhalation toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Skin sensitisation Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Respiratory sensitisation Category 1, Skin sensitisation Category 1, Carcinogenicity Category 2, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic	No changes

[48] Changes based on changes to tebuconazole and propiconazole

[49] Changes based on changes to tebuconazole

[50] Changes based on changes to tebuconazole

[51] Changes based on changes to tebuconazole

[52] Changes based on changes to tebuconazole and mixture rules

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
			environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[53]	
Gelseal Ultra	HSR101006	Skin irritation Category 2, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Skin irritation Category 2, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	No changes
Elito	HSR101009	Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Reproductive toxicity Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[54]	No changes
Prozole	HSR101041	Flammable liquid Category 4, Eye irritation Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Flammable liquid Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to soil organisms, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[55]	No changes
ORD-X170S	HSR101093	Flammable liquid Category 3, Serious eye damage Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Flammable liquid Category 3, Acute inhalation toxicity Category 4, Serious eye damage Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[56]	No changes
Raxil Star	HSR101132	Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment chronic Category 2	Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment chronic Category 2, [57]	Controls added: HSW7

[53] Changes based on changes to tebuconazole, propiconazole, and polymethylene polyphenylisocyanate

[54] Changes based on changes to tebuconazole

[55] Changes based on changes to propiconazole

[56] Changes based on changes to tebuconazole and mixture rules

[57] Changes based on changes to tebuconazole

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
Unicorn	HSR101162	Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment chronic Category 2	Reproductive toxicity Category 2, Hazardous to the aquatic environment chronic Category 2[58]	No changes
Hylite NCF	HSR101201	Acute oral toxicity Category 4, Acute dermal toxicity Category 4, Skin corrosion Category 1B, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Acute dermal toxicity Category 4, Acute oral toxicity Category 4, Skin corrosion Category 1B, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[59]	No changes
Soluble Copper Azole	HSR101208	Corrosive to metals Category 1, Acute oral toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Corrosive to metals Category 1, Acute oral toxicity Category 4, Skin corrosion Category 1C, Serious eye damage Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	No changes
ORD-X46P	HSR101272	Flammable liquid Category 4, Acute inhalation toxicity Category 4, Aspiration hazard Category 1, Skin irritation Category 2, Serious eye damage Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Flammable liquid Category 4, Acute inhalation toxicity Category 4, Aspiration hazard Category 1, Skin irritation Category 2, Serious eye damage Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	No changes
ORD-X46S	HSR101275	Flammable liquid Category 4, Acute inhalation toxicity Category 4, Aspiration hazard Category 1, Skin irritation Category 2, Eye irritation Category 2, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Flammable liquid Category 4, Acute inhalation toxicity Category 4, Aspiration hazard Category 1, Skin irritation Category 2, Eye irritation Category 2, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	No changes

[58] Changes based on changes to tebuconazole

[59] Changes based on changes to propiconazole

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
Propistrong	HSR101283	Aspiration hazard Category 1, Eye irritation Category 2, Skin sensitisation Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Aspiration hazard Category 1, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to soil organisms, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[60]	No changes
Kestrel	HSR101293	Skin irritation Category 2, Eye irritation Category 2, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Skin irritation Category 2, Eye irritation Category 2, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	No changes
Prune Seal (new formulation)	HSR101311	Skin irritation Category 2, Eye irritation Category 2, Respiratory sensitisation Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment chronic Category 2	Skin irritation Category 2, Eye irritation Category 2, Respiratory sensitisation Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment chronic Category 2	No changes
BUZZ ULTRA 750 WG FUNGICIDE	HSR101335	Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Reproductive toxicity Category 2, Hazardous to terrestrial vertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	No changes
GPFC-RTU 424	HSR101395	Hazardous to the aquatic environment chronic Category 3	Hazardous to the aquatic environment chronic Category 3	No changes
Custodia	HSR101411	Acute oral toxicity Category 4, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 2, Hazardous to the aquatic environment chronic Category 2,	Acute oral toxicity Category 4, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment chronic Category 2[61]	Controls removed: HSW15

[60] Changes based on changes to propiconazole

[61] Changes based on mixture rules

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
Protim Optimum	HSR000006	Flammable liquid category 3, Aspiration hazard category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (single exposure) Category 3 narcotic effects, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[62]	No changes
Vacsol Azure	HSR000007	Flammable liquid category 3, Aspiration hazard category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (single exposure) Category 3 narcotic effects, Hazardous to terrestrial invertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[63]	No changes
TimTech AZ	HSR000093	Flammable liquid category 3, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1	Aspiration hazard Category 1, Flammable liquid Category 3, Skin sensitisation Category 1, Carcinogenicity Category 2, Reproductive toxicity Category 1, Specific target organ toxicity (single exposure) Category 3 narcotic effects, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[64]	No changes
Copper Naphthenate Formulation Type 3	HSR000128	Flammable liquid category 3, Aspiration Hazard Category 1, Skin irritation category 2, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Skin irritation Category 2, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to terrestrial invertebrates, Hazardous to the aquatic	No changes

[62] Changes based on changes to tebuconazole, propiconazole and permethrin. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[63] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[64] Changes based on changes to tebuconazole, propiconazole and permethrin. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
			environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[65]	
Copper Naphthenate Formulation Type 4	HSR000129	Flammable liquid category 4, Aspiration Hazard Category 1, Skin irritation category 2, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 4, Skin irritation Category 2, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[66]	No changes
TimTech AZUS	HSR000132	Flammable liquid category 3, Aspiration Hazard Category 1, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (single exposure) Category 3 narcotic effects, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[67]	No changes
J57.10A	HSR000945	Flammable liquid category 3, Aspiration hazard category 1, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Specific target organ toxicity (single exposure) category 3 respiratory irritation, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (single exposure) Category 3 narcotic effects, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[68]	Controls removed: HPC4C
J57.10B	HSR000955	Flammable liquid category 3, Aspiration hazard category 1, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous	Aspiration hazard Category 1, Flammable liquid Category 3, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (single	Controls removed: HPC4C

[65] Changes based on changes to tebuconazole and permethrin. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[66] Changes based on changes to tebuconazole and permethrin. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[67] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[68] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
		to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	exposure) Category 3 narcotic effects, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[69]	
J57.10C	HSR000974	Flammable liquid category 3, Aspiration hazard category 1, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (single exposure) Category 3 narcotic effects, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[70]	Controls removed: HPC4C
Taratek 1995	HSR001762	Flammable liquid category 4, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Flammable liquid Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[71]	Controls removed: HPC4C
Protim Optimum II	HSR002441	Flammable liquid category 3, Aspiration hazard category 1, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (single exposure) Category 3 narcotic effects, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[72]	Controls removed: HPC4C
Protim Optimum III	HSR002442	Flammable liquid category 3, Aspiration hazard category 1, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated	Aspiration hazard Category 1, Flammable liquid Category 3, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (single	Controls removed: HPC4C

[69] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[70] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[71] Changes based on changes to tebuconazole, propiconazole and permethrin. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[72] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
		exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	exposure) Category 3 narcotic effects, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[73]	
J57.23I	HSR007648	Flammable liquid category 3, Acute oral toxicity category 4, Acute dermal toxicity category 3, Aspiration hazard category 1, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[74]	Controls removed: HPC2 HPC4C
J57.23K	HSR007650	Flammable liquid category 3, Acute oral toxicity category 4, Acute dermal toxicity category 3, Aspiration hazard category 1, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[75]	Controls removed: HPC2 HPC4C
Wocosen ME-3WP	HSR007772	Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[76]	Controls removed: HPC4C

[73] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[74] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[75] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[76] Changes based on changes to tebuconazole, propiconazole and permethrin. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
Protim Aquazole Concentrate	HSR007777	Flammable liquid category 4, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 2,	Flammable liquid Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[77]	Controls removed: HPC4C
PROTIM Aquazole Ready-to-use	HSR007778	Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[78]	Controls removed: HPC4C
TNL2436	HSR007948	Flammable liquid category 4, Acute oral toxicity category 4, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Flammable liquid Category 4, Acute oral toxicity Category 4, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[79]	Controls removed: HPC4C
IV 64 WB Timber Concentrate	HSR100111	Skin irritation category 2, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Skin irritation Category 2, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[80]	Controls removed: HPC4C
Premix B	HSR100274	Flammable liquid category 3, Acute oral toxicity category 4, Skin irritation category 2, Serious eye	Flammable liquid Category 3, Acute oral toxicity Category 4, Skin irritation Category 2, Serious eye	Controls removed:

[77] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[78] Changes based on changes to tebuconazole, propiconazole and permethrin. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[79] Changes based on changes to tebuconazole, propiconazole and permethrin. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[80] Changes based on changes to tebuconazole, propiconazole and permethrin. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
		damage category 1, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[81]	HPC4C
Premix BR	HSR100275	Flammable liquid category 3, Acute oral toxicity category 4, Skin irritation category 2, Serious eye damage category 1, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Flammable liquid Category 3, Acute oral toxicity Category 4, Skin irritation Category 2, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[82]	Controls removed: HPC4C
J57.41	HSR100280	Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Reproductive toxicity category 2, Specific target organ toxicity (repeated exposure) category 1, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[83]	No change
J57.47	HSR100405	Flammable liquid category 4, Acute oral toxicity category 4, Acute dermal toxicity category 3, Aspiration hazard Category 1, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 4, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic	Controls removed: HPC2 HPC4C

[81] Changes based on changes to tebuconazole, propiconazole and permethrin. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[82] Changes based on changes to tebuconazole, propiconazole and permethrin. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[83] Changes based on changes to tebuconazole, propiconazole and permethrin. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
			environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[84]	
J57.52	HSR100482	Skin irritation category 2, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Reproductive toxicity category 2, Specific target organ toxicity (repeated exposure) category 1, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Skin irritation Category 2, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[85]	No change
J57.48A Concentrate	HSR100503	Flammable liquid category 4, Acute oral toxicity category 4, Acute inhalation toxicity category 4, Aspiration hazard category 1, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 4, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[86]	Controls removed: HPC4C
J57.48B-RTU	HSR100504	Flammable liquid category 3, Aspiration hazard category 1, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Specific target organ toxicity (single exposure) Category 3 narcotic effects, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[87]	Controls removed: HPC4C

[84] Changes based on changes to tebuconazole, propiconazole and permethrin. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[85] Changes based on changes to propiconazole

[86] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[87] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared. Some classifications usually triggered by aromatic hydrocarbon solvents have not been included in this proposed classification for consistency with the original application appraisal.

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
J57.55	HSR100582	Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Reproductive toxicity category 2, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[88]	No changes
XYLA Concentrate	HSR100591	Flammable liquid category 3, Aspiration hazard Category 1, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1	Aspiration hazard Category 1, Flammable liquid Category 3, Skin sensitisation Category 1, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Specific target organ toxicity (single exposure) Category 3 narcotic effects, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[89]	Controls removed: HPC4C
J57.56	HSR100617	Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Reproductive toxicity category 2, Specific target organ toxicity (repeated exposure) category 1, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category	Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[90]	No changes
WBA Concentrate	HSR100640	Flammable liquid category 4, Acute oral toxicity category 4, Acute inhalation toxicity category 4, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1	Flammable liquid Category 4, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[91]	Controls removed: HPC4C

[88] Changes based on changes to propiconazole and mixture rules.

[89] Changes based on changes to tebuconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[90] Changes based on changes to propiconazole.

[91] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
J57.58A	HSR100656	Flammable liquid category 3, Acute oral toxicity category 4, Acute inhalation toxicity category 4, Skin irritation category 2, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Acute inhalation toxicity Category 4, Skin irritation Category 2, Serious eye damage Category 1, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 1, Specific target organ toxicity (single exposure) Category 3 narcotic effects, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[92]	Controls removed: HPC4C
J57.58B	HSR100657	Flammable liquid category 3, Aspiration hazard Category 1, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1	Aspiration hazard Category 1, Flammable liquid Category 3, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Specific target organ toxicity (single exposure) Category 3 narcotic effects, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[93]	Controls removed: HPC4C
Osmose Protim Aquazole	HSR100940	Acute oral toxicity category 4, Acute dermal toxicity category 4, Skin irritation category 2, Serious eye damage category 1, Respiratory sensitisation category 1, Skin sensitisation category 1, Reproductive toxicity category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1	Acute oral toxicity category 4, Acute dermal toxicity category 4. Acute inhalation toxicity category 4, Skin irritation category 2, Serious eye damage category 1, Skin sensitisation category 1, Reproductive toxicity category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1[94]	Controls removed: HPC4C
Protim Optimum CA	HSR100985	Flammable liquid category 3, Aspiration hazard category 1, Eye irritation category 2, Respiratory	Aspiration hazard Category 1, Flammable liquid Category 3, Eye irritation Category 2, Skin	Controls removed:

[92] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[93] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[94] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
		sensitisation category 1, Skin sensitisation category 1, Carcinogenicity category 2, Reproductive toxicity category 2, Specific target organ toxicity (repeated exposure) category 1, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1	sensitisation Category 1, Carcinogenicity Category 2, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2,Specific target organ toxicity (single exposure) Category 3 narcotic effects, Hazardous to terrestrial vertebrates, Hazardous to terrestrial invertebrates, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[95]	HPC4C
J57.74	HSR101046	Flammable liquid category 4, Aspiration hazard category 1, Eye irritation category 2, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[96]	Controls removed: HPC4C
Protim Optimum HF	HSR101265	Flammable liquid category 4, Aspiration hazard category 1, Eye irritation category 2, Carcinogenicity category 2, Reproductive toxicity category 2, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Carcinogenicity Category 2, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[97]	No changes
Protim Optimum HFII 0.6% and Protim Optimum 1.2%	HSR101305	Flammable liquid category 4, Aspiration hazard category 1, Reproductive toxicity category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 4, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to the	No changes

[95] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[96] Changes based on changes to propiconazole.

[97] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared. During the transfer of substances from HSNO classifications to GHS, the substances Protim Optimum HF 0.6% and Protim Optimum HF 1.2% were merged. This substance is now a range from 0.6% to 1.2% of active ingredients.

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
			aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[98]	
Protim Optimum HFII 2.0%	HSR101307	Flammable liquid category 4, Aspiration hazard category 1, Reproductive toxicity category 2, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 4, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[99]	No changes
Protim Optimum LO 0.6% and Protim Optimum LO 1.2%	HSR101403	Flammable liquid category 3, Aspiration hazard Category 1, Skin irritation Category 2, Skin sensitisation Category 1, Carcinogenicity Category 2, Reproductive toxicity Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Aspiration hazard Category 1, Flammable liquid Category 3, Skin irritation Category 2, Skin sensitisation Category 1, Carcinogenicity Category 2, Reproductive toxicity Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[100]	No changes
Protim Optimum LO 2.0%	HSR101404	Aspiration hazard Category 1, Flammable liquid Category 3, Skin irritation Category 2, Skin sensitisation Category 1, Carcinogenicity Category 2, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Aspiration hazard Category 1, Flammable liquid Category 3, Skin irritation Category 2, Skin sensitisation Category 1, Carcinogenicity Category 2, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[101]	No changes
J57.81	HSR101394	Flammable liquid Category 4, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Aspiration hazard Category 1, Eye irritation Category 2, Respiratory sensitisation Category 1, Skin sensitisation Category 1, Reproductive toxicity	Aspiration hazard Category 1, Flammable liquid Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to the	No changes

[98] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared. During the transfer of substances from HSNO classifications to GHS, the substances Protim Optimum HF II 0.6% and Protim Optimum HF 1.2% II were merged. This substance is now a range from 0.6% to 1.2% of active ingredients. Some classifications usually triggered by aromatic hydrocarbon solvents have not been included in this proposed classification for consistency with the original application appraisal.

[99] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[100] Changes based on changes to propiconazole.

[101] Changes based on mixture rules.

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
		Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[102]	
Protim Optimum PTB 0.6% and Protim Optimum PTB 1.2%	HSR101405	Flammable liquid category 4, Acute oral toxicity category 4, Acute inhalation toxicity category 4, Aspiration hazard category 1, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Reproductive toxicity category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1,	Aspiration hazard Category 1, Flammable liquid Category 4, Skin sensitisation Category 1, Carcinogenicity Category 2, Reproductive toxicity Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[103]	No changes
Protim Optimum PTB 2%	HSR101406	Flammable liquid category 4, Aspiration hazard category 1, Skin sensitisation category 1, Carcinogenicity category 2, Reproductive toxicity category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Aspiration hazard Category 1, Flammable liquid Category 4, Skin sensitisation Category 1, Carcinogenicity Category 2, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[104]	No changes
J57.23A	HSR007640	Flammable liquid Category 3, Acute oral toxicity Category 4, Aspiration hazard Category 1, Eye irritation Category 2, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Aspiration hazard Category 1, Flammable liquid Category 3, Acute oral toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[105]	No changes

[102] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[103] Changes based on changes to propiconazole and bifenthrin. Changes to bifenthrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[104] Changes based on bifenthrin and mixture rules. Changes to bifenthrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[105] Changes based on changes to propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
J57.23B	HSR007641	Flammable liquid Category 3, Acute oral toxicity Category 4, Aspiration hazard Category 1, Skin sensitisation Category 1, Eye irritation Category 2, Reproductive toxicity Category 2, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	Aspiration hazard Category 1, Flammable liquid Category 3, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[106]	No changes
J57.23C	HSR007642	Flammable liquid category 3, Acute oral toxicity category 4, Acute dermal toxicity category 3, Aspiration hazard category 1, Eye irritation category 2, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2,Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[107]	No changes
J57.23D	HSR007643	Flammable liquid category 3, Acute oral toxicity category 4, Acute dermal toxicity category 3, Aspiration hazard category 1, Eye irritation category 2, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Flammable liquid Category 3, Acute oral toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[108]	Controls removed: HPC4C
J57.23E	HSR007644	Flammable liquid category 3, Acute oral toxicity category 4, Acute dermal toxicity category 3, Acute inhalation toxicity category 4, Aspiration hazard category 1, Eye irritation category 2, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2,Hazardous to the aquatic	Controls removed: HPC2 HPC4C

[106] Changes based on changes to tebuconazole, propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[107] Changes based on changes to propiconazole.

[108] Changes based on changes to propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
		Hazardous to the aquatic environment chronic category 1,	environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[109]	
J57.23F	HSR007645	Flammable liquid category 3, Acute oral toxicity category 4, Acute dermal toxicity category 3, Aspiration hazard category 1, Eye irritation category 2, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2,Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[110]	Controls removed: HPC2 HPC4C
J57.23G	HSR007646	Flammable liquid category 3, Acute oral toxicity category 4, Acute dermal toxicity category 3, Aspiration hazard category 1, Eye irritation category 2, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[111]	Controls removed: HPC2 HPC4C
J57.23H	HSR007647	Flammable liquid category 3, Acute oral toxicity category 4, Acute dermal toxicity category 3, Acute inhalation toxicity category 4, Aspiration hazard category 1, Eye irritation category 2, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[112]	Controls removed: HPC2 HPC4C

[109] Changes based on changes to propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[110] Changes based on changes to propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[111] Changes based on changes to propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[112] Changes based on changes to propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

Name	Approval number	Current GHS Classifications	Proposed GHS classifications	Effects on controls
J57.23J	HSR007649	Flammable liquid category 3, Acute oral toxicity category 4, Acute dermal toxicity category 3, Aspiration hazard category 1, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[113]	Controls removed: HPC2 HPC4C
J57.23L	HSR007651	Flammable liquid category 3, Acute oral toxicity category 4, Acute dermal toxicity category 3, Acute inhalation toxicity category 4, Aspiration hazard category 1, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 3, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Specific target organ toxicity (repeated exposure) Category 2, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1[114]	Controls removed: HPC2 HPC4C
Protim Optimum HF Premix	HSR101473	Flammable liquid category 3, Acute oral toxicity category 4, Acute dermal toxicity category 3, Acute inhalation toxicity category 4, Aspiration hazard category 1, Eye irritation category 2, Respiratory sensitisation category 1, Skin sensitisation category 1, Specific target organ toxicity (repeated exposure) category 2, Hazardous to the aquatic environment acute category 1, Hazardous to the aquatic environment chronic category 1,	Aspiration hazard Category 1, Flammable liquid Category 4, Acute oral toxicity Category 4, Acute inhalation toxicity Category 4, Eye irritation Category 2, Skin sensitisation Category 1, Reproductive toxicity Category 1, Hazardous to the aquatic environment acute Category 1, Hazardous to the aquatic environment chronic Category 1	No changes

[113] Changes based on changes to propiconazole, permethrin and mixture rules. Changes to permethrin have been included as the active is also included in the reassessment of synthetic pyrethroid substances that is currently being prepared.

[114] Changes based on changes to propiconazole.

Appendix 3. Ecotoxicological and toxicological hazard assessments of the substances

Tebuconazole

Acute toxicity

Tebuconazole is of low acute toxicity by dermal or inhalation routes of administration. However, it has moderate acute toxicity by the oral route. The lethal dose (LD50) reported from various studies in DAR and RAC opinion are:

Table 1: Acute toxicity studies with tebuconazole

Study	Dose level	Results	Classification
Acute oral toxicity-rat (OECD TG 401)	Males: 1600, 2300, 3000, 3900 and 5000 mg/kg bw Females: 730, 950, 1230, 1600, 2300, 3000, 3900 and 5000 mg/kg bw	LD_{50} (males)= 4000 mg/kg bw LD_{50} (females)= 1700 mg/kg bw Mortalities: total of 7 males (from 3000-5000 mg/kg bw) and 22 females (from 950-5000 mg/kg bw).	Cat 4 (GHS)
Acute oral toxicity-rat (Based on relevant OECD guidelines)	Fasted: 1000, 2500, 4500 and 5000 mg/kg bw (male) 1000, 2500, 3150, 3550 and 5000 mg/kg bw (female) Non-fasted: 500, 1000, 3550, 3750, 4000, 5000 mg/kg bw (male) 500, 1000, 2500, 3550, 4250, 4500 mg/kg bw (female)	LD_{50} (males) > 5000 mg/kg bw (fasted) and 4264 mg/kg bw (non-fasted) LD_{50} (males): 3933 mg/kg bw (fasted) and 3352 mg/kg bw (non-fasted) Mortalities: A total of 2 fasted males (5000 mg/kg bw) and 7 fasted females (from 3150-5000 mg/kg bw) and a total of 9 non-fasted males (from 3750-5000 mg/kg bw) and 12 non-fasted females (from 2500-4500 mg/kg bw).	-
Acute oral toxicity-mice (Similar to OECD TG 401)	Males: 1600, 2300, 3000, 3900 and 5000 mg/kg bw. Females: 3000, 3900 and 5000 mg/kg bw.	LD_{50} = 2800 mg/kg bw (male) and 5200 mg/kg bw (female). Mortality: A total of 13 males (from 1600-5000 mg/kg bw) and 4 females (from 3900-5000 mg/kg bw).	-

Study	Dose level	Results	Classification
Acute oral toxicity- mice (Based on relevant OECD guidelines)	100, 500, 1000, 1800, 2500, 3150 and 3550 mg/kg bw (male) 500, 1000, 1800, 2500, 3550 and 5000 mg/kg bw (female)	LD_{50} = 1615 mg/kg bw (male) and 3023 mg/kg bw (female). Mortality: A total of 17 fasted male mice (1000-3550 mg/kg bw) and 10 fasted female mice (from 1800-5000 mg/kg bw).	Cat 4 (GHS)
Acute dermal toxicity- rat (OCED TG 402)	2000 mg/kg bw	LD_{50} > 2000 mg/kg bw	Not classified
Acute dermal toxicity- rat (Based on relevant OECD guidelines)	5000 mg/kg bw	LD_{50} > 5000 mg/kg bw	Not classified
Acute inhalation toxicity (OECD TG 403)	Nominal concentration: 4000 mg/m³ (aerosol) Analytical concentration: 371 mg/m³ (aerosol), 5093 mg/m³ (dust)	LC_{50} > 371 mg/ m³ (aerosol) and LC_{50} > 5093 mg/m³ (dust)	Not classified
Acute inhalation toxicity (Based on relevant guidelines)	Nominal concentration: 100, 250, 2500, 5000 mg/m³ (aerosol exposure 1x4 hrs) 0, 100, 300, 1000 mg/m³ (aerosol exposure 5x6 hrs) Analytical concentration: 16, 49, 387, 818 mg/m³ (aerosol exposure 1x4 hrs) 0, 24, 60, 240 mg/m³ (aerosol exposure 5x6 hrs)	LC_{50} (male)> 818 mg/kg bw (1x4 hrs) and > 240 mg/m³ (female)	Not classified

Tebuconazole is classified as acute oral toxicity Category 4 following principles of GHS. The classification is based on the lowest acute oral LD50 of tebuconazole (1700 mg/kg bw in rats and 1615 mg/kg bw in mice).

Skin irritancy

Two skin irritation studies (patch-test) were reported in rabbits, where animals were exposed for 4 hours. No irritant effects (erythema and oedema formation) were observed during the course of the studies. Based on these results, tebuconazole is not classified as a skin irritant.

Eye irritancy

The eye irritation potential of tebuconazole was tested in rabbits in two studies. In the first study, tebuconazole caused discharge, redness and swelling of the conjunctiva that resolved by eight days after dosing. Tebuconazole did not cause corneal opacities or lesions of the iris. In the second study, it did not cause corneal opacities or lesions of the iris. Reddening of conjunctiva was observed in one animal (average score 0.3; reversible at 48 hours). Based on these results, tebuconazole is not classified as an eye irritant.

Contact sensitisation

Three skin sensitisation studies were conducted in guinea pigs (Guinea Pig Maximization Test and Buehler Patch Test). Tebuconazole showed no skin-sensitising potential and is therefore not classified as a contact sensitiser.

Genotoxicity

A battery of in-vitro and in-vivo assays showed no evidence for genotoxic potential, no indication of gene mutations, chromosome anomalies or increases in DNA repair activity. Hence, no classification is warranted for genotoxicity.

Carcinogenicity

In a two-year carcinogenicity study in the rat, there was increase in C-cell adenomas and carcinomas of the thyroid in all treated males and no clear dose-response relationship was observed. The incidences were within the range of spontaneously occurring thyroid C-cell tumours in old male Wistar rats. There was no evidence of progression from adenoma to carcinoma from histopathology data. A NOAEL for carcinogenicity was determined at 180 ppm for males and females, equivalent to 53.1 mg/kg bw/day for males and 80.5 mg/kg bw/day for females.

In mice at 1500 ppm, there was a statistically significant increase in incidence of liver tumours. The incidences of carcinomas at this dose were 21% (versus 0% in controls) in males and 26% (versus 2% in controls) in females. Hepatocellular tumours caused by a variety of chemical substances at hepatotoxic doses occur frequently, and it is thought that under these circumstances, elevated incidences of spontaneous, relatively frequent tumours in rodents have no relevance for humans if the exposure to human beings lies in a non-toxic range. No evidence for carcinogenic effects of tebuconazole on other organs may be inferred from the incidence, type, location, or distribution among the study groups of the neoplasms observed. A NOAEL for carcinogenicity effects was determined at 500 ppm for males and females, equivalent to 85 and 103 mg/kg bw/day for males and females, respectively.

Table 2: Carcinogenicity studies of tebuconazole

Study	Dose levels (ppm)	NOAEL (mg/kg bw/day)	LOAEL (mg/kg bw/day)	Findings
2-year oral chronic/ carcinogenicity - rat	0, 100, 300, 1000	55.0 M / 86.3 F (1000 ppm)	-	C-cell adenomas and carcinomas of the thyroid were increased in all treated males. A slightly higher frequency of endometrial adenocarcinoma in females
21-months oral chronic/ carcinogenicity - mouse	0, 20, 60, 180	53.1 M / 80.5 F (180 ppm)	-	No increase in tumour incidence was found. The study was repeated with higher doses.

Study	Dose levels (ppm)	NOAEL (mg/kg bw/day)	LOAEL (mg/kg bw/day)	Findings
21-months oral chronic/ carcinogenicity - mouse	0, 500, 1500	85 M / 103 F (500 ppm)	App. 280 (1500 ppm)	At 1500 ppm (~280 mg/kg bw/day), an increased incidence of liver tumours was observed.

Based on these effects, tebuconazole is not classified for carcinogenicity.

Reproductive/developmental toxicity

No classification for reproductive and developmental toxicity has been assigned for tebuconazole in the EPA's current classification.

Two oral developmental toxicity studies were conducted in rats. In both studies tebuconazole was administered from gestation days 6-15. Compared to concurrent controls, these studies showed an increased incidence of resorptions, post-implantation loss and/or external malformations at the high dose (100 or 120 mg/kg bw/d) in the presence of maternal toxicity (reduced body weight gain). Maternal toxicity was also observed at the intermediate dose (30 mg/kg bw/d) in one study. Thus, embryotoxic/teratogenic findings were not observed in the absence of maternal toxicity in rats.

Three oral developmental toxicity studies are available in rabbits for which tebuconazole was administered from gestation days 6-18. At 30 mg/kg bw/d (the high dose in one study, intermediate dose in two studies) compared to concurrent controls, no embryotoxicity/teratogenicity was seen in one study, an increased incidence of resorptions and post-implantation loss that were within laboratory's historical control range were seen in one study, and the final study showed an increased incidence of post-implantation loss and external malformations outside the laboratory's historical incidence. No maternal toxicity was observed at this dose level in any study. At 100 mg/kg bw/d (the high dose in two studies), resorptions, post-implantation loss and external malformations were seen in the presence of maternal toxicity (reduced body weight gain). While embryotoxic/teratogenic findings were not seen across all studies in the absence of maternal toxicity, overall, the data is considered to demonstrate that the findings are not exclusively secondary to maternal toxicity.

Two oral developmental toxicity studies are available in mice which is not the preferred rodent species for developmental toxicity studies. In both these studies tebuconazole was administered from gestation days 6-15 at the same dose levels. Compared to concurrent controls, in one study an increased incidence was seen in post-implantation loss and external malformations at the low dose (10 mg/kg bw/d) with the later finding outside the laboratory's control incidence (no such information was reported for post-implantation loss). No increased incidence in these findings were seen in this study at the intermediate dose (30 mg/kg bw/d), though an increased incidence in external malformations outside the laboratory's historical control incidence was seen in the other study at this dose level. At the high dose (100 mg/kg bw/d), an increased incidence was seen in resorptions, post-implantation loss and external malformations in both studies that were outside the laboratories historical control incidence when reported. No maternal toxicity was seen in either study up to or including the high dose. The embryotoxic/teratogenic findings in mice, which is not the preferred rodent test species, support such observed findings in rabbits being attributed to tebuconazole exposure.

The maternal NOAELs were 10 mg/kg bw/d in rats, 30 mg/kg bw/d in rabbits and 100 mg/kg bw/d in mice. The developmental NOAELs were 30 mg/kg bw/d in the rat, 10 mg/kg bw/d in the rabbit, whereas only a LOAEL of

10 mg/kg bw/d was identified in mice. Based on the effects observed through species (malformations, post-implantation loss, resorptions) and the absence of overt maternal toxicity, a Classification of Repr. 2 H361d "Suspected of damaging the unborn child" was proposed by EFSA (and is also the current classification in Annex VI of Regulation (EC) No 1272/2008).

Table 3. Summary on reproductive toxicity studies of tebuconazole

Study	Dose levels (mg/kg bw/day)	NOAEL (mg/kg bw/day)	Findings
Two-generation, dietary- rat	0, 100, 300, 1000 ppm	21.6-27.1 / 27.8-33.9 males/females (300 ppm)	Decreased litter size and food consumption, retarded weight gains for parents and pups. Decreased organ weights. No effects on reproductive parameters
Embryotoxicity, gavage- rat	0, 10, 30, 100	Maternal: 10 Foetal: 30	Reduced weight gains and liver affections Increased number of resorptions, of malformations and runts. Decreased number of live foetuses and foetal body weight
Embryotoxicity, gavage	0, 30, 60, 120	Maternal: 30 Foetal: 60	Reduced weight gains and liver affections Increased number of resorptions, of malformations and runts. Decreased number of live foetuses and foetal body weight
Developmental neurotoxicity, dietary	0, 100, 300, 1000 ppm	22 and 41.3 mg/kg bw/day during gestation and lactation, respectively (300 ppm)	Mortality. Reduced body weight and feed consumption, and prolonged gestation in dams. Mortality, reduced pup weight and body weight gain, reduced brain weight, delay in vaginal patency, and decrease in cerebellar thickness in, pups
Developmental neurotoxicity, perinatal dosing, gavage, dams, and pups	0, 6, 20, 60	Maternal: 20 Pups: 20	Impaired spatial learning following perinatal dosing and repeated dosing of pups after weaning
Embryotoxicity gavage- rabbit	0, 3, 10, 30	Maternal: 30 Foetal: 10	No maternal effects increased number of losses
Embryotoxicity, gavage- rabbit	0, 10, 30, 100	Maternal: 30 Foetal: 30	Reduced body weight gain and increased post implantation loss Increased malformations and anomalies (external and skeletal)
Embryotoxicity gavage- rabbit	0, 10, 30, 100	Maternal: 30 Foetal: 10	Decreased food consumption and body weight gain malformations, both external and skeletal

Based on the observed findings in three species (malformations, post-implantation loss, resorptions) tebuconazole should be classified as reproductive toxicity Category 2 following the principles GHS.

Target organ or systemic toxicity

The current classification IUCLID is based on a 1-year chronic toxicity study in dogs. Target organ classifications are generally based on 90 or 28-day toxicity studies. There were a number of 90 or 28-day toxicity studies reported in the DAR. No significant or severe toxicities were observed in these studies. Therefore, tebuconazole should not be classified for target organ toxicity.

Aquatic ecotoxicity

Tebuconazole is not considered readily biodegradable and to have a low potential for bioaccumulation with log KOW<4 and a reported BCF of <500.

There is reliable acute data available for all three trophic levels, based on this information the lowest relevant acute aquatic toxicity value is an EC50 of 0.1444 mg ai/L for Lemna gibba (7-day, static) based on frond number. As this value is between 0.1 and 1.0 mg ai/L, an acute M-factor of 1 is assigned to the classification. Based on this endpoint, tebuconazole is classified as hazardous to the aquatic environment acute category 1 with an M-factor of 1 following the principles of GHS.

The lowest relevant chronic aquatic toxicity value is a NOEC of 0.01 mg ai/L for Daphnia magna (21-dat, semi-static). As this value is between 0.001 and 0.01 mg ai/L, a chronic M-factor of 10 is assigned to the classification. Based on this endpoint, tebuconazole is classified as hazardous to the aquatic environment chronic category 1 with an M-factor of 10 following the principles of GHS.

Soil ecotoxicity

Tebuconazole is considered to have moderate to high persistence in soil (DT50>30 days).

Tebuconazole is currently not classified under GHS. This is based on study data indicating an acute 14-day LC50 of 1381 mg ai/kg dry weight for earthworm in the EPA's chemical database. Based on this endpoint, tebuconazole is not classified as toxic to soil organisms.

Terrestrial vertebrate ecotoxicity

Tebuconazole is currently classified toxic to terrestrial vertebrates based on study data indicating an acute LD50 of 1555 mg ai/kg bw for bobwhite quail in the EPA's chemical database. Based on this endpoint, tebuconazole is classified as hazardous to terrestrial vertebrates following the principles of GHS.

Terrestrial invertebrate ecotoxicity

Tebuconazole is currently not classified based on study data indicating an acute oral LD50 of >83.05 µg ai/bee for honeybee in the EPA's chemical database IUCLID. Based on this endpoint, tebuconazole is not classified following the principles of the GHS.

Propiconazole

Acute toxicity

Propiconazole is of low acute toxicity by dermal or inhalation routes of administration. However, it has moderate acute toxicity by the oral route. The lethal dose (LD50) reported in various studies are:

Table 4: Acute toxicity studies with propiconazole

Study	Dose level	Results	Classification
Acute oral toxicity- rat (OECD TG 425; OPPTS 870.1100)	175, 550, 2000 mg/kg bw	LD_{50} = 550 mg/kg bw Mortalities at 2000 (2/2) and 550 (1/3) mg/kg bw	Cat 4 (GHS)
Acute oral toxicity- mouse (Similar to OECD TG 401)	800, 1500, 2500 or 3000 mg/kg	LD_{50} = 1490 mg/kg bw 1/10 deaths at 800 mg/kg, 4/10 deaths at 1500 mg/kg, 9/10 deaths at 2500 mg/kg, 10/10 deaths at 3000 mg/kg	Cat 4 (GHS)
Acute dermal toxicity- rat (OCED TG 402; EC No 440/2008; OPPTS 870.1200)	5000 mg/kg bw	LD_{50} > 5000 mg/kg bw	Not classified
Acute dermal toxicity- rat (OCED TG 402)	3000, 4000 mg/kg bw	LD_{50} > 4000 mg/kg bw	Not classified
Acute oral toxicity- rabbit (Similar to OECD TG 402)	0, 2000, 6000 mg/kg bw	LD_{50} > 6000 mg/kg bw	Not used for classification
Acute inhalation toxicity (OECD TG 403)	0, 5836 ± 186 mg/m^3	LC_{50} (4 h): > 5800 mg/m^3	Not classified

The rat was the most sensitive species with LD50 of 550 mg/kg bw and classification should be based on the most appropriate sensitive species tested. Hence, propiconazole is classified as acute oral toxicity category 4 following the principles of GHS.

Skin irritancy

Propiconazole was previously classified as 6.3B (equivalent to GHS skin irritant category 3) in New Zealand. However, following New Zealand's adoption of a GHS classification system on 1 May 2021, skin irritation Category 3 has no longer been adopted as a classification. Therefore, the classification of propiconazole for skin irritancy is not warranted.

Eye irritancy

Propiconazole is currently classified as an eye irritant in New Zealand. Based on a new study submitted for renewal of the approval of the active substance propiconazole in the EU, it is a weak irritant, and no classification was required.

Based on the available information, classification of propiconazole for skin irritancy is not warranted.

Contact sensitisation

Information in the EPA's chemical database IUCLID indicates that propiconazole should be classified as sensitiser based on maximisation test, but also indicates that no sensitisation was observed in the Buehler test. The maximisation test is more sensitive than the Buehler test. Hence, propiconazole is a contact sensitiser and is classified as contact sensitisation category 1 following the principles of GHS. The classification is based on a study showing 30% and 50% of sensitisation 24 hours and 48 hours after challenge with 30% propiconazole. It is noted that induction was not tested at concentrations of 1% and lower and therefore it is unknown if the response at 1% would have been higher than 60%. Therefore, category 1A could not be excluded with the available information and RAC concluded the classification of category 1.

Table 5: Skin sensitisation studies with propiconazole

Study	Dose level	Results	Classification
Guinea pig maximisation test (OECD TG 406)	Day 0: Induction: intradermal 5% propiconazole, in peanut oil Day 8: Induction: 100% propiconazole (or vaseline) occlusive for 48 hours Day 21: Challenge: 30% propiconazole (or vaseline) occlusive for 24 hours	Test group: 6/20 (24 h after challenge) 10/20 (48 h after challenge) Vehicle control: 0/10 (24 h after challenge) 0/10 (48 h after challenge)	Category 1 (GHS)

In a new study, propiconazole caused no sensitisation after an intradermal injection dose of 1%. It was noted that in the induction phase skin reactions observed in control animals were like the test animals, while 24 hours after challenge one control animal (that received only vehicle) showed significant dermal response. The study was regarded as unacceptable because of the non-specific positive reactions in vehicle control animals. Also, no positive controls were included in this study and therefore negative results might be interpreted as an intrinsic resistance of the animals to sensitisation.

Genotoxicity and mutagenicity

There was no evidence of mutagenicity in available in vitro and in vivo genotoxicity studies.

Carcinogenicity

Three studies (2-year chronic toxicity and carcinogenicity study in rat, 2-year carcinogenicity study in CD-1 mouse and 18-month carcinogenicity study in male CD-1 mouse) were reported for propiconazole. Propiconazole induced liver tumours in male CD-1 mice at dose levels of 107.8 and 344.3 mg/kg bw/day. The statistically significant neoplastic findings in liver appeared only in one species in one sex (male mice) and malignancy (hepatocellular carcinomas) only occurred at doses above the maximum tolerable dose. The mechanistic studies supported CAR-mediated mode of action as plausible for propiconazole which is likely not relevant for humans. Overall, RAC concluded that the liver tumours found in mice are not of concern for humans. Hence, no classification is warranted for carcinogenicity.

Reproductive/ developmental toxicity

Two oral developmental toxicity studies were conducted in rat. In both studies propiconazole was administered from gestation days 6-15. In the first study cleft palate was observed in a single foetus (1/302, incidence 0.33%) at the intermediate dose (90 mg/kg bw/day) and in two foetuses (2/285, incidence 0.70%) from separate litters at the high dose (360/300 mg/kg bw/day). Cleft palate was again observed in a supplementary study conducted with a single propiconazole administered dose (300 mg/kg bw/day) in two foetuses from separate litters (2/2064 foetuses, incidence 0.097%). Cleft palate was not observed in foetuses from the concurrent control animals in either study (270 foetuses in the first study and 2122 foetuses in the supplemental study) and had not been seen in historical

control data for the testing laboratory (5431 foetuses). The incidence of cleft palate seen in the two rat propiconazole studies was also above historical control data submitted for other laboratories (4/25522 foetuses; 0.016%).

Additionally in the first study, a statistically significant increased incidence of visceral variations (short and absent renal papilla(e) and dilated ureters) were observed at the high dose (360/300 mg/kg bw/day) along with a statistically significant increased incidence of skeletal variations (rudimentary ribs and nonossified sternebrae) at the intermediate (90 mg/kg bw/day) and high dose.

In a rabbit developmental toxicity study with propiconazole administered from gestation days 7-19, compared to concurrent controls a statistically significant increased incidence of resorptions, abortions, early deliveries, and increased incidence of fully formed (13th) rib was observed at the high dose (400 mg/kg bw/day).

Cleft is a rare malformation in rats and was seen in two independent studies in both the absence of maternal toxicity (90 mg/kg bw/day) and the presence of maternal toxicity (360/300 and 300 mg/kg bw/day) and demonstrated a dose response pattern. The observed incidences were also above historical control data for the testing laboratory and other laboratories. An increased incidence of skeletal variations was also seen in the absence (90 mg/kg bw/day) and presence of maternal toxicity (300 mg/kg bw/day) and demonstrated a dose response pattern. Consequently, these findings were not considered a chance (spontaneous) finding and were attributed to propiconazole exposure. In contrast the increased incidence of visceral findings in the rat and observed resorptions, abortions, early deliveries, and skeletal findings in the rabbit were only observed at the high dose and in the presence of maternal toxicity.

The RAC noted that an increased incidence of cleft palate had also been observed in response to exposure to other triazoles (e.g. cyproconazole and epoxiconazole) and overall, concluded that this finding in both studies in rats was relevant to humans and warranted propiconazole be classified as a presumed human developmental toxicant classification [1B H360D (May damage the unborn child)]. The RAC also stated that the observed skeletal variations in rats at 90 mg/kg bw/day and resorptions, abortions, and early deliveries in rabbits at 400 mg/kg bw/day contribute to (i.e., support) propiconazole being considered a presumed human developmental toxicant. Based on the cleft palate observed in rats, propiconazole is classified as reproductive toxicity category 1 following the principles of GHS.

Target organ or systemic toxicity

The current classification in IUCLID is based on neurotoxic effects. However, no clinical signs nor biochemical or histopathological changes were observed which might indicate that propiconazole is neurotoxic. Most of the repeated toxicity studies reported hepatotoxicity as a common toxic effect. The main reported hepatic effects were liver weight increases, hypertrophy, vacuolation, necrosis, and mineralization.

Table 6: Hepatotoxicity reported after repeated exposures to propiconazole

Study	Lowest reported dose (mg/kg bw/day)	Guidance value for STOT RE classification (mg/kg bw/day)
28-day oral toxicity in rat	150	30 ≤ C ≤ 300
90-day oral toxicity in rat	461/481	10 ≤ C ≤ 100
90-day oral toxicity in mouse (2 studies)	65-71-85	10 ≤ C ≤ 100
2-year oral toxicity in rat	96-130	1.25 ≤ C ≤ 12.5
2-year oral toxicity in mouse	49-55	1.25 ≤ C ≤ 12.5
18-month oral toxicity in mouse	59	2.2 ≤ C ≤ 22
2-generation reproduction toxicity in rat	44-49	4 ≤ C ≤ 40 (assuming 32 weeks of exposure in F0)

In the above table, four studies (90-day and 2-year oral toxicity studies in rat, and 2-year and 18-month oral toxicity studies in mouse) showed that the hepatotoxicity appeared at doses well above the respective limit dose for warranting classification as STOT RE 2. RAC did not consider these studies relevant for classification. However, the other three studies (28-day in rat, 90-day oral toxicity studies in mice and 2-generation reproduction toxicity in rat) showed hepatotoxicity at doses either warranting classification as STOT RE Category 2 or on the border for classification.

In the 28-day oral toxicity study in the rat, the effects reported at 150 mg/kg bw/day were described as minimal hypertrophy of hepatocytes and small focus organising necrosis in liver parenchyma, while the dose showing moderate hypertrophy and multiple areas of necrosis was 450 mg/kg bw/d, and hence above the limit for classification.
In the 90-day oral toxicity studies, the severity of hepatocellular necrosis was observed to be slight or very slight in all animals except in two individuals where it was scored as moderate.

The 2-generation reproduction toxicity study in rat reported at 44-49 mg/kg bw/day liver hypertrophy in F0 and F1 in males affecting 93 and 33% of examined males and 50% of F1 females. These alterations were not significant in other generations. The incidence and relevance of these alterations were not considered by RAC as toxicologically relevant for warranting classification. In the same study, liver hypertrophy was consistently reported in four different generations in almost 100% of male and female, although in this case these effects were found at 215-243 mg/kg bw/day, which is above the limits for warranting classification as STOT RE category 2.

Overall, RAC noted that the hepatotoxicity associated with repeated exposure of propiconazole either appeared at concentrations above the cut-off values for warranting classification or when appeared below these limits, is seen with a severity and incidence not considered indicative of toxicologically relevant disturbances. Hence, propiconazole is not classified for target organ toxicity.

Aquatic ecotoxicity

Propiconazole is not considered readily biodegradable and to have a low potential for bioaccumulation with log KOW<4 and a reported BCF of 180 L/kg.

There is reliable acute data available for all three trophic levels, based on this information the lowest relevant acute aquatic toxicity value is a LC50 of 0.51 mg ai/L for Americamysis bahia (96-hour, flow-through). As this value is between 0.1 and 1.0 mg ai/L, an acute M-factor of 1 is assigned to the classification. A lower value is available in IUCLID, the EPA's chemical database based on the green algae, Chlamydomonas noctigama. However, this endpoint was deemed unreliable for hazard classification following a review of the literature. Based on the A. bahia endpoint, propiconazole is classified as hazardous to the aquatic environment acute category 1 with an M-factor of 1 following the principles of GHS.

The lowest relevant chronic aquatic toxicity value is a NOEC of 0.068 mg ai/L for Cyprinodon variegatus (FLC, flow-through). As this value is between 0.01 and 0.1 mg, ai/L a chronic M-factor of 1 is assigned to the classification. Based on this endpoint, propiconazole is classified as hazardous to the aquatic environment chronic category 1 with an M-factor of 1 following the principles of GHS.

Soil ecotoxicity

Propiconazole is considered to have moderate to high persistence in soil (DT50>30 days).
Propiconazole is currently not classified following principles of GHS. This is based on data in IUCLID suggesting propiconazole does not have an adverse effect on soil microbes up to and including 100 ppm. However, a seedling emergence value of 4.32 mg ai/kg wet weight was available from ECHA's more recent assessment report of propiconazole. There is also an acute earthworm endpoint (LC50) in this document of 205 mg ai/kg wet weight, corrected to an EC50 of 20.5 mg ai/kg wet weight for the hazard classification. Based on lowest endpoint obtained from the seedling emergence, propiconazole is classified as hazardous to soil organisms following the principles of GHS.

Terrestrial vertebrate ecotoxicity

Propiconazole is currently classified toxic to terrestrial vertebrates based on an acute LD50 of 1344 mg ai/kg bw for rabbit in the EPA's chemical database. Based on this endpoint, propiconazole is classified as hazardous to terrestrial vertebrates following the principles of GHS.

Terrestrial invertebrate ecotoxicity

Propiconazole is currently not classified based on an acute contact LC50 of >25 µg ai/bee for honeybee in the EPA's chemical database. Based on this endpoint, propiconazole is not classified following the principles of GHS.

Appendix 4: Māori impact assessment

Māori Impact Assessment (MIA)

for Notified Reassessment Application – Chemical Review

KEY DETAILS	
Applicant	*Environmental Protection Authority*
Active ingredient	*TEBUCONAZOLE*
Purpose	*Broad-spectrum fungicide for cereals (barley, wheat, oat, ryecorn, triticale), pasture and ryegrass, pome and stone fruits, kiwifruit, grapes, onion, pea, and ornamental plants. Used to prevent wood decay from fungus, and as a preservative for other materials.*
End-user	*Certified handlers (growers and contractors) in commercial operations*
Proposed additional hazard classifications	***Reproductive toxicity Category 2***
Active ingredient	*PROPICONAZOLE*
Purpose	*Broad-spectrum fungicide for cereals (barley, wheat, oat), pasture and ryegrass, pome fruits, olive, kiwifruit, avocado, and turf. Used to prevent wood decay from fungus, and as a preservative for other materials.*
End-user	*Certified handlers (growers and contractors) in commercial operations*
Proposed additional hazard classifications	***Skin sensitisation Category 2*** ***Reproductive toxicity Category 1*** ***Hazardous to soil organisms***

This advice is prepared by Kaupapa Kura Taiao under s 58(1)(a) of the Hazardous Substances and New Organisms Act 1996 ("the Act / HSNO").

Impact Assessment

Kaupapa Kura Taiao (The EPA's Māori Policy and Operations team) has undertaken a Māori impact assessment to consider potential impacts of the reassessment on the economic, social, and cultural well-being of Māori, and the relationship of Māori with the environment, pursuant to sections 5(b), 6(d) and 8 of the Hazardous Substances and New Organisms Act 1996 (HSNO). The cultural assessment includes tangible and intangible taonga, such as culturally significant species, resources, and places, and the customary values, practices and uses associated with these taonga. Key findings of the assessment are outlined below.

General comments

Māori will be reassured by the following points in relation to this chemical review:

- The proposed additional hazard classifications will more accurately reflect the toxicity and ecotoxicity attributes of tebuconazole and propiconazole.
- The proposed changes will help to make users aware of these attributes so they can take steps to enhance the safe use of formulations containing tebuconazole and propiconazole.
- Formulations containing these actives are typically used by certified professional handlers in commercial operations, not by novice users in home environments. Therefore, potential for exposure is in lower in respect of vulnerable groups associated with kāinga (domestic settings).

Reproductive toxicity is a serious issue for Māori that raises concerns (including of a spiritual nature) in relation to: Hauātanga - impairment of functions and potential to participate fully at work, home or in society; Interference with whakapapa (genealogy) and whanaungatanga (family relationships); Te whānau tamariki - issues concerning

fertility, pregnancy, birth and developmental defects, and; Ngā whakakino ki ngā pūnaha ā tinana - adverse effects on body organs and/or systems.

The classification for skin sensitisation can be addressed by using appropriate personal protective equipment to protect taha hauora (human health and well-being).

The 'Hazardous to soil organisms' classification recognises the potential for harm to culturally significant earth-dwelling creatures belonging to a realm known as Te Aitanga a Punga (the progeny of Punga) e.g., noke / toke (earthworms) and iroiro (nematodes).

Consultation

As part of reassessment preparations, the proposal was circulated for comment to Te Herenga, the Environmental Protection Authority's national network of Māori environmental practitioners and kaitiaki (environmental guardians). One response was received, which supports the application to update classifications and controls of these substances.

Impact on the relationship of Māori and their culture and traditions with their environment and taonga

This application is not likely to significantly affect the relationship of Maori and their culture and traditions with their environment and taonga, including culturally significant species, resources, and places, and the customary values, practices and uses associated with these taonga.

Impact on the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural well-being

This application is not likely to significantly affect the ability and capacity of Māori to maintain their economic, social, and cultural well-being.

Treaty of Waitangi principles

The Principles of the Treaty of Waitangi have been considered in relation to this application, as summarised below.

The active protection principle: the Crown has a duty to actively protect Māori interests.
No issues arise.

The informed decision-making principle: the Crown has a duty to make informed decisions.
No issues arise.

The partnership principle: to act fairly, reasonably, and in good faith.
No issues arise.

Appendix 5. Control codes for changes in Table 4 Appendix 2

The default EPA control codes are listed below in Table 5.

Table 5. EPA control codes used in this application

Control code	EPA Notice	Control description
LAB	EPA Labelling Notice 2017	Requirements for labelling of hazardous substances
PKG	EPA Packaging Notice 2017	Requirements for packaging of hazardous substances
SDS	EPA Safety Data Sheet Notice 2017	Requirements for safety data sheets for hazardous substances
DIS	EPA Disposal Notice 2017	Requirements for disposal of hazardous substances
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	Hazardous Property Controls preliminary provisions
HPC-2	EPA Hazardous Property Controls Notice 2017 Part 2	Certain substances restricted to workplaces only
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	Hazardous substances in a place other than a workplace
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	Site and storage controls for class 9 substances
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	Use of class 9 substances
HPC-4C	EPA Hazardous Property Controls Notice 2017 Part 4C	Qualifications required for application of class 9 pesticides

The requirements in Table 6 below are not set for a substance under its approval but apply in their own right under the HSW legislation according to the classification of the substance. They are listed in this document for information purposes only.

Table 6. HSW Requirements referred to in this application

Control code	Regulation Part	Description
HSW1	Part 1	Application
HSW2	Part 2	Labelling, signage, safety data sheets, and packaging
HSW3	Part 3	General duties relating to risk management
HSW4	Part 4	Certified handlers and supervision and training of workers
HSW5	Part 5	Emergency management
HSW7	Part 7	Controlled substance licences
HSW8	Part 8	Controls applying to all class 1 to 5 substances
HSW9	Part 9	Class 1 substances
HSW10	Part 10	Class 2, 3, and 4 substances
HSW11	Part 11	Controls relating to adverse effects of unintended ignition of class 2 and 3.1 substances
HSW12	Part 12	Class 5 substances
HSW13	Part 13	Class 6 and 8 substances
HSW14	Part 14	Fumigants
HSW15	Part 15	Gases under pressure
HSW16	Part 16	Tank wagons and transportable containers
HSW17	Part 17	Stationary container systems
HSW19	Part 19	Tracking hazardous substances