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EXECUTIVE SUMMARY OF THE RISK ASSESSMENT FOR PROPICONAZOLE CONTAINING PRODUCTS:

Bumper 250 EC/Principle 250 EC/Propin 250EC

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Background:
According to regulation 8(1)(d) and 10(3)(e) respectively, the Registrar (Act 36 of 1947) may not grant or renew a registration after 1 June 2024 if a product contains substances of concern. Propiconazole has been classified in Europe as Repr.1B (H360D) and as such would be considered a substance of concern. However, in exceptional circumstances, the Registrar may grant a registration for a product (agricultural remedy) containing a substance of concern and the Applicant can submit a derogation to achieve this. The Regulation states:

"Before commencing an application for derogation of an agricultural remedy, the applicant must conduct a risk assessment to evaluate the risks associated with the use of the remedy according to the proposed uses for which a derogation is sought and determine whether the associated risks can be sufficiently mitigated".

The Propiconazole Derogation Group comprising of: ICA International Chemicals (Pty) Ltd, Sharda International Africa (Pty) Ltd. and Adama South Africa (Pty) Ltd, is submitting a derogation for emulsifiable concentrate (EC) formulation products containing 250 g/L propiconazole that includes dietary and non-dietary human health risk assessments but also environmental risk assessments and hereby demonstrate safe use of these products.

Executive summary:
This derogation consists of several independent core reports, the outcome of which is presented in this executive summary. The core reports are identical for the three members of the derogation, however for each product a separate addendum was prepared that presents confidential data and/or data that are specific to the individual products.

The core reports consist of:

- A general toxicological profile of propiconazole where the toxicological reference values used in the risk assessments are rationalised. In that toxicological section, the relevance of the Repr.1B (H360D) concluded by the EU Authorities [ECHA-CLP classification] in the context of human health risk assessments is also discussed.
- Dietary (consumer) risk assessments.
- Non-dietary (Operator, worker, bystander and resident) risk assessments.
- Environmental assessment.

It was considered appropriate, to encompass all possible uses in the risk assessments rather than conduct a risk assessment per company in so far as the supported uses presented in Appendix 1 are supported by ICA International Chemicals (Pty) Ltd, Sharda International Africa (Pty) Ltd and Adama South Africa (Pty) Ltd.

This derogation demonstrates that the hazard represented by propiconazole Repr.1B (H360D) classification is extremely unlikely to have any negative deleterious health effect on consumers, and users when the products are used according to their recommended GAP.

Indeed, despite a very conservative approach to the risk assessments, (worst case scenarios) the consumer risk assessments demonstrate safe use to consumers for all crops with a high safety margin. The non-dietary risk assessments also demonstrate safe use assuming an appropriate level of PPE (personal protection equipment) is used. It is emphasised by the derogation group that SANS 10206 :2020. Ed 3: "The handling, storage and disposal of pesticides" should be strictly followed by individuals entitled to use the products.

Finally, the impact of propiconazole on the environment is considered in yet another separate report and demonstrate that propiconazole is unlikely to have any serious irreversible effects on the environment.

Toxicological assessment [Report EWC 2402743.UK0-6336]

To support the derogation application and inform the human health risk assessments, a summary review of the toxicological profile of propiconazole has been carried out, considering recent and relevant authoritative regulatory evaluations and the derivation of human health-based reference values.

Toxicological information has been sourced from evaluations conducted by: the Joint Meeting on Pesticide Residues (JMPR), the expert ad hoc body administered jointly by the United Nations (UN) Food and Agriculture Organization (FAO) and the World Health Organization (WHO) and the European Union (EU) European Food Safety Authority (EFSA) and European Chemicals Agency (ECHA).

Subsequent to the 2004 toxicological assessment of propiconazole, the JMPR has scrutinised the regulatory evaluations of other jurisdictions (i.e.: the European Union (EU)), and, on this basis have defended the hazard characterisation and conclusions made during the 2004 assessment (FAO and WHO, 2021). The 2004 JMPR evaluation of propiconazole has therefore been considered to be the primary source of toxicological information to support the derogation application.

It is however noted that while the JMPR and the EU regulatory authority, EFSA have largely reviewed the same toxicological datasets as part of their respective evaluations, their interpretation of the study findings diverges on several endpoints. These differences are discussed in the main report.

Acute toxicity:

Propiconazole has low acute dermal and inhalation toxicity and is not a skin or an eye irritant. The substance has moderate acute oral toxicity and requires classification in GHS Cat 4. H302 (Harmful if swallowed) and is a skin sensitiser, requiring classification in GHS Cat 1. H317 (May cause an allergic skin reaction).

C*arcinogenicity:*

Based on authoritative evaluations of the data, propiconazole is not considered to be carcinogenic in humans. Classification in respect of carcinogenicity was discussed by the ECHA Committee for Risk Assessment (RAC) in the context of the human health hazard criteria indicated in Regulation (EC) No. 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures (referred to as the "CLP Regulation"). The RAC concluded that the liver tumours observed in mice after exposure to propiconazole were not of concern for humans and no classification in respect of carcinogenicity was warranted (ECHA, 2016). The JMPR also concluded that propiconazole was unlikely to pose a carcinogenic risk to humans.

M*utagenicity/ Genotoxicity*

There is a consensus across regulatory authorities that propiconazole is not genotoxic, based on the findings of a standard battery of *in vitro* and *in vivo* studies. No classification is warranted.

***R**eproductive toxicity:*
Fertility and sexual function: propiconazole does not affect fertility, mating or gestation.
Development toxicology: in a generational study, reproductive effects (i.e.: decreased litter size and the number of viable pups) were observed at or above dose levels producing parental toxicity. Developmental effects in the available studies generally concurred with severe maternal toxicity. While a low incidence of cleft palate was observed in two prenatal developmental toxicity rat studies only, and may be secondary to maternal toxicity, the authoritative reviews could not definitively rule out the findings as incidental or not relevant to humans, and taking into account other effects (i.e.: skeletal variations in rats study and resorptions, abortions and early deliveries in rabbits) propiconazole was classified as a reproductive toxicant Category 1B H360D (May damage the unborn child) in accordance with the relevant EU Regulation (EC) No 1272/2008.

Within the EU legislative framework, the CLP Regulation serves as a hazard identification process, with direct risk management consequences, to ensure that the hazards presented by chemical substances are clearly communicated to workers and consumers in the EU, across the supply chain. As such, the CLP Regulation does not facilitate the assessment of exposures to the chemical substances, the characterisation of the hazards (i.e.: via health-based reference values) or the assessment of health risks.

Regulation (EC) No. 1107/2009, regulating pesticides in Europe has set several hazard-based "cut-off" criteria. The classification for reproductive toxicity Cat 1A or B is one of the hazard-based "cut-off" criteria. It was a key factor in the ban of propiconazole pesticide uses in Europe.
It is noted that "cut off "criteria are specific to Regulation (EC) No. 1107/2009, and that propiconazole is still widely registered worldwide: US, Australia, Canada etc and is also still registered in Europe for biocidal products.

Propiconazole is not neurotoxic and has not been considered as having endocrine disruption potential.

Reference values:
To assess the potential risk caused using a pesticidal product, reference values are derived from experimentally determined "no-observed-adverse-effect levels "(NOAELs). The NOAEL for the most critical effect is often referred to as the "point of departure" (POD)L. The reference values are derived by dividing the POD by an appropriate safety factor (SF, also referred to as an uncertainty factor (UF)), which, as the name conveys, ensures that the derived reference value is sufficiently conservative and protective towards human health, based on the effects observed in the studies.

Consumer risk assessments: ADI and ARfD
The ADI (Acceptable Daily Intake) is commonly defined as the amount of a chemical to which a person can be exposed on a daily basis over an extended period of time (usually a lifetime) without suffering a deleterious effect.
The ARfD (Acute Reference Dose) of a chemical is an estimate of the amount a substance in food and/or drinking water, normally expressed on a body weight basis, that can be ingested in a period of 24 h or less without appreciable health risk to the consumer.

Operator/worker bystanders and residents risk assessments: AOEL and AAOEL
The AOEL (Acceptable Operator Exposure Level) is the minimum amount of active substance to which human may be exposed without adverse health effects over an extended period.

The AAOEL (Acute Acceptable Operator Exposure Level) of a chemical is an estimate of the amount a substance, normally expressed on a body weight basis, a human can be exposed to over a short time period without appreciable health risk.

In the 2021 JMPR, the respective experts from the FAO and the WHO scrutinised EFSA's concerns and conclusions on certain aspects of the toxicological profile of propiconazole made following the evaluation of the renewal of the substance as a plant protection active substance in the EU (FAO and WHO, 2021). The JMPR concluded that based on the information presented in the EU documentation, the concerns identified, including those pertaining to the interpretation of the toxicity data, were not substantiated and did not therefore merit any review of propiconazole in advance of the normal periodic review.
Consequently, the health-based reference values: the ADI and the ARfD, established by the JMPR in 2004 (as indicated in the table below) are still considered to be valid for assessing the dietary risks associated with the use of propiconazole and have been used recently by the JMPR in this regard. (FAO and WHO, 2024).

Since the focus of the JMPR evaluation is the assessment of dietary risks arising from potential exposures to pesticide residues, the JMPR does not derive health-based reference values for non-dietary risk assessments and therefore the reference values established during the EU evaluation of propiconazole have been considered.

During the renewal evaluation of propiconazole, EFSA (2017) maintained the systemic AOEL set during the first review of 0.1 mg/kg bw/day, based on parental toxicity observed in the two-generation study in rats. The AOEL is based on the relevant parental NOAEL of 8.4 mg/kg bw/day in the two-generation study in rats based on liver toxicity observed at higher doses. An uncertainty factor of 100 was applied. No correction factor for oral absorption was applied to derive the AOEL. The resulting value for the AOEL was determined to be 0.08 mg/bw/day, rounded by EFSA to 0.1 mg/kg bw/day.

At renewal, an AAOEL of 0.1 mg/kg bw was established on the same basis as the ARfD. No correction factor for oral absorption was applied to derive the AAOEL.

Taking into account that the 2004 JMPR evaluation of propiconazole made a comparable interpretation of the relevant critical effects in the two-generation reproductive toxicity study (i.e.: parental toxicity and liver effects), the EU AOEL and AAOEL values have been used to inform the non-dietary risk assessments submitted in support of the derogation application.

The following health-based reference values are considered to be relevant to inform the dietary and non-dietary risk assessments for EC products containing 250 g/L propiconazole and are sufficiently conservatively protective in respect of human health:

Reference endpoint	**Derived value**	**Source**
ADI	**0-0.07 mg/kg bw/day**	JMPR (FAO and WHO, 2004)
ARfD	**0.3 mg/kg bw/day**	JMPR (FAO and WHO, 2004)
AOEL	**0.1 mg/kg bw/day**	EFSA (2017)
AAOEL	**0.1 mg/kg bw**	EFSA (2017)

Dietary exposure assessment [Report EWC 2402743.UK0-0492]
The uses supported in South Africa by the propiconazole derogation group, are presented in the Good Agricultural Practice (GAP) Appendix 1. The supported crops are Pecan, Mango, Apricot/Cherry/Peach/Plum, Wheat and Barley. The traces pesticides leave in treated products are called "residues". A maximum residue level (MRL) is the highest level of a pesticide residue that is legally tolerated in or on food or feed when pesticides are applied correctly (Good Agricultural Practice).

Using the Bryant Christie (BC) Global database for pesticide (Maximum residue level) MRLs, a report has been run for propiconazole on all supported crops.

The highest Global MRLs (Maximum Residue levels) for each crop are listed in the table below. It should be noted that different methods of MRL calculation are used in different countries, and sometimes even the same dataset may result in a different MRL value. However, it is true in all countries that the MRL is a highly conservative value used to facilitate trade between countries and to monitor GAP compliant application, whereas the lower STMR (Supervised Trial Median Residue) and HR (Highest Residue) values are intended for risk assessment calculations.

Table 1: MRLs for propiconazole around the world

Crop	MRL (mg/kg)							Comments
	Codex	**Taiwan**	**USA**	**GCC**	**Argentina**	**Australia**	**South Africa**	
Pecan	0.02*	0.02	0.1	0.02	0.02	**0.2**	0.05	AUS, USA and S.A MRLs for whole tree-nut group
Mango	N.E	**1.0**	N.E	N.E	0.01 (default)	0.05	0.01 (default)	-
Apricot	**4.0** (Po)	1.0	**4.0**	N.E	**4.0**	**4.0**	0.2	Codex - Included in the peach MRL (group FS 2001) AUS and USA MRL for whole stone fruit group (excl. plum) S.A MRL for whole stone fruit group
Cherry	3.0 (Po)	0.01	**4.0**	N.E	3.0	**4.0**	0.01 (default)	AUS and USA MRL for whole stone fruit group (excl. plum)
Peach	4.0 (Po)	4.0	4.0	**5.0**	4.0	4.0	4.0	AUS, ARG, USA and S.A MRL for whole stone fruit group (excl. plum)
Plum	0.4 (Po)	1.0	0.6	0.6	0.4	**2.0**	0.2	S.A MRL for whole stone fruit group
Wheat	0.09	0.02	0.3	0.09	**0.4**	0.05*	0.1	AUS MRL for whole cereal group (excl. sweetcorn)
Barley	2.0	0.2	**3.0**	2.0	1.5	0.05*	0.05	AUS MRL for whole cereal group (excl. sweetcorn)

Highest Global MRL for each crop presented in **bold**
Po – MRL based on a post-harvest use
* MRL set at the LOQ level
Default MRL - When a specific MRL has not been set on a commodity for a pesticide, some markets defer to a set default MRL value. Policies regarding the use of default MRLs vary by country.
N.E – Not established
GCC – Gulf Cooperation Council

To present a worst-case risk assessment for consumers, the highest global MRL for each crop has been used in chronic and acute consumer risk assessment calculations (see bold values in Table X). The current Codex toxicological reference values: Acceptable Daily Intake (ADI) and Acute

Reference Dose (ARfD), which were agreed by the 2004 JMPR and further elaborated on in the main body of toxicological assessment are as follows:

- ADI = 0.07 mg/kg bw/day used for chronic risk assessment
- ARfD = 0.3 mg/kg bw used for acute risk assessment

The WHO models have been used for the chronic (IEDI – International Estimated Daily Intake) and acute (IESTI – International Estimate of Short-Term Intake) calculations. The results from each assessment are presented below. Safe use is demonstrated when IEDI<100% of the ADI and IESTI <100% of the ArfD.

Chronic risk assessment	Acute risk assessment
Maximum IEDI (based on G08 diet): 10% of ADI	Maximum IESTI = 90% of ARfD (based on consumption of peaches in the Japanese Child 1-6 years diet)
Maximum IEDI for South Africa (G05 diet): 3% of ADI	

This assessment using the most conservative approach to dietary risk assessment (i.e. the highest worldwide MRLs have been used as the input values for each crop) demonstrates that there is no unacceptable dietary chronic or acute risk to consumers.

The chronic risk assessment is not considered further as the maximum IEDI for South Africa (G05 diet) = 3% of the ADI and considering the conservatism of the assessment there is no necessary refinement/mitigation required.

For the acute assessment, although is it already demonstrated above that there is no unacceptable dietary risk to consumers because the highest IESTI = 90% of ARfD (based on consumption of peaches in the Japanese Child 1-6 years diet) refinements have been conducted.

Due to the public availability of JMPR reports and evaluations, comparisons between the South African GAPs and the Codex GAPs for each relevant crop have been made in the sections below. The comparisons show that the current South African GAPs are within the risk envelope for propiconazole already assessed by the JMPR. As a result, to demonstrate the level of conservatism in the risk calculations using the highest Global MRLs, an additional acute calculation has been performed using the STMR (supervised trial median residue) and/ or HR (highest residue) values listed by the JMPR for each crop.

The result for the refined acute risk assessment is presented below and clearly demonstrates that there is no unacceptable dietary acute risk to consumers.

Acute extreme worst-case assessment	Acute assessment with refinements
Maximum IESTI = 90% of ARfD (based on consumption of peaches in the Japanese Child 1-6 years diet)	Maximum IESTI = 40% of ARfD (based on consumption of peaches in the Japanese Child 1-6 year diet)

In addition to the above risk assessment, potential contamination of drinking water following the propiconazole uses has also been explored and a drinking water assessment conducted.

The Predicted Environmental Concentration in ground water, PECgw values for propiconazole have been determined in a separate document (2402743.UK0 – 1442 Propiconazole FOCUS PECgw report). All PECgw values for propiconazole were ≤0.001 µg/L for all crops and all FOCUS scenarios modelled following applications made in accordance with each GAP. To determine the consumer exposure to propiconazole through drinking water, the following exposure calculations have been presented below.

$$\left(\left(\frac{concentration\ in\ water\ x\ consumption}{bodyweight}\right) \div ADI\right) \times 100$$

- Exposure to infants (5kg bodyweight, consumption 0.75 L/day) = <0.001% of the ADI
- Exposure to children (10 kg bodyweight, consumption 1 L/day) = <0.001% of the ADI
- Exposure to adults (60kg bodyweight, consumption 2 L/day) = <0.001% of the ADI

The most conservative approach for consumer risk assessment was taken and an acute and chronic assessment was conducted using the highest Global MRL for each crop. This risk assessment demonstrated that there is no unacceptable risk to consumers using the highest MRLs as input values for the assessment. Although not required, some refinements (i.e. relying upon effective experimental data) were also conducted further demonstrating that the South African supported uses are safe to the consumers. This conclusion applies also to drinking water.

Non-dietary exposure assessment [Report EWC 2402743.UK0-3547]

A risk assessment has been conducted in accordance with the newly updated EFSA (European Food Safety Agency) (2022) guidance[1] on the assessment of exposure of operators, workers, residents, and bystanders to plant protection products.

The EFSA (2022) guidance document is designed to assist risk assessors when quantifying potential non-dietary, systemic exposures as part of regulatory risk assessment for plant protection products (PPPs). To support users in performing the assessment of exposure and risk, an online calculator (reflecting the guidance content) was also developed. The underlying principles of the guidance document and the related exposure calculator are the transparency of data, the traceability of information and the reproducibility of the outcomes. In establishing the guidance document and calculator, the EFSA working group considered only databases of raw data or peer-reviewed publications that could be accessed (if requested) by third parties in accordance with the Aarhus Convention2. The EFSA guidance is based on a comprehensive, peer reviewed dataset and is continually reviewed and amended as and when new data become available.

Considering the above, the EFSA web calculator has been selected as the most appropriate model to assess non-dietary exposure to propiconazole resulting from the application of the product Bumper 250 EC / Principle 250 EC / Propin 250 EC using vehicle mounted and/or handheld spraying equipment.

The EFSA web calculator is publicly available and accessible at: https://r4eu.efsa.europa.eu/

[1] EFSA (2022) Guidance on the assessment of exposure of operators, workers, residents, and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032

[2] UN (1998) Convention on access to information, public participation in decision making and access to justice in environmental matters.

Exposure to propiconazole resulting from the aerial application of the product to field crops has been estimated using a combination of data taken from the EFSA model (mixing and loading activities) and the US EPA Occupational Pesticide Handler Exposure Surrogate Reference Table[3] (application by fixed wing aircraft). The EFSA mixing and loading data for large-scale equipment are considered the most representative dataset for mix/load activities that would occur prior to aerial application. The US EPA exposure values for fixed wing aerial applications are derived from the Agricultural Handler Exposure Task Force (AHETF). For other areas of the risk assessment (residents/bystander exposure) the risk assessment relies upon US EPA Pesticide Handler Exposure Database (PHED) data for 'flaggers' (ground-based individuals marking target crops during aerial spraying activities).

The data used in the calculations is openly available and is detailed in the Exposure Surrogate Reference Table for Pesticide Risk Assessment (US EPA) with further details of the exposure calculations are provided in the appendix. As the US AHETF model data only provides a mean statistical output, it is only possible to assess longer term exposure with this model.

Non-dietary risk assessments have been undertaken for the product considering the endpoints listed below in Table X and the product uses detailed in Table 1 above. (proposed GAP).

Table 2: Product information and toxicological reference values used for exposure assessment.

Product code and name	Bumper 250 EC/Principle 250 EC/Propin 250 EC
Formulation type	Emulsifiable concentrate (EC)
Category	Fungicide
Active substance (incl. content)	Propiconazole 250 g/L
AOEL systemic	0.1 mg/kg bw/d
AAOEL systemic	0.3 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption	EFSA (2017)[4] default dermal absorption values for an EC formulation: Concentrate: 25% Dilution: 70%

The assessment confirms an acceptable risk assessment can be achieved for the products Bumper 250 EC/Principle 250 EC/Propin 250 EC for the proposed uses on orchard and field crops. A summary of the risk assessment for operators, workers, residents and bystanders is presented in the tables below. It should be noted that in the absence of actual studies with the products to derive a dermal absorption value and conduct more realistic risk assessments, the latter relied upon default values that are in essence extremely conservative. Despite this conservative approach, the risk assessments demonstrate that no health hazard to humans are expected when the products are used according to the recommendations.

[3] US EPA (2021) Occupation Pesticide Handler Unit Exposure Surrogate Reference Table (May 2021)
[4] EFSA (2017) Guidance on dermal absorption: EFSA Journal 2017;15(6):4873, 60 pp.

Wheat, barley

	Result	PPE **/ Risk mitigation measures
Operators	Acceptable	**Results of risk assessment:** Vehicle mounted and aerial equipment: Gloves during mixing/loading Hand-held equipment: None*
Workers	Acceptable	None*
Residents	Acceptable	None
Bystanders	Acceptable	None

None* means no PPE required but standard workwear (arms, body and legs covered)

Pecan nuts

	Result	PPE **/ Risk mitigation measures
Operators	Acceptable	**Results of risk assessment:** Vehicle mounted equipment: Gloves during mixing/loading and application Hand-held equipment: Gloves and face shield during mixing/loading and gloves and rainsuit during application
Workers	Acceptable	None*
Residents	Acceptable	None
Bystanders	Acceptable	None

None* means no PPE required but standard workwear (arms, body and legs covered)

Mango

	Result	PPE** / Risk mitigation measures
Operators	Acceptable	**Results of risk assessment:** Vehicle mounted spray equipment: Gloves during mixing/loading and application Hand-held equipment: Gloves and face shield during mixing/loading and gloves and rainsuit during application
Workers	Acceptable	None*
Residents	Acceptable	None
Bystanders	Acceptable	None

None* means no PPE required but standard workwear (arms, body and legs covered)

Apricot, Cherry, Peach, Plum

	Result	PPE** / Risk mitigation measures
Operators	Acceptable	**Results of risk assessment:** Vehicle mounted spray equipment: Gloves during mixing/loading and application

	Result	PPE** / Risk mitigation measures
		Hand-held equipment: Gloves and face shield during mixing/loading and gloves and rainsuit during application.
Workers	Acceptable	No re-entry restrictions when Gloves are worn when handling treated crops
Residents	Acceptable	None
Bystanders	Acceptable	None

For workers, standard workwear (arms, body and legs covered) and additional PPE required, in this instance, gloves.

** PPE = Personal Protective Equipment

Potential precautionary measures based on classification and labelling:
The products Bumper 250 EC / Principle 250 EC / Propin 250 EC contain 250 g/L of the active substance propiconazole which is classified as a skin sensitizer (Category 1) [5].

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS)[6] and Regulation (EC) No 1272/2008 stipulates that in the absence of product specific data, mixtures containing substances (or mixtures of substances) are considered as sensitizing, if at least one of the ingredients is present at or above the appropriate generic cut-off value/concentration limits detailed in Table 3.4.5 of the GHS (2023) guidance document. The GHS generic concentration limit is 1% for substances (or mixtures of substances) classified as category 1 skin sensitizers. Therefore, where product specific data is not available, the concentrated products may be classified as potential skin sensitizers (Category 1). Refer to the company addendum for more details on the products classification.

The maximum proposed in-use spray dilutions of the products contain propiconazole (0.5%) below the 1% generic concentration limit for skin sensitization classification.

Thus, the spray solutions of the plant protection products in the evaluation are not considered as sensitizers for residents and bystanders or workers as they are only exposed to the diluted sprays. If the product is warranted a skin sensitization classification (Category 1) then protective gloves, protective clothing and eye protection/face protection should be worn by the operator for mixing and loading.

It is noted that all users of pesticides should in any case comply with SANS 10206 :2020. Ed 3: "The handling, storage and disposal of pesticides" and that the above-mentioned PPEs for sensitizer for mixing and loading activities are strongly recommended in all cases when handling pesticides to provide additional protection against spills and splashes.

Environmental assessment [Report EWC 2402743.UK0-0560]
The assessment of the environmental risks caused by agricultural remedies becomes increasingly important in practical environmental protection. Ecotoxicological risk assessment is used to assess the potential hazard of existing or new environmental chemicals regarding the ecosystem. The combination of exposure assessment and hazard assessment allows the assessment of hazards induced by an environmental chemical and the analysis and final evaluation of the existing risk.

[5] ECHA (2016) Committee for Risk Assessment Annex 1 – Background document to the Opinion proposing harmonized classification and labelling at EU level of propiconazole (ISO): CAS Number: 60207-90-1. CLH-O-0000001412-86-139/F.
[6] United Nations (2023) Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Tenth revised edition.

Exposure: what are the environmental concentrations the non-target organisms are exposed to? The expected environmental concentration is assessed with the aid of computer models and Predicted Environmental Concentrations (PECs) are derived for surface water PECsw, for soil PECsoil and for groundwater PECgw.

Hazard:

The hazard of a substance considers various ecotoxicological effects such as acute toxicity, chronic toxicity and bioaccumulation. Tests on non-target organisms are conducted according to widely accepted OECD guidance to determine the acute (LD/LC/EC50) or chronic (NOEC/NOEL) toxicity endpoints. The LD/LC/EC50 is the "Concentration or dose where 50 % effect or mortality was observed/calculated "and the NOEC is the "No Observed Effect Concentration or Dose".

The assessment of the risks of agricultural remedies for the terrestrial environment is based on the calculation of risk indicators (e.g. TER, HQ) which compare the acute (LD/LC/EC50) or chronic (NOEC/NOEL) toxicity endpoints generated from experimental data with the formulation or the active substance to the potential exposure in the environment. Currently TER 'Toxicity exposure ratio' values are used for the risk assessments of terrestrial vertebrates, earthworms and non-target plants when HQ 'Hazard quotients' values are used for the risk assessment of bees and non-target arthropods.

If the risk indicators (TER, HQ) are above the TER trigger or below the HQ trigger then the risk is considered acceptable.

The assessment of the risks of agricultural remedies for the aquatic environment is based on the calculation of PEC/RAC ratios. RAC is the "regulatory acceptable concentrations "which is derived by applying an assessment factor (AF) of 100 or 10 to the lowest acute or chronic toxicity value obtained from the respective tests. Both the trigger values and the assessment factors are conservative.

To assess the environmental risk to non-target organisms following the supported uses of the derogation group propiconazole containing products, the European model has been followed: The European model is well known for being very conservative in order to achieve the highly ambitious protection goal set out by the European commission. Furthermore, it is noted that the European guidance sets are revised regularly, in order to reflect changes of test guidelines and of scientific knowledge. in EU Guidance documents (EFSA, SANCO, EPPO, etc.).

The risk assessments conducted reflect the South African Data requirements as per Appendix A&B "Toxicological Requirements for Registration of New Pesticides RSA", in order to cover all relevant areas considered under the South African Jurisdiction.

Overview of the risk assessment outcome

An assessment has been conducted to evaluate the environmental risks associated with the supported uses of the propiconazole containing products.

The comprehensive overview of the uses supported by the members of the derogation group as well as the outcome of the risk assessments for all non-target organisms in scope are presented below in Table 3. It demonstrates that the uses supported by the derogation group are safe to all non-target organisms with minimal mitigations measures such as buffer zones. The largest recommended buffer zone is 20m for aerial use on wheat.

Table 3: Outcome of the risk assessment for all non-target organisms for all supported uses

Use No.	Crop and/or situation	F, Fn, Fpn G, Gn, Gpn or I	Application				Application rate			PHI (days)	Conclusion						
			Method/Kind	Timing/Growth stage of crop & season	Max. number per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
1	Pecan nuts	F	Foliar Spray (ground application)	1st application BBCH 15 2nd application 10 days after T1 3rd application 21 days after T2	3	10-21 days	a) 0.5-1.0 b) 1.5-3.0	a) 125-250 b) 375-750	1000 – 2000	90	A	A	R	A	A	A	R
2	Mango	F	Foliar Spray (ground application)	BBCH 65-70	2	10-14 days	a) 0.3 b) 0.6	a) 75 b) 150	1500	120	A	A	A	A	A	A	A
3	Apricot, Cherry, Peach, Plum	F	Foliar Spray (ground application)	BBCH 55-69	3	7 days	a) 0.4 b) 1.2	a) 100 b) 300	2000	10/14	A	A	A	A	A	A	A
4	Cherry, Peach	F	Foliar Spray (ground application)	BBCH 10-39, 60, 65, 69 and 91-97	3	14 days	a) 0.6 b) 1.8	a) 150 b) 450	3000	10/14	A	A	A	A	A	A	R
5	Wheat	F	Foliar Spray (ground & aerial application)	BBCH 29-59	2 per crop	10 days	0.6	a) 150 b) 300	300 (aerial application: 30 L/ha water volume)	40	A	A	A (ground) R (aerial)	A	A	A	A (ground) R (aerial)
6	Barley	F	Foliar Spray (ground & aerial application)	BBCH 25-59	2 per crop	10 days	0.5	a) 125 b) 250	300 (aerial application: 30 L/ha water volume)	40	A	A	A (ground) R (aerial)	A	A	A	A (ground) R (aerial)

Ground application will be done at the maximum rate of 3 x 1 L product/ha in pecan nuts (minimum 10-day interval). Areal application will be done at the

maximum rate of 2 x 0.66 L product/ha on wheat (minimum 10-day interval).

Explanation for column “Conclusion”

A	Acceptable, Safe use
R	Risk mitigation measures required: **Aquatics** low risk to aquatic organisms following the uses of Propiconazole when using a 10 m buffer zone in pecan nuts and a 5 m buffer zone in wheat and barley (only for aerial application). **Non target plants**: acceptable risk at a distance of 15 m in pecan nuts, a distance of 10 m in cherry and peach, a distance of 20 m in wheat and a distance of 15 m in barley (only for aerial application).

Appendix 1: ALL intended uses

GAP rev. 1, date: 29.09.2019

PPP (product name/code):	**Bumper 250 EC/Principle 250 EC/Propin 250 EC**	Formulation type:	EC [a, b]
Active substance 1:	**Propiconazole**	Conc. of as 1:	250g/L [c]
Safener:	**NA**	Conc. of safener:	NA
Synergist/adjuvant	NA	Conc. of adjuvant:	NA
Applicant:	**Propiconazole derogation group**	Professional use:	☒
		Non professional use:	☐

Fungicide

1	2	3	4	5	6	7	8	9	10	11*	12	13	14
					Application				**Application rate**				
Use No.	**Country**	**Crop and/or situation**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	Method/Kind	Timing/Growth stage of crop & season	Max. number per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	**PHI** (days)	**Remarks:** product variant, other dose rate expressions dose range (min-max)

1	ZA	Pecan nuts	F	Scab (*Fusicladium effusum*)	Foliar Spray (ground application)	1st application BBCH 15 2nd application 10 days after T1 3rd application 21 days after T2	3	10-21 days	a) 0.5-1.0 b) 1.5-3.0	a) 125-250 b) 375-750	1000 - 2000	90	50 ml product/100 L water = 0.05 x 250 g/100L = 12.5g as/100L Adama, Sharda ,ICA
2	ZA	Mango	F	Powdery mildew (*Oidium mangiferae*)	Foliar Spray (ground application)	BBCH 65-70	2	10-14 days	a) 0.3 b) 0.6	a) 75 b) 150	1500	120	20 ml product/100 L water= 0.02x250 g/100L= 5g as/100L Adama, Sharda, ICA
3	ZA	Apricot, Cherry, Peach, Plum	F	Blossom blight (*Monilinia laxa*)	Foliar Spray (ground application)	BBCH 55-69	3	7 days	a) 0.4 b) 1.2	a) 100 b) 300	2000	10/14	20 ml product/100 L water= 0.02x250 g/100L= 5g as/100L Adama, Sharda, ICA
4	ZA	Cherry, Peach	F	Powdery mildew (*Sphaerotheca pannosa*)	Foliar Spray (ground application)	BBCH 10-39 BBCH 60 BBCH 65 BBCH 69 BBCH 91-97	3	14 days	a) 0.6 b) 1.8	a) 150 b) 450	3000	10/14	20 ml product/100 L water= 0.02x250 g/100L= 5g as/100L Do not exceed 3 applications per season of propiconazole on stone fruit, respecting the BBCHs Adama, Sharda, ICA
5	ZA	Wheat	F	Stem, foliar and ear diseases	Foliar Spray (ground & aerial application)	BBCH 29-59	2 per crop	10 days	0.6	a) 150 b) 300	300	40	Aerial application: 30 L/ha water volume Adama, Sharda, ICA
6	ZA	Barley	F	Foliar diseases	Foliar Spray (ground & aerial application)	BBCH 25-59	2 per crop	10 days	0.5	a) 125 b) 250	300	40	Aerial application: 30 L/ha water volume Adama, Sharda, ICA

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references

2 Use official codes/nomenclatures of EU Member States

3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)

4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.

6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

8 The maximum number of application possible under practical conditions of use must be provided.

9 Minimum interval (in days) between applications of the same product

10 For specific uses other specifications might be possible, e.g.: g/m^3 in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.

11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).

12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.

13 PHI - minimum pre-harvest interval

14 Remarks may include: Extent of use/economic importance/restrictions

Appendix 2: Members of the propiconazole derogation group and their product

Company	Product	Registration number
ICA International Chemicals (Pty) Ltd	Principle 250 EC	L10533
Sharda International Africa (Pty) Ltd	Propin 250 EC	L10487
Adama South Africa (Pty) Ltd	Bumper 250 EC	L6034