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ENVIRONMENTAL (RISK) ASSESSMENT FOR THE PROPOSED APPLICATION OF PRODUCTS CONTAINING PROPICONAZOLE

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Background

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 their emulsifiable concentrate formulations (EC) containing 250 g/L propiconazole that includes dietary and non-dietary human health risk assessments as well as environmental risk assessments and hereby demonstrate safe use of these products, when used according to their recommended use pattern.

This report covers the environmental risk assessment.

Product code and name	Bumper 250 EC/Principle 250 EC/Propin 250 EC 250 EC
Formulation type	Emulsifiable concentrate (EC)
Category	Fungicide
Active substance (incl. content)	Propiconazole 250 g/L

Principle of Ecotoxicological assessment

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 potential risk.

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 ($LD/LC/EC_{50}$) or chronic (NOEC/NOEL) toxicity endpoints. The $LD/LC/EC_{50}$ 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 ($LD/LC/EC_{50}$) 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 EC products containing 250 g/kg propiconazole, 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 uses of the emulsifiable concentrate products containing 250 g propiconazole/L.

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 1.

Table 1: Identified GAP for the product Bumper 250 EC/Principle 250 EC/Propin 250 EC 250 EC

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, a 5 m buffer zone in wheat and barley (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 (aerial application).

List of endpoints used for ecotoxicological assessment

The following tables present the endpoints for the active substance propiconazole and its metabolites as well as for the supported products according to data requirements presented in the Appendices A[1] and B[2] of the 'Toxicological requirements for registration of new pesticides in South Africa' for active substances and plant protection products, respectively.

Endpoints taken from the EU dRAR for Propiconazole (2017) as well as endpoints derived from experimental data from studies with the supported products are presented in the table below. The most sensitive endpoints that have been used for the risk assessment are shown in bold.

Summary of effects on birds and other terrestrial vertebrates

Table 2: Summary of endpoints for toxicity of propiconazole and the formulated product to birds and other terrestrial vertebrates

Species	Test substance	Time scale	End point	Toxicity	Reference / Owner
Birds					
Mallard duck (*Anas platyrhynchos*)	Propiconazole	Acute oral	LD_{50}	> 2510 mg a.s./kg bw	dRAR 2017
Bobwhite quail (*Colinus virginianus*)	Propiconazole	Acute oral	LD_{50}	> 2510 mg a.s./kg bw	dRAR 2017
Japanese quail (*Coturnix japonica*)	Propiconazole 25% EC	Acute oral	**LD_{50}**	1807.07 mg product/kg bw (**equivalent to 451.8 mg a.s./kg bw**)	Desai, 2008 SHARDA
Mallard duck (*Anas platyrhynchos*)	Propiconazole	One generation reproduction	NOEL	300 mg a.s./kg diet (**equivalent to 25.5 mg a.s./kg bw/day**)	dRAR 2017
Mammals					
Rat	Propiconazole	Acute oral	**LD_{50}**	**550 mg a.s./kg bw**	dRAR 2017
Rat	Propin 250 EC 250 EC	Acute oral	**LD_{50}**	300 < LD_{50} <2000 mg product/kg bw (equivalent to 75 < LD_{50} < 500 mg a.s./kg bw)[1]	Srinivasa, 2008 SHARDA
Rat	Bumper 25 EC	Acute oral	**LD_{50}**	300 < LD_{50} <2000 mg product/kg bw (equivalent to 75 < LD_{50} < 500 mg a.s./kg bw)[1]	Haferkorn, 2010 ADAMA
Rat	Propiconazole	2-generation reproduction	NOAEL	100 mg a.s./kg diet (**equivalent to 8.4 mg a.s./kg bw/day males** and 9.7 mg a.s./kg bw/day females**)**	dRAR 2017

[1] Based on a nominal concentration of 25% a.s.
Values in **bold** have been used in the risk assessment

[1] APPENDIX A: Toxicological requirements for registration of new pesticides in South Africa registration of agricultural remedies (act 36 of 1947), Evaluation of complete dossier for plant protection active substances)
[2] APPENDIX B: Toxicological requirements for registration of new pesticides in South Africa registration of agricultural remedies (act 36 of 1947), Evaluation of complete dossier for plant protection products (formulation)

Summary of effects on aquatic organisms

Table 3: Summary of endpoints for toxicity of propiconazole and the formulated product to aquatic organisms

Group	Test substance	Time-scale (Test type)	End point	Toxicity	Reference / Owner
Fish					
Spot *Leiostomus xanthurus* (marine species)	Propiconazole	Acute - static	96 h LC_{50}	2.6 mg a.s./L (mm)	dRAR 2017
Zebra fish *Danio rerio*	Propiconazole 25% EC	Acute – static	**96 h LC_{50}**	7.83 mg product/L (**equivalent to 1.96 mg a.s./L**) (mm) [1]	Neri, 2009 SHARDA
Sheepshead minnow *Cyprinodon variegates* (marine species)	Propiconazole	Full life cycle – flow-through	100 d NOEC	0.068 mg a.s./L (mm)	dRAR 2017
Fathead minnow *Pimephales promelas*	Propiconazole	Full life cycle – flow-through	**NOAEC Reproduction**	**0.188 mg a.s./L (mm)**	dRAR 2017
Bluegill sunfish *Lepomis macrochirus*	^{14}C-Propiconazole	Bio-accumulation - Flow-through	BCF_{SS}	180	dRAR 2017
Aquatic invertebrates					
Daphnia magna	Propiconazole	Acute – static	**48 h EC_{50}**	**10.2 mg a.s./L (nom)**	dRAR 2017
Daphnia magna	Propiconazole 25% EC	Acute – static	48 h EC_{50}	72.54 mg product/L (equivalent to 18.14 mg a.s./L) (mm) [1]	Neri, 2009 SHARDA
Daphnia magna	Propiconazole	Full Life-Cycle – semi-static	21 d NOEC adult growth **21 d EC_{10} Reproduction**	0.37 mg a.s./L (mm) **0.35 mg a.s./L (mm)**	dRAR 2017
Sediment-dwelling organisms					
Chironomus riparius	Propiconazole	Chronic – static	**28 d NOEC Emergence**	**25 mg a.s./kg dw sediment (nom)**	dRAR 2017
Algae					
Green algae *Pseudokirchneriella subcapitata*	Propiconazole	Static	72 h E_rC_{50} 72 h NOE_rC	9.0 mg a.s./L (mm) 0.46 mg a.s./L (mm)	dRAR 2017
Green algae *Pseudokirchneriella subcapitata*	Propiconazole 25% EC	Static	**72 h E_rC_{50}**	23.87 mg product/L (**equivalent to 5.97 mg a.s./L**) (mm) [1]	Neri, 2009 SHARDA

nom: based on nominal concentrations; mm: based on mean measured concentrations
Values in **bold** have been used in the risk assessment
[1] Based on a nominal concentration of 25% a.s.

Summary of effects on arthropods

Bees

Table 4: Summary of endpoints for toxicity of propiconazole and the formulated product to bees

Species	Test substance	Time-scale (Test type)	End point	Toxicity	Reference / Owner
Honeybees (*Apis mellifera*)	Propiconazole in A6097AF[1]	Acute oral	LD_{50}	800.7 µg product/bee **203.4 µg a.s/bee**	dRAR 2017
		Acute contact	LD_{50}	182.3 µg product/bee **46.3 µg a.s/bee**	dRAR 2017
Honeybees (*Apis mellifera*)	Propiconazole 25% EC	Acute oral	LD_{50}	>100 µg product/bee **>25 µg a.s/bee**	Colli, 2008 SHARDA
Honeybees (*Apis mellifera*)	Propiconazole in A6097AF[1]	Adult chronic	10 d-LDD_{50}	277 µg product/bee/day 70.4 µg a.s./bee/day	dRAR 2017
Honeybees (*Apis mellifera*)	Propiconazole in A6097AF[1]	Larval development	NOED	3.9 µg product/larvae 1.0 µg a.s./larvae	dRAR 2017
Honeybees (*Apis mellifera*)	Propiconazole in A6097AF[1]	Larval development	NOED	82 µg product/larvae 21 µg a.s./larvae	dRAR 2017

[1] EC formulation containing 248 g/ propiconazole/L
Values in **bold** have been used in the risk assessment

Non-target arthropods other than bees

Table 5: Summary of endpoints from laboratory tests with the formulated product on non-target arthropods

Species	Test Substance	Test substrate	End point	Toxicity	Reference / Owner
Laboratory test / Tier I					
Aphidius rhopalosiphi	Propiconazole in A6097K[1]	Glass plate	48h LR_{50} / ER_{50}	> 1000 mL product/ha **> 250 g a.s./ha**	dRAR 2017
Chrysoperla carnea	Propiconazole in A6097K[1]	Glass plate	LR_{50} / ER_{50}	> 1000 mL product/ha **> 250 g a.s./ha**	dRAR 2017
Poecilus cupreus	Propiconazole in A6097K[1]	Quartz sand	LR_{50}	> 1000 mL product/ha **> 250 g a.s./ha**	dRAR 2017
Coccinella septempunctata	Propiconazole in A6097G[1]	Glass plate	LR_{50} / ER_{50}	> 500 mL product/ha **> 125 g a.s./ha**	dRAR 2017
Extended laboratory test / Tier II					

Aphidius rhopalosiphi	Propiconazole in A6097K[1]	Potted barley plant	LR_{50} / ER_{50}	> 1000 mL product/ha **> 250 g a.s./ha**	dRAR 2017
Aged residue study / Tier II					
Typhlodromus pyri	Propiconazole in A6097AF[1]	Leaf discs	LR_{50} / ER_{50} After 7, 14, and 21 days	> 500 mL product/ha **> 125 g a.s./ha**	dRAR 2017
Semi-field and field studies					
The effects of propiconazole containing product (EC 250, A 6097 K) to predatory mite (mainly *Euseius stipulatus*) populations was studied in the field conditions in Portuguese apricot orchard. The test substance was tested at two rates (68 – 71 ml product/ha as 20 % drift rate and 329 – 352 ml/product/ha as a full rate) and compared to a water control. The test applications were made three times during the period of 3 weeks. No statistically significant differences in mite density were found in the two treatments. dRAR 2017					

Values in **bold** have been used in the risk assessment
[1] EC Formulation containing propiconazole 250 g/L.

Summary of effects on non-target soil meso- and macrofauna

Table 6: Summary of endpoints for toxicity of propiconazole, its metabolites and the formulated product to earthworms and other soil macroorganisms

Test organism	Test substance	Time scale	End point	Toxicity	Reference / Owner
Earthworms					
Eisenia foetida	Propiconazole	Acute 14 day	LD_{50}	**686 mg a.s./kg d.w. soil**	dRAR 2017
	Propiconazole in Propiconazole 25% EC	Acute 14 day	LD_{50}	611.3 mg product/kg d.w. soil **152.9 mg a.s./kg d.w. soil**	Neri, 2009 SHARDA
	1,2,4-triazole (CGA71019)	Acute 14 day	LD_{50}	**>1000 mg/kg d.w. soil**	dRAR 2017
	CGA091305 (R116857)	Acute 14 day	LD_{50}	**>1000 mg/kg d.w. soil**	dRAR 2017
	Propiconazole in A6097AF[1]	Chronic, 56 d	NOEC reproduction	**6.17 mg a.s./kg d.w. soil**	dRAR 2017
	SYN547889 (CGA217495)	Chronic, 56 d	NOEC reproduction	**556 mg/kg d.w. soil**	dRAR 2017
	NOA436613	Chronic, 56 d	NOEC reproduction	**309 mg/kg d.w. soil**	dRAR 2017

	CGA091305	Chronic, 56 d	NOEC reproduction	**309 mg/kg d.w. soil**	dRAR 2017
	1,2,4-triazole (CGA71019)	Chronic, 56 d	NOEC reproduction	**1.0 mg/kg d.w. soil**	dRAR 2017
Other soil macroorganisms					
Folsomia candida	Propiconazole in A6097AF[1]	Chronic, 28 d	NOEC reproduction	391 mg product/kg d.w. soil **100 mg a.s./kg d.w. soil**	dRAR 2017
	1,2,4-triazole (CGA71019)	Chronic, 28 d	NOEC reproduction	**1.8 mg/kg d.w. soil**	dRAR 2017
	SYN547889 (CGA217495)	Chronic, 28 d	NOEC reproduction	**1000 mg/kg d.w. soil**	dRAR 2017
	CGA091305	Chronic, 28 d	NOEC reproduction	**309 mg/kg d.w. soil**	dRAR 2017
	NOA436613	Chronic, 28 d	NOEC reproduction	**1000 mg/kg d.w. soil**	dRAR 2017
Hypoaspis aculeifer	Propiconazole in A6097AF[1]	Chronic, 14 d	NOEC reproduction	88 mg product/kg d.w. soil **22.4 mg a.s./kg d.w. soil**	dRAR 2017
	1,2,4-triazole (CGA71019)	Chronic, 14 d	NOEC reproduction	**171 mg/kg d.w. soil**	dRAR 2017
	SYN547889 (CGA217495)	Chronic, 14 d	NOEC reproduction	**1000 mg/kg d.w. soil**	dRAR 2017
	CGA091305	Chronic, 14 d	NOEC reproduction	**1000 mg/kg d.w. soil**	dRAR 2017
	NOA436613	Chronic, 14 d	NOEC reproduction	**1000 mg/kg d.w. soil**	dRAR 2017

[1] EC formulation containing 248 g/ propiconazole/L
Values in **bold** have been used in the risk assessment

Summary of effects on soil nitrogen transformation

Table 7: Summary of endpoints for toxicity of propiconazole, its metabolites and the formulated product to micro-organisms

Test substance	Test type	End point	Toxicity	Reference / Owner
Propiconazole in A6097AF[1]	Nitrate formation	NOEC	6.52 mg product/kg dry soil equivalent to **1.66 mg a.s./kg d.w. soil**	dRAR 2017

Propiconazole 25% EC	Carbon and Nitrogen transformation	NOEC	606.25 g a.s./ha equivalent to **0.9392 mg a.s./kg dry soil**	Dottorini, 2008 SHARDA
1,2,4-triazole (CGA71019)	Nitrate formation	NOEC	**0.333 mg/kg dry soil**	dRAR 2017
SYN547889 (CGA217495)	Nitrate formation	NOEC	**6.25 mg/kg dry soil**	dRAR 2017
CGA091305	Nitrate formation	NOEC	**0.377 mg/kg dry soil**	dRAR 2017
NOA436613	Nitrate formation	NOEC	**6.25 mg/kg dry soil**	dRAR 2017

[1] EC formulation containing 248 g/ propiconazole/L
Values in **bold** have been used in the risk assessment

Summary of effects on terrestrial non-target higher plants

Table 8: Summary of endpoints for toxicity of the formulated product to terrestrial non-target higher plants

Test organism	Test substance	Test type	End point	Toxicity	Reference / Owner
Maize *Zea mays* L. (Monocot.) Wild Oat *Avena fatua* L. (Monocot.) Onion *Allium cepa* (Monocot.) Sugar beet *Beta vulgaris* L. (Dicot.) Oilseed rape *Brassica napus* L. (Dicot.) Soybean *Glycine max* (L.) (Dicot.)	A6097K[1]	seedling emergence and vegetative vigour	**ER_{50}**	> 500 g product/ha equivalent to **125 g a.s./ha**	dRAR 2017

Values in **bold** have been used in the risk assessment
[1] EC formulation containing 250g/ propiconazole/L

Summary of effects on biological methods for sewage treatment

Table 9: Summary of endpoints for effects of propiconazole on biological methods for sewage treatment

Test organism	Test substance	Test type	End point	Toxicity	Reference / Owner
Activated sludge from STP	Propiconazole	Activated sludge respiration Inhibition test	Respiration inhibition 3 h EC_{50}	> 100 mg a.s./L	dRAR 2017

Risk assessments

Birds and other terrestrial vertebrates

The available acute toxicity studies demonstrate that Propriconazole exhibit low toxicity to birds, reflected in the limit endpoints LD_{50} > 2510 mg a.s./kg bw. However, the acute study with the formulation shows a higher toxicity (LD_{50} = 451.8 mg a.s./kg bw).
Therefore the acute risk to birds from the proposed uses of Propiconazole 25% EC will be assessed using the endpoint for the product.
The lowest long-term NOEL of 25.5 mg/kg bw/day from the Mallard duck study will be used in the risk assessment in order to provide a worst-case scenario.

The rat was noted to be the most sensitive species to Propiconazole with a LD_{50} of 550 mg a.s./kg bw. Overall Propiconazole is of low acute toxicity to mammals and there is no increase in toxicity apparent due to formulating as Propiconazole 25% EC (75 < LD_{50} < 500 mg a.s./kg bw). The acute assessment can be carried out with the endpoint for the active substance alone.

The parental toxicity NOAEL of 100 ppm in the two-generation reproduction study in rat corresponds to average intake of 8.4 mg/kg bw /day for males. This value is used in the risk assessment.

Since the available data for the relevant propiconazole metabolites CGA131013 (triazolyl alanine) and CGA142856 (triazolyl acetic acid) indicate that they are not more acutely toxic to mammals than the parent, it is reasonable to assume that the avian and mammalian risk assessment for these metabolites is covered by that for the parent.

The results of the acute and reproductive screening assessments, according to the EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009), are summarised in the following tables.

Dietary risk assessment for birds

Uses no. 5 and 6 on cereals (wheat and barley)

Table 10: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in wheat (use no. 5; worst-case use)

Intended use	Wheat				
Active substance	Propiconazole				
Application rate (kg a.s./ha)	2 × 0.15 (min. interval 10 days)				
Acute toxicity (mg a.s./kg bw)	451.8				
TER criterion	10				
Crop scenario Growth stage	**indicator species for screening**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals BBCH 29-59	Small omnivorous bird	158.8	1.32	31.46	14.4
Reprod. toxicity (mg a.s./kg bw/d)	25.5				
TER criterion	5				
Crop scenario Growth stage	**indicator species for screening**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**

Cereals BBCH 29 - 59	Small omnivorous bird	64.8	1.50 x 0.53	7.73	**3.3**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.

Based on the available data and risk assessment, a low acute risk via dietary exposure to birds can be concluded for the foliar spray application of the product to wheat crops (highest aerial application rate) covering the use in barley. However, a potential long-term risk via dietary exposure to birds can be concluded for the foliar spray application of the product to wheat crops. Therefore a first-tier risk assessment is required.

Table 11 First-tier assessment of the reproductive risk for birds due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in wheat (use no. 5; worst-case)

Intended use	Wheat				
Active substance	Propiconazole				
Application rate (kg a.s./ha)	2 × 0.15 (min. interval 10 days)				
Reprod. toxicity (mg a.s./kg bw/d)	25.5				
TER criterion	5				
Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals, BBCH 10-29	Small omnivorous bird “lark”	10.9	1.50 x 0.53	1.29	19.7
Cereals, BBCH 30-39	Small omnivorous bird “lark”	5.4	1.50 x 0.53	0.64	39.8
Cereals, BBCH ≥ 40	Small omnivorous bird “lark”	3.3	1.50 x 0.53	0.39	65.2

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.

Based on the first-tier risk assessment the TER_{lt} values for Propiconazole are all above the trigger value indicating an acceptable chronic risk to birds for the uses on wheat and barley according to the GAP.

Uses no. 1,2 3, 4 in orchards (pecan nuts, mango, apricot, cherry, plum and peach)

Table 12: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in pecan nuts (use no. 1; worst-case use)

Intended use	Pecan nuts				
Active substance	Propiconazole				
Application rate (kg a.s./ha)	3 × 0.25 (min. interval 10 days)				
Acute toxicity (mg a.s./kg bw)	451.8				
TER criterion	10				
Crop scenario Growth stage	**indicator species for screening**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards BBCH ≥15	Small insectivorous bird	46.8	1.47	17.16	26.3
Reprod. toxicity (mg a.s./kg	25.5				

bw/d)					
TER criterion	5				
Crop scenario Growth stage	**indicator species for screening**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards BBCH ≥15	Small insectivorous bird	18.2	1.75 x 0.53	4.22	6.0

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.

Based on the available data and risk assessment, a low acute and chronic risk via dietary exposure to birds can be concluded for the foliar spray application of the product to pecan nuts (highest ground application rate) covering the uses in mango, apricot, cherry, plum and peach.

Dietary risk assessment for mammals

Uses no. 5 and 6 on cereals (wheat and barley)

Table 13: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in wheat (use no. 5; worst-case)

Intended use	Wheat				
Active substance	Propiconazole				
Application rate (kg a.s./ha)	2 × 0.15 (min. interval 10 days)				
Acute toxicity (mg a.s./kg bw)	550				
TER criterion	10				
Crop scenario Growth stage	**indicator species for screening**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Cereals BBCH 29-59	small herbivorous mammal	118.4	1.32	23.46	23.4
Reprod. toxicity (mg a.s./kg bw/d)	8.4				
TER criterion	5				
Crop scenario Growth stage	**indicator species for screening**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals BBCH 29 - 59	Small herbivorous mammal	48.3	1.50 x 0.53	5.76	**1.5**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.

Based on the available data and risk assessment, a low acute risk via dietary exposure to wild mammals can be concluded for the foliar spray application of the product to wheat crops (highest aerial application rate) covering the use in barley. However, a potential long-term risk via dietary exposure to wild mammals can be concluded for the foliar spray application of the product to wheat crops. Therefore a first-tier risk assessment is required for the uses in wheat as well as in barley (only for the most sensitive generic focal species).

Table 14: First-tier assessment of the reproductive risk for mammals due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in wheat (use no. 5; worst-case)

Intended use	Wheat				
Active substance	Propiconazole				
Application rate (kg a.s./ha)	2 × 0.15 (min. interval 10 days)				
Reprod. toxicity (mg a.s./kg bw/d)	8.4				
TER criterion	5				
Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals, BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9	1.50 x 0.53	0.23	37.3
Cereals, BBCH ≥ 40	Small herbivorous mammal "vole"	21.7	1.50 x 0.53	2.57	**3.3**
Cereals, BBCH 10-29	Small omnivorous mammal "mouse"	7.8	1.50 x 0.53	0.92	9.1
Cereals, BBCH 30-39	Small omnivorous mammal "mouse"	3.9	1.50 x 0.53	0.46	18.2
Cereals, BBCH ≥ 40	Small omnivorous mammal "mouse	2.3	1.50 x 0.53	0.27	30.8

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.

Table 15: First-tier assessment of the reproductive risk for mammals due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in barley (use no. 6)

Intended use	Barley				
Active substance	Propiconazole				
Application rate (kg a.s./ha)	2 × 0.125 (min. interval 10 days)				
Reprod. toxicity (mg a.s./kg bw/d)	8.4				
TER criterion	5				
Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Cereals, BBCH ≥ 40	Small herbivorous mammal "vole"	21.7	1.50 x 0.53	2.14	**3.9**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.

Based on the first-tier risk assessment the TER_{lt} values for Propiconazole are above the trigger value indicating an acceptable chronic risk, except for small herbivorous mammals "vole" (BBCH ≥ 40) where the TER is close to the trigger of 5. However, the vole is not a relevant mammalian species in South Africa. Therefore, an acceptable long-term risk to mammals can be concluded following the proposed uses in wheat and barley.

Uses no. 1,2 3, 4 in orchards (pecan nuts, mango, apricot, cherry, plum and peach)

Table 16: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in pecan nuts (use no. 1; worst-case)

Intended use	Pecan nuts				
Active substance	Propiconazole				
Application rate (kg a.s./ha)	3 × 0.25 (min. interval 10 days)				
Acute toxicity (mg a.s./kg bw)	550				
TER criterion	10				
Crop scenario Growth stage	**indicator species for screening**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Orchards BBCH ≥15	Small herbivorous mammal	136.4	1.47	50.01	11.0
Reprod. toxicity (mg a.s./kg bw/d)	8.4				
TER criterion	5				
Crop scenario Growth stage	**indicator species for screening**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards BBCH 15	Small herbivorous mammal	72.3	1.75 x 0.53	16.8	**0.5**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.

Based on the available data and risk assessment, a low acute risk via dietary exposure to mammals can be concluded for the foliar spray application of the product to pecan nuts (highest ground application rate) covering the use in mango, apricot, cherry, plum and peach. However, there is a potential long-term risk via dietary exposure to wild mammals for the foliar spray application of the product to pecan nuts. Therefore a first-tier risk assessment is required for the use no. 1 as well as for the uses no. 2, 3 and 4 but only for the most sensitive generic focal species from use no. 1.

Table 17: First-tier assessment of the reproductive risk for mammals due to the worst-case use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in pecan nuts (use no. 1)

Intended use	Pecan nuts (BBCH ≥ 15)				
Active substance	Propiconazole				
Application rate (kg a.s./ha)	3 × 0.25 (min. interval 10 days)				
Reprod. toxicity (mg a.s./kg bw/d)	8.4				
TER criterion	5				
Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**

Orchards, BBCH 10-19	Small herbivorous mammal "vole"	57.8	1.75 x 0.53	13.32	**0.6**
Orchards, BBCH 20-40	Small herbivorous mammal "vole"	43.4	1.75 x 0.53	10.00	**0.8**
Orchards, BBCH ≥ 40	Small herbivorous mammal "vole"	21.7	1.75 x 0.53	5.00	**1.7**
Orchards, BBCH 10-19	Large herbivorous mammal "lagomorph"	11.5	1.75 x 0.53	2.65	**3.2**
Orchards, BBCH 20-40	Large herbivorous mammal "lagomorph"	8.6	1.75 x 0.53	1.98	**4.2**
Orchards, BBCH ≥ 40	Large herbivorous mammal "lagomorph"	4.3	1.75 x 0.53	0.99	8.5
Orchards, BBCH 10-19	Small omnivorous mammal "mouse"	6.2	1.75 x 0.53	1.43	5.9
Orchards, BBCH 20-40	Small omnivorous mammal "mouse"	4.7	1.75 x 0.53	1.08	7.8
Orchards, BBCH ≥ 40	Small omnivorous mammal "mouse"	2.3	1.75 x 0.53	0.53	15.8

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.

Based on the first-tier risk assessment the TER_{lt} values for Propiconazole are above the trigger value indicating an acceptable chronic risk for small omnivorous mammals, but not for small herbivorous mammals "vole" (BBCH 10-≥40) and large herbivorous mammals "lagomorph" (BBCH 10-40). However, the vole is not considered as a relevant mammalian species in South Africa. Therefore, an acceptable long-term risk to small herbivorous mammals can be concluded following the proposed use on pecan nuts.

For large herbivorous mammals "lagomorph" the TER values are below the trigger of 5 but remain close to that trigger especially so, for BBCH 20-40. This shows the risk is not considered to be high.

However, an expert statement (Krüger J., 2024) was prepared, demonstrating that lagomorphs including the critically endangered riverine rabbit (*Bunolagus monticularis*) will in effect not be exposed to propiconazole when used on pecan nuts because they do not enter disturbed or unnatural areas, and they won't feed on annual weeds that might be present. They certainly would not feed on any nuts dropping from the trees. Therefore, there is no risk to riverine rabbits. This conclusion also applies to other lagomorphs e.g., cape hare (*Lepus capensis*), scrub hare (*Lepus saxatilis*) which are very common over most of South Africa but have not been identified as species at risk other than those affecting wildlife in general. As for Rock rabbits (*Pronolagus species*) they also have very specific habitat requirements, restricted to rocky outcrops.

Table 18: First-tier assessment of the reproductive risk for mammals due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in cherry and peach (use no. 4)

Intended use	Cherry, Peach (BBCH 10 – 97)				
Active substance	Propiconazole				
Application rate (kg a.s./ha)	3 × 0.15 (min. interval 14 days)				
Reprod. toxicity (mg a.s./kg bw/d)	8.4				
TER criterion	5				
Crop scenario	**Generic focal species**	**SV_m**	**MAF_m ×**	**DDD_m**	**TER_{lt}**

Growth stage			**TWA**	**(mg/kg bw/d)**	
Orchards, BBCH 10-19	Small herbivorous mammal "vole"	57.8	1.52 x 0.53	13.32	**1.2**
Orchards, BBCH 20-40	Small herbivorous mammal "vole"	43.4	1.52 x 0.53	10.00	**1.6**
Orchards, BBCH ≥ 40	Small herbivorous mammal "vole"	21.7	1.52 x 0.53	5.00	**3.2**
Orchards, BBCH 10-19	Large herbivorous mammal "lagomorph"	11.5	1.52 x 0.53	2.65	6.1
Orchards, BBCH 20-40	Large herbivorous mammal "lagomorph"	8.6	1.52 x 0.53	1.98	8.1

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.

Based on the first-tier risk assessment the TER_{lt} values for Propiconazole are above the trigger value indicating an acceptable chronic risk for small omnivorous mammals and large herbivorous mammals, but not for small herbivorous mammals "vole" (BBCH 10-≥40). However, the vole is not considered as a relevant mammalian species in South Africa. Therefore, an acceptable long-term risk to small herbivorous mammals can be concluded following the proposed use on cherry and peach.

Table 19: First-tier assessment of the reproductive risk for mammals due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in apricot, cherry and peach plum (use no. 3)

Intended use	Apricot, Cherry, Peach Plum (BBCH 55-69)				
Active substance	Propiconazole				
Application rate (kg a.s./ha)	3 × 0.1 (min. interval 7 days)				
Reprod. toxicity (mg a.s./kg bw/d)	8.4				
TER criterion	5				
Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards, BBCH ≥ 40	Small herbivorous mammal "vole"	21.7	1.99 x 0.53	2.23	**3.7**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.

Based on the first-tier risk assessment the TER_{lt} value is below the trigger value of 5 for small herbivorous mammals "vole" (BBCH ≥40) indicating a potential risk for mammals following the proposed use on apricot, cherry, peach and plum. However, the vole is not considered as a relevant mammalian species in South Africa. Therefore, an acceptable long-term risk for mammals can be concluded following the proposed use no. 3 on apricot, cherry, peach and plum.

Table 20: First-tier assessment of the reproductive risk for mammals due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in Mango (use no. 2)

Intended use	Mango (BBCH 65-70)
Active substance	Propiconazole
Application rate (kg a.s./ha)	2 × 0.075 (min. interval 10 days)

Reprod. toxicity (mg a.s./kg bw/d) **TER criterion**		8.4 5			
Crop scenario **Growth stage**	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Orchards, BBCH ≥ 40	Small herbivorous mammal "vole"	21.7	1.50 x 0.53	1.29	6.5

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in **bold** fall below the relevant trigger.

Based on the first-tier risk assessment the TER_{lt} values for Propiconazole are above the trigger value indicating an acceptable chronic risk for mammals following the proposed use on mango.

Risks for birds and mammals through drinking water

Table 21: Ratios of effective application rate (AR_{eff}) to acute and long-term endpoints for propiconazole following the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in pecan nuts (worst-case) - puddle scenario

Birds			
Effective application rate (g a.s./ha) =	437.5 [a]		
Dietary toxicity (mg a.s./kg bw/d) =	451.8	quotient =	0.968
Reprod. toxicity (mg a.s./kg bw/d) =	25.5	quotient =	17.16
Mammals			
Effective application rate (g a.s./ha) =	437.5 [a]		
Dietary toxicity (mg a.s./kg bw/d) =	550	quotient =	0.795
Reprod. toxicity (mg a.s./kg bw/d) =	8.4	quotient =	52.08

[a] 250 g a.s./ha * MAF_m (1.75)

The ratios of effective application rate (AR_{eff}) to acute and long-term endpoints fall below the trigger of 3000 ($K_{oc} \geq 500$ L/kg) indicating that further assessment of the acute and long-term risk to birds and mammals from drinking water from puddles is not required for propiconazole.

Effects of secondary poisoning

Risk to earthworm-eating birds

Table 22: Assessment of the risk for earthworm-eating birds due to exposure to propiconazole (secondary poisoning) for the intended use in pecan nuts (worst-case)

Parameter	propiconazole	Comments
PEC_{soil} (mg/kg soil)	0.394	Maximum initial PEC_{soil}
P_{OW}	5248	log P_{ow} = 3.7
Koc (mL/g)	955	Geometric mean
foc	0.02	Default
BCF_{worm}	3.34	$BCF_{worm/soil}$ = ($PEC_{worm,ww}$/ $PEC_{soil,dw}$) = (0.84 + 0.012 × P_{ow}) / foc × Koc
PEC_{worm}	1.32	PEC_{worm} = PEC_{soil} × $BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	1.38	DDD = PEC_{worm} × 1.05
NOEL (mg/kg bw/d)	25.5	
TER_{lt}	18.4	Trigger = 5

Risk to fish-eating birds

Table 23: Assessment of the risk for fish-eating birds due to exposure to propiconazole via bioaccumulation in fish (secondary poisoning) for the intended use in pecan nuts (worst-case)

Parameter	propiconazole	Comments
PEC_{sw} (mg/L)	0.029	Maximum initial PEC_{SW} for multiple application
BCF_{fish}	181	Highest BCF from fish bioaccumulation studies
PEC_{fish}	5.249	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.835	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	25.5	
TER_{lt}	31	Trigger = 5

The risk assessments demonstrate an acceptable risk to earthworm-eating and fish-eating birds from all proposed uses of Bumper 250 EC/Principle 250 EC/Propin 250 EC.

Risk to earthworm-eating mammals

Table 24: Assessment of the risk for earthworm-eating mammals due to exposure to propiconazole (secondary poisoning) for the intended use in pecan nuts (worst-case)

Parameter	propiconazole	Comments
PEC_{soil} (mg/kg soil)	0.394	Maximum initial PEC_{soil}
P_{OW}	5248	log P_{ow} = 3.7
Koc (mL/g)	955	Geometric mean
foc	0.02	Default
BCF_{worm}	3.34	$BCF_{worm/soil} = (PEC_{worm,ww}/ PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	1.32	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	1.69	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	8.4	
TER_{lt}	4.99	Trigger = 5

Risk to fish-eating mammals

Table 25: Assessment of the risk for fish-eating mammals due to exposure to propiconazole via bioaccumulation in fish (secondary poisoning) for the intended use in pecan nuts (worst-case)

Parameter	propiconazole	Comments
PEC_{sw} (mg/L)	0.029	Maximum initial PEC_{SW} for multiple application
BCF_{fish}	181	Highest BCF from fish bioaccumulation studies
PEC_{fish}	5.249	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.745	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	8.4	
TER_{lt}	11	Trigger = 5

The risk assessments demonstrate an acceptable risk to earthworm-eating and fish-eating mammals from all proposed uses of Bumper 250 EC/Principle 250 EC/Propin 250 EC.

Aquatic life

The available acute aquatic toxicity data for fish, aquatic invertebrates and algae demonstrate that there is no increase in toxicity apparent due to formulating as Propiconazole 25% EC, as the endpoints are within the same order of magnitude.
The lowest acute aquatic toxicity value for the active substance is an EC_{50} of 0.51 mg a.s./L for aquatic invertebrate *Americamysis bahia*, which is between 0.1 and ≤1 mg/L leading to an M-factor of 1. The lowest chronic aquatic toxicity value for the active substance is a NOEC of 0.068 mg a.s./L for the fish species *Cyprinodon variegatus*, which is between 0.01 and ≤ 0.1 mg/L leading to an M-factor of 1 for this non-rapidly degradable substance. Therefore, Propiconazole is classified as Aquatic Acute 1 and Chronic 1.

Since all available data in Table 4 indicate that the relevant metabolites (i.e. SYN547889, NOA436613, CGA91305 and CGA71019) are not more acutely toxic to aquatic organisms than the parent, then the risk assessment for the metabolites is covered by that for the parent.

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the methods followed in the European union. In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}) from entry via drift and regulatory acceptable concentrations (RAC) are given for the most sensitive organisms in freshwater and sediment and for the worst-case uses of Bumper 250 EC/Principle 250 EC/Propin 250 EC according to the GAP. Propiconazole is recommended for application to cereals and fruit crops and therefore exposure to marine or estuarine environments is not expected to arise.

The resulting PEC/RAC ratios are also presented in the tables. Safe use is demonstrated when PEC/RAC < 1.

The acute fish toxicity endpoint for *Danio rerio* and the algae endpoint *Pseudokirchneriella subcapitata* tested with Propiconazole 25% EC were used in the risk assessment. The other endpoints are from studies conducted with the active substance.

Table 26: Aquatic organisms: Acceptability of risk (PEC/RAC < 1) for Propiconazole for each organism group for the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in pecan nuts (use no. 1: 3 × 250 g a.s./ha (min. interval 10 days))

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**
Test species		***O. mykiss***	***P. promelas***	***D. magna***	***D. magna***	***P. subcapitata***	***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	EC_{10}	E_rC_{50}	NOEC
(µg/L)		1960	188	10200	350	5970	25000 µg/kg sediment
AF[a]		100	10	100	10	10	10
RAC (µg/L)		19.6	18.8	102	35	597	2500
Entry route	**PEC_{SW} (µg/L)**	**PEC/RAC ratio**					
Drift							
3 m (default distance)[b]	29.0	**1.480**	**1.543**	0.284	0.829	0.049	0.099[c]
5 m[b]	19.1	0.974	**1.016**	-	-	-	-
10 m[b]	10.9	-	0.580	-	-	-	-

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

[a] Assessment factor adjusted in line with EFSA/2013/3290

[b] Worst-case PEC_{SW} from multiple application

[c] Considering worst-case PEC_{sed} (= 248.5 µg a.s./kg sediment)

Table 27: Aquatic organisms: Acceptability of risk (PEC/RAC < 1) for Propiconazole for each organism group for the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in cherry and peach (use no. 4: 3 × 150 g a.s./ha (min. interval 10 days) covering the use no. 2 in mango at 2 × 75 g a.s./ha and the use no. 3 in apricot, cherry, plum and peach at 3 × 100 g a.s./ha)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**
Test species		***O. mykiss***	***P. promelas***	***D. magna***	***D. magna***	***P. subcapitata***	***C. riparius***
Endpoint (µg/L)		LC_{50} 1960	NOEC 188	EC_{50} 10200	EC_{10} 350	E_rC_{50} 5970	NOEC 25000 µg/kg sediment
AF[a]		100	10	100	10	10	10
RAC (µg/L)		19.6	18.8	102	35	597	2500
Entry route	**PEC_{SW} (µg/L)**	**PEC/RAC ratio**					
Drift							
3 m (default distance)[b]	14.6	0.745	0.777	0.143	0.417	0.024	0.038[c]

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

[a] Assessment factor adjusted in line with EFSA/2013/3290

[b] Worst-case PEC_{SW} from single application

[c] Considering worst-case PEC_{sed} (= 94.4 µg a.s./kg sediment)

Table 28: Aquatic organisms: Acceptability of risk (PEC/RAC < 1) for Propiconazole for each organism group for the uses of Bumper 250 EC/Principle 250 EC/Propin 250 EC in wheat (use no. 5 : 2 × 150 g a.s./ha (min. interval 10 days) covering the use no. 6 in barley: 2 × 125 g a.s./ha (min. interval 10 days)) - ground application

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**
Test species		***O. mykiss***	***P. promelas***	***D. magna***	***D. magna***	***P. subcapitata***	***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	EC_{10}	E_rC_{50}	NOEC
(µg/L)		1960	188	10200	350	5970	25000 µg/kg sediment
AF[a]		100	10	100	10	10	10
RAC (µg/L)		19.6	18.8	102	35	597	2500
Entry route	**PEC_{SW} (µg/L)**	**PEC/RAC ratio**					
Drift							
1 m (default distance)[b]	1.6	0.082	0.085	0.016	0.046	0.003	0.004[c]

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

[a] Assessment factor adjusted in line with EFSA/2013/3290

[b] Worst-case PEC_{SW} from multiple application

[c] Considering worst-case PEC_{sed} (= 9.9 µg a.s./kg sediment)

Table 29: Aquatic organisms: Acceptability of risk (PEC/RAC < 1) for Propiconazole for each organism group for the uses of Bumper 250 EC/Principle 250 EC/Propin 250 EC in wheat (use no. 5 : 2 × 150 g a.s./ha (min. interval 10 days) covering the use no. 6 in barley: 2 × 125 g a.s./ha (min. interval 10 days)) - aerial application

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Sed. dwell. prolonged**
Test species		***O. mykiss***	***P. promelas***	***D. magna***	***D. magna***	***P. subcapitata***	***C. riparius***
Endpoint (µg/L)		LC_{50} 1960	NOEC 188	EC_{50} 10200	EC_{10} 350	E_rC_{50} 5970	NOEC 25000 µg/kg sediment
AF[a]		100	10	100	10	10	10
RAC (µg/L)		19.6	18.8	102	35	597	2500
Entry route	**PEC_{SW} (µg/L)**	**PEC/RAC ratio**					
Drift							
3 m (default distance)[b]	22.2	**1.133**	**1.181**	0.218	0.634	0.037	0.055[c]
5 m[b]	18.3	0.934	0.973	-	-	-	-

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

[a] Assessment factor adjusted in line with EFSA/2013/3290

[b] Worst-case PEC_{SW} from multiple application

[c] Considering worst-case PEC_{sed} (= 138.6 µg a.s./kg sediment)

The risk assessments for Propiconazole, based on PEC_{SW} and PEC_{sed} values from entry via drift, demonstrates an acceptable risk to aquatic organisms for use in cereals (downward spray application) and fruit crops (mango, apricot, cherry and peach plum) without mitigation measures or with a 10 m buffer distance for use in pecan nuts. A 5 m spray drift buffer is required to demonstrate an acceptable risk following aerial application in cereals.

With Log Kow of 3.72 and a fish BCF of 180, Propiconazole does not have the potential for bioaccumulation.

Bees

According to the 'Guidelines on the management of the risk of Agricultural Remedies on insect pollinators (DAFF, 2017)' with a contact LD_{50} of 46.3 µg a.s/bee from a study conducted in conformance with the OECD guidelines 214 (see Table 4), propiconazole can be classified as non-toxic ($LD_{50} \geq 11$ µg/bee) to bees. Therefore, no additional toxicology data will be required for any residues that may be present in pollen and nectar.

During the latest EU Evaluation of propiconazole (2017) a low risk to adult (acute oral, acute contact and chronic) and to larvae honeybees was concluded at the screening step for all representative uses of propiconazole following a risk assessment conducted in accordance with EFSA (2013). As this guidance is not agreed at EU level, the evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

Table 30: First-tier assessment of the risk for bees due to the worst-case use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in pecan nuts (use no.1: 3 x 250 g a.s./ha)

Intended use **Active substance** **Application rate (g a.s./ha)**	Pecan nuts Propiconazole 3 × 250		
Test design	**LD_{50} (lab.) (µg a.s./bee)**	**Single application rate (g a.s./ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	203.4	250	1.23
Contact toxicity	46.3		5.40
Product **Application rate (g a.s./ha)**	Bumper 250 EC/Principle 250 EC/Propin 250 EC 3 × 250		
Test design	**LD_{50} (lab.) (µg a.s./bee)**	**Single application rate (g a.s./ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	> 25	250	< 10

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in **bold** breach the relevant trigger.

The calculated oral and contact Hazard Quotients for Propiconazole and Bumper 250 EC/Principle 250 EC/Propin 250 EC are below the trigger value of 50, indicating an acceptable acute risk to honeybees following the proposed worst-case use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in pecan nuts, covering all other uses.

Additional studies were carried out with the product A6097AF (containing 248 g Propiconazole/L). The chronic adult LDD_{50} (10 d) was 70.4 µg a.s/bee/day. The repeated exposure larval NOED (8 d) was 21 µg a.s./larvae/dev. period. It can thus be concluded that propiconazole as contained in Bumper 250 EC/Principle 250 EC/Propin 250 EC poses no unacceptable chronic risk to adult honeybees or to honeybee larvae, considering the proposed use rate.

Based on the first-tier assessment, the acute oral and contact risk to bees is considered to be acceptable for the intended uses of Bumper 250 EC/Principle 250 EC/Propin 250 EC. In addition, the available data indicate no concerns for chronic oral exposure to adult honeybees and oral exposure to honeybee larvae.

Overall, it can be concluded that the risk to bees from the application of Bumper 250 EC/Principle 250 EC/Propin 250 EC according to good agricultural practice is acceptable.

Non-target arthropods (other than bees)

Valid and reliable Tier I data are available for four species of non-target arthropods, *Aphidius rhopalosiphi*, *Chrysoperla carnea*, *Peocilus cupreus* and *Coccinella septempunctata*. No reliable Tier I endpoint is available for *Typhlodromus pyri*. Nevertheless, Tier II studies were conducted with *A. rhopalosiphi* (extended lab.) and *T. pyri* (aged residue). A field study carried out on predatory mite populations in a Portuguese orchard is also available. No significant treatment-related effects were observed in this study. Please refer to Table 5.

The risk to non-target arthropods is assessed using the approach recommended in the published ESCORT 2 document (Candolfi *et al.* 2001) and the EC Guidance Document on Terrestrial Ecotoxicology.

The risk assessment for Bumper 250 EC/Principle 250 EC/Propin 250 EC is based on Tier I glass plate tests on the standard test species *Aphidius rhopalosiphi* as well as the ground dwelling predator *Poecilus cupreus* and also the foliar dwelling predators *Chrysoperla carnea* and *Coccinella septempunctata*. Data indicated low toxicity to *Aphidius rhopalosiphi*, *Poecilus cupreus* and *Chrysoperla carnea* at the proposed maximum single field rate of 1.0 L formulation/ha (equivalent to 250 g a.s./ha) for application on pecan nuts. No effects on mortality and reproduction > 50 % were observed in *Coccinella septempunctata* at the rate of 0.5 L formulation/ha (equivalent to 125 g a.s./ha).

The potential risk of Bumper 250 EC/Principle 250 EC/Propin 250 EC to in-field non-target arthropods has been assessed by calculation of the hazard quotient (HQ = exposure/toxicity) based on the predicted environmental rate (PER) and the lowest lethal rate (LR_{50}) values for the species *Aphidius rhopalosiphi*, *Chrysoperla carnea* and *Poecilus cupreus* exposed to A6097K (250 g propiconazole/L EC product) and *Coccinella septempunctata* exposed to A6097G. In addition the potential in-field risk has been assessed based on higher-tier studies with the *Typhlodromus pyri* exposed to the comparable formulation A6097AF containing 25.4% w/w of propiconazole.

Table 31: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the worst-case use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in pecan nuts (use no. 1: 3 x 250 g a.s./ha)

Intended use	Pecan nuts		
Product	Bumper 250 EC/Principle 250 EC/Propin 250 EC		
Application rate (g a.s./ha)	3 × 250		
MAF	2.3		
Test species Tier I	**LR_{50} (lab.) (g a.s./ha)**	**$PER_{in\text{-}field}$ (g a.s./ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Aphidius rhopalosiphi	> 250	575	**< 2.3**
Poecilius cuprueus	> 250		**< 2.3**
Chrysoperla carnea	> 250		**< 2.3**
Coccinella septempunctata	> 125		**< 4.6**
Test species Higher-tier	**Rate with ≤ 50 % effect (g a.s./ha)**	**$PER_{in\text{-}field}$ (g a.s./ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Aphidius rhopalosiphi	>250	575	**No**
Typhlodromus pyri	>125		**No**

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; HQ above the relevant trigger of 2 are shown in **bold**.

Based on all the available Tier I studies, the resulting in-field HQ values for *A. rhopalosiphi*, *P. cupreus*, *C carnea* and *C. septempunctata* indicates an unacceptable risk to in-field non-target arthropods for the worst-case use of propiconazole in pecan nuts. The higher tier risk assessment based on the endpoints from Tier II (extended laboratory and aged residue) studies on *A. rhopalosiphi* and *T. pyri* also demonstrates an unacceptable risk.

Table 32: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in Apricot, Cherry, Peach, Plum (use no. 3: 3 x 100 g a.s./ha)

Intended use	Apricot, Cherry, Peach, Plum		
Product	Bumper 250 EC/Principle 250 EC/Propin 250 EC		
Application rate (g a.s./ha)	3 × 100		
MAF	2.3		
Test species Tier I	**LR_{50} (lab.) (g a.s./ha)**	**$PER_{in\text{-}field}$ (g a.s./ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Aphidius rhopalosiphi	> 250	230	< 0.92
Poecilius cuprueus	> 250		< 0.92
Chrysoperla carnea	> 250		< 0.92
Coccinella septempunctata	> 125		< 1.84
Test species Higher-tier	**Rate with ≤ 50 % effect (g a.s./ha)**	**$PER_{in\text{-}field}$ (g a.s./ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	>125	230	**No**

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient.

The resulting in-field HQ values for *A. rhopalosiphi*, *P. cupreu*s, *C. carnea* and *C. septempunctata* are below the trigger value of 2 indicating that the risk to in-field non-target arthropods is acceptable, for the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in Apricot, Cherry, Peach, Plum at an application rate of 3 x 100 g a.s./ha. The higher tier risk assessment for *T. pyri* demonstrates an unacceptable risk.

Table 33: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in cherry and peach (use no. 4: 3 x 150 g a.s./ha)

Intended use	Cherry, Peach		
Product	Bumper 250 EC/Principle 250 EC/Propin 250 EC		
Application rate (g a.s./ha)	3 × 150		
MAF	2.3		
Test species Tier I	**LR_{50} (lab.) (g a.s./ha)**	**$PER_{in\text{-}field}$ (g a.s./ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Aphidius rhopalosiphi	> 250	345	< 1.38
Poecilius cuprueus	> 250		< 1.38
Chrysoperla carnea	> 250		< 1.38
Coccinella septempunctata	> 125		**< 2.76**
Test species Higher-tier	**Rate with ≤ 50 % effect (g a.s./ha)**	**$PER_{in\text{-}field}$ (g a.s./ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	> 125	345	**No**

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; HQ above the relevant trigger of 2 are shown in **bold**..

The resulting in-field HQ values for *A. rhopalosiphi*, *P. cupreu*s and *C. carnea* are below the trigger

value of 2 indicating that the risk to in-field non-target arthropods is acceptable. However, there is no acceptable in-field risk for *Coccinella septempunctata* for the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in cherry and peach at 3 x 150 g a.s./ha. The higher tier risk assessment for *T. pyri* demonstrates an unacceptable risk.

Table 34: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in wheat (use no. 5: 2 x 150 g a.s./ha)

Intended use	Wheat		
Product	Bumper 250 EC/Principle 250 EC/Propin 250 EC		
Application rate (g a.s./ha)	2 × 150		
MAF	1.7		
Test species Tier I	**LR_{50} (lab.) (g a.s./ha)**	**$PER_{in\text{-}field}$ (g a.s./ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Aphidius rhopalosiphi	> 250	255	< 1.02
Poecilius cuprueus	> 250		< 1.02
Chrysoperla carnea	> 250		< 1.02
Coccinella septempunctata	> 125		**< 2.04**
Test species Higher-tier	**Rate with ≤ 50 % effect (g a.s./ha)**	**$PER_{in\text{-}field}$ (g a.s./ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	> 125	255	**No**

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; HQ above the relevant trigger of 2 are shown in **bold**..

The resulting in-field HQ values for *A. rhopalosiphi*, *P. cupreu*s and *C. carnea* are below the trigger value of 2 indicating that the risk to in-field non-target arthropods is acceptable. For *Coccinella septempunctata* the trigger is only marginally exceeded, therefore an acceptable risk can be concluded. The higher tier risk assessment for *T. pyri* demonstrates an unacceptable risk.

In the field study conducted with the formulation A6097K on predatory mite populations (mainly *Euseius stipulatus*) in Portuguese apricot orchard that was previously submitted in the EU evaluation there were no statistically significant differences between the control and applications corresponding to a rate of 1.0 - 2.3 L preparation/ha. Therefore, the in-field risk to predatory mite populations is acceptable following use of Bumper 250 EC/Principle 250 EC/Propin 250 EC according to the proposed use pattern.

It has to be noted that all available studies on non-target arthropods provide limit endpoints above the highest test concentration or very high endpoints. In addition, the aged residue study demonstrates no significant effects 7 days after treatment. This demonstrates that any mild effects observed in-field will not cause long-term effects at the population level. Moreover, an acceptable risk to arthropods such as bees and soil arthropods (*Folsomia* and *Hypoaspis*) has been demonstrated. Consequently, an acceptable risk to non-target arthropods from all proposed uses of Bumper 250 EC/Principle 250 EC/Propin 250 EC can be assumed, and an assessment of the off-field non-target arthropods is not necessary.

Non-target soil meso- and macrofauna

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna)

was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

Experimental data for propiconazole and all the pertinent soil metabolites (i.e. SYN547889, NOA436613, CGA91305 and CGA71019) are available for earthworms, and other soil macroorganisms (*Hypoaspis aculeifer* and *Folsomia candida*).

First-tier risk assessment

An acute risk assessment is no longer required in the EU but is still required in South Africa. The potential acute and long-term risk of Propiconazole 25% EC, propiconazole, SYN547889, NOA436613, CGA091305 and CGA71019 to earthworms was assessed by calculating acute and long-term TER values by comparing either EC_{50} or NOEC values and the maximum instantaneous PEC_{soil}.

For propiconazole and its metabolite CGA091305 the log P_{OW} is > 2 (3.7 and 2.1 respectively), therefore endpoints from these studies were corrected by dividing the endpoints by 2.

The results of the first-tier risk assessments for soil macro-organisms are summarised in the following tables.

Table 35: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in pecan nuts (use no. 1: 3 x 250 g a.s./ha (10-day interval); worst-case GAP in tree crops covering uses no. 2-4)

Intended uses		Pecan nuts		
Acute effects on earthworms				
Test species	**Compound**	**LD_{50} (mg/kg dw)**	**$PEC_{soil\ accumulation}$[a] (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Eisenia fetida	Propiconazole	343 (corr.)	0.724	474
	Propiconazole in Propiconazole 25% EC	152.9	0.724	211
	1,2,4-triazole (CGA71019)	>1000	0.066	>15152
	CGA091305	>500 (corr.)	0.107	>4673
Chronic effects on earthworms				
Test species	**Compound**	**NOEC (mg/kg dw)**	**$PEC_{soil\ accumulation}$[a] (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Eisenia fetida	Propiconazole in A6097AF	3.09 (corr.)	0.724	**4.3**
	SYN547889 (CGA217495)	556	0.275	2022
	NOA436613	309	0.200	1545
	CGA091305	154.5 (corr.)	0.107	1444
	1,2,4-triazole (CGA71019)	1.0	0.066	15.2

Chronic effects on other soil macro- and mesofauna				
Test species	**Compound**	**NOEC (mg/kg dw)**	**$PEC_{soil\ accumulation}$[a] (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Folsomia candida	Propiconazole in A6097AF	50 (corr.)	0.724	69.1
	SYN547889 (CGA217495)	1000	0.275	3636
	NOA436613	1000	0.200	5000
	CGA091305	154.5 (corr.)	0.107	1444
	1,2,4-triazole (CGA71019)	1.8	0.066	27.3
Hypoaspis aculeifer	Propiconazole in A6097AF	11.2 (corr.)	0.724	15.5
	SYN547889 (CGA217495)	1000	0.275	3636
	NOA436613	1000	0.200	5000
	CGA091305	500 (corr.)	0.107	4673
	1,2,4-triazole (CGA71019)	171	0.066	2591

TER values shown in **bold** fall below the relevant trigger
[a] The PEC_{soil} values cover uses in mango, apricot, cherry, plum and peach

Table 36: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in wheat (use no. 5: 2 x 150 g a.s./ha (10-day interval); worst-case GAP in field crops covering use no. 6)

Intended uses		Wheat		
Acute effects on earthworms				
Test species	**Compound**	**LD_{50} (mg/kg dw)**	**$PEC_{soil\ accumulation}$[a] (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Eisenia fetida	Propiconazole	343 (corr.)	0.383	896
	Propiconazole in Propiconazole 25% EC	152.9	0.383	399
	1,2,4-triazole (CGA71019)	>1000	0.034	>29412
	CGA091305	>500 (corr.)	0.036	>13889
Chronic effects on earthworms				
Test species	**Compound**	**NOEC (mg/kg dw)**	**$PEC_{soil\ accumulation}$[a] (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Eisenia fetida	Propiconazole in A6097AF	3.09 (corr.)	0.383	8.1

	SYN547889 (CGA217495)	556	0.092	6043
	NOA436613	309	0.073	4233
	CGA091305	154.5 (corr.)	0.036	4292
	1,2,4-triazole (CGA71019)	1.0	0.034	29.4
Chronic effects on other soil macro- and mesofauna				
Test species	**Compound**	**NOEC (mg/kg dw)**	**$PEC_{soil\ accumulation}$[a] (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Folsomia candida	Propiconazole in A6097AF	50 (corr.)	0.383	130.5
	SYN547889 (CGA217495)	1000	0.092	10870
	NOA436613	1000	0.073	13699
	CGA091305	154.5 (corr.)	0.036	4292
	1,2,4-triazole (CGA71019)	1.8	0.034	52.9
Hypoaspis aculeifer	Propiconazole in A6097AF	11.2 (corr.)	0.383	29.2
	SYN547889 (CGA217495)	1000	0.092	10870
	NOA436613	1000	0.073	13699
	CGA091305	500 (corr.)	0.036	13889
	1,2,4-triazole (CGA71019)	171	0.034	5029

TER values shown in **bold** fall below the relevant trigger
[a] The PEC_{soil} values cover use barley

The above risk assessments demonstrate an acceptable risk to soil macro-organisms from all proposed uses of Bumper 250 EC/Principle 250 EC/Propin, except for the chronic risk to earthworms from exposure to propiconazole in tree crops where the TER value is below the trigger of 5 but remain close to that trigger. However, it has to be noted that the corrected NOEC value of 3.09 mg a.s./kg soil was used in a very conservative approach. As the study was conducted with a peat content of 5%, a correction of the endpoint is not necessary.
Therefore, when using the more realistic $NOEC_{reproduction}$ of 24.15 mg A6097AF/kg soil dw equivalent to **6.17 mg a.s./kg soil dw**, the TER_{LT} is calculated as 8.5 and 16.1 for the uses in tree crops and field crops, respectively, indicating a low risk to earthworms.

Therefore, an acceptable risk to earthworms and other non-target soil organisms can be concluded from all proposed uses of Bumper 250 EC/Principle 250 EC/Propin 250 EC.

Soil micro-organisms

The evaluation of the risk for soil micro-organisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

Studies are available for the product Propiconazole 25% EC, the active substance Propiconazole and its relevant soil metabolites CGA71019, CGA091305, NOA436613 and SYN547889.

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna).

The results of the first-tier risk assessment for soil micro-organisms are summarised in the following table.

Table 37: Assessment of the risk for effects on soil micro-organisms due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in pecan nuts (use no. 1: 3 x 250 g a.s./ha (10-day interval); worst-case GAP in tree crops covering all uses)

Intended use	Pecan nuts [a]		
N-mineralisation			
Compound	**NOEC (mg/kg dw)**	**$PEC_{soil\ accumulation}$[a] (mg/kg dw)**	**Risk acceptable?**
Propiconazole	1.66	0.724	Yes
Propiconazole in Propiconazole 25% EC	0.9392	0.724	Yes
SYN547889 (CGA217495)	6.25	0.275	Yes
NOA436613	6.25	0.200	Yes
CGA091305	0.377	0.107	Yes
1,2,4-triazole (CGA71019)	0.333	0.066	Yes

[a] The PEC_{soil} values cover all uses

The results of the first-tier risk assessment demonstrate an acceptable risk to non-target soil micro-organisms from all proposed uses of Bumper 250 EC/Principle 250 EC/Propin 250 EC.

Terrestrial non-target higher plants

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

No studies are available on the active substance propiconazole, however a study on the formulation A6097K containing 250 g propiconazole/L is available for seedling emergence and vegetative vigour and is considered relevant for the risk assessment. Since no observable effects >50% on seedling emergence or vegetative vigour were observed at rates up to and including 500 g A6097K/ha for all six species tested, the ER_{50} was determined to be above the limit dose tested (> 125 g a.s./ha).

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90^{th} percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000).

The results of the risk assessment for non-target terrestrial plants are shown below.

Table 38: Assessment of the risk for non-target plants due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in pecan nuts (use no. 1: 3 x 250 g a.s./ha (10-day interval))

Intended use	Pecan nuts			
Active substance	Propiconazole			
Application rate (g a.s./ha)	250			
Scenario	**ER_{50} (g a.s./ha)**	**Drift rate [a]**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**TER criterion: TER ≥ 5**
Vegetative vigour and seedling emergence	> 125	29.20% at 3 m	73.0	**> 1.71**
		19.89% at 5 m	49.7	**> 2.51**
		11.81% at 10 m	29.5	**> 4.23**
		5.55% at 15 m	13.88	> 9.01

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values in **bold** fall below the relevant trigger
[a] Drift value for one application in fruit crops (early)

The above risk assessment demonstrates an acceptable risk to non-target terrestrial plants in off-crop areas from the proposed uses of Bumper 250 EC/Principle 250 EC/Propin 250 EC in pecan nuts when using a 15 m buffer zone.

Table 39: Assessment of the risk for non-target plants due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in apricot, cherry, peach and plum (use no. 3: 3 x 100 g a.s./ha (7-day interval) covering use no. 2)

Intended use	Apricot, Cherry, Peach, Plum			
Active substance	Propiconazole			
Application rate (g a.s./ha)	100			
Scenario	**ER_{50} (g a.s./ha)**	**Drift rate [a]**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**TER criterion: TER ≥ 5**
Vegetative vigour and seedling emergence	> 125	15.73% at 3 m	15.73	> 7.95

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values in **bold** fall below the relevant trigger
[a] Drift value for one application in fruit crops (late)

Table 40: Assessment of the risk for non-target plants due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in wheat (use no. 5: 2 x 150 g a.s./ha (10-day interval) covering use no. 6; ground spray application)

Intended use	Wheat (ground spray application)			
Active substance	Propiconazole			
Application rate (g a.s./ha)	150			
Scenario	**ER_{50} (g a.s./ha)**	**Drift rate [a]**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**TER criterion: TER ≥ 5**
Vegetative vigour and seedling emergence	> 125	2.77% at 1 m	4.16	> 30.1

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values in **bold** fall below the relevant trigger
[a] Drift value for one application in field crops

The above risk assessments demonstrate an acceptable risk to non-target terrestrial plants in off-crop areas from the proposed uses of Bumper 250 EC/Principle 250 EC/Propin 250 EC in fruit crops (uses no. 2 and no. 3) and cereals (uses no. 5 and 6: ground spray application) without the need for risk mitigation measures.

Table 41: Assessment of the risk for non-target plants due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in cherry and peach (use no. 4: 3 x 150 g a.s./ha (14-day interval))

Intended use	Cherry and peach			
Active substance	Propiconazole			
Application rate (g a.s./ha)	150			
Scenario	**ER_{50} (g a.s./ha)**	**Drift rate [a]**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**TER criterion: TER ≥ 5**
Vegetative vigour and seedling emergence	> 125	29.20% at 3 m	43.8	> **2.85**
		19.89% at 5 m	29.8	> **4.19**
		11.81% at 10 m	17.7	> 7.06

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values in **bold** fall below the relevant trigger
[a] Drift value for one application in fruit crops (early)

The above risk assessment demonstrates an acceptable risk to non-target terrestrial plants in off-crop areas from the proposed uses of Bumper 250 EC/Principle 250 EC/Propin 250 EC in cherry and peach when using a 10 m buffer zone.

Table 42: Assessment of the risk for non-target plants due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in wheat (use no. 5: 2 x 150 g a.s./ha (10-day interval); aerial spray application)

Intended use	Wheat (aerial spray application)			
Active substance	Propiconazole			
Application rate (g a.s./ha)	150			
Scenario	**ER_{50} (g a.s./ha)**	**Drift rate [a]**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**TER criterion: TER ≥ 5**
Vegetative vigour and seedling emergence	> 125	33.2% at 3 m	49.8	> **2.51**
		27.3% at 5 m	41.0	> **3.05**
		20.9% at 10 m	31.4	> **3.99**
		17.9% at 15 m	26.9	> **4.66**
		14.1% at 20 m	21.2	> 5.91

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values in **bold** fall below the relevant trigger
[a] Drift value for aerial application as used in the environmental fate section for PECsw calculation.

Table 43: Assessment of the risk for non-target plants due to the use of Bumper 250 EC/Principle 250 EC/Propin 250 EC in barley (use no. 6: 2 x 125 g a.s./ha (10-day interval) ; aerial spray application)

Intended use	Barley (aerial spray application)			
Active substance	Propiconazole			
Application rate (g a.s./ha)	125			
Scenario	**ER_{50} (g a.s./ha)**	**Drift rate [a]**	**$PER_{off\text{-}field}$ (g a.s./ha)**	**TER criterion: TER ≥ 5**
Vegetative vigour and seedling emergence	> 125	33.2% at 3 m	41.5	**> 3.01**
		27.3% at 5 m	34.1	**> 3.66**
		20.9% at 10 m	26.1	**> 4.78**
		17.9% at 15 m	22.4	> 5.59

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values in **bold** fall below the relevant trigger
[a] Drift value for aerial application as used in the environmental fate section for PECsw calculation.

The above risk assessments demonstrate an acceptable risk to non-target terrestrial plants in off-crop areas from the proposed uses of Bumper 250 EC/Principle 250 EC/Propin 250 EC in wheat (use no. 5: aerial spray application) and barley (use no. 6: aerial spray application) when using a 20 m and 15 m buffer zone, respectively. It has to be noted that ER_{50} values for seedling emergence and vegetative vigour are both unbound values and that propiconazole is not a herbicide, therefore these buffer zones are very conservative.

Biological methods for sewage treatment

Propiconazole had no significant inhibitory effect on the respiration rate of activated sludge at the concentrations tested. The 3- hour EC_{50} was > 100 mg a.s./L based on nominal concentrations. Therefore, a low risk can be concluded for biological methods of sewage treatment.

Conclusion

The quantitative risk assessment of propiconazole mammalian toxicology, eco-toxicology and environmental fate data package concludes that it is highly unlikely that the environment will be at unacceptable risk due to the intended uses of the supported products to pecan nuts, mango, apricot, cherry, peach, plum and cereals, according to Good Agricultural Practices (GAP).

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Supported products

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