

ATTRIBUT SG70
(700 g/kg propoxycarbazone-sodium)

Herbicide

**Dossier for Renewal of Approval according to
Commission Regulation 844/2012**

Document M-CP, Section 10

Ecotoxicological studies on the plant protection product

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Germany



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CP 10 ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

Introduction

Ecotoxicological studies described in this document address data requirements specified in Commission Regulation No. 284/2013 of 1 March 2013 ('Data requirements for plant protection products'). Experimental details of ecotoxicological studies done with the formulated product ATTRIBUT SG70 that also satisfy data requirements specified in Commission Regulation No. 283/2013 ('Data requirements for active substances') were included in Document M-CA; only the conclusions will be reported here in summary form.

ATTRIBUT SG70 is considered to be ecotoxicologically equivalent to MKH 6561 WG 70, the representative product of the former dossier submitted for Annex I inclusion in the year 2000. For further details please refer to CONFIDENTIAL information provided separately in Document J of the the dossier for the new representative formulation P-010246-01). It is proposed to use toxicity data for MKH 6561 WG 70 to support ATTRIBUT SG70.

Intended application pattern

The formulation is intended for use as an herbicide for cereals. The optimal use pattern for this formulation is summarised in the table below.

Table 10 -1 Intended application pattern of ATTRIBUT SG70

Crop	Application method	Maximum individual application rate (kg a.s./ha)	Number of applications	Minimum application interval (days)	Application timing BBCH
Winter & spring cereals	Spray	0.042	1	-	BBCH 11- 33
		0.070	1	-	BBCH 11- 33

Definition of the residue for risk assessment

Justification for the residue definition for risk assessment is provided in M-CA Sec.7, Point CA 7.4.1 (environmental matrices). The proposed residue definitions relevant for risk assessment for each compartment are listed in the table below.

Table 10 -2 Definition of the residue for risk assessment

Compartment	Residue definition (Name; alternative code)
Soil	Propoxycarbazone-sodium (MKH 6561)
	M05 (MKH 6561-sulfonamide methyl ester; STJ 4934)
	M07 (MKH 6561-saccharin; MKH 7284)
	M08 (MKH 6561-4-hydroxy-saccharin, KTS 9357)
	M09 (MKH 6561-propoxytriazolinonamide; KTS 9304)
	M10 (MKH6561-N-methyl propoxytriazolinone; MKH 7017)
	M11 (MKH6561-methoxy-saccharin)
Groundwater	Propoxycarbazone-sodium (MKH 6561)
	M05 (MKH 6561-sulfonamide methyl ester; STJ 4934)
	M07 (MKH 6561-saccharin; MKH 7284)
	M08 (MKH 6561-4-hydroxy-saccharin, KTS 9357)
	M09 (MKH 6561-propoxytriazolinonamide; KTS 9304)
	M10 (MKH6561-N-methyl propoxytriazolinone; MKH 7017)
	M11 (MKH6561-methoxy-saccharin)
Surface water / sediment	Propoxycarbazone-sodium (MKH 6561)
	M04 (MKH 6561-carboxylic acid; MKH 9018)
	M05 (MKH 6561-sulfonamide methyl ester; STJ 4934)
	M06 (MKH6561-sulfonamide Acid; MKH 7283)
	M07 (MKH 6561-saccharin; MKH 7284)
	M08 (MKH 6561-4-hydroxy-saccharin, KTS 9357)
	M09 (MKH 6561-propoxytriazolinonamide; KTS 9304)
	M10 (MKH6561-N-methyl propoxytriazolinone; MKH 7017)
	M11 (MKH6561-methoxy-saccharin)

CP 10.1 Effects on birds and other terrestrial vertebrates

The risk assessment for birds and mammals was carried out according to the EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)¹, which follows a tiered approach to assess the effects of plant protection products on birds and mammals. It consists of an initial screening assessment followed by a Tier 1 assessment (where necessary), for both acute and long term (reproductive) assessments. The screening step starts by using generic 'indicator species' and is based on a multiplication of hypothetical worst-case assumptions. The risk to birds and mammals was assessed using Toxicity / Exposure Ratio (TER), i.e. by comparing the relevant Daily Dietary Dose (DDD) with the appropriate endpoint:

$TER_A = \text{acute } D_{50} / DDD$

$TER_{LT} = \text{long-term and reproduction NOEL} / DDD_{LT}$

¹ European Food Safety Authority; Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. [139 pp.]

CP 10.1.1 Effects on birds**Summary**

The acute and long-term risk of ATTRIBUT SG70 to birds was assessed from toxicity-exposure ratios between toxicity endpoints, estimated from studies with propoxycarbazone-sodium and maximum residues potentially occurring on food items following the use according to the proposed use pattern. The TER values, calculated for recommended scenarios, all exceed the trigger value of 100 for acute risk and of 5 for long-term risk at the screening step, indicating acceptable risk to birds following the use of ATTRIBUT SG70.

Due to the log Pow < 3 of propoxycarbazone-sodium, bioaccumulation of the substance in prey like earthworms or fish is not likely. The risk to birds from exposure via drinking water has been assessed and considered acceptable.

Toxicity

The avian toxicity studies with the active substance propoxycarbazone-sodium relevant for the risk assessment are summarised in the table below. For details, please refer to Document M-CA, Section 8 Point CA 8.1 of this submission (published dossier number: P-010245-02).

Table 10.1-1 Acute and long-term toxicity of propoxycarbazone-sodium to birds, endpoints relevant for the risk assessment

Test substance	Species	Test design	Endpoint	Reference	EU agreed endpoint
Propoxy-carbazone-sodium	Bobwhite quail	acute	LD ₅₀ 2000 mg a.s./kg bw	(1994) 48741 M-007896-01-1 KCA 8.1.1.1 /01	Yes
	Bobwhite quail	reproduction weeks	NOEL 4 mg a.s./kg bw	& (2013) EBMIL003 M-449836-01-1 KCA 8.1.1.3 /03	New study

Studies shaded in grey have been reviewed as part of the first EU review of propoxycarbazone-sodium (in Baseline Dossier for the active substance P-010245-01). Other studies are part of the Supplemental Dossier (P-010245-02).

Endpoints used for risk assessmentShort-term endpoints

According to the risk assessment scheme of EFSA GD birds and mammals (2009) a short-term risk assessment is not required. However, the endpoint from short-term dietary studies, e.g. 5-day dietary study in birds (OECD 205, for details please refer to Point CA 8.1 in document M-CA, Section 8) should be used in an acute risk assessment when indicating a higher toxicity via the dietary exposure route (lower DD_{50}).

For propoxycarbazone-sodium, there is no indication that 5-day exposure via dietary route might provoke higher toxicity than one application via gavage in acute study.

Reproductive endpoints

The acute oral LD₅₀ value used in the acute avian assessment divided by 10 to obtain LD₅₀/10 will be compared with the lowest NO(A)EL from the reproduction studies.

For propoxycarbazone-sodium the acute oral LD₅₀ value is > 2000 mg/kg bw generating an LD₅₀/10 value of >200 mg/kg bw. The worst-case NOEL is 45 mg/kg bw/day and therefore the NOEL will be used in the risk assessment.

Metabolites of propoxycarbazone-sodium

From toxicological studies performed in mammals there is no indication that the metabolites are more toxic than the active substance propoxycarbazone-sodium. For this reason and also considering animal welfare, no toxicity studies in birds with the metabolites were deemed necessary.

Risk assessment for birds

Screening step

The crop groupings, indicator species and critical use patterns relevant to the use of propoxycarbazone-sodium according to the EFSA Guidance Document on Risk Assessment for Birds and Mammals are shown in the table below.

Table 10.1-2 Screening step: crop groupings, indicator species and critical use pattern relevant to the use of propoxycarbazone-sodium

Crop group	Use pattern			Indicator species	Shortcut value (SV)	
	Appl. Rate [kg a.s./ha]	No. of appl.	Application timing		For long-term RA based on RUD _m	For acute RA based on RUD ₉₀
Cereals	0.04	1	BBCH 11- 33	Small omnivorous bird	64.8	158.8
	0.070	1	BBCH 11- 33			

The resulting DDDs and TERs for acute and long term exposure are presented in the tables below.

Table 10.1-3 Screening step: acute DDD and TER calculation for birds

Test substance	Crop	Indicator species	LD ₅₀ [mg a.s./kg bw]	Appl. rate [kg a.s./ha]	SV ₉₀	MAF ₉₀	DDD	TER _A	Trigger
Propoxycarbazone-sodium	Cereals	Small omnivorous bird	> 2000	0.042	158.8	1	6.67	> 300	10
				0.070			11.12	> 180	

The TER_A values are above the Regulation (EU) No 546/2011 trigger of 10 for acute exposure. Accordingly, a safe use of the product in cereals can be concluded.

Table 10.1-4 Screening step: long-term DDD and TER calculation for birds

Test substance	Crop	Indicator species	NOEL [mg a.s./kg bw/d]	Appl. rate [kg a.s./ha]	SV _m	MAF _m	ftwa	DDD	TER _{LT}	Trigger
Propoxy-carbazone-sodium	Cereals	Small omnivorous bird	45	0.042	64.8	1	0.53	1.44	31	5
				0.070				2.40	19	

The TER_{LT} values are above the Regulation (EU) No 546/2011 trigger of 5 for long-term exposure. Accordingly, a safe use of the product in cereals can be concluded.

Risk for birds through drinking water

Two scenarios are provided in the EFSA (2009) Guidance Document on Risk Assessment for Birds and Mammals, for assessing the risk from drinking water.

Leaf scenario

The leaf scenario is only relevant for birds, possibly drinking water from puddles in leaf whorls after application of a pesticide to a crop and subsequent rainfall or irrigation. As ATTRIBUT SG70 is applied in cereals, no pools in leaf axils where an acute exposure possibly might occur are to be expected.

Puddle scenario

This scenario is relevant for birds taking water from puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or annual weeds.

In the EFSA Guidance Document (2009) it is stated that "Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals ..., no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (K_{oc} < 500 L/kg) or 3000 in the case of more sorptive substances (K_{oc} ≥ 500 L/kg)."

Table 10.1-5 Evaluation of potential concern for exposure of birds drinking water

Test substance	K _{oc} [L/kg]	Effective Application rate [g a.s./ha]	NO(A)EL [mg a.s./kg bw/d]	Ratio (effective application rate) / NO(A)EL	No concern if ratio	Conclusion
Propoxy-carbazone-sodium	8.8	70	45	1.56	≤ 50	No concern

The evaluation confirms that the long-term risk for birds from drinking water that may contain residues from the use of propoxycarbazone-sodium is acceptable. The evaluation for long-term risk represents the worst case, also covering the acute risk from drinking water.

Effects of secondary poisoning

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for birds if feeding on contaminated prey like fish or earthworms. For organic chemicals, a log P_{OW} ≥ 3 is used to trigger an in-depth evaluation of the potential for bioaccumulation.

Table 10.1-6 Log P_{ow} values

Substance	log P _{ow}	Reference
Propoxycarbazone-sodium	-1.55 (pH 7)	M-CA, Sec.2, Point CA Partition co-efficient n-octanol/water
M05	-0.34 (pH 7)	
M06	-2.9 (pH 7)	
M07	-2.0 (pH 7)	
M08	-1.9 (pH 7.5)	
M09	-0.07 (pH 7)	
M10	0.39 (pH 7)	
M11	-2.8 (pH 7)	

As summarised in the table above, the log P_{ow} values of propoxycarbazone-sodium and its metabolites are below that trigger. Thus, a risk assessment for a generic earthworm eating bird and a generic fish eating bird is not necessary since bioaccumulation of the substance is not likely.

CP 10.1.1.1 Acute oral toxicity

The risk assessment based on the active substance revealed TER values well above the respective triggers indicating acceptable acute and long-term risk to birds. Therefore, a further acute study on birds with the formulation was not taken into consideration, also considering animal welfare reasons.

CP 10.1.1.2 Higher tier data on birds

In view of the results presented above no further studies are necessary.

CP 10.1.2 Effects on terrestrial vertebrates other than birds

Summary

The acute and long-term risk of ATTRIBUT SG70 to mammals was assessed from toxicity-exposure ratios between toxicity endpoints, estimated from studies with propoxycarbazone-sodium and maximum residues potentially occurring on food items following application according to the proposed use pattern.

The TER values, calculated for recommended scenarios, all exceed the trigger value of 10 for acute risk and of 5 for long-term risk at the screening step, indicating acceptable risk to mammals following use of ATTRIBUT SG70.

Due to the log P_{ow} < 3 of propoxycarbazone-sodium, bioaccumulation of the substance in prey like earthworms or fish is not likely. The risk to mammals from exposure via drinking water has been assessed and considered acceptable.

Toxicity

The mammalian toxicity studies with the active substance propoxycarbazone-sodium relevant for the risk assessment are summarised in the table below. For details please refer to Document M-CA, Section 9 of this submission (published dossier number: P-010245-02).

Table 10.1-7 Acute and long-term toxicity of propoxycarbazone-sodium to mammals; endpoints relevant for ecotoxicological risk assessment

Test substance	Test design	Species	Endpoint	Reference	EU agreed endpoint
Propoxy-carbazone-sodium	acute, oral	Rat	LD ₅₀ > 5000 mg a.s./kg bw	██████████ (1994) 23480 M-001552-01-1 KCA 5.2.1 /01	Yes
	2-generation	Rat	NOAEL 16000 ppm corresponding to 1231 mg/kg bw/d	██████████ (1999) 109096 M-012427-03-1 KCA 5.6.1 /02	Yes

Studies shaded in grey have been reviewed as part of the first EU review of propoxycarbazone-sodium in Baseline Dossier for the active substance P-010245-01).

Metabolites of propoxycarbazone-sodium

From toxicological studies performed in mammals there is no indication that the metabolites are more toxic than the active substance propoxycarbazone-sodium. For details please refer to Document M-CA Section 5, Point CA 5.8. Since the metabolites proved to be less toxic than the parent, potential risk is considered to be covered by that of the parent propoxycarbazone-sodium.

Risk assessment for other terrestrial vertebrates

The risk assessment procedure for wild mammals follows the same principles as described in detail for birds under Point CP 10.1.1 above, i.e. EFSA Guidance Document on Risk Assessment for Birds & Mammals (2009).

Screening step

The crop groupings, indicator species and critical use patterns relevant to the use of propoxycarbazone-sodium according to the EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009) are shown in the table below.

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Table 10.1-8 Screening step crop groupings, indicator species and critical use pattern relevant to the use of propoxycarbazone-sodium

Crop group	Use pattern			Indicator species	Shortcut value (SV)	
	Appl. Rate [kg a.s./ha]	No. of appl.	Application timing		For long-term RA based on RUD _m	For acute RA based on RUD _a
Cereals	0.042	1	BBCH 11- 33	Small herbivorous mammal	48.3	118.4
	0.070	1	BBCH 11- 33			

The resulting DDDs and TERs for acute and long term exposure are presented in the tables below.

Table 10.1-9 Screening step: acute DDD and TER calculation for mammals

Test substance	Crop	Indicator species	LD ₅₀ [mg a.s./kg bw]	Appl. rate [kg a.s./ha]	SV ₉₀	MAC ₉₀	DDD	TER _A	Trigger
Propoxy-carbazone-sodium	Cereals	Small herbivorous mammal	5000	0.042	118.4	0.0001	4.83	1005	10
				0.070			1.6	> 43	

The TER_A values are above the Regulation (EU) No 546/2011 trigger of 10 for acute exposure. Accordingly, a safe use of the product in cereals can be concluded.

Table 10.1-10 Screening step: long-term DDD and TER calculation for mammals

Test substance	Crop	Indicator species	NOAEL [mg a.s./kg bw/d]	Appl. rate [kg a.s./ha]	SV _m	MAC _m f _{70%}	DDD	TER _{LT}	Trigger
Propoxy-carbazone-sodium	Cereals	Small herbivorous mammal	1231	0.042	48.3	0.0001	1.08	1145	5
				0.070			1.79	687	

The TER_{LT} values are above the Regulation (EU) No 546/2011 trigger of 5 for long-term exposure. Accordingly, a safe use of the product in cereals can be concluded.

Risk for mammals through drinking water

Assessing the risk for wild mammals from drinking water follows the same principles as described above in detail under Point CP 10.1.1.

Table 10.1-11 Evaluation of potential concern for exposure of mammals drinking water

Test substance	K _e [L/kg]	Effective Application rate [g a.s./ha]	NO(A)ED [mg a.s./kg bw/d]	Ratio (effective application rate) / NO(A)EL	No concern if ratio	Conclusion
Propoxycarbazone-sodium	28.8	70	1231	≤ 0.06	≤ 50	No concern

The evaluation confirms that the long-term risk for mammals (covering acute risk) from drinking water that may contain residues from the use of propoxycarbazone-sodium is acceptable.

Effects of secondary poisoning

As outlined under Point CP 10.1.1 above, propoxycarbazone-sodium and its metabolites have low $log_{10} K_{ow}$ values < 3 and a risk assessment is not required.

CP 10.1.2.1 Acute oral toxicity to mammals

The acute oral toxicity of the formulated product ATTRIBUT SG70 (performed with MKH 6561 70 WG) was determined in a study on rats. The result is shortly summarised in the table below. For more details please refer to Document M-CP Section 7.

Table 10.1-12 Mammalian toxicity data of the formulated product ATTRIBUT SG70

Test substance	Test species	Test design	Ecotoxicological endpoint	Reference	EU agreed endpoint
MKH 6561 70 WG	Rat	acute, oral	LD ₅₀ > 2000 mg/kg	██████████ (1998) 277 01-005537-01.1 also filed under KCP 7.1.1.01	Yes

Studies shaded in grey have been reviewed as part of the first EU review of propoxycarbazone-sodium (in SANCO dossier of former representative formulation of Annex I inclusion ATTRIBUT 70WG, Dossier P-010244-01).

The acute oral study on rats was conducted according to OECD 423 and demonstrated that dosing fasted rats with MKH 6561 70 WG at a dose of 2000 mg/kg bw did not elicit any observable toxicity (no mortality, no effects on body weight, no clinical signs, no pathological findings). Thus, the toxic class assigned was "LD₅₀ > 2500 mg/kg bw". These experimental data do not suggest any increased risk by the formulated product for wild mammals and the risk assessment can be based on the data for the active substance propoxycarbazone-sodium.

CP 10.1.2.2 Higher tier data on mammals

In view of the results presented above no further studies are necessary.

CP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

As the risk assessments demonstrate low toxicity for birds and mammals, no effects on other terrestrial vertebrates (reptiles and amphibians) are to be expected following application of ATTRIBUT SG70 according to the proposed use pattern. Further studies are not considered necessary.

CP 10.2 Effects on aquatic organisms**Summary**

The acute and long-term risk of ATTRIBUT SG70 to aquatic organisms was assessed from toxicity-exposure ratios between toxicity endpoints, estimated from studies with propoxycarbazone-sodium and its metabolites and maximum PEC_{SW} values following the use according to the proposed use pattern.

The TER_A values for propoxycarbazone-sodium and its metabolites all exceed the trigger value of 100 for acute risk at FOCUS Step 1. The TER_{LT} values for propoxycarbazone-sodium and its metabolites

all exceed the trigger value of 10 for long-term risk at FOCUS Step 1 with the exception of *Lemna* exposed to propoxycarbazone-sodium.

The risk to *Lemna* has been refined by using FOCUS Step 3 and Step 4 values. Acceptable risk to aquatic plants following use of ATTRIBUT SG70 according to the proposed use pattern is indicated:

- without mitigation following application of 42 g/ha in spring cereals for all FOCUS scenarios;
- without mitigation following application of 42 g/ha in winter cereals for FOCUS scenarios D1, D3, D4, D5, D6 and R1 and with a 10 m spray drift and run-off buffer for FOCUS scenarios R3 and R4;
- without mitigation following application of 70 g/ha in spring cereals for FOCUS scenarios D1 (stream), D3, D4, D5 and R4 and with a 5 m spray drift buffer for FOCUS scenarios D1 (ditch);
- without mitigation following application of 70 g/ha in winter cereals for FOCUS scenarios D1 (stream), D3, D4, D5, D6 and R1 (pond) and with a 5 m spray drift buffer for FOCUS scenario D1 (ditch) and with a 10 m spray drift and run-off buffer for FOCUS scenarios R1 and R4 and with a 20 m spray drift and run-off buffer for FOCUS scenario R3.

Further refinement of the D2 (ditch and stream) scenario should be addressed by Member States during national registration.

Toxicity

ATTRIBUT SG70

Tests with MKH 650-70 WG were performed with green algae and aquatic plants and have been conducted and evaluated during the first EU review and are still considered adequate. For detailed information on studies already evaluated during the first EU review of propoxycarbazone-sodium, please refer to corresponding section in the Baseline Dossier and in the Monograph.

The results of acute and chronic tests with propoxycarbazone-sodium on fish and *Daphnia* demonstrate that the active substance is not toxic to these organisms ($LC_{50} > 77.2$ mg a.s./L for rainbow trout and $EC_{50} > 140$ mg a.s./L for *Daphnia*, see Table 10.2-2 below).

As can be expected for an herbicide, tests with algae and aquatic plants show that these organisms are more sensitive to propoxycarbazone-sodium. For algae, the lowest $E_bC_{50} = 1.57$ mg a.s./L was obtained for *Pseudokirchneriella subcapitata*. Most sensitive organisms (> 100 times more sensitive) are aquatic macrophytes: for *Lemna gibba* the lowest $EC_{50} = 0.00453$ mg a.s./L and for *Myriophyllum spicatum* the $EC_{50} = 0.0292$ mg a.s./L.

Therefore, studies with the formulated product were performed only with algae and *Lemna*. A summary of the aquatic toxicity profile of ATTRIBUT SG70 is provided in the table below.

Table 10.2-1 Toxicity of ATTRIBUT SG70 to aquatic organisms

Test substance	Species	Test design	Endpoint [mg product/L]	Reference	EU agreed endpoint
MKH 6561 WG 70	<i>P. subcapitata</i>	72 h	E _r C ₅₀ > 113.4 (nom) (corresp. to 80.2 mg a.s./L) E _b C ₅₀ > 11.46 (nom) (corresp. to 8.1 mg a.s./L)	(1998) DOM 98048 M-006091-01-1 KCP 10.2.1 /08	Yes
MKH 6561 WG 70	<i>L. gibba</i>	7 d, static	E _r C ₅₀ (frond area) 0.0158 (nom) (corresp. to 0.012 mg a.s./L)	(1999) DOM 98097 M-009766-02-1 KCP 10.2.1 /22	Yes

Studies shaded in grey have been reviewed as part of the first EU review of propoxycarbazone-sodium (in SANCO dossier of former representative formulation of Annex I inclusion ATTRIBUT 70WG; Dossier P-010244-01).

Results show that the toxicity of the formulation ATTRIBUT SG70 is a reflection of the toxicity of the active substance. The risk assessment can therefore be based on the most sensitive endpoints derived for the active substance.

Propoxycarbazone-sodium and its metabolites

A summary of the relevant acute and long-term endpoints for aquatic risk assessment is provided below. Full details of the tests on the active substance and the metabolites are provided in Doc M-CA, Section 8, Points CA 8.2.1 to 8.6. Only studies representing the worst case for key species are presented in the table below.

Table 10.2-2 Aquatic endpoints for propoxycarbazone-sodium and its metabolites

Test substance	Species	Test design	Endpoint [mg/L]	Reference	EU agreed endpoint
Propoxy- carbazone- sodium	<i>O. mykiss</i>	96 h static	LC ₅₀ 77.2 (nom)	(1998) 108066 M-004219-01-1 KCA 8.2.1 /01	Yes
	<i>P. promelas</i>	ELS flow through 3 d	NOEC 105 (nom)	(1999) 108453 M-015904-01-1 KCA 8.2.2.1 /01	Yes
	<i>D. magna</i>	48 h, static	EC ₅₀ 110 (nom)	(1998) 107841 M-002122-01-1 KCA 8.2.4.1 /01	Yes
	<i>D. magna</i>	static renewal 21 d	NOEC 110 (nom)	(1999) 108845 M-016508-01-1 KCA 8.2.5.1 /02	Yes
	<i>P. subcapitata</i> ^a	96 h	E _r C ₅₀ 7.36 (mm) E _b C ₅₀ 1.57 (mm)	(1999) 108820 M-012242-01-1 KCA 8.2.6.1 /01	Yes
	<i>L. gibba</i>	14 d static-	EC ₅₀ (biomass) 0.0064 (mm)	(1999) 108338	Yes

Test substance	Species	Test design	Endpoint [mg/L]	Reference	EU agreed endpoint
		renewal		M-009972-01-1 KCA 8.2.7 /01	
	<i>L. gibba</i>	7 day, static	E _r C ₅₀ (frond no) 0.00664 (nom) E _r C ₅₀ (frond area) 0.00453 (nom)	(2004) DOM 23101 M-001604-01-1 KCA 8.2.7 /05	New study
	<i>Myriophyllum spicatum</i>	14 d static	E _r C ₅₀ (wet weight) 0.063 (nom) E _y C ₅₀ (wet weight) 0.0292 (nom)	(2013) 70401245 M-466605-02-1 KCA 8.2.7 /08	New study
M04	<i>L. macrochirus</i>	96 h, static	LC ₅₀ 100 (nom)	(1998) DOM 98054 M-005115-01-1 KCA 8.2.1 /03	Evaluated during the first EU review
	<i>D. magna</i>	48 h, static	EC ₅₀ > 100 (nom)	(1998) DIBF/Dgr 199 M-005032-01-1 KCA 8.2.4 /03	Yes
	<i>P. subcapitatus</i>	72 h	E _r C ₅₀ > 100 (nom) E _r C ₅₀ > 100 (nom)	(1999) DOM 98051 M-007702-02-1 KCA 8.2.6.1 /04	Yes
	<i>L. gibba</i>	d, static	EC ₅₀ > 14.2 (nom)	(1999) DOM 98094 M-009770-01-1 KCA 8.2.7 /03	Yes
M05	<i>B. rerio</i>	96 h semi-static	LC ₅₀ 79 (nom)	(1999) 742072 M-017346-01-1 KCA 8.2.1 /05	Yes
	<i>D. magna</i>	48 h semi-static	EC ₅₀ > 63 (nom)	(1999) 742050 M-017326-01-1 KCA 8.2.4.1 /04	Yes
	<i>S. subspicatus</i>	7 h	E _r C ₅₀ > 62 (mm) E _r C ₅₀ > 62 (mm)	(1999) 742094 M-017343-01-1 KCA 8.2.6.1 /05	Yes
	<i>L. gibba</i>	7 d, static	EC ₅₀ > 89.4 (mm)	(1999) DOM 99081 M-018594-01-1 KCA 8.2.7 /04	Yes
M06	<i>O. mykiss</i>	acute, 96 h, static	LC ₅₀ > 100 (nom)	& (2006) 30183230 M-278097-01-1 KCA 8.2.1 /07	New study
	<i>D. magna</i>	48 h,	EC ₅₀ > 100 (nom)	&	New study

Test substance	Species	Test design	Endpoint [mg/L]	Reference	EU agreed endpoint
		static		(2006) 30183220 M-278971-01-1 KCA 8.2.4.1 /05	
	<i>P. subcapitata</i>	72 h	ErC ₅₀ > 100 (nom)	█ & █ (2006) 30181210 M-293396-01-1 KCA 8.2.6 /06	New study
	<i>L. gibba</i>	7 d, static	EC ₅₀ > 100 (nom)	█ (2006) 30184240 M-281240-01-1 KCA 8.2.7 /07	New study
M07	<i>O. mykiss</i>	96 h static	LC ₅₀ > 100 (nom)	█ & █ (2006) 30193220 M-278099-01-1 KCA 8.2.1 /06	New study
	<i>D. magna</i>	48 h, static	EC ₅₀ > 100 (nom)	█ & █ (2006) 30192220 M-278973-01-1 KCA 8.2.4.1 /06	New study
	<i>P. subcapitata</i>	72 h	ErC ₅₀ > 100 (nom)	█ & █ (2006) 30191210 M-281243-01-1 KCA 8.2.6.1 /07	New study
	<i>L. gibba</i>	7 d, static	EC ₅₀ > 100 (nom)	█ (2006) 30194240 M-281250-01-1 KCA 8.2.7 /08	New study
M08	<i>D. magna</i>	48 h static	EC ₅₀ > 100 (nom)	█ & █ (2006) 30202220 M-278974-01-1 KCA 8.2.4.1 /07	New study
	<i>P. subcapitata</i>	72 h	ErC ₅₀ 30.8 (gmm ^b)	█ & █ (2006) 30201210 M-281220-01-1 KCA 8.2.6.1 /08	New study
	<i>L. gibba</i>	7 d, static	EC ₅₀ > 100 (nom)	█ (2006) 30203240 M-281362-01-1 KCA 8.2.7 /09	New study
M10	<i>L. macrochirus</i>	96 h, static	LC ₅₀ > 100 (nom)	█ (1998) DOM 98052 M-005052-01-1 KCA 8.2.1 /04	Evaluated during the first EU review
	<i>D. magna</i>	48 h,	EC ₅₀ > 100 (nom)	█ (1998)	Yes

Test substance	Species	Test design	Endpoint [mg/L]	Reference	EU agreed endpoint
		static		HBF/Dm 198 M-005036-01-1 KCA 8.2.6.1 /02	
	<i>P. subcapitata</i> ^a	96 h	E _r C ₅₀ > 100 (nom) E _b C ₅₀ > 100 (nom)	(1998) DOM 98049 M-006193-01-1 KCA 8.2.6.1 /03	Yes
	<i>L. gibba</i>	7 d, static	EC ₅₀ > 100 (nom)	(1999) DOM 98114 M-009757-01-1 KCA 8.2.7 /03	Yes

^a formerly *Selenastrum capricornutum*

^b geometric mean of the measured test concentration

Studies shaded in grey have been reviewed as part of the first EU review of propoxycarbazone-sodium (in Baseline Dossier for the active substance P-010245-01). Other studies are part of the Supplemental Dossier (P-010245-02).

Selection of algae endpoint

Processes in ecosystems are dominantly rate driven and therefore the unit development per time (growth rate) appears most suitable to measure effects in algae. Also, growth rates and their inhibition can easily be compared between species, test durations and test conditions, which is not the case for biomass. After numerous discussions, the current test guidelines OECD TG 201, the EU-Method C3, the EC regulation for Classification and Labelling (EC regulation 1272/2008) and the PPR Opinion (EFSA Journal 461, 344; 2007) list growth rate as the most suitable endpoint of the algae inhibition test. Also in the new Aquatic Guidance Document (EFSA Journal 2013;11(7):3290, 268 pp. doi:10.2903/j.efsa.2013.3290) it is stated that growth rate is the preferred endpoint to be used.

Therefore, for newly submitted studies only the growth rate endpoints are reported in the table above and will be considered for the risk assessment. However, the current EU agreed endpoint for propoxycarbazone-sodium is based on biomass. The biomass endpoint is lower than the growth rate endpoint and can be considered worst case.

Selection of macrophytes endpoint

Aquatic plants are clearly the most sensitive group of organisms when exposed to propoxycarbazone-sodium. In addition to *Lemna gibba*, a second macrophyte species *Myriophyllum spicatum* was tested, showing that *Lemna* is the most sensitive species.

An additional study on the most sensitive species *Lemna* with propoxycarbazone-sodium was conducted in 2004 ((1999) DOM 23101, M-001604-01-1) to demonstrate technical equivalence of the active substance after the change of specification of propoxycarbazone-sodium technical. The EC₅₀ for average growth rate were determined to be 6.64 µg a.s./L for frond numbers, 4.53 µg a.s./L for total frond area and > 320 µg a.s./L for dry weight of plants.

As the new endpoint of E_rC₅₀ 4.53 µg/L from the new *Lemna gibba* study is the lowest endpoint of all studies with aquatic plants, the risk assessment will be based on this endpoint as a worst case approach.

Metabolites

A full aquatic data package (acute fish, acute *Daphnia*, algae and *Lemna*) is available for surface water metabolites M04 and M06 and for soil metabolites M05, M07 and M10. Soil metabolite M08 was

tested on *Daphnia*, algae and *Lemna*. All metabolites were found to be non-toxic to fish and *Daphnia* and showed no herbicidal activity against algae and *Lemna*. Therefore, no studies were conducted with soil metabolites M09 and M11 (for details please refer to Document M-CA, Section 8, Point CA 8.2). To address these metabolites, a risk assessment for algae and *Lemna* is conducted, assuming ten-fold toxicity of the structurally similar metabolites M10 and M08 for metabolites M09 and M11, respectively. This can be considered a worst case approach.

Risk assessment for aquatic organisms

The risk assessment was conducted following the EU (2002) Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev.4 (final) 17 October 2002).

The initial risk assessments were carried out by comparing the PEC_{SW} values with the acute and long-term toxicity endpoints. Acute and long-term toxicity exposure ratios (TER_A and TER_{LT}) were calculated using the following equations:

$$TER_A = LC_{50} \text{ or } EC_{50} / \text{max. PEC}_{SW}$$

$$TER_{LT} = EC_{50} \text{ or } NOEC / \text{max. PEC}_{SW}$$

Exposure

PEC_{SW} values were calculated according to FOCUS Step 1 to 4 and were taken from Document M-CP, Section 9. For full details of the assumptions used in the exposure calculations please refer to that section.

Maximum Step 1 & 2 values for propoxycarbazone-sodium and for metabolites of propoxycarbazone-sodium are presented in Table 10.2-3 and Table 10.2-4, respectively.

Table 10.2-3 Maximum PEC_{SW} and PEC_{SED} values for propoxycarbazone-sodium after application to winter and spring cereals (FOCUS Step 1 & 2)

Crop / Application rate	FOCUS Step/ Scenario	Propoxycarbazone-sodium	
		PEC _{SW} (µg/L)	PEC _{SED} (µg/kg)
Winter and Spring cereals (1 x 42 g a.s./ha)	Step 1	3.666	5.474
	Step 2	3.581	1.434
Winter and Spring cereals (1 x 70 g a.s./ha)	Step 1	22.776	9.124
	Step 2	5.968	2.390

Values in bold are used in the risk assessment as a worst case approach

Table 10.2-4 Maximum PEC_{SW} values of the metabolites of propoxycarbazone-sodium following application to winter and spring cereals (FOCUS Step 1 & 2)

Application	FOCUS Step	PEC _{SW} (µg/L)							
		M04	M05	M06	M07	M08	M09	M10	M11
Winter and Spring cereals (1 x 42 g a.s./ha)	Step 1	0.242	1.437	0.036	1.651	0.443	0.700	2.800	1.865
	Step 2	0.242	0.298	0.036	0.514	0.161	0.256	1.045	0.516
Winter and Spring cereals (1 x 70 g a.s./ha)	Step 1	0.403	2.395	0.060	2.751	0.738	1.166	4.667	3.109
	Step 2	0.403	0.497	0.060	0.856	0.268	0.426	1.741	0.860

Values in bold are used in the risk assessment as a worst case approach

Maximum PEC_{SW} of propoxycarbazone-sodium at Step 3 following application to winter and spring cereals are shown in Table 10.2-5 and Table 10.2-6, respectively.

Table 10.2-5 FOCUS Step 3 - Maximum PEC_{SW} values for propoxycarbazone-sodium after application to winter cereals

Scenario	Main entry path	Winter cereals: 1 × 42 g a.s./ha	Winter cereals: 1 × 70 g a.s./ha
		PEC _{SW, max} (µg/L)	PEC _{SW, max} (µg/L)
D1 (Ditch)	Drift	0.287	0.480
D1 (Stream)	Drift	0.240	0.400
D2 (Ditch)	Drainage	4.288	7.291
D2 (Stream)	Drainage	2.675	4.551
D3 (Ditch)	Drift	0.266	0.444
D4 (Pond)	Drift	0.009	0.015
D4 (Stream)	Drift	0.221	0.352
D5 (Pond)	Drift	0.009	0.015
D5 (Stream)	Drift	0.209	0.349
D6 (Ditch)	Drift	0.272	0.453
R1 (Pond)	Runoff	0.012	0.019
R1 (Stream)	Runoff	0.279	0.470
R3 (Stream)	Runoff	0.740	1.229
R4 (Stream)	Runoff	0.497	0.822

Table 10.2-6 FOCUS Step 3 - Maximum PEC_{SW} values for propoxycarbazone-sodium after application to spring cereals

Scenario	Main entry path	Spring cereals: 1 × 42 g a.s./ha	Spring cereals: 1 × 70 g a.s./ha
		PEC _{SW, max} (µg/L)	PEC _{SW, max} (µg/L)
D1 (Ditch)	Drift	0.281	0.468
D1 (Stream)	Drift	0.219	0.366
D3 (Ditch)	Drift	0.266	0.443
D4 (Pond)	Drift	0.009	0.015
D4 (Stream)	Drift	0.221	0.368
D5 (Pond)	Drift	0.009	0.015
D5 (Stream)	Drift	0.208	0.348
R4 (Stream)	Drift	0.175	0.292

In some risk assessment scenarios, FOCUS Step 4 values are required; where necessary these values are presented in the relevant tables below.

Risk assessment for aquatic organismsAcute risk assessment

The acute risk assessment for propoxycarbazone-sodium and its metabolites based on FOCUS Step 1 is presented in the table below.

Table 10.2-7 TER_A calculations based on FOCUS Step 1

Test substance	Species	Endpoint [µg/L]	PEC _{W, max} [µg/L] ^a	TER _A	Trigger
Propoxycarbazone- sodium	Fish, acute	LC ₅₀ 77200	22.76	3396	100
	<i>Daphnia</i> , acute	EC ₅₀ > 100000	0.403	4830	
M04	Fish, acute	LC ₅₀ 100000	0.403	24839	
	<i>Daphnia</i> , acute	EC ₅₀ > 100000	0.403	48139	
M05	Fish, acute	LC ₅₀ 79000	2.79	3298	
	<i>Daphnia</i> , acute	EC ₅₀ > 63000	2.79	26305	
M06	Fish, acute	LC ₅₀ 100000	0.403	166667	
	<i>Daphnia</i> , acute	EC ₅₀ > 100000	0.403	166667	
M07	Fish, acute	LC ₅₀ 100000	2.51	36350	
	<i>Daphnia</i> , acute	EC ₅₀ > 100000	2.51	36350	
M08	<i>Daphnia</i> , acute	EC ₅₀ 100000	0.73	> 135501	
M10	Fish, acute	LC ₅₀ > 100000	4.667	> 21427	
	<i>Daphnia</i> , acute	EC ₅₀ 100000	4.667	> 21427	

^a FOCUS Step 1 values calculated for 1 x 70 g/ha are used in the risk assessment as a worst case approach

All TER_A values are greater than the Regulation (EU) No 546/2011 trigger of 100, indicating acceptable acute risk to fish and *Daphnia* following application of ATTRIBUT SG70 according to the proposed use pattern.

Chronic risk assessment

The chronic risk assessment for propoxycarbazone-sodium and its metabolites based on FOCUS step 1 is presented in the table below.

Table 10.2-8 TER_{LT} calculations based on FOCUS Step 1

Test substance	Species	Endpoint [µg/L]	PEC _{SW, max} [µg/L] ^a	TER _{LT}	Trigger ^o
Propoxycarbazone-sodium	Fish, chronic	NOEC	105000	22.776	4610
	<i>Daphnia</i> , chronic	NOEC	110000		4830
	Algae	E _b C ₅₀	1570		69
	<i>Lemna gibba</i>	EC ₅₀	4.33		0.20
M04	Algae	E _{r/b} C ₅₀	100000	0.403	248139
	<i>Lemna gibba</i>	EC ₅₀	14200		35236
M05	Algae	E _{r/b} C ₅₀	62000	2.395	25887
	<i>Lemna gibba</i>	EC ₅₀	> 89400		> 37328
M06	Algae	E _{r/b} C ₅₀	100000	0.066	666667
	<i>Lemna gibba</i>	EC ₅₀	> 100000		> 1666667
M07	Algae	E _{r/b} C ₅₀	100000	2.751	36350
	<i>Lemna gibba</i>	EC ₅₀	> 100000		> 36350
M08	Algae	E _{r/b} C ₅₀	30800	0.738	41734
	<i>Lemna gibba</i>	EC ₅₀	> 100000		> 135501
M11 ^b	Algae	E _{r/b} C ₅₀	3080	3.109	991
	<i>Lemna gibba</i>	EC ₅₀	> 10000		> 3216
M10	Algae	E _{r/b} C ₅₀	> 100000	4.667	> 21427
	<i>Lemna gibba</i>	EC ₅₀	> 100000		> 21427
M09 ^c	Algae	E _{r/b} C ₅₀	> 10000	1.166	> 8576
	<i>Lemna gibba</i>	EC ₅₀	> 10000		> 8576

^a FOCUS Step 1 values calculated for 1 x 750 g/ha are used in the risk assessment as a worst case approach

^b As no data is available for M11, it is assumed as a worst case approach that M11 is 10 fold more toxic than the structurally similar metabolite M08.

^c As no data is available for M09, it is assumed as a worst case approach that M09 is 10 fold more toxic than the structurally similar metabolite M10.

In bold: value below the trigger of 10

For propoxycarbazone-sodium, all TER values are greater than the Regulation (EU) No 546/2011 trigger value of 10 with the exception of *Lemna*. For metabolites of propoxycarbazone-sodium all TER values are above the trigger value of 10, indicating acceptable risk when based on FOCUS Step 1 PEC_{SW} values.

Thus, for *Lemna*, the TER calculations for both application rates based on FOCUS Step 2 PEC_{SW} values are presented below.

Table 10.2-9 TER_{LT} calculations based on FOCUS Step 2 for propoxycarbazone-sodium

Crop	Species	Endpoint [µg/L]	PEC _{sw,max} [µg/L]	TER _{LT}	Trigger
Cereals (1 x 42 g a.s./ha)	<i>Lemna gibba</i>	EC ₅₀ 4.53	3.581	1.27	10
Cereals (1 x 70 g a.s./ha)			5.968	0.76	

In bold: value below the trigger of 10

For both intended application rates, TER values are below the trigger of 10 when based on FOCUS Step 2. Therefore, a risk assessment based on more realistic FOCUS Step 3 values is presented in the tables below.

Table 10.2-10 TER_{LT} calculations for propoxycarbazone-sodium based on FOCUS Step 3 following application in winter and spring cereals, 1 x 42 g/ha

		1 x 42 g/ha				
		Winter cereals		Spring cereals		
Species	Endpoint [µg/L]	FOCUS Step 3 scenario	PEC _{sw,max} [µg/L]	TER	PEC _{sw,max} [µg/L]	TER
<i>L. gibba</i>	4.53	D1 (ditch)	0.287	16	0.281	16
		D1 (stream)	0.340	19	0.219	21
		D2 (ditch)	4.288	1.1	-	-
		D2 (stream)	2.675	1.7	-	-
		D3 (ditch)	0.766	17	0.266	17
		D4 (pond)	0.009	503	0.009	503
		D4 (stream)	0.271	21	0.221	20
		D5 (pond)	0.009	503	0.009	503
		D5 (stream)	0.209	22	0.208	22
		D6 (ditch)	0.72	17	-	-
		R1 (pond)	0.012	378	-	-
		R1 (stream)	0.299	16	-	-
		R3 (stream)	0.740	6.1	-	-
		R4 (stream)	0.497	9.1	0.175	26

- FOCUS scenario not relevant for spring cereals

In bold: value below the trigger of 10

Table 10.2-11 TER_{LT} calculations for propoxycarbazone-sodium based on FOCUS Step 3 following application in winter and spring cereals, 1 x 70 g/ha

			1 × 70 g/ha			
			Winter cereals		Spring cereals	
Species	Endpoint [µg/L]	FOCUS Step 3 scenario	PEC _{sw, max} [µg/L]	TER	PEC _{sw, max} [µg/L]	TER
<i>L. gibba</i>	4.53	D1 (ditch)	0.480	9.4	0.468	9.7
		D1 (stream)	0.400	11	0.366	12
		D2 (ditch)	7.291	0.6	-	-
		D2 (stream)	4.554	1.0	-	-
		D3 (ditch)	0.444	10	0.445	10
		D4 (pond)	0.015	302	0.015	302
		D4 (stream)	0.352	23	0.368	12
		D5 (pond)	0.015	302	0.015	302
		D5 (stream)	0.349	23	0.348	13
		D6 (ditch)	0.453	10	-	-
		R1 (pond)	0.019	238	-	-
		R1 (stream)	0.470	9.6	-	-
		R3 (stream)	1.29	3.7	-	-
		R4 (stream)	0.822	5.5	0.292	16

- FOCUS scenario not relevant for spring cereals

In bold: value below the trigger of 10

The majority of the TER values are greater than the trigger of 10 when based on FOCUS Step 3, indicating acceptable risk to aquatic plants with the following exceptions:

- D2 (ditch and stream), R3 (stream) and R4 (stream) for the application rate of 42 g/ha in winter cereals;
- D1 (ditch), D2 (ditch and stream), R1 (stream), R3 (stream) and R4 (stream) for the application rate of 70 g/ha in winter cereals;
- D1 (ditch) for the application rate of 70 g/ha in spring cereals.

For the above identified failing scenarios, refinement needs to be considered and is presented in the tables below. The refinement is based on FOCUS Step 4 values taking into account mitigation measures.

Table 10.2-12 TER_{LT} calculations for propoxycarbazone-sodium based on FOCUS Step 4 following application in winter cereals, 1 x 42 g/ha

Application rate			1 × 42 g/ha	
Crop			Winter cereals	
Mitigation			10 m D + R	
Species	Endpoint [µg/L]	FOCUS Step 4 scenario	PEC _{sw, max} [µg/L]	TER
<i>L. gibba</i>	4.53	D2 (ditch)	4.288	1.1
		D2 (stream)	0.675	1.7
		R3 (stream)	0.327	14
		R4 (stream)	0.227	20

D = drift mitigation, R = runoff mitigation

In bold: value below the trigger of 10Table 10.2-13 TER_{LT} calculations for propoxycarbazone-sodium based on FOCUS Step 4 following application in winter cereals, 1 x 70 g/ha

Application rate			1 × 70 g/ha					
Crop			Winter cereals					
Mitigation			5 m D		10 m D + R		20 m D + R	
Species	Endpoint [µg/L]	FOCUS Step 4 scenario	PEC [µg/L]	TER	PEC _{sw, max} [µg/L]	TER	PEC _{sw} [µg/L]	TER
<i>L. gibba</i>	4.53	D1 (ditch)	0.154	29.4	-	-	-	-
		D2 (ditch)	7.291	0.6	7.291	0.6	7.291	0.6
		D2 (stream)	4.551	1.0	4.551	1.0	4.551	1.0
		R1 (stream)	0.470	9.6	0.193	23	-	-
		R3 (stream)	1.229	8.7	0.543	8.3	0.281	16
		R4 (stream)	0.822	5.5	0.374	12	-	-

D = drift mitigation, R = runoff mitigation

In bold: value below the trigger of 10Table 10.2-14 TER_{LT} calculations for propoxycarbazone-sodium based on FOCUS Step 4 following application in spring cereals, 1 x 70 g/ha

Application rate			1 × 70 g/ha	
Crop			Spring cereals	
Mitigation			5 m D	
Species	Endpoint [µg/L]	FOCUS Step 4 scenario	PEC _{sw, max} [µg/L]	TER
<i>L. gibba</i>	4.53	D1 (ditch)	0.144	31

D = drift mitigation, R = runoff mitigation

The TER values are greater than the trigger of 10 when based on FOCUS Step 4, indicating acceptable risk to aquatic plants when considering the following mitigation measures:

- 10 m D + R buffer zone following the application rate of 42 g/ha in winter cereals for scenarios R3 (stream) and R4 (stream);

- 10 m D + R buffer zone following the application rate of 70 g/ha in winter cereals for scenarios R1 (stream) and R4 (stream);
- 20 m D + R buffer zone following the application rate of 70 g/ha in winter cereals for scenarios R3 (stream);
- 5 m D buffer zone following the application rate of 70 g/ha in spring cereals for scenarios D1 (ditch).

Further refinement of the D2 (ditch and stream) scenario should be addressed by Member States during national registration.

CP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

No new studies with the product were required.

CP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

No new studies with the product were required.

CP 10.2.3 Further testing on aquatic organisms

No new studies with the product were required.

CP 10.3 Effects on arthropods

CP 10.3.1 Effects on bees

Summary

The acute toxicity of propoxycarbazone-sodium to bees was assessed from hazard quotients between toxicity endpoints, estimated from oral and contact studies with the active substance and the product ATTRIBUT SG70. Propoxycarbazone-sodium was also subjected to a chronic laboratory feeding study with adult honey bees and to a bee brood feeding study.

The hazard quotients are less than 50, indicating acceptable risk to bees. No adverse lethal and sub-lethal effects on adult honey bees were found in a 10-day feeding study at the highest concentration tested of 1600 mg a.s./kg feeding solution. No adverse effects were found on mortality, bee brood development (eggs, young larvae, old larvae, pupae) and colony development by feeding honey bee colonies sugar syrup at a concentration of 0.175 g a.s./L.

Acceptable risk to bees following use of ATTRIBUT SG70 according to the proposed use pattern is indicated.

Toxicity

The ecotoxicological endpoints of honeybee laboratory studies are provided in the following tables.

Table 10.3-1 Acute toxicity to bees

Test substance	Test species / test design	Endpoint	Reference	EU agreed endpoint
Propoxycarbazone-sodium, tech.	Honeybee, 48 h oral and contact toxicity	oral LD ₅₀ > 319 µg a.s./bee contact LD ₅₀ > 200 µg a.s./bee	██████████ (1998) 4150036 M-006195-01-1 KCA 8.3.1.1.1 /01 KCA 8.3.1.1.2 /01	Yes
MKH 6561 WG 70	Honeybee, 48 h oral and contact toxicity	oral LD ₅₀ > 402 µg prod/bee contact LD ₅₀ > 200 µg prod/bee	██████████ (1998) 4160036 M-005113-01-1 KCP 10.3.1.1.1 /01 KCP 10.3.1.1.2 /01	Yes
ATTRIBUT SG70	Honeybee, 48 h oral and contact toxicity	oral LD ₅₀ > 109 µg a.s./bee contact LD ₅₀ > 100 µg a.s./bee	██████████ (2012) 70472035 M-466729-01-1 KCP 10.3.1.1.1 /01	New study

Studies shaded in grey have been reviewed as part of the first EU review of propoxycarbazone-sodium (in case of KCA: Baseline Dossier for the active substance P-010245-01; in case of KCP: in SANCO dossier of former representative formulation of Annex I inclusion ATTRIBUT 70WG P-010244-01). Other studies are part of the Dossier of the new representative formulation ATTRIBUT SG70 (P-010290-01).

An additional study with the product ATTRIBUT SG70 on acute oral toxicity to honey bees was conducted, which was not submitted during the first Annex I inclusion process. It has been conducted according to most recent Guidance documents OECD 213 and 214 (1998). A single concentration of 100 µg a.s./bee was tested. No significant lethal and sub-lethal were found, verifying the results of the test submitted during the first Annex I inclusion process conducted according to EPPO 170 (██████████ (1998), 4150036, M-006195-01-1) that can still be considered as valid. Nevertheless, the risk assessment will be based on the lower endpoint of the new study as a worst case approach.

Table 10.3-2: Chronic toxicity to adult bees and bee brood feeding test

Test substance	Test species	Endpoint	Reference	EU agreed endpoint
Propoxycarbazone-sodium	Honeybee, 10 d chronic adult feeding study	LC ₅₀ > 600 ppm (corresponding to LD ₅₀ > 47 µg a.s./bee/d) NOEC 1600 ppm (corresponding to NOED > 45 µg a.s./bee/d)	██████████ (2014) 70407136 M-484627-01-1 KCA 8.3.1.2/01.	New study
ATTRIBUT SG70	Honeybee brood feeding (Oomen et al., 1992)	No adverse effects on bee brood development (eggs, young larvae, old larvae) and mortality of adult bees and pupae by feeding honey bee colonies sugar syrup at a concentration of 0.175 g a.s./L	██████████ (2013) 70473031 M-466734-01-1 KCA 8.3.1.3/01.	New study

Details of the studies are presented in Document M-CA, Section 8, Point CA 8.3.1, as well as within the existing Review Report for propoxycarbazone-sodium. The studies are part of the Supplemental Dossier (P-010245-02).

Risk assessment for bees

An indication of hazard (Hazard Quotient or Q_H) can be derived according to the EPPQ risk assessment scheme, by calculating the ratio between the application rate (expressed in g or mL/ha) and the lowest laboratory contact and oral LD₅₀ (expressed in µg/bee).

Q_{HO} and Q_{HC} resp. = Application rate [g/ha] / LD₅₀ oral or LD₅₀ contact [µg/bee]

Q_H values can be calculated using data from the studies performed with each of the active ingredients and with the formulation. Q_H values higher than 50 are assumed to reflect levels of concern which trigger higher tiered tests for clarification of the risk to honey bees.

Table 10.3-3: Hazard quotients for bees – oral exposure

Test substance	Oral LD ₅₀ [µg/bee]	Application rate [g/ha]	Hazard quotient Q_{HO}	Trigger	Acceptable risk for adult bees
Propoxycarbazone- sodium, tech.	> 319 µg a.s./bee	70	< 0.22	50	Yes
ATTRIBUT SG70	> 109 µg a.s./bee	70	0.64	50	Yes

The hazard quotients for oral exposure are below the trigger of concern ($Q_{HO} < 50$). Therefore acceptable risk to bees is expected using the product according to the proposed use pattern.

Table 10.3-4: Hazard quotients for bees – contact exposure

Test substance	Contact LD ₅₀ [µg/bee]	Application rate [g/ha]	Hazard quotient Q_{HC}	Trigger	Acceptable risk for adult bees
Propoxycarbazone- sodium, tech.	> 200 µg a.s./bee	70	0.35	50	Yes
ATTRIBUT SG70	> 100 µg a.s./bee	70	< 0.70	50	Yes

The hazard quotients for contact exposure are below the trigger of concern ($Q_{HC} < 50$). Therefore acceptable risk to bees is expected using the product according to the proposed use pattern.

Additional considerations for the risk assessment

In addition to the acute laboratory studies with adult honey bees, a 10 day chronic feeding test with bees exposed to propoxycarbazone-sodium was conducted. No agreed and ring tested guideline for testing chronic toxicity on honey bees was available at test start. The test was therefore designed to comply with modifications with OECD 213 (1998) and CEB No.: 230 (November 2003). Bees were fed with propoxycarbazone-sodium (techn.) treated sugar solution ad libitum for 10 consecutive days. Nominal concentration of 1600, 800, 400, 200 and 100 mg a.s./kg feeding solution (ppm) were tested. Taking into account the actual mean daily intake of the bees, these concentrations corresponded to doses of 7.6, 3.5, 1.7, 0.9 and 0.47 µg a.s./bee per day. No test item related behavioural abnormalities occurred at any time of the test and the NOEC was determined to be 1600 ppm, corresponding to 47 µg a.s./bee/day.

In order to investigate potential risk of propoxycarbazone-sodium to bee brood, a bee brood feeding study was conducted according to Oomen P.A., de Ruijter, A. & van der Steen, J. (OEPP/EPPO Bulletin 22:613-616 (1992)). The method recommends testing the formulated product at a "concentration for high-volume use". ATTRIBUT SG70 is intended to be applied at a maximum

application rate of 100 g product/ha in a maximum water volume of 400 L/ha according to the use pattern. Therefore, bees were fed with 1 L treated sugar solution at a concentration of 0.250 g product/L (corresponding to 0.175 g propoxycarbazone-sodium/L). This corresponds to the concentration of the spraying solution during application to the crop. The test can be considered as a worst case approach as bees were fed directly in the hive with a treated sugar solution at this very high concentration. The test item ATTRIBUT SG70 did not result in any adverse effects on the termination rate of eggs and of development of young and old larvae. No statistical significant difference occurred for mortality of pupae or adult worker bees and no behavioural abnormalities were noted at any time of the test.

Overall it can be concluded that propoxycarbazone-sodium poses acceptable risk to bees following the use of ATTRIBUT SG70 according to the proposed use pattern.

CP 10.3.1.1 Acute toxicity to bees

CP 10.3.1.1.1 Acute oral toxicity to bees

For information on studies already evaluated during the first EU review of propoxycarbazone-sodium, please refer to corresponding section in the Baseline Dossier and in the Monograph.

A new study with the product ATTRIBUT SG70 was conducted according to recent guidelines OECD 213 and 214 (1998). The study was not submitted during the first Annex I inclusion process and is submitted within this Supplemental Dossier for the propoxycarbazone-sodium Renewal of Approval and summarised below.

Report:	[REDACTED]; [REDACTED]; 2012; M-466729-01
Title:	Effects of propoxycarbazone-sodium SG 70 W (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory
Report No:	70472035
Document No:	M-466729-01-1
Guidelines:	OECD 213 and 214, 1998
Deviations:	none
GLP/GE:	Yes

Executive Summary

In an acute laboratory study the contact and oral toxicity of Propoxycarbazone-sodium SG 70 to the honey bee, *Apis mellifera* L. were tested. The test was conducted exposing female worker bees to a single dose of 100.0 µg a.s./bee by topical application (contact limit test) and 50 worker bees per dose were exposed for 48 hours for feeding (oral limit test) to a single dose of 109.5 µg a.s. per bee. In addition bees were exposed to control and reference item groups.

In both tests, five replicate cages, each containing 10 bees, were used for the test item treatments, controls and reference treatments. Mortality and sub-lethal effects were assessed 4, 24 and 48 h after test initiation for contact and oral toxicity.

A mortality of 2% in the contact toxicity and no mortality in the oral toxicity test were observed after 48 hours of exposure in the test item group. In addition, no sub-lethal effects were observed in the test item and the control groups. All validity criteria according to OECD 213 and OECD 214 were fulfilled.

In conclusion, the toxicity of Propoxycarbazone-sodium SG 70 was tested in an acute contact and an oral toxicity test on honey bees. The LD₅₀ (48 h) was >100 µg a.s./bee in the contact toxicity test, and > 109.5 µg a.s./bee in the oral toxicity test.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:

Test item:	Propoxycarbazone-sodium SG 70 W (ATTRIBUT SG70)
Description:	Light-beige solid
Lot/Batch #:	Batch ID: EFKE002641; Specification No.: 10200001542 - 02
Purity:	71.0% w/w (analytical) propoxycarbazone-sodium (MKH 6561)

2. Vehicle and/or positive control:

Positive control: Perfekthion EG (analytical content: 41.7 g dimethoate/L)

3. Test organisms:

Species:	Honey bee (<i>Apis mellifera</i> L.)
Age:	Adult worker bees
Source:	Honey bee colonies, disease-free and queen-right, bred by [REDACTED]
Diet/Food:	Ready-to-use syrup (Apiinter; 30% sucrose, 31% glucose, 39% fructose) or libitum
Collection:	With glass tubes, from the outer honeycombs (away from the brood) without the use of smoke and without anaesthetics, collected on the morning of use.

4. Environmental conditions:

Temperature:	25°C
Relative humidity:	60 - 70%
Light:	Darkness (except during observation)
Ventilation:	Ventilation to avoid possible accumulation of pesticide vapour

B. STUDY DESIGN

1. Experimental treatments

Contact test: The test was conducted with 100 µg a.s./bee prepared in an appropriate carrier (tap water with 0.5% Adhäsit) and administered as a 5.0 µL droplet per bee (dorsal thorax) to each of ten bees in each of the cages. A control with a 5.0 µL droplet (only tap water with 0.5% Adhäsit) and 5 µL droplets of dimethoate (0.30, 0.20, 0.15 and 0.10 µg dimethoate per bee), dissolved in tap water with 0.5% Adhäsit were run in parallel. Immediately before application, bees were anaesthetized for ca. 20 seconds with CO₂ until they were completely immobilized.

Oral test: The test was conducted with a measured dose level of 109.5 µg test item/bee, in 50% w/w aqueous sugar syrup. A control (50% (w/w) aqueous syrup solution (50% tap water, 50% ready-to-use sugar syrup) and the toxic reference solutions (nominal 0.30, 0.15, 0.08 and 0.05 µg dimethoate per bee) were prepared analogically.

Before offering the food, bees starved for 20 min. The treated food was offered in syringes, which were weighed before and after introduction into the cages. Duration of uptake was 1 hour and 55 minutes for the test item treatments.

Five replicate cages per treatment group with each cage containing ten bees were exposed for 48 h in both tests.

2. Observations

Mortality and sub-lethal effects were assessed 4, 24 and 48 h after test initiation for contact and oral toxicity.

3. Statistical calculations

Results obtained with the bees treated with the test and reference item were compared to those obtained with the control in both the contact and oral tests. The contact and oral LC₅₀ values of the reference item were estimated with Probit Analysis (according to Finney 1971). The NOED of the test item was estimated using Fisher's Exact test (pairwise comparison, one-sided greater, $\alpha = 0.05$), which is a distribution-free test and does not require testing for normality or homogeneity prior to analysis. The software used to perform the statistical analysis was FoxRat Professional, Version 2.10.05, © ToxStat Solutions GmbH.

II. RESULTS AND DISCUSSION

A. FINDINGS AND OBSERVATIONS

Contact Test: At the end of the contact toxicity test (48 hours after application), 100% mortality occurred at 100.0 $\mu\text{g a.s./bee}$. There was no mortality in the control group (water + 0.5% Adhäsit). No test item induced behavioural effects were observed at any time in the contact toxicity test.

Oral Test: In the oral toxicity test, the maximum nominal test level of Propoxycarbazone-sodium SG 70 (i.e. 100 $\mu\text{g a.s./bee}$) corresponded to an actual intake of 109.5 $\mu\text{g a.s./bee}$. This dose level led to no mortality after 48 hours. In the control group (50% sugar solution), no mortality occurred. No test item induced behavioural effects were observed at any time in the oral toxicity test.

The contact and oral LD₅₀ (24 h) values of the reference item dimethoate were calculated to be 0.21 and 0.14 $\mu\text{g a.i./bee}$ respectively.

Table 10.3-5 10 days chronic oral toxicity of propoxycarbazone-sodium technical to honey bees

Test Item	Propoxycarbazone-sodium SG 70	
	Apis mellifera L.	
Test Organism		
Exposure	contact (solution in Adhäsit (0.5%)/water)	oral (sugar solution)
Application Rate	100.0	109.5
LC ₅₀ [$\mu\text{g a.s./bee per day}$]	> 100	> 109.5
LC ₂₀ [$\mu\text{g a.s./bee per day}$]	> 100	> 109.5
LC ₁₀ [$\mu\text{g a.s./bee per day}$]	> 100	> 109.5
NOED* [$\mu\text{g a.s./bee per day}$]	100	109.5

* The NOEC/NOED was estimated using Fisher's Exact test (pairwise comparison, one-sided greater, $\alpha = 0.05$)

All validity criteria according to OECD 213 and OECD 214 were fulfilled, since the mortality in the control group was 0.0% (should be $\leq 10\%$) and the LD₅₀ (24 h) value of the toxic standard was 0.21 μg a.i./bee in the contact test (should be between 0.10 and 0.30 μg a.i./bee) and 0.14 μg a.i./bee in the oral test (should be between 0.10 and 0.35 μg a.i./bee).

III. CONCLUSIONS

In an acute contact and an oral toxicity test with Propoxycarbazone-sodium SG 70 on honey bees, the LD₅₀ (48 h) was >100 μg a.s./bee in the contact toxicity test and > 109.5 μg a.s./bee in the oral toxicity test.

CP 10.3.1.1.2 Acute contact toxicity to bees

See Point CP 10.3.1.1.1.

CP 10.3.1.2 Chronic toxicity to bees

A 10 day chronic oral toxicity study was conducted with the active substance propoxycarbazone-sodium. The corresponding summary is filed in the Supplemental Dossier for the active substance P-010245-02 in Document MCA, Section 8 under Point CA 8.3.1.2.01 (██████████ (2014), 70407136, M-484627-01-1). No significant mortality or test item related behavioural abnormalities occurred at any time of the test. An additional study with the formulated product is therefore not deemed necessary.

CP 10.3.1.3 Effects on honey bee development and other honey bee life stages

A honey bee brood feeding study (according to Oomen et al.) has been conducted with the product ATTRIBUT SG70 (██████████, 2013, 70473031, M-466734-01-1). As this study serves to derive an endpoint for the active substance, reference is made to the submitted Supplemental Dossier for the active substance P-010245-02, Document MCA, Section 8, Point 8.3.1.3). No adverse effects on mortality, bee brood development (eggs, young larvae, old larvae, pupae) and colony development were found after feeding honey bee colonies sugar syrup at a concentration of 0.175 g a.s./L.

CP 10.3.1.4 Sub-lethal effects

There is no particular study design / test guideline to assess "sub-lethal effects" in honey bees. However, in each laboratory study as well as in the bee brood test, sub-lethal effects were determined. No adverse sub-lethal effects were found in any of the tests.

CP 10.3.1.5 Cage and tunnel tests

Not necessary when considering the outcome of the risk assessment and the results of the lower-tiered studies.

CP 10.3.1.6 Field tests with honeybees

Not necessary when considering the outcome of the risk assessment and the results of the lower-tiered studies.

CP 10.3.2 Effects on non-target arthropods other than bees

Summary

Toxicity of propoxycarbazone-sodium to non-target arthropods other than bees was assessed from hazard quotients between toxicity endpoints, estimated from Tier 1 laboratory studies with the

standard indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* and the product ATTRIBUT SG70.

The in-field and the off-field HQ values are below the trigger value indicating that the risk to in-field and off-field non-target arthropods is acceptable following use of ATTRIBUT SG70 according to the proposed use pattern.

Toxicity

Laboratory tests with standard indicator species *Aphidius rhopalosiphi*, *Typhlodromus pyri*, *Coccinella septempunctata* and *Pardosa* ssp have been conducted and evaluated during the first EU review and are still considered adequate. The endpoints are summarised in the following table.

Table 10.3-6 Effects of ATTRIBUT SG70 on non-target arthropods other than bees

Test species	Test substance study type	Ecotoxicological endpoint	EU agreed endpoint/ Reference
<i>Aphidius rhopalosiphi</i>	MKH 6561 WG 70, lab., glass plates [g product/ha] 5 100	LR ₅₀ > 100 g/ha corr. Mortality [%] Effect on Parasitaton Efficiency [%] 5.0 0.0 5.0 0.0	Yes ██████████ (1999) M-006190-01-1, KCA 8.3.2.1/01
<i>Typhlodromus pyri</i>	MKH 6561 WG 70, lab., glass plates [g product/ha] 100 500	LR ₅₀ > 200 g/ha corr. Mortality [%] Effect on Reproduction [%] 12.0 1.0 22.0	Yes ██████████ (1999) M-016607-01-1, KCA 8.3.2.2/01
<i>Coccinella septempunctata</i>	MKH 6561 WG 70 lab., glass plates [g product/ha] Control 100	LR ₅₀ > 400 g/ha corr. Mortality [%] No of larvae/female 0.0 24	Yes ██████████ (1999) M-011866-01-1, KCA 8.3.2/02
<i>Pardosa</i> ssp	MKH 6561 WG 70, lab. quartz sand [g product/ha] 100	LR ₅₀ > 100 g/ha corr. Mortality [%] Effect on Food Uptake [%] -3 ^a	Yes ██████████ (1999) M-006613-01-1, KCA 8.3.2/01

^a: A negative value indicates a higher feeding activity in the treatment than in the control.

Studies shaded in grey have been reviewed as part of the first EU review of propoxycarbazone-sodium (in Baseline Dossier for the active substance P-010245-01).

Risk assessment for other non-target arthropods

The risk assessment was performed according to Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2 final (2002)) and to the Guidance Document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods (ESCORT 2, Candolfi et al. 2000²).

² Candolfi et al.: Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods; ESCORT 2 workshop (European Standard Characteristics Of Non-Target Arthropod Regulatory Testing), Wageningen, NL, March 21-23, 2000, SETAC Europe; SETAC publication August 2001

According to ESCORT 2 and the Terrestrial Guidance Document, the following equations are used to calculate the hazard quotients (HQ) for the Tier 1 assessment:

$$\text{In field-HQ} = \text{PER}_{\text{in-field}} / \text{LR}_{50}$$

with $\text{PER}_{\text{in-field}} = \text{Application rate} \times \text{MAF}$

$$\text{Off field-HQ} = \text{PER}_{\text{off-field}} / \text{LR}_{50} \times \text{correction factor}$$

with $\text{PER}_{\text{off-field}} = (\text{Application rate} \times \text{MAF} \times (\text{drift factor} / \text{VDF}) \times \text{LR}_{50})$

where:

Drift factor = 0.0277 (90th percentile for a single application, according to Ganzelmeier)

MAF = 1 (single application).

VDF (Vegetation distribution factor) = 10 (can be applied in case of 2-D test design to adjust the drift data determined for 2-D surfaces to the 3-D structure of the off-field habitat).

Correction factor = 10 (to account for uncertainty with the extrapolation from *Aphidius* and *Typhlodromus* as indicator species to all off-field NTAs)

The Tier 1 laboratory studies for *Aphidius rhopalosiph* and for *Typhlodromus pyri* resulted in LR₅₀ values > 100 g product/ha and > 200 g product/ha, respectively. These values are used for the Tier 1 risk assessment.

The risk assessment below is conducted for the maximum single application rate of 100 g product/ha, covering application rate of 60 g product/ha.

Table 10.3-7 HQ for terrestrial non-target arthropods for the in-field scenario

Crop	Species	Appl. rate [g prod/ha]	MAF	PER _{in-field} [g/ha]	LR ₅₀ [g prod/ha]	HQ	Trigger
Cereals	<i>A. rhopalosiph</i>	100	1	100	> 100	< 1	2
	<i>T. pyri</i>				200	< 0.5	

Table 10.3-8 HQ for terrestrial non-target arthropods for the off-field scenario

Crop	Species	Appl. rate [g/ha]	MAF	Drift (%)	VDF	Corr. factor	PER _{off-field} [g/ha]	LR ₅₀ [g/ha]	HQ	Trigger
Cereals	<i>A. rhopalosiph</i>	100		2.77	10	10	2.77	> 100	< 0.028	2
	<i>T. pyri</i>							> 200	< 0.014	

The HQ values calculated for the in-field and for the off-field risk assessment are below the trigger value of 2 indicating acceptable risk to non-target arthropods of ATTRIBUT SG70 according to the proposed use pattern.

In addition laboratory studies are available for *Coccinella septempunctata* and *Pardosa* ssp, also concerning potential sub-lethal effects. Even though the Tier 1 risk assessment based on the LR₅₀ for the two indicator species *Aphidius rhopalosiph* and for *Typhlodromus pyri* is considered to be protective, the two additional studies confirm the conclusion of the Tier 1 risk assessment, since no relevant adverse effects on mortality or reproduction were observed at the highest test rate of 100 g product/ha.

CP 10.3.2.1 Standard laboratory testing for non-target arthropods

No new studies were conducted.

For detailed information on studies already evaluated during the first EU review of propoxycarbazone-sodium, please refer to corresponding section in the provided Baseline Dossier for the active substance (dossier number P-010245-01) or to the Monograph.

CP 10.3.2.2 Extended laboratory testing, aged residue studies with non-target arthropods

Further tests with non-target arthropods are not necessary when considering the outcome of the risk assessment and the results of the lower-tiered studies.

CP 10.3.2.3 Semi-field studies with non-target arthropods

Further tests with non-target arthropods are not necessary when considering the outcome of the risk assessment and the results of the lower-tiered studies.

CP 10.3.2.4 Field studies with non-target arthropods

Further tests with non-target arthropods are not necessary when considering the outcome of the risk assessment and the results of the lower-tiered studies.

CP 10.3.2.5 Other routes of exposure for non-target arthropods

No other routes of exposure for non-target arthropods than already addressed above under Point CP 10.3.2 are considered relevant.

CP 10.4 Effects on non-target soil meso- and macrofauna

The risk assessment procedure follows the requirements according to current regulatory requirements and the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2 final (2002)).

Summary

The risks of propoxycarbazone-sodium on non-target soil meso- and macro-fauna, represented by earthworms, Collembola and soil mites, was assessed from toxicity-exposure ratios between toxicity endpoints, estimated from studies with propoxycarbazone-sodium and its metabolites and maximum PEC_{soil} values following the use according to the proposed use pattern.

All TER values exceed the trigger value of 5 for long-term risk, indicating acceptable risk to earthworms and soil macro-organisms following application of ATTRIBUT SG70 according to the proposed use pattern.

CP 10.4.1 Earthworms

Toxicity

Long-term toxicity endpoints relevant for the risk assessment for earthworms are presented in the table below. For details please refer to the submitted Supplemental Dossier for the active substance P-010245-02, Document M-CA, Section 8, Point CA 8.4.

Table 10.4-1 Long-term toxicity of ATTRIBUT SG70, propoxycarbazone-sodium and its metabolites to earthworms; endpoints relevant for the risk assessment

Test substance	Species	Test design	NOEC [mg/kg soil]	Reference	EU agreed endpoint
MKH 6561 WG 70	<i>Eisenia fetida</i>	reproduction, 56 d	1.39 ^a	(1998) HBF/RG 282 M-005114-01-1 KCA 8.4.1/01	Yes
Propoxy- carbazone- sodium	<i>Eisenia fetida</i>	reproduction, 56 d	5.0	(2012) 70403022 M-466608-01-1 KCA 8.4.1/03	New study
M05	<i>Eisenia fetida</i>	reproduction, 56 d	5.0	(2012) 70415022 M-466675-01-1 KCA 8.4.1/04	New study
M07	<i>Eisenia fetida</i>	reproduction, 56 d	5.0	(2013) 70425022 M-466699-01-1 KCA 8.4.1/06	New study
M08	<i>Eisenia fetida</i>	reproduction, 56 d	5.0	(2014) 71792022 M-485902-01-1 KCA 8.4.1/07	New study
M09	<i>Eisenia fetida</i>	reproduction, 56 d	3.15	(1999) HBF/Rg 315 M-024207-01-1 KCA 8.4.1/02	Yes
M10	<i>Eisenia fetida</i>	reproduction, 56 d	5.0	(2014) 71822022 M-484633-01-1 KCA 8.4.1/08	New study
M11	<i>Eisenia fetida</i>	reproduction, 56 d	5.0	(2014) 71812022 M-485903-01-1 KCA 8.4.1/09	New study

^a NOEC given in study report is 0.350 kg a.s./ha; endpoint was re-calculated during first Annex I review, considering a vessel surface area of 198 cm² and 500 g dws per vessel. NOEC was highest tested concentration. Studies shaded in grey have been reviewed as part of the first EU review of propoxycarbazone-sodium (in Baseline Dossier for the active substance P-010245-01). Other studies are part of the Supplemental Dossier (P-010245-02).

Studies shaded in grey have been reviewed as part of the first EU review of propoxycarbazone-sodium (in Baseline Dossier for the active substance P-010245-01). Other studies are part of the Supplemental Dossier (P-010245-02).

Exposure

The maximum PEC_{soil} values were calculated following the recommendations of the FOCUS soil working group and were taken from Document M-CP, Section 9. For full details of the assumptions used in the exposure calculations please refer to that section.

Table 10.4-2 Initial maximum PEC_{soil} values and accumulation potential of propoxycarbazone-sodium and its metabolites

Crop / Application rate	Test substance	Maximum PEC _{soil} [mg/kg]	PEC _{plateau, overall} [mg/kg]
Cereals / 42 g a.s./ha	Propoxycarbazone- sodium	0.042	0.047
	M05	0.004	-
	M07	0.005	-
	M08	0.004	0.008
	M09	0.003	0.004
	M10	0.009	0.010
	M11	0.001	-
Cereals / 70 g a.s./ha	Propoxycarbazone- sodium	0.070	0.078
	M05	0.007	-
	M07	0.008	-
	M08	0.007	0.014
	M09	0.004	0.006
	M10	0.014	0.017
	M11	0.009	-

Values in bold are used for the risk assessment as a worst case approach.

Risk assessment for earthworms

The long-term TER values based on the maximum PEC_{soil} values are presented in the table below.

Table 10.4-3 Long-term TER values for earthworms

Crop/ Application rate	Test substance	NOEC [mg/kg dry soil]	PEC _{soil} [mg/kg dry soil]	TER _{LT}	Trigger
Cereals/ 70 g a.s./ha	MK 6561 WG 70	1.30	0.078	18	5
	Propoxycarbazone- sodium	5.0	0.078	64	
	M05	10	0.007	1429	
	M07	5.0	0.008	625	
	M08	5.0	0.014	357	
	M09	316	0.006	52667	
	M10	5.0	0.017	294	
	M11	5.0	0.009	556	

The TER_{LT} values are greater than the Regulation (EU) No 546/2011 trigger of 5, indicating acceptable long-term risk to earthworm following application of ATTRIBUT SG70 according to the proposed use pattern.

CP 10.4.1.1 Earthworms – sub-lethal effects

No new study with the product on earthworms is considered necessary.

For information on studies already evaluated during the first EU review of propoxycarbazone-sodium, please refer to corresponding section KCA 8.4.1 in the Baseline Dossier of the active substance P-010245-01 or to the Monograph.

CP 10.4.1.2 Earthworms – field studies

No further earthworm field studies are necessary.

CP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)**Toxicity**

Toxicity studies with propoxycarbazone-sodium and soil metabolites M05, M06, M07, M08, M09, M10 and M11 on non-target soil meso- and macrofauna other than earthworms represented by collembola *Folsomia candida* and soil mite *Hypoaspis aculeifer* are summarised in the table below. Detailed descriptions of the studies are given under Point A 8.4.1 in document M-CA Section 8 of propoxycarbazone-sodium.

Table 10.4-4 Toxicity of propoxycarbazone-sodium and its metabolites to other non-target soil macro-organisms; endpoints relevant for the risk assessment

Test substance	Species	Test design	NOEC [mg/kg soil]	Reference	EU agreed endpoint
Propoxy-carbazone-sodium	<i>Folsomia candida</i>	reproduction, 28 d	500	█ (2012) 70404016 M-466609-01-1 KCA 8.4.2/01	New study
	<i>Hypoaspis aculeifer</i>	reproduction, 14 d	1000	█ (2012) 70405089 M-466611-01-1 KCA 8.4.2/02	New study
M05	<i>Folsomia candida</i>	reproduction, 28 d, limit test	10	█ (2012) 70412016 M-466656-01-1 KCA 8.4.2/03	New study
	<i>Hypoaspis aculeifer</i>	reproduction, 14 d, limit test	10	█ (2012) 70411089 M-466654-01-1 KCA 8.4.2/04	New study
M07	<i>Folsomia candida</i>	reproduction, 28 d	9.0	█ (2012) 70422016 M-466684-01-1 KCA 8.4.2/05	New study
	<i>Hypoaspis aculeifer</i>	reproduction, 14 d, limit test	10	█ (2012) 70421089 M-466680-01-1	New study

Test substance	Species	Test design	NOEC [mg/kg soil]	Reference	EU agreed endpoint
M08	<i>Folsomia candida</i>	reproduction, 28 d, limit test	10	KCA 8.4.2/06 █ (2014) 71793016 M-484422-01-1	New study
	<i>Hypoaspis aculeifer</i>	reproduction, 14 d, limit test	10	KCA 8.4.2/07 █ (2014) 71794089 M-484430-01-1	New study
M09	<i>Folsomia candida</i>	reproduction, 28 d, limit test	10	KCA 8.4.2/08 █ (2012) 70445016 M-466718-01-1	New study
	<i>Hypoaspis aculeifer</i>	reproduction, 14 d, limit test	10	KCA 8.4.2/09 █ (2012) 70444089 M-466715-01-1	New study
M10	<i>Folsomia candida</i>	reproduction, 28 d, limit test	10	KCA 8.4.2/11 █ (2014) 71823016 M-484425-01-1	New study
	<i>Hypoaspis aculeifer</i>	reproduction, 14 d, limit test	10	KCA 8.4.2/12 █ (2014) 71824089 M-484437-01-1	New study
M11	<i>Folsomia candida</i>	reproduction, 28 d, limit test	10	KCA 8.4.2/13 █ (2014) 71813016 M-484423-01-1	New study
	<i>Hypoaspis aculeifer</i>	reproduction, 14 d, limit test	10	KCA 8.4.2/14 █ (2014) 71814089 M-484433-01-1	New study

The studies are part of the Supplemental Dossier (E-010245-02).

Risk assessment for other non-target soil meso- and macrofauna (other than earthworms)

TER calculations, based on the ecotoxicological endpoints given in Table 10.4-4 and worst case PEC values given in Table 10.4-2 are presented in the table below.

Table 10.4-5 Long-term TER values for other non-target soil meso- and macrofauna

Crop/ Application rate	Test substance	NOEC [mg/kg dry soil]	PEC _{soil} [mg/kg dry soil]	TER _{LT}	Trigger
Collembola, reproduction					
Cereals/ 70 g a.s./ha	Propoxycarbazone- sodium	500	0.078	6410	5
	M05	10	0.007	1429	
	M07	9.0	0.008	1250	
	M08	10	0.014	714	
	M09	10	0.006	1667	
	M10	10	0.017	588	
	M11	10	0.009	1111	
Soil mites, reproduction					
Cereals/ 70 g a.s./ha	Propoxycarbazone- sodium	1000	0.078	12824	5
	M05	10	0.007	1429	
	M07	10	0.008	1250	
	M08	10	0.014	714	
	M09	10	0.006	1667	
	M10	10	0.017	588	
	M11	10	0.009	1111	

The TER_{LT} values are greater than the Regulation (EU) No 546/2011 trigger of 5, indicating acceptable long-term risk to soil macro-organisms, represented by Collembola and soil mites, following application of ATTRIBUT SG70 according to the proposed use pattern.

CP 10.4.2.1 Species level testing

In view of the results presented above further studies are not necessary.

CP 10.4.2.2 Higher tier testing

In view of the results presented above field studies are not necessary.

CP 10.5 Effects on soil nitrogen transformation

Summary

The risk of propoxycarbazone-sodium was evaluated by comparison of no-effect concentrations, derived from laboratory tests with ATTRIBUT SG70 and metabolites of propoxycarbazone-sodium with PEC_{soil} values.

Acceptable risk to soil nitrogen transformation was shown following the use of ATTRIBUT SG70 according to the proposed use pattern.

Toxicity

Endpoints relevant for the risk assessment for soil nitrogen transformation are presented in the table below. For details please refer to Document M-CA, Section 8, Point CA 8.5 of this submission.

Table 10.5-1 Effects of propoxycarbazone-sodium and metabolites on soil nitrogen transformation

Test substance	Study design	Endpoint	Reference	EU agreed endpoint
MKH 6561 WG 70	Nitrogen-mineralisation 28-day study	no negative effects at 0.07 and 0.35 kg/ha, difference to control < 25%	(1998) AJO/174598 M-004247-01-1 KCA 8.5/02	Yes
M05	Nitrogen-mineralisation 28-day study	no negative effects at 0.07 and 0.35 kg/ha, difference to control < 25%	(1999) AJO/197699 M-015916-01-1 KCA 8.5/06	Yes
M07	Nitrogen-mineralisation 28-day study	no negative effects at 0.07 and 0.35 kg/ha, difference to control < 25%	(1999) AJO/197499 M-012596-01-1 KCA 8.5/10	Yes
M08	Nitrogen-mineralisation 28-day study	no effects > 25% up to 0.466 mg/kg soil dry weight	(2012) 70463080 M-466704-01-1 KCA 8.5/11	New study
M09	Nitrogen-mineralisation 28-day study	no negative effects at 0.07 and 0.35 kg/ha, difference to control < 25%	(1999) AJO/199599 M-015913-01-1 KCA 8.5/08	Yes
M10	Nitrogen-mineralisation 28-day study	no negative effects at 0.07 and 0.35 kg/ha, difference to control < 25%	(1999) AJO/199399 M-015942-01-1 KCA 8.5/03	Yes
M11	Nitrogen-mineralisation 28-day study	no effects > 25% up to 0.467 mg/kg soil dry weight	(2012) 70467080 M-466720-01-1 KCA 8.5/12	New study

Studies shaded in grey have been reviewed as part of the first EU review of propoxycarbazone-sodium (in Baseline Dossier for the active substance P-010245-01). Other studies are part of the Supplemental Dossier (P-010245-02).

For information on studies already evaluated during the first EU review of propoxycarbazone-sodium, please refer to corresponding section in the Baseline Dossier of the active substance (dossier number P-010245-01) provided along on a separate data medium or to the Monograph.

Risk assessment for soil nitrogen transformation

The risk assessment is based on the nitrogen-mineralisation endpoints given in Table 10.5-1 and worst case PEC_{soil} values given in Table 10.4-2 and presented in the table below.

Table 10.5-2 Risk assessment for soil nitrogen transformation

Test substance	Test design	Endpoint [mg/kg dry soil]	PEC _{soil,max} [mg/kg]	Acceptable risk
Propoxycarbazone-sodium (tested as MKH 6561 WG 70)	N-cycle, 28 days	0.467 ^a	0.078	yes
M05	N-cycle, 28 days	0.467 ^a	0.007	yes
M07	N-cycle, 28 days	0.467 ^a	0.008	yes
M08	N-cycle, 28 days	0.467	0.014	yes
M09	N-cycle, 28 days	0.467 ^a	0.006	yes
M10	N-cycle, 28 days	0.467 ^a	0.017	yes
M11	N-cycle, 28 days	0.467	0.009	yes

^a Endpoint of 0.35 kg/ha recalculated assuming a soil depth of 5 cm and a bulk density of 1.5 g/cm³

According to regulatory requirements the risk is acceptable. If the effect on nitrogen transformation at the maximum PEC_{soil} values is < 25% after 100 days. In no case, deviations from the control exceeded 25% after 28 days, indicating low risk to soil micro-organisms up to 0.467 mg/kg dry soil.

CP 10.6 Effects on terrestrial non-target higher plants

Summary

The risk of ATTRIBUT SG70 to terrestrial non-target higher plants was assessed from toxicity-exposure ratios between toxicity endpoints, estimated from seedling emergence and vegetative vigour studies with ATTRIBUT SG70 and predicted environmental rates in the off-field.

The deterministic risk assessment indicated acceptable risk to off-field non-target plants for an application rate of 42 g a.s./ha when nozzles with at least 75% drift reduction are used. Considering a distance of 5 m, no drift reducing nozzles are necessary.

For an application rate of 70 g a.s./ha acceptable risk is indicated when nozzles with at least 90% drift reduction are used. Considering a distance of 5 m, nozzles with at least 50% drift reduction should be applied. Considering a distance of 10 m, no drift reducing nozzles are necessary.

The risk assessment was refined using a probabilistic assessment based on the HR₅ derived from the vegetative vigour and seedling emergence studies.

The probabilistic risk assessment indicated acceptable risk to off-field non-target plants for an application rate of 42 g a.s./ha without the need of additional mitigation measures.

The use of the product with an application rate of 70 g a.s./ha will not produce unacceptable effects on terrestrial non-target plants growing near treated fields when consideration is given to a 5 m buffer zone, or alternatively 50% drift reducing spray nozzles.

Toxicity

The endpoints for non-target terrestrial plants relevant for the risk assessment are provided in the table below. For details please refer to the Supplemental Dossier for the active substance of this submission (dossier number P-010245-02), Document M-CA, Section 8, Point CA 8.6.

Table 10.6-1 Effects of ATTRIBUT SG70 on terrestrial non-target higher plants, endpoints relevant for the risk assessment

Test organism	Study type	Test duration	Lowest ER ₅₀ (g a.s./ha)	Most sensitive species	References	EU agreed endpoint
Terrestrial non-target plants; 10 species	Seedling emergence; Tier 2 dose response	21 days	1.57	Canola (dry weight)	██████████ et al. (1999) 108843-1	es
Terrestrial non-target plants; 10 species	Vegetative vigour; Tier 2 dose response	21 days	1.55	Canola (shoot height)	M-021505-02-1 KCA 8601	es

Studies shaded in grey have been reviewed as part of the first EU review of propoxycarbazone-sodium (in Baseline Dossier for the active substance P-0024504).

Exposure

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. For one application to cereals, 2.77%, 0.57% and 0.29% of the full application rate are assumed to reach areas at 1 m, 5 m and 10 m from the edge of the crop, respectively. The amount of spray drift from one application reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000)³ from spray-drift predictions of Ganzelmeier & Rautmann (2000)⁴. The corresponding off-field predicted environmental rates (PER_{off-field}) are presented in the table below.

Table 10.6-2 Predicted environmental rates (PER) at 1 m, 5 m and 10 m distance from the field edge

Crop	Timing of application	Number of applications	Maximum application rate [g a.s./ha]	Distance [m]	Drift [%]	PER no drift reduction [g a.s./ha]
Cereals	BBCH 15-33	1	70	1	2.77	1.163
				5	0.57	0.239
				10	0.29	0.122
Cereals	BBCH 15-33	1	70	1	2.77	1.939
				5	0.57	0.399
				10	0.29	0.203

Risk assessment for terrestrial non-target higher plants

Deterministic risk assessment

The deterministic risk assessment is based on the lowest endpoint of 1.55 g a.s./ha (shoot height, ER₅₀ of vegetative vigour in canola (*Brassica rapa*)) and 1.57 g a.s./ha (dry weight, ER₅₀ of seedling emergence in canola (*Brassica rapa*)).

³ BBA (2000) Bundesanzeiger Jg. 52 (Official Gazette), Nr 100, S. 9879-9880 (25.05.2000) Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden. Public domain.

⁴ Ganzelmeier H., Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Aspects of Applied Biology 57, 2000, Pesticide Application. Public domain.

According to the Terrestrial Guidance Document (SANCO/10329/2002 rev 2 final (2002)), the risk to non-target terrestrial plants is assessed by comparing the exposure in field margins caused by drift with the lowest ER₅₀ obtained from the non-target plant studies. An assessment factor of 5 is required in order to prove safe use.

Table 10.6-3 Deterministic off-crop risk assessment for non-target terrestrial plants: seedling emergence

Crop/ Appl. Rate [g a.s./ha]	ER ₅₀ [g a.s./ha]	Distance [m]	Drift [%]	PER [g a.s./ha]	TER			
					no drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
Cereals/ 1 x 42	1.57	1	2.77	1.63	1.3	2.7	4	13
		5	0.57	0.239	6	13	26	65
		10	0.29	0.12	13	26	52	129
Cereals/ 1 x 70	1.57	1	2.77	1.39	0.8	1.6	3.2	8.0
		5	0.57	0.399	3.9	7.8	16	39
		10	0.29	0.203	7.7	15	31	77

Bold letters: TERs that do not meet the trigger of 5

Table 10.6-4 Deterministic off-crop risk assessment for non-target terrestrial plants: vegetative vigour

Crop/ Appl. Rate [g a.s./ha]	ER ₅₀ [g a.s./ha]	Distance [m]	Drift [%]	PER [g a.s./ha]	TER			
					no drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
Cereals/ 1 x 42	1.55	1	2.77	1.63	1.5	2.7	5.3	13
		5	0.57	0.239	6.5	13	26	65
		10	0.29	0.12	13	26	51	127
Cereals/ 1 x 70	1.55	1	2.77	1.39	0.8	1.6	3.2	8.0
		5	0.57	0.399	3.9	7.8	16	39
		10	0.29	0.203	7.6	15	31	76

Bold letters: TERs that do not meet the trigger of 5

According to the results of the deterministic approach when based on the most sensitive endpoint for vegetative vigour, for an application rate of 42 g a.s./ha, TER values are greater than the trigger of 5 when nozzles with at least 75% drift reduction are used. Considering a distance of 5 m, no drift reducing nozzles are necessary.

For an application rate of 70 g a.s./ha, TER values are greater than the trigger of 5 when nozzles with at least 90% drift reduction are used. Considering a distance of 5 m, nozzles with at least 50% drift reduction should be applied. Considering a distance of 10 m, no drift reducing nozzles are necessary.

The results of the deterministic risk assessment indicate the necessity of mitigation measures. However, as an alternative approach a probabilistic risk assessment has been conducted.

Probabilistic risk assessment

The HR₅ (the rate below which less than 5% of the species will be harmed above the ER₅₀ level) was calculated from the data set of ER₅₀ growth inhibition levels. The EU guidance document for terrestrial ecotoxicology states: 'If the ED₅₀⁵ for less than 5% of the species is below the highest predicted

⁵ The ER₅₀ is meant

exposure level, the risk for terrestrial plants is assumed to be acceptable.' Thus, the HR₅ itself (TER = 1) can be regarded to be protective.

The HR₅ was calculated according to [REDACTED] & [REDACTED] (2000)⁶ using the software package ETX 2.0 by RIVM.

The HR₅ calculation was based on the ER₅₀-values for the lowest value of either dry weight, shoot height or phytotoxicity as a worst case approach. A summary of all ER₅₀-values included on the HR₅ calculation is provided in the table below.

Table 10.6-5 Summary of definitive ER₅₀-values (seedling emergence) used for HR₅ calculation

Test design	Test species	Ecotoxicological endpoint		Reference
		ER ₅₀ [g a.s./ha]	Parameter	
Tier 2 dose response seedling emergence test	Canola	1.57	Dry weight	[REDACTED] et al. (1999) 108843-1 M-021505-02-1 Study filed under KCA 8.6.2/01 (in Supplemental Dossier for the active substance P-010245-02)
	Corn	11.93	Dry weight	
	Oat	13.27	Dry weight	
	Onion	2.96	Dry weight	
	Rye	5.97	Dry weight	
	Sugar beet	6.94	Dry weight	

Four 'greater than' figures (buckwheat, flax, soybean and sunflower) were excluded from the calculation.

For seedling emergence median HR₅ of 1.29 g a.s./ha (with lower and upper 90% confidence limits were 0.26 g/ha and 2.65 g/ha, Goodness of fit: accepted, p = 0.01, [REDACTED] Darling test for normality) was obtained from the calculation with six ER₅₀-values of the remaining species.

Table 10.6-6 Summary of definitive ER₅₀-values (vegetative vigour) used for HR₅ calculation

Test design	Test species	Ecotoxicological endpoint		Reference
		ER ₅₀ [g a.s./ha]	Parameter	
Tier 2 dose response vegetative vigour test	Buckwheat	3.20	Shoot height	[REDACTED] et al. (1999) 108843-1 M-021505-02-1 Study filed under KCA 8.6.2/01 (in Supplemental Dossier for the active substance P-010245-02)
	Canola	1.55	Shoot height	
	Corn	3.85	Dry weight	
	Flax	17.64	Dry weight	
	Oat	2.27	Dry weight	
	Onion	3.67	Shoot height	
	Rye	19.35	Phytotoxicity	
	Soybean	6.24	Phytotoxicity	
	Sugar beet	2.91	Dry weight	
	Sunflower	4.52	Phytotoxicity	

⁶ [REDACTED], T. & [REDACTED], J.S. (2000): Uncertainty of the hazardous concentration and fraction affected for normal species sensitivity distributions. Ecotoxicology and Environmental Safety, 46: 1-18.

For vegetative vigour a median **HR₅ of 1.34 g a.s./ha** (with lower and upper 90% confidence limits were 0.59 g/ha and 2.14 g/ha; Goodness of fit: accepted - $p = 0.01$, Anderson-Darling test for normality) was obtained from the calculation with ten ER₅₀-values.

Table 10.6-7 Probabilistic off-crop risk assessment for non-target terrestrial plants: seedling emergence

Crop/ Appl. Rate [g a.s./ha]	HR ₅ [g a.s./ha]	Distance [m]	Drift [%]	PER [g a.s./ha]	TER			
					no drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
Cereals/ 1 x 42	1.29	1	2.77	1.163	1.1	2.2	4.4	11
		5	0.57	0.239	5.4	11	22	54
Cereals/ 1 x 70	1.29	1	2.77	1.163	0.67	1.3	2.7	6.9
		5	0.57	0.399	3.4	6.7	13	34

Bold letters: TERs which do not meet the trigger of 1

Table 10.6-8 Probabilistic off-crop risk assessment for non-target terrestrial plants: vegetative vigour

Crop/ Appl. Rate [g a.s./ha]	HR ₅ [g a.s./ha]	Distance [m]	Drift [%]	PER [g a.s./ha]	TER			
					no drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
Cereals/ 1 x 42	1.34	1	2.77	1.163	1.2	2.3	4.6	12
		5	0.57	0.239	5.6	11	22	56
Cereals/ 1 x 70	1.34	1	2.77	1.163	0.67	1.4	2.8	6.9
		5	0.57	0.399	3.4	6.7	13	34

Bold letters: TERs which do not meet the trigger of 1

When using the respective HR₅ derived from the data on seedling emergence and vegetative vigour, for an application rate of 42 g a.s./ha, a threshold TER of 1 is exceeded with conventional spraying equipment.

For an application rate of 70 g a.s./ha, a threshold TER of 1 is exceeded at 1 m distance with 50% drift reducing spraying equipment. Considering a distance of 5 m, no drift reducing nozzles are necessary.

CP 10.6.1 Summary of screening data

As propoxycarbazone-sodium is an herbicide, screening data with the product are not necessary.

CP 10.6.2 Testing on non-target plants

For information on studies already evaluated during the first EU review of propoxycarbazone-sodium, please refer to corresponding section in the Baseline Dossier and in the Monograph.

For the newly submitted study on canola (█████ & █████ (2004), 200994, **M-059849-01-1**) to demonstrate technical equivalence of two formulations of MKH 6561 WG 70 containing the old and new specification of propoxycarbazone-sodium, please refer to the Supplemental Dossier P-010245-02 for the active substance, Document M-CA, Section 8, Point CA 8.6 of this submission.

CP 10.6.3 Extended laboratory studies on non-target plants

No extended laboratory studies on non-target plants are considered necessary as acceptable risk to non-target plants was demonstrated in the risk assessment under Point CP 10.6 above.

CP 10.6.4 Semi-field and field tests on non-target plants

No semi-field and field tests on non-target plants are considered necessary as acceptable risk to non-target plants was demonstrated in the risk assessment under Point CP 10.6 above.

CP 10.7 Effects on other terrestrial organisms (flora and fauna)

Further studies on other terrestrial organisms are not necessary.

CP 10.8 Monitoring data

Monitoring data are not necessary.

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