Final REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA 6100 A

Product name(s): ALIVE

Chemical active substance:

Propaquizafop, 100g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: October 2020

MS Finalisation date: May 2021, March 2022

Version history

When	What
May 2021	Finalisation of the assessment of ppp by zRMS.
March 2022	Final version of RR after Comenting period

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9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel-opmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g saf-ener/ synergist per ha	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. num-ber a) per use b) per crop/ season	Min. inter-val between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/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 arthro-	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1.	PL	**Sugar beet**	F	Common barn-yardgrass *(Echi-nochloa crus-galli)*; Spring wild-oat *(Avena fatua)* ; Red fingergrass *(Digi-taria sanguinalis)* ; Yellow bristlegrass *(Setaria pumila)* ; Green bristlegrass *(Setaria viridis)* ; Perennial ryegrass *(Lolium perenne)*	Broadcast spraying	BBCH 13-29* BBCH 12-35**	a) 1 1	-	a) 0.6 b) 0.6	a) 0.060 0.060	200-300	28	*weeds grow stage **crop grow stage							
2	PL	**Sugar beet**	F	Silky bentgrass *(Apera spica-venti)*; self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 12-	a) 1 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 0.050-0.070	200-300	28	*weeds grow stage for dose rate 0.5 L/ha							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
						35***							** weeds grow stage for dose rate 0.7 L/ha ***crop grow stage							
3	PL	**Sugar beet**	F	Couch grass *(Agropyron repens)*	Broadcast spraying	BBCH 13-16* BBCH 12-35**	a) 1 b) 1 OR a) 1 b) 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 0.120	200-300	28	*weeds grow stage **crop grow stage							
4.	PL	**Winter oilseed rape**	F	Common barnyardgrass *(Echinochloa crus-galli)*; Spring wild-oat *(Avena fatua)* ; Red fingergrass *(Digitaria sanguinalis)* ; Yellow bristlegrass *(Setaria pumila)* ; Green bristlegrass *(Setaria viridis)* ; Perennial ryegrass *(Lolium perenne)*	Broadcast spraying	BBCH 13-29* BBCH 12-30**	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 0.060 b) 0.060	200-300	42	*weeds grow stage **crop grow stage Proposal mixture against self-seeding of cereals and annual weeds: Agil-S 100 EC 0,5 - 0,7 l/ha + Olejan 85 EC/Olemix 84 EC 1,5 l/ha							
5.	PL	**Winter oilseed rape**	F	Silky bentgrass *(Apera spica-venti)* ; self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 12-	a) 1 1	-	a) 0.5-0.7 0.5-0.7	a) 0.050-0.070 0.050-0.070	200-300	42	*weeds grow stage for dose rate 0.5 L/ha							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
						30***							** weeds grow stage for dose rate 0.7 L/ha ***crop grow stage							
6.	PL	**Winter oilseed rape**	F	Couch grass *(Agropyron repens)*	Broadcast spraying	BBCH 13-16* BBCH 12-30**	a) 1 b) 1 OR a) 1 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 0.120	200-300	42	*weeds grow stage **crop grow stage							
7.	PL	**Potato**	F	Common barnyardgrass *(Echinochloa crus-galli)*; Spring wild-oat *(Avena fatua)* ; Red fingergrass *(Digitaria sanguinalis)* ; Yellow bristlegrass *(Setaria pumila)* ; Green bristlegrass *(Setaria viridis)* ; Perennial ryegrass *(Lolium perenne)*	Broadcast spraying	BBCH 13-29* BBCH 10-35**	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 0.060 b) 0.060	200-300	40	*weeds grow stage **crop grow stage							
8.	PL	**Potato**	F	Silky bentgrass *(Apera spica-venti)* ; self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 10-35***	a) 1 1	-	a) 0.5-0.7 0.5-0.7	a) 0.050-0.070 0.050-0.070	200-300	40	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
													rate 0.7 L/ha ***crop grow stage							
9.	PL	**Potato**	F	Couch grass *(Agropyron repens)*	Broadcast spraying	BBCH 13-16* BBCH 10-35**	a) 1 b) 1 OR a) 1 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 0.120	200-300	40	*weeds grow stage **crop grow stage							
10.	PL	**Onion**	F	Common barnyardgrass *(Echinochloa crus-galli)*; Spring wild-oat *(Avena fatua)* ; Red fingergrass *(Digitaria sanguinalis)* ; Yellow bristlegrass *(Setaria pumila)* ; Green bristlegrass *(Setaria viridis)* ; Perennial ryegrass *(Lolium perenne)*	Broadcast spraying	BBCH 13-29* BBCH 11-12** BBCH 09-53***	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 0.060 b) 0.060	200-300	30	*weeds grow stage **crop grow stage *** grow stage crop for seeds							
11.	PL	**Onion**	F	Silky bentgrass *(Apera spica-venti)* ; self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 11-12*** BBCH 09-53****	a) 1 1	-	a) 0.5-0.7 0.5-0.7	a) 0.050-0.070 0.050-0.070	200-300	30	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose rate 0.7 L/ha ***crop							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
													grow stage ****grow stage crop for seeds							
12.	PL	**Onion**	F	Couch grass *(Agropyron repens)*	Broadcast spraying	BBCH 13-16* BBCH 11-12** BBCH 09-53***	a) 1 b) 1 OR a) 1 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 0.120	200-300	30	*weeds grow stage **crop grow stage *** grow stage crop for seeds							
13.	PL	**Bean**	F	Common barnyardgrass *(Echinochloa crus-galli)*; Spring wild-oat *(Avena fatua)* ; Red fingergrass *(Digitaria sanguinalis)* ; Yellow bristlegrass *(Setaria pumila)* ; Green bristlegrass *(Setaria viridis)* ; Perennial ryegrass *(Lolium perenne)*	Broadcast spraying	BBCH 13-29* min. BBCH 13**	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 0.060 b) 0.060	200-300	45	*weeds grow stage **crop grow stage							
14.	PL	**Bean**	F	Silky bentgrass *(Apera spica-venti)* ; self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** min. BBCH 13***	a) 1 1	-	a) 0.5-0.7 0.5-0.7	a) 0.050-0.070 0.050-0.070	200-300	45	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose rate 0.7 L/ha ***crop							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
													grow stage							
15.	PL	**Bean**	F	Couch grass *(Agropyron repens)*	Broadcast spraying	BBCH 13-16* min. BBCH 13**	a) 1 b) 1 OR a) 1 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 0.120	200-300	45	*weeds grow stage **crop grow stage							
16.	PL	**Green peas; Peas for dry seeds**	F	Common barnyardgrass *(Echinochloa crus-galli)*; Spring wild-oat *(Avena fatua)* ; Red fingergrass *(Digitaria sanguinalis)* ; Yellow bristlegrass *(Setaria pumila)* ; Green bristlegrass *(Setaria viridis)* ; Perennial ryegrass *(Lolium perenne)*	Broadcast spraying	BBCH 13-29* min. BBCH 12**	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 0.060 b) 0.060	200-300	45	*weeds grow stage **crop grow stage							
17.	PL	**Green peas; Peas for dry seeds**	F	Silky bentgrass *(Apera spica-venti)* ; self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** min. BBCH 12***	a) 1 1	-	a) 0.5-0.7 0.5-0.7	a) 0.050-0.070 0.050-0.070	200-300	45	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose rate 0.7 L/ha ***crop grow stage							
18.	PL	**Green peas;**	F	Couch grass *(Agropy-*	Broadcast	BBCH 13-	a) 1		a) 1.25-	a) 0.125-	200-300	45	*weeds							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
		Peas for dry seeds		*ron repens)*	spraying	16* min. BBCH 12**	b) 1 OR a) 1 2	12	1.5 b) 1.25-1.5 OR a) 0.6 1.2	0.150 b) 0.125-0.150 OR a) 0.060 0.120			grow stage **crop grow stage							
19.	PL	**Cabbage**	F	Common barn-yardgrass *(Echi-nochloa crus-galli)*; Spring wild-oat *(Avena fatua)* ; Red fingergrass *(Digi-taria sanguinalis)* ; Yellow bristlegrass *(Setaria pumila)* ; Green bristlegrass *(Setaria viridis)* ; Perennial ryegrass *(Lolium perenne)*	Broadcast spraying	BBCH 13-29* min. BBCH 13**	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 0.060 b) 0.060	200-300	Growth stage restricted	*weeds grow stage **crop grow stage							
20.	PL	**Cabbage**	F	Silky bentgrass *(Apera spica-venti)* ; self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** min. BBCH 13***	a) 1 1	-	a) 0.5-0.7 0.5-0.7	a) 0.050-0.070 0.050-0.070	200-300	28	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose rate 0.7 L/ha ***crop grow stage							
21.	PL	**Cabbage**	F	Couch grass *(Agropy-ron repens)*	Broadcast spraying	BBCH 13-16* min. BBCH 13**	a) 1 b) 1 OR		a) 1.25-1.5 b) 1.25-1.5	a) 0.125-0.150 b) 0.125-	200-300	28	*weeds grow stage **crop grow stage							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
							a) 1 2	12	OR a) 0.6 1.2	0.150 OR a) 0.060 0.120										
22.	PL	**Carrot; Parsley**	F	Common barn-yardgrass *(Echi-nochloa crus-galli)*; Spring wild-oat *(Avena fatua)* ; Red fingergrass *(Digi-taria sanguinalis)* ; Yellow bristlegrass *(Setaria pumila)* ; Green bristlegrass *(Setaria viridis)* ; Perennial ryegrass *(Lolium perenne)*	Broadcast spraying	BBCH 13-29* min. BBCH 12**	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 0.060 b) 0.060	200-300	28	*weeds grow stage **crop grow stage							
23.	PL	**Carrot; Parsley**	F	Silky bentgrass *(Apera spica-venti)* ; self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** min. BBCH 12***	a) 1 1	-	a) 0.5-0.7 0.5-0.7	a) 0.050-0.070 0.050-0.070	200-300	28	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose rate 0.7 L/ha ***crop grow stage							
24.	PL	**Carrot; Parsley**	F	Couch grass *(Agropy-ron repens)*	Broadcast spraying	BBCH 13-16* min. BBCH 12**	a) 1 b) 1 OR a) 1 2	12	a) 1.25-1.5 b) 1.25-1.5 OR	a) 0.125-0.150 b) 0.125-0.150	200-300	28	*weeds grow stage **crop grow stage							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
									a) 0.6 1.2	OR a) 0.060 0.120										
25.	PL	**Strawberry**	F	Common barn-yardgrass *(Echi-nochloa crus-galli)*; Spring wild-oat *(Avena fatua)* ; Red fingergrass *(Digi-taria sanguinalis)* ; Yellow bristlegrass *(Setaria pumila)* ; Green bristlegrass *(Setaria viridis)* ; Perennial ryegrass *(Lolium perenne)*	Broadcast spraying	BBCH 13-29* BBCH 91-92**	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 0.060 b) 0.060	200-300	N.A.	*weeds grow stage **crop grow stage							
26.	PL	**Strawberry**	F	Silky bentgrass *(Apera spica-venti)* ; self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 91-92***	a) 1 1	-	a) 0.5-0.7 0.5-0.7	a) 0.050-0.070 0.050-0.070	200-300	N.A.	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose rate 0.7 L/ha ***crop grow stage							
27.	PL	**Strawberry**	F	Couch grass *(Agropy-ron repens)*	Broadcast spraying	BBCH 13-16* BBCH 91-92**	a) 1 b) 1 OR a) 1 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6	a) 0.125-0.150 b) 0.125-0.150 OR	200-300	N.A>	*weeds grow stage **crop grow stage							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
									1.2	a) 0.060 0.120										
28.	CEU	**OSR**	F	Annual and perennial grass weeds	Spray	Post emer-gence BBCH 12-39	a) 1 b) 1	NA	a) 1.2 b) 1.2	a) 0.12 b) 0.12	200-400	90	Weeds max BBCH 20							
Minor uses according to Article 51 (zonal uses)																				
29.	PL	**Spring oilseed rape**	F	Common barn-yardgrass *(Echi-nochloa crus-galli)*; Spring wild-oat *(Avena fatua)* ; Red fingergrass *(Digi-taria sanguinalis)* ; Yellow bristlegrass *(Setaria pumila)* ; Green bristlegrass *(Setaria viridis)* ; Perennial ryegrass *(Lolium perenne)*	Broadcast spraying	BBCH 13-29* BBCH 12-30**	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 0.060 b) 0.060	200-300	90	*weeds grow stage **crop grow stage							
30.	PL	**Spring oilseed rape**	F	Silky bentgrass *(Apera spica-venti)* ; self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 12-30***	a) 1 1	-	a) 0.5-0.7 0.5-0.7	a) 0.050-0.070 0.050-0.070	200-300	90	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose rate 0.7 L/ha ***crop grow stage							
31.	PL	**Spring oilseed rape**	F	Couch grass *(Agropy-ron repens)*	Broadcast spraying	BBCH 13-16* BBCH 12-30**	a) 1 b) 1 OR		a) 1.25-1.5 b) 1.25-1.5 OR	a) 0.125-0.150 b) 0.125-0.150	200-300	90	*weeds grow stage **crop grow stage							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
							a) 1 2	12	a) 0.6 1.2	OR a) 0.060 0.120										
32.	PL	**Opium poppy; Common flax; Linen flax; Broccoli; Brussels sprouts; Broad beans; Faba bean; Field peas; White lupine; Yellow lupine; Narrow-leaved lupine**	F	Common barn-yardgrass *(Echi-nochloa crus-galli)*; Spring wild-oat *(Avena fatua)* ; Red fingergrass *(Digi-taria sanguinalis)* ; Yellow bristlegrass *(Setaria pumila)* ; Green bristlegrass *(Setaria viridis)* ; Perennial ryegrass *(Lolium perenne)*	Broadcast spraying	BBCH 13-29* BBCH 13**	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 0.060 b) 0.060	200-300	Poppy, common flax -90. Broccoli; Brussels sprouts-28. Broad beans; Faba bean; Field peas; White lupine; Yellow lupine; Narrow-leaved lupine -45.	*weeds grow stage **crop grow stage							
33.	PL	**Opium poppy; Common flax; Linen flax; Broccoli; Brussels sprouts; Broad beans; Faba bean; Field peas; White lupine; Yellow lupine; Narrow-leaved lupine**	F	Silky bentgrass *(Apera spica-venti)* ; self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 13***	a) 1 1	-	a) 0.5-0.7 0.5-0.7	a) 0.050-0.070 0.050-0.070	200-300	Poppy, common flax -90. Broccoli; Brussels sprouts-28. Broad beans; Faba bean; Field peas; White lupine; Yellow lupine; Narrow-	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose rate 0.7 L/ha ***crop grow stage							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
												leaved lupine - 45.								
34.	PL	**Opium poppy; Common flax; Linen flax; Broccoli; Brussels sprouts; Broad beans; Faba bean; Field peas; White lupine; Yellow lupine; Narrow-leaved lupine**	F	Couch grass *(Agropyron repens)*	Broadcast spraying	BBCH 13-16* BBCH 13**	a) 1 b) 1 OR a) 1 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 0.120	200-300	Poppy, common flax -90. Broccoli; Brussels sprouts-28. Broad beans; Faba bean; Field peas; White lupine; Yellow lupine; Narrow-leaved lupine - 45.	*weeds grow stage **crop grow stage							
35.	PL	**Root celery; Parsnip; Swede**	F	Common barnyardgrass *(Echinochloa crus-galli)*; Spring wild-oat *(Avena fatua)* ; Red fingergrass *(Digitaria sanguinalis)* ; Yellow bristlegrass *(Setaria pumila)* ; Green bristlegrass *(Setaria viridis)* ; Perennial ryegrass *(Lolium perenne)*	Broadcast spraying	BBCH 13-29* BBCH 12**	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 0.060 b) 0.060	200-300	28	*weeds grow stage **crop grow stage							
36.	PL	**Root celery; Parsnip;**	F	Silky bentgrass *(Apera spica-venti)* ;	Broadcast spraying	BBCH 13-21*	a) 1 1	-	a) 0.5-0.7 0.5-0.7	a) 0.050-0.070	200-300	28	*weeds grow stage							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
		Swede		self-seeding of cereals		BBCH 25-30** BBCH 12***				0.050-0.070			for dose rate 0.5 L/ha ** weeds grow stage for dose rate 0.7 L/ha ***crop grow stage							
37.	PL	**Root celery; Parsnip; Swede**	F	Couch grass *(Agropyron repens)*	Broadcast spraying	BBCH 13-16* BBCH 12**	a) 1 b) 1 OR a) 1 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 0.120	200-300	28	*weeds grow stage **crop grow stage							
38.	PL	**Garlic; Shallot**	F	Common barnyardgrass *(Echinochloa crus-galli)*; Spring wild-oat *(Avena fatua)* ; Red fingergrass *(Digitaria sanguinalis)* ; Yellow bristlegrass *(Setaria pumila)* ; Green bristlegrass *(Setaria viridis)* ; Perennial ryegrass *(Lolium perenne)*	Broadcast spraying	BBCH 13-29* BBCH 11-12**	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 0.060 b) 0.060	200-300	30	*weeds grow stage **crop grow stage							
39.	PL	**Garlic; Shallot**	F	Silky bentgrass *(Apera spica-venti)* ; self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 11-	a) 1 1	-	a) 0.5-0.7 0.5-0.7	a) 0.050-0.070 0.050-0.070	200-300	30	*weeds grow stage for dose rate 0.5 L/ha							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
						12***							** weeds grow stage for dose rate 0.7 L/ha ***crop grow stage							
40.	PL	**Garlic; Shallot**	F	Couch grass *(Agropyron repens)*	Broadcast spraying	BBCH 13-16* BBCH 11-12**	a) 1 b) 1 OR a) 1 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 0.120	200-300	30	*weeds grow stage **crop grow stage							
41.	PL	**Fodder beet; Beetroot**	F	Common barnyardgrass *(Echinochloa crus-galli)*; Spring wild-oat *(Avena fatua)* ; Red fingergrass *(Digitaria sanguinalis)* ; Yellow bristlegrass *(Setaria pumila)* ; Green bristlegrass *(Setaria viridis)* ; Perennial ryegrass *(Lolium perenne)*	Broadcast spraying	BBCH 13-29* BBCH 12-35**	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 0.060 b) 0.060	200-300	28	*weeds grow stage **crop grow stage							
42.	PL	**Fodder beet; Beetroot**	F	Silky bentgrass *(Apera spica-venti)* ; self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 12-35***	a) 1 1	-	a) 0.5-0.7 0.5-0.7	a) 0.050-0.070 0.050-0.070	200-300	28	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
													rate 0.7 L/ha ***crop grow stage							
43.	PL	**Fodder beet; Beetroot**	F	Couch grass *(Agropyron repens)*	Broadcast spraying	BBCH 13-16* BBCH 12-35**	a) 1 b) 1 OR a) 1 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 0.120	200-300	28	*weeds grow stage **crop grow stage							
44.	PL	**Jerusalem Artichokes; Horseradish; Black radish; Japanese radish (daikon); Radish; Salsify; White turnip; Black turnip**	F	Common barn-yardgrass *(Echinochloa crus-galli)*; Spring wild-oat *(Avena fatua)* ; Red fingergrass *(Digitaria sanguinalis)* ; Yellow bristlegrass *(Setaria pumila)* ; Green bristlegrass *(Setaria viridis)* ; Perennial ryegrass *(Lolium perenne)*	Broadcast spraying	BBCH 13-29* min. BBCH 12**	a) 1 b) 1	-	a) 0.6 b) 0.6	a) 0.060 b) 0.060	200-300	28	*weeds grow stage **crop grow stage							

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

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

Explanation for column 15 – 21 “Conclusion”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Remarks table:

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
(5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of application possible under practical conditions of use must be provided
(9) Minimum interval (in days) between applications of the same product.
(10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions

9.1.1 Overall conclusions

ZRMS comments:

Since report in dRR format is prepared by the Applicant, all remarks, comments, additional calculations and assessment done by the zRMS are included in the commenting boxes or highlighted in blue or grey.

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2),

- According to screening and tier I assessments, all the TER_a and TER_{lt} values for the active substance Propaquizafop are greater than the Annex VI trigger of 10 and 5, respectively, indicating that SHA 6100 A / ALIVE presents no unacceptable acute and long-term risk to mammals according to the all intended use.

Propaquizafop has been shown to have the potential for bioaccumulation, however, there is no risk to earthworm and fish-eating mammals according to the intended use of SHA 6100 A / ALIVE.

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

Not relevant

9.1.1.3 Effects on aquatic organisms (KCP 10.2)

Propaquizafop
Calculated PEC/RAC ratios in all FOCUS Steps 1-2 scenarios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish acute and fish prolonged as characterised by a LC50 and a NOEC for respectively *Cyprinus carpio and Oncorhynchus mykiss* of 190 µg/L and 19 µg/L in connection with an assessment factor of 100 and 10, respectively).

Metabolites of Propaquizafop
For all the intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

9.1.1.4 Effects on bees (KCP 10.3.1)

First-tier assessments indicate that no unacceptable risk for bees exposed to the product SHA 6100 A / ALIVE is expected according to the proposed intended uses.
According to EU Reg. 284 /2009, the chronic toxicity test for adult bees, the chronic test for larvae should be provided for authorisation of plant protection product.

9.1.1.5 First-tier assessments indicate that no unacceptable risk for bees exposed to the product SHA 6100 A / ALIVE is expected according to the proposed intended uses.

9.1.1.6 Effects on arthropods other than bees (KCP 10.3.2)

The tier I in-field HQ values calculated for Propaquizafop for the representative species T. pyri indicate no potential high risk for non-target arthropods.
For A. rhopalosiphi, the tier I in-field HQ values cannot be determined with precision. However, the higher-tier assessment showed a mortality <50% at rates greater than the in-crop rate of the control at 800 g/ha, the risk posed to A. rhopalosiphi in-crop is thus considered acceptable.
These results indicate an acceptable infield risk to non-target arthropods.
The tier I off-field HQ values calculated for Propaquizafop for the representative species *T. pyri* indicate no potential high risk to non-target arthropods.
For *A. rhopalosiphi*, the tier I off-field HQ was not determined. However, the higher-tier assessment showed a mortality <50% at rates greater than the off-crop rate of the control at 560 g/ha, the risk posed to *A. rhopalosiphi* off-crop is thus considered acceptable.

9.1.1.7 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

All the TER values on earthworms for Propaquizafop and its relevant metabolites are higher than the Annex VI trigger values, indicating that SHA 6100 A / ALIVE poses low acute and chronic risk to earthworms and other soil meso- and macrofauna when applied according to the proposed use rate.
Risk assessments conducted with relevant PEC_{soil} for SHA 6100 A / ALIVE indicate a low risk to soil microorganisms when applied according to the proposed use rate.

9.1.1.8 Effects on non-target terrestrial plants (KCP 10.6)

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for SHA 6100 A / ALIVE shows that the Annex VI trigger value of 5 is not exceeded according to the use rates when following risk mitigations measures are taken:

Spe3: To protect non-target plants respect an unsprayed buffer zone of 5 m to non-agricultural land OR respect 50% drift reduction technology to non-agricultural land.

9.1.1.9 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

The EFSA conclusions drawn from the EFSA Scientific Report (2008) 204, 1-171 are the following:
Propaquizafop up to a concentration of 100 mg a.s./L (the highest concentration tested) did not adversely affect the biodegradation activity of sewage micro-organisms. It was not expected that the concentrations of Propaquizafop in biological sewage treatment plants would reach a concentration of more than 100 mg a.s./L if the product were to be applied according to the GAP and therefore the risk to biological methods of sewage treatment was considered to be low.

Therefore, the risk to biological methods of sewage treatment was assessed as low.

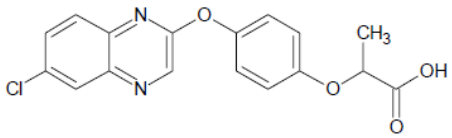
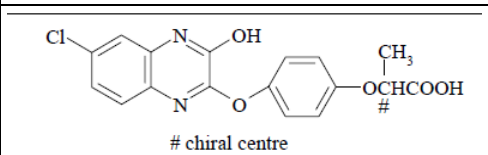
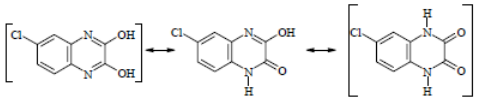
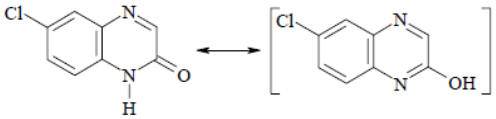
9.1.2 Grouping of intended uses for risk assessment

Not relevant.

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of SHA 6100 A / ALIVE is indicated in the table.

Table 9.1-2 Metabolites of Propaquizafop

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
Quizalofop QUIZ		344.8 g/mol	Soil: 87.9% Water: 90.2% Sediment: 45.4%	Yes, for aquatic organisms, non-target soil meso- and macrofauna and soil microbial activity
Hydroxy-Quizalofop QUIZ-OH Hydroxy-propaquizafop acid CGA 294972	 # chiral centre	360.8 g/mol	Soil: 32.6% Water: 4.1% Sediment: 11.2%	Yes, for aquatic organisms, non-target soil meso- and macrofauna and soil microbial activity
Dihydroxy quinoxaline Dihydroxychloroquinoxalin CHHQ CGA 294970		196.6 g/mol	Soil: 13.7% Water: 1% Sediment: 10%	Yes, for aquatic organisms, non-target soil meso- and macrofauna and soil microbial activity
Hydroxy quinoxaline CHQ CGA 290291 CQO		180.6 g/mol	Soil: 8.8% Water: 2.3% Sediment: 6.4%	Yes, for aquatic organisms, non-target soil meso- and macrofauna and soil microbial activity

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with Propaquizafop and its relevant metabolites. Full details of these studies are provided in the respective EU DAR.

Effects on birds of SHA 6100 A / ALIVE were not evaluated as part of the EU assessment of Propaquizafop.

However, the provision of further data on the SHA 6100 A / ALIVE is not considered essential, because active substance data on toxicity to birds can be used and additional formulation data are not considered essential.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
Bobwhite Quail	Propaquizafop	Oral Acute	**LD_{50} > 2000 mg a.s/kg bw**	EFSA,2008
Japanese quail	Preparation	Oral Acute (limit test)	LD50 > 2000 mg form/kg bw	EFSA,2008
Mallard duck	Propaquizafop	Dietary Short-term	LC_{50} > 827 mg/kg bw/d*	EFSA,2008
Bobwhite quail	Propaquizafop	Dietary Long-term	**NOEC > 20.2 mg/kg bw/d**	EFSA,2008

* corrected according to Evaluation Table, Open point 5.2

9.2.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.2-2: Screening step assessment of the acute and long-term/reproductive risk for birds due to the use of SHA 6100 A / ALIVE in all crop

Intended use	**All crop**				
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE				
Application rate (g/ha)	1 × 150				
Acute toxicity (mg/kg bw)	> 2000				
TER criterion	10				
Crop scenario Growth stage	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Oilseed rape – as a worrst case	Small omnivorous bird	158.8	1.00	23.82	84.00
Reprod. toxicity (mg/kg bw/d)	> 20.2				
TER criterion	5				
Crop scenario Growth stage	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Oilseed rape – as a worrst case	Small omnivorous bird	64.8	0.53	5.15	**3.92**

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 screening step assessment acute risk for birds is shown to be acceptable. Next first tier assessment is shown for long term/reproductive toxicity.

Table 9.2-3: First tier assessment of the long-term/reproductive risk for birds due to the use of SHA 6100 A / ALIVE in Sugarbeet

Intended use	**Sugarbeet**				
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE				
Application rate (g/ha)	1 × 150				
Reprod. toxicity (mg/kg bw/d)	> 20.2				
TER criterion	5				
Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Sugarbeet late (summer/ autumn) (BBCH 30-49)	Small granivorous bird “Finch”	11.4	0.53	0.91	22.29
Sugarbeet early (spring) (BBCH 10-19)	Small omnivorous bird “lark”	10.9	0.53	0.87	23.31
Sugarbeet BBCH 10-19	Small insectivorous bird “wagtail”	5.9	0.53	0.47	43.07
Sugarbeet BBCH 20 - 49	Small insectivorous bird “wagtail”	2.8	0.53	0.22	90.75
Sugarbeet BBCH 20 - 49	Small insectivorous bird “wagtail”	9.7	0.53	0.77	26.19

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.

First tier reproductive risk assessment indicates safe use of SHA 6100 A / ALIVE in Sugarbeet for all generic focal species.

Table 9.2-4: First tier assessment of the long-term/reproductive risk for birds due to the use of SHA 6100 A / ALIVE in Oilseed rape

Intended use	**Oilseed rape**
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE
Application rate (g/ha)	1 × 150
Reprod. toxicity (mg/kg bw/d)	> 20.2
TER criterion	5

Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Oilseed rape late – late (with seeds) (BBCH 30-99)	Small insectivorous bird “dunnock”	2.7	0.53	0.21	94.11
Oilseed rape early (shoots) (BBCH 10-19)	Large herbivorous bird “goose”	15.9	0.53	1.26	15.98
Oilseed rape BBCH 10 - 29	Small omnivorous bird “lark”	10.9	0.53	0.87	23.31
Oilseed rape BBCH 30 - 39	Small omnivorous bird “lark”	3.3	0.53	0.26	77.00
Oilseed rape BBCH 10 - 19	medium herbivorous/granivorous bird “pigeon”	22.7	0.53	1.80	11.19
Oilseed rape BBCH 20 - 29	medium herbivorous/granivorous bird “pigeon”	3.5	0.53	0.28	72.60
Oilseed rape BBCH 30 - 39	medium herbivorous/granivorous bird “pigeon”	1.1	0.53	0.09	230.99
Oilseed rape BBCH 10 - 19	Small insectivorous bird “wagtail”	5.9	0.53	0.47	43.07
Oilseed rape BBCH 20 - 29	Small insectivorous bird “wagtail”	2.8	0.53	0.22	90.75

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.

First tier reproductive risk assessment indicates safe use of SHA 6100 A / ALIVE in Oilseed rape for all generic focal species.

Table 9.2-5: First tier assessment of the long-term/reproductive risk for birds due to the use of SHA 6100 A / ALIVE in Potato

Intended use	**Potato**
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE
Application rate (g/ha)	1 × 150
Reprod. toxicity (mg/kg bw/d)	> 20.2
TER criterion	5

Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Potato BBCH 10 - 39	Small omnivorous bird “lark”	10.9	0.53	0.87	23.31
Potato BBCH 10 - 19	Small insectivorous bird “wagtail”	11.3	0.53	0.90	22.49
Potato BBCH > 20	Small insectivorous bird “wagtail”	9.7	0.53	0.77	26.19

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.

First tier reproductive risk assessment indicates safe use of SHA 6100 A / ALIVE in Potato for all generic focal species.

Table 9.2-6: First tier assessment of the long-term/reproductive risk for birds due to the use of SHA 6100 A / ALIVE in Bulbs and onion like crops

Intended use	**Bulbs and onion like crops**
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE
Application rate (g/ha)	1 × 150
Reprod. toxicity (mg/kg bw/d)	> 20.2
TER criterion	5

Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bulbs and onion like crops BBCH 10 - 39	Small granivorous bird “Finch”	11.4	0.53	0.91	22.29
Bulbs and onion like crops BBCH > 40	Small granivorous bird “Finch”	6.9	0.53	0.55	36.82
Bulbs and onion like crops BBCH 10 - 39	Small omnivorous bird “lark”	10.9	0.53	0.87	23.31
Bulbs and onion like crops BBCH > 40	Small omnivorous bird “lark”	6.5	0.53	0.52	39.09
Bulbs and onion like crops BBCH 10 - 19	Small insectivorous bird “wagtail”	11.3	0.53	0.90	22.49
Bulbs and onion like crops BBCH > 20	Small insectivorous bird “wagtail”	9.7	0.53	0.77	26.19

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.

First tier reproductive risk assessment indicates safe use of SHA 6100 A / ALIVE in Bulbs and onion like

crops for all generic focal species.

Table 9.2-7: First tier assessment of the long-term/reproductive risk for birds due to the use of SHA 6100 A / ALIVE in Pulses

Intended use	**Pulses**
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE
Application rate (g/ha)	1 × 150
Reprod. toxicity (mg/kg bw/d)	> 20.2
TER criterion	5

Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Pulses BBCH 10 - 49	Small granivorous bird “Finch”	11.4	0.53	0.91	22.29
Pulses BBCH > 50	Small granivorous bird “Finch”	3.4	0.53	0.27	74.73
Pulses BBCH 10 - 49	Small omnivorous bird “lark”	10.9	0.53	0.87	23.31
Pulses BBCH > 50	Small omnivorous bird “lark”	3.3	0.53	0.26	77.00
Pulses Leaf development BBCH 10-19	medium herbivorous/granivorous bird “pigeon”	22.7	0.53	1.80	11.19
Pulses BBCH 10 - 19	Small insectivorous bird “wagtail”	11.3	0.53	0.90	22.49
Pulses BBCH > 20	Small insectivorous bird “wagtail”	9.7	0.53	0.77	26.19

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.

First tier reproductive risk assessment indicates safe use of SHA 6100 A / ALIVE in Pulses for all generic focal species.

Table 9.2-8: First tier assessment of the long-term/reproductive risk for birds due to the use of SHA 6100 A / ALIVE in Leafy vegetables

Intended use	**Leafy vegetables**
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE
Application rate (g/ha)	1 × 150
Reprod. toxicity (mg/kg bw/d)	> 20.2
TER criterion	5

Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Leafy vegetables BBCH 10 - 49	Small granivorous bird “Finch”	12.6	0.53	1.00	20.17
Leafy vegetables BBCH > 50	Small granivorous bird “Finch”	3.8	0.53	0.30	66.87
Leafy vegetables BBCH 10 - 49	Small omnivorous bird “lark”	10.9	0.53	0.87	23.31
Leafy vegetables BBCH > 50	Small omnivorous bird “lark”	3.3	0.53	0.26	77.00
Leafy vegetables Leaf development BBCH 10-19	medium herbivorous/granivorous bird “pigeon”	37.0	0.53	2.94	6.87
Leafy vegetables BBCH 10 - 19	Small insectivorous bird “wagtail”	11.3	0.53	0.90	22.49
Leafy vegetables BBCH > 20	Small insectivorous bird “wagtail”	9.7	0.53	0.77	26.19

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.

First tier reproductive risk assessment indicates safe use of SHA 6100 A / ALIVE in Leafy vegetables for all generic focal species.

Table 9.2-9: First tier assessment of the long-term/reproductive risk for birds due to the use of SHA 6100 A / ALIVE in Root and stem vegetables

Intended use	**Root and stem vegetables**
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE
Application rate (g/ha)	1 × 150
Reprod. toxicity (mg/kg bw/d)	> 20.2
TER criterion	5

Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Root and stem vegetables BBCH 10 - 39	Small granivorous bird “Finch”	11.4	0.53	0.91	22.29
Root and stem vegetables BBCH > 40	Small granivorous bird “Finch”	3.4	0.53	0.27	74.73
Root and stem vegetables BBCH 10 - 39	Small omnivorous bird “lark”	10.9	0.53	0.87	23.31
Root and stem vegetables BBCH > 40	Small omnivorous bird “lark”	3.3	0.53	0.26	77.00
Root and stem vegetables BBCH 10 - 19	Small insectivorous bird “wagtail”	11.3	0.53	0.90	22.49
Root and stem vegetables BBCH >20	Small insectivorous bird “wagtail”	9.7	0.53	0.77	26.19

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.

First tier reproductive risk assessment indicates safe use of SHA 6100 A / ALIVE in Root and stem vegetables for all generic focal species.

Table 9.2-10: First tier assessment of the long-term/reproductive risk for birds due to the use of SHA 6100 A / ALIVE in strawberries

Intended use	**Strawberries**
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE
Application rate (g/ha)	1 × 150
Reprod. toxicity (mg/kg bw/d)	> 20.2
TER criterion	5

Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
BBCH 10 - 39	Small omnivorous bird “lark”	10.9	0.53	0.87	23.31
BBCH > 40	Small omnivorous bird “lark”	4.4	0.53	0.35	57.75
Late (Flowering/ development of fruit/ Maturity of fruit) BBCH 61-89	Frugivorous bird “Starling”	13.4	0.53	1.07	18.96
BBCH > 20	Small insectivorous bird “wagtail”	9.7	0.53	0.77	26.19

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.

First tier reproductive risk assessment indicates safe use of SHA 6100 A / ALIVE in strawberries for all generic focal species.

Conclusion

According to screening and tier I assessments, all the TER_a and TER_{lt} values for the active substance Propaquizafop are greater than the Annex VI trigger of 10 and 5, respectively, indicating that SHA 6100 A / ALIVE presents no unacceptable acute and long-term risk to birds according to the intended use on all crops.

zRMS comments:

All the TER_a and TER_{lt} values for the active substance Propaquizafop are greater than the Annex VI trigger of 10 and 5, respectively, indicating that SHA 6100 A / ALIVE presents no unacceptable acute and long-term risk to birds according to the intended use on all crops.

9.2.2.2 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Leaf scenario

Since SHA 6100 A / ALIVE is intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario must be considered.

Table 9.2-11: Assessment of the acute risk for birds due to exposure to ~~lambda-cyhalothrin~~ via contaminated drinking water in leaf whorls

Intended use		**~~Brassica~~s All crops**				
Active substance		Propaquizafop / SHA 6100 A / ALIVE				
Application rate (g/ha)		1 × 150				
Acute toxicity (mg/kg bw)		2000				
TER criterion		10				
(Single) applic. rate (g/ha)	**Water applic. rate (L/ha)**	**$C_{spray-sol.}$ (g/L)**	**$PEC_{leaf-whorl}$ = $C_{spray-sol.}$/5 (mg/L)**	**DW uptake (L/kg bw/d)**	**Daily dose (mg/kg bw/d)**	**TER_a**
150	200	0.75	0.15	0.46	0.069	28985.5

$C_{spray-sol}$: concentration in spray solution; $PEC_{leaf-whorl}$: concentration in pools in leaf whorls; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Puddle scenario

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 (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 2220 L/kg, Propaquizafop belongs to the group of more sorptive substances.

Effective application rate (g/ha)	=	~~120~~150			
Acute toxicity (mg/kg bw)	=	> 2000	quotient	=	~~<0.06~~ 0.075
Reprod. toxicity (mg/kg bw/d)	=	> 20.2	quotient	=	<~~5.94~~ 7.42

As the ratios do not exceed the value of 3000 for Propaquizafop, it is not necessary to conduct a drinking water risk assessment for bird.

zRMS comments:

Assessment of the acute risk for birds due to exposure to Propaquizafop / SHA 6100 A / ALIVE via contaminated drinking water in leaf whorls was verified and then accepted by zRMS.

As the ratios do not exceed the value of 3000 for Propaquizafop, it is not necessary to conduct a drinking water risk assessment for bird.

9.2.2.3 Effects of secondary poisoning

The log P_{ow} of Propaquizafop amounts to 4.78 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

Table 9.2-12: Assessment of the risk for earthworm-eating birds due to exposure to Propaquizafop via bioaccumulation in earthworms (secondary poisoning) for the intended use in all crops

Parameter	Propaquizafop	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.200	B8
log P_{ow} / P_{ow}	4.78 / 60255.96	LOEP
Koc	2200	Estimated using Briggs equation from log Kow
foc	0.02	Default
BCF_{worm}	16.453	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	3.291	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	3.455	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	20.2	LOEP
TER_{lt}	5.85	No risk, TERlt > 5

TER values shown in bold fall below the relevant trigger.

Conclusion
The daily dose value was compared with long-term NOAEL value of 20.2 mg/kg bw/day which resulted in a TER value of 5.85. This value exceeds the relevant Annex VI trigger of 5 and confirms that the risk posed to birds by the consumption of earthworms is low.

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water as a limit value for admissible concentrations of Propaquizafop in water.

Table 9.2-13: Assessment of the risk for fish-eating birds due to exposure to Propaquizafop via bioaccumulation in fish (secondary poisoning) for the intended use in all crops

Parameter	Propaquizafop	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.01401	B8
BCF_{fish}	1243	LOEP
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	17.288	PECfish = PECwater × BCFfish
Daily dietary dose (mg/kg bw/d)	1.457	DDD = PECfish × 0.159 x TWA
NOEL (mg/kg bw/d)	20.2	LOEP
TER_{lt}	13.87	No risk, TERlt > 5

TER values shown in bold fall below the relevant trigger.

Conclusion
The daily dose value was compared with long-term NOAEL value of 20.2 mg/kg bw/day which resulted in a TER value of 13.87. This value exceeds the relevant Annex VI trigger of 5 and confirms that the risk posed to birds by the consumption of fish is low.

zRMS comments:

The risk for fish-eating mammals due to exposure to Propaquizafop via bioaccumulation in fish

(secondary poisoning) for the intended use in all crops is considered acceptable.

9.2.2.4 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, pills or treated seed

Not relevant.

9.2.4 Overall conclusions

According to screening and tier I assessments, all the TER_a and TER_{lt} values for the active substance Propaquizafop are greater than the Annex VI trigger of 10 and 5, respectively, indicating that SHA 6100 A / ALIVE presents no unacceptable acute and long-term risk to birds according to the intended use on all crops.

Propaquizafop has been shown to have the potential for bioaccumulation, however, there is no risk to earthworm and fish-eating birds according to the intended use of SHA 6100 A / ALIVE.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with Propaquizafop. Full details of these studies are provided in the respective EU DAR.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Mouse	Propaquizafop	Oral Acute	**LD_{50} = 3009 mg a.s/kg bw**	EFSA,2008
Rat	Propaquizafop	Two-generation study Long term	**NOAEL = 15 mg a.s/kg bw/d**	EFSA,2008

9.3.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.3-2: Screening step assessment of the acute and long-term/reproductive risk for mammals due to the use of SHA 6100 A / ALIVE in all crop

Intended use	**All crops**				
Active substance/product	Propaquizafop				
Application rate (g/ha)	1 ×150				
Acute toxicity (mg/kg bw)	3009				
TER criterion	10				
Crop scenario Growth stage	**Indicator species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
All crops	Small herbivorous mammal	136.4	1.00	20.46	147.10
Reprod. toxicity (mg/kg bw/d)	15				
TER criterion	5				
Crop scenario Growth stage	**Indicator species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
All crops	Small herbivorous mammal	72.3	0.53	5.75	**2.61**

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 screening step assessment acute risk for mammals is shown to be acceptable. In case of long term/reproductive risk first tier assessment is shown for assessment.

Table 9.3-3: First tier assessment of the long-term/reproductive risk for mammals due to the use of SHA 6100 A / ALIVE in sugar beet

Intended use	**Sugar beet**				
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE				
Application rate (g/ha)	1 × 150				
Reprod. toxicity (mg/kg bw/d)	15				
TER criterion	5				
Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Sugar beet BBCH 10 - 19	Small insectivorous mammal “shrew”	4.2	0.53	0.33	44.92
Sugar beet BBCH > 20	Small insectivorous mammal “shrew”	1.9	0.53	0.15	99.30
Sugar beet BBCH	Large herbivorous mammal “lagomorph”	14.3	0.53	1.14	13.19

10-39					
Sugar beet BBCH 10-39	Small omnivorous mammal “mouse”	7.8	0.53	0.62	24.19

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.

No unacceptable long-term risk for reproduction was indicated at Tier 1 risk assessment for use of SHA 6100 A / ALIVE in Sugar beet.

Table 9.3-4: First tier assessment of the long-term/reproductive risk for mammals due to the use of SHA 6100 A / ALIVE in OSR

Intended use	**OSR**				
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE				
Application rate (g/ha)	1 × 150				
Reprod. toxicity (mg/kg bw/d)	15				
TER criterion	5				
Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
OSR BBCH 10 - 19	Small insectivorous mammal “shrew”	4.2	0.53	0.33	44.92
OSR BBCH > 20	Small insectivorous mammal “shrew”	1.9	0.53	0.15	99.30
OSR All season	Large herbivorous mammal “lagomorph”	14.3	0.53	1.14	13.19
OSR BBCH 10-29	Small omnivorous mammal “mouse”	7.8	0.53	0.62	24.19
OSR BBCH 30 - 39	Small omnivorous mammal “mouse”	2.3	0.53	0.18	82.03

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.

No unacceptable long-term risk for reproduction was indicated at Tier 1 risk assessment for use of SHA 6100 A / ALIVE in OSR.

Table 9.3-5: First tier assessment of the long-term/reproductive risk for mammals due to the use of SHA 6100 A / ALIVE in potatoes

Intended use	**potatoes**				
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE				
Application rate (g/ha)	1 × 150				
Reprod. toxicity (mg/kg bw/d)	15				
TER criterion	5				
Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
potatoes BBCH 10 - 19	Small insectivorous mammal “shrew”	4.2	0.53	0.33	44.92
potatoes BBCH > 20	Small insectivorous mammal “shrew”	1.9	0.53	0.15	99.30
potatoes BBCH 10 - 40	Large herbivorous mammal “lagomorph”	14.3	0.53	1.14	13.19
potatoes BBCH 10 - 39	Small omnivorous mammal “mouse”	7.8	0.53	0.62	24.19

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.

No unacceptable long-term risk for reproduction was indicated at Tier 1 risk assessment for use of SHA 6100 A / ALIVE in potatoes.

Table 9.3-6: First tier assessment of the long-term/reproductive risk for mammals due to the use of SHA 6100 A / ALIVE in Bulbs & onion like crops

Intended use	**Bulbs & onion like crops**
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE
Application rate (g/ha)	1 × 150
Reprod. toxicity (mg/kg bw/d)	15
TER criterion	5

Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bulbs & onion like crops BBCH 10 - 19	Small insectivorous mammal “shrew”	4.2	0.53	0.33	44.92
Bulbs & onion like crops BBCH > 20	Small insectivorous mammal “shrew”	1.9	0.53	0.15	99.30
Bulbs & onion like crops BBCH > 40	Small herbivorous mammal “vole”	43.4	0.53	3.45	**4.35**
Bulbs & onion like crops BBCH 10 - 39	Small omnivorous mammal “mouse”	7.8	0.53	0.62	24.19
Bulbs & onion like crops BBCH > 40	Small omnivorous mammal “mouse”	4.7	0.53	0.37	40.14

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.

According to Fluazifop-P Confirmatory data_Addendum Vol3 B9 Revised Oct 2014:
There are many reports from the literature that the optimum or prime habitat‘ of common voles is undisturbed grassland or set-aside at a vegetation height of minimum 20 cm (De Jonge and Dienske, 1979; Delattre et al., 1996; Butet and Leroux, 2001; Giraudoux et al., 1994; Gorman and Reynolds, 1993) or perennial crops like alfalfa (Truszkowski, 1982).
The preference for primary habitats is underlined by the findings of Briner et al. (2005), who demonstrated by using automatic radio tracking, that M. arvalis developed high population densi-ties containing 90% of the total home range in wild flower strips neighbouring crop fields, but hardly ever entered the nearby crops, even when those were highly palatable. Also, Koks et al. (2007) showed that vole abundance was twice as high in set aside land and in high and dense veg-etation than in neighbouring non fallow habitat types like plantations or cereals.
Therefore, it can be stated that
a.) When local population densities are low, Common voles are prone to spend much less time in crop fields, which only serve as transient habitats.
b.) Secondary populations of the Common vole in-field (as opposed to the primary population in the margins) are also of little to no importance for the survival of the local populations, since har-vest and ploughing will destroy their home range habitat at least once a year.
Since this species is so prolific, it can additionally be stated that a slight reduction in the growth potential of secondary populations in field crops will usually also be of little to no importance for the population of local predator species.
Therefore, it is may be more appropriate to consider the other small mammals, such as the wood mouse (*Apodemus sylvaticus*) and common shrew (*Sorex araneus*), as relevant focal species in crop habitats. The risk assessment is considered to be covered through the assessment of other small mammalian species for

the following reasons:
- High fecundity and population recuperation of the vole;
- Primary source of food outside crops fields for the vole;
- Necessity of population control measures since the vole is considered a crop pest when high population levels are reached;
- Other agricultural techniques being also means of population control.

No unacceptable long-term risk for reproduction was indicated at Tier 1 risk assessment for use of SHA 6100 A / ALIVE in Bulbs & onion like crops.

Table 9.3-7: First tier assessment of the long-term/reproductive risk for mammals due to the use of SHA 6100 A / ALIVE in pulses

Intended use	**pulses**
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE
Application rate (g/ha)	1 × 150
Reprod. toxicity (mg/kg bw/d)	15
TER criterion	5

Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
pulses BBCH 10 - 19	Small insectivorous mammal “shrew”	4.2	0.53	0.33	44.92
pulses BBCH > 20	Small insectivorous mammal “shrew”	1.9	0.53	0.15	99.30
pulses BBCH 40 - 49	Small herbivorous mammal “vole”	72.3	0.53	5.75	**2.61**
pulses BBCH > 50	Small herbivorous mammal “vole”	21.7	0.53	1.73	8.69
pulses BBCH 10 - 49	Large herbivorous mammal “lagomorph”	14.3	0.53	1.14	13.19
pulses BBCH > 50	Large herbivorous mammal “lagomorph”	4.3	0.53	0.34	43.88
pulses Pre harvest seed BBCH 81-99	Small omnivorous mammal “mouse”	6.6	0.53	0.52	28.59
pulses BBCH 10 - 49	Small omnivorous mammal “mouse”	7.8	0.53	0.62	24.19
pulses BBCH > 50	Small omnivorous mammal “mouse”	2.3	0.53	0.18	82.03

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.

According to Fluazifop-P Confirmatory data_Addendum Vol3 B9 Revised Oct 2014:
There are many reports from the literature that the optimum or prime habitat‘ of common voles is undisturbed grassland or set-aside at a vegetation height of minimum 20 cm (De Jonge and Dienske, 1979; Delattre et al., 1996; Butet and Leroux, 2001; Giraudoux et al., 1994; Gorman and Reynolds, 1993) or perennial crops like alfalfa (Truszkowski, 1982).
The preference for primary habitats is underlined by the findings of Briner et al. (2005), who demonstrated by using automatic radio tracking, that M. arvalis developed high population densi-ties containing 90% of the total home range in wild flower strips neighbouring crop fields, but hardly ever entered the nearby crops, even when those were highly palatable. Also, Koks et al. (2007) showed that vole abundance was twice as high in set aside land and in high and dense veg-etation than in neighbouring non fallow habitat types like plantations or cereals.

Therefore, it can be stated that
a.) When local population densities are low, Common voles are prone to spend much less time in crop fields, which only serve as transient habitats.
b.) Secondary populations of the Common vole in-field (as opposed to the primary population in the margins) are also of little to no importance for the survival of the local populations, since har-vest and ploughing will destroy their home range habitat at least once a year.
Since this species is so prolific, it can additionally be stated that a slight reduction in the growth potential of secondary populations in field crops will usually also be of little to no importance for the population of local predator species.
Therefore, it is may be more appropriate to consider the other small mammals, such as the wood mouse (*Apodemus sylvaticus*) and common shrew (*Sorex araneus*), as relevant focal species in crop habitats. The risk assessment is considered to be covered through the assessment of other small mammalian species for the following reasons:

- High fecundity and population recuperation of the vole;
- Primary source of food outside crops fields for the vole;
- Necessity of population control measures since the vole is considered a crop pest when high population levels are reached;
- Other agricultural techniques being also means of population control.

No unacceptable long-term risk for reproduction was indicated at Tier 1 risk assessment for use of SHA 6100 A / ALIVE in pulses.

Table 9.3-8: First tier assessment of the long-term/reproductive risk for mammals due to the use of SHA 6100 A / ALIVE in leafy vegetables

Intended use	**leafy vegetables**
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE
Application rate (g/ha)	1 × 150
Reprod. toxicity (mg/kg bw/d)	15
TER criterion	5

Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
leafy vegetables BBCH 10 - 19	Small insectivorous mammal “shrew”	4.2	0.53	0.33	44.92
leafy vegetables BBCH > 20	Small insectivorous mammal “shrew”	1.9	0.53	0.15	99.30
leafy vegetables BBCH 40 - 49	Small herbivorous mammal “vole”	72.3	0.53	5.75	**2.61**
leafy vegetables BBCH > 50	Small herbivorous mammal “vole”	21.7	0.53	1.73	8.69
leafy vegetables All season	Large herbivorous mammal “lagomorph”	14.3	0.53	1.14	13.19
leafy vegetables BBCH 10 - 49	Small omnivorous mammal “mouse”	7.8	0.53	0.62	24.19
leafy vegetables BBCH > 50	Small omnivorous mammal “mouse”	2.3	0.53	0.18	82.03

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.

According to **Fluazifop-P Confirmatory data_Addendum Vol3 B9 Revised Oct 2014:**
There are many reports from the literature that the optimum or prime habitat‘ of common voles is undis-

turbed grassland or set-aside at a vegetation height of minimum 20 cm (De Jonge and Dienske, 1979; Delattre et al., 1996; Butet and Leroux, 2001; Giraudoux et al., 1994; Gorman and Reynolds, 1993) or perennial crops like alfalfa (Truszkowski, 1982).
The preference for primary habitats is underlined by the findings of Briner et al. (2005), who demonstrated by using automatic radio tracking, that M. arvalis developed high population densi-ties containing 90% of the total home range in wild flower strips neighbouring crop fields, but hard-ly ever entered the nearby crops, even when those were highly palatable. Also, Koks et al. (2007) showed that vole abundance was twice as high in set aside land and in high and dense veg-etation than in neighbouring non fallow habitat types like plantations or cereals.
Therefore, it can be stated that
a.) When local population densities are low, Common voles are prone to spend much less time in crop fields, which only serve as transient habitats.
b.) Secondary populations of the Common vole in-field (as opposed to the primary population in the margins) are also of little to no importance for the survival of the local populations, since har-vest and ploughing will destroy their home range habitat at least once a year.
Since this species is so prolific, it can additionally be stated that a slight reduction in the growth potential of secondary populations in field crops will usually also be of little to no importance for the population of local predator species.
Therefore, it is may be more appropriate to consider the other small mammals, such as the wood mouse (Apodemus sylvaticus) and common shrew (Sorex araneus), as relevant focal species in crop habitats. The risk assessment is considered to be covered through the assessment of other small mammalian species for the following reasons:

- High fecundity and population recuperation of the vole;
- Primary source of food outside crops fields for the vole;
- Necessity of population control measures since the vole is considered a crop pest when high population levels are reached;
- Other agricultural techniques being also means of population control.

No unacceptable long-term risk for reproduction was indicated at Tier 1 risk assessment for use of SHA 6100 A / ALIVE in leafy vegetables.

Table 9.3-9: First tier assessment of the long-term/reproductive risk for mammals due to the use of SHA 6100 A / ALIVE in Root & stem vegetables

Intended use	**Root & stem vegetables**
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE
Application rate (g/ha)	1 × 150
Reprod. toxicity (mg/kg bw/d)	15
TER criterion	5

Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Root & stem vegetables BBCH 10 - 19	Small insectivorous mammal “shrew”	4.2	0.53	0.33	44.92
Root & stem vegetables BBCH > 20	Small insectivorous mammal “shrew”	1.9	0.53	0.15	99.30
Root & stem vegetables BBCH > 40	Small herbivorous mammal “vole”	21.7	0.53	1.73	8.69
Root & stem vegetables BBCH	Small omnivorous mammal “mouse”	7.8	0.53	0.62	24.19

10 - 39					
Root & stem vegetables BBCH > 40	Small omnivorous mammal “mouse”	2.3	0.53	0.18	82.03

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.

No unacceptable long-term risk for reproduction was indicated at Tier 1 risk assessment for use of SHA 6100 A / ALIVE in Root & stem vegetables.

Table 9.3-10: First tier assessment of the long-term/reproductive risk for mammals due to the use of SHA 6100 A / ALIVE in strawberries

Intended use	**strawberries**				
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE				
Application rate (g/ha)	1 × 150				
Reprod. toxicity (mg/kg bw/d)	15				
TER criterion	5				
Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
BBCH > 20	Small insectivorous mammal “shrew”	1.9	0.53	0.15	99.30
BBCH > 40	Small herbivorous mammal “vole”	28.9	0.53	2.30	6.53
BBCH 10-39	Large herbivorous mammal “lagomorph”	14.3	0.53	1.14	13.19
BBCH > 40	Large herbivorous mammal “lagomorph”	5.7	0.53	0.45	33.10
BBCH 10-39	Small omnivorous mammal “mouse”	7.8	0.53	0.62	24.19
BBCH > 40	Small omnivorous mammal “mouse”	3.1	0.53	0.25	60.86

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.

No unacceptable long-term risk for reproduction was indicated at Tier 1 risk assessment for use of SHA 6100 A / ALIVE in Root & stem vegetables.

zRMS comments:

The acute TER_A values are greater than value 10, indicating an acceptable risk to mammals from Exposure to propaquizafop following the use of Alive.

The long-term TER_{LT} values are greater than value of 5 for Root & steam Vegetables**,** Strawberries, Potatoes and OSR indicating an acceptable risk to mammals from exposure to propaquizafop following the use of Alive.

However, based on the worst-case use rate higher tier risk refinement is required for the small herbivorous vole in the following crops:

- Bulb and onion like crops (BBCH ≥ 40)

- Leafy vegetables (BBCH 40-49)
- Pulses (BBCH 40-49)

According to the GAP for **leafy vegetables and pulses the application is at BBCH <40.**

Therefore, no further refinement for these crops for vole is required further.

The generic focal species for the small herbivorous scenario (Tier 1) is the vole (*Microtus arvalis*) feeding on grass exclusively. The vole weighs 25 g. The relevant RUD as presented in Appendix F of the guidance document (EFSA 2009) is 54.2 mg a.s./kg (for grass and cereals). No interception by the crop is taken into account.

In a conservative approach for Tier 1 it is assumed that the vole solely feeds on green plant material of the category grasses and cereals with the highest default mean RUD of 54.2 mg a.s./kg.

In contrast to these worst-case assumptions, voles are reported to feed on other food items as well. Thus, voles in varying significant proportions feed also on dicotyledonous plants (as broad-leafed weeds) for which the default RUD of 28.7 mg a.s./kg is distinctly lower.

We agree that a lot are many reports from the literature that the optimum or prime habitat‘ of common voles is undisturbed grassland or set-aside at a vegetation height of minimum 20 cm (De Jonge and Dienske, 1979; Delattre et al., 1996; Butet and Leroux, 2001; Giraudoux et al., 1994; Gorman and Reynolds, 1993) or perennial crops like alfalfa (Truszkowski, 1982).

Leutert (1983)[1] investigated the food piles of voles (the animals are known to harvest the plant material and take it to protected places as the entrance of their burrows or special food chambers) in fertilized and unfertilized meadows. The author gives percentages of the plant coverage of grasses and dicotyledonous weeds (herbs and legumes) on the study area and the relative frequencies in the food piles of the animals. The average occurrence in food piles from three trials (in June and September 1980 and June 1981) here was 60% monocotyledonous and 40% dicotyledonous plants and 29% versus 71% on fertilized and unfertilized meadows, respectively. In this case, the percentages of the two plant categories more or less reflect the coverage of the investigated plots (62% and 38% or 29 and 71% mono- and dicots in fertilized and unfertilized meadows, respectively). Taking the average of the preferences in the two meadow types results in a vole diet of 44.5% mono- and 55.5% dicotyledonous plants.

In addition, for meadows in Hessia (Germany) based on an analysis of stomach contents Rinke (1990[2] and 1991[3]) reports percentages of around 37% and 63% mono- and dicotyledonous plants, respectively in the diet of voles was observed. However, on these permanent meadows, the biomass of dicotyledonous plants accounts for only about 30% and that of grasses 70% of the total biomass. This indicates a

[1] Leutert A. (1983): Einfluss der Feldmaus, *Microtus arvalis* (Pall.), auf die floristische Zusammensetzung von Wiesen-ékosystemen. Veröffentlichung des Geobotanischen Institutes der Eidg. Techn. Hochschule, Stiftung Rübel, Zürich.

[2] Rinke T. (1990): Zur Nahrungsökologie von *Microtus arvalis* (Pallas, 1779) auf Dauergrünland. Z. Säugetierkunde 55; 106-116.

[3] Rinke T. (1991): Percentage of volume versus number of species: Availability and intake of grasses and forbs in *Microtus arvalis*. Folia Zoologica 40(2); 143-151.

clear preference of voles for dicotyledonous plants.

Alive is a herbicide used as a treatment against grass weeds. It exerts its activity very quickly with symptoms already appearing a few days after application. The destruction of green plant matter, however, renders the plants less attractive and palatable for herbivorous mammals and it can be assumed that especially the fraction of grasses as the target plants of the treatment will decrease in the diet of the herbivorous species. Accordingly, the proportions of plant material in the diet of voles will decrease in general and/or will shift towards feed items with lower residue levels. However, it is even more likely that voles will avoid feeding on the treated areas.

It should be noted also that the ground vegetation height is considered to be a critical component of habitat quality based on literature data.

Numerous studies have demonstrated that cover (e.g. tall vegetation) is the most important determinant of habitat selection for voles. For example, a study in Finland that used radio-telemetry to assess habitat use by field vole (*Microtus agrestis*) in vegetative buffer strips, the authors found that radio-tracked voles consistently preferred buffer zones (>15 m wide, with tall vegetation) over crop fields (Yletyinen and Norrdahl, 2008). Clear habitat preference by voles was demonstrated in a radio tracking study done in Switzerland. Briner *et al.* (2005[4]) found that wildflower strips adjacent to crop land were high quality habitats for common vole *Microtus arvalis* and could support large populations without the risk of voles dispersing into adjacent fields.

The authors' conclusion that vegetation cover is a more important characteristic for habitat selection of voles **than food is consistent with those of other researchers** (Lima and Dill 1990[5], Sullivan 2006[6], Byers and Young 1978[7], Sullivan *et al.* 1998.

The common vole (*Microtus arvalis*) was identified in SANCO/4145/2000 and EFSA Guidance Document (2009) as the small herbivorous focal species feeding in different crops mainly due to its high abundance and strong preference for grassland habitats.

The bulb and onion like crops, leafy vegetables, and pulses (at Tier 1), are rotated crops without grassland patches and are unlikely to have established small mammal territories.

They can be considered unsuitable habitat for the common vole.

It should be noted that for leafy vegetables and pulses the vole is identified as a generic focal species only from BBCH40-49.

Based on the weight of evidence approach zRMS is in the opinion that the wood mouse

(Apodemus sylvaticus) is the far more realistic focal species for the risk assessment of small mammals

[4]Briner, T.; Nentwig, W.; Airoldi, J. P. (2005): Habitat quality of wildflower strips for common voles Microtus arvalis and its relevance for agriculture. Agric. Ecosyst. Environ. 105, 173–179.

[5] Lima S. L. and Dill L.M. (1990): Behavioural decisions made under the risk of predation – a review and prospectus. Can. J. Zool. 68, 619-640.

[6] Sullivan T.P. (2006): Vole populations, tree fruit orchards and living mulches. Report of center of Sustaining Agricultural and Natural Resources, Washington State University, Wenatchee, WA.

[7] Byers R. E. and Young R.S. (1978): Effect of orchard culture on pine vole activity. J. Am. Soc. Hort. Sci. 103, 625-626.

(omnivorous), for which the outcome of the Tier 1 risk assessment does not indicate a risk.

However, the decision on taking the wood mouse as focal species for Bulbs & onion like crops instead of the vole should preferably be made on MS-Level.

Higher-tier risk assessment

Not relevant

Conclusion

According to screening and tier I assessments, all the TER_a and TER_{lt} values for the active substance Propaquizafop are greater than the Annex VI trigger of 10 and 5, respectively, indicating that SHA 6100 A / ALIVE presents no unacceptable acute and long-term risk to mammals according to the intended use in all crops.

9.3.2.2 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Puddle scenario

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 (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 2220 L/kg, Propaquizafop belongs to the group of more sorptive substances.

Effective application rate (g/ha)	=	120		
Acute toxicity (mg/kg bw)	=	3009	quotient	= 0.04
Reprod. toxicity (mg/kg bw/d)	=	15	quotient	= 8.00

As the ratios do not exceed the value of 3000 for Propaquizafop, it is not necessary to conduct a drinking water risk assessment for bird.

9.3.2.3 Effects of secondary poisoning

The log P_{ow} of Propaquizafop amounts to 4.78 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

Table 9.3-11: Assessment of the risk for earthworm-eating mammals due to exposure to Propaquizafop via bioaccumulation in earthworms (secondary poisoning) for the intended use in all crops

Parameter	Propaquizafop	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.029	B8
log P_{ow} / P_{ow}	4.78 / 60255.96	LOEP
Koc	2200	Estimated using Briggs equation from log Kow
foc	0.02	Default
BCF_{worm}	16.453	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.477	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.611	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	15	LOEP
TER_{lt}	24.56	No risk, TERlt > 5

TER values shown in bold fall below the relevant trigger.

Conclusion
The daily dose value was compared with long-term NOAEL value of 15 mg/kg bw/day which resulted in a TER value of 24.56. This value exceeds the relevant Annex VI trigger of 5 and confirms that the risk posed to mammals by the consumption of earthworms is low.

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water as a limit value for admissible concentrations of Propaquizafop in water.

Table 9.3-12: Assessment of the risk for fish-eating mammals due to exposure to Propaquizafop via bioaccumulation in fish (secondary poisoning) for the intended use in all crops

Parameter	Propaquizafop	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.01401	B8
BCF_{fish}	1243	LOEP
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	17.288	PECf.ish = PECwater × BCFfish
Daily dietary dose (mg/kg bw/d)	1.301	DDD = PECfish × 0.142 x TWA
NOEL (mg/kg bw/d)	15	LOEP
TER_{lt}	11.53	No risk, TERlt > 5

TER values shown in bold fall below the relevant trigger.

Conclusion
The daily dose value was compared with long-term NOAEL value of 15 mg/kg bw/day which resulted in a TER value of 11.53. This value exceeds the relevant Annex VI trigger of 5 and confirms that the risk posed to mammals by the consumption of fish is low.

zRMS comments:

The risk for fish-eating mammals due to exposure to Propaquizafop via bioaccumulation in fish

(secondary poisoning) for the intended use in all crops is considered acceptable.

9.3.2.4 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, pills or treated seed

Not relevant.

9.3.4 Overall conclusions

According to screening and tier I assessments, all the TER_a and TER_{lt} values for the active substance Propaquizafop are greater than the Annex VI trigger of 10 and 5, respectively, indicating that SHA 6100 A / ALIVE presents no unacceptable acute and long-term risk to mammals according to the all intended use.

Propaquizafop has been shown to have the potential for bioaccumulation, however, there is no risk to earthworm and fish-eating mammals according to the intended use of SHA 6100 A / ALIVE.

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

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with Propaquizafop and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of SHA 6100 A / ALIVE were not evaluated as part of the EU assessment of Propaquizafop.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Propaquizafop and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Mirror carp *Cyprinus carpio*	Propaquizafop	96 hr, f	**LC_{50} = 0.19 mg a.s./L**	EFSA, 2008
Rainbow trout *Oncorhynchus mykiss*	Propaquizafop	28 d, f (ELS)	**NOEC = 0.019 mg a.s./L**	EFSA, 2008
Rainbow trout *Oncorhynchus mykiss*	Quizalofop	96 hr, s	**LC_{50} > 100 mg a.s./L $_{nom}$***	EFSA, 2008
Rainbow trout *Oncorhynchus mykiss*	Quizalofop	28 d ,f	**NOEC = 46.2 mg a.s./L $_{mm}$****	EFSA, 2008
Rainbow trout *Oncorhynchus mykiss*	Hydroxy quizalofop	96 hr, s	**LC_{50} > 100 mg a.s./L $_{mm}$***	EFSA, 2008
Rainbow trout *Oncorhynchus mykiss*	Dihydroxy quinoxaline	96 h, s	**LC_{50} > 11.2 mg a.s./L $_{mm}$***	EFSA, 2008
Rainbow trout *Oncorhynchus mykiss*	Quizalofop phenol	96 h, s	LC_{50} = 1.3 mg a.s./L $_{mm}$*	EFSA, 2008
Rainbow trout *Oncorhynchus mykiss*	Hydroxy quinoxaline	96 h, s	**LC_{50} = 15.6 mg a.s./L $_{mm}$***	EFSA, 2008
Daphnia magna	Propaquizafop	48 h, s	**EC_{50} > 0.9 mg a.s./L**	EFSA, 2008
Daphnia magna	Propaquizafop	21 d, f	**NOEC = 0.44 mg a.s./L**	EFSA, 2008
Daphnia magna	Quizalofop	48 h, s	**EC_{50} = 57.7 mg a.s./L $_{mm}$****	EFSA, 2008
Daphnia magna	Quizalofop	21 d, ss	**NOEC = 0.82 mg a.s./L $_{mm}$****	EFSA, 2008
Daphnia magna	Hydroxy quizalofop	48 h, s	**EC_{50} > 100 mg a.s./L $_{nom}$***	EFSA, 2008
Daphnia magna	Dihydroxy quinoxaline	48 h, s	**EC_{50} > 9.8 mg a.s./L $_{mm}$***	EFSA, 2008
Daphnia magna	Quizalofop phenol	48 h, s	EC_{50} = 2.8 mg a.s./L $_{mm}$*	EFSA, 2008
Daphnia magna	Hydroxy quinoxaline	48 h, s	**EC_{50} > 19.2 mg a.s./L $_{mm}$***	EFSA, 2008
Chironomus riparius	Quizalofop	28 d, s Water spiked sys.	**NOEC = 35.7 mg a.s./L $_{nom}$****	EFSA, 2008
Chironomus riparius	Quizalofop phenol	28 d, s Sediment spiked sys.	NOEC = 10 mg a.s./kg $_{nom}$**	EFSA, 2008
Chironomus riparius	Dihydroxy quinoxaline	28 d, s Sediment spiked sys.	**NOEC > 1.48 mg a.s./kg $_{mm}$*****	EFSA, 2008
Pseudokirchneriella subcapitata	Propaquizafop	72 h, s	**E_bC_{50} > 2.1 mg a.s./L** **E_rC_{50} > 2.1 mg a.s./L**	EFSA, 2008
Pseudokirchneriella subcapitata	Quizalofop	72 h, s	**E_bC_{50} = 54.5 mg a.s./L $_{mm}$****	EFSA, 2008
Pseudokirchneriella subcapitata	Hydroxy quizalofop	72 h, s	**E_bC_{50} > 100 mg a.s./L $_{nom}$*** **E_rC_{50} > 100 mg a.s./L $_{nom}$**	EFSA, 2008

Species	Substance	Exposure System	Results	Reference
Scenedesmus subspicatus	Dihydroxy quinoxaline	72 h, s	**E_bC_{50} > 8.6 mg a.s./L $_{mm}$*** **E_rC_{50} > 8.6 mg a.s./L $_{mm}$**	EFSA, 2008
Scenedesmus subspicatus	Quizalofop phenol	72 h, s	E_bC_{50} > 4.5 mg a.s./L $_{nom}$*	EFSA, 2008
Scenedesmus subspicatus	Hydroxy quinoxaline	72 h, s	**E_bC_{50} > 18.8 mg a.s./L $_{mm}$*** **E_rC_{50} > 18.8 mg a.s./L $_{mm}$**	EFSA, 2008
Lemna gibba	Propaquizafop	7 d, s	**EC_{50} > 1.4 mg a.s./L**	EFSA, 2008
Lemna gibba	Quizalofop	14 d, s	EC_{50} =28 mg a.s./L $_{nom}$*** NOEC = 3.2 mg a.s./L $_{nom}$	EFSA, 2008
Glyceria fluitans	Quizalofop	14 d, s	EC_{50} > 0.190 mg a.s./L* **NOEC = 0.094 mg a.s./L**	EFSA, 2008

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations
* Endpoint from propaquizafop DAR
** Endpoint from quizalofop-P-ethyl DAR
*** Endpoint from quizalofop-P-tefuryl DAR

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – SHA 6100 A / ALIVE

Species	Substance	Exposure System	Results	Reference
Rainbow trout *Oncorhynchus mykiss*	SHA 6100 A / ALIVE	96 h, ss	LC_{50} = 0.3428 mg a.s./L	KCP 10.2.1-01
Daphnia magna	SHA 6100 A / ALIVE	48h, ss	EC_{50} = 0.25 mg a.s./L	KCP 10.2.1-02 Kulec-Płoszczyca E., W/150/17
Pseudokirchneriella subcapitata	SHA 6100 A / ALIVE	72h, s	ErC_{50} = 0.5338 mg a.s./L EyC_{50} = 0.2789 mg a.s./L	KCP 10.2.1-03 Kulec-Płoszczyca E., W/149/17
Lemna gibba	SHA 6100 A / ALIVE	7d, ss	ErC_{50} = 0.9293 mg a.s./L	KCP 10.2.1-04 Kulec-Płoszczyca E., W/151/17
Common carp *Cyrpinus carpio*	Formulation	96 h, f	LC_{50} = 0.11 mg/L	EFSA, 2008
Daphnia magna	Formulation	48 h, s	EC_{50} > 0.24 mg a.s./L	EFSA, 2008
Scenedesmus subspicatus	Formulation	72 h, s	E_bC_{50} = 0.27 mg a.s./L E_rC_{50} = 0.15 mg a.s./L	EFSA, 2008
Higher-tier studies (micro- or mesocosm studies)				
Not required. A low level of risk to aquatic organisms expected following the recommended use of products containing Propaquizafop, based on the current GAP.				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

9.5.1.1 Justification for new endpoints

There is no deviation from the EU agreed endpoints.

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).
The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.

In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}, PEC_{SED}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Propaquizafop for each organism group based on FOCUS Steps 1 and 2 calculations for the use of SHA 6100 A / ALIVE to appln. hand (crop < 50 cm) (1 x 150 g/ha)

Group		**Fish acute**	**Fish acute***	**Fish pro-longed**	**Inverteb.* acute**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae***	**Algae**	**Higher plant***	**Higher plant**
Test species		***Cyprinus carpio***		***Oncorhyn-chus mykiss***	***Daphnia magna***	***Daphnia magna***	***Daphnia magna***	***Pseudokirch-neriella sub-capitata***	***Pseudokirch-neriella sub-capitata***	***Lemna gibba***	***Lemna gibba***
End-point		LC_{50}	LC_{50}	NOEC	EC_{50}	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	E_rC_{50}/E_yC_{50}	EC_{50}	EC_{50}
(µg/L)		190	342.8	19	250	900	440	278.9	2100	929.3	1400
AF		100	100	10	100	100	10	10	10	100	10
RAC (µg/L)		1.9	34.28	1.9	2.5	9	44	27.89	210	9.293	140
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**										
Step 1											
	14.01	**7.37**	0.40	**7.37**	**5.60**	**1.55**	0.32	0.50	0.6671	**1.51**	0.1
Step 2											
N-Europe											
Oct-Feb	2.53	**1.33**		**1.33**	**1.01**	0.28	0.06	0.09		0.27	
March-May	1.38	0.73		0.73	0.55		0.03	0.05		0.15	
June-Sept											
S-Europe											
Oct-Feb	2.03	**1.07**		**1.07**	0.81		0.05	0.07		0.22	

Group		Fish acute	Fish acute*	Fish pro-longed	Inverteb.* acute	Inverteb. acute	Inverteb. prolonged	Algae*	Algae	Higher plant*	Higher plant
March-May											
June-Sept	1.53	0.81		0.81	0.61		0.03	0.05		0.16	
Step 3											
D1/ditch	0.959	0.50		0.50	0.38		0.02	0.03		0.10	
D1/stream	0.839	0.44		0.44	0.34		0.02	0.03		0.09	
D2/ditch	0.960	0.51		0.51	0.38		0.02	0.03		0.10	
D2/stream	0.854	0.45		0.45	0.34		0.02	0.03		0.09	
D3/ditch	0.945	0.50		0.50	0.38		0.02	0.03		0.10	
D4/pond	0.033	0.02		0.02	0.01		0.00	0.00		0.004	
D4/stream	0.819	0.43		0.43	0.33		0.02	0.03		0.09	
D5/pond	0.033	0.02		0.02	0.01		0.001	0.001		0.004	
D5/stream	0.884	0.47		0.47	0.35		0.02	0.03		0.10	
D6/ditch	0.956	0.50		0.50	0.38		0.02	0.03		0.10	
R1/pond	0.033	0.02		0.02	0.01		0.001	0.00		0.004	
R1/stream	0.623	0.33		0.33	0.25		0.01	0.02		0.07	
R3/stream	0.865	0.46		0.46	0.35		0.02	0.03		0.09	
R4/stream	0.627	0.33		0.33	0.25		0.01	0.02		0.07	

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

***Data from formulation studies**

Table 9.5-4: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Quizalofop for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SHA 6100 A / ALIVE to appln. hand (crop < 50 cm) (1 x 150 g/ha)**

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plant**	**Higher plant**		**Sed. dwell. prolonged**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Glyceria fluitans***	***Glyceria fluitans***		***Chironomus riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	EC_{50}	NOEC		NOEC
(µg/L)		100000	46200	57700	820	54500	190	94		35700
AF		100	10	100	10	10	100	10		10
RAC (µg/L)		1000	4620	577	82	5450	1.9	9.4		3570
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**								**$PEC_{sed-max}$ (µg/kg)**	
Step 1										
	48.83	0.05	0.01	0.08	0.60	0.01	**25.70**	**5.19**	189.14	0.05
Step 2										
N-Europe										
Oct-Feb	15.79	0.02	0.003	0.03	0.19	0.003	**8.31**	**1.68**	61.45	0.02
March-May	6.78	0.01	0.001	0.01	0.08	0.001	**3.57**	0.72	25.97	0.01
June-Sept										
S-Europe										
Oct-Feb	12.79	0.01	0.003	0.02	0.16	0.002	**6.73**	**1.36**	49.56	0.01
March-May										
June-Sept	9.78	0.01	0.002	0.02	0.12	0.002	**5.15**	**1.04**	37.68	0.01

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher plant**	**Higher plant**		**Sed. dwell. prolonged**
Step 3										
D1/ditch	1.638	0.002	0.0004	0.003	0.020	0.0003	0.86	0.17	5.897	0.002
D1/stream	1.033	0.001	0.0002	0.002	0.013	0.0002	0.54	0.11	3.341	0.001
D2/ditch	2.921	0.003	0.0006	0.005	0.036	0.0005	**1.54**	0.31	5.106	0.001
D2/stream	1.873	0.002	0.0004	0.003	0.023	0.0003	0.99	0.20	2.826	0.001
D3/ditch	0.065	0.0001	0.00001	0.0001	0.001	0.00001	0.03	0.01	0.091	0.0000
D4/pond	0.062	0.0001	0.00001	0.0001	0.001	0.00001	0.033	0.01	0.357	0.0001
D4/stream	0.195	0.0002	0.00004	0.0003	0.002	0.00004	0.10	0.02	0.174	0.00005
D5/pond	0.040	0.00004	0.00001	0.0001	0.0005	0.00001	0.021	0.00	0.253	0.0001
D5/stream	0.173	0.0002	0.00004	0.0003	0.002	0.00003	0.09	0.02	0.070	0.00002
D6/ditch	2.059	0.002	0.0004	0.004	0.025	0.0004	**1.08**	0.22	1.263	0.0004
R1/pond	0.087	0.0001	0.00002	0.0002	0.001	0.00002	0.046	0.01	0.576	0.0002
R1/stream	0.575	0.001	0.0001	0.001	0.007	0.0001	0.30	0.06	0.454	0.0001
R3/stream	0.803	0.001	0.0002	0.001	0.010	0.0001	0.42	0.09	10.46	0.003
R4/stream	1.115	0.001	0.0002	0.002	0.014	0.0002	0.59	0.12	0.573	0.0002

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

Table 9.5-5: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Hydroxy-Quizalofop for each organism group based on FOCUS Steps 1 and 2 calculations for the use of SHA 6100 A / ALIVE to appln. hand (crop < 50 cm) (1 x 150 g/ha)**

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Cyprinus carpio***	***Daphnia magna***	***Pseudokirchneriella sub-capitata***
Endpoint (µg/L)		LC_{50} 100000	EC_{50} 100000	E_rC_{50}/E_yC_{50} 100000
AF		100	100	10
RAC (µg/L)		1000	1000	10000
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1				
	15.88	0.02	0.02	0.002
Step 2				
N-Europe				
Oct-Feb	5.74	0.01	0.006	0.001
March-May	2.38	0.002	0.002	0.0002
June-Sept				
S-Europe				
Oct-Feb	4.62	0.005	0.005	0.0005
March-May				
June-Sept	3.50	0.004	0.004	0.0004

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

Table 9.5-6: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Dihydroxy-quinoxaline for each organism group based on FOCUS Steps 1 and 2 calculations for the use of SHA 6100 A / ALIVE to appln. hand (crop < 50 cm) (1 x 150 g/ha)**

Group		**Fish acute**	**Inverteb. acute**	**Algae**		**Sed. dwell. prolonged**
Test species		***Cyprinus carpio***	***Daphnia magna***	***Scenedesmus subspicatus***		***Chironomus riparius***
Endpoint		LC_{50}	EC_{50}	E_rC_{50}/E_yC_{50}		NOEC
(µg/L)		11200	9800	8600		1480
AF		100	100	10		10
RAC (µg/L)		112	98	860		148
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**				**PEC_{sed}-max (µg/kg)**	
Step 1						
	3.45	0.03	0.04	0.004	15.83	0.11
Step 2						
N-Europe						
Oct-Feb	1.24	0.01	0.01	0.001	5.72	0.04
March-May	0.53	0.005	0.005	0.0006	2.40	0.02
June-Sept						
S-Europe						
Oct-Feb	1.00	0.01	0.01	0.001	4.62	0.03
March-May						
June-Sept	0.77	0.007	0.008	0.0009	3.51	0.02

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

Table 9.5-7: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Hydroxy-Quinoxaline for each organism group based on FOCUS Steps 1 and 2 calculations for the use of SHA 6100 A / ALIVE to appln. hand (crop < 50 cm) (1 x 150 g/ha)**

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Cyprinus carpio***	***Daphnia magna***	***Scenedesmus subspicatus***
Endpoint (µg/L)		LC_{50} 15600	EC_{50} 19200	E_rC_{50}/E_yC_{50} 18800
AF		100	100	10
RAC (µg/L)		156	192	1880
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**			
Step 1				
	2.15	0.01	0.01	0.001
Step 2				
N-Europe				
Oct-Feb	0.74	0.005	0.004	0.0004
March-May	0.32	0.002	0.002	0.0002
June-Sept				
S-Europe				
Oct-Feb	0.60	0.004	0.003	0.0003
March-May				
June-Sept	0.46	0.003	0.002	0.0002

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

9.5.3 Overall conclusions

Propaquizafop
Calculated PEC/RAC ratios in all FOCUS Steps 1-2 and scenarios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish acute and fish prolonged as characterised by a LC_{50} and a NOEC for respectively *Cyprinus carpio* and *Oncorhynchus mykiss* of 190 µg/L and 19 µg/L in connection with an assessment factor of 100 and 10, respectively).

Metabolites of Propaquizafop
For all the intended uses, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

zRMS comments:

Calculated PEC/RAC ratios in all FOCUS Steps 1-2 and scenarios for Propaquizafop indicates an acceptable risk for the most sensitive group of aquatic organisms (risk for fish acute and fish prolonged as characterised by a LC_{50} and a NOEC for respectively Cyprinus carpio and Oncorhynchus *mykiss* of 190 µg/L and 19 µg/L in connection with an assessment factor of 100 and 10, respectively).
For all the intended uses, calculated PEC/RAC ratios for metabolites of Propaquizafop indicates an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with Propaquizafop. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on bees of SHA 6100 A / ALIVE were not evaluated as part of the EU assessment of Propaquizafop. New data submitted with this application ~~are listed in **Błąd! Nie można odnaleźć źródła odwołania.** and~~ summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Propaquizafop	Oral	LD_{50} > 20 µg/bee	EFSA, 2008 ~~DAR, 2005~~
		Contact	LD_{50} > 200 µg/bee	EFSA, 2008 ~~DAR, 2005~~
Apis mellifera	Formulation 100 g/L EC	Oral	LD_{50} > 189 product/bee; (approximately >18.9 µg a.s./bee)	EFSA, 2008 DAR, 2005
		Contact	LD_{50} > 189 product/bee; (approximately >18.9 µg a.s./bee)	EFSA, 2008 ~~DAR, 2005~~
Apis mellifera	SHA 6100 A / ALIVE	Oral	LD_{50} /24h = 331.9 µg/bee (32.2 µg a.i./bee) LD_{50} /48h = 342.8 µg/bee (33.2 µg a.i./bee)	KCP 10.3.1.1.1 Paweł Parma. 2017, Report No. B/116/16
		Contact	LD_{50} /24h > 400 µg/bee (40 µg a.i./bee) LD_{50} /48h > 400 µg/bee (40 µg a.i./bee)	KCP 10.3.1.1.2 Paweł Parma. 2017, Report No. B/117/16
Higher-tier studies (tunnel test, field studies)				
None				

9.6.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints. In addition, new acute toxicity studies were performed with the formulation SHA 6100 A / ALIVE and therefore the resulting endpoints are used in the risk assessment on the product.

9.6.2 Risk assessment

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).

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of SHA 6100 A / ALIVE in all crops

Intended use	All crops		
Active substance	Propaquizafop		
Application rate (g/ha)	1 x 150		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	20	120	7.50
Contact toxicity	200		0.75
Product	SHA 6100 A / ALIVE		
Application rate (g/ha)	1 x 1546.5		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	342.8	1546.5*	4.51
Contact toxicity	> 400		3.87

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.
* Based on a density of 1.031 g/mL

zRMS comments:

The risk to bees for SHA 6100A/ALIVE was assessed in line with the Terrestrial Guidance document (2002).

Both hazard quotients for oral and contact toxicity for honey bees are considerably lower than 50, indicating that the proposed uses of SHA 6100A/ALIVE poses an acceptable risk.

According to EU Reg. 284 /2009, the chronic toxicity test for adult bees, the chronic test for larvae should be provided for authorisation of plant protection product.

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

9.6.3 Effects on bumble bees

Not relevant.

9.6.4 Effects on solitary bees

Not relevant.

9.6.5 Overall conclusions

First-tier assessments indicate that no unacceptable risk for bees exposed to the product SHA 6100 A / ALIVE is expected according to the proposed intended uses.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with Propaquizafop. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on non-target arthropods of SHA 6100 A / ALIVE were not evaluated as part of the EU assessment of Propaquizafop. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	Propaquizafop (100 g/l EC formulation)	Laboratory test Glass plate (2D)	LR_{50} > 8 g a.s /ha (4% mortality at exposure equivalent to 4% spray-drift)	EFSA,2008 DAR,2005
Typhlodromus pyri (protonymphs)	Propaquizafop (100 g/l EC formulation)	Laboratory test Glass plate (2D)	LR_{50} = 200 g a.s /ha	EFSA,2008 DAR,2005
Aphidius rhopalosiphi	Propaquizafop (100 g/l EC formulation)	Laboratory test Glass plate (2D)	LR_{50} < 150 g a.s /ha (100% mortality)	EFSA,2008 DAR,2005
Chrysoperla carnea (adults)	Propaquizafop (100 g/l EC formulation)	Laboratory test Glass plate (2D)	At dose 200 g a.s./ha: Corrected mortality: 12% Reduction in reproductive capacity: 0%	EFSA,2008 DAR,2005
Coccinella Septempunctata (adults)	Propaquizafop (100 g/l EC formulation)	Laboratory test Glass plate (2D)	At dose 200 g a.s./ha: Corrected mortality: 23 % Reduction in reproductive capacity: 6.1 %	EFSA,2008 DAR,2005
Poecilus cupreus (adults)	Propaquizafop (100 g/l EC formulation)	Laboratory test Quartz sand (2D)	At dose 200 g a.s./ha: Corrected mortality: 3% Reduction in feeding rate: 19%	EFSA,2008 DAR,2005
Aleochara bilineata (adults)	Propaquizafop (100 g/l EC formulation)	Laboratory test Quartz sand (2D)	At dose 200 g a.s./ha: Reduction in reproductive capacity: 17%	EFSA,2008 DAR,2005
Typhlodromus pyri (protonymphs)	Propaquizafop (100 g/l EC formulation)	Extended laboratory Bean leaves (3D)	At dose 200 g a.s./ha: Corrected mortality: 3.2% Reduction In reproductive capacity:	EFSA,2008 DAR,2005

Species	Substance	Exposure System	Results	Reference
			15%	
Aphidius rhopalosiphi (adults)	Propaquizafop (100 g/l EC formulation)	Extended laboratory Barley Seedlings (3D)	At dose 150 ga.s./ha: Corrected mortality: 6.7 % Reduction in reproductive capacity: 59%	EFSA,2008 DAR,2005
Aphidius rhopalosiphi (adults)	Propaquizafop (100 g/l EC formulation)	Extended laboratory Barley Seedlings (3D)	At dose 28 g a.s./ha: Corrected mortality: 8% Reduction in reproduction: 34%	EFSA,2008 DAR,2005
			At dose 200 g a.s./ha: Corrected mortality: 0% Reduction in reproduction: 66%	EFSA,2008 DAR,2005
Aphidius rhopalosiphi	SHA 6100 A / ALIVE	Extended laboratory Barley Seedlings (3D)	LR50 > 8L/ha (>800 g a.i./ha) ER50 = 5.3L/ha (530 g.a.i./ha) At 8L/ha (800 g a.i./ha): Mortality 46.7% Reduction in reproduction: 59.9%	KCP 10.4.2-3 Parma P., B/118/16, 2018
Typhlodromus pyri (protonymphs)	SHA 6100 A / ALIVE	Laboratory test	LR50 > 6L/ha (>600 g a.i./ha) ER50 > 6L/ha (>600 g a.i./ha) At 6L/ha (600 g a.i./ha): Mortality 8.3% Reduction in reproduction: -8.3% (stimulation)	KCP 10.4.2-2 Parma P., B/119/16, 2018

9.7.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods 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), and in consideration of the recommendations of the guidance document ESCORT 2.

Risk assessment for in-field exposure

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of SHA 6100 A / ALIVE in all crops

Intended use	All crops		
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE		
Application rate (g a.s./ha)	1 × 150		
MAF	1		
Test species Tier I	**LR_{50} (lab.) (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	>600	150	0.28
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Aphidius rhopalosiphi	530	150	Yes

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment. Criteria values shown in bold breach the relevant trigger.

* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

Conclusion

The tier I in-field HQ values calculated for Propaquizafop for the representative species *T. pyri* indicate no potential high risk for non-target arthropods.
For *A. rhopalosiphi*, the tier I in-field HQ values cannot be determined with precision. However, the higher-tier assessment showed a mortality <50% at rates greater than the in-crop rate of the control at 800 g/ha, the risk posed to *A. rhopalosiphi* in-crop is thus considered acceptable.
These results indicate an acceptable infield risk to non-target arthropods.

9.7.2.1 Risk assessment for off-field exposure

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of SHA 6100 A / ALIVE in all crops

Intended use	All crops				
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE				
Application rate (g a.s./ha)	1 x 150				
MAF	1				
vdf	10 (Tier 1) / 1 (Higher-tier)				
Test species Tier I	**LR_{50} (lab.) (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	>600	0.0277	0.42	10	0.007
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**corr. $PER_{off\text{-}field}$ below rate with ≤ 50 % effect?**
Aphidius rhopalosiphi	530	0.0277	4.16	5	Yes

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

Conclusion

The tier I off-field HQ values calculated for Propaquizafop for the representative species *T. pyri* indicate no potential high risk to non-target arthropods.
For *A. rhopalosiphi*, the tier I off-field HQ was not determined. However, the higher-tier assessment showed a mortality <50% at rates greater than the off-crop rate of the control at 530 g/ha, the risk posed to *A. rhopalosiphi* off-crop is thus considered acceptable.

zRMS comment:

The calculations of the risk assessment for in – field for SHA 6100l/Alive for two indicator species were accepted by zRMS-PL. HQ in - field and HQ off-field are below 2 based on laboratory studies (Tier1) in case of T.pyri species.

For the second species - A. rhopalosiphi the PER in-field and PER_{off}-field corrected (based on the extended laboratory studies) are below the rate with ≤ 50 % effects, indicted the acceptable risk.

However, it should be noted that according ESCORT 2 the one additional species is required due to the fact that the tier 1 glass plate studies for A. rhopalosiphi is not provided.

It can be assumed there is a potential in-field and off-field risk at tier 1 for one species.

However, there are available studies for three additional species for Propaquizafop 100 EC evaluted at EU level.

Based on the comparison on the content of active substance and co – formulates in Propaquizafop 100 EC and in Alive in PART C the total difference between the composition of both formulation is 1.04%. From the physico-chemical and ecotoxicological point of view both formulations can be considered comparable. Therefore, the laboratory studies for additional species NTA is nor required.

No risk is conluded for these species in -field and off-field for aplication rate of 200 g a.s./ha, which covers the proposed uses for Alive.

Therefore, this assessment indicates that Alive poses low risk to in-field and off-field non-target arthropods following application according to the proposed use patterns.

9.7.2.2 Additional higher-tier risk assessment

Not relevant.

9.7.2.3 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

Calculations indicate no risk to non-target arthropods in in-field and off-field areas following application of SHA 6100 A / ALIVE according to the proposed use pattern.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with Propaquizafop and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of SHA 6100 A / ALIVE were not evaluated as part of the EU assessment of Propaquizafop. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
Eisenia foetida	Propaquizafop	Overspray 14 d, acute 10 % peat, 20% Kaolinite clay and 70% sand	LC_{50} > 1000 mg a.s /kg soil **$LC_{50,corr}$ > 500 mg a.s./kg soil***	EFSA,2008 DAR, 2005
Eisenia foetida	Propaquizafop 100g/l formulation	Mixed into substrate 14 d, Acute 10 % peat, 20% Kaolinite clay and 70% sand	LC_{50} = 54.6 mg a.s /kg soil **$LC_{50,corr}$ = 27 mg a.s./kg soil***	EFSA,2008 DAR, 2005
Eisenia foetida	Propaquizafop 100g/l formulation	Overspray 28 d, chronic 10 % peat, 20% Kaolinite clay and 69% sand	NOEC = 3.9 mg a.s./kg soil (corrected to 1**.95 mg a.s./kg soil**)*	E EFSA,2008 DAR, 2005
Eisenia foetida	Quizalofop	Mixed into substrate 14 d, Acute 10 % sphagnum peat, 20% Kaolinite clay and 70% sand	LC_{50} = 948 mg a.s /kg soil **$LC_{50,corr}$ = 474 mg a.s./kg soil***	EFSA,2008 DAR, 2005
Eisenia foetida	Quizalofop	Mixed into substrate 14 d, Chronic 10 % sphagnum peat, 20% Kaolinite clay and 70% sand	**NOEC > 50 mg a.s /kg soil**	EFSA,2008 DAR, 2005
Eisenia foetida	Dihydroxy quinoxaline	Mixed into substrate 14 d, acute 10 % sphagnum peat, 20% Kaolinite clay and 70% sand	LC_{50} > 1000 mg a.s /kg soil **$LC_{50,corr}$ > 500 mg a.s./kg soil***	EFSA,2008 DAR, 2005
Eisenia foetida	Hydroxy quizalofop	Mixed into substrate 14 d, acute 10 % sphagnum peat, 20% Kaolinite clay and 70% sand	LC_{50} > 1000 mg a.s /kg soil **$LC_{50,corr}$ > 500 mg a.s./kg soil***	EFSA,2008 DAR, 2005
Folsomia candida	Propaquizafop 100g/l formulation	Mixed into substrate 28 d, chronic 10 % peat, 20% Kaolinite clay and 70% sand	NOEC: 5.4 mg a.s./kg soil: (corrected to 2.7 mg a.s./kg soil)*	EFSA,2008 DAR, 2005
Eisenia andrei	SHA 6100 A / ALIVE	Mixed into substrate: 5% sphagnum peat, 20% kaolin clay, 75% air-dried quartz sand Chronic 8 wks	EC50 > 560 mg/kg (>55.3 mg a.i./kg) NOEC = 18.0 mg/kg (1.7 mg a.i./kg)	KCP 10.4.1.1 Pieczka P., G/49/17, 2018
Folsomia candida	SHA 6100 A / ALIVE	Mixed into substrate: 5% sphagnum peat,	LC50 = 92.4 mg/kg (9.0 mg a.i./kg)	KCP 10.4.2-1 Pieczka P.,

Species	Substance	Exposure System	Results	Reference
		20% kaolin clay, 75% air-dried quartz sand Chronic 28 d	EC50 = 68.6 mg/kg (6.7 mg a.i./kg) NOEC = 32 mg/kg (3.1 mg a.i./kg)	G/50/1, 2018

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

9.8.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

9.8.2 Risk assessment

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).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for Propaquizafop only.

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of SHA 6100 A / ALIVE all crops

Intended use	All crops		
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Propaquizafop	>500	0.200	2500
Propaquizafop 100 g/L EC	27	0.200	135
Quizalofop	474	0.137	3460
Hydroxy quizalofop	>500	0.053	9434
Dihydroxy quinoxaline	>500	0.017	29412
Hydroxy quinoxaline	> 500*	0.007	7143
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Propaquizafop	1.95	0.029	67.2
SHA 6100 A / ALIVE	0.85	0.029	29.3
Quizalofop	50	0.126	396.8

Chronic effects on other soil macro- and mesofauna			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
SHA 6100 A / ALIVE	1.55	0.029	53
Propaquizafop	2.7	0.029	93

*TER values shown in bold fall below the relevant trigger.

The earthworms' acute and chronic TER values for the active substance and its metabolites were far above the relevant Annex VI trigger of 10 and 5. Therefore it is concluded that active substance and the relevant metabolites do not pose an acute or chronic risk to earthworms.

The soil macro- and mesofauna chronic TER values for the active substance and the metabolites were also above the relevant Annex VI trigger of 5. Therefore it is concluded that active substances and the relevant metabolites do not pose a chronic risk to other soil macro- and mesofauna.

zRMS comments:

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate). The risk assessment considering the agreed PEC_s value was presented by ZRMS-PL below:

The chronic TER values for active substances and their metabolites were above the relevant Annex VI trigger of 10 and 5, respectively.

Therefore, it is concluded that the active substances do not pose an acute and long-term risk to earthworms and other soil macro- and mesofauna when SHA6100/ALIVE is applied according to the proposed uses rates

9.8.2.2 Higher-tier risk assessment

Not required.

9.8.3 Overall conclusions

All the TER values on earthworms for Propaquizafop and its relevant metabolites are higher than the Annex VI trigger values, indicating that SHA 6100 A / ALIVE poses low acute and chronic risk to earthworms and soil other meso- and macrofauna when applied according to the proposed use rate.

Therefore, it can be concluded that SHA 6100 A / ALIVE poses low long-term risk to earthworms and other non-target soil organisms when applied according to the proposed use rate.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with Propaquizafop and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as

in Appendix 2 of this document (new studies).

Effects on soil microorganisms of formulation were not evaluated as part of the EU assessment of Propaquizafop. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Propaquizafop	28 d, loamy sand	Effect < 25% up to 1.5 kg/ha (equivalent to 2.0 mg a.s./kg soil)	EFSA,2008 DAR, 2005
N-mineralisation	Propaquizafop	56 d, silt loam soil	Effect < 25% at 0.750 kg/ha (equivalent to 1.0 mg/ kg dry soil)	EFSA,2008 DAR, 2005
C-mineralisation	Propaquizafop	28 d, sand loam and clay/clay loam	Effect < 25% up to 1.5 kg/ha (equivalent to 2.0 mg a.s./kg soil)	EFSA,2008 DAR, 2005
N-mineralisation	Propaquizafop (100 g/l EC formulation)	90 d	Effect < 25% at 0.750 Kg/ha (equivalent to 1.0 mg/ kg dry soil)	EFSA,2008
N-mineralisation	Metabolite Dihydroxy-quinoxaline	28 d, sandy loam	Effect < 25% at 0.53 mg/kg dry soil	EFSA,2008 DAR, 2005
C-mineralisation	SHA 6100 A / ALIVE	28d	Effect < 25% at 0.80 mg a.s./kg soil	KCP 10.5-2 Paweł Pieczka. 2017, Report No. G/4/17
N-mineralisation	SHA 6100 A / ALIVE	28 d	Effect < 25% at 0.16 mg a.s./kg soil	KCP 10.5-1 Paweł Pieczka. 2017, Report No. G/48/17

9.9.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints. In addition, new studies were performed with the formulation SHA 6100 A / ALIVE and therefore the resulting endpoints are used in the risk assessment on the product.

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms 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).

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of SHA 6100 A / ALIVE in all crops

Intended use	All crops		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Propaquizafop	2 (at 28 d)	0.029	Yes
Dihydroxy-quinoxaline	0.53 (at 28 d)	0.012	Yes
SHA 6100 A / ALIVE	0.16 (at 28 d)	0.029	Yes
C-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Propaquizafop	2 (at 28 d)	0.029	Yes
SHA 6100 A / ALIVE	0.8 (at 28 d)	0.029	Yes

9.9.3 Overall conclusions

Risk assessments conducted with relevant PEC_{soil} for SHA 6100 A / ALIVE indicate a low risk to soil microorganisms when applied according to the proposed use rate.

zRMS comments:

The risk assessment for soil micro-organism after exposure of the active substance and its metabolits as well as for product is accepted by the zRMS. The effects on the nitrogen transformations are acceptable (<25%) at concentration which is higher than the maximum relevant PECsoil for the maximum application rate of active substances and the product SHA 6100A/ALIVE.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with Propaquizafop. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on non-target terrestrial plants of SHA 6100 A / ALIVE were not evaluated as part of the EU assessment of Propaquizafop. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
Lettuce[1)] m Oilseed rape[2)] m Carrot[3)] m Pea[4)] m Oat[5)] d Onion[6)] d	Preparation Agil 100 EC	21 d Seedling emergence	[1)] ER_{50} emergence > 400 g/ha [2)] ER_{50} emergence > 400 g/ha [3)] ER_{50} emergence > 400 g/ha [4)] ER_{50} emergence > 400 g/ha [5)] **ER_{50} survival = 34.4 g/ha** [6)] ER_{50} emergence > 400 g/ha	EFSA,2008 DAR,2005
Lettuce[1)] m Oilseed rape[2)] m Carrot[3)] m Pea[4)] m Oat[5)] d Onion[6)] d	Preparation Agil 100 EC	21 d Vegetative vigour	[1)] ER_{50} seedling > 400 g/ha [2)] ER_{50} seedling > 351 g/ha [3)] ER_{50} seedling > 400 g/ha [4)] ER_{50} seedling > 400 g/ha [5)] **ER_{50} seedling = 26.6 g/ha** [6)] ER_{50} seedling > 400 g/ha	EFSA,2008 DAR,2005
pea sunflower cabbage carrot onion oats	SHA 6100 A / ALIVE	21 d Vegetative vigour	ER50 seedling > 240 g/ha ER50 seedling > 240 g/ha ER50 seedling > 240 g/ha ER50 seedling > 240 g/ha ER50 seedling 240 g/ha **ER50 seedling = 11.2 g/ha**	KCP 10.6.2-1 Pieczka P., G/52/17, 2019
pea sunflower cabbage carrot onion oats	SHA 6100 A / ALIVE	21 d Seedling emergence	ER50 emergence > 240 g/ha ER50 emergence > 240 g/ha ER50 emergence > 240 g/ha ER50 emergence > 240 g/ha ER50 emergence >240 g/ha **ER50 dry weight > 120 g/ha**	KCP 10.6.2-2 Pieczka P., G/51/17, 2020

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not required for herbicides as ER_{50} tests should be provided.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

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.

Table 9.10-2: Assessment of the risk for non-target plants due to the use of SHA 6100 A / ALIVE in all crops

Intended use	All crops
Active substance/product	Propaquizafop / SHA 6100 A / ALIVE
Application rate (g a.s./ha)	1 x 150
MAF	1

Test species	**More sensitive test species**	**ER_{50} (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**
~~Seedling emergence~~	~~Oat~~	~~34.4~~	0.0277	4.16	~~8.28~~
~~Vegetative vigour~~	~~Oat~~	~~26.6~~			~~6.40~~
Vegetative vigour	Oat	11.2			**2.70**
Seedling emergence	Oats	120			28.84

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The calculated TER value are ~~higher than~~ below the trigger of 5 for vegetative vigour test, indicating ~~no~~ potential risk to non-target plants.

zRMS comments:

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.
The risk assessment to non- target plants was verified by zRMS based on product data and PERoff- field.
The calculated TER value is below the trigger of 5 for vegetative vigour test, indicating potential risk to non-target plants.
The risk mitigation measures were required and were submitted under Point 9.10.2.4.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no-spray buffer zones of 5 or 10 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.

Table 9.10-3: Risk assessment for non-target terrestrial plants due to the use of SHA 6100 A / ALIVE in all crops considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		All crops			
Active substance/product		Propaquizafop / SHA 6100 A / ALIVE			
Application rate (g/ha)		1 × 150			
MAF		1.0			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off-field}$ (g/ha)**	**$PER_{off-field}$ 50 % drift red. (g/ha)**	**$PER_{off-field}$ 75 % drift red. (g/ha)**	**$PER_{off-field}$ 90 % drift red. (g/ha)**
1/3	2.77%	4.155	2.078	1.039	0,416
5	0.57%	0.855	0.428	0.214	0,086
10	0.29%	0.435	0.218	0.109	0,044
Toxicity value		**TER**			
ER_{50} = 11.2 g/ha		**criterion: TER ≥ 5**			
1/3		**2.70**	5.39	10.78	26.96
5		13.10	26.20	52.40	130.99
10		25.75	51.49	102.99	257.47

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

zRMS comments:

Based on calculation above SHA 6100 A / ALIVE shows that the Annex VI trigger value of 5 is not exceeded according to the use rates when following risk mitigations measures are taken:

- *To protect non-target plants respect an unsprayed buffer zone of 5 m to non-agricultural land OR respect 50% drift reduction technology to non-agricultural land.*

The final risk mitigation measures is required at MSs level.

9.10.3 Overall conclusions

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for SHA 6100 A / ALIVE shows that the Annex VI trigger value of 5 is not exceeded according to the use rates when following risk mitigations measures are taken:
Spe3: To protect non-target plants respect an unsprayed buffer zone of 5 m to non-agricultural land OR respect 50% drift reduction technology to non-agricultural land.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Effects on biological methods of sewage treatment was already evaluated for Annex I inclusion of Propaquizafop under directive 91/414/EEC, through the study "Test for activated sludge respiration inhibition of CGA 233380 tech." Grade, R. (2001). The results are presented below:

Test type / organism	Endpoint
Activated sludge	EC_{50} > 100 mg/l
Pseudomonas sp	no data available – not required

The EFSA conclusions drawn from the EFSA Scientific Report (2008) 204, 1-171 are the following: Propaquizafop up to a concentration of 100 mg a.s./L (the highest concentration tested) did not adversely affect the biodegradation activity of sewage micro-organisms. It was not expected that the concentrations of Propaquizafop in biological sewage treatment plants would reach a concentration of more than 100 mg a.s./L if the product were to be applied according to the GAP and therefore the risk to biological methods of sewage treatment was considered to be low.

Therefore, the risk to biological methods of sewage treatment was assessed as low.

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

	SHA 6100 A / ALIVE
Classification and proposed labelling	
With regard to ecotoxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Aquatic Acute Category 1 Aquatic Chronic Category 2 Code(s) for hazard pictogram(s): GHS09 Signal word: Warning Hazard statement(s): H411 Toxic to aquatic life with long-lasting effects Precautionary statement: P391, P501

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2.1 - 1		2019	"Propaquizafop 10% EC Rainbow trout, Acute toxicity test". . Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	Y	Sharda Cropchem Limited
KCP 10.2.1 - 2	Kulec-Płoszczyca E	2019	"Propaquizafop 10% EC Daphnia magna, acute immobilisation test". Kulec-Płoszczyca E., W/150/17, 2019. Institute of Industrial Organic Chemistry - Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1 - 3	Kulec-Płoszczyca E	2019	"Propaquizafop 10% EC Raphidocelis subcapitata SAG 61.81 (formerly Pseudokirchneriella subcapitata) Growth inhibition test". Kulec-Płoszczyca E., W/149/17, 2019. Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.2.1 - 4	Kulec-Płoszczyca E	2019	"Propaquizafop 10% EC Lemna gibba CPCC 310, Growth inhibition test". Kulec-Płoszczyca E., W/151/17, 2019. Institute of Industrial Organic Chemistry - Branch Pszczyna GLP	N	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 10.3.1.1.1	Pawel Parma	2017	Propaquizafop 10% EC: "Honeybees (Apis mellifera L.), Acute Oral Toxicity Test" Study code: G/116/16 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.1.2	Pawel Parma	2017	"Propaquizafop 10% EC Honeybees (Apis mellifera L.), Acute Contact Toxicity Test". Parma P., B/117/16, 2017. Institute of Industrial Organic Chemistry - Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.1.1	Pieczka P	2018	"Propaquizafop 10% EC Earthworm Reproduction Test (Eisenia andrei))" Pieczka P., G/49/17, 2018 Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2-1	Pieczka P	2018	"Propaquizafop 10% EC Collembolan (Folsomia candida) Reproduction Test". Pieczka P., G/50/1, 2018 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2-2	Pawel Parma	2018	"A laboratory test for evaluating the effects of Propaquizafop 10% EC on the predatory mite, Typhlodromus pyri (Sch.)". Parma P., B/119/16, 2018. Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Cropchem Limited
KCP 10.4.2-3	Pawel Parma	2018	"An extended laboratory test for evaluating the effects of Propaquizafop 10% EC on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani - Perez)	N	Sharda Cropchem Lim-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Parma P., B/118/16, 2018. Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished		ited
KCP 10.5-1	Paweł Pieczka	2017	Propaquizafop 10% EC: “Soil Microorganisms: Carbon Transformation Test” Study code: G/47/17 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Crop-chem Lim-ited
KCP 10.5-2	Paweł Pieczka	2017	"Propaquizafop 10% EC Soil Microorganisms: Nitrogen Transformation Test”. Pieczka P., G/48/17, 2017. Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Crop-chem Lim-ited
KCP 10.6.2-1	Paweł Pieczka	2019	“Propaquizafop 10% EC Terrestrial Plant Test: Vegetative Vigour Test”. Pieczka P., G/52/17, 2019 Institute Of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Sharda Crop-chem Lim-ited

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title	Y/N	Owner

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study** **Y/N**	Owner
			Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished		

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study** **Y/N**	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study** **Y/N**	**Owner**
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • the mortality in the control was 0% at exposure termination (should not exceed 10% or 1 fish if less than 10 fish are used); • the dissolved oxygen concentrations were within the range of 85 – 100% of air saturation value (obligatory above 60% of air saturation value). **Agreed endpoint:** **96h LC_{50}=1.4106 mg item/L (based on geomean concentration)**

Reference:	KCP 10.2.1 - 1
Report:	"Propaquizafop 10% EC Rainbow trout, Acute toxicity test". . Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD No. 203 (1992)

Deviations:	Yes The date of study completion in the Study plan was December 2018 but due to necessity of Sponsor's acceptance the date was postponed.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The acute toxicity of the test item Propaquizafop 10% EC on the rainbow trout was determined in a 96-hour a semi-static test with daily renewals. The fish were exposed to the test item concentrations: 5, 2.5, 1.25, 0.625, 0.313, 0.156 mg/L plus control. The test vessels were glass aquaria with a capacity of 10 L. There was one replicate of each test item concentration and the control. Seven fish were introduced into each aquarium. The fish were observed for mortality and intoxication symptoms after 3, 6, 24, 48, 72 and 96 h of exposure.
The endpoint values were determined based on the nominal test item concentrations, nominal concentrations of propaquizafop, geometric means of determined concentrations of test item.

Material and methods

Test item:	Name: Propaquizafop 10% EC Batch number: SCL – 421258 Content: 100 g/l of propaquizafop Production date: 19th January, 2018 Expiry date: 18th January, 2020
Test organism:	Rainbow trout (*Oncorhynchus mykiss* Walb.) Supplier: 'The Culture of Salmonidae Fish in Zawoja', Poland Age: approximately 5.5 months
Test design:	Semi-static test with daily renewal Exposure time: 96 hours Number of replicates: 1 replicates per each concentration and the control Number of fish: 7 fish in each aquarium Ratio of fish weight per volume (10 L): 0.75 g/L
Nominal test item concentration:	5, 2.5, 1.25, 0.625, 0.313, 0.156 mg/L plus the control
Nominal concentrations of propaquizafop:	0.486, 0.243, 0.121, 0.061, 0.030, 0.015 mg/L plus the control
Geometric means of determined test item concentrations:	1.930, 1.153, 0.543, 0.407, 0.227, 0.158 mg/L plus the control
Test conditions:	Temperature: 13.5 – 14.1°C pH: control: 7.01 – 7.69 / treatments: 7.00 - 7.88 Oxygen: control: 92 – 100 % / treatments: 85 - 98 % Lighting: 16 h light : 8 h dark
Endpoint values:	LC_{50}, LOEC and NOEC.
Statistical analysis:	Probit method calculations and analysis by Fisher's Exact Binominal Test with Bonferroni Correction or Student-t test for Homogenenous Variances with Bonferroni-Holm Adjustment.

Validity criteria: - the mortality in the control was 0% at exposure termination (should not exceed 10% or 1 fish if less than 10 fish are used);
- dissolved oxygen concentrations were within the range of 85 – 100% of air saturation value (obligatory above 60% of air saturation value).

Findings

Endpoint values for mortality of fish based on the nominal test item concentrations

Endpoint values [mg/L]	Time of exposure			
	24 h	**48 h**	**72 h**	**96 h**
LC_{50}	>5	4.6470 (n.d.)	3.5264 (n.d.)	3.5264 (n.d.)
NOEC	≥5	2.5*	2.5	2.5
LOEC	>5	5*	5	5

n.d. – not determined
* Student-t test for Homogenenous Variances with Bonferroni-Holm Adjustment.

Endpoint values for mortality of fish based on the nominal concentrations of propaquizafop

Endpoint values [mg/L]	Time of exposure			
	24 h	**48 h**	**72 h**	**96 h**
LC_{50}	>0.486	0.4539 (n.d.)	0.3428 (n.d.)	0.3428 (n.d.)
NOEC	≥0.486	0.243*	0.243	0.243
LOEC	>0.486	0.486*	0.486	0.486

n.d. – not determined
* Student-t test for Homogenenous Variances with Bonferroni-Holm Adjustment.

Endpoint values for mortality of fish based on geometric means of determined concentrations of test item

Endpoint values [mg/L]	Time of exposure			
	24 h	**48 h**	**72 h**	**96 h**
LC_{50}	>1.930	1.7055 (1.3794 – 2.5170)	1.4106 (1.1401 – 1.8702)	1.4106 (1.1401 – 1.8702)
NOEC	≥1.930	1.1530*	1.1530	1.1530
LOEC	>1.930	1.930*	1.930	1.930

*Student-t test for Homogenenous Variances with Bonferroni-Holm Adjustment.

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • the immobilisation of Daphnia magna in the control was 0% (criterion: not more than 10%), • the dissolved oxygen concentrations in the test vessels were within the range of 8.4 – 9.7 mg/L (criterion: not less than 3 mg/L). **Agreed endpoint:** **48 h EC_{50}=1.34 mg product/L**

Reference:	KCP 10.2.1 - 2
Report:	"Propaquizafop 10% EC *Daphnia magna*, acute immobilisation test". Kulec-Płoszczyca E., W/150/17, 2019. Institute of Industrial Organic Chemistry - Branch Pszczyna
Guideline(s):	OECD Guideline No. 202 (2004)
Deviations:	Yes The study plan stated the deadline for final report was December 2018. However, due to obligation acquire the Sponsor's acceptance of the report, the deadline was postponed.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The aim of the study was to assess the impact of Propaquizafop 10% EC on *Daphnia magna* to determine the concentration of the test item causing 50% immobilization of *Daphnia magna*. The test was conducted in a semi-static design with a renewal after 24 h of exposure. The test was performed with six concentrations: 10, 5.0, 2.5, 1.25, 0.63, 0.31 mg/L plus the control. The test was performed in glass beakers of 150 mL capacity, containing 100 mL of either the test item concentration or the control per replicate. Four replicates were used for the test item concentration and the control, each with five *Daphnia magna*.

The daphnids were observed for immobilization after 24 and 48 h of exposure. The daphnids were considered immobile if they showed no ability to swim within 15 seconds after gentle swirling of the test vessel.

The endpoint values were determined based on the nominal test item concentrations and nominal concentrations of propaquizafop, and geometric mean of determined test item concentrations.

Material and methods

Test item: Name: Propaquizafop 10% EC
Batch number: SCL – 421258
Content: 100 g/l of propaquizafop
Production date: 19th January, 2018
Expiry date: 18th January, 2020

Test organisms: *Daphnia magna* Straus; not first brood progeny

Source: neonates collected from Institute of Industrial Organic Chemistry, Branch Pszczyna

Age: less than 24 h old

Test design: Semi-static test with renewal after 24 h of exposure
Exposure time: 48 hours
Number of replicates: 4 replicates per each concentration and the control
Number of daphnia: 5 daphnia/replicate

Test medium: Elendt M7

Nominal test item concentration: 10, 5.0, 2.5, 1.25, 0.63, 0.31 mg/L plus the control

Nominal concentrations of propaquizafop: 0.97, 0.49, 0.24, 0.12, 0.06, 0.03 mg/L plus the control

Geometric means of determined test item concentrations: 6.06, 2.61, 1.30, 0.82, 0.43, 0.24 mg/L plus the control

Test conditions: Temperature: 19.4 - 20.6°C
pH: control: 7.28 – 7.60 / treatments: 7.35 - 7.83

Oxygen: control: 8.8 – 9.3 mg/L / treatments: 8.5 - 9.7 mg/L
Lighting: 16 h light : 8 h dark; fluorescent light source

Endpoints: EC_{50}/48 h, LOEC/48 h and NOEC/48 h.

Statistical analysis: Probit method calculations and analysis by Step-down Cochran-Armitage test procedure.

Validity criteria: The immobilization of *Daphnia magna* in the control was 0% (criterion: not more than 10%)

The dissolved oxygen concentrations in the test vessels were within the range of 8.4 – 9.7 mg/L (criterion: not less than 3 mg/L).

Findings

Immobilization of *Daphnia magna* – definitive test

Nominal test item concentration [mg/L])	**Number of *Daphnia magna***	**Number of immobilized daphnids after 24h**				**Number of immobilized daphnids after 48h**				**Total of immobilised Daphnia magna [%]**	
		A	**B**	**C**	**D**	**A**	**B**	**C**	**D**	**24h**	**48h**
Control	20	0	0	0	0	0	0	0	0	0	0
0.31	20	0	0	0	0	0	0	0	0	0	0
0.63	20	0	0	0	0	0	0	0	0	0	0
1.25	20	0	0	0	0	0	0	0	0	0	0
2.5	20	0	0	1	0	1	3	2	1	5	35
5.0	20	1	1	0	1	5	5	5	5	15	100
10	20	5	5	5	5	5	5	5	5	100	100

Endpoints

Endpoint	**Values based on nominal test item concentrations**		**Values based on nominal concentrations of propaquizafop**		**Values based on geometric means of determined test item concentrations**	
	24 h	**24 h**	**24 h**	**48 h**	**48 h**	**48 h**
EC_{50}	**5.93** (n.d.)	**5.93** (n.d.)	**0.58** (n.d.)	**0.25** (n.d.)	**3.23** (1.88 – 6.91)	**1.34** (n.d.)
EC_{20}	**4.46** (n.d.)	**4.46** (n.d.)	**0.43** (n.d.)	**0.23** (n.d.)	**2.37** (0.52 – 3.42)	**1.25** (n.d.)
EC_{10}	**3.85** (n.d.)	**3.85** (n.d.)	**0.37** (n.d.)	**0.22** (n.d.)	**2.01** (0.22 – 2.89)	**1.20** (n.d.)
NOEC	**5.0**	**5.0**	**0.49**	**0.24**	**2.61**	**1.30**
LOEC	**2.5**	**2.5**	**0.24**	**0.12**	**1.30**	**0.82**

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • the biomass in the control increased by a factor of 144.5 within the 72-hour test period (criterion: at least a 16-fold growth), • the coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 1.7% (criterion: it must not exceed 7%), • the mean coefficient of variation for the section-by-section growth rate in the control culture was 19.5% (criterion: it must not exceed 35%).

Agreed endpoints:

Time of exposure:	End-point	Nominal test item concentra-tions	Nominal concentra-tions of propaquizafop	Geometric means of determined test item concentrations
24 hours	ErC_{50}	**>10** **calc. 10.11** (7.88 – 14.36)	**>0.9715** **calc. 0.9825** (0.7659 – 1.3954)	n.d.
	ErC_{20}	**1.54** (1.09 – 1.96)	**0.1492** (0.1056 – 0.1909)	n.d.
	ErC_{10}	**<0.63** calc. 0.57 (0.32 – 0.85)	**<0.0612** **calc. 0.0557** (0.0306 – 0.0825)	n.d.
	LOEC	**≤0.63**	**≤0.0612**	**≤0.246**
	NOEC	**<0.63**	**<0.0612**	**<0.246**
	EyC_{50}	**3.21** (2.62 – 4.02)	**0.3122** (0.2543 – 0.3902)	**0.274** (n.d.)
	EyC_{20}	**<0.63** **calc. 0.50** (0.29 – 0.71)	**<0.0612** **calc. 0.0481** (0.0279 – 0.0693)	(n.d.)
	EyC_{10}	n.d.	n.d.	(n.d.)
	LOEC	**≤0.63**	**≤0.0612**	**≤0.246**
	NOEC	**<0.63**	**<0.0612**	**<0.246**
48 hours	ErC_{50}	**4.30** (4.07 – 4.54)	**0.4179** (0.3957 – 0.4413)	n.d.
	ErC_{20}	**2.64** (2.40 – 2.85)	**0.2561** (0.2330 – 0.2766)	**0.225** (0.183 – 0.256)
	ErC_{10}	**2.04** (1.80 – 2.26)	**0.1982** (0.1745 – 0.2193)	n.d.
	LOEC	**≤0.63**	**≤0.0612**	**≤0.246**
	NOEC	**<0.63**	**<0.0612**	**<0.246**
	EyC_{50}	**2.43** (2.32 – 2.54)	**0.2359** (0.2255 – 0.2467)	**0.351** (0.340 – 0.361)
	EyC_{20}	**1.30** (1.21 – 1.39)	**0.1263** (0.1172 – 0.1348)	n.d.
	EyC_{10}	**0.94** (0.85 – 1.02)	**0.0911** (0.0824 – 0.0993)	n.d.
	LOEC	**≤0.63**	**≤0.0612**	**≤0.246**
	NOEC	**<0.63**	**<0.0612**	**<0.246**
72 hours	ErC_{50}	**5.49** (5.31 – 5.68)	**0.5338** (0.5161 – 0.5521)	n.d.
	ErC_{20}	**3.64** (3.43 – 3.82)	**0.3535** (0.3338 – 0.3713)	**0.289** (0.265 – 0.308)
	ErC_{10}	**2.93** (2.71 – 3.13)	**0.2850** (0.2635 – 0.3043)	n.d.
	LOEC	**2.5**	**0.2429**	**0.534**
	NOEC	**1.25**	**0.1214**	**0.389**
	EyC_{50}	**2.87** (2.77 – 2.98)	**0.2789** (0.2690 – 0.2893)	**0.387** (0.377 – 0.398)
	EyC_{20}	**1.80** (1.70 – 1.90)	**0.1752** (0.1649 – 0.1846)	**<0.246** **calc. 0.209** (0.193 – 0.224)
	EyC_{10}	**1.41** (1.30 – 1.52)	**0.1374** (0.1266 – 0.1472)	n.d.
	LOEC	**1.25**	**0.1214**	**0.389**
	NOEC	**0.63**	**0.0612**	**0.246**

(-) — 95 % confidence interval
n.d. – not determined
Note: ErC refers to growth rate; EyC refers to yield.

Reference:	KCP 10.2.1 - 3
Report:	"Propaquizafop 10% EC *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*) Growth inhibition test*".* Kulec-Płoszczyca E., W/149/17, 2019. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD No. 201 (2006)
Deviations:	Yes The study plan stated that the Study Completion Date was December 2018. However, due to a delay in compilation of the report, the Study Completion Date is postponed till March 2019.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The influence of the test item Propaquizafop 10% EC on the growth of the green algal species *Raphidocelis subcapitata (*formerly *Pseudokirchneriella subcapitata)* was investigated in a 72-hour test. The test was performed in glass flasks with a capacity of 250 mL containing 100 mL of either the test item concentration or the control per replicate. The initial density of the algae was 1 x 104 cells/mL. The following test item concentrations were used: 10, 5.0, 2.5, 1.25, 0.63 mg/L plus the control. Six replicates were maintained for the control and three replicates for each test concentrations. The number of algal cells was determined with an indirect method, which involves a spectrophotometric measurement of the absorbance of algal suspension at 670 nm and converting its value into the number of cells using a standard curve. The absorbance for each replicate of each test item concentration and the control were measured after 24, 48, and 72 h of exposure. The endpoint values were determined based on the nominal test item concentrations, nominal concentrations of propaquizafop and geometric means of determined test item concentrations.

Material and methods

Test item:	Name: Propaquizafop 10% EC Batch number: SCL – 421258 Content: 100 g/l of propaquizafop Production date: 19th January, 2018 Expiry date: 18th January, 2020
Test organism:	The unicellular, fresh-water green algae *Raphidocelis subcapitata (*formerly *Pseudokirchneriella subcapitata*), from Culture Collection of Algae at Göttingen University, Germany.
Test design:	Exposure time: 72 hours; Number of replicates: 3 replicates for each concentration and 6 for the control Initial algal cell density: 1 x 104 cells/mL
Nominal test item concentrations:	10, 5.0, 2.5, 1.25, 0.63 mg/L plus the control.
Nominal concentrations of propaquizafop:	0.9715, 0.4858, 0.2429, 0.1214, 0.0612 mg/L plus the control.
Geometric means of determined test item concentrations:	0.448, 0.347, 0.534, 0.389, 0.246 mg/L plus the control.
Test conditions:	Temperature: 22.4 – 22.6°C pH: control: 7.42 – 8.43 / treatments: 7.30 - 8.47

Lighting: constant illumination and shaking; 7088 – 7230 lux
Medium: AAP

Endpoint values: ErC_{50}, EyC_{50}, LOEC and NOEC.

Statistical analysis: Probit method calculations and analysis by Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential test procedure, Multiple Sequentially-rejective Welsh-t-test after Bonferroni-Holm.

Validity criteria: - the biomass in the control increased by a factor of 144.5 within the 72-hour test period (criterion: at least a 16-fold growth),
- the coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 1.7% (criterion: it must not exceed 7%),
- the mean coefficient of variation for the section-by-section growth rate in the control culture was 19.5% (criterion: it must not exceed 35%).

Findings

Time of exposure:	Endpoint	Nominal test item concentrations	Nominal concentrations of propaquizafop	Geometric means of determined test item concentrations
24 hours	ErC_{50}	**>10** **calc. 10.11** (7.88 – 14.36)	**>0.9715** **calc. 0.9825** (0.7659 – 1.3954)	n.d.
	ErC_{20}	**1.54** (1.09 – 1.96)	**0.1492** (0.1056 – 0.1909)	n.d.
	ErC_{10}	**<0.63** calc. 0.57 (0.32 – 0.85)	**<0.0612** **calc. 0.0557** (0.0306 – 0.0825)	n.d.
	LOEC	**≤0.63**	**≤0.0612**	**≤0.246**
	NOEC	**<0.63**	**<0.0612**	**<0.246**
	EyC_{50}	**3.21** (2.62 – 4.02)	**0.3122** (0.2543 – 0.3902)	**0.274** (n.d.)
	EyC_{20}	**<0.63** **calc. 0.50** (0.29 – 0.71)	**<0.0612** **calc. 0.0481** (0.0279 – 0.0693)	(n.d.)
	EyC_{10}	n.d.	n.d.	(n.d.)
	LOEC	**≤0.63**	**≤0.0612**	**≤0.246**
	NOEC	**<0.63**	**<0.0612**	**<0.246**
48 hours	ErC_{50}	**4.30** (4.07 – 4.54)	**0.4179** (0.3957 – 0.4413)	n.d.
	ErC_{20}	**2.64** (2.40 – 2.85)	**0.2561** (0.2330 – 0.2766)	**0.225** (0.183 – 0.256)
	ErC_{10}	**2.04** (1.80 – 2.26)	**0.1982** (0.1745 – 0.2193)	n.d.
	LOEC	**≤0.63**	**≤0.0612**	**≤0.246**
	NOEC	**<0.63**	**<0.0612**	**<0.246**
	EyC_{50}	**2.43** (2.32 – 2.54)	**0.2359** (0.2255 – 0.2467)	**0.351** (0.340 – 0.361)
	EyC_{20}	**1.30** (1.21 – 1.39)	**0.1263** (0.1172 – 0.1348)	n.d.
	EyC_{10}	**0.94** (0.85 – 1.02)	**0.0911** (0.0824 – 0.0993)	n.d.
	LOEC	**≤0.63**	**≤0.0612**	**≤0.246**

	NOEC	**<0.63**	**<0.0612**	**<0.246**
72 hours	ErC_{50}	**5.49** (5.31 – 5.68)	**0.5338** (0.5161 – 0.5521)	n.d.
	ErC_{20}	**3.64** (3.43 – 3.82)	**0.3535** (0.3338 – 0.3713)	**0.289** (0.265 – 0.308)
	ErC_{10}	**2.93** (2.71 – 3.13)	**0.2850** (0.2635 – 0.3043)	n.d.
	LOEC	**2.5**	**0.2429**	**0.534**
	NOEC	**1.25**	**0.1214**	**0.389**
	EyC_{50}	**2.87** (2.77 – 2.98)	**0.2789** (0.2690 – 0.2893)	**0.387** (0.377 – 0.398)
	EyC_{20}	**1.80** (1.70 – 1.90)	**0.1752** (0.1649 – 0.1846)	**<0.246 calc. 0.209** (0.193 – 0.224)
	EyC_{10}	**1.41** (1.30 – 1.52)	**0.1374** (0.1266 – 0.1472)	n.d.
	LOEC	**1.25**	**0.1214**	**0.389**
	NOEC	**0.63**	**0.0612**	**0.246**

(-) — 95 % confidence interval
n.d. – not determined
Note: ErC refers to growth rate; EyC refers to yield.

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

- -the doubling time of frond number in the control was 1.7 days, criterion: less than 2.5 days (the factor of frond number in the control between 0 and 7 day was 16.7).
- the average specific growth rate in the control between day 0 and day 7 was 0.402 d-1 (minimum requirement: higher than 0.275 d^{-1}).

Agreed endpoints:

Endpoint values based on the geometric means of determined test item concentrations [mg/L]

Endpoint values	Frond number			Dry weight
	0-2 d	0-4 d	0-7 d	0-7 d
	Growth rate			
ErC_{50}	7.26 (5.49 – 9.68)	4.82 (4.16 – 5.58)	4.12 (3.75 – 4.52)	3.26 (2.98 – 3.58)
ErC_{20}	2.54 (1.46 – 3.58)	1.87 (1.44 – 2.27)	1.90 (1.61 – 2.18)	1.51 (1.31 – 1.71)
ErC_{10}	1.47 (0.68 – 2.28)	1.14 (0.80 – 1.47)	1.27 (1.02 – 1.51)	1.01 (0.84 – 1.18)
LOEC	5.94	5.94	1.44	1.44
NOEC	1.44	1.44	0.52	0.52
	Yield			
EyC_{50}	5.13 (3.74 – 7.17)	2.73 (2.26 – 3.33)	2.21 (1.96 – 2.51)	1.42 (1.26 – 1.64)
EyC_{20}	1.56 (0.86 – 2.27)	1.02 (0.75 – 1.29)	1.10 (0.93 – 1.27)	0.74 (0.58 – 0.87)
EyC_{10}	0.83 (0.36 – 1.35)	0.61 (0.40 – 0.83)	0.77 (0.60 – 0.92)	0.52 (0.37 – 0.65)
LOEC	1.44	0.52	0.52	1.44
NOEC	0.52	0.21	0.21	0.52

Reference:	KCP 10.2.1 - 4
Report:	"Propaquizafop 10% EC *Lemna gibba* CPCC 310, Growth inhibition test". Kulec-Płoszczyca E., W/151/17, 2019. Institute of Industrial Organic Chemistry - Branch Pszczyna
Guideline(s):	OECD Guideline No. 221 (2006)
Deviations:	Yes The study plan stated that the Study Completion Date was December 2018. However, due to a delay in compilation of the report, the Study Completion Date is postponed till April 2019.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The growth of *Lemna gibba* exposed to the test item, Propaquizafop 10% EC, was investigated in a 7 day semi-static test with daily renewals. The study was conducted with seven concentrations of test item: 50, 15.6, 4.9, 1.5, 0.48, 0.15, 0.047 mg/L plus the control. Each concentration was divided into three replicates with nine initial frond number each, whereas the control group was divided into six replicates with nine initial frond number each.
The total number of fronds in each test vessels counted twice during exposure (in day 2 and 4) and at exposure termination (day 7). The observations of plant development, i.e. size of fronds necrosis, chlorosis, colony break-up, gibbosity, changes in the appearance of root were performed at the same time.
The endpoint values were determined based on the nominal test item concentration and nominal concentration of S-metolachlor and terbuthylazine in test item.

Material and methods

Test item:	Name: Propaquizafop 10% EC Batch number: SCL – 421258 Content: 100 g/l of propaquizafop Production date: 19th January, 2018 Expiry date: 18th January, 2020
Test organisms:	The freshwater aquatic plant, *Lemna gibba* CPCC 310, obtained from the Canadian Phycological Culture Centre (CPCC), Department of Biology, University of Waterloo, Ontario, Canada.
Test design:	Test design: semi-static system with daily renewals Exposure time: 7 days Number of replicates: 3 replicates per each concentration and 6 for the control Initial frond number: 9; i.e. 3 plants per 3 fronds Test medium: 20X AAP
Nominal test item concentrations:	50, 15.6, 4.9, 1.5, 0.48, 0.15, 0.047 mg/L plus the control
Nominal concentrations of propaquizafop:	4.86, 1.51, 0.48, 0.15, 0.047, 0.015, 0.0046 mg/L plus the control
Geometric means of determined test item	

concentrations: 24.4, 5.94, 1.44, 0.52, 0.21, 0.16, 0.10 mg/L plus the control

Test conditions: Temperature: 22.9 – 23.2°C
pH: control: 7.43 – 8.80 / Treatments: 7.38 – 8.86
Lighting: constant illumination, 6623 – 6700 lux

Endpoint values: ErC_{50}, ErC_{20}, ErC_{10}, EyC_{50}, EyC_{20}, EyC_{10}, LOEC and NOEC, based on frond number and dry weight.

Statistics: Probit method calculations and analysis by Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure.

Validity criteria: - the doubling time of frond number in the control was 1.7 days, criterion: less than 2.5 days (the factor of frond number in the control between 0 and 7 day was 16.7).
- the average specific growth rate in the control between day 0 and day 7 was 0.402 d-1 (minimum requirement: higher than 0.275 d^{-1}).

Findings

Endpoint values based on the nominal test item concentrations [mg/L]

Endpoint values	Frond number			Dry weight
	0-2 d	0-4 d	0-7 d	0-7 d
Growth rate				
ErC_{50}	18.561 (14.760 – 23.439)	13.228 (11.730 – 14.910)	11.582 (10.713 – 12.495)	9.553 (8.853 – 10.300)
ErC_{20}	8.033 (5.030 – 10.622)	6.179 (4.957 – 7.279)	6.199 (5.389 – 6.929)	5.079 (4.485 – 5.629)
ErC_{10}	5.185 (2.703 – 7.444)	4.151 (3.073 – 5.144)	4.471 (3.705 – 5.169)	3.651 (3.097 – 4.166)
LOEC	15.6	15.6	4.9	4.9
NOEC	4.9	4.9	1.5	1.5
Yield				
EyC_{50}	14.061 (10.645 – 18.639)	8.329 (6.911 – 10.036)	7.001 (6.285 – 7.872)	4.703 (4.138 – 5.331)
EyC_{20}	5.460 (3.063 – 7.620)	3.743 (2.624 – 4.731)	4.039 (3.393 – 4.595)	2.479 (1.888 – 2.955)
EyC_{10}	3.330 (1.489 – 5.119)	2.464 (1.515 – 3.333)	3.029 (2.385 – 3.574)	1.774 (1.215 – 2.239)
LOEC	4.9	1.5	1.5	4.9
NOEC	1.5	0.48	0.48	1.5

Endpoint values based on the nominal concentrations of propaquizafop [mg/L]

Endpoint values	Frond number			Dry weight
	0-2 d	0-4 d	0-7 d	0-7 d
Growth rate				
ErC_{50}	1.8001 (1.4326 – 2.2738)	1.2840 (1.1395 – 1.4466)	1.1244 (1.0408 – 1.2121)	0.9293 (0.8619 – 1.0012)
ErC_{20}	0.7790 (0.4897 – 1.0288)	0.6018 (0.4837 – 0.7080)	0.6056 (0.5271 – 0.6762)	0.4973 (0.4397 – 0.5506)
ErC_{10}	0.5028 (0.2635 – 0.7206)	0.4050 (0.3005 – 0.5012)	0.4383 (0.3638 – 0.5061)	0.3587 (0.3048 – 0.4088)
LOEC	1.51	1.51	0.48	0.48

NOEC	0.48	0.48	0.15	0.15
Yield				
EyC_{50}	1.3655 (1.0363 – 1.8081)	0.8112 (0.6746 – 0.9757)	0.6832 (0.6141 – 0.7671)	0.4613 (0.4067 – 0.5221)
EyC_{20}	0.5316 (0.3003 – 0.7397)	0.3667 (0.2582 – 0.4623)	0.3961 (0.3335 – 0.4500)	0.2454 (0.1877 – 0.2916)
EyC_{10}	0.3247 (0.1466 – 0.4972)	0.2422 (0.1498 – 0.3265)	0.2979 (0.2352 – 0.3508)	0.1764 (0.1215 – 0.2219)
LOEC	0.48	0.15	0.15	0.48
NOEC	0.15	0.047	0.047	0.15

Endpoint values based on the geometric means of determined test item concentrations [mg/L]

Endpoint values	**Frond number**			**Dry weight**
	0-2 d	**0-4 d**	**0-7 d**	**0-7 d**
Growth rate				
ErC_{50}	7.26 (5.49 – 9.68)	4.82 (4.16 – 5.58)	4.12 (3.75 – 4.52)	3.26 (2.98 – 3.58)
ErC_{20}	2.54 (1.46 – 3.58)	1.87 (1.44 – 2.27)	1.90 (1.61 – 2.18)	1.51 (1.31 – 1.71)
ErC_{10}	1.47 (0.68 – 2.28)	1.14 (0.80 – 1.47)	1.27 (1.02 – 1.51)	1.01 (0.84 – 1.18)
LOEC	5.94	5.94	1.44	1.44
NOEC	1.44	1.44	0.52	0.52
Yield				
EyC_{50}	5.13 (3.74 – 7.17)	2.73 (2.26 – 3.33)	2.21 (1.96 – 2.51)	1.42 (1.26 – 1.64)
EyC_{20}	1.56 (0.86 – 2.27)	1.02 (0.75 – 1.29)	1.10 (0.93 – 1.27)	0.74 (0.58 – 0.87)
EyC_{10}	0.83 (0.36 – 1.35)	0.61 (0.40 – 0.83)	0.77 (0.60 – 0.92)	0.52 (0.37 – 0.65)
LOEC	1.44	0.52	0.52	1.44
NOEC	0.52	0.21	0.21	0.52

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • the average mortality for the total number of controls was 0.0% at the end of the experiment (criterion: it must not exceed 10%), • the LD_{50}/24 h of the reference item (dimethoate) was 0.11 µg/bee (criterion: 0.10 - 0.35 µg a.i./bee). **Agreed endpoints:** **48 h LD_{50} (oral) =342.8 µg test item /bee) (263.5-526.2) correspond to 48 h LD_{50}=33.2 (µg a.i./bee) (25.6-51.0)**

Reference:	KCP 10.3.1.1.1
Report:	"Propaquizafop 10% EC Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test Parma P., B/116/16, 2017. Institute of Industrial Organic Chemistry - Branch Pszczyna
Guideline(s):	OECD No. 213 (1998) EU Method C.16. (2008)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The acute oral toxicity of Propaquizafop 10% EC was studied on the honeybee *Apis mellifera* L.
3-week-old honeybees were exposed to the test item at five concentrations: 25.0, 50.0, 100.0, 200.0 and 400.0µg test item/bee. Each group of bees was fed with 100 µL of a 50% sucrose solution containing the test item. During the experiment, the insects were caged in groups of 10. The recommended reference item, i.e. dimethoate was used to verify the sensitivity of the honeybees and the precision of the test procedure.
After the administration, the insects were observed for mortality and other signs of toxicity. These observations were made at 4 h after the beginning of the test and thereafter at 24 h and 48 h. The acute oral toxicity test ended after the 48-hour exposure.

Material and methods

Test item:	Name: Propaqiuzafop 10% EC Batch number: SCL - 86421 Content: 100 g/l of propaquizafop Manufacturing date: 8th March 2016 Expiry date: 7th March 2018
Test organisms:	the honeybee, *Apis mellifera* L., strain: carnica Source: an apiary at the Institute of Industrial Organic Chemistry, Branch Pszczyna Age: approximately 3 weeks
Test design:	Test item: - exposure time: 48 hours - number of doses: 5 doses and a control

- number of replicates: 3 replicates
- number of bees: 10 bees/replicate

Reference item:
- exposure time: 24 hours
- number of doses: 3 doses
- number of replicates: 3 replicates
- number of bees: 10 bees/replicate

Test medium: 50% solution of sucrose in water

Test item doses: 25.0, 50.0, 100.0, 200.0 and 400.0 µg test item/bee and a control

Test conditions: Temperature: 24 – 25°C
Relative air humidity: 67 – 69%
Place: a dark room

Statistical analysis: - the oral LD_{50} values for the test item 24 and 48 hours after dose administration,
- the oral LD_{50}/24h value for the reference item (dimethoate).
regression analysis using the log-probit method

Validity criteria: - the average mortality for the total number of controls was 0.0% at the end of the experiment (criterion: it must not exceed 10%),
- the LD_{50}/24 h of the reference item (dimethoate) was 0.11 µg/bee (criterion: 0.10 - 0.35 µg a.i./bee).

Findings

Honeybee mortality and the LD_{50} after 24 hours of exposure

Dose		No. of honeybees tested	Mortality after 24 h after the beginning of the treatment		LD_{50}	
(µg test item /bee)	(µg a.i./bee)		[no.]	[%]	(µg test item /bee)	(µg a.i./bee)
0.0 (Control)		30	0	0.0		
25.0	**2.4**	30	0	0.0		
50.0	**4.8**	30	0	0.0	**331.9** (265.8-467.4)	**32.2** (25.8-45.3)
100.0	**9.7**	30	1	3.3		
200.0	**19.4**	30	9	30.0		
400.0	**38.8**	30	17	56.7		

Honeybee mortality and the LD_{50} after 48 hours of exposure

Dose		No. of honeybees tested	Mortality after 48 h after the beginning of the treatment		LD_{50}	
(µg test item /bee)	(µg a.i./bee)		[no.]	[%]	(µg test item /bee)	(µg a.i./bee)
0.0 (Control)		30	0	0.0		
25.0	**2.4**	30	0	0.0		
50.0	**4.8**	30	1	3.3	**342.8** (263.5-526.2)	**33.2** (25.6-51.0)
100.0	**9.7**	30	1	3.3		
200.0	**19.4**	30	9	30.0		
400.0	**38.8**	30	17	56.7		

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • the average mortality for the total number of controls was 0.0% after 48 h (criterion: it must not exceed 10%), • the 24-hour LD_{50} of the reference item (dimethoate) was 0.26 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee) **Agreed endpoints:** **48 h LD_{50} (oral) >400 µg test item /bee) (263.5-526.2) correspond to 48 h LD_{50}>40 (µg a.i./bee) (25.6-51.0)**

Reference:	KCP 10.3.1.1.2
Report:	"Propaquizafop 10% EC Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test". Parma P., B/117/16, 2017. Institute of Industrial Organic Chemistry - Branch Pszczyna
Guideline(s):	OECD No. 214 (1998) EU Method C.17. (2008)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The acute contact toxicity of Propaquizafop 10% EC was studied on the honeybee *Apis mellifera* L. Approximately 3-week-old honeybees were exposed to test item, at the five concentrations 25.0, 50.0, 100.0, 200.0 and 400.0 µg /honeybee. A microapplicator was used to apply 1 mL/bee of the test item. During the experiment, the insects were caged in groups of 10. The recommended reference item, i.e. dimethoate was used to verify the sensitivity of the honeybees and the precision of the test procedure. After the application, the insects were observed for mortality and signs of toxicity. These observations were made 4, 24 and 48 hours after the beginning of the treatment. The acute contact toxicity test finished after the 48-hour observation.

Material and methods

Test item:	Name: Propaqiuzafop 10% EC Batch number: SCL - 86421 Content: 100 g/l of propaquizafop Manufacturing date: 8th March 2016 Expiry date: 7th March 2018
Test organisms:	the honeybee, *Apis mellifera* L., strain: carnica Source: an apiary at the Institute of Industrial Organic Chemistry, Branch Pszczyna Age: approximately 3 weeks
Test design:	Test item: - exposure time: 48 hours - number of doses: 5 doses and a control - number of replicates: 3 replicates - number of bees: 10 bees/replicate

	Reference item: - exposure time: 24 hours - number of doses: 3 doses - number of replicates: 3 replicates - number of bees: 10 bees/replicate
Test medium:	50% (w/v) aqueous sucrose solution
Test item doses:	25.0, 50.0, 100.0, 200.0 and 400.0 µg test item/bee and a control
Test conditions:	Temperature: 24 – 25.5°C Relative air humidity: 58 – 64% Place: a dark room
Statistical analysis:	regression analysis using the log-probit method
Validity criteria:	- the average mortality for the total number of controls was 0.0% after 48 h (criterion: it must not exceed 10%), - the 24-hour LD_{50} of the reference item (dimethoate) was 0.26 µg a.i./bee (criterion: 0.10 - 0.30 µg a.i./bee)

Findings

Honeybee mortality and the LD_{50} after 24 hours of exposure

Dose		No. of honeybees tested	Mortality after 24 h after the beginning of the treatment		LD_{50}	
(µg test item /bee)	(µg a.i./bee)		[no.]	[%]	(µg test item /bee)	(µg a.i./bee)
0.0 (Control)		30	0	0.0	**> 400.0**	**> 40.0**
25.0	**2.5**	30	0	0.0		
50.0	**5.0**	30	0	0.0		
100.0	**10.0**	30	0	0.0		
200.0	**20.0**	30	0	0.0		
400.0	**40.0**	30	0	0.0		

Honeybee mortality and the LD_{50} after 48 hours of exposure

Dose		No. of honeybees tested	Mortality after 48 h after the beginning of the treatment		LD_{50}	
(µg test item /bee)	(µg a.i./bee)		[no.]	[%]	(µg test item /bee)	(µg a.i./bee)
0.0 (Control)		30	0	0.0	**> 400.0**	**> 40.0**
25.0	**2.5**	30	0	0.0		
50.0	**5.0**	30	0	0.0		
100.0	**10.0**	30	0	0.0		
200.0	**20.0**	30	1	3.3		
400.0	**40.0**	30	0	0.0		

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of zRMS: The study is considered acceptable. All validity criteria were met.

- each replicate produced 120.1 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment)
- the coefficient of variation of reproduction was 26.4% (criterion: ≤ 30%)
- adult mortality over the initial 4 weeks of the experiment was 2.5 %

  (criterion: ≤ 10%)

Agreed endpoints:

Parameter	Value [mg of test item/kg dry weight of artificial soil]	Value [mg of propaquizafop/kg dry weight of artificial soil]
EC_{10}	**<10 (7.8)**	**<1.0 (0.8)**
EC_{20}	**16.6**	**1.6**
EC_{50}	**>560**	**>54.3**
NOEC	**18.0**	**1.7**
LOEC	**32.0**	**3.1**
LC_{50} (mortality)	**>560**	**>54.3**

Reference:	KCP 10.4.1.1
Report:	"Propaquizafop 10% EC Earthworm Reproduction Test (*Eisenia andrei*))" Pieczka P., G/49/17, 2018 Institute of Industrial Organic Chemistry, Branch Pszczyna
Guideline(s):	OECD No. 222 (2016)
Deviations:	Yes The study was finished in December 2018, not in September 2018 as it was planned.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The aims of the study were to assess the impact of Propaquizafop 10% EC on reproduction of the earthworm, *Eisenia andrei*. The test item in the form of an aqueous suspension was mixed with a suitable amount of the artificial soil. The concentrations of the test item were 10, 18, 32, 56, 100, 180, 320 and 560 mg/kg dry weight of the artificial soil. There were also untreated control. Each of concentrations were divided into four replicates, control was divided into eight replicates. The experiment lasted 8 weeks. After 4 weeks, all adult earthworms were removed from the test containers and observed. The impact of the test item on reproduction was evaluated after an additional 4-week period on the basis of the number of juveniles hatched from cocoons during the experiment.

Material and methods

Test item:	Name: Propaquizafop 10% EC Batch number: SCL – 421258 Content: 100 g/l of propaquizafop Production date: 19th January, 2018 Expiry date: 18th January, 2020
Test organism:	The earthworm *Eisenia fetida* obtained from a standard laboratory culture cultivated at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Department of Ecotoxicology, Laboratory of Soil Toxicology [SOP/G/34]
Test design:	Test duration: 8 weeks Number of replicates: 4 replicates/concentration + 8 replicates/control Number of mites: 10 earthworms/replicate
Artificial soil:	5% sphagnum peat, 20% kaolin clay, 75% air-dried quartz sand
Concentrations of the test item:	control, 10, 18, 32, 56, 100, 180, 320, 560 mg/kg dry weight of the artificial soil
Test conditions:	Temperature: 18.5 – 22°C pH at the beginning of the test: 5.85 – 6.00 pH at the end of the test: 5.90 – 6.14 Soil moisture content at the beginning of the test: 19.0 – 20.6% Soil moisture content at the end of the test: 20.0 – 21.6% Lighting: 16 h light and 8 h dark Light intensity at the beginning of the test 566 – 589 lux Light intensity at the end of the test: 562 – 592 lux
Endpoints:	- EC_{10}, EC_{20}, EC_{50}, NOEC, LOEC

- LC_{50}, NOEC, LOEC

Statistical analysis: EC_{10}, EC_{20}, EC_{50} – the 4-parameter logistic method
LC_{50} – probit analysis
NOEC (reproduction) – the Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Welch-t test for In-homogeneous Variances with Bonferroni-Holm Adjustment.
NOEC (survival) – Fisher's Exact Binomial Test with Bonferroni Correction

Validity criteria: - each replicate produced 120.1 juveniles (mean) at the end of the experiment - (criterion: ≥ 30 juveniles by the end of the experiment),
- the coefficient of variation of reproduction was 26.4% (criterion: ≤ 30%),
- adult mortality over the initial 4 weeks of the experiment was 2.5 % (criterion: ≤ 10%).

Findings

Endpoint values determined during the earthworm reproduction test

Parameter	Value [mg of test item/kg dry weight of artificial soil]	Value [mg of propaquizafop/kg dry weight of artificial soil]
EC_{10}	<10 (7.8)	<1.0 (0.8)
EC_{20}	16.6	1.6
EC_{50}	>560	>54.3
NOEC	18.0	1.7
LOEC	32.0	3.1
LC_{50} (mortality)	>560	>54.3

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Comments of zRMS: The study is considered acceptable. All validity criteria were met.

- mean adult mortality was 13.8% (criterion: ≤ 20%)
- the mean number of juveniles per vessel at the end of the test: 713.9 (criterion: ≥ 100 juveniles at the end of the test)
- the coefficient of variation calculated for the number of juveniles was 21.0 (criterion: ≤ 30%)

Agreed endpoints:

Impact of the Propaquizafop 10% EC on survival of *Folsomia candida*.

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of a.s./kg dry soil]
LC_{10}	62.9 (0.0 – 87.0)	6.1 (0.0 – 8.4)
LC_{20}	71.8 (0.0 – 99.7)	7.0 (0.0 – 9.7)
LC_{50}	92.4 (26.7 – 359.3*)	9.0 (2.6 – 34.9)
NOEC	56.0	5.4
LOEC	100.0	9.7

* value determined above the range of the tested concentrations

Impact of the Propaquizafop 10% EC on reproduction of *Folsomia candida*.

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of a.s./kg dry soil]
EC_{10}	43. 2 (29.6 – 52.6)	4.2 (2.9 – 5.1)
EC_{20}	50.7 (37.9 – 60.4)	4.9 (3.7 – 5.9)
EC_{50}	68.6 (57.2 – 83.6)	6.7 (5.5 – 8.1)
NOEC	32.0	3.1
LOEC	56.0	5.4

Reference:	KCP 10.4.2 - 1
Report:	"Propaquizafop 10% EC Collembolan (*Folsomia candida*) Reproduction Test". Pieczka P., G/50/1, 2018 Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD No. 232 (2016)
Deviations:	Yes At the end of the test the soil moisture content was determined by drying small sample of the artificial soil in 105°C instead of weighing the test vessels as it is mentioned in OECD Guideline. Physiological or pathological symptoms or distinct changes in behavior were not described.
GLP:	Yes
Acceptability:	Yes

Duplication (if vertebrate study):	No

Summary

The aim of the study was to assess the impact of Propaquizafop 10% EC on reproduction of the collembolans, *Folsomia candida*. Eight concentrations of the test item were used. These were 5.6, 10, 18, 32, 56, 100, 180, and 320 mg of the test item/kg of dry weight of the artificial soil. Each concentration was divided into four replicates. There was also an untreated control group divided into eight replicates. The test item in the form of aqueous solution was mixed with the artificial soil. The control artificial soil was mixed with deionized water alone. The experiment lasted 28 days. After that, the collembolans were extracted from the artificial soil. The numbers of adults and juveniles were determined separately.

Material and methods

Test item:	Name: Propaquizafop 10% EC Batch number: SCL – 421258 Content: 100 g/l of propaquizafop Production date: 19th January, 2018 Expiry date: 18th January, 2020
Test organism:	The *Folsomia candida* Source: standard laboratory culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna, Laboratory of Soil Toxicology. Age: 9 – 12 days old
Test design:	Test duration: 28 day Number of replicates: 4 replicates/concentration + 8 replicates/control Number of mites: 10 collembolans/replicate
Artificial soil:	5% sphagnum peat, 20% kaolin clay, and 75% air-dried industrial sand
Concentrations of the test item:	a control, 5.6, 10, 18, 32, 56, 100, 180, and 320 mg of the test item/kg of dry weight of the artificial soil
Test conditions:	Temperature: 18.0 – 22.0°C pH at the beginning of the test: 6.42 – 6.50 pH at the end of the test: 6.32 – 6.50 Soil moisture content at the beginning of the test: 13.5 – 14.4% Soil moisture content at the end of the test: 12.7 – 14.2% Lighting: 16 h light and 8 h dark; Light intensity at the beginning of the test: 612 – 627 lux Light intensity at the end of the test: 616 – 629 lux
Endpoints:	EC_{10}, EC_{20}, EC_{50}, NOEC, LOEC LC_{10}, LC_{20}, LC_{50}, NOEC, LOEC
Statistical analysis:	EC_{10}, EC_{20}, and EC_{50} – a probit analysis LC_{10}, LC_{20}, and LC_{50} - a probit analysis NOEC(number of juveniles and mortality of adults): - Shapiro-Wilk's Test on Normal Distribution, - Levene's Test on Variance Homogeneity (with Residuals), - Williams Multiple Sequential t-test Procedure,
Validity criteria:	- mean adult mortality was 13.8% (criterion: ≤ 20%) - the mean number of juveniles per vessel at the end of the test: 713.9 (criterion: ≥ 100 juveniles at the end of the test)

- the coefficient of variation calculated for the number of juveniles was 21.0 (criterion: ≤ 30%)

Findings

Impact of the Propaquizafop 10% EC on survival of *Folsomia candida*.

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of a.s./kg dry soil]
LC_{10}	62.9 (0.0 – 87.0)	6.1 (0.0 – 8.4)
LC_{20}	71.8 (0.0 – 99.7)	7.0 (0.0 – 9.7)
LC_{50}	92.4 (26.7 – 359.3*)	9.0 (2.6 – 34.9)
NOEC	56.0	5.4
LOEC	100.0	9.7

* value determined above the range of the tested concentrations

Impact of the Propaquizafop 10% EC on reproduction of *Folsomia candida*.

Endpoint	Value [mg of test item/kg dry soil]	Value [mg of a.s./kg dry soil]
EC_{10}	43. 2 (29.6 – 52.6)	4.2 (2.9 – 5.1)
EC_{20}	50.7 (37.9 – 60.4)	4.9 (3.7 – 5.9)
EC_{50}	68.6 (57.2 – 83.6)	6.7 (5.5 – 8.1)
NOEC	32.0	3.1
LOEC	56.0	5.4

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • mortality of the control group was 0.0% on day 7 of exposure (criterion: a maximum of 20%) • mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 88.3% on day 7 of exposure (criterion: a minimum of 50%), • the mean number of eggs per female in the control group was 4.7 (required: ≥ 4 eggs per female) **Agreed endpoints:** **LR_{50}>6L/ha** **ER_{50}> 6 l/ha**

Reference:	KCP 10.4.2 - 2
Report	"A laboratory test for evaluating the effects of Propaquizafop 10% EC on the predatory mite, *Typhlodromus pyri* (Sch.)". Parma P., B/119/16, 2018. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	ESCORT 1 ESCORT 2 Guidelines developed by the IOBC, BART, and EPPO
Deviations:	Yes The study finished in June 2018, not in January 2018.

	Different baths of the test item were used. During the study sponsor's address has changed.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Summary

The aim of the study was to assess the impact of Propaquizafop 10% EC on mortality and reproduction of the predatory mite, *Typhlodromus pyri*. Four concentrations of the test item were used. These were 0.38, 0.96, 2.4 and 6.0 L/ha. Each concentration was divided into three replicates. There was also an untreated control and reference product group. Mortality was observed after 7 days of post treatment of the test item. Observations of reproduction of the control group and all groups treated with the test item were made after 8, 11, and 14 days of the treatment. Mortality of *Typhlodromus pyri* after 7 days of the treatment and the reproduction reduction (Pr) after 14 days of the treatment were test endpoints.

Materials and methods

Test item: Name: Propaquizafop 10% EC
Batch number: SCL – 421258
Content: 100 g/l of propaquizafop
Production date: 19th January, 2018
Expiry date: 18th January, 2020
Test organism: the predatory mite, *Typhlodromus pyri* (Sch.)
Age: 24-hours old protonymphs
Source: Research Institute of Pomology and Floriculture, Skierniewice, Poland
Test design: Test duration: 14 days
Number of treatments: 6 (1-control, 4-treatments and 1- reference item)
Number of replications: 3
Number of mites in each replicate: 20
Application rates: 0.38, 0.96, 2.4 and 6.0 of Propaquizafop 10% EC/ha
Test condition: Temperature: 24 – 26.5°C
Relative humidity: 66 – 80%
Light and photoperiod: 16 h light: 8 h dark
Light intensity: 886 lux
Endpoints: - mite mortality after 7 days of the treatment
- LR_{50}, $NOER_{mortality}$
- reproduction reduction (Pr) after 14 days of the treatment
- ER_{50}, $NOER_{reproduction}$
Statistical analysis: Probit analysis, Multiple sequentially-rejective Fisher test after Bonferroni- Holm test, Shapiro-Wilk's test on normal distribution, Levene's test on variance homogeneity, Multiple Sequentially-rejective t-test after Bonferroni-Holm
Validity criteria: - mortality of the control group was 0.0% on day 7 of exposure (criterion: a maximum of 20%),
- mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 88.3% on day 7 of exposure (criterion: a minimum of 50%),
- the mean number of eggs per female in the control group was 4.7 (required: ≥ 4 eggs per female).

Findings

The effects of Propaquizafop 10% EC on mortality and fecundity of *Typhlodromus pyri*

Study group [application rate]	**Parameter (endpoint)**				
	Mortality		**Reproduction**		
Test item	**[%]**	**LR_{50}**	**Mean**	**Reproduction**	**ER_{50}**

L/ha	g a.i./ha		L/ha	g a.i./ha	**number of eggs/ female (Rr) [no.]**	**reduction Pr [%]**	L/ha	g a.i./ha
Control (0.0)		0.0	-		4.7	-	-	
0.38	38	0.0	**> 6.0**	> 600	6.1	(- 29.8)[a]	**> 6.0**	> 600
0.96	96	1.7			4.2	10.4		
2.4	240	6.7			4.8	(- 1.8)[a]		
6.0	600	8.3			5.1	(- 8.3)[a]		
$NOER_{mortality}$			**≥ 6.0**	≥ 600	**$NOER_{reproduction}$**		**≥ 6.0**	≥ 600
Reference item		-						
mL/ha	**g a.i./ha**							
9.0	**3.6**	88.3	not determined		not assessed			

[a]: the negative value shows that the mean number of mummies was higher than in the control group

Conclusions:
On the basis of the obtained results it can be concluded that Propaquizafop 10% EC at the rates of 0.38, 0.96, 2.4 and 6.0 L/ha has no adverse effect on mortality and reproduction of the mites.

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • after 48 hours, mortality of the control group was 0.0% (criterion: a maximum of 10.0%) - after 48 hours mortality of the group treated with the reference item at the rate of 5.0 mL/ha was 73.3% (criterion: a minimum of 50%), • all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity) • the mean number of mummies per female in the control group was 15.8 (criterion: a minimum of 5.0 mummies/female), • all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring) • **Agreed endpoints:** **LR_{50}> 8 L/ha** **ER_{50}>5.3 L/ha**

Reference:	KCP 10.4.2 - 3
Report	"An extended laboratory test for evaluating the effects of Propaquizafop 10% EC on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani - Perez) Parma P., B/118/16, 2018. Institute of Industrial Organic Chemistry Branch Pszczyna

Guideline(s):	ESCORT 1 ESCORT 2 Guidelines developed by the IOBC, BART, and EPPO
Deviations:	Yes The study was finished in June 2018, not in November 2017. Relative humidity in the laboratory room exceeded the recommended ranges.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Summary

The aim of the study was to assess the impact of Propaquizafop 10% EC on mortality and fecundity of the parasitic wasp, *Aphidius rhopalosiphi*. Four application rates of the test item and a control were used. The rates were 1.0, 2.0, 4.0 and 8.0 L of Propaquizafop 10% EC/ha. Each concentration was divided into six replicates. Adult wasps, less than 48 hours old were exposed to the test item applied to barley plants. Mortality was determined 2, 24 and 48 hours after the release of wasps to the test arenas. Females, which survived 48-hour exposure to test the item and the ones from the control group were subjected to fecundity assessments. To allow the oviposition, fifteen female wasps from the groups treated with the test item and the control group were individually introduced into fecundity units containing barley plants infested with the aphid, *Rhopalosiphuna padi*. After 24 hour oviposition, the wasps were removed from the test arenas and the number of mummies (parasitized aphids in which wasps in pupae were developing) was recorded after 12 days. Mortality of the wasps after 48 hours of exposure and the percentage of fecundity reduction 12 days after the oviposition were the endpoints.

Materials and methods

Test item:	Name: Propaquizafop 10% EC Batch number: SCL - 86421 Content: 100 g/l of propaquizafop Production date: 8th March 2016 Expiry date: 7th March 2018
Test organism:	Species: *Aphidius rhopalosiphi* (DeStefani-Perez) Age: adult females (24 - 48 hours after emerging from mummies) Source: a laboratory culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was obtained from Katz Biotech AG (Baruth, Germany)
Test design:	Test duration: 12 days Number of treatments: 6 (1-control, 4-treatments and 1- reference item) Number of replications: 6 replicates/group Number of wasps: 5 wasps/replicate
Plant material:	Barley (*Hordeum vulgare*) plant
Application rates:	1.0, 2.0, 4.0 and 8.0 L of Propaquizafop 10% EC/ha
Test conditions:	Temperature: 19 – 21°C Relative humidity: 68 – 73% Photoperiod: 16 h light: 8 h dark Light intensity: 1077 lux (mortality and oviposition phase), 4466 lux (fecundity phase)
Endpoints:	- wasp mortality after 48 hours of exposure - determination of the LR_{50} and the $NOER_{mortality}$

- reduction in fecundity (Pr) of surviving female wasps exposed to Propaquizafop 10% EC, recorded 12 days after the oviposition period
- determination of the ER_{50} and the $NOER_{fecundity}$

Statistical analysis: Probit analysis, Step-down Cochran-Armitege test procedure, Shapiro- Wilk's test on normal distribution, Levene's test on variance homogeneity, multiple sequentially-rejective median (2x2 table) test after Bonferroni-Holm procedure.

Validity criteria:
- after 48 hours, mortality of the control group was 0.0% (criterion: a maximum of 10.0%),
- after 48 hours mortality of the group treated with the reference item at the rate of 5.0 mL/ha was 73.3% (criterion: a minimum of 50%),
- all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity),
- the mean number of mummies per female in the control group was 15.8 (criterion: a minimum of 5.0 mummies/female),
- all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring).

Findings

The effects of Propaquizafop 10% EC on mortality and fecundity of *Aphidius rhopalosiphi*

Study group [application rate]		**Parameter (endpoint)**							
		Mortality				**Fecundity**			
Test item		**Total [%]**	**Corrected***	**LR_{50}**		**mean no. of mummies/ female**	**fecundity reduction Pr [%]**	**ER_{50}**	
L/ha	g a.i./ ha			**L/ha**	g a.i./ ha			**L/ha**	g a.i./ ha
Control (0.0)		0.0	-	-		15.8	-	-	
1.0	100	0.0	-	**> 8.0**	> 800	11.7+	**26.2**	**5.3**	530
2.0	200	10.0	-			10.3+	**35.0**		
4.0	400	10.0+	-			9.4+	**40.5**		
8.0	800	46.7+	-			6.3+	**59.9**		
$NOER_{mortality}$				**2.0**	200	**$NOER_{fecundity}$**		**< 1.0**	< 100
Reference item			-						
mL/ha	g a.i./ ha								
5.0	2.0	73.3	not determined			not assessed			

+: statistically significant difference

Conclusions:

On the basis of the obtained results it can be concluded that Propaquizafop 10% EC at the rates of i.e. 1.0 and 2.0 L/ha has no adverse effect on mortality of the wasps. However, at the rate of i.e. 4.0 and 8.0 L/ha such an effect is observed. The test item at the rates of 1.0, 2.0, 4.0 and 8.0 L/ha has adverse effect on fecundity of the wasps.

A 2.4.2.1 KCP 10.4.2.1 Species level testing

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • the variation between replicate samples in the control should be less than ± 15% The coefficients of variation (CV) in the control group were 3.0, 11.5, 11.8 and 3.3 %, after 0, 7, 14, and 28 days of incubation **Agreed endpoints:** On the basis of the results, it was concluded that at the concentration corresponding to the PEC: 0.16 mg of active substance/ kg of soil, did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Reference:	KCP 10.5-1
Report:	"Propaquizafop 10% EC Soil Microorganisms: Nitrogen Transformation Test". Pieczka P., G/48/17, 2017. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD Guideline No. 21 (2000) EU Method C.21.
Deviations:	Yes The address of the Sponsor was changed. The study finished in October, not in August as it was planned. The temperature in the test room was 20 – 23°C. According to the study plan it should be 18 – 22°C.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The aim of the study was to assess the impact of Propaquizafop 10% EC on the processes of nitrogen transformation in aerobic surface soils. The effect of the test item was investigated in agricultural soil which was collected from a place belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna. The test was carried out for 28 days. On 0, the 7th, 14 th and 28 th day of incubation, soil samples were collected to determine the quantities of nitrates. The concentrations of the test item were 0.16 mg of active substance/kg of soil and 0.80 mg of active substance/kg of soil. The treated and the control soils were divided into three replicates.

Material and methods

Test item: Name: Propaquizafop 10% EC
Batch number: SCL - 86421
Content: 100 g/l of propaquizafop

	Production date: 8th March 2016 Expiry date: 7th March 2018
Soil:	Agricultural soil collected from a place belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna.
Test design:	Test duration: 28 days Soil portion: 3; weighing 1500 g each Number of replications: 3; weighing 500 g each The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil.
Concentrations of the test material:	control; PEC: 0.16 mg of the active substance/kg of soil and 5 x PEC: 0.80 mg of the active substance/kg of soil
Test conditions:	Temperature: 20 – 23°C, Soil moisture: 42.7% – 51.9% of the maximum water holding capacity Ilumination: incubation in darkness
Endpoints:	The concentration of nitrate ions [mg/kg dry soil] after 0, 7, 14 and 28 days of incubation. The nitrate formation rate [mg/kg dry weight of soil/day] for selected time intervals of soil incubation, i.e. 0 - 7, 0 – 14, 0 – 28 days. Percent deviation from the control in nitrate formation rate calculated for selected time intervals i.e. 0 - 7, 0 – 14, 0 – 28 days.
Statistical analysis:	- Shapiro-Wilk's test on Normal Distribution - Levene's Test on Variance Homogenity (with Residuals) - Williams Multiple Sequential t-test Procedure
Validity criteria:	- the variation between replicate samples in the control should be less than ± 15%

Findings

The difference in the nitrate formation rate between the control soil and the one treated with the test item at the concentration corresponding to the PEC: 0.16 mg of active substance /kg of soil did not exceed 25% on 28 day of analysis.

Nitrate formation rate* [mg nitrate/kg dry weight of soil/day] for selected time intervals.

Time interval [d]	Control				PEC 0.16 mg of active substance/kg of soil				5 x PEC 0.8 mg of active substance/kg of soil			
	Replicate			Mean ± SD	Replicate			Mean ± SD	Replicate			Mean ± SD
	I	II	III		I	II	III		I	II	III	
0 - 7	-12.72	-16,39	-5,75	-11.62 ± 5.41	-9,75	-3,74	-8,74	-7.41 ± 3.22	-5,60	1,21	-2,30	-2.23+ ± 3.40
0 - 14	7.87	1,78	0,64	3.43 ± 3.89	2,83	2,50	11,32	5.55 ± 5.00	5,83	3,77	-1,20	2.80 ± 3.61
0 - 28	-1,06	-1,18	-1,87	-1.37 ± 0.44	-1,37	-0,87	-1,23	-1.16 ± 0.26	-0,38	-1,35	-1,34	-1.08 ± 0.62

+ statistically significant difference between the control and the treated group (α=0.05)
* - Rate of nitrate ions formation per a day = [(mg nitrate / kg of soil dry weight on sampling day 'a') - (mg nitrate / kg of soil dry weight on day 0)]/ 'a' day; 'a' = 7. 14. 28 day

Conclusions

On the basis of the results, it was concluded that at the concentration corresponding to the PEC: 0.16 mg of active substance/ kg of soil, did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. • the variation between replicate samples in the control should be less than ± 15% The coefficient of variation in the control group was as follows: 1.9, 9.2, 2.2 and 3.8% on 0, the 7th, 14th and 28th day of soil incubation, respectively **Agreed endpoints:** On the basis of the results, it was concluded that at the concentration corresponding to the PEC: 0.16 mg of active substance/ kg of soil, did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Reference:	KCP 10.5-2
Report:	"Propaquizafop 10% EC Soil Microorganisms: Carbon Transformation Test". Pieczka P., G/47/17, 2017. Institute of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD Guideline No. 217 (2000)
Deviations:	Yes The address of the Sponsor was changed. The study finished in October 2017, not in August 2017. The temperature in the test room was 20 – 23°C. According to the study plan should be 18 – 22°C.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The aim of the study was to assess the impact of Propaquizafop 10% EC on soil microorganisms activity in the processes of carbon transformation. The effect of the test item was investigated in agricultural soil which was freshly collected from the field. The test was carried out for 28 days. On 0, the 7th, 14th and 28th day of incubation, the respiration rates in the treated and control soil samples were determined. The application rates of test item were control, low concentration level of 0.16 mg of the active substance/kg of soil and high concentration level of 0.80 mg of the active substance/kg of soil

Material and methods

Test item:	Name: Propaquizafop 10% EC Batch number: SCL - 86421 Content: 100 g/l of propaquizafop Production date: 8th March 2016 Expiry date: 7th March 2018
Soil:	Agricultural soil taken from the area belonging to the Institute of Industrial Organic Chemistry, Branch Pszczyna.
Test design:	Test duration: 28 days Soil portion: 3; weighing 1500 g each Number of replications: 3; weighing 500 g each

Concentrations of the test material:	control; PEC: 0.16 mg of the active substance/kg of soil and 5 x PEC: 0.80 mg of the active substance/kg of soil
Test conditions:	Temperature: 20 – 23°C, Soil moisture: 42.1% to 48.4% of the maximum water holding capacity Ilumination: incubation in darkness
Endpoints:	The mean respiration rate in the treated soil samples was compared with that in the control, and the percent deviation of the treated from the control was calculated after 0, 7, 14, and 28 days of incubation.
Statistical analysis:	In order to determine significance in the soil respiration rate of differences between the control and the treated groups the Williams Multiple Sequential t-test Procedure were used.
Validity criteria:	- the variation between replicate samples in the control should be less than ± 15%

Findings

The difference in the soil respiration rate between the control soil and the one treated with the test item at the concentrations 0.16 mg of the active substance/kg of soil and 0.80 mg of the active substance/kg of soil did not exceed 25% on any day of analysis.

Conclusions

On the basis of the results, it was concluded that Propaquizafop 10% EC at the concentrations corresponding to the 0.16 mg of the active substance/kg of soil and 0.80 mg of the active substance/kg of soil did not have any long-term adverse effects on the process of carbon transformation in aerobic surface soils.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS: The study is considered acceptable. All validity criteria were met.

- the seedling emergence (validity criterion: at least 70%) was as follows:
  88.1 – 92.9% – pea,
  88.1 – 95.2% – sunflower,
  85.7 – 92.9% – cabbage,
  85.0 – 97.5% – carrot,
  80.0 – 87.5% – onion,
  90.0 - 100% – oats,
- the mean survival of the emerged control seedlings for pea, sunflower, cabbage and carrot was 100% and for onion and oats was 95 % (validity criterion: at least 90%),

Agreed endpoints:

Endpoint value	**Pea** *Pisum sativum*	**Sunflower** *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*

	Plant number							
	ER_{50}	**mL/ha[a]**	> 2400.0	> 2400.0	> 2400.0	> 2400.0	> 2400.0 (2382.2 - > 2400.0)	157.6 (117.0 – 213.8)
		g/ha[b]	> 240.0	> 240.0	> 240.0	> 240.0	> 240.0 (238.2 - >240.0)	15.8 (11.7 – 21.4)
	NOER	**mL/ha[a]**	≥ 2400.0	≥ 2400.0	≥ 2400.0	≥ 2400.0	≥ 2400.0	44.4
		g/ha[b]	≥ 240.0	≥ 240.0	≥ 240.0	≥ 240.0	≥ 240.0	4.44
	Shoot length (plants without roots)							
	ER_{50}	**mL/ha[a]**	> 2400.0	> 2400.0	> 2400.0	> 2400.0	> 2400.0	118.8 (80.1 – 167.2)
		g/ha[b]	> 240.0	> 240.0	> 240.0	> 240.0	> 240.0	11.9 (8.0 – 16.7)
	NOER	**mL/ha[a]**	800.0	266.7	≥ 2400.0	800.0	800.0	44.4
		g/ha[b]	80.0	26.7	≥ 240.0	80.0	80.0	4.4
	Plant dry weight (plants without roots)							
	ER_{50}	**mL/ha[a]**	> 2400.0	> 2400.0	> 2400.0	> 2400.0	> 2400.0	111.7
		g/ha[b]	> 240.0	> 240.0	> 240.0	> 240.0	> 240.0	11.2
	NOER	**mL/ha[a]**	≥ 2400.0	≥ 2400.0	≥ 2400.0	800.0	800.0	44.4
		g/ha[b]	≥ 240.0	≥ 240.0	≥ 240.0	80.0	80.0	4.4

a: value for the test item, i.e. Propaquizafop 10% EC expressed as mL/ha
b: value for the active substance, i.e. propaquizafop expressed as g/ha

The following order of the test plant sensitivity was noticed:
oats > carrot, onion > sunflower, pea > cabbage

Reference:	KCP 10.6.2-1
Report:	"Propaquizafop 10% EC Terrestrial Plant Test: Vegetative Vigour Test". Pieczka P., G/52/17, 2019 Institute Of Industrial Organic Chemistry Branch Pszczyna
Guideline(s):	OECD No. 227 (2006)
Deviations:	Yes According to OECD Guideline No. 227 (2006), the light intensity should be 350 ± 50µE/m2/s. In the experiment, the light intensity was between 84.1 – 125.7 µE/m2/s. The study was finished in August 2019 and not in November 2018.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The study, aimed at evaluating the effect of Propaquizafop 10% EC on vegetative vigour of six terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species. Seeds of the test plant species were sown in plastic pots. The plants were grown to the 2- to 4- true leaf stage. The test item was sprayed onto the plants leaf surface. For each species, six application rates were used. Untreated control group was conducted simultaneously. During the experiment, the plants were observed for visual phytotoxicity (7, 14 and 21 days after the test item application). The experiment finished 21 days after the spraying. At the end of the experiment, the number of surviving plants was counted. Next, the plants were cut down, and the lengths of their shoots were determined. Finally, they were dried at 60ºC to a constant weight and weighed.
The results concerning the shoot length, the dry weight, and the number of plants at the end of the experiment were statistically analyzed to determine the ER_{10}, ER_{25}, ER_{50}, and NOER.

Material and methods

Test item:	Name: Propaquizafop 10% EC Batch number: SCL – 421258 Content: 100 g/l of propaquizafop Production date: 19th January, 2018 Expiry date: 18th January, 2020
Test species::	pea (*Pisum sativum*), sunflower (*Helianthus annuus*), cabbage (*Brassica oleracea var. capitata*), carrot (*Daucus carota*), onion (*Allium cepa*), oats (*Avena sativa*).
Test design:	Number of rates: 6 application rates + control Number of replicates: 4 or 7 replicates/rate Number of plants per application rate – 20 or 21 Test termination: 21 days after the spraying
Soil:	sandy loam
Application rates:	- a control, 9.9, 29.6, 88.9, 266.7, 800.0 and 2400.0 ml of the test item/ha in cultivation of pea, sunflower, cabbage, carrot and onion - a control, 1.6, 4.9, 14.8, 44.4, 133.3 and 400.0 ml of the test item/ha in cultivation of oats
Test conditions:	Temperature: 21.6 – 27.4°C Humidity: 49.8 – 91.8% Controlled light – dark cycles (16h:8h) Light intensity: 84.1 – 125.7 µE/m2/s Carbon dioxide concentration: 317 – 341 ppm
Endpoints:	ER_{10}, ER_{25}, ER_{50}, NOER.
Statistical analysis:	ER_{10}, ER_{25}, ER_{50} – probit or logit or Weibull analysis NOER - Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals) or Bartlett's Test Procedure on Variance Homogenity, Williams Multiple Sequential t-test Procedure or Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment or Fisher's Exact Binomial Test with Bonferroni Correction.
Validity criteria:	- the seedling emergence (validity criterion: at least 70%) was as follows: 88.1 – 92.9% – pea, 88.1 – 95.2% – sunflower, 85.7 – 92.9% – cabbage, 85.0 – 97.5% – carrot, 80.0 – 87.5% – onion, 90.0 - 100% – oats, - the mean survival of the emerged control seedlings for pea, sunflower, cabbage and carrot was 100% and for onion and oats was 95 % (validity criterion: at least 90%),

- the control seedlings did not exhibit any visible phytotoxic symptoms,
- environmental conditions for all plants belonging to the same species were identical.

Findings

Endpoint value		Pea *Pisum sativum*	Sunflower *Helianthus annuus*	Cabbage *Brassica oleracea var. capitata*	Carrot *Daucus carota*	Onion *Allium cepa*	Oats *Avena sativa*
Plant number							
ER_{50}	**mL/ha[a]**	> 2400.0	> 2400.0	> 2400.0	> 2400.0	> 2400.0 (2382.2 - > 2400.0)	157.6 (117.0 – 213.8)
	g/ha[b]	> 240.0	> 240.0	> 240.0	> 240.0	> 240.0 (238.2 - >240.0)	15.8 (11.7 – 21.4)
NOER	**mL/ha[a]**	≥ 2400.0	≥ 2400.0	≥ 2400.0	≥ 2400.0	≥ 2400.0	44.4
	g/ha[b]	≥ 240.0	≥ 240.0	≥ 240.0	≥ 240.0	≥ 240.0	4.44
Shoot length (plants without roots)							
ER_{50}	**mL/ha[a]**	> 2400.0	> 2400.0	> 2400.0	> 2400.0	> 2400.0	118.8 (80.1 – 167.2)
	g/ha[b]	> 240.0	> 240.0	> 240.0	> 240.0	> 240.0	11.9 (8.0 – 16.7)
NOER	**mL/ha[a]**	800.0	266.7	≥ 2400.0	800.0	800.0	44.4
	g/ha[b]	80.0	26.7	≥ 240.0	80.0	80.0	4.4
Plant dry weight (plants without roots)							
ER_{50}	**mL/ha[a]**	> 2400.0	> 2400.0	> 2400.0	> 2400.0	> 2400.0	111.7
	g/ha[b]	> 240.0	> 240.0	> 240.0	> 240.0	> 240.0	11.2
NOER	**mL/ha[a]**	≥ 2400.0	≥ 2400.0	≥ 2400.0	800.0	800.0	44.4
	g/ha[b]	≥ 240.0	≥ 240.0	≥ 240.0	80.0	80.0	4.4

a: value for the test item, i.e. Propaquizafop 10% EC expressed as mL/ha
b: value for the active substance, i.e. propaquizafop expressed as g/ha

The following order of the test plant sensitivity was noticed:
oats > carrot, onion > sunflower, pea > cabbage

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

- the seedling emergence (validity criterion: at least 70%) was as follows:
  88.1 – 92.9% – pea,
  88.1 – 95.2% – sunflower,
  85.7 – 92.9% – cabbage,
  85.0 – 97.5% – carrot,
  80.0 – 87.5% – onion,
  90.0 - 100% – oats,
- the mean survival of the emerged control seedlings for pea, sunflower, cabbage and carrot was 100% and for onion and oats was 95 % (validity criterion: at least 90%),
- the control seedlings did not exhibit any visible phytotoxic symptoms,
- environmental conditions for all plants belonging to the same species were identical.

Agreed endpoints:

The ER_{50} and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight

lpoint value	Sunflower *Helianthus*	Cabbage *Brassica*	Pea *Pisum sativum*	Carrot *Daucus*	Onion *Allium cepa*	Oats *Avena sat*

			annuus	*oleracea var. capitata*		*carota*		
	Plant number							
ER_{50}		**mL/ha[a]**	> 2400	> 2400	> 2400	> 2400	> 2400	> 1200
		g/ha[b]	> 240	> 240	> 240	> 240	> 240	> 120
NOER		**mL/ha[a]**	≥ 2400	88.9	≥ 2400	≥ 2400	≥ 2400	≥ 1200
		g/ha[b]	≥ 240	8.9	≥ 240	≥ 240	≥ 240	≥ 120
	Shoot length (plants without roots)							
ER_{50}		**mL/ha[a]**	> 2400	> 2400*	> 2400	> 2400	> 240*	> 1200*
		g/ha[b]	> 240	> 240*	> 240	> 240	> 240*	> 120*
NOER		**mL/ha[a]**	≥ 2400	800	800	≥ 2400	≥ 2400	≥ 1200
		g/ha[b]	≥ 240	80	80	≥ 240	≥ 240	≥ 120
	Plant dry weight (plants without roots)							
ER_{50}		**mL/ha[a]**	> 2400	> 2400*	> 2400	> 2400	> 2400	> 1200
		g/ha[b]	> 240	> 240*	> 240	> 240	> 240	> 120
NOER		**mL/ha[a]**	≥ 2400	800	800	≥ 2400	≥ 2400	≥ 1200
		g/ha[b]	≥ 240	80	80	≥ 240	≥ 240	≥ 120

a: value for the test item, i.e. Propaquizafop 10% EC expressed as mL/ha
b: value for the active substance, i.e. Propaquizafop 10% EC expressed as g/ha
* - value obtained above the tested range of rates

Reference:	KCP 10.6.2-2
Report:	"Propaquizafop 10% EC Terrestial Plant Test: Seedling Emergence and Seedling Growth Test". Pieczka P., G/51/17, 2020 Institute of Industrial Organic Chemistry
Guideline(s):	OECD No. 208 (2006)
Deviations:	Yes - According to OECD Guideline No. 208 (2006), the light intensity should be 350 ± 50µE/m^2/s. However, these values are recommended for tests conducted in green-houses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 80.1 – 129.9 µE/m^2 /s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. The study was finished in October 2020 and not in November 2018 as it had been planned.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The study, aimed at evaluating the effect of Propaquizafop 10% EC on seedling emergence and seedling growth of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species. The test item was sprayed onto the soil surface. Eight application rates were used. There was also a concurrent control group. Seeds of the test plant species were sown in plastic pots (3 (sunflower, cabbage, pea) or 5 (carrot, onion, oats) seeds/pot). The experiment was conducted in a special room. Suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for

emergence (every day and then every 2 – 3 days) and visual phytotoxicity (after 7 and 14 days). The experiment finished 14 days after the emergence of 50% of the control seedlings. At the end of the experiment, the number of surviving plants was determined. Next, the plants were cut down, measured, dried to a constant weight at 60ºC, and weighed. The results concerning the emergence, the shoot length, and the dry weight were statistically analyzed in order to determine the ER_{10}, ER_{25}, ER_{50}, and NOER.

Material and methods

Test item:	Propaquizafop 10% EC Batch number: SCL – 421258 Content: Propaquizafop - 100 g/l Production date: 19th January, 2018 Expiry date: 18th Januray, 2020
Test species::	sunflower (Helianthus annuus), cabbage (Brassica oleracea var. capitata), pea (Pisum sativum), carrot (Daucus carota), onion (Allium cepa), oats (Avena sativa).
Test design:	Number of rates: 5 application rates + control Number of replicates: 7 replicates/rate (sunflower, cabbage, pea), 4 (carrot, onion, oats) Number of plants per application rate – 21 or 20 Test termination: 14 days after the emergence of 50% of the control seedlings
Soil:	sandy loam
Application rates:	- control, 29.6, 88.9, 266.7, 800.0 and 2400.0 ml of the test item/ha for sunflower, cabbage, pea, carrot, onion. - control, 14.8, 44.4, 133.3, 400.0 and 1200 ml of the test item/ha for oats.
Test conditions:	Temperature: 17.9 – 31.9°C Humidity: 45.0 – 89.4% Controlled light – dark cycles (16h:8h) Light intensity: 80.1 – 129.19 µE/m^2/s CO_2 concentration: 322 – 372 ppm
Endpoints:	ER_{10}, ER_{25}, ER_{50}, NOER.
Statistical analysis:	ER_{10}, ER_{25}, ER_{50} – probit analysis, nonlinear regression using the 4- parameter logistic NOER: Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure or Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment.
Validity criteria:	The seedling emergence in the control (validity criterion: at least 70%) was as follows: 76.2% – sunflower, 95.2% – cabbage, 95.2% – pea, 75% – carrot, 90% – onion, 80% – oats, - the mean survival of the emerged control seedlings was 100% for all tested species (validity criterion: at least 90%); - the control seedlings did not exhibit any visible phytotoxic effects;. - environmental conditions for all plants of the same species were identical.

Findings

The ER_{50} and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight

Endpoint value		**Sunflower** *Helianthus annuus*	Cabbage *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Onion** *Allium cepa*	**Oats** *Avena sativa*
Plant number							
ER_{50}	**mL/ha[a]**	> 2400	> 2400	> 2400	> 2400	> 2400	> 1200
	g/ha[b]	> 240	> 240	> 240	> 240	> 240	> 120
NOER	**mL/ha[a]**	≥ 2400	88.9	≥ 2400	≥ 2400	≥ 2400	≥ 1200
	g/ha[b]	≥ 240	8.9	≥ 240	≥ 240	≥ 240	≥ 120
Shoot length (plants without roots)							
ER_{50}	**mL/ha[a]**	> 2400	> 2400*	> 2400	> 2400	> 240*	> 1200*
	g/ha[b]	> 240	> 240*	> 240	> 240	> 240*	> 120*
NOER	**mL/ha[a]**	≥ 2400	800	800	≥ 2400	≥ 2400	≥ 1200
	g/ha[b]	≥ 240	80	80	≥ 240	≥ 240	≥ 120
Plant dry weight (plants without roots)							
ER_{50}	**mL/ha[a]**	> 2400	> 2400*	> 2400	> 2400	> 2400	> 1200
	g/ha[b]	> 240	> 240*	> 240	> 240	> 240	> 120
NOER	**mL/ha[a]**	≥ 2400	800	800	≥ 2400	≥ 2400	≥ 1200
	g/ha[b]	≥ 240	80	80	≥ 240	≥ 240	≥ 120

a: value for the test item, i.e. Propaquizafop 10% EC expressed as mL/ha
b: value for the active substance, i.e. Propaquizafop 10% EC expressed as g/ha
* - value obtained above the tested range of rates

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

A 2.8 KCP 10.8 Monitoring data