

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SHA 6100 A

Product name: ALIVE

Chemical active substance:

Propaquizafop, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT - Poland

Applicant: Sharda Cropchem España S.L.

Submission date: October 2020

MS Finalisation date: 12/2021 03/2022 06/2022

Version history

When	What
December 2021	ZRMS evaluated the dRR
January 2022	Applicant update
March 2022	Assessment of the updated dRR
June 2022	The Final Registration Report supplemented with the required endorsements by MRiRW

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by SHARDA CROPCHEM ESPAÑA S.L.

This application is for approval of Propaquizafop 10% EC, a emulsifiable concentrate 100 g/L of propaquizafop for use as herbicide on sugar beet, winter oilseed rape, potato, onion, bean, green peas; peas for dry seeds, cabbage, carrot, parsley, strawberry, spring oilseed rape, opium poppy, common flax, linen flax, broccoli, brussels sprouts, broad beans, faba bean, filed peas, white lupine, yellow lupine, narrow-leaved lupine, root celery, parsnip, swede, garlic, shallot, fodder beet, beetroot, Jerusalem artichoke, horseradish, black radish, Japanese radish, radish, salsify, white turnip, black turnip, alfalfa, yellow alfalfa, black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, lentil, white melilot, yellow melilot, grass pea.

zRMS: Poland

1.2 Letters of Access

Not applicable. Letter of access not needed.

1.3 Justification for submission of tests and studies

This dossier relied on new tests and studies, providing data and information specific to the formulation Propaquizafop 10% EC as required by the EU regulations.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	SHA6100A
Product name in MS	ALIVE
Authorization number	-
Function	Herbicide
Applicant	Sharda Cropchem España S.L

Active substance(s) (incl. content)	Propaquizafop, 100 g/L
Formulation type	Emulsifiable Concentrate [Code: EC]
Packaging	COEX (HDPE/EVOH): 250 mL, 500 mL, 1 L, 5 L, 10 L, 20 L
Coformulants of concern for national authorizations	-
Restrictions related to identity	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

2.2 Conclusion

The evaluation of the application for Propaquizafop 10% EC resulted in the decision to grant the authorization.

Physical and chemical properties:

Authorization can be granted for 2 years.

Efficacy section:

Uses (from 1 to 49) with exception of Use 28 requested for propaquizafop 10% EC are identical to those of the reference product Agil S 100 EC (reg nr R208/2014) registered in POLAND for more than 10 years and, therefore, not in a scope of data protection anymore. Those uses can be accepted in the opinion of ZRMs. Uses 28 – only for MAR and N-E EPPO zone Applicant submitted sufficient number of trials.

Toxicology section:

Classification of SHA 6100 A / ALIVE is: Acute Tox.4/ H302, Asp.Tox.1/ H304, Skin Sens 1/ H317, Eye Dam.1/H318. The risk for the operator is acceptable with use of personal protective equipment. Implication for labelling: P280: Wear protective gloves, protective clothing.

No unacceptable risk anticipated for the worker for maintenance activities for re-entering: sugar beet, winter oilseed rape, potato, carrot, parsley, spring oilseed rape, opium poppy, common flax, linen flax, root celery, parsnip, swede, fodder beet, beetroot, jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip, alfalfa, yellow alfalfa, black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, white melilot, yellow melilot and osr, treated with ALIVE, even without suitable protective clothing.

But for onion, bean, green peas, peas for dry seeds, cabbage, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, garlic, shallot, lentil, grass pea and strawberry treated with ALIVE, with suitable protective clothing. P280: Wear protective gloves, protective clothing

No undue risk to any resident exposure to ALIVE..

Metabolism and Residues section:

The evaluation of the application for Propaquizafop 10% EC resulted in the decision to grant the authorization.

Uses not accepted (insufficient data on field trials / possibility of extrapolation):

Bean;

Green peas;

Peas for dry seeds;

Jerusalem Artichokes;

Broccoli;
Brussels sprouts;
Broad beans;
Faba bean;
Field peas;
White lupine;
Yellow lupine;
Narrow-leaved lupine
Alfalfa;
Yellow alfalfa;
Black medic;
Red clover;
White clover;
Crimson clover;
Common sainfoin;
Vetch;
Little white bird's-foot;
Lentil;
White melilot;
Yellow melilot;
Grass pea.

Ecotoxicology section:

The evaluation of the application for Propaquizafop 10% EC resulted in the decision to grant the authorization.

2.3 Substances of concern for national monitoring

Not relevant.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Acute Tox. 4 Asp. Tox. 1 Skin Sens. 1 Eye Dam. 1 Aquatic Chronic: Cat 2
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS05, GHS07, GHS08, GHS09
Signal word:	Danger
Hazard statement(s):	H302, H304, H317, H318, H411
Precautionary statement(s):	P280, P301+P310, P331, P302+P352, P305+P351+P338, P391, P405, P501
Additional labelling phrases:	Repeated exposure may cause skin dryness or cracking [EUH066] To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH066	Repeated exposure may cause skin dryness or cracking

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	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.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L
P280	Wear protective gloves, protective clothing.
Worker protection:	
-	Work wear (arms, body and legs covered) - sugar beet, winter oilseed rape, potato, carrot, parsley, osr, spring oilseed rape, opium poppy, common flax, linen flax, root celery, parsnip, swede, fodder beet, beet-root, jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip, alfalfa, yellow alfalfa, black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, white

	melilot, yellow melilot
	Work wear (arms, body and legs covered) and gloves - onion, bean, green peas, peas for dry seeds, cabbage, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, garlic, shallot, lentil, grass pea, strawberry
	Wear protective gloves, protective clothing.
-	Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.
Environmental protection	
SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	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.
Other specific restrictions	
-	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
-	-	-

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 0, date: July 2020

PPP (product name/code): ALIVE/SHA6100A
 Active substance 1: propaquizafop
 Active substance 2: -
 Safener: -
 Synergist: -
 Applicant: SHARDA Cropchem España S.L.
 Zone(s): Central
 Verified by MS: yes

Formulation type: EC (Emulsifiable Concentrate)
 Conc. of as 1: 100 g/L
 Conc. of as 2: -
 Conc. of safener: -
 Conc. of synergist: -
 Professional use:
 Non professional use:

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destina- tion / 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 safen- er/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Zonal uses (field or outdoor uses, certain types of protected crops)													
1.	PL	Sugar beet	F	Common barn-yardgrass (<i>Echinochloa crus-galli</i>); Spring wild-oat (<i>Avena fatua</i>); Red fingergrass (<i>Digitaria sanguinalis</i>); Yellow bristlegrass (<i>Setaria pumila</i>); Green bristlegrass (<i>Setaria viridis</i>); Perennial ryegrass (<i>Lolium perenne</i>)	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 60	*weeds grow stage **crop grow stage
2	PL	Sugar beet	F	Silky bentgrass (<i>Apera spica-venti</i>); self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 12-35***	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 0.050-0.070	200-300	28 60	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose rate 0.7 L/ha ***crop grow stage
3	PL	Sugar beet	F	Couch grass (<i>Agropyron repens</i>)	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 b) 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 b) 0.120	200-300	28 60	*weeds grow stage **crop grow stage
4.	PL	Winter oilseed rape	F	Common barn-yardgrass (<i>Echinochloa crus-galli</i>);	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 90	*weeds grow stage **crop grow stage

			Spring wild-oat (<i>Avena fatua</i>) ; Red fingergrass (<i>Digitaria sanguinalis</i>) ; Yellow bristlegrass (<i>Setaria pumila</i>) ; Green bristlegrass (<i>Setaria viridis</i>) ; Perennial ryegrass (<i>Lolium perenne</i>)									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
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5.	PL	Winter oilseed rape	F	Silky bentgrass (<i>Apera spica-venti</i>); self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 12-30***	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 0.050-0.070	200-300	42 90	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose rate 0.7 L/ha ***crop grow stage
6.	PL	Winter oilseed rape	F	Couch grass (<i>Agropyron repens</i>)	Broadcast spraying	BBCH 13-16* BBCH 12-30**	a) 1 b) 1 OR a) 1 b) 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 b) 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 b) 0.120	200-300	42 90	*weeds grow stage **crop grow stage
7.	PL	Potato	F	Common barnyardgrass (<i>Echinochloa crus-galli</i>); Spring wild-oat (<i>Avena fatua</i>); Red fingergrass (<i>Digitaria sanguinalis</i>); Yellow bristlegrass (<i>Setaria pumila</i>); Green bristlegrass (<i>Setaria viridis</i>); Perennial ryegrass (<i>Lolium perenne</i>)	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 (<i>Apera spica-venti</i>); self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 10-35***	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 0.050-0.070	200-300	40	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose rate 0.7 L/ha

													***crop grow stage
9.	PL	Potato	F	Couch grass (<i>Agropyron repens</i>)	Broadcast spraying	BBCH 13-16* BBCH 10-35**	a) 1 b) 1 OR a) 1 b) 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 b) 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 b) 0.120	200-300	40	*weeds grow stage **crop grow stage
10.	PL	Onion	F	Common barn-yardgrass (<i>Echinochloa crus-galli</i>); Spring wild-oat (<i>Avena fatua</i>); Red fingergrass (<i>Digitaria sanguinalis</i>); Yellow bristlegrass (<i>Setaria pumila</i>); Green bristlegrass (<i>Setaria viridis</i>); Perennial ryegrass (<i>Lolium perenne</i>)	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 (<i>Apera spica-venti</i>); self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 11-12*** BBCH 09-53****	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 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 grow stage ****grow stage crop for seeds
12.	PL	Onion	F	Couch grass (<i>Agropyron repens</i>)	Broadcast spraying	BBCH 13-16*	a) 1		a) 1.25-1.5	a) 0.125-0.150	200-	30	*weeds grow

				<i>ron repens)</i>	spraying	BBCH 11-12** BBCH 09-53***	b) 1 OR a) 1 b) 2	12	b) 1.25-1.5 OR a) 0.6 b) 1.2	b) 0.125-0.150 OR a) 0.060 b) 0.120	300		stage **crop grow stage *** grow stage crop for seeds
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13.	PL	Bean	F	Common barnyardgrass (<i>Echinochloa crus galli</i>); Spring wild oat (<i>Avena fatua</i>); Red fingergrass (<i>Digitaria sanguinalis</i>); Yellow bristlegrass (<i>Setaria pumila</i>); Green bristlegrass (<i>Setaria viridis</i>); Perennial ryegrass (<i>Lolium perenne</i>)	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 Residues: not accepted
14.	PL	Bean	F	Silky bentgrass (<i>Apera spica venti</i>); self seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** min. BBCH 13***	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 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 Residues: not accepted
15.	PL	Bean	F	Couch grass (<i>Agropyron repens</i>)	Broadcast spraying	BBCH 13-16* min. BBCH 13**	a) 1 b) 1 OR a) 1 b) 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 b) 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 b) 0.120	200-300	45	*weeds grow stage **crop grow stage Residues: not accepted
16.	PL	Green peas; Peas for dry seeds	F	Common barnyardgrass (<i>Echinochloa crus galli</i>);	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 stag

			Spring wild oat (<i>Avena fatua</i>); Red fingergrass (<i>Digitaria sanguinalis</i>); Yellow bristlegrass (<i>Setaria pumila</i>); Green bristlegrass (<i>Setaria viridis</i>); Perennial ryegrass (<i>Lolium perenne</i>)											Residues: not accepted e
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17.	PL	Green peas; Peas for dry seeds	F	Silky bentgrass (<i>Apera spica-venti</i>); self seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** min. BBCH 12***	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 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 Residues: not accepted
18.	PL	Green peas; Peas for dry seeds	F	Couch grass (<i>Agropyron repens</i>)	Broadcast spraying	BBCH 13-16* min. BBCH 12**	a) 1 b) 1 OR a) 1 b) 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 b) 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 b) 0.120	200-300	45	*weeds grow stage **crop grow stage
19.	PL	Cabbage	F	Common barnyardgrass (<i>Echinochloa crus-galli</i>); Spring wild-oat (<i>Avena fatua</i>); Red fingergrass (<i>Digitaria sanguinalis</i>); Yellow bristlegrass (<i>Setaria pumila</i>); Green bristlegrass (<i>Setaria viridis</i>); Perennial ryegrass (<i>Lolium perenne</i>)	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 30	*weeds grow stage **crop grow stage
20.	PL	Cabbage	F	Silky bentgrass (<i>Apera spica-venti</i>);	Broadcast spraying	BBCH 13-21* BBCH 25-30** min. BBCH	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 0.050-0.070	200-300	28 30	*weeds grow stage for dose rate 0.5 L/ha

21.	PL	Cabbage	F	Couch grass (<i>Agropyron repens</i>)	Broadcast spraying	BBCH 13-16* min. BBCH 13**	a) 1 b) 1 OR a) 1 b) 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 b) 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 b) 0.120	200-300	28 30	*weeds grow stage **crop grow stage
22.	PL	Carrot; Parsley	F	Common barn-yardgrass (<i>Echinochloa crus-galli</i>); Spring wild-oat (<i>Avena fatua</i>); Red fingergrass (<i>Digitaria sanguinalis</i>); Yellow bristlegrass (<i>Setaria pumila</i>); Green bristlegrass (<i>Setaria viridis</i>); Perennial ryegrass (<i>Lolium perenne</i>)	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 30	*weeds grow stage **crop grow stage
23.	PL	Carrot; Parsley	F	Silky bentgrass (<i>Apera spica-venti</i>); self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** min. BBCH 12***	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 0.050-0.070	200-300	28 30	*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 (<i>Agropyron repens</i>)	Broadcast spraying	BBCH 13-16* min. BBCH 12**	a) 1 b) 1 OR a) 1	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 1.25-1.5 b) 1.25-1.5	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.125-0.150 b) 0.125-0.150	200-300	28 30	*weeds grow stage **crop grow stage

							b) 2		a) 0.6 b) 1.2	a) 0.060 b) 0.120			
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25.	PL	Strawberry	F	Common barn-yardgrass (<i>Echinochloa crus-galli</i>); Spring wild-oat (<i>Avena fatua</i>); Red fingergrass (<i>Digitaria sanguinalis</i>); Yellow bristlegrass (<i>Setaria pumila</i>); Green bristlegrass (<i>Setaria viridis</i>); Perennial ryegrass (<i>Lolium perenne</i>)	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 (<i>Apera spica-venti</i>); self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 91-92***	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 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 (<i>Agropyron repens</i>)	Broadcast spraying	BBCH 13-16* BBCH 91-92**	a) 1 b) 1 OR a) 1 b) 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 b) 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 b) 0.120	200-300	N.A>	*weeds grow stage **crop grow stage
28.	CEU	OSR	F	Annual and perennial grass weeds	Spray	Post emergence BBCH 12-39	a) 1 c) 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													

29.	PL	Spring oilseed rape	F	Common barn-yardgrass (<i>Echinochloa crus-galli</i>); Spring wild-oat (<i>Avena fatua</i>); Red fingergrass (<i>Digitaria sanguinalis</i>); Yellow bristlegrass (<i>Setaria pumila</i>); Green bristlegrass (<i>Setaria viridis</i>); Perennial ryegrass (<i>Lolium perenne</i>)	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 (<i>Apera spica-venti</i>); self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 12-30***	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 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 (<i>Agropyron repens</i>)	Broadcast spraying	BBCH 13-16* BBCH 12-30**	a) 1 b) 1 OR a) 1 b) 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 b) 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 b) 0.120	200-300	90	*weeds grow stage **crop grow stage
32.	PL	Opium poppy; Common flax; Linen flax; Broccoli; Brussels sprouts;	F	Common barn-yardgrass (<i>Echinochloa crus-galli</i>); Spring wild-oat (<i>Avena fatua</i>);	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.	*weeds grow stage **crop grow stage Residues: accepted only Opium

		Broad beans; Faba bean; Field peas; White lupine; Yellow lupine; Narrow-leaved lupine	Red fingergrass (<i>Digitaria sanguinalis</i>); Yellow bristlegrass (<i>Setaria pumila</i>); Green bristlegrass (<i>Setaria viridis</i>); Perennial ryegrass (<i>Lolium perenne</i>)								Broad beans; Faba bean; Field peas; White lupine; Yellow lupine; Narrow-leaved lupine 45.	poppy; Common flax; Linen flax
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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 (<i>Apera spica-venti</i>); self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 13***	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 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-leaved lupine -45.	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose rate 0.7 L/ha ***crop grow stage Residues: accepted only Opium poppy; Common flax; Linen flax
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 (<i>Agropyron repens</i>)	Broadcast spraying	BBCH 13-16* BBCH 13**	a) 1 b) 1 OR a) 1 b) 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 b) 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 b) 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 Residues: accepted only Opium poppy; Common flax; Linen flax
35.	PL	Root celery; Parsnip; Swede	F	Common barnyardgrass (<i>Echinochloa crus-galli</i>); Spring wild-oat (<i>Avena fatua</i>);	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 30 For parsnip 60 for Root celery; Swedes	*weeds grow stage **crop grow stage

			Red fingergrass (<i>Digitaria sanguinalis</i>);										
			Yellow bristlegrass (<i>Setaria pumila</i>);										
			Green bristlegrass (<i>Setaria viridis</i>);										
			Perennial ryegrass (<i>Lolium perenne</i>)										

36.	PL	Root celery; Parsnip; Swede	F	Silky bentgrass (<i>Apera spica-venti</i>) ; self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 12***	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 0.050-0.070	200- 300	28 30 For parsnip 60 for Root celery; Swedes	*weeds grow stage 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 (<i>Agropy- ron repens</i>)	Broadcast spraying	BBCH 13-16* BBCH 12**	a) 1 b) 1 OR a) 1 b) 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 b) 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 b) 0.120	200- 300	28 30 For parsnip 60 for Root celery; Swedes	*weeds grow stage **crop grow stage
38.	PL	Garlic; Shallot	F	Common barn- yardgrass (<i>Echi- nochloa crus-galli</i>); Spring wild-oat (<i>Av- ena fatua</i>) ; Red fingergrass (<i>Digi- taria sanguinalis</i>) ; Yellow bristlegrass (<i>Setaria pumila</i>) ; Green bristlegrass (<i>Setaria viridis</i>) ; Perennial ryegrass (<i>Lolium perenne</i>)	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 (<i>Apera spica-venti</i>) ; self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 11-12***	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 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 grow stage
40.	PL	Garlic; Shallot	F	Couch grass (<i>Agropyron repens</i>)	Broadcast spraying	BBCH 13-16* BBCH 11-12**	a) 1 b) 1 OR a) 1 b) 2	12	a) 1.25-1.5 b) 1.25-1.5 OR a) 0.6 b) 1.2	a) 0.125-0.150 b) 0.125-0.150 OR a) 0.060 b) 0.120	200-300	30	*weeds grow stage **crop grow stage
41.	PL	Fodder beet; Beetroot	F	Common barn-yardgrass (<i>Echinochloa crus-galli</i>); Spring wild-oat (<i>Avena fatua</i>); Red fingergrass (<i>Digitaria sanguinalis</i>); Yellow bristlegrass (<i>Setaria pumila</i>); Green bristlegrass (<i>Setaria viridis</i>); Perennial ryegrass (<i>Lolium perenne</i>)	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 60	*weeds grow stage **crop grow stage
42.	PL	Fodder beet; Beetroot	F	Silky bentgrass (<i>Apera spica-venti</i>); self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** BBCH 12-35***	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 0.050-0.070	200-300	28 60	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose rate 0.7 L/ha ***crop grow stage
43.	PL	Fodder beet; Beetroot	F	Couch grass (<i>Agropyron repens</i>)	Broadcast spraying	BBCH 13-16* BBCH 12-35**	a) 1 b) 1		a) 1.25-1.5 b) 1.25-1.5	a) 0.125-0.150 b) 0.125-0.150	200-300	28 60	*weeds grow stage **crop grow stage

							OR						
							a) 1 b) 2	12	OR		OR		
									a) 0.6 b) 1.2		a) 0.060 b) 0.120		

44.	PL	Jerusalem Artichokes; Horseradish; Black radish; Japanese radish (daikon); Radish; Salsify; White turnip; Black turnip	F	Common barnyardgrass (<i>Echinochloa crus-galli</i>); Spring wild-oat (<i>Avena fatua</i>); Red fingergrass (<i>Digitaria sanguinalis</i>); Yellow bristlegrass (<i>Setaria pumila</i>); Green bristlegrass (<i>Setaria viridis</i>); Perennial ryegrass (<i>Lolium perenne</i>)	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 Turnips, horseradish: 60 days Black radish; Japanese radish (daikon); Radish; Salsify, Jerusalem Artichokes: 30 days	*weeds grow stage **crop grow stage Residues: Jerusalem Artichokes — not accepted
45.	PL	Jerusalem Artichokes; Horseradish; Black radish; Japanese radish (daikon); Radish; Salsify; White turnip; Black turnip	F	Silky bentgrass (<i>Apera spica-venti</i>); self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** min. BBCH 12***	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 0.050-0.070	200-300	28 Turnips, horseradish: 60 days Black radish; Japanese radish (daikon); Radish; Salsify, Jerusalem Artichokes: 30 days	*weeds grow stage for dose rate 0.5 L/ha ** weeds grow stage for dose rate 0.7 L/ha ***crop grow stage Residues: Jerusalem Artichokes — not accepted
46	PL	Jerusalem Artichokes; Horseradish; Black radish; Daikon; Radish; Salsify;	F	Couch grass (<i>Agropyron repens</i>)	Broadcast spraying	BBCH 13-16* min. BBCH 12**	a) 1 b) 1 OR a) 1 b) 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 a) 0.060	200-300	28 Turnips, horseradish: 60 days Black radish;	*weeds grow stage **crop grow stage Residues: Jerusalem Artichokes — not

		White turnip; Black turnip						b) 1.2	b) 0.120		Japanese radish (daikon); Radish; Salsify, Jerusalem Artichokes; 30 days	accepted
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47.	PL	Alfalfa; Yellow alfalfa; Black medic; Red clover; White clover; Crimson clover; Common sainfoin; Vetch; Little white bird's-foot; Lentil; White melilot; Yellow melilot; Grass pea	F	Common barnyardgrass (<i>Echinochloa crus-galli</i>); Spring wild-oat (<i>Avena fatua</i>); Red fingergrass (<i>Digitaria sanguinalis</i>); Yellow bristlegrass (<i>Setaria pumila</i>); Green bristlegrass (<i>Setaria viridis</i>); Perennial ryegrass (<i>Lolium perenne</i>)	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 Residues: not accepted
48.	PL	Alfalfa; Yellow alfalfa; Black medic; Red clover; White clover; Crimson clover; Common sainfoin; Vetch; Little white bird's-foot; Lentil; White melilot; Yellow melilot; Grass pea	F	Silky bentgrass (<i>Apera spica-venti</i>); self-seeding of cereals	Broadcast spraying	BBCH 13-21* BBCH 25-30** min. BBCH 13***	a) 1 b) 1	-	a) 0.5-0.7 b) 0.5-0.7	a) 0.050-0.070 b) 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 Residues: not accepted
49.	PL	Alfalfa; Yellow alfalfa; Black medic; Red clover; White clover; Crimson clover;	F	Couch-grass (<i>Agropyron repens</i>)	Broadcast spraying	BBCH 13-16* min. BBCH 13**	a) 1 b) 1 OR a) 1 b) 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 a) 0.060	200-300	45	*weeds grow stage **crop grow stage Residues: not accepted

		Common sain-foin; Vetch; Little white bird's-foot; Lentil; White melilot; Yellow melilot; Grass pea							b) 1.2	b) 0.120			

Field of use: Herbicide

Remarks table heading: (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
 (c) g/kg or g/l

Remarks columns: 1 Numeration necessary to allow references
 2 Use official codes/nomenclatures of EU Member States
 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

(d) Select relevant
 (e) Use number(s) in accordance with the list of all intended GAPS in Part B, Section 0 should be given in column 1
 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

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

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of yellow brown liquid, with a aromatic odour. It is not explosive, has no oxidising properties. The product is not flammable/has a flash point of 100 °C. It has a self ignition temperature of 445 °C. In aqueous solution, it has a pH value around 5.47 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/EVOH. Its technical characteristics are acceptable for a *emulsifiable concentrate* formulation. The intended concentration of use is 0.166% to 0.75%.

3.2 Efficacy (Part B, Section 3)

PROPAQUIZAFOP 10% EC is an herbicide for post-emergence application to a long range of different crops for the control of annual and perennial grasses. Propaquizafop 10% EC is an Emulsifiable Concentrate (EC) formulation containing 120 g/L propaquizafop

In compliance with the GAP the following dose rates are applied for registration:

- Single application to annual and perennial monocotyledonous weeds, target rate: 0.5-1.5 L/ha

This document serves the registration of Propaquizafop 10% EC (120 g/L Propaquizafop) in the Central zone of the EU. The objective of this document is to prove and support the label claims of the herbicidal efficacy and crop safety of Propaquizafop 10% EC in sugarbeet, winter oilseed rape, potato, onion, bean, green peas (Peas for dry seeds), cabbage, carrot, parsley, strawberry, oilseed rape, opium poppy, common flax, linen flax, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine among others, as claimed in the GAP table.

Comprehensive field trials were conducted in France, Poland, Germany, United Kingdom, Czech Republic, Latvia, Italy, Spain and Lithuania during the years 2016, 2017 and 2018. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

3.3 Efficacy data

Preliminary tests

The activity of propaquizafop is well known, as it has been marketed for more than 30 years by e.g. ADAMA for used in field crops and a wide range of other crops to control monocotyledonous weeds. Based on the knowledge about the active substance (+30 years) and the experiences with Propaquizafop 10% EC in the label claimed crops, the necessary application rates to obtain sufficient control of the pest organism are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Minimum effective dose tests

PROPAQUIZAFOP 10% EC was tested in the efficacy trials at a wide range of dose rates. The purpose of “Section 6.1.2, Minimum effective dose tests” is to demonstrate the dose response of PROPAQUIZAFOP 10% EC on annual and perennial monocotyledonous weeds.

Annual grassweeds: In order to prove and to support the requested dose rates of 1.2 L/ha Propaquizafop 10% EC [100 g propaquizafop per hectare] for the control of annual grassweeds in the GAP claimed crops, the assessment results of 30 efficacy trials performed in the Maritime (11), the North-east (11) and the Mediterranean (8) EPPO zone in 2016, 2017 and 2018, are reported. Propaquizafop 10% EC was included in these trials at 1.2 L/ha to demonstrate the recommended dose rate as well as at lower dose rates (0.6 L/ha, 0.8 L/ha or 1.0 L/ha). As the most accurate representation of whole plot product performance, the assessment data at 14-208 days after the application was summarised and presented.

Based on results achieved in 30 trials, it can be concluded that the recommended dose rate of 1.2 L/ha PROPAQUIZAFOP 10% EC applied once post emergence is required for consistent control of frequently occurring annual grassweed species in field crops.

Perennial grassweeds: In order to prove and to support the requested dose rates of 1.2 L/ha Propaquizafop 10% EC [100g propaquizafop per hectare] for the control of perennial grassweeds in the GAP claimed crops, the assessment results of 9 efficacy trials performed in the the Maritime (2) EPPO zone, the North-East (6) EPPO zone and Mediterranean (1) EPPO zone in 2016 and 2017, are reported. PROPAQUIZAFOP 10% EC was included in these trials at 1.2 L/ha to demonstrate the recommended dose rate as well as at lower dose rates (0.6 L/ha, 0.8 L/ha or 1.0 L/ha). As the most accurate representation of whole plot product performance, the assessment data at 15-104 days after the application was summarised and presented.

Based on results achieved in 9 trials, it can be concluded that the recommended dose rate of 1.2 L/ha PROPAQUIZAFOP 10% EC applied once post emergence is required for consistent control of frequently occurring perennial grassweed species in field crops.

Conclusion: PROPAQUIZAFOP 10% EC applied at 1.2 L/ha to control annual grassweeds and perennial grassweeds achieved excellent control of all target weeds. As grassweeds often occur as a complex of several weed species with different susceptibility towards propaquizafop, one application of PROPAQUIZAFOP 10% EC at the recommended rates should be used to efficiently control all weeds claimed on the label.

Efficacy tests and conclusions regarding authorization of intended uses

EPPO Standard PP 1/226 Number of efficacy trials provides guidance on the number of trials in target crops needed to demonstrate the efficacy of a plant protection product at the recommended dose. Where authorization is sought across a range of diverse conditions, such as across an authorization zone (PP 1/278 Principles of zonal data production and evaluation), then the number of trials conducted may need to increase. These trials should be done across the range of climatic and environmental conditions likely to be encountered, and over at least 2 years.

Applicant submitted in total 22 efficacy trials carried out on winter oilseed rape in three different growing seasons for post-emergence use. It is in line with appropriate EPPO standards. Also, to give additional support to the label claims and recommendations on efficacy of Propaquizafop 10% EC in the Central zone, 9 trials conducted in field crops in the Mediterranean EPPO zone (soybeans: 4 trials (ES-1, IT-2, FR), tomato (3 trials: IT-2, ES-1) and sunflower (2 trials: FR-1, ES-1)) and Maritime EPPO zone (sunflower: 1 trial from FR, soybean-1 trial from FR) have been added to the efficacy section. Data from trials conducted on various crops has been added as Propaquizafop is a contact graminicide and it is assumed that there are no significant differences in the competition from the different crop types against the grass weeds in the time frame from application and up to the evaluation (one to nine months after application) included in the summary tables. Data from each group has been summarized separately as well as together.

The field experiments of the herbicide – ALIVE (product code: SHA 6100 A) were carried out by testing

unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized. The reports include a detailed data about conditions, agro-technological procedures, fore-crop as well as technical details etc. Submitted efficacy trials are correctly performed according to appropriate EPPO standards.

cMS should use scale of efficacy in line with its national guidelines (ex. SANCO). Applicant presented scale of weed sensitivity according to SANCO scale. However, for Poland we should used different scale: S (susceptible) > 85%; MS (moderately susceptible) 70-85%; MT (moderately tolerant) 60-70%; T (tolerant) < 60%.

We are dealing with the active substances used commonly for many years in many countries. So, in the list of weeds controlled should include only those species that occurred (with appropriate intensity) a minimum of two localizations, and in the case of the species with the highest hazard of the plants at least in four locations. The level (>5%) of weed infestation in all studies was sufficient. Only trials with greater than 5 weeds/m² or over 2% ground cover have been included.

Applicant submitted following number of trials for:

- **winter oilseed rape:** 22 trials were presented (MAR: 9 – FR-3; UK-2; DE-2; CZ-2; MED: lack of trials; S-E: lack of trials and N-E: 13 – PL-7; LT-4, LV-2). Only for MAR and N-E EPPO zone Applicant submitted sufficient number of trials. cMS from S-E and MED should decide if trials from other EPPO zone can be acceptable.
- **sunflower:** 3 trials were presented (MAR; 1 -FR; MED: 2 trials – FR, ES). This crop is not requested for registration in GAP table.
- **tomato:** 3 trials were presented (MED: 3 trials – IT-2, ES-1). This crop is not requested for registration in GAP table.
- **soybean:** 5 trials were presented (MAR: 1 -FR; MED: 4 trials –ES-1, IT-2, FR). This crop is not requested for registration in GAP table.

Also, Concerned Member States will need to consider the relevance of the submitted formulation comparability data in relation to the current authorized uses for the reference product in their own Member State. The evaluation was conducted in accordance with Uniform Principles.

cMS should decide which weed species can be accepted on the basis on presented documentation and their national rules.

Following weed species should be consider by each cMS if they can be acceptable on the basis on submitted documentation:

- **winter oilseed rape:**
 - Maritime EPPO zone – ALOMY (3), LOLSS (2), TRZAW (4), HORVW (2), AGREE (2)
 - N-E EPPPO zone – TRZAW (7), ECHCG (2), APESV (4), AGREE (5)
- **sunflower, soybean, tomato:**
 - MED EPPO zone: ECHCG (6), DIGSA (5), SETVI (2)

Applicant submitted limited data for most studied weeds. In the opinion of Evaluator weeds studied only in 1 trial should be excluded from GAP table and label project.

Following weed species should be excluded due to not enough number of trials (only 1 trial was presented):

- **winter oilseed rape:**
 - Maritime EPPO zone – POAAN (1), AVEFA (1), ECHCX (1), APESV (1)
 - N-E EPPPO zone – TTLWI (1), SETPF (1), VOLCE (1), ELYRE (1), LOLMU (1), ELYRE (1)
- **sunflower, soybean, tomato:**
 - MED EPPO zone: PHAMI (1), AVELU (1), VSTEG (1), SORHA (1)

Applicant correctly presented results. Due to the limited number of results for particular weeds species, it

is difficult to make a clear conclusion for the label, especially for weeds which are considered to be major. Therefore, the sufficiency of results should be considered on the national level based on importance of weed in their country.

Extrapolations results from registered products containing propaquizafop should be considered by individual member states on a national level based on current registration, data protection and experience with similar active compounds products. The spectrum of weeds should be checked with label claims on these reference products.

ASSESSMENT FOR POLAND (N-E EPPO ZONE):

For Poland (N-E) we can take into consideration results from neighbouring countries (DE, CZ) from other EPPO zones. So, for winter oilseed rape Applicant submitted in total 17 valid trials (DE-2, CZ-2, PL-7, LT-4, LV-2).

Winter oilseed rape:

Following weed species can be accepted in the Polish label:

- ALOMY – 3 trials – minor weed, so number of trials is sufficient – MS
- TRZAW – 11 trials —major weed, so number of trials is acceptable – S
- APESV – 5 trials – major weed, so number of trials is sufficient – MS
- ECHCG – 2 trials – minor weed, so number of trials is acceptable – MS
- AGREE – 7 trials – major weeds, so number of trials is acceptable – MS
- HORVW – 2 trials – major weed, so at least 4 trials are required. Applicant submitted enough number of trials for self-seeding of winter wheat. So, in the opinion of Evaluator HORVW can be accepted in the label as self-seeding of winter cereals – S.
- LOLSS – 2 trials – minor weed. However, we can not include group of plants in the label. Trials should be presented for each species, ex. *Lolium multiflorum* not group or family.

Based on the summarized data, it is therefore considered that claims for control of weeds in winter oilseed rape by ALIVE (product code: SHA 6100 A) applied at the proposed label rate 1,2 product/ha and according to other label recommendations, are fully supported.

Without any efficacy trials minor uses can be registered only on the basis on Article 51: spring oilseed rape, opium poppy; common flax; linen flax; broccoli; brussels sprouts; broad beans; faba bean; field peas; white lupine; yellow lupine; narrow-leaved lupine; root celery; parsnip; swede; garlic; shallot; fodder beet; beetroot; Jerusalem artichokes; horseradish; black radish; Japanese radish (daikon); radish; salsify; white turnip; black turnip; alfalfa; yellow alfalfa; black medic; red clover; white clover; crimson clover; common sainfoin; vetch; little white bird's-foot; lentil; white melilot; yellow melilot; grass pea for control of annual grass- and broadleaved weeds.

In Polish label following weeds species can be included as:

- *Susceptible*: self-seeding of cereals (ex. winter wheat, winter barley).
- *Moderately susceptible*: ALOMY, APESV, ECHCG, AGREE

Due to the fact that in Polish label most of entries are based on Agil-S 100 EC in which such weeds as ALOMY, APESV, ECHCG, AGREE are classified as a susceptible weed, in the opinion of Evaluator such classification should be preserved in the Polish label project. In most studies the efficacy was higher than 85%, only in a few trials' efficacy was lower and in consequence the average efficacy was lower. However, taking into account that the study only covers winter oilseed rape and the label is for a wide range of crops, the classification should remain unchanged as it is more representative for the majority of the crops included (according to the Agil-s 100 EC registration).

Uses (from 1 to 49) with exception of Use 28 requested for propaquizafop 10% EC are identical to those of the reference product Agil S 100 EC (reg nr R208/2014) registered in POLAND for more than 10 years and, therefore, not in a scope of data protection anymore. Those uses can be accepted in the opinion of ZRMs. Comments of zRMS: EPPO Standard PP 1/226 Number of efficacy trials provides guidance on the number of trials in target crops needed to demonstrate the efficacy of a plant protection product at the

recommended dose. Where authorization is sought across a range of diverse conditions, such as across an authorization zone (PP 1/278 Principles of zonal data production and evaluation), then the number of trials conducted may need to increase. These trials should be done across the range of climatic and environmental conditions likely to be encountered, and over at least 2 years.

Applicant submitted in total 22 efficacy trials carried out on winter oilseed rape in three different growing seasons for post-emergence use. It is in line with appropriate EPPO standards. Also, to give additional support to the label claims and recommendations on efficacy of Propaquizafop 10% EC in the Central zone, 9 trials conducted in field crops in the Mediterranean EPPO zone (soybeans: 4 trials (ES-1, IT-2, FR), tomato (3 trials: IT-2, ES-1) and sunflower (2 trials: FR-1, ES-1)) and Maritime EPPO zone (sunflower: 1 trial from FR, soybean-1 trial from FR) have been added to the efficacy section. Data from trials conducted on various crops has been added as Propaquizafop is a contact graminicide and it is assumed that there are no significant differences in the competition from the different crop types against the grass weeds in the time frame from application and up to the evaluation (one to nine months after application) included in the summary tables. Data from each group has been summarized separately as well as together.

The field experiments of the herbicide – ALIVE (product code: SHA 6100 A) were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized. The reports include a detailed data about conditions, agro-technological procedures, fore-crop as well as technical details etc. Submitted efficacy trials are correctly performed according to appropriate EPPO standards.

cMS should use scale of efficacy in line with its national guidelines (ex. SANCO). Applicant presented scale of weed sensitivity according to SANCO scale. However, for Poland we should used different scale: S (susceptible) > 85%; MS (moderately susceptible) 70-85%; MT (moderately tolerant) 60-70%; T (tolerant) < 60%.

We are dealing with the active substances used commonly for many years in many countries. So, in the list of weeds controlled should include only those species that occurred (with appropriate intensity) a minimum of two localizations, and in the case of the species with the highest hazard of the plants at least in four locations. The level (>5%) of weed infestation in all studies was sufficient. Only trials with greater than 5 weeds/m² or over 2% ground cover have been included.

Applicant submitted following number of trials for:

- winter oilseed rape: 22 trials were presented (MAR: 9 – FR-3; UK-2; DE-2; CZ-2; MED: lack of trials; S-E: lack of trials and N-E: 13 – PL-7; LT-4, LV-2). Only for MAR and N-E EPPO zone Applicant submitted sufficient number of trials. cMS from S-E and MED should decide if trials from other EPPO zone can be acceptable.
- sunflower: 3 trials were presented (MAR; 1 -FR; MED: 2 trials – FR, ES). This crop is not requested for registration in GAP table.
- tomato: 3 trials were presented (MED: 3 trials – IT-2, ES-1). This crop is not requested for registration in GAP table.
- soybean: 5 trials were presented (MAR: 1 -FR; MED: 4 trials –ES-1, IT-2, FR). This crop is not requested for registration in GAP table.

Also, Concerned Member States will need to consider the relevance of the submitted formulation comparability data in relation to the current authorized uses for the reference product in their own Member State. The evaluation was conducted in accordance with Uniform Principles.

cMS should decide which weed species can be accepted on the basis on presented documentation and their national rules.

Following weed species should be consider by each cMS if they can be acceptable on the basis on submitted documentation:

- winter oilseed rape:

- Maritime EPPO zone – ALOMY (3), LOLSS (2), TRZAW (4), HORVW (2), AGREE (2)
- N-E EPPPO zone – TRZAW (7), ECHCG (2), APESV (4), AGREE (5)
- sunflower, soybean, tomato:
- MED EPPO zone: ECHCG (6), DIGSA (5), SETVI (2)

Applicant submitted limited data for most studied weeds. In the opinion of Evaluator weeds studied only in 1 trial should be excluded from GAP table and label project.

Following weed species should be excluded due to not enough number of trials (only 1 trial was presented):

- winter oilseed rape:
- Maritime EPPO zone – POAAN (1), AVEFA (1), ECHCX (1), APESV (1)
- N-E EPPPO zone – TTLWI (1), SETPF (1), VOLCE (1), ELYRE (1), LOLMU (1), ELYRE (1)
- sunflower, soybean, tomato:
- MED EPPO zone: PHAMI (1), AVELU (1), VSTEG (1), SORHA (1)

Applicant correctly presented results. Due to the limited number of results for particular weeds species, it is difficult to make a clear conclusion for the label, especially for weeds which are considered to be major. Therefore, the sufficiency of results should be considered on the national level based on importance of weed in their country.

Extrapolations results from registered products containing propaquizafop should be considered by individual member states on a national level based on current registration, data protection and experience with similar active compounds products. The spectrum of weeds should be checked with label claims on these reference products.

ASSESSMENT FOR POLAND (N-E EPPO ZONE):

For Poland (N-E) we can take into consideration results from neighbouring countries (DE, CZ) from other EPPO zones. So, for winter oilseed rape Applicant submitted in total 17 valid trials (DE-2, CZ-2, PL-7, LT-4, LV-2).

Winter oilseed rape:

Following weed species can be accepted in the Polish label:

- ALOMY – 3 trials – minor weed, so number of trials is sufficient – MS
- TRZAW – 11 trials – major weed, so number of trials is acceptable – S
- APESV – 5 trials – major weed, so number of trials is sufficient – MS
- ECHCG – 2 trials – minor weed, so number of trials is acceptable – MS
- AGREE – 7 trials – major weeds, so number of trials is acceptable – MS
- HORVW – 2 trials – major weed, so at least 4 trials are required. Applicant submitted enough number of trials for self-seeding of winter wheat. So, in the opinion of Evaluator HORVW can be accepted in the label as self-seeding of winter cereals – S.
- LOLSS – 2 trials – minor weed. However, we can not include group of plants in the label. Trials should be presented for each species, ex. *Lolium multiflorum* not group or family.

Based on the summarized data, it is therefore considered that claims for control of weeds in winter oilseed rape by ALIVE (product code: SHA 6100 A) applied at the proposed label rate 1,2 product/ha and according to other label recommendations, are fully supported.

Without any efficacy trials minor uses can be registered only on the basis on Article 51: spring oilseed rape, opium poppy; common flax; linen flax; broccoli; brussels sprouts; broad beans; faba bean; field peas; white lupine; yellow lupine; narrow-leaved lupine; root celery; parsnip; swede; garlic; shallot;

fodder beet; beetroot; Jerusalem artichokes; horseradish; black radish; Japanese radish (daikon); radish; salsify; white turnip; black turnip; alfalfa; yellow alfalfa; black medic; red clover; white clover; crimson clover; common sainfoin; vetch; little white bird's-foot; lentil; white melilot; yellow melilot; grass pea for control of annual grass- and broadleaved weeds.

In Polish label following weeds species can be included as:

- Susceptible: self-seeding of cereals (ex. winter wheat, winter barley).
- Moderately susceptible: ALOMY, APESV, ECHCG, AGREE

Due to the fact that in Polish label most of entries are based on Agil-S 100 EC in which such weeds as ALOMY, APESV, ECHCG, AGREE are classified as a susceptible weed, in the opinion of Evaluator such classification should be preserved in the Polish label project. In most studies the efficacy was higher than 85%, only in a few trials' efficacy was lower and in consequence the average efficacy was lower. However, taking into account that the study only covers winter oilseed rape and the label is for a wide range of crops, the classification should remain unchanged as it is more representative for the majority of the crops included (according to the Agil-s 100 EC registration).

Uses (from 1 to 49) with exception of Use 28 requested for propaquizafop 10% EC are identical to those of the reference product Agil S 100 EC (reg nr R208/2014) registered in POLAND for more than 10 years and, therefore, not in a scope of data protection anymore. Those uses can be accepted in the opinion of ZRMs.

Justification for the expiry of data protection for the product AGIL-S 100 EC

GAP for plant protection product – ALIVE was developed based on the AGIL-S 100 EC label dated 01/08/2019, which in our opinion reflects all uses as for agent AGIL-S 100 EC. In the exception of use 28 which was accepted on the basis on presented documentation and trials.

The active substance propaquizafop was approved for use in plant protection products from 1 December 2009 by Commission Directive No 2009/37/EC of 23 April 2009 as an existing active substance under the provisions of Article 8(2) of Directive 91/414/EEC. Therefore, considering the provisions specified in the Technical Guideline on data protection under Regulation (EC) No 1107/2009 (2019/C 229/01), the data protection for the substance propaquizafop expired on 31.11.2014. In addition, the plant protection product AGIL 100 EC was authorized for placing on the market by MRiRW permit No 26/2002 dated 08.03.2002, for use in the following areas: sugar beet, fodder beet (seed plantations), winter oilseed rape, broad beans, peas for dry seed, red beet, broad beans, green peas, onions, head cabbage (white, red), savoy cabbage, Brussels sprouts, carrots, parsley, celery, tomato (seed-ling), cucumber, beans, berry plants (gooseberry, currants, strawberry, raspberry), orchards (fruit trees) and nurseries, forest nurseries (from sowing to 3 years after sowing), forest crops (from planting of seedlings to 4 years after planting). Then, the authorization No. 26/2002 was changed by the decision of MRiRW No. R- 324/2003p of 12.08.2003, decision of MRiRW No. R-132/2004o of 19.03.2004, decision of MRiRW No. R-195/2007 of 7.05.2007, MRRW decision no. R-206/2009 of 25 November 2009, MRRW decision no. R-198/2011d of 5 July 2011, decision R-56/2012d of 22 February 2012 and MRRW decision no. R-206/2012d of 22 August 2012. In the process of re-registration, the authorization of MRiRW No. R-208/2014 dated 14.10.2014 was issued for the agent AGIL-S 100 EC, which was amended by MRiRW Decision No. R - 603/2015d dated 20.07.2015, by MRiRW decision no. R - 367/2016d of 20.07.2016, by MRiRW decision no. R - 315/2017d of 04.07.2017, by MRiRW decision no. R -204 /2018d of 09.05.2018 and by decision R - 500/2019d of 01.08.2019. Currently, AGIL-S 100 EC is approved for use in the following crops: sugar beet, winter oilseed rape, potato, onion, green peas, peas for dry seeds, beans, head cabbage, carrots, parsley, strawberries, spring oilseed rape, poppy, flax, linseed, celery root, parsnips, swedes, garlic, shallots, broccoli, Brussels sprouts, broad beans, pansies, white lupins, yellow lupins, blue lupins, fodder beets, red beets, Jerusalem artichokes horseradish, black radish, Japanese radish (daikon), radish, salsify, white turnip, black turnip, lucerne, lucerne sickle, alfalfa, red clover, white clover, blood-red clover, sainfoin, vetch, serradella, lentils, white bracts, yellow bracts, and lupins. In view of the above, in accordance with the provisions set out in the Technical Guidance on Data Protection under Regulation (EC) No 1107/2009 (2019/C 229/01), data protection for the plant protection product AGIL-S 100 EC has expired.

ALIVE and AGIL-S 100 EC contains one active compound – propachizafop (100 g/L). The ALIVE formulation is considered comparable to that of Agil-S 100 EC. The applicant relies on unprotected data supporting Agil-S 100 EC, as allowed for under article 34 of Regulation (EU) No 1107/2009.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Resistance is a natural phenomenon embodied in the process of the evolution of biological systems and has been experienced over and over again in the past. According to Heap (2013) resistance is the naturally occurring inheritable ability of some weed biotypes within a population to survive an herbicide treatment that would, under normal conditions of use, effectively control that weed population. Selection of resistant biotypes may eventually result in control failures.

The risk of resistance was analysed following the EPPO-Standard (2003), the classification of the Herbicide Resistance Action Committee (HRAC) and the international Survey of Herbicide Resistant Weeds (Heap 2018). So far 8 cases of resistance in 8 monocotyledonous weed species have been reported to have developed resistance to propaquizafop. Of these, four cases have been reported from Europe, i.e. one from Germany (BROST), one from Italy (SORHA), one from Belgium (ALOMY) and one too in Greece (SORHA). The active substance is therefore classified as a medium inherent risk, while several target plants have high inherent risk.

The evaluation of the agronomic risk comes to the conclusion, that Propaquizafop 10% EC bears a low risk of resistance.

The Registration of Propaquizafop 10% EC is endorsed.

Applicant submitted detailed information's about possibilities of development the resistance or cross-resistance. Evaluator accepted the strategy management about possible development of resistance or cross-resistance proposed by Applicant.

Always follow HRAG guidelines for the prevention and managing herbicide resistant grass and broad-leaved weeds.

The proposed resistance risk management strategy is acceptable. Final assessment of the resistance risk has to be carried out on member state level since the agronomic factors influencing the risk of resistance development tend to vary between the Member States.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

The crop safety of applying PROPAQUIZAFOP 10% EC in Oilseed rape was tested in 22 efficacy trials and 19 selectivity trials, conducted in the Maritime (9 eff and 8 sel) and the North-East (13 eff and 13 sel) EPPO zones.

In the evaluation process the fact that the active ingredient – propaquizafop is used in many plant protection products and has been commonly used in crop protection for many years were taken into consideration.

The Applicant submitted in total 19 selectivity and 33 efficacy studies conducted on herbicide (ALIVE) containing this active substance. In Poland three different growing seasons were studied: 2016, 2017 and 2018. However, in LV, LT, CZ, DE, UK and FR only one growing season (2016) was studied. CMS should decide if it is acceptable.

The selectivity evaluation of the herbicide was performed according to appropriate EPPO guidelines. The evaluation of herbicide selectivity was carried out 4-5 per season. Results were described in percent of destruction of plant for herbicides treatment compared to plant for untreated, where 0% means no phytotoxicity and 100% - complete destruction.

Phytotoxicity assessment was carried out with the use of different cultivars of winter oilseed rape. Dosages N (1,2 l/ha) and higher (even 2,5N: 3,0 l/ha) were studied during trials. Experimental details and assessments methods were in accordance to Eppo standards.

No phytotoxicity symptoms were observed for any tested dosage for all tested winter oilseed rape varieties. The crop developed normally and did not involve a loss in yield at harvest.

Phytotoxicity effect for uses (from 1 to 49) requested for propaquizafop 10% EC are identical to those of the reference product Agil S 100 EC (reg nr R208/2014) registered in POLAND for more than 10 years and, therefore, not in a scope of data protection anymore and phytotoxicity results for them were not required. ZRM's agree with this statement for Poland.

Effects on yield and quality

Nineteen selectivity trials were harvested. The trials harvested were conducted in the Maritime zone (8) and the North-East zone (13) in 2016, 2017 and 2018 to evaluate the effect of PROPAQUIZAFOP 10% EC on yield of Oilseed rape.

When applied at rates ranging from 1.2 to 3.0 L/ha PROPAQUIZAFOP 10% EC did not adversely affect yield of Oilseed rape.

Thousand Grain Weight, oil content and moisture content were measure in a number of trials harvested. PROPAQUIZAFOP 10% EC did not adversely affect any of these yield quality parameters at any of the dose rates tested (including the proposed label dose rates and dose rates representing the twice recommended dose rates to simulate sprayer overlap).

For crops claimed on the label not supported with trials, the applicant wishes to bridge to the trials conducted in Oilseed rape where equivalence between the selectivity of PROPAQUIZAFOP 10% EC and the reference propaquizafop product currently on the market was demonstrated and no negative impact of the application was observed. The applicant therefore wishes to cite the original registrant's data on propaquizafop now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Effect on transformation processes

Propaquizafop 10% EC is composed of propaquizafop which has been widely used for a number years on Oilseed rape crops without identifying any quality problems on the treated crops.

Impact on treated plants or plant products to be used for propagations

Special tests to investigate this purpose are not required.

Not applicable.

Assuming a long history of safe use of a.s.: propaquizafop no special trials dedicated to evaluation of effects of ALIVE on transformation process were undertaken.

3.3.3 Observations on other undesirable or unintended side-effects

Impact on succeeding crops.

The EU requirements on plant protection products requires, that sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops if studies and evaluations presented in the other part of the dossier, show that significant residues of the active substance, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials up to sowing or planting time of possible suc-

ceeding crops. Therefore, the Applicant should present the assessment of the possible effect of ALIVE (product code: SHA 6100 A) on crops grown as rotational or replacement crops following crops treated with that product, prepared in accordance to the EPPO Standard Efficacy evaluation of plant protection products.

Effects on succeeding crops (PP 1/207 (2)). This standard is intended as a general standard on the methods used to examine whether the active substance of a plant protection product can cause negative effects on crops grown after a crop treated with that product. These crops can be grown as normal rotational crops as well as replacement crops in case of crop failure.

Propaquizafop has been used commercial for more than 30 years in different crops with no major problems of damage to succeeding crops reported.

A radiolabelled study has been performed to assess the affect of propaquizafop on succeeding crops. The concentrations of radioactive residues in all succeeding crops were low ranging from 0.004 mg/kg in sugar beet roots and foliage sown 270 days after the second treatment to 0.167 mg/kg in straw from spring wheat sown 30 days after the second treatment. Parent material was extensively broken down into numerous metabolites with the majority of the residue being incorporated into the lignin fraction. Propaquizafop shows no tendency to accumulate in succeeding crops. As propaquizafop residues are unlikely to be present in succeeding crops, field trials on representative crops are not required

It is possible to conclude that no special measures are needed to avoid any impact of propaquizafop on succeeding crops.

Propaquizafop shows no tendency to accumulate in succeeding crops. As propaquizafop residues are unlikely to be present in succeeding crops, field trials on representative crops are not required **It is possible to conclude that no special measures are needed to avoid any impact of propaquizafop on succeeding crops**

Impact on other plants including adjacent crops

The results confirm that no further testing is necessary and that no negative impact on adjacent crops is expected.

As every plant protection product – including ALIVE (product code: SHA 6100 A) should not be used during wind that may cause drift spray solution on adjacent plants, especially dicotyledonous crops / plants. Such recommendation will be contained on the label - instruction of use.

Taking all these factors into account, it is considered that there is a low risk to graminaceous species in field margins (broad-leaved plant species are insensitive). Thus, the risk to non-target plants is considered acceptable and no further testing is necessary.

Please, for more information, refer to Registration Report, Part B, Section 6.

Effects on beneficial and other non-target organisms

There were no adverse effects on beneficial and other non-target organisms observed in any of the efficacy and crop safety trials conducted.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Analytical methods for determination of propaquizafop in Propaquizafop 10% EC were not evaluated as part of the EU review of propaquizafop. Therefore all relevant data are provided and are considered adequate.

	Propaquizafop
Author(s), year	Kedzierzyn-Kozle, 2017
Principle of method	GC/MS
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	277-417 mg/L R ² =0.9999 y=243208x-876812
Precision – Repeatability Mean n = 7 (%RSD)	0.04%
Accuracy n = 7 (% Recovery)	8 % w/v: 100.1% 10 % w/v: 99.8% 12 % w/v: 99.2%
Interference/ Specificity	Interferences from impurities constitute didn't exceed 0,71% of total peak area in test sample and 0.3% of total peak area in analytical standard. In both cases do not contribute acceptable 3%.
Comment	-

The GC/MS analytical method for the determination of propaquizafop content in the test item was fully validated, according to SANCO/3030/99 rev. 5 guidance document.

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions **except for acid matrices**.

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014).

Noticed data gaps are:

- Plant matrices:
 1. Method for high acid content matrices should be provided by the applicant.
 2. ILV and confirmatory methods for plant matrices should be provided with currently required LOQs (Reg. (EU) 2019/973).
 3. Extraction efficiency for plant matrices methods need to be demonstrated at least in one crop/matrix
 - Animal matrices:
 1. ILV and confirmatory methods should be provided by the applicant. Extraction efficiency need to be demonstrated.
 - Appendix 1. *List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review* should be supplemented.

These data gaps should be filled during the reassessment of the product.

The Applicant has completed the dRR (January 2022)

The additions have been accepted and are sufficient.

Noticed data gaps are:

none

3.5 Mammalian toxicology (Part B, Section 6)

The assessment of all acute toxicological properties of ALIVE is derived from the classification of the active compound and co-formulants.

3.5.1 Acute toxicity

Classification for ALIVE was calculated based on classification of active ingredient and co-formulants. Based on those calculations for formulation, ALIVE is classified as: Acute Tox. 4 (oral), Eye Damage Category 1, Skin sensitisation, Category 1 and Aspiration toxicity, Category 1.

3.5.2 Operator exposure

Operator exposure to ALIVE was not evaluated as part of the EU review of Propaquizafop for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential operator exposure has been undertaken for Propaquizafop using EFSA AOEM Model and default dermal absorption values (25% concentrate and 70% dilution).

Conclusion: According to the EFSA AOEM Model, it can be concluded that the risk for the operator is acceptable with use of personal protective equipment.

Implication for labelling: P280: Wear protective gloves/protective clothing.

3.5.3 Worker exposure

Worker exposure to ALIVE was not evaluated as part of the EU review of Propaquizafop for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential worker exposure has been undertaken for Propaquizafop using EFSA AOEM Model and default dermal absorption values (25% concentrate and 70% dilution).

Conclusion:

According to the EFSA AOEM Model, it can be concluded there is no unacceptable risk anticipated for the worker for maintenance activities for re-entering: sugar beet, winter oilseed rape, potato, carrot, parsley, spring oilseed rape, opium poppy, common flax, linen flax, root celery, parsnip, swede, fodder beet, beetroot, jerusalem artichokes, horseradish, black radish, daikon, radish, salsify, white turnip, black turnip, alfalfa, yellow alfalfa, black medic, red clover, white clover, crimson clover, common sainfoin, vetch, little white bird's-foot, white melilot, yellow melilot and osr, treated with ALIVE, even without suitable protective clothing.

According to the EFSA AOEM Model, it can be concluded there is no unacceptable risk anticipated for the worker wearing adequate work clothing and personal protective equipment (gloves) for maintenance activities for re-entering: onion, bean, green peas, peas for dry seeds, cabbage, broccoli, brussels sprouts, broad beans, faba bean, field peas, white lupine, yellow lupine, narrow-leaved lupine, garlic, shallot, lentil, grass pea and strawberry treated with ALIVE.

3.5.4 Bystander and resident exposure

Bystander and resident exposure to ALIVE was not evaluated as part of the EU review of Propaquizafop for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential residents and bystander's exposures has been undertaken for Propaquizafop using EFSA AOEM Model and default dermal absorption value (25% concentrate and 70% dilution).

Conclusion: According to the EFSA AOEM Model, it can be concluded that there is no undue risk to any bystander after accidental short-term exposure nor to any resident exposure to ALIVE.

Implication for labelling: None

3.6 Residues and consumer exposure (Part B, Section 7)

Toxicological reference values for the dietary risk assessment of Propaquizafop

Reference value	Source	Year	Value	Study relied upon	Safety factor
Propaquizafop					
ADI	EFSA	2008	0.015 mg/kg bw/day	mouse long-term study	100
ARfD	EFSA	2008	Non applicable	-	-

3.6.1 Residues

Sugar beet

Proposed uses:

1 application, BBCH 12-35, 0.050 – 0.150 kg as/ha, PHI: 28 days

or

2 application (interval 12 days), BBCH 12-35, 0.060 kg as/ha, PHI: 28 days

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014). Residue trials were evaluated at the European Community level too.

Trials GAP: 1x 0.15-0.2 kg as/ha, BBCH 37, PHI 91

GAP supported by available data *Propaquizafop*, SANCO/131/08 final, 26 May 2009:

1x 0.2 kg as/ha, BBCH 12-39, PHI na

PHI evaluated under review of the existing maximum residue levels for quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop according to Article 12 of Regulation (EC) No 396/2005 for sugar beet was 60 days. Therefore, 60 days is proposed.

Available data can cover the proposed use.

The residues arising from the proposed uses will not exceed the MRLs established for sugar beets (0.06 mg/kg, Reg. (EU) 2019/973).

Uses are accepted.

Fodder beet; Beetroot

According to the SANTE/2019/12752 extrapolation from sugar beet to fodder beet and beetroot is possible. The residues arising from the proposed uses will not exceed the MRLs established for beetroot (0.06 mg/kg, Reg. (EU) 2019/973). Uses are accepted. Accepted PHI: 60 days.

Oilseed rape

Proposed uses:

1 application, BBCH 12-35, 0.050 – 0.150 kg as/ha, PHI: 42 days

or

2 application (interval 12 days), BBCH 12-35, 0.060 kg as/ha, PHI: 42 days

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014).

GAP on which EU a.s. assessment is based: 1x 0.2 kg as/ha, BBH 31, PHI 90

GAP evaluated under review of the existing maximum residue levels: 1x 0.20 kg as/ha, BBH 11-31, PHI 90

GAP supported by available data *Propaquizafop, SANCO/131/08 final, 26 May 2009*:

1x 0.2 kg as/ha, BBCH 12-39, PHI na

PHI evaluated under review of the existing maximum residue levels for quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop according to Article 12 of Regulation (EC) No 396/2005 for oilseed rape was 90 days. Therefore, 90 days is proposed.

Available data can cover the proposed use.

The residues arising from the proposed uses will not exceed the MRLs established for oilseed rape (2.0 mg/kg, Reg. (EU) 2019/973).

Uses are accepted.

According to the SANTE/2019/12752 extrapolation from oilseed rape to poppy seed and flax is possible.

The residues arising from the proposed uses will not exceed the MRLs established for linseeds (0.3 mg/kg) and poppy seeds (0.7 mg/kg).

Potatoes

Proposed uses:

1 application, BBCH 10-35, 0.050 – 0.150 kg as/ha, PHI: 40 days

or

2 application (interval 12 days), BBCH 10-35, 0.060 kg as/ha, PHI: 40 days

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014).

Trials GAP: 1 x 0.2 kg a.s./ha, PHI: 49-171d

GAP evaluated under review of the existing maximum residue levels: 1x 0.15 kg as/ha, BBH 11-31, PHI 30

Available data can cover the proposed use.

The residues arising from the proposed uses will not exceed the MRLs established for potatoes (0.1 mg/kg, Reg. (EU) 2019/973).

Uses are accepted.

Onion

Proposed uses:

1 application, BBCH 9-53, 0.050 – 0.150 kg as/ha, PHI: 30 days

or

2 application (interval 12 days), BBCH 9-53, 0.060 kg as/ha, PHI: 30 days

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014).

GAP evaluated under review of the existing maximum residue levels: 1x 0.20 kg as/ha, PHI 30

Available data can cover the proposed use.

The residues arising from the proposed uses will not exceed the MRLs established for onion (0.04 mg/kg, Reg. (EU) 2019/973).

Uses are accepted.

According to the SANTE/2019/12752 extrapolation from onion to garlic and shallot is possible.

The residues arising from the proposed uses will not exceed the MRLs established for garlic and shallot (0.04 mg/kg, Reg. (EU) 2019/973).

Bean

Proposed uses:

1 application, BBCH 13-30, 0.050 – 0.150 kg as/ha, PHI: 45 days

or

2 application (interval 12 days), BBCH 13-30, 0.060 kg as/ha, PHI: 45 days

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014).

Study Schwager L., 1991 (90003816):

This study was performed on been for dry seed (pulses). **Storage stability data are required as to verify the validity of the results.**

The data included in the Registration Report are not sufficient as to perform an evaluation.

Heyer R., 1995a – Analytical report; Beinhauer K., 1994a – Field report:

This study was performed on been for dry seed (pulses). **Storage stability data are required as to verify the validity of the results.**

The data included in the Registration Report are not sufficient as to perform an evaluation.

Uses are not accepted.

Green peas; Peas for dry seeds

Proposed uses:

1 application, BBCH 13-30, 0.050 – 0.150 kg as/ha, PHI: 45 days

or

2 application (interval 12 days), BBCH 13-30, 0.060 kg as/ha, PHI: 45 days

Only two trials are referenced (on fresh peas) in the RR Agil 100 EC.

The data included in the Registration Report are not sufficient as to perform an evaluation the uses on fresh and dry peas.

Uses are not accepted. **Additionally storage stability data for High protein content matrices are required.**

Alfalfa; Yellow alfalfa; Black medic; Red clover; White clover; Crimson clover; Common sainfoin; Vetch; Little white bird's-foot; Lentil; White melilot; Yellow melilot; Grass pea

The data included in the Registration Report (RR Agil 100 EC) are not sufficient as to perform an evaluation the uses on above crops.

Head cabbage

Proposed uses:

1 application, BBCH 13-30, 0.050 – 0.150 kg as/ha, PHI: 28 days

or

2 application (interval 12 days), BBCH 13-30, 0.060 kg as/ha, PHI: 28 days

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014).

GAP on which EU a.s. assessment is based: 1x 0.15 kg as/ha, BBCH 29, PHI 30

Available data can cover the proposed use.

The residues arising from the proposed uses will not exceed the MRLs established for head cabbage (0.6 mg/kg, Reg. (EU) 2019/973).

PHI = 30 days is proposed by zRMS. Use is accepted.

Broccoli; Brussels sprouts

According to the SANTE/2019/12752 extrapolation from head cabbage to broccoli and brussels sprouts is not possible. Uses are not accepted.

Carrot; Parsley

Proposed uses:

1 application, BBCH 12-30, 0.050 – 0.150 kg as/ha, PHI: 28 days

or

2 application (interval 12 days), BBCH 12-30, 0.060 kg as/ha, PHI: 28 days

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014).

GAP on which EU a.s. assessment is based: 1x 0.15 kg as/ha, BBCH 29, PHI 30

Available data can cover the proposed use on carrot.

The residues arising from the proposed uses will not exceed the MRLs established for carrot (0.2 mg/kg, Reg. (EU) 2019/973).

PHI = 30 days is proposed by zRMS. Use on carrot is accepted.

According to the SANTE/2019/12752 extrapolation from carrot to parsley is possible. Use on parsley is accepted (PHI: 30 days).

The residues arising from the proposed uses will not exceed the MRLs established for parsley (0.2 mg/kg, Reg. (EU) 2019/973).

Root celery; Parsnip; Swedes

According to the SANTE/2019/12752 extrapolation from carrot to Whole subgroup (c) other root and tuber vegetables except sugar beets (0213000) is possible.

MRLs for

Carrots: 0.2 mg/kg

Celeriacs/turnip rooted celeries: 0.08 mg/kg

Parsnip: 0.2 mg/kg

Swedes: 0.06 mg/kg

Use on parsnip is accepted. The residues arising from the proposed uses will not exceed the MRLs established for head parsnip (0.2 mg/kg, Reg. (EU) 2019/973).

Use on root celery and swedes are not accepted (when extrapolation is from carrot). The residues arising from the proposed uses may exceed the MRLs established for root celery and swedes (Reg. (EU) 2019/973).

Despite this, extrapolation from sugar beets to celery root and swedes is possible.

MRL for sugar beet is 0.06 mg/kg. Then, the residues arising from the proposed uses will not exceed the MRLs established for root celery and swedes.

Uses are accepted. PHI proposed: 60 days (see sugar beet).

Jerusalem Artichokes; Horseradish; Black radish; Japanese radish (daikon); Radish; Salsify; White turnip;

Black turnip

MRLs:

Jerusalem Artichokes: 0.08 mg/kg - not accepted (extrapolation from sugar beet is not possible)

Horseradish: 0.08 mg/kg - accepted extrapolation from sugar beet with PHI: 60 days

Black radish: 0.2 mg/kg - accepted extrapolation from carrots with PHI: 30 days

Japanese radish (daikon): 0.2 mg/kg - accepted extrapolation from carrots with PHI: 30 days

Radish: 0.2 mg/kg - accepted extrapolation from carrots with PHI: 30 days

Salsify: 0.2 mg/kg - accepted extrapolation from carrots with PHI: 30 days

White turnip: 0.08 mg/kg: - accepted extrapolation from sugar beet with PHI: 60 days

Black turnip: 0.08 mg/kg: - accepted extrapolation from sugar beet with PHI: 60 days

Strawberry

Proposed uses:

1 application, BBCH 13-30, 91-92, 0.050 – 0.150 kg as/ha, PHI: na

or

2 application (interval 12 days), BBCH 13-16, 91-92, 0.060 kg as/ha, na

Applicant refers to the unprotected data RR Agil 100 EC (Registration No. R-208/2014).

The data included in the Registration Report (RR Agil 100 EC) are not sufficient as to perform an evaluation the uses on strawberry. Additionally the storage stability data are required as to cover the high acid commodities.

Uses at BBCH 13-30 are not accepted. Use at BBCH 91-92 is accepted.

Conclusions:

- Uses not accepted (insufficient data on field trials / possibility of extrapolation):

Bean, Green peas, Peas for dry seeds, **Jerusalem Artichokes**, Broccoli, Brussels sprouts, Broad beans Faba bean, Field peas, White lupine Yellow lupine Narrow-leaved lupine, Alfalfa, Yellow alfalfa, Black medic, Red clover, White clover, Crimson clover, Common sain-foin, Vetch, Little white bird's-foot, Lentil, White melilot, Yellow melilot, Grass pea

- Strawberries: only post-harvest use is accepted (BBCH 91-92)

- Uses with the changed by evaluator PHI:

Sugar beet, Root celery, Swedes, Fodder beet, Beetroot, Turnips, Horseradish (proposed PHI: 60 days)

Winter oilseed rape, Spring oilseed rape, Opium poppy, Common flax, Linen flax; (proposed PHI: 90 days)

Cabbage, Carrot, Parsley, Parsnip, Black radish, Japanese radish (daikon), Radish, Salsify (proposed PHI: 30 days)

- Storage stability studies are required as to cover the high acid, high protein content (dry legume vegetables/pulses) commodities and animal commodities.

3.6.1 Consumer exposure

TMDI (% ADI) according to EFSA PRIMo 3.1	40 % (based on NL toddler)
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IESTI (% ARfD) according to EFSA PRIMo 3.1	Not applicable as no ARfD was considered applicable during active ingredient inclusion (EFSA 2008)
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The accepted uses of Propaquizafop in the formulation Propaquizafop 10% EC do not represent unacceptable chronic risk for the consumer.

3.7 Environmental fate and behaviour (Part B, Section 8)

Concentrations of Propaquizafop in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentrations (PEC values) in soil, surface water, sediment and ground water are provided.

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC_{soil} calculations have been conducted with Propaquizafop and its relevant metabolites Quizalofop, Hydroxy-quizalofop, Dihydroxy quinoxaline and Hydroxy quinoxaline using the EU agreed endpoints (EFSA Scientific Report (2008) 204, 1-171).

Maximum PEC_{soil} value on worst case were:

Substance	PEC _{soil} mg/kg dw
	150 g as/ha
Propaquizafop	0.200
Quizalofop	0.137
Hydroxy-quizalofop	0.053
Dihydroxy quinoxaline	0.017
Hydroxy quinoxaline	0.007

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

PEC_{gw} have been realised for Propaquizafop and its metabolites Quizalofop, Hydroxy-quizalofop, Dihydroxy quinoxaline and Hydroxy quinoxaline using the FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models and EU agreed endpoints (EFSA Scientific Report (2008) 204, 1-171).

PEC_{gw} values were all below 0.001 µg/l (including its metabolites).

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The PEC_{SW/SED} of Propaquizafop and its relevant metabolites Quizalofop, Hydroxy-quizalofop, Dihydroxy quinoxaline and Hydroxy quinoxaline have been assessed with the models FOCUS STEP 1, 2 and 3, using EU agreed endpoints (EFSA Scientific Report (2008) 204, 1-171). Please refer to Part B, Section 9, Point 8.9 for more details about the results obtained.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The vapour pressure at 20 °C of the active substance Propaquizafop is < 10⁻⁵ Pa. Hence the active substance Propaquizafop is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Propaquizafop due to volatilization with subsequent deposition should not be considered.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Birds

According to screening and tier I assessments, all the TERA and TERIt values for the active sub-stance 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.

Mammals

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.

3.8.2 Effects on aquatic species

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.

3.8.3 Effects on bees

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 should be provided for authorisation of plant protection product when the new GD for bees will be implemented at EU level.

3.8.4 Effects on other arthropod species other than bees

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.

3.8.5 Effects on soil organisms

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.

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

3.8.6 Effects on non-target terrestrial plants

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.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

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.

3.9 Relevance of metabolites (Part B, Section 10)

Not relevant. Propaquizafop metabolites Quizalofop, Hydroxy-quizalofop, Dihydroxy quinoxaline and Hydroxy quinoxaline are predicted to occur in groundwater at concentrations below 0.001 µg/L.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Not relevant. Propaquizafop 10% EC does not contain active substances considered as candidate for substitution.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 1 Copy of the product label

Sekcja pozostałości:

Brak zgody na następujące zastosowania:

Fasola, Groszek zielony, groszek na suche nasiona

Brokuły, Brukselka,

Bób, Groch, Łubin biały, Łubin żółty, Łubin wąskolistny

~~Topinambur, karczochy~~

Lucerna siewna, lucerna sierpowata, lucerna nerkowata, koniczyna łąkowa, koniczyna biała, koniczyna krwistoczerwona, sparceta siewna, wyka, seradela drobna, soczewica, nostryk biały, nostryk żółty, groszek siewny;

Lnianka siewna

Zmiany okresu karencji:

Okresy karencji powinny wynosić:

Rzepak ozimy, rzepak jary, len zwyczajny, mak lekarski – 90 dni

Burak cukrowy, seler, brukiew, burak czerwony, burak pastewny, chrzan, czarna rzepa, biała rzepa - 60 dni

Ziemniak – 40 dni

Marchew, pietruszka, kapusta, pasternak, czarna rzodkiew, rzodkiew japońska, rzodkiew zwyczajna, salsefia, cebula, czosnek, szalotka – 30 dni

Truskawka: nie wymagane (stosować tylko w fazie BBCH 91-92).

Załącznik do zezwolenia MRiRW nr R -/..... z dnia2022

Posiadacz zezwolenia:

Sharda Cropchem España S.L., Edificio Atalayas Business Center, Carril Condomina nº 3, 12th Floor, 30006 Murcia, Królestwo Hiszpanii, tel.: +34868127589, fax.: +34868127588, e-mail: eu.regn@shardaintl.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

Sharda Cropchem Ltd., Prime Business Park, Dashrathlal Joshi Road, Vile Parle (West), Mumbai – 400 056, Indie, Tel.: + 91 22 6261 5615, Fax: + 91 22 6678 2828/ 2808, Email: regn@shardaintl.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

.....

ALIVE

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

Propachizafop (substancja z grupy pochodnych kwasów arylofenksypropionowych) - **100 g/l** (9,70%)

Zezwolenie MRiRW nr R- /2022 z dnia . .2022 r.

	
NIEBEZPIECZEŃSTWO	
H302	Działa szkodliwie po połknięciu.
H304	Połknięcie i dostanie się przez drogi oddechowe może grozić śmiercią.
H317	Może powodować reakcję alergiczną skóry.
H318	Powoduje poważne uszkodzenie oczu.
H411	Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska należy postępować zgodnie z instrukcją użycia.
P273	Nie wypuszczać do środowiska.
P280	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.
P301+P310+P331	W PRZYPADKU POŁKNIECIA: Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ lub lekarzem. NIE wywoływać wymiotów.
P302+P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody.
P305+P351+P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P391	Zebrać wyciek.
P501	Zawartość / pojemnik usuwać zgodnie z przepisami miejscowymi / regionalnymi / narodowymi / międzynarodowymi

OPIS DZIAŁANIA

HERBICYD selektywny o działaniu układowym, stosowany nalistnie w formie koncentratu do sporządzania emulsji wodnej.

Zgodnie z klasyfikacją HRAC substancja czynna propachizafop zaliczana jest do grupy A.

DZIAŁANIE NA CHWASTY

Środek pobierany jest bardzo szybko poprzez liście, a następnie przemieszczany do korzeni i rozłogów chwastów powodując zahamowanie wzrostu i rozwoju rośliny. Efekt działania środka widoczny jest już po upływie 3 dni od zabiegu i objawia się żółknięciem, a następnie zamieraniem najmłodszych liści.

Opady deszczu występujące w godzinę po zabiegu nie mają wpływu na działanie środka.

Chwasty wrażliwe:	chwastnica jednostronna, miotła zbożowa, owies głuchy, palusznik krwawy, perz właściwy, samosiewy zbóż, włośnica sina, włośnica zielona, życica trwała.
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STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych lub samobieżnych lub ciągnikowych opryskiwaczy sadowniczych wyposażonych w belkę herbicydową.

Burak cukrowy, rzepak ozimy, ziemniak, cebula, groch zielony, groch na suche nasiona, fasola, kapusta głowiasta, marchew, pietruszka, truskawka.

Wielkość dawki środka zależy od gatunku zwalczanego chwastu, a efektywność ich zwalczania zależy od fazy rozwojowej, w której środek jest stosowany.

a) zwalczanie chwastnicy jednostronnej, owsa głuchego, palusznika krwawego, włośnicy sinej, włośnicy zielonej, życicy trwałej.

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,6 l/ha.

Środek stosować od fazy trzech liści do końca fazy krzewienia chwastów (BBCH 13-29)

b) zwalczanie samosiewów zbóż i miotły zbożowej

Maksymalna dawka dla jednorazowego zastosowania: 0,7 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,5-0,7 l/ha.

Niższą z zalecanych dawek stosować od fazy 3 liści do początku fazy krzewienia chwastów (BBCH 13-21), natomiast wyższą gdy chwasty znajdują się w fazie od pełni krzewienia do początku fazy strzelania w źdźbło (BBCH 25-30)

c) zwalczanie perzu właściwego.

Maksymalna dawka dla jednorazowego zastosowania: 1,5 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 1,25 – 1,5 l/ha.

ALIVE do zwalczania perzu właściwego można stosować w dawkach dzielonych.

Pierwszy zabieg

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,6 l/ha.

Drugi zabieg

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,6 l/ha.

Odstęp między zabiegami: co najmniej 12 dni.

Środek stosować gdy rośliny perzu wykształciły 3-6 liści (osiągnęły wysokość 15-20 cm) (BBCH 13-16).

Po wykonaniu zabiegu zwalczania perzu przez miesiąc nie wykonywać uprawy mechanicznej gleby.

UWAGA:

Chwasty dwuliścienne można zwalczać na co najmniej trzy dni przed lub w trzy dni po zastosowaniu środka ALIVE.

Burak cukrowy

Termin stosowania: zabieg wykonać gdy rośliny buraka wytworzyły pierwszą parę liści do momentu, gdy zakryły nie więcej niż 50 % międzyrzędzi (BBCH 12-35).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

Uwaga:

Na plantacjach, na których wykonuje się przerywkę buraków środek stosować na 10 dni przed przerywką lub w 10 dni po przerywce (gdy chwasty prosowate lub perz pojawiły się ponownie).

Rzepak ozimy

a) Termin stosowania: środek stosować jesienią, gdy rośliny rzepaku wykształciły co najmniej pierwszą parę liści lub wiosną, nie później niż do początku fazy wydłużania pędu, braku międzywęźli (rozeta) (BBCH 12-30).

W celu zwiększenia szybkości działania jesienią można stosować środek ALIVE w mieszaninie z adiuwantem Olejan 85 EC lub Olemix 84 EC.

Maksymalna dawka dla jednorazowego zastosowania:

ALIVE 0,7 l/ha + Olejan 85 EC/Olemix 84 EC 1,5 l/ha.

Zalecana dawka dla jednorazowego zastosowania:

ALIVE 0,5 - 0,7 l/ha + Olejan 85 EC/Olemix 84 EC 1,5 l/ha.

Uwaga:

Mieszanina środka ALIVE z adiuwantem Olejan 85 EC lub Olemix 84 EC zwalcza tylko chwasty roczne i samosiewy zbóż.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

b) zwalczanie miotły zbożowej, chwastnicy jednostronnej, wyczyńca polnego, samosiewów zbóż (np. pszenicy ozimej, jęczmienia ozimego) i perzu właściwego.

Termin stosowania: środek stosować jesienią, gdy rośliny rzepaku wykształciły co najmniej pierwszą parę liści lub wiosną, nie później niż do widocznych 9 lub więcej międzywęźli (BBCH 12-39).

Maksymalna dawka dla jednorazowego zastosowania: 1,2 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 1,2 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste.

Ziemniak

Termin stosowania: zabieg wykonać po zakończeniu uprawy międzyrzędowej od początku fazy rozwoju pierwszych liści do fazy zakrywania międzyrzędzi, gdy 50% powierzchni gleby jest zakryta (BBCH 10-35).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

~~Groch uprawiany na świeże nasiona, groch uprawiany na suche nasiona~~

~~Termin stosowania: zabieg wykonać nie wcześniej niż po wykształceniu przez rośliny uprawne 2-3 liści (BBCH >12).~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.~~

~~Zalecana ilość wody: 200-300 l/ha.~~

~~Zalecane opryskiwanie: średniokropliste.~~

Cebula

Termin stosowania:

Cebulę z siewu opryskiwać od fazy 1-2 liści (BBCH 11-12). Plantacje nasienne opryskiwać po wschodach do chwili, gdy pędy nasienne osiągnęły wysokość 10-15 cm (BBCH 09-53).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

Kapusta głowiasta

Termin stosowania: zabieg wykonać po przyjęciu się rozsady i po wzejściu chwastów jednoliściennych (BBCH>13).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

Marchew, pietruszka

Termin stosowania: zabieg wykonać od fazy dwóch liści właściwych rośliny uprawnej (BBCH>12)

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

Fasola

Termin stosowania: zabieg wykonać po wschodach fasoli, od pierwszej pary potrójnych liści (BBCH>13).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

Truskawka

Termin stosowania: zabieg wykonać po zbiorze owoców (BBCH 91-92).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOBSZAROWYCH

Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik.

Rzepak jary, mak lekarski, len zwyczajny, ~~lnianka siewna~~, seler korzeniowy, pasternak, brukiew, czosnek pospolity, cebula szalotka, brokuł, kapusta brukselska, ~~bób, bobik, peluszkę, lubin biały, lubin żółty, lubin wąskolistny~~, burak pastewny, burak ćwikłowy, **topinambur**, chrzan pospolity, rzodkiew czarna, rzodkiew japońska (daikon), rzodkiewka, salsefia, rzepa biała, rzepa czarna, ~~lucerna siewna, lucerna sierpowata, lucerna nerkowata, konieczyna czerwona, konieczyna biała, konieczyna krwistoczerwona (inkarnatka), esparceta siewna, wyka, seradela, soczewica, nostrzyk biały, nostrzyk żółty, lędźwian siewny~~

Termin stosowania:

- Rzepak jary - zabieg wykonać od fazy 2 liści rzepaku do początku wydłużania pędu rzepaku jarego (BBCH 12 – 30),
- Mak lekarski - zabieg wykonać od fazy 3 liści maku lekarskiego (od BBCH 13),
- Len zwyczajny, ~~lnianka siewna~~ - zabieg wykonać od fazy 3 liści lnu zwyczajnego i ~~lnianki siewnej~~ (od BBCH 13),
- Seler korzeniowy - zabieg wykonać od fazy 2 liści selera korzeniowego (od BBCH 12),
- Pasternak - zabieg wykonać od fazy 2 liści pasternaku (od BBCH 12),
- Brukiew - zabieg wykonać od fazy 2 liści brukwi (od BBCH 12),
- Czosnek pospolity - zabieg wykonać po fazie 1-2 liści czosnku pospolitego (od BBCH 11-12),

- Cebula szalotka - zabieg wykonać w fazie 1-2 liści cebuli szalotki (BBCH 11-12),
~~Brokuł - zabieg wykonać od fazy 3 liści brokułu (od BBCH 13),~~
- ~~Kapusta brukselska - zabieg wykonać od fazy 3 liści kapusty brukselskiej (od BBCH 13),~~
- ~~Bób - zabieg wykonać od fazy 3 liści bobu (od BBCH 13),~~
- ~~Lubin biały, lubin żółty, lubin wąskolistny, peluszką, bobik - zabieg wykonać od fazy 3 liści rośliny uprawnej (od BBCH 13),~~
- Burak pastewny, burak ćwikłowy - zabieg wykonać od fazy 2 liści właściwych (pierwszej pary liści) do fazy, gdy liście zakrywają 50% powierzchni gleby (od BBCH 12-35),
- **Topinambur**, chrzan pospolity, rzodkiew czarna, rzodkiew japońska (daikon), rzodkiewka, salsefia, rzepa biała, rzepa czarna - zabieg wykonać od fazy dwóch liści właściwych rośliny uprawnej (BBCH>12),
- ~~Lucerna siewna, lucerna sierpowata, lucerna nerkowata, koniczyna czerwona, koniczyna biała, koniczyna krwistoczerwona (inkarnatka), espareceta siewna, wyka, seradela, soczewica, nostryk biały, nostryk żółty, lędźwian siewny - zabieg wykonać od fazy 3 liści rośliny uprawnej (BBCH > 13).~~

Wielkość dawki środka zależy od gatunku zwalczanego chwastu, a efektywność ich zwalczania zależy od fazy rozwojowej, w której środek jest stosowany.

a) zwalczanie chwastnicy jednostronnej, owsa głuchego, paluszniaka krwawego, włośnicy sinej, włośnicy zielonej, życicy trwałej

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,6 l/ha.

Środek stosować od fazy trzech liści do końca fazy krzewienia chwastów (BBCH 13-29).

b) zwalczanie samosiewów zbóż i miotły zbożowej

Maksymalna dawka dla jednorazowego zastosowania: 0,7 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,5-0,7 l/ha.

Niższą z zalecanych dawek stosować od fazy 3 liści do początku fazy krzewienia chwastów (BBCH 13-21), natomiast wyższą gdy chwasty znajdują się w fazie od pełni krzewienia do początku fazy strzelania w źdźbło (BBCH 25-30).

c) zwalczanie perzu właściwego

Maksymalna dawka dla jednorazowego zastosowania: 1,5 l/ha.

Zalecana dawka dla jednorazowego zastosowania: 1,25 – 1,5 l/ha.

Środek do zwalczania perzu właściwego można stosować w dawkach dzielonych.

Pierwszy zabieg

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,6 l/ha.

Drugi zabieg

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,6 l/ha.

Odstęp między zabiegami: co najmniej 12 dni.

Środek stosować gdy rośliny perzu wykształciły 3-6 liści (osiągnęły wysokość 15-20 cm) (BBCH 13-16).

Po wykonaniu zabiegu zwalczania perzu przez miesiąc nie wykonywać uprawy mechanicznej gleby.

Zalecana ilość wody: 200-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1 lub 2 (dawki dzielone).

UWAGA:

Chwasty dwuliścienne można zwalczać na co najmniej trzy dni przed lub w trzy dni po zastosowaniu środka.

NASTĘPSTWO ROŚLIN

Środek rozkłada się w ciągu okresu wegetacji nie stwarzając zagrożenia dla roślin uprawianych następczo. W przypadku wcześniejszego zaorania plantacji traktowanej środkiem (np. w wyniku wymarznienia lub uszkodzenia roślin przez choroby czy szkodniki) można uprawiać rośliny dwuliścienne lub rośliny, do odchwaszczania których zaleca się środek.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

~~Burak cukrowy, kapusta głowiasta, fasola, marchew, pietruszka, seler korzeniowy, pasternak, brokuł, kapusta brukselska, burak pastewny, burak ćwikłowy, topinambur, chrzan pospolity, rzodkiew czarna, rzodkiew japońska (daikon), rzodkiewka, salsefia, rzepa biała, rzepa czarna – 28 dni.~~

Rzepak ozimy – 42 dni.

Ziemniak – 40 dni.

~~Groch zielony, groch na suche nasiona, bób, łubin biały, łubin żółty, łubin wąskolistny, peluszką, bobik, lucerna siewna, lucerna sierpowata, lucerna nerkowata, koniczyna, koniczyna czerwona, koniczyna biała, koniczyna krwistoczerwona (inkarnatka), espareeta siewna, wyka, seradela, soczewica, nostryk biały, nostryk żółty, lędzwan siewny – 45 dni.~~

~~Cebula, czosnek pospolity, cebula szalotka, brukiew – 30 dni.~~

~~Rzepak jary, mak lekarski, len zwyczajny, lnianka siewna – 90 dni.~~

Rzepak ozimy, rzepak jary, len zwyczajny, mak lekarski – 90 dni

Burak cukrowy, seler, brukiew, burak czerwony, burak pastewny, chrzan, czarna rzepa, biała rzepa - 60 dni

Ziemniak – 40 dni

Marchew, pietruszka, kapusta, pasternak, czarna rzodkiew, rzodkiew japońska, rzodkiew zwyczajna, salsefia, cebula, czosnek, szalotka, topinambur – 30 dni

Truskawka – nie dotyczy.

1. Strategia zarządzania odpornością

W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:

- postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin – stosować środek w zalecanej dawce, w zalecanym terminie zapewniającym optymalne zwalczanie chwastów,
- dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,
- stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować mieszankę herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),
- stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
- dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
- używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw itp.,
- używać kwalifikowanego materiału siewnego,
- czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
- informować posiadacza zezwolenia o nie satysfakcjonującym zwalczaniu chwastów,
- w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.

2. Środka nie stosować:

- podczas wiatru stwarzającego możliwość znoszenia cieczy użytkowej na sąsiednie rośliny uprawne, zwłaszcza rośliny jednoliścienne (np. kukurydza, zboża),
- podczas długotrwałej suszy lub w temperaturze powietrza przekraczającej 27°C.

3. Podczas stosowania środka nie dopuścić do:
- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
 - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.

Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszałem) i uzupełnić wodą do potrzebnej ilości.

Po wlaniu środka do zbiornika opryskiwacza nie wyposażonego w mieszało hydrauliczne ciecz w zbiorniku mechanicznie wymieszać.

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową.

W przypadku przerw w opryskiwaniu przed ponownym przystąpieniem do pracy, należy dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne, ochronę oczu i ochronę twarzy podczas sporządzania cieczy użytkowej.

Stosować rękawice ochronne podczas wykonywania zabiegu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.

W celu ochrony roślin niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od terenów nieużytkowanych rolniczo lub wyznaczenie strefy ochronnej o szerokości 1 m i zastosowanie rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,

- w temperaturze 0°C - 30°C,
- w szczelnie zamkniętych pojemnikach, z dala od źródeł ciepła.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

NIE wywoływać wymiotów.

W razie wypadku lub złego samopoczucia podczas stosowania środka, należy niezwłocznie zasięgnąć porady medycznej (pokazać etykietę lub opakowanie).

W przypadku połknięcia: natychmiast skontaktować się z ośrodkiem zatruc lub lekarzem.

W przypadku dostania się do oczu: ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 2 Letter of Access

Not relevant.

Appendix 3 Lists of data considered for national authorization

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.3.1 KCP 2.3.2 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.6.1	Barbara Krzysiak-Warzała	2017	Propaquizafop 10% EC: Analysis of active substances content and physicochemical properties of initial preparation and preparation after accelerated storage procedure (CIPAC MT 46.3) Study Report No.100/2017/BA-AD Institute of Heavy Organic Synthesis "Blachownia" Analytical Department GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 2.7.5	Barbara Krzysiak-Warzała	2020	Propaquizafop 10% EC: Evaluation of stability of the product after storage in accordance with CropLife Technical Monograph No. 17 (6 months, 1 year, 2 years) Study Report No.101/2017/BA-AD Institute of Heavy Organic Synthesis "Blachownia" Analytical Department GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 2.2.1	Daniel Buczkowski	2017	Propaquizafop 10% EC: Determination of explosive properties Study Report No. BW-14/17 Institute of Industrial Organic Chemistry, Poland GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 2.2.2	Przemysław Grojs	2017	Propaquizafop 10% EC: Determination of oxidising properties	N	Y	Data/study report never submitted	Sharda Crop-

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Study Report No. BW-54/17 Institute of Industrial Organic Chemistry, Poland GLP Unpublished			before to <Poland>	chem Limited
KCP 5.1.1.	Kedzierzyn-Kozle	2017	Propaquizafop 10% EC: Analysis of active substances content and physicochemical properties of initial preparation and preparation after accelerated storage procedure ISCO, Report No 100/2017/BA-AD GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-01	Düsterloh K.	2008	Development and Validation of a residue analytical method for the determination of Quizalofop-P-Ethyl and its metabolites (all expressed as Quizalofop-P-Ethyl equivalents) in sugar beet tops and roots. RCC Ltd, Switzerland, RCC Study number B72922, GLP, Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-01	Lentheric I.	2008	ILV (Independent Laboratory Validation) of a Residue Analytical Method for the Determination of Quizalofop-P-Ethyl and its Metabolites (all expressed as Quizalofop-P-Ethyl equivalents) in Sugar Beet Tops and Roots Harlan Laboratories S.A. Study S16134 GLP, Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-06	Bedoret, T.	2013c	Residue of quizalofop-ethyl, quizalofop and quizalofop conjugate at harvest following one application of SHAQPE120 in grapevine in open field conditions. France, Spain and Italy, season 2012 Redebel Report no.: SHA-G140TO142-12 GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-02	Pigeon, O.	2009	Residue of quizalofop-p-ethyl (and its metabolites) in sunflower in open field conditions at harvest or at intervals following one application of quizalofop-p-ethyl 5% EC. Greece, Italy, Spain and Southern France – Saison 2008 REdebel Report no.: B21852 GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2.1-03	Düsterloh, K.	2008	Validation of residue analytical method for the determination of quizalofop-p-ethyl technical 95% and its metabolites (all expressed as quizalofop-pethyl equivalents) in oil seed rape Harlan Report no.: B91618 GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-05	Bedoret, T.	2013b	Residue of quizalofop-ethyl, quizalofop and quizalofop conjugate at intervals or at harvest following one application of SHAQPE120 in peas in open field conditions. France, Spain and Italy, Season 2012 Redebel Report no.: SHA-G103TO110-12 GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-04	Bedoret, T.	2013a	Residue of quizalofop-ethyl, quizalofop and quizalofop conjugate at intervals following one application of SHAQPE50 or SHAQPE120 in winter oilseed rape in open field conditions. France, Season 2011-2012 Redebel Report no.: SHA-G101TO102-12 GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-07	Carole Meseguer	2018	Validation of the common moiety Method for the Determination of Quizalofop, Quizalofop-P-ester(s) and Quizalofop conjugate(s) expressed as quizalofop (sum of isomers) in various crops types. Study code S17-06616 GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-08	Pivato M.	2017	Validation of the analytical procedure for the determination of quizalofop free acid and quizalofop-P-ethyl after hydrolysis in grape vine by liquid chromatography Chelabs Study no FR 16.563341.0012 GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-09	Pivato M.	2017	Validation of the analytical procedure for the determination of quizalofop free acid and quizalofop-P-ethyl after hydrolysis in	N	Y	Data/study report never submitted before to <Poland>	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			fresh pea by liquid chromatography Chelabs Study no FR 16.563341.0011 GLP Unpublished				
KCP 5.2.1-10	Pivato M.	2017	Validation of the analytical procedure for the determination of quizalofop free acid and quizalofop-P-ethyl after hydrolysis in dried peas by liquid chromatography Chelabs Study no FR 16.563341.0010 GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-11	Pivato, M.	2016	Validation of the analytical procedure for the determination of quizalofop free acid and quizalofop-P-ethyl after hydrolysis in milk by liquid chromatography Chelab Report no.: 16.563341.0001 GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-12	Pivato, M.	2016	Validation of the analytical procedure for the determination of quizalofop free acid and quizalofop-P-ethyl after hydrolysis in eggs by liquid chromatography Chelab Report no.: 16.563341.0003 GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-13	Pivato, M.	2016	Validation of the analytical procedure for the determination of quizalofop free acid and quizalofop-P-ethyl after hydrolysis in meat by liquid chromatography Chelab Report no.: 16.563341.0004 GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-14	Pivato, M.	2016	Validation of the analytical procedure for the determination of quizalofop free acid and quizalofop-P-ethyl after hydrolysis in fat by liquid chromatography Chelab Report no.: 16.563341.0002	N	Y	Data/study report never submitted before to <Poland>	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 5.2.1-15	Pivato, M.	2016	Validation of the analytical procedure for the determination of quizalofop free acid and quizalofop-P-ethyl after hydrolysis in kidney by liquid chromatography Chelab Report no.: 16.563341.0006 GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-16	Pivato, M.	2016	Validation of the analytical procedure for the determination of quizalofop free acid and quizalofop-P-ethyl after hydrolysis in liver by liquid chromatography Chelab Report no.: 16.563341.0005 GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-17	Markowicz, A.	2020	Independent laboratory validation of a method for the determination of quizalofop free acid and quizalofop-p-ethyl after hydrolysis in meat (poultry) by liquid chromatography. Food Safety Laboratory Report no.: ZBBZ-2016/09/DPL/2A GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-18	Markowicz, A.	2019	Independent laboratory validation of a method for determination of quizalofop free acid and quizalofop-p-ethyl after hydrolysis in fat by liquid chromatography. Food Safety Laboratory Report no.: ZBBZ-2016/09/DPL/1A GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 5.2.1-19	Paszek, G.	2021	Validation of an analytical method for the determination of residues of propaquizafop, quizalofop-ester, quizalofop and quizalofop conjugate in olive, tomato and orange. SGS Poland Report no.: VAL/11/2020 GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
CP 6.0-	Anonymous	2020	Biological Assessment Dossier: PROPAQUIZAFOP 10%	N	Y	Data/study report never submitted	Sharda Crop-

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
001			EC (100 g/l propaquizafop) – EU Central zone Sharda Cropchem España - Unpublished			before to <Poland>	chem Limited
KCP 8.3.1.1	G. Rousseau	2013	Freezing storage stability study of residues of quizalofop in pea whole plant, pea dry seed, oil seed rape grain and grape (0, 6 and 12 months) Walloon Agricultural Research Centre, CRA-W GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 10.2.1 - 1		2019	“Propaquizafop 10% EC Rainbow trout, Acute toxicity test”. Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	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	Y	Data/study report never submitted before to <Poland>	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	Y	Data/study report never submitted before to <Poland>	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 Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
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	N	Y	Data/study report never submitted before to <Poland>	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.1.2	Pawel Parma	2017	Unpublished "Propaquizafop 10% EC Honeybees (<i>Apis mellifera</i> L.), Acute Contact Toxicity Test". Parma P., B/117/16, 2017. Institute of Industrial Organic Chemistry - Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 10.4.1.1	Pieczka P	2018	"Propaquizafop 10% EC Earthworm Reproduction Test (<i>Eisenia andrei</i>)" Pieczka P., G/49/17, 2018 Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
KCP 10.4.2-1	Pieczka P	2018	"Propaquizafop 10% EC Collembolan (<i>Folsomia candida</i>) Reproduction Test". Pieczka P., G/50/1, 2018 Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	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, <i>Typhlodromus pyri</i> (Sch.)". Parma P., B/119/16, 2018. Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	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, <i>Aphidius rhopalosiphi</i> (De Stefani - Perez) Parma P., B/118/16, 2018. Institute of Industrial Organic Chemistry Branch Pszczyna GLP Unpublished	N	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
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	Y	Data/study report never submitted before to <Poland>	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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
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	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited
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	Y	Data/study report never submitted before to <Poland>	Sharda Cropchem Limited

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIIA 5.3.1/01	Krainz A.	2010	Validation of a residue analytical method for the determination of propaquizafop and its metabolite quizalofop-P (expressed as quizalofop) in apple, tomato, oilseed rape and wheat grain Harlan Laboratories Ltd., Itingen, Switzerland Quena Plant Protection N.V. Report No.: 90012134 GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIIA 5.3.1/02	Perny A.	2004	Validation study of the analytical method for the determination of propaquizafop in lupin and soybean Anadiag, Haguenau, France Quena Plant Protection N.V. Report No.:	N	N	N	Quena Plant Protection N.V.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			90011535 GLP, Unpublished				
IIIA 5.6/01	Krainz A.	2009	Validation of a residue analytical method for the determination of propaquizafop and its metabolite quizalofop-P in surface water Harlan Laboratories Ltd., Itingen, Switzerland Quena Plant Protection N.V. Report No.: 90011787 GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.1/01	Hänni, R., Schuler, A.	1987	CGA233380, Analytical determination of Ro 17-3664/000 and its metabolites Ro 17-3102 and Ro 16-1981 in agricultural products and soil samples. Dr. R. Maag Ltd., Company Report No. 041-6954 (art. 90003669) No GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.1/07	Adams, S.P.	1996	Validation of Method REM 163.04, by fortification of untreated pea seed with CGA 233380, CGA 287422, CGA 129674 and CGA 290291 Ciba Agriculture Company Report no. HR0495ER (art. 90003682) GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.1/09	Wolf, S.	2003a	Development and Validation of a residue analytical method for propaquizafop and propaquizafop-acid in sunflower seed, wheat grain, tomato and apple. Quena Plant Protection N.V. Company Report no. 845105 (art. 90005421) GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.1/02	Tribolet, R.	1993	Determination of total residues of parent compound and metabolites CGA 287422 and CGA 129674 as CGA 289746 by gas chromatography (GC), Plant materials, soil ciba geigy LTd. Company report no. REM 163-04 (art. 90003672) GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.2/02	Tribolet, R.	1995c	Determination of residue of parent compound as CGA 289746 by high performance liquid chromatography (HPLC), plant materials, soil. Ciba Geigy Ltd. Company report no. REM 163.07 (art. 90003681) GLP unpublished	N	N	N	Quena Plant Protection N.V.
IIA,	Reichert, N.	2003	1 st Amendment of final report ILV of the analytical method for	N	N	N	Quena

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
4.2.1/11			the determination of propaquizafop and propaquizafop-acid in Wheat (Frain) and Tomao. Quena Plant protection N.V. Company report no. IF-03/00061233 (art. 90005492) GLP, Unpublished				Plant Protection N.V.
IIA, 4.2.1/04	Tribolet, R.	1995a	Validation by Analysis of fortified specimens and determination of recoveries. Validation of Method REM 163.04 Ciba Geigy Ltd. Company report no. special study 113/95 (art. 90003678) GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.1/08	Krainz, A.	2003a	Development and validation of a residue analytical method for propaquizafop and propaquizafop-acid in potato (tubers), sugar beet (roots and tops with leaves), soya (seeds, straw and whole plant) and sunflower (seeds and whole plants) Quena Plant Protection N.V. Company Report no. 845104 (art. 90005414) GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.1/03	Tribolet, R.	1994a	Validation by analysis of fortified specimens and determination of recoveries Ciba Geigy Ltd. Company report no. Special study 119/94 (art. 90003675) GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.1/10	Tribolet, R.	1992	CGA233380, determination of total residues of parent compound and metabolites CGA 287422 and CGA 129674 as CGA289746 in animal tissues. Ciba-Geigy Ltd. Company report no. REM 163.02 (art. 90003671) Not GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.1/03	Krainz, A.	2003b	Development and Validation of a residue analytical method for propaquizafop and propaquizafop-acid in soil. Quena plant protection N.V. Company report no. 845103 (art. 90005283) GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.1/04	Krainz, A.	2003c	Development and validation of a residue analytical method for propaquizafop and propaquizafop-acid in soil Quena Plant Protection N.V. Company Report No. 846117 (art. 90005475)	N	N	N	Quena Plant Protection N.V.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIA, 4.2.3/01	Mostert, I.	1992	GLP, Unpublished Determination of residues of parent compound and metabolite CGA 287422 as CGA 289746 by gas chromatography (GC), Ciba-Geigy Ltd. Company report No. REM 163.01 (art. 90003670) Not GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.3/02	Tribolet, R.	1994b	Validation by analysis of fortified specimens and determination of recoveries Ciba Geigy Ltd. Company report no. Special study 133/94 (art. 90003674) GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.3/03	Tribolet, R.	1995d	Determination of parent compound by high performance liquid chromatography (HPLC) Ciba Geigy Ltd. Company report no. REM 163.05 (art. 90003679) GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.3/04	Tribolet, R.	1999a	Determination of Parent Compound and metabolite CGA 287422 by High performance liquid chromatography (HPLC) Novartis Crop Protection AG Company Report No. REM 163.08 (art. 90003684) GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.3/05	Tribolet, R.	1999b	Validation of Method REM 163.08 by analysis of fortified water specimens for propaquizafop (CGA 233380) and its metabolite CGA 287422 and Evaluation of recoveries Novartis Crop Protection AG Company report no. special study 321/99 (art. 90003685) GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.4/01	Tribolet, R.	1994c	Sampling of air and determination of residues of parent compound by high performance liquid chromatography, air Ciba-Geigy Ltd. Company Report No. REM 163.03 (art. 90003673) GLP, Unpublished	N	N	N	Quena Plant Protection N.V.
IIA, 4.2.4/02	Wolf, S.	2003b	Developent and validation of a residue analytical method for propaquizafop and propaquizafop-acid in air. Quena plant protection N.V. Company report no. 845106 (art. 90005357) GLP, Unpublished	N	N	N	Quena Plant Protection N.V.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS : Data protection started with: <insert authorization number of first authorization>	Owner

List of data relied on and 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS : Data protection started with: <insert authorization number of first authorization>	Owner