

FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: A-200SL-OR3-C

Product name(s): LEPTOSAR 200 SL

Chemical active substance(s):

Acetamiprid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: CIECH Sarzyna S.A.

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When	What
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December 2021	zRMS finalised evaluation
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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

Field of use: insecticide

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 destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1.	PL	Winter oilseed rape (BRSNW)	F	Pollen Beetles (<i>Meligethes aeneus</i>) – MELIAE	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-69	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
2.	PL	Winter oilseed rape (BRSNW)	F	Rape stem weevil (<i>Ceutorhynchus napi</i>) - CEUTNA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 17-59 BBCH 30-59	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
3.	PL	Winter oilseed rape (BRSNW)	F	Cabbage stem weevils (<i>Ceutorhynchus pallidactylus</i>) – CEUTQU	Foliar spray	After reaching thresholds or after warning service appeal BBCH 17-59	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-

						BBCH 30-59							
4.	PL	Winter oilseed rape (BRSNW)	F	Cabbage seed weevil (<i>Ceutorhynchus obstrictus</i>) – CEUTAS	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-71	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
5.	PL	Winter oilseed rape (BRSNW)	F	Brassica pod midge (<i>Dasineura brassicae.</i>) - DASYBR	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-71	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
6.	PL	Maize (ZEMAX)	F	European corn borer (<i>Ostrinia nubilalis</i>) - PYRUNU	Foliar spray	After reaching thresholds or after warning service appeal BBCH 51-75	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	300-500	n.a.	-

Minor uses according to Article 51 (zonal uses)													
41.	PL	Spring oilseed rape (BRSNS) white mustard (SINAL); black mustard (BRSNI), Chinese mustard (BRSJU) turnip rape (BRSRO)	F	Pollen beetles (<i>Meligethes aeneus</i>) – MELIAE	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-69	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
42.	PL	Spring oilseed rape (BRSNS) white mustard (SINAL); black mustard (BRSNI), Chinese mustard (BRSJU) turnip rape (BRSRO)	F	Rape stem weevil (<i>Ceutorhynchus napi</i>) - CEUTNA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 20-59	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
43.	PL	Spring oilseed rape (BRSNS) white mustard (SINAL); black mustard (BRSNI), Chinese mustard (BRSJU) turnip rape (BRSRO)	F	Cabbage stem weevils (<i>Ceutorhynchus pallidactylus</i>) – CEUTQU	Foliar spray	After reaching thresholds or after warning service appeal BBCH 20-59	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
44.	PL	Spring oilseed rape (BRSNS) white mustard (SINAL); black mustard (BRSNI), Chinese mustard (BRSJU) turnip rape (BRSRO)	F	Cabbage seed weevil (<i>Ceutorhynchus obstrictus</i>) – CEUTAS	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-71	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
45.	PL	Spring oilseed rape (BRSNS); white mustard (SINAL); black mustard (BRSNI), Chinese mustard (BRSJU); turnip rape (BRSRO)	F	Brassica pod midge (<i>Dasineura brassicae.</i>) - DASYBR	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-71	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
46.	PL	Flax (LIUUT) - seeds and fiber production	F	Large flax flea beetle (<i>Aphthona euphorbiae</i>) - APHTEU; Small flax flea beetle (<i>Longitarsus parvulus</i>) - LONIPA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 10-14	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-

47.	PL	Flax (LIUUT) -seeds and fiber production	F	Cabbage thrips (<i>Thrips angusticeps</i>) - THRIAN; Flax thrips (<i>Thrips lini</i>) - THRILI	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-61	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
48.	PL	Common hemp (CNISA) - seeds and fiber production	F	Hemp flea beetle (<i>Psylliodes attenuata</i>) - PSYIAT	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-14	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
49.	PL	Common hemp (CNISA) - seeds and fiber production	F	European maize borer (<i>Ostrinia nubilalis</i>) - PYRUNU	Foliar spray	After reaching thresholds or after warning service appeal (June)	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
50.	PL	Common hemp (CNISA) - seeds and fiber production	F	Aphids (<i>Aphididae</i>) – APXXSP; Thrips (<i>Thysanoptera</i>) - ITHYSO	Foliar spray	After reaching thresholds or after warning service appeal (BBCH 39-59)	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-400	n.a.	-
51.	PL	Soybean (GLXMA) – seeds production	F	Sitona (<i>Sitona sp.</i>) - SITNSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-19	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-500	n.a.	-
52.	PL	Soybean (GLXMA) – seeds production	F	Bishop bug (<i>Lygus rugulipennis</i>) – LYGURU; Aphids (<i>Aphididae</i>) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 61-65	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-500	n.a.	-
53.	PL	Opium poppy (PAPSO) – seeds production	F	Capsule midge (<i>Dasineura papaveris</i>) - DASYPA; Capsule weevils (<i>Neogloecianus</i>)	Foliar spray	After reaching thresholds or after warning service appeal	a) 1 b) 1	n.a.	a) 0,15 l/ha b) 0,15 l/ha	a) 30 g/ha b) 30 g/ha	200-400	n.a.	-

				<i>maculaalba</i>) - CEUTMA		BBCH 10-39							
54.	PL	Sunflower (HELAN) – seeds production	F	Aphids (<i>Aphididae</i>) – APXXSP; Lygus bug (<i>Lygus sp.</i>) - LYGUSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 10-65	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha a) 0,25 l/ha b) 0,25 l/ha	a) 60 g/ha b) 60 g/ha a) 50 g/ha b) 50 g/ha	300-500	n.a.	-
55.	PL	Pumpkin (CUUPE) – seeds production	F	Lygus bug (<i>Lygus sp.</i>) - LYGUSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 21-69 BBCH ≥50	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	200-500	n.a.	-
56.	PL	sugar maize <i>Zea mays</i> L. convar. <i>saccharata</i> Koern. (ZEAMS); Popcorn (ZEAME); sorghum (SORVU), proso true millet (PANMI)	F	European corn borer (<i>Ostrinia nubilalis</i>) - PYRUNU; Aphids (<i>Aphididae</i>) – APXXSP;	Foliar spray	After reaching thresholds or after warning service appeal BBCH 51-75	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	300-500	n.a.	-
57.	PL	Spring rye (SECCS), Durum wheat (TRZDU), Spelt wheat (TRZSP), einkorn wheat (TRZMO) emmer wheat (TRZDI)	F	Cereal leaf beetle (<i>Oulema melanopus</i>) – LEMAME	Foliar spray	After reaching thresholds or after warning service appeal BBCH 37-65	a) 1 b) 1	n.a.	a) 0,2 l/ha b) 0,2 l/ha	a) 40 g/ha b) 40 g/ha	200-400	n.a.	-
58.	PL	Spring rye (SECCS), Spring triticale (TTLWS), Durum wheat (TRZDU), Spelt wheat (TRZSP), einkorn wheat (TRZMO) emmer wheat (TRZDI)	F	Cereal bug (<i>Eurygaster maura</i>)- EURYMA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-59	a) 1 b) 1	n.a.	a) 0,2 l/ha b) 0,2 l/ha	a) 40 g/ha b) 40 g/ha	200-400	n.a.	-

59.	PL	Spring wheat (TRZAS)	F	Cereal bug (<i>Eurygaster maura</i>)- EURYMA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-59	a) 1 b) 1	n.a.	a) 0,2 l/ha b) 0,2 l/ha	a) 40 g/ha b) 40 g/ha	200-400	n.a.	-
60.	PL	Winter wheat (TRZAW)	F	Cereal bug (<i>Eurygaster maura</i>)- EURYMA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-59	a) 1 b) 1	n.a.	a) 0,2 l/ha b) 0,2 l/ha	a) 40 g/ha b) 40 g/ha	200-400	n.a.	-
61.	PL	Winter triticale (TTLWI), Winter rye (SECCW)	F	Cereal bug (<i>Eurygaster maura</i>)- EURYMA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 30-59	a) 1 b) 1	n.a.	a) 0,2 l/ha b) 0,2 l/ha	a) 40 g/ha b) 40 g/ha	200-400	n.a.	-
62.	PL	tomato (LYPES), aubergine (SOLME), Paprika (CPSAN)	G	Glasshouse whitefly (<i>Trialeurodes vaporariorum</i>) – TRIAVAC Common cotton thrips (<i>Thrips tabaci</i>) – THRITB; Western grass thrips (<i>Frankliniella occidentalis</i>) - FRANOC; Leaf miner (<i>Phytomyza sp.</i>) - PHYYS; Aphids (<i>Aphididae</i>) – APXXSP; , Lygus bug (<i>Lygus sp.</i>) - LYGUSP; Flea beetle (<i>Psylliodes</i>) - IPSYIG	Foliar spray	After reaching thresholds or after warning service appeal BBCH 20 – 89	a) 1 b) 1	n.a.	a) 0,3 l/ha b) 0,3 l/ha	a) 60 g/ha b) 60 g/ha	300-750	3	-
63.	PL	Wild apple (MABSY)	F	Aphids (<i>Aphididae</i>) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-87 BBCH 51 - 87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
64.	PL	Wild apple (MABSY)	F	Codling moth (<i>Cydia pomonella</i>) - CARPPO	Foliar spray	After reaching thresholds or	a) 2	7-14	a) 0,125 L/ha b) 0,25L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-

						after warning service appeal BBCH 69-74	b) 2						
65.	PL	Wild apple (MABSY)	F	Pear leaf blister moth (<i>Leucoptera scitella</i>) - LEUCSC	Foliar spray	After reaching thresholds or after warning service appeal BBCH 57-69	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
66.	PL	Wild apple (MABSY)	F	Apple fruit sawfly (<i>Hoplocampa testudinea</i>) - HOPLTE	Foliar spray	After reaching thresholds or after warning service appeal BBCH 65-69	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
67.	PL	Wild apple (MABSY)	F	Apple leaf midge (<i>Dasineura mali</i>) - DASYMA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-73	a) 2 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25g/ha b) 50 g/ha	200-750	14	-
68.	PL	Wild apple (MABSY)	F	Bracken clock (<i>Phyllopertha horticola</i>) - PHPHHO	Foliar spray	After reaching thresholds or after warning service appeal BBCH 59-73	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
69.	PL	Pear (PYUCO), Chinese pear (PYUPY)	F	Aphids (Aphididae) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-87 BBCH 51 - 87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-

70.	PL	Pear (PYUCO), Chinese pear (PYUPY)	F	Codling moth (<i>Cydia pomonella</i>) - CARPPO	Foliar spray	After reaching thresholds or after warning service appeal BBCH-71-87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
71.	PL	Pear (PYUCO), Chinese pear (PYUPY)	F	Cherry slug sawfly(<i>Caliroa limacina</i>) - ERICLI	Foliar spray	After reaching thresholds or after warning service appeal BBCH 71-87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
72.	PL	Pear (PYUCO), Chinese pear (PYUPY)	F	Apple bud weevil(<i>Anthonomus piri</i>) - ANTHPY	Foliar spray	After reaching thresholds or after warning service appeal BBCH 51-59	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
73.	PL	Pear (PYUCO), Chinese pear (PYUPY)	F	Pear leaf midge (<i>Dasineura pyri</i>) - DASYPY	Foliar spray	After reaching thresholds or after warning service appeal BBCH 71-79	a) 2 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
74.	PL	Pear (PYUCO), Chinese pear (PYUPY)	F	Pear psylla (<i>Cacopsylla pyri</i>) - PSYLPI; Pear sucker (<i>Cacopsylla pyrisuga</i>) - PSYLPY; , Pear psyllid (<i>Cacopsylla pyricola</i>) - PSY LPC	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-87 BBCH 51 - 87	a) 2 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
75.	PL	Quince (CYDOB), medlar (MSPGE)	F	Aphids (<i>Aphididae</i>) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-87 BBCH 51 - 87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-

76.	PL	Quince (CYDOB), medlar (MSPGE)	F	Codling moth (<i>Cydia pomonella</i>) - CARPPO	Foliar spray	After reaching thresholds or after warning service appeal BBCH 71-87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
77.	PL	Sour cherry (PRNCE), sweet cherry (PRNAV),	F	Cherry fruit fly (<i>Rhagoletis cerasi</i>) - RHAGCE	Foliar spray	After reaching thresholds or after warning service appeal BBCH 76-81	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
78.	PL	Sour cherry (PRNCE), sweet cherry (PRNAV),	F	Aphids (<i>Aphididae</i>) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-87 BBCH 51 - 87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	250-750	14	-
79.	PL	Sour cherry (PRNCE), sweet cherry (PRNAV),	F	Cherry slug sawfly (<i>Caliroa limacina</i>) - ERICLI	Foliar spray	After reaching thresholds or after warning service appeal BBCH 71-87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
80.	PL	Sour cherry (PRNCE), sweet cherry (PRNAV),	F	Cherry fruit moth (<i>Argyresthia ephippiella</i>) - ARGYEP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 51-59	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
81.	PL	Sour cherry (PRNCE), sweet cherry (PRNAV),	F	Cherry-stone weevil (<i>Anthonomus rectirostris</i>) - ANTHRE	Foliar spray	After reaching thresholds or after warning service appeal BBCH 57-69	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
82.	PL	Sour cherry (PRNCE), sweet cherry (PRNAV),	F	Apple brown tortrix (<i>Pandemis heparana</i>) - PANDHE; Reticulated tortrix (<i>Adoxophyes</i>	Foliar spray	After reaching thresholds or after warning	a) 2 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25g/ha b) 50 g/ha	200-750	14	-

				orana) - CAPURE; European leaf roller (<i>Archips rosana</i>) - CACORO; Whelk (<i>Tortricidae</i>) - 1TORTF; and other leaf caterpillars		service appeal BBCH 11-87 BBCH 51 - 87							
83.	PL	Peach (PRNPS), Nectarine (PRNPN),apricot (PRNAR)	F	Apple brown tortrix (<i>Pandemis heparana</i>) - PANDHE; Reticulated tortrix (<i>Adoxophyes</i> <i>orana</i>) - CAPURE; European leaf roller (<i>Archips rosana</i>) - CACORO; Whelk (<i>Tortricidae</i>) - 1TORTF; and other leaf caterpillars	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-87 BBCH 51 - 87	a) 2 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a)25 g/ha b) 50 g/ha	200-750	14	-
84.	PL	Peach (PRNPS), Nectarine (PRNPN),apricot (PRNAR)	F	Aphids (<i>Aphididae</i>) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-87 BBCH 51 - 87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
85.	PL	Plum (PRNDO)	F	Aphids (<i>Aphididae</i>) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-87 BBCH 51 - 87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
86.	PL	Plum (PRNDO)	F	Plum fruit sawfly (<i>Hoplocampa minuta</i>) - HOPLMI; Plum sawfly (<i>Hoplocampa flava</i>) - HOPLFL;	Foliar spray	After reaching thresholds or after warning service appeal BBCH 69-87	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
87.	PL	Plum (PRNDO)	F	Plum fruit moth (<i>Laspeyresia funebrana</i>) - LASPFU	Foliar spray	After reaching thresholds or after warning service appeal BBCH 71-81	a) 2 b) 2	14-21	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-

88.	PL	Plum (PRNDO)	F	European brown scale (<i>Parthenolecanium corni</i>) - LECACO	Foliar spray	After reaching thresholds or after warning service appeal BBCH 54-59	a) 1 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25g/ha b) 50 g/ha	200-750	14	-
89.	PL	Plum (PRNDO)	F	Apple brown tortrix (<i>Pandemis heparana</i>) - PANDHE; Reticulated tortrix (<i>Adoxophyes orana</i>) - CAPURE; European leaf roller (<i>Archips rosana</i>) - CACORO; Whelk (<i>Tortricidae</i>) - 1TORTF; and other leaf caterpillars	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-87 BBCH 51 - 87	a) 2 b) 2	7-10	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
90.	PL	Hazelnut (CYLAV)	F	Aphids (Aphididae) – APXXSP; , Hazelnut weevil (<i>Curculio nucum</i>) - CURCNU; (<i>Oberea linearis</i>) - OBERLI; European brown scale (<i>Parthenolecanium corni</i>) - LECACO; , Reticulated tortrix (<i>Adoxophyes orana</i>) - CAPURE; European leaf roller (<i>Archips rosana</i>) - CACORO; other totrix and other leaf caterpillars	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11 – 65 BBCH 51 - 65	a) 2 b) 2	7-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
91.	PL	walnut (IUGRE)	F	Aphids (Aphididae) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 50 – 65	a) 2 b) 2	10-14	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	14	-
92.	PL	Tobacco (NIOTA)	F	Common cotton thrips (<i>Thrips tabaci</i>) - THRITB; Aphids (Aphididae) – APXXSP	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11 – 85 BBCH 30 - 85	a) 2 b) 2	7-10	a) 0,125 L/ha b) 0,25 L/ha	a) 25g/ha b) 50 g/ha	200-750	na	-

93.	PL	Common osier (SAXVI) Purple willow (SAXPU)	F	Aphids (<i>Aphididae</i>) – APXXSP, Balsam poplar leaf beetle (<i>Chrysomela populi</i>) - CHRSP; (<i>Chrysomela saliceti</i>)- CHRSSA, Blue willow beetle (<i>Phratora vulgatissima</i>) - PHRRVU; Brassy willow leaf beetle (<i>Phratora vitellinae</i>) - PHRRVI; Cream-bordered green pea moth (<i>Earias clorana</i>) - EARICH; , Gall midge (<i>Dasineura marginemtorquens</i>) - RHABMA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-69 BBCH 51 - 69	a) 2 b) 2	10	a) 0,125 L/ha b) 0,25 L/ha	a) 25 g/ha b) 50 g/ha	200-750	na	-
94.	PL	Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	F	Aphids (<i>Aphididae</i>) – APXXSP, Springtails (<i>Collembola</i>) - 1COLLO; Larch case-bearer (<i>Coleophora laricella</i>) - COLELA	Foliar spray	After reaching thresholds or after warning service appeal BBCH 11-69	a) 1 b) 1	n.a.	a) 0,25 L/ha b) 0,25 L/ha a) 0,20 L/ha b) 0,20 L/ha	a) 50 g/ha b) 50 g/ha a) 40 g/ha b) 40 g/ha	200-400	na	-

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

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

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

Explanation for column 15 “Conclusion”

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

zRMS Comments:	Calcareous soils. The safe use in sunflower and soybean was confirmed if formulation is applied every second year.
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Table 8.1-2: Assessed (critical) uses during approval of acetamiprid concerning the Section Environmental Fate

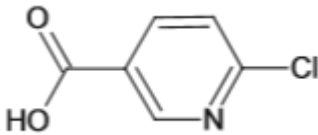
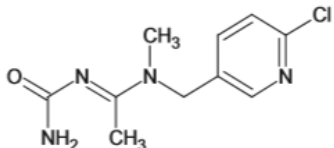
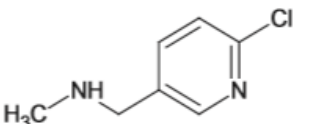
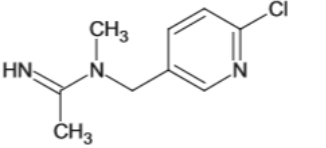
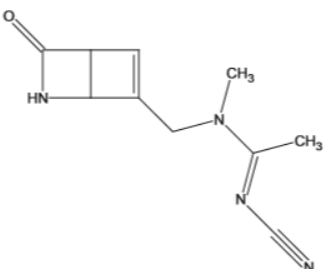
1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Application Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg 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	PHI (days)	Remarks: e.g. safener/syner- gist per ha e.g. recommended or mandatory tank mixtures
1	EU	Tomato	G	Aphids	Foliar	BBCH 61 – 89 (January- December)	a) 2 (7) b) 2 (7)	a) 0.5 b) 1.0	a) 0.100 b) 0.200	300 – 1500	3	Use in greenhouse is in permanent structure
2	EU	Pome fruit	F	Aphids	Foliar	BBCH 77 – 87 (June - September)	a) 2 (14) b) 2 (14)	a) 0.375 b) 0.750	a) 0.075 b) 0.150	300 – 1000	14	
3	EU	Potato	F	Colorado potato beetle / aphids	Foliar	BBCH 45 – 93 (May-October)	a) 3 (7) b) 3 (7)	a) 0.250 b) 0.750	a) 0.05 b) 0.150	400 – 600	7	

**Remarks
table:**

- | | |
|---|---|
| <ul style="list-style-type: none"> (1) Numeration necessary to allow references (2) Use official codes/nomenclatures of EU (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure) (4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application (5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named (6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated | <ul style="list-style-type: none"> (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 |
|---|---|

8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of acetamiprid potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
IC-0 ¹⁾	157.55		Soil: 11.3 % Water/sediment: 29.5 %	PEC sw/sed: potential risk to aquatic and soil organisms PEC gw: leaching potential to groundwater PECs
IM 1-2 ²⁾	240.69		Soil: 55 % Water/sediment: 13.4%	PEC sw/sed: potential risk to aquatic and soil organisms PEC gw: leaching potential to groundwater PECs
IM 1-4 ³⁾	156.61		Soil: 72 % Water/sediment: 43%	PEC sw/sed: potential risk to aquatic and soil organisms PEC gw: leaching potential to groundwater
IM 1-5 ⁴⁾	197.66		Soil: 20 % Water/sediment: 0%	PEC sw/sed: potential risk to aquatic and soil organisms PEC gw: leaching potential to groundwater PECs
IB 1-1 ⁵⁾	204.23		Soil: 0 % Water/sediment: 35 %	PEC sw/sed: potential risk to aquatic and soil organisms

1) 6-Chloronicotinic acid

2) (E)-N'-Carbamoyl-N-[(6-chloro-3-pyridyl)methyl]N-methylacetamidine

3) 1-(6-Chloro-3-pyridyl)-N-methylmethanamine

4) N-[(6-Chloro-3-pyridyl)methyl]-N-methylacetamidine

5) (E)-N'-Cyano-N-[(3-oxo-2-azabicyclo[2.2.0]hex-5-en-6-yl)methyl]-N-methylacetamidine

zRMS Comments:	Calculations of PECs for active substance metabolites are required if maximum occurrence is over 10%.
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8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

Studies on the aerobic degradation in soil have previously been evaluated within an EU peer review process. The relevant endpoints are provided in EFSA Journal 2016;14(11):4610.

8.3.1.1 Acetamiprid and its metabolites

Table 8.3-1: Summary of aerobic degradation rates for Acetamiprid - laboratory studies

Ref. EFSA Journal 2016;14(11):4610 **Modelling endpoints**

Parent Soil type	Dark aerobic conditions						St. (X ²)	Method of calculation
	X ^a	pH ^a	t. °C / % MWHC	DT ₅₀ /DT ₉₀ (d)	DT ₅₀ (d) 20 °C pF2/10kPa ^b			
Collombey loamy sand, Morgenroth, 1997		7.6	20/50% pF2.5	1.4 / 4.7	1.2		7.7	SFO
Clay loam Burr, 1997		7.4	20/45% MWHC	4.7 / 15.8	4.7		11.8	SFO
Sandy loam, Burr 1997		5.6	20/45% MWHC	2.5 / 8.3	2.5		8.8	SFO
Silty Clay loam Burr, 1997		7.9- 8.5	20/45% MWHC	0.8 / 2.8	0.8		9.5	SFO
Sandy loam Simmonds 2002		8.0	20/45% MWHC	1.1 / 3.7	1.1		9.9	SFO
Clay Simmonds 2002		7.7	20/45% MWHC	1.1 / 3.8	1.1		9.7	SFO
Clay loam Simmonds 2002		7.9	20/45% MWHC	1 / 3.2	1		8.6	SFO
Geometric mean (if not pH dependent)					1.45			
pH dependence, <i>No</i>								

^a) Measured in water

^b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Table 8.3-2: Summary of aerobic degradation rates for IM-1-2 - laboratory studies

Ref. EFSA Journal 2016;14(11):4610 **Modelling endpoints**

IM-1-2		Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was acetamiprid						
Soil type	X^a	pH^a	t. °C / % MWHC	DT₅₀/ DT₉₀ (d)	f. f. k_f / k_{dp}	DT₅₀ (d) 20 °C pF2/10kPa^b	St. (X²)	Method of calculation
Sandy loam Simmonds 2002		8.0	20/45% MWHC	1.6 / 5.3	0.97	1.6	12.3	SFO
Clay Simmonds 2002		7.7	20/45% MWHC	1.9 / 6.3	0.68	1.9	13.0	SFO
Clay loam Simmonds 2002		7.9	20/45% MWHC	1.6 / 5.3	0.66	1.6	12.3	SFO
Geometric mean (if not pH dependent)						1.7		
Arithmetic mean					0.77			
pH dependence, <i>No</i>								

^a) Measured in water

^b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Table 8.3-3: Summary of aerobic degradation rates for IM-1-4 - laboratory studies

Ref. EFSA Journal 2016;14(11):4610 **Modelling endpoints**

IM-1-4		Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was IM-1-2						
Soil type	X^a	pH^a	t. °C / % MWHC	DT₅₀/ DT₉₀ (d)	f. f. k_f / k_{dp}	DT₅₀ (d) 20 °C pF2/10kPa^b	St. (X²)	Method of calculation
Collombey loamy sand, Morgenroth, 1997		7.6	20/50% pF2.5	46.2 / 154	0.56	40.0	22.8	SFO
Clay loam Burr, 1997		7.4	20/45% MWHC	169 / 560	0.61	169	10.5	SFO
Sandy loam, Burr 1997		5.6	20/45% MWHC	166 / 552.8	0.75	166	6.7	SFO
Silty Clay loam Burr, 1997		7.9-8.5	20/45% MWHC	3.7 / 12.3	1	3.7	9.1	SFO
Sandy loam Simmonds 2002		8.0	20/45% MWHC	4.8 / 16.1	0.44	4.8	22.3	SFO
Clay Simmonds 2002		7.7	20/45% MWHC	2.3 / 7.8	0.97	2.3	18.1	SFO
Clay loam Simmonds 2002		7.9	20/45% MWHC	3 / 10	0.71	3.0	14.9	SFO
Geometric mean (if not pH dependent)						14.6		
Arithmetic mean					0.72			
pH dependence, <i>No</i>								

^a) Measured in water

^b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Table 8.3-4: Summary of aerobic degradation rates for IC-0 - laboratory studies

Ref. EFSA Journal 2016;14(11):4610 **Modelling endpoints**

IC-0		Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was IM-1-4						
Soil type	X ^a	pH ^{a)}	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _f / k _{dp}	DT ₅₀ (d) 20 °C pF2/10kPa _{b)}	St. (X ²)	Method of calculation
Silty Clay loam Burr, 1997		7.9-8.5	20/45% MWHC	3.6 / 11.8	0.3	3.6	32.6	SFO
Sandy loam Simmonds 2002		8.0	20/45% MWHC	1.4 / 4.6	1	1.4	5.1	SFO
Clay Simmonds 2002		7.7	20/45% MWHC	2.7 / 8.9	0.39	2.7	11.6	SFO
Clay loam Simmonds 2002		7.9	20/45% MWHC	1.8 / 6.0	1	1.8	11.9	SFO
Sandy loam Lowden, 1997		6.7	20/45% MWHC	3.1 / 10.1	-*	3.1	10	SFO
Silty Clay loam Lowden, 1997		7.8	20/45% MWHC	2.4 / 8.0	-*	2.4	9.1	SFO
Clay loam Lowden, 1997		7.2	20/45% MWHC	5.6 / 18.5	-*	5.6	9.8	SFO
Geometric mean (if not pH dependent)						2.7		
Arithmetic mean					0.67			
pH dependence, <i>No</i>								

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Table 8.3-5: Summary of aerobic degradation rates for IM-1 -5- laboratory studies

Ref. EFSA Journal 2016;14(11):4610 **Modelling endpoints**

IM-1-5		Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was acetamiprid						
Soil type	X ^a	pH ^{a)}	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _f / k _{dp}	DT ₅₀ (d) 20 °C pF2/10kPa _{b)}	St. (X ²)	Method of calculation
Silty Clay loam Burr, 1997		7.9-8.5	20/45% MWHC	319 / 1059	0.21	319	5.1	SFO
Sandy loam Simmonds 2002		8.0	20/45% MWHC	-	0.16 ^{c)}	1000 ^{d)}	-	SFO
Clay Simmonds 2002		7.7	20/45% MWHC	-	0.12 ^{c)}	1000 ^{d)}	-	SFO
Clay loam Simmonds 2002		7.9	20/45% MWHC	486 / 1614	0.12	486	10.3	SFO
Loam (France) Jewkes 2014		7.5	78.4% pF2 moisture	663/2203	-	559	4.7	SFO
Loam (Hungary) Jewkes 2014		7.8	60.7% pF2 moisture	420/1395	-	296	3.5	SFO
Sandy Clay Loam Jewkes 2014		7.6	66.4% pF2 moisture	378/1254	-	284	2.8	SFO
Geometric mean (if not pH dependent)						495		
Arithmetic mean					0.15			
pH dependence, <i>No</i>								

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^{c)} formation fraction based on maximum fraction of occurrence (persistent metabolite)

^{d)} default DT50 value used as no decline of IM-1-5 was observed for this soil

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Ref. EFSA Journal 2016;14(11):4610

Parent	Dark anaerobic conditions						
Soil type	X ¹¹	pHa)	t. oC / % MWHC	DT50 / DT90 (d)	DT50 (d) 20 °Cb)	St. (χ2)	Method of calculation
Loam		7.4	20 / 100% MWHC	69.0 / 410.6		4.7	FOMC α:1.591 β:126.319

a) Measured in water

b) Normalised using a Q10 of 2.58

8.4 Field studies (KCP 9.1.1.2)

Soil type	Location	pH	DT50 [d]	DT90 [d]	X ²	Method of calculation
Clay loam	Italy	8.9 ¹⁾	0.4	19.8	14.1	DFOP
Sandy loam	United Kingdom	5.9 ¹⁾	3.7	22.7	19.5	FOMC
Silty clay loam	France	8.7 ¹⁾	9.6	31.3	16.4	SFO
Sandy loam	Spain	7.0 ¹⁾	0.7	11.2	11.4	FOMC
Loam	Spain	7.45 ²⁾	12.96	43.06	28.1	SFO
Loam	Southern France	7.36 ²⁾	2.26	7.52	13.0	SFO
Loam	Northern France	7.49 ²⁾	2.24	7.43	12.1	SFO
Loam	Hungary	8.06 ²⁾	2.14	15.32	25.9	FOMC

1) measured in 1M KCl

2) measured in 0.01 M CaCl

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

Studies on field dissipation rates with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.4.1.1 Acetmiprid and its metabolites

Triggering endpoints

Table 8.4-1: Summary of aerobic degradation rates for acetamiprid - field studies

Ref. EFSA Journal 2016;14(11):4610

Soil type	Location	pH	DT50 [d]	DT90 [d]	X ²	Method of calculation
Clay loam	Italy	8.9 ¹⁾	0.4	19.8	14.1	DFOP
Sandy loam	United Kingdom	5.9 ¹⁾	3.7	22.7	19.5	FOMC
Silty clay loam	France	8.7 ¹⁾	9.6	31.3	16.4	SFO
Sandy loam	Spain	7.0 ¹⁾	0.7	11.2	11.4	FOMC
Loam	Spain	7.45 ²⁾	12.96	43.06	28.1	SFO
Loam	Southern France	7.36 ²⁾	2.26	7.52	13.0	SFO
Loam	Northern France	7.49 ²⁾	2.24	7.43	12.1	SFO
Loam	Hungary	8.06 ²⁾	2.14	15.32	25.9	FOMC

- 1) measured in 1M KCl
 2) measured in 0.01 M CaCl

Field study, metabolite maximum occurrence

Metabolite formation	Aerobic conditions, metabolite max. formation proportion of maximum measured parent.						
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X ¹⁰	pH	Depth (cm)	IM-1-4	IM-1-2	IM-1-5
Clay loam Wicks 1999	Italy		8.9 ^{a)}	0 – 10	50% after 28d	39% after 4d	Not analysed
Sandy loam Wicks 1999	United Kingdom		5.9 ^{a)}	0 – 10	50% after 30d	< 3.9% after 2-7d	Not analysed
Silty clay loam Wicks 1999	France		8.7 ^{a)}	0 – 10	73% after 28d	18% after 2d	Not analysed
Sandy loam Wicks 1999	Spain		7 ^{a)}	0 – 10	55% after 31d	9% after 2d	Not analysed
Loam Kellner 2012a	Spain		7.45 ^{b)}	0 - 10	Not analysed	Not analysed	60% after 28d
Loam Kellner 2012b	Southern France		7.36 ^{b)}	0 – 10	Not analysed	Not analysed	25% after 29d
Loam Kellner 2012c	Northern France		7.49 ^{b)}	0 – 10	Not analysed	Not analysed	45% after 7d
Loam Finger 2013	Hungary		8.06 ^{b)}	0 - 10	Not analysed	Not analysed	24% after 169d

^{a)} Measured in 1 M KCl

^{b)} Measured in 0.01 M CaCl

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Studies on soil accumulation with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. These studies have previously been evaluated within an EU peer review process. The relevant endpoints are provided in EFSA Journal 2016;14(11):4610.

8.5.1 Acetamiprid and its metabolites

Table 8.5-1: Summary of soil adsorption/desorption for acetamiprid

Ref. EFSA Journal 2016;14(11):4610

Parent								
Soil Type		OC %	Soil pH ^{a)}	K _d (mL/g)	K _{doc} (mL/g)	K _F (mL/g)	K _{Foc} (mL/g)	1/n
I	Sand	0.43	5.7			0.60	138.39	0.842
II	Loamy sand	1.04	7.6			1.35	129.98	0.825
III	Sandy loam	1.57	7.1			1.12	71.09	0.893
IV	Silt loam	1.39	7.7			1.69	121.81	0.835
V	Silt loam	4.39	7.1			3.13	71.38	0.907
Arithmetic mean (if not pH dependent)							106.5	0.860
pH dependence, No								

^{a)} Measured in unknown medium

Table 8.5-2: Summary of soil adsorption/desorption for IM 1-2

Ref. EFSA Journal 2016;14(11):4610

IM-1-2							
Soil Type	OC %	Soil pH ^{a)}	K _d (mL/g)	K _{doc} (mL/g)	K _F (mL/g)	K _{Foc} (mL/g)	1/n
Clay Loam 02/06	2.3	7.6			0.45	19	0.886
Sandy Loam 02/16	1.3	7.5			0.27	21	0.856
Clay Loam 01/24	3.8	6.1			3.60	95	0.927
Sandy Loam 02/18	0.2	7.4			0.16	80	0.944
Arithmetic mean (if not pH dependent)						54	0.903
pH dependence, No							

^{a)} Measured in CaCl₂ medium

Table 8.5-3: Summary of soil adsorption/desorption for IM 1-4

IM-1-4							
Soil Type	OC %	Soil pH ^{a)}	K _d (mL/g)	K _{doc} (mL/g)	K _F (mL/g)	K _{Foc} (mL/g)	1/n
I Sand*	0.43	5.7			2.1	488	0.597
II Loamy sand	1	7.6			2.24	223	0.714
III Sandy loam	1.57	7.1			2.16	138	0.712
IV Silt loam	1.39	7.7			2.67	192	0.816
V Silt loam	4.39	7.1			5.79	132	0.813
Arithmetic mean (if not pH dependent)						171	0.764
pH dependence, No							

^{a)} Measured in unknown medium

* Sand soil was excluded during the previous evaluation due to low 1/n value

Table 8.5-4: Summary of soil adsorption/desorption for IC-0

Ref. EFSA Journal 2016;14(11):4610

IC-0							
Soil Type	OC %	Soil pH ^{a)}	K _d (mL/g)	K _{doc} (mL/g)	K _F (mL/g)	K _{Foc} (mL/g)	1/n
I Sand	0.43	5.7			0.643	258	0.967
II Loamy sand	2.54	7.6			1.027	70	1.007
III Sandy loam	0.76	7.1			0.569	129	0.971
IV Silt loam	2.05	7.7			0.833	70	0.894
V Silt loam	1.41	7.1			0.69	84	0.926
Pond sediment*	4.32				2.121	85	0.867
Arithmetic mean (if not pH dependent)						122	0.953
pH dependence, No							

^{a)} Measured in unknown medium

* Sediment excluded during the previous evaluation

Table 8.5-5: Summary of soil adsorption/desorption for IM-1-5

Ref. EFSA Journal 2016;14(11):4610

IM-1-5							
Soil Type	OC %	Soil pH ^{a)}	K _d (mL/g)	K _{doc} (mL/g)	K _F (mL/g)	K _{Foc} (mL/g)	1/n
Spain (Canals)	3.3	7.6			5.70	173	0.8788
S France (Meauzac)	1.14	7.6			4.89	429	0.9030
Hungary	2.03	7.8			7.58	374	0.8454
N France (Meistratzheim)	2.04	8.3			6.60	324	0.9176
Arithmetic mean (if not pH dependent)						325	0.886
pH dependence, No							

^{a)} Measured in CaCl₂

8.5.2 Column leaching (KCP 9.1.2.1)

Ref. EFSA Journal 2016;14(11):4610

Column leaching

no data submitted and no data required
Leachate: 0.3-1.3 % total residues/radioactivity in leachate
0.06 % active substance, 0.84 % IM-1-4
88.9- 93.7 % total residues/radioactivity retained in the four upper soil layers

8.5.3 Lysimeter studies (KCP 9.1.2.2)

No data submitted and no data required

8.5.4 Field leaching studies (KCP 9.1.2.3)

No data submitted and no data required

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

These studies have previously been evaluated within an EU peer review process. The relevant endpoints are provided in EFSA Journal 2016;14(11):4610.

8.6.1 Acetamiprid and its metabolites

Table 8.6-1: Summary of degradation in water/sediment of acetamiprid

Ref. EFSA Journal 2016;14(11):4610

Parent	Distribution (<i>max in water 101.42% after 0 d. Max. sed 39.05 % after 14 d</i>)									
Water / sediment system	pH water phase	pH sed ^{a)}	t. °C	DT ₅₀ /DT ₉₀ whole sys.	St. (X ²)	DT ₅₀ /DT ₉₀ water	St. (X ²)	DT ₅₀ /DT ₉₀ sed	St. (X ²)	Method of calculation
Manningtree	6.37/5.9	n.r.	20	23.1	7.6	4.9	8.3	n.c.		SFO/DFOP
Ongar	7.58/7.3	n.r.	20	31.6	6.7	6.1	5.9	n.c.		SFO/DFOP
Geometric mean at 20°C ^{b)}				27						

^{a)} Measured in unknown medium

^{b)} Normalised using a Q10 of 2.58

Table 8.6-2: Summary of observed metabolites

Ref. EFSA Journal 2016;14(11):4610

Metabolite IM-1-2	Distribution (max in water 10.96 % after 7 d. Max. sed. 3.93 % after 14 d). Max in total system 13.4 % after 7 days No acceptable fit possible
Metabolite IM-1-4	Distribution (max in water 12.33 % after 30 d. Max. sed. 30.71 % after 30 d). Max in total system 43 % after 30 days; Max 81.5% in aerobic mineralisation study No acceptable fit possible
Metabolite IC-0	Distribution (max in water 26.15 % after 62 d. Max. sed. 5.61 % after 100 d). Max in total system 29.5 % after 62 days No acceptable fit possible
Metabolite IB-1-1	35% AR (30 d)

Evaluator's Comments:	Calculations of PEC _s for active substances, their metabolites and formulation were accepted.							
	The endpoints used for PECs assessment were agreed at the EU level.							
	The risk envelope was used and accepted.							
	The PECs for formulation used in orchards – apple, pear, quince, cherry, peach, plum, hazelnut, walnut, common osier, purple willow was added (application rate of 125 mL/ha should be used).							
	The following PECs are presented in the tables below (max values are in bold):							
	PECs [mg/kg soil]							
	Crop	Winter and spring OSR*	Maize	Winter and spring cereals	Tomato	Pumpkin	Orchards	Forest and ornamental nurseries plants*
	Application rate g a.s./ha	60	60	40	60	60	2 x 25	50
	Acetamiprid	0.0160	0.0200	0.0107	0.0240	0.0320	0.0225	0.0267
IC-0	0.0013	0.0016	0.0009	0.0019	0.0026	0.0015	0.0021	
IM-1-2	0.0095	0.0119	0.0063	0.00143	0.0190	0.0086	0.0158	
IM-I-4	0.0081 0.0085**	0.0101 0.0107**	0.0054 0.0057**	0.0122 0.0128**	0.0162 0.0171**	0.0133 0.0162**	0.0135 0.0164**	
IM-I-5	0.0029 0.0053**	0.0036 0.0067**	0.0019 0.0035**	0.0043 0.0080**	0.0057 0.0107**	0.0047 0.0209**	0.0047 0.0212**	
Formulation	0.0939	0.1173	0.0624	0.1408	0.1877	0.0781	0.1563	
* - risk envelope ** PECs accum								
These values will be used in further risk assessment.								

There are no deviations from the EU agreed endpoints.

For determination of the predicted environmental concentrations of the active substance and relevant metabolites in soil the following guideline was used: “Soil persistence models and EU registration” (The final report of the work of the Soil Modelling Work group of FOCUS). In case of IM-1-5 metabolite it was assessed that it occurs in calcareous soils and those are not typical in Poland.

The PEC of acetamiprid in soil have been assessed with the ESCAPE model (version 2.0), the focus groundwater interception values taken from FOCUS guidance (Generic Guidance for Tier 1 FOCUS

Ground Water Assessments (version: 2.2, May 2014) and the maximum DT₅₀ values established in the EU peer review for active substance. It has to be point out that during the soil degradation studies of acetamiprid, metabolites has been found. Therefore, the predicted environmental concentrations in soil for metabolites were also calculated.

Table 8.7-1 and 8.7-2 provide the input parameters used in the PEC_{soil} calculations.

Table 8.7-1: Input parameters related to application for PEC_{soil} calculations

Use No.	1-94							
Crop	Winter oilseed rape (<i>Flax, common hemp, soybean, sunflower, opium poppy</i>)	Maize	Summer oilseed rape	Winter & spring cereals	Tomato	Pumpkin	Orchards – <i>apple, pear, quince, cherry, peach, plum, hazelnut, walnut, tobacco, common osier, purple willow</i>	Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations
Application rate (g as/ha)	60	60	60	40	60	60	2x25	50
Number of applications/interval	1/n.a	1/n.a	1/n.a	1/n.a	1/n.a	1/n.a	2/7	1/n.a
Crop interception (%)	80	75	80	80	70	60	60	60
BBCH	30	51	20	30	20	21	11	11
Tillage depth	5 cm for permanent crops 20 cm for annual crops							

Table 8.7-2: Input parameter for active substance and relevant metabolites for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Acetamiprid	222.68	-	12.96	EFSA Journal 2016;14(11):4610
Metabolite IC-0	157.55	11.3	5.6	EFSA Journal 2016;14(11):4610
Metabolite IM-1-2	240.69	55	1.9	EFSA Journal 2016;14(11):4610
Metabolite IM-1-4	156.62	72	146	EFSA Journal 2016;14(11):4610
Metabolite IM-1-5	197.67	20 (only in calcareous soils)	1000	EFSA Journal 2016;14(11):4610

Winter oilseed rape and summer oilseed rape

Acetamiprid and its metabolites

Table 8.7-3: PEC_{soil} for acetamiprid on winter oilseed rape and summer oilseed rape

PEC _{soil} (mg/kg)		Winter oilseed rape; BBCH 30; CI 80%; application rate 60g Summer oilseed rape; BBCH 20; CI 80%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0160	-	-	-
Short term	24h	0.0152	0.0156		
	2d	0.0144	0.0152		
	4d	0.0129	0.0144		
Long term	7d	0.0110	0.0133		
	14d	0.0076	0.0113		
	21d	0.0052	0.0096		
	28d	0.0036	0.0083		
	42d	0.0017	0.0064		
	50d	0.0011	0.0056		
	100d	0.0001	0.0030		
Plateau concentration (20 cm) after year 10		Not required since DT ₅₀ in soil is <100d			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Not required			

PEC_{soil} of metabolites

Table 8.7-4: PEC_{soil} for IC-0 on winter oilseed rape and summer oilseed rape

PEC _{soil} (mg/kg)		Winter oilseed rape; BBCH 30; CI 80%; application rate 60g Summer oilseed rape; BBCH 20; CI 80%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0013	-	-	
Short term	24h	0.0011	0.0012		
	2d	0.0010	0.0011		
	4d	0.0008	0.0010		
Long term	7d	0.0005	0.0009		
	14d	0.0002	0.0006		
	21d	0.0001	0.0005		
	28d	<0.0001	0.0004		
	42d	<0.0001	0.0002		
	50d	<0.0001	0.0002		
	100d	<0.0001	0.0001		

Plateau concentration (20 cm) after year 10	Not required since DT ₅₀ in soil is <100d
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})	Not required

Table 8.7-5: PEC_{soil} for IM-1-2 on winter oilseed rape and summer oilseed rape

PEC _{soil} (mg/kg)		Winter oilseed rape; BBCH 30; CI 80%; application rate 60g Summer oilseed rape; BBCH 20; CI 80%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0095	-	-	-
Short term	24h	0.0066	0.0081		
	2d	0.0046	0.0068		
	4d	0.0022	0.0051		
Long term	7d	0.0007	0.0035		
	14d	0.0001	0.0019		
	21d	<0.0001	0.0013		
	28d	<0.0001	0.0009		
	42d	<0.0001	0.0006		
	50d	<0.0001	0.0005		
	100d	<0.0001	0.0003		
Plateau concentration (20 cm) after year 10		Not required since DT ₅₀ in soil is <100d			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Not required			

Table 8.7-6: PEC_{soil} for IM-1-4 on winter oilseed rape and summer oilseed rape

PEC _{soil} (mg/kg)		Winter oilseed rape; BBCH 30; CI 80%; application rate 60g Summer oilseed rape; BBCH 20; CI 80%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0081	-	-	-
Short term	24h	0.0081	0.0081		
	2d	0.0080	0.0081		
	4d	0.0080	0.0080		
Long term	7d	0.0078	0.0080		
	14d	0.0076	0.0078		
	21d	0.0073	0.0077		
	28d	0.0071	0.0076		
	42d	0.0066	0.0073		
	50d	0.0064	0.0072		
	100d	0.0050	0.0065		

Plateau concentration (20 cm) after year 10	0.0004	-		-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})	0.0085			

Table 8.7-7: PEC_{soil} for IM-1-5 on winter oilseed rape and summer oilseed rape

PEC _{soil} (mg/kg)		Winter oilseed rape; BBCH 30; CI 80%; application rate 60g Summer oilseed rape; BBCH 20; CI 80%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0029	-		-
Short term	24h	0.0029	0.0029		
	2d	0.0028	0.0029		
	4d	0.0028	0.0028		
Long term	7d	0.0028	0.0028		
	14d	0.0028	0.0028		
	21d	0.0028	0.0028		
	28d	0.0028	0.0028		
	42d	0.0028	0.0028		
	50d	0.0028	0.0028		
	100d	0.0027	0.0028		
Plateau concentration (20 cm) after year 10		0.0025	-		
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.0053			

Maize – 60 g ai/ha

Table 8.7-8: PEC_{soil} for acetamiprid on maize

PEC _{soil} (mg/kg)		Maize; BBCH 51; CI 75%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0200	-	-	-
Short term	24h	0.0190	0.0195		
	2d	0.0180	0.0190		
	4d	0.0161	0.0180		
Long term	7d	0.0138	0.0167		
	14d	0.0095	0.0141		
	21d	0.0065	0.0120		
	28d	0.0045	0.0104		
	42d	0.0021	0.0080		
	50d	0.0014	0.0070		
	100d	0.0001	0.0037		

Plateau concentration (20 cm) after year 10	Not required since DT ₅₀ in soil is <100d
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})	Not required

PEC_{soil} of metabolites

Table 8.7-9: PEC_{soil} for IC-0 on maize

PEC _{soil} (mg/kg)		Maize; BBCH 51; CI 75%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0016	-	-	-
Short term	24h	0.0014	0.0015		
	2d	0.0012	0.0014		
	4d	0.0010	0.0013		
Long term	7d	0.0007	0.0011		
	14d	0.0003	0.0008		
	21d	0.0001	0.0006		
	28d	0.0001	0.0004		
	42d	<0.0001	0.0003		
	50d	<0.0001	0.0003		
	100d	<0.0001	0.0001		
Plateau concentration (20 cm) after year 10		Not required since DT ₅₀ in soil is <100d			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Not required			

Table 8.7-10: PEC_{soil} for IM-1-2 on maize

PEC _{soil} (mg/kg)		Maize; BBCH 51; CI 75%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0119	-	-	-
Short term	24h	0.0083	0.0101		
	2d	0.0057	0.0085		
	4d	0.0028	0.0063		
Long term	7d	0.0009	0.0043		
	14d	0.0001	0.0023		
	21d	<0.0001	0.0016		
	28d	<0.0001	0.0012		
	42d	<0.0001	0.0008		
	50d	<0.0001	0.0007		
	100d	<0.0001	0.0003		
Plateau concentration (20 cm)		Not required since DT ₅₀ in soil is <100d			

after year 10	
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})	Not required

Table 8.7-11: PEC_{soil} for IM-1-4 on maize

PEC _{soil} (mg/kg)		Maize; BBCH 51; CI 75%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0101	-	-	-
Short term	24h	0.0101	0.0101		
	2d	0.0100	0.0101		
	4d	0.0099	0.0100		
Long term	7d	0.0098	0.0100		
	14d	0.0095	0.0098		
	21d	0.0092	0.0096		
	28d	0.0089	0.0095		
	42d	0.0083	0.0092		
	50d	0.0080	0.0090		
	100d	0.0063	0.0081		
Plateau concentration (20 cm) after year 10		0.0005			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.0107			

Table 8.7-12: PEC_{soil} for IM-1-5 on maize

PEC _{soil} (mg/kg)		Maize; BBCH 51; CI 75%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0036	-	-	-
Short term	24h	0.0036	0.0036		
	2d	0.0036	0.0036		
	4d	0.0036	0.0036		
Long term	7d	0.0035	0.0036		
	14d	0.0035	0.0035		
	21d	0.0035	0.0035		
	28d	0.0035	0.0035		
	42d	0.0035	0.0035		
	50d	0.0034	0.0035		
	100d	0.0033	0.0034		
Plateau concentration (20 cm) after year 10		0.0031	-		

PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})	0.0067			
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Orchards (1x50g) – forest and ornamental nurseries plants, restockings, afforestations and forest trees’ seed plantations; Christmas trees grown on plantations

Table 8.7-13: PEC_{soil} for acetamiprid for the intended use in orchards

PEC _{soil} (mg/kg)		Orchards; BBCH 11; CI 60%; application rate 50g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0267	-	-	-
Short term	24h	0.0253	0.0260		
	2d	0.0240	0.0253		
	4d	0.0215	0.0240		
Long term	7d	0.0183	0.0222		
	14d	0.0126	0.0188		
	21d	0.0087	0.0160		
	28d	0.0060	0.0138		
	42d	0.0028	0.0106		
	50d	0.0018	0.0093		
	100d	0.0001	0.0050		
Plateau concentration (5 cm) after year 10		Not required since DT ₅₀ in soil is <100d			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Not required			

PEC_{soil} of metabolites

Table 8.7-14: PEC_{soil} for IC-0 for the intended use in orchards

PEC _{soil} (mg/kg)		Orchards; BBCH 11; CI 60%; application rate 50g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0021	-	-	-
Short term	24h	0.0019	0.0020		
	2d	0.0017	0.0019		
	4d	0.0013	0.0017		
Long term	7d	0.0009	0.0014		
	14d	0.0004	0.0010		
	21d	0.0002	0.0008		
	28d	0.0001	0.0006		
	42d	<0.0001	0.0004		
	50d	<0.0001	0.0004		
	100d	<0.0001	0.0002		

Plateau concentration (5 cm) after year 10	Not required since DT ₅₀ in soil is <100d
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})	Not required

Table 8.7-15: PEC_{soil} for IM-1-2 for the intended use in orchards

PEC _{soil} (mg/kg)		Orchards; BBCH 11; CI 60%; application rate 50g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0158	-	-	-
Short term	24h	0.0110	0.0134		
	2d	0.0076	0.0114		
	4d	0.0037	0.0084		
Long term	7d	0.0012	0.0058		
	14d	0.0001	0.0031		
	21d	<0.0001	0.0021		
	28d	<0.0001	0.0016		
	42d	<0.0001	0.0010		
	50d	<0.0001	0.0009		
	100d	<0.0001	0.0004		
Plateau concentration (5 cm) after year 10		Not required since DT ₅₀ in soil is <100d			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Not required			

Table 8.7-16: PEC_{soil} for IM-1-4 for the intended use in orchards

PEC _{soil} (mg/kg)		Orchards; BBCH 11; CI 60%; application rate 50g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0135	-	-	-
Short term	24h	0.0134	0.0135		
	2d	0.0134	0.0134		
	4d	0.0132	0.0134		
Long term	7d	0.0131	0.0133		
	14d	0.0126	0.0131		
	21d	0.0122	0.0128		
	28d	0.0118	0.0126		
	42d	0.0111	0.0122		
	50d	0.0106	0.0120		
	100d	0.0084	0.0107		
Plateau concentration (5 cm) after year 10		0.0029	-		

PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})	0.0164			
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Table 8.7-17: PEC_{soil} for IM-1-5 for the intended use in orchards

PEC _{soil} (mg/kg)		Orchards; BBCH 11; CI 60%; application rate 50g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0047	-	-	-
Short term	24h	0.0047	0.0047		
	2d	0.0047	0.0047		
	4d	0.0047	0.0047		
Long term	7d	0.0047	0.0047		
	14d	0.0047	0.0047		
	21d	0.0047	0.0047		
	28d	0.0047	0.0047		
	42d	0.0046	0.0047		
	50d	0.0046	0.0047		
	100d	0.0044	0.0046		
Plateau concentration (5 cm) after year 10		0.0165	-		
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.0212			

Orchards (2x 25g) – apple, pear, quince, cherry, peach, plum, hazelnut, walnut, tobacco, common osier and purple willow

Table 8.7-18: PEC_{soil} for acetamiprid for the intended use in orchards

PEC _{soil} (mg/kg)		Orchards; BBCH 11; CI 60%; application rate 2x25g; interval 7d			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0133	-	0.0225	-
Short term	24h	0.0126	0.0130	0.0213	0.0219
	2d	0.0120	0.0126	0.0202	0.0213
	4d	0.0108	0.0120	0.0182	0.0203
Long term	7d	0.0092	0.0111	0.0155	0.0188
	14d	0.0063	0.0094	0.0106	0.0162
	21d	0.0043	0.0080	0.0073	0.0146
	28d	0.0030	0.0069	0.0050	0.0132
	42d	0.0014	0.0053	0.0024	0.0105
	50d	0.0009	0.0046	0.0016	0.0093
	100d	0.0001	0.0025	0.0001	0.0050
Plateau concentration (5 cm)		Not required since DT ₅₀ in soil is <100d			

after year 10	
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})	Not required

PEC_{soil} of metabolites

Table 8.7-19: PEC_{soil} for IC-0 for the intended use in orchards

PEC _{soil} (mg/kg)		Orchards; BBCH 11; CI 60%; application rate 2x25g; interval 7d			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0011	-	0.0015	-
Short term	24h	0.0009	0.0010	0.0013	0.0014
	2d	0.0008	0.0009	0.0012	0.0013
	4d	0.0007	0.0008	0.0009	0.0012
Long term	7d	0.0004	0.0007	0.0006	0.0011
	14d	0.0002	0.0005	0.0003	0.0009
	21d	0.0001	0.0004	0.0001	0.0007
	28d	<0.0001	0.0003	<0.0001	0.0006
	42d	<0.0001	0.0002	<0.0001	0.0004
	50d	<0.0001	0.0002	<0.0001	0.0004
	100d	<0.0001	0.0001	<0.0001	0.0002
Plateau concentration (5 cm) after year 10		Not required since DT ₅₀ in soil is <100d			
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})		Not required			

Table 8.7-20: PEC_{soil} for IM-1-2 for the intended use in orchards

PEC _{soil} (mg/kg)		Orchards; BBCH 11; CI 60%; application rate 2x25g; interval 7d			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0079	-	0.0086	-
Short term	24h	0.0055	0.0167	0.0059	0.0073
	2d	0.0038	0.0057	0.0041	0.0061
	4d	0.0018	0.0042	0.0020	0.0051
Long term	7d	0.0006	0.0029	0.0007	0.0037
	14d	<0.0001	0.0016	0.0001	0.0033
	21d	<0.0001	0.0010	<0.0001	0.0023
	28d	<0.0001	0.0008	<0.0001	0.0017
	42d	<0.0001	0.0005	<0.0001	0.0011
	50d	<0.0001	0.0004	<0.0001	0.0010
	100d	<0.0001	0.0002	<0.0001	0.0005
Plateau concentration (5 cm) after year 10		Not required since DT ₅₀ in soil is <100d			

PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})	Not required
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Table 8.7-21: PEC_{soil} for IM-1-4 for the intended use in orchards

PEC _{soil} (mg/kg)		Orchards; BBCH 11; CI 60%; application rate 2x25g; interval 7d			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0068	-	0.0133	-
Short term	24h	0.0067	0.0068	0.0133	0.0133
	2d	0.0067	0.0067	0.0132	0.0133
	4d	0.0066	0.0067	0.0131	0.0132
Long term	7d	0.0066	0.0067	0.0129	0.0131
	14d	0.0063	0.0066	0.0125	0.0129
	21d	0.0061	0.0064	0.0121	0.0127
	28d	0.0059	0.0063	0.0117	0.0125
	42d	0.0055	0.0061	0.0109	0.0121
	50d	0.0053	0.0060	0.0105	0.0119
	100d	0.0042	0.0054	0.0083	0.0106
Plateau concentration (5 cm) after year 10		0.0015	-	0.0029	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.0082	-	0.0162	-

Table 8.7-22: PEC_{soil} for IM-1-5 for the intended use in orchards

PEC _{soil} (mg/kg)		Orchards; BBCH 11; CI 60%; application rate 2x25g; interval 7d			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0023	-	0.0047	-
Short term	24h	0.0023	0.0023	0.0047	0.0047
	2d	0.0023	0.0023	0.0047	0.0047
	4d	0.0023	0.0023	0.0047	0.0047
Long term	7d	0.0023	0.0023	0.0047	0.0047
	14d	0.0023	0.0023	0.0046	0.0047
	21d	0.0023	0.0023	0.0046	0.0046
	28d	0.0023	0.0023	0.0046	0.0046
	42d	0.0023	0.0023	0.0045	0.0046
	50d	0.0023	0.0023	0.0045	0.0046
	100d	0.0022	0.0023	0.0044	0.0045
Plateau concentration (5 cm) after year 10		0.0082	-	0.0163	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.0105	-	0.0209	-

Winter & spring cereals

Table 8.7-23: PEC_{soil} for acetamiprid on winter & spring cereals

PEC _{soil} (mg/kg)		Winter & spring cereals; BBCH 30; IC 80%; application rate 40g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0107	-	-	-
Short term	24h	0.0101	0.0104		
	2d	0.0096	0.0101		
	4d	0.0086	0.0096		
Long term	7d	0.0073	0.0089		
	14d	0.0050	0.0075		
	21d	0.0035	0.0064		
	28d	0.0024	0.0055		
	42d	0.0011	0.0042		
	50d	0.0007	0.0037		
	100d	0.0001	0.0020		
Plateau concentration (20 cm) after year 10		Not required since DT ₅₀ in soil is <100d			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Not required			

PEC_{soil} of metabolites

Table 8.7-24: PEC_{soil} for IC-0 on winter & spring cereals

PEC _{soil} (mg/kg)		Winter & spring cereals; BBCH 30; IC 80%; application rate 40g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0009	-	-	-
Short term	24h	0.0008	0.0008		
	2d	0.0007	0.0008		
	4d	0.0005	0.0007		
Long term	7d	0.0004	0.0006		
	14d	0.0002	0.0004		
	21d	0.0001	0.0003		
	28d	<0.0001	0.0002		
	42d	<0.0001	0.0002		
	50d	<0.0001	0.0001		
	100d	<0.0001	0.0001		
Plateau concentration (20 cm) after year 10		Not required since DT ₅₀ in soil is <100d			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Not required			

Table 8.7-25: PEC_{soil} for IM-1-2 on winter & spring cereals

PEC _{soil} (mg/kg)		Winter & spring cereals; BBCH 30; IC 80%; application rate 40g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0063	-	-	-
Short term	24h	0.0044	0.0054		
	2d	0.0031	0.0046		
	4d	0.0015	0.0034		
Long term	7d	0.0005	0.0023		
	14d	<0.0001	0.0012		
	21d	<0.0001	0.0008		
	28d	<0.0001	0.0006		
	42d	<0.0001	0.0004		
	50d	<0.0001	0.0004		
	100d	<0.0001	0.0002		
Plateau concentration (20 cm) after year 10		Not required since DT ₅₀ in soil is <100d			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Not required			

Table 8.7-26: PEC_{soil} for IM-1-4 on winter & spring cereals

PEC _{soil} (mg/kg)		Winter & spring cereals; BBCH 30; IC 80%; application rate 40g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0054	-	-	-
Short term	24h	0.0054	0.0054		
	2d	0.0054	0.0054		
	4d	0.0053	0.0054		
Long term	7d	0.0052	0.0053		
	14d	0.0051	0.0052		
	21d	0.0049	0.0052		
	28d	0.0047	0.0051		
	42d	0.0044	0.0049		
	50d	0.0043	0.0048		
	100d	0.0034	0.0043		
Plateau concentration (20 cm) after year 10		0.0003	-		
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.0057			

Table 8.7-27: PEC_{soil} for IM-1-5 on winter & spring cereals

PEC _{soil} (mg/kg)		Winter & spring cereals; BBCH 30; IC 80%; application rate 40g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0019	-	-	-
Short term	24h	0.0019	0.0019		
	2d	0.0019	0.0019		
	4d	0.0019	0.0019		
Long term	7d	0.0019	0.0019		
	14d	0.0019	0.0019		
	21d	0.0019	0.0019		
	28d	0.0019	0.0019		
	42d	0.0018	0.0019		
	50d	0.0018	0.0019		
	100d	0.0018	0.0018		
Plateau concentration (20 cm) after year 10		0.0016	-		
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.0035			

Tomatoes

Table 8.7-28: PEC_{soil} for acetamiprid on tomatoes

PEC_{soil} (mg/kg)		Tomatoes; BBCH 20; IC 70%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0240	-	-	-
Short term	24h	0.0228	0.0234		
	2d	0.0216	0.0228		
	4d	0.0194	0.0216		
Long term	7d	0.0165	0.0200		
	14d	0.0114	0.0169		
	21d	0.0078	0.0144		
	28d	0.0054	0.0124		
	42d	0.0025	0.0096		
	50d	0.0017	0.0084		
	100d	0.0001	0.0045		
Plateau concentration (20 cm) after year 10		Not required since DT_{50} in soil is <100d			
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil\ plateau}$)		Not required			

PEC_{soil} of metabolites

Table 8.7-29: PEC_{soil} for IC-0 on tomatoes

PEC_{soil} (mg/kg)		Tomatoes; BBCH 20; IC 70%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0019	-	-	-
Short term	24h	0.0017	0.0018		
	2d	0.0015	0.0017		
	4d	0.0012	0.0015		
Long term	7d	0.0008	0.0013		
	14d	0.0003	0.0009		
	21d	0.0001	0.0007		
	28d	0.0001	0.0005		
	42d	<0.0001	0.0004		
	50d	<0.0001	0.0003		
	100d	<0.0001	0.0002		
Plateau concentration (20 cm) after year 10		Not required since DT_{50} in soil is <100d			
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil\ plateau}$)		Not required			

Table 8.7-30: PEC_{soil} for IM-1-2 on tomatoes

PEC _{soil} (mg/kg)		Tomatoes; BBCH 20; IC 70%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0143	-	-	-
Short term	24h	0.0099	0.0121		
	2d	0.0069	0.0102		
	4d	0.0033	0.0076		
Long term	7d	0.0011	0.0052		
	14d	0.0001	0.0028		
	21d	<0.0001	0.0019		
	28d	<0.0001	0.0014		
	42d	<0.0001	0.0009		
	50d	<0.0001	0.0008		
	100d	<0.0001	0.0004		
Plateau concentration (20 cm) after year 10		Not required since DT ₅₀ in soil is <100d			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Not required			

Table 8.7-31: PEC_{soil} for IM-1-4 on tomatoes

PEC _{soil} (mg/kg)		Tomatoes; BBCH 20; IC 70%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0122	-	-	-
Short term	24h	0.0121	0.0121		
	2d	0.0120	0.0121		
	4d	0.0119	0.0120		
Long term	7d	0.0118	0.0120		
	14d	0.0114	0.0118		
	21d	0.0110	0.0116		
	28d	0.0106	0.0114		
	42d	0.0100	0.0110		
	50d	0.0096	0.0108		
	100d	0.0076	0.0097		
Plateau concentration (20 cm) after year 10		0.0007	-		
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.0128			

Table 8.7-32: PEC_{soil} for IM-1-5 on tomatoes

PEC _{soil} (mg/kg)		Tomatoes; BBCH 20; IC 70%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0043	-	-	-
Short term	24h	0.0043	0.0043		
	2d	0.0043	0.0043		
	4d	0.0043	0.0043		
Long term	7d	0.0043	0.0043		
	14d	0.0042	0.0043		
	21d	0.0042	0.0042		
	28d	0.0042	0.0042		
	42d	0.0042	0.0042		
	50d	0.0041	0.0042		
	100d	0.0040	0.0041		
Plateau concentration (20 cm) after year 10		0.0037	-		
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.0080			

Pumpkin

Table 8.7-33: PEC_{soil} for acetamiprid on pumpkin

PEC _{soil} (mg/kg)		Pumpkin; BBCH 21; IC 60%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0320	-	-	-
Short term	24h	0.0303	0.0312		
	2d	0.0288	0.0304		
	4d	0.0258	0.0288		
Long term	7d	0.0220	0.0267		
	14d	0.0151	0.0225		
	21d	0.0104	0.0192		
	28d	0.0072	0.0166		
	42d	0.0034	0.0127		
	50d	0.0022	0.0111		
	100d	0.0002	0.0060		
Plateau concentration (20 cm) after year 10		Not required since DT ₅₀ in soil is <100d			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Not required			

PEC_{soil} of metabolites

Table 8.7-34: PEC_{soil} for IC-0 on pumpkin

PEC _{soil} (mg/kg)		Pumpkin; BBCH 21; IC 60%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0026	-	-	-
Short term	24h	0.0023	0.0024		
	2d	0.0020	0.0023		
	4d	0.0016	0.0020		
Long term	7d	0.0011	0.0017		
	14d	0.0005	0.0012		
	21d	0.0002	0.0009		
	28d	0.0001	0.0007		
	42d	<0.0001	0.0005		
	50d	<0.0001	0.0004		
	100d	<0.0001	0.0002		
Plateau concentration (20 cm) after year 10		Not required since DT ₅₀ in soil is <100d			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Not required			

Table 8.7-35: PEC_{soil} for IM-1-2 on pumpkin

PEC _{soil} (mg/kg)		Pumpkin; BBCH 21; IC 60%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0190	-	-	-
Short term	24h	0.0132	0.0161		
	2d	0.0092	0.0137		
	4d	0.0044	0.0101		
Long term	7d	0.0015	0.0070		
	14d	0.0001	0.0037		
	21d	<0.0001	0.0025		
	28d	<0.0001	0.0019		
	42d	<0.0001	0.0013		
	50d	<0.0001	0.0011		
	100d	<0.0001	0.0005		
Plateau concentration (20 cm) after year 10		Not required since DT ₅₀ in soil is <100d			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		Not required			

Table 8.7-36: PEC_{soil} for IM-1-4 on pumpkin

PEC _{soil} (mg/kg)		Pumpkin; BBCH 21; IC 60%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0162	-	-	-
Short term	24h	0.0161	0.0162		
	2d	0.0161	0.0161		
	4d	0.0159	0.0161		
Long term	7d	0.0157	0.0159		
	14d	0.0152	0.0157		
	21d	0.0147	0.0154		
	28d	0.0142	0.0152		
	42d	0.0133	0.0147		
	50d	0.0128	0.0144		
	100d	0.0101	0.0129		
Plateau concentration (20 cm) after year 10		0.0009	-		
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.0171			

Table 8.7-37: PEC_{soil} for IM-1-5 on pumpkin

PEC _{soil} (mg/kg)		Pumpkin; BBCH 21; IC 60%; application rate 60g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0057	-	-	-
Short term	24h	0.0057	0.0057		
	2d	0.0057	0.0057		
	4d	0.0057	0.0057		
Long term	7d	0.0057	0.0057		
	14d	0.0057	0.0057		
	21d	0.0056	0.0057		
	28d	0.0056	0.0057		
	42d	0.0055	0.0056		
	50d	0.0055	0.0056		
	100d	0.0053	0.0055		
Plateau concentration (20 cm) after year 10		0.0050	-		
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.0107			

8.7.2.1 PEC_{soil} of LEPTOSAR 200 SL

Table 8.7-38: PEC_{soil} for LEPTOSAR 200 SL on recommended uses

Active substance/ reparation	Max. application rate (L/ha)	Crop interception (%)	Amount of the product (g/ha)*	PEC _{act} (mg formulation /kg soil)**	Tillage depth (cm)	PEC _{soil,plateau} (mg/kg)	PEC _{accu} = PEC _{act} + PEC _{soil,plateau} (mg/kg)
Winter oilseed rape (Flax, common hemp, soybean, sunflower)	0.3	80	352	0.0939	n/a	Not required	
Maize	0.3	75	352	0.1173	n/a		
Summer oilseed rape	0.3	80	352	0.0939	n/a		
Spring & winter cereals	0.2	80	234	0.0624	n/a		
Pumpkin	0.3	60	352	0.1877	n/a		
Tomato	0.3	70	352	0.1408	n/a		
Orchards – apple, pear, quince, cherry, peach, plum, hazelnut, walnut, tobacco, common osier, purple willow and forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations	0.25	60	293	0.1563	n/a		

* Based on the density of the formulation = 1.172 g/mL

** based on the recommended crop interception, soil density of 1.5 g/cm³ and soil depth of 5 cm

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

Evaluator's Comments:	<p>The submitted PEC_{gw} assessment was accepted.</p> <p>All used endpoints were agreed at the EU level or recalculated. The recommended FOCUS models were used: FOCUS PEARL and FOCUS PELMO.</p> <p>Calculations of PEC_{gw} for active substance and its relevant metabolites at Tier 1 were provided with PUF = 0. At Tier 2, for metabolite IM-1-5 the PUF = 0.5 was used and accepted, as it was agreed at the EU level.</p> <p>The simulations were conducted for applications every year and every other year, if relevant.</p> <p>The geometric mean of K_{foc} values were used in modelling, this approach was accepted. The application dates were accepted.</p> <p>The winter oilseed rape was not accepted as a representative crop for soybean; the bean and peas were used.</p> <p>Additionally, in accordance with national PL requirements the PEC_{gw} assessment was amended with calculations provided for surrogate crops.</p> <p>The correct PEC_{gw} value for active substance and its metabolites IC-0, IM-1-2, IM 1-4 should be: < 0.001, not 0.000000 (PEARL) and 0.000 (PELMO) presented in Tables 8.8-5 and 8.8-6.</p> <p>Calcareous Calcareous soils. The metabolite IM-1-5 occurred only in the soils stated to be calcareous and is a relevant groundwater metabolite. Based on submitted PEC_{gw} assessment the maximum PEC_{GW} values for acetamipirid and its all metabolites were below the trigger value of 0.1 µg/L if formulation is applied every year for following crops: winter and spring oilseed rape and flax, common hemp, opium poppy, maize, winter and spring cereals, orchards apple, pear, quince, cherry, peach, plum), hazelnut, walnut, common osier, purple willow, forest and ornamental nurseries plants, and forest trees' seed plantations, Christmas trees grown on plantations, pumpkins, tomatoes and tobacco.</p> <p>The safe use (PEC_{gw} below the trigger value of 0.1 µg/L) was provided for sunflower and soybean if the formulation is used every other year.</p> <p>Neutral and acidic soils. For intended uses the PEC_{gw} for active substance and its metabolites were below the trigger value of 0.1 µg/L.</p>
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8.8.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints.

The calculation of the predicted environmental concentrations in ground waters (PEC_{GW}) of acetamiprid and relevant metabolites have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PEARL and FOCUS PELMO. Calculation were performed for all FOCUS scenarios (if available).

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	Winter oilseed rape (Flax, common hemp, soybean late crop, sunflower, opium poppy)	Maize	Summer oilseed rape	Spring cereals	Winter cereals	Orchards – apple, pear, quince, cherry, peach, plum, hazelnut, walnut, tobacco, common osier, purple willow	Orchards (Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations)	Pumpkin -potatoes used as surrogate crop	Tomato	Opium poppy-S OSR used as surrogate crop	Soybean – Bean+peas used as surrogate crop	Sunflower - Maize used as surrogate crop	Tobacco – Vines used as surrogate crop
Rate (g)	60	60	60	40		2x 25	50 40	60	60	30	60	50	2x 25
Mounting (a)	0.012	0.015	0.012	0.008		2x0.01	0.020 0.016	0.024 0.009	0.030	0.018	0.039	0.04	2x0.0075
Interval	1/n.a	1/n.a	1/n.a	1/n.a		2/7d	1/n.a	1/n.a	1/n.a	1/n.a			2/7d
	30 (spring app.)	51	30 (spring app.)	30 (spring app.)		11 51	11-49	21 51	11	10-39	11-59	10-65	30-85
Rotation	-	Please see data in table 8.8-3	Please see data in table 8.8-3	Please see data in table 8.8-3	-	Please see data in table 8.8-3	Please see data in table 8.8-3	Please see data in table 8.8-3	Please see data in table 8.8-3	-	Please see data in table 8.8-3		
Duration	80	75	80	80		60	60	60 85	50	40	35	20	70
	annual										biennial		annual
For	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3												

Table 8.8-2: Application dates used for groundwater risk assessment

Crop	Scenario	Application dates (absolute)
Winter oilseed rape BBCH 30 (Flax, common hemp, anybean , late corn , sunflower , opium poppy)	Châteaudun	1 March
	Hamburg	
	Kremsmünster	
	Okehampton	
	Piacenza	
	Porto	
Winter cereals BBCH 30	Châteaudun	1 March
	Hamburg	
	Jokioinen	
	Kremsmünster	
	Okehampton	
	Piacenza	
	Porto	
	Sevilla	
	Thiva	
Opium poppy- S OSR used as surrogate crop BBCH 10	Châteaudun	1 April
	Hamburg	
	Kremsmünster	

Table 8.8-3: Application dates for growth stages estimated using AppDate 3.05

Crop	BBCH	NO	Int.	Application dates in scenarios								
				Châteaudun	Hamburg	Jokioinen	Kremsmünster	Okehampton	Piacenza	Porto	Sevilla	Thiva
Maize	51	1	-	15.07	05.07	-	05.07	30.06	08.07	15.07	16.05	30.05
Spring cereals	30 (spring)	1	-	16.04	28.04	05.06	27.04	22.04	-	16.04	-	-
Orchards – – apple, pear, quince, cherry, peach, plum, hazelnut, walnut, tobacco, common osier, purple willow	11 51	2	7	03.04 10.04 03.05 10.05	18.04 25.04 26.05 02.06	11.05 18.05	18.04 25.04 26.05 02.06	28.03 04.04	03.04 10.04	19.03 26.03	18.03 25.03	19.03 26.03
Orchards (Forest and ornamental nurseries plants, restocking , afforestation and forest trees' seed plantations; Christmas trees grown on plantations)	11	1	-	03.04	18.04	11.05	18.04	28.03	03.04	19.03	18.03	19.03
Pumpkin	21 51	1	-	13.05 05.06	30.05 04.07	29.06 -	30.05 04.07	22.05 -	02.05 -	06.04 -	17.02 -	18.03 -
Tomato	11	1	-	13.05	03.04	-	03.04	-	13.05	19.03	17.04	13.04
Summer OSR	30 (spring)	1	-	-	-	13.06	-	24.04	-	27.04	-	-
Tobacco	30	2	7	01.06 08.06	01.06 08.06	-	01.06 08.06	-	-	-	-	-

Sunflower - Maize used as surrogate crop	10	1	-	2.05	6.05		6.05	-	-	-	-	-
Soybean - Bean used as surrogate crop	11	1	-	-	14.04		14.04	-	-	-	-	-
Soybean - peas used as surrogate crop	11	1	-	08.04	14.04		-	-	-	-	-	-

8.8.2.1 Acetamipryd Acetamiprid and its metabolites

Table 8.8-3: Input parameters related to active substance acetamipryd acetamiprid and metabolites (IC-0, IM-1-2, IM 1-4, IM 1-5) for PECgw calculations

Compound	Acetamipryd Acetamiprid	Metabolite IC-0	Metabolite IM-1-2	Metabolite IM 1-4	Metabolite IM 1-5	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	222.68	157.55	240.69	156.62	197.67	EFSA Journal 2016;14(11):4610
Water solubility (mg/l):	2950 mg/l (25 °C); pH 7	1x10 ⁶ (25 °C)	1x10 ⁶ (25 °C)	1x10 ⁶ (25 °C)	1x10 ⁶ (25 °C)	EFSA Journal 2016;14(11):4610
Saturated vapour pressure (Pa):	1 x 10 ⁻⁶ Pa (25 °C)	1x10 ⁻⁸ (20 °C)	1x10 ⁻⁸ (20 °C)	1x10 ⁻⁸ (20 °C)	1x10 ⁻⁸ (20 °C)	EFSA Journal 2016;14(11):4610
DT ₅₀ in soil (d)	1.45 (geomean mean normalisation to 10 kPa or pF ₂ , 20 °C with Q ₁₀ of 2.58)	2.7 (geomean mean)	1.7 (geomean mean)	14.6 (geomean mean)	495 (geomean mean)	EFSA Journal 2016;14(11):4610
K _{foc} (mL/g)	102.1 (geomean mean)	106.5 (geomean mean)	41.7 (geomean mean)	167.1 (geomean mean)	307.9 (geomean mean)	EFSA Journal 2016;14(11):4610
K _{fom} (mL/g)	59.2	61.8	24.2	96.9	178.6	Calculated from K _{foc} (K _{fom} = K _{foc} /1.724)
1/n	0.860 (arithmetic mean)	0.953 (arithmetic mean)	0.903 (arithmetic mean)	0.764 (arithmetic mean)	0.886 (arithmetic mean)	EFSA Journal 2016;14(11):4610
Plant uptake factor	0	0	0	0	0	Conservative default
Formation fraction	-	0.67 (from IM 1-4)	0.77 (from parent)	0.72 (from IM 1-2)	0.15 (from parent)	EFSA Journal 2016;14(11):4610

Table 8.8-5: PEC_{gw} FOCUS modelling results - PEARL (v 4.4.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)					
		Acetamipryd Acetamiprid	Metabolite IC-0	Metabolite IM-1-2	Metabolite IM 1-4	Every year	Every other year
						Metabolite IM 1-5	Metabolite IM 1-5
Winter OSR; 1x60 g a.s./ha; IC 80%; 1 st March; n.a. interval; BBCH 30; (spring app.)							-
Winter oilseed rape (<i>Flax, common hemp, soybean late appl. sunflower, opium poppy</i>)						Tier 1; PUF=0	-
	Châteaudun	0.000000	0.000000	0.000000	0.000000	0.008590	
	Hamburg	0.000000	0.000000	0.000000	0.000000	0.035940	-
	Kremsmünster	0.000000	0.000000	0.000000	0.000000	0.025686	-
	Okehampton	0.000000	0.000000	0.000000	0.000000	0.034109	-
	Piacenza	0.000000	0.000000	0.000000	0.000000	0.017209	-
	Porto	0.000000	0.000000	0.000000	0.000000	0.018925	-
Maize; 1x60 g a.s./ha; IC 75%; relative app.date; n.a. interval; BBCH 51							-
Maize						Tier 1; PUF=0	-
	Châteaudun	0.000000	0.000000	0.000000	0.000000	0.027768	
	Hamburg	0.000000	0.000000	0.000000	0.000000	0.043343	-
	Kremsmünster	0.000000	0.000000	0.000000	0.000000	0.031469	-
	Okehampton	0.000000	0.000000	0.000000	0.000000	0.047008	-
	Piacenza	0.000000	0.000000	0.000000	0.000000	0.041077	-
	Porto	0.000000	0.000000	0.000000	0.000000	0.022156	-
	Sevilla	0.000000	0.000000	0.000000	0.000000	0.000328	-
Thiva	0.000000	0.000000	0.000000	0.000000	0.020886	-	
Spring cereals; 1x40 g a.s./ha; IC 80%; relative app.date; n.a. interval; BBCH 30							-
Spring cereals						Tier 1; PUF=0	-
	Châteaudun	0.000000	0.000000	0.000000	0.000000	0.001076	
	Hamburg	0.000000	0.000000	0.000000	0.000000	0.021326	-
	Jokioinen	0.000000	0.000000	0.000000	0.000000	0.000000	-
	Kremsmünster	0.000000	0.000000	0.000000	0.000000	0.014037	-
	Okehampton	0.000000	0.000000	0.000000	0.000000	0.019590	-
	Porto	0.000000	0.000000	0.000000	0.000000	0.009078	-
Winter cereals; 1x40 g a.s./ha; IC 80%;1 March; n.a. interval; BBCH 30							-
Winter cereals						Tier 1; PUF=0	-
	Châteaudun	0.000000	0.000000	0.000000	0.000000	0.001910	
	Hamburg	0.000000	0.000000	0.000000	0.000000	0.019112	-
	Jokioinen	0.000000	0.000000	0.000000	0.000000	0.000000	-
	Kremsmünster	0.000000	0.000000	0.000000	0.000000	0.014000	-

	Okehampton	0.000000	0.000000	0.000000	0.000000	0.021284	-
	Piacenza	0.000000	0.000000	0.000000	0.000000	0.013461	-
	Porto	0.000000	0.000000	0.000000	0.000000	0.010179	-
	Sevilla	0.000000	0.000000	0.000000	0.000000	0.000000	-
	Thiva	0.000000	0.000000	0.000000	0.000000	0.000109	-
Orchards – apple, pear, quince, cherry, peach, plum, hazelnut, walnut, tabacco , common osier, purple willow	Orchards; 2 x 25 g a.s./ha; IC 60%; relative app.date; 7 days interval; BBCH 11						-
						Tier 1; PUF=0	Tier 2; PUF=0.5
	Châteaudun	0.000000	0.000000	0.000000	0.000000	0.043491 0.104081	0.061042
	Hamburg	0.000000	0.000000	0.000000	0.000000	0.056531 0.102858	0.065135
	Jokioinen	0.000000	0.000000	0.000000	0.000000	0.008703	-
	Kremsmünster	0.000000	0.000000	0.000000	0.000000	0.032459 0.068446	0.045767
	Okehampton	0.000000	0.000000	0.000000	0.000000	0.031864	-
	Piacenza	0.000000	0.000000	0.000000	0.000000	0.045443	-
	Porto	0.000000	0.000000	0.000000	0.000000	0.017831	-
	Sevilla	0.000000	0.000000	0.000000	0.000000	0.038226	-
	Thiva	0.000000	0.000000	0.000000	0.000000	0.050674	-
	Orchards; 2 x 25 g a.s./ha; IC 60%; relative app.date; 7 days interval; BBCH 51						-
						Tier 1; PUF=0	Tier 2; PUF=0.5
	Châteaudun	0.000000	0.000000	0.000000	0.000000	0.103234	0.060579
	Hamburg	0.000000	0.000000	0.000000	0.000000	0.103814	0.065786
	Kremsmünster	0.000000	0.000000	0.000000	0.000000	0.068325	0.045781
Orchards (Forest and ornamental nurseries plants, restockings , afforestations and forest trees' seed plantations; Christmas trees grown on plantations)	Orchards; 1 x 50 g a.s./ha; IC 60%; relative app.date; n.a. interval; BBCH 11						-
						Tier 1; PUF=0	Tier 2; PUF=0.5
	Châteaudun	0.000000	0.000000	0.000000	0.000000	0.010417 0.104298	0.061128
	Hamburg	0.000000	0.000000	0.000000	0.000000	0.010275 0.102815	0.065078
	Jokioinen	0.000000	0.000000	0.000000	0.000000	0.000138	
	Kremsmünster	0.000000	0.000000	0.000000	0.000000	0.068402 0.068457	0.045755
	Okehampton	0.000000	0.000000	0.000000	0.000000	0.074121	
	Piacenza	0.000000	0.000000	0.000000	0.000000	0.092152	
	Porto	0.000000	0.000000	0.000000	0.000000	0.041943	
	Sevilla	0.000000	0.000000	0.000000	0.000000	0.087951	
	Thiva	0.000000	0.000000	0.000000	0.000000	0.012553	
	Orchards; 1 x 40 g a.s./ha; IC 60%; relative app.date; n.a. interval; BBCH 11						-
	Châteaudun	0.000000	0.000000	0.000000	0.000000	Tier 1; PUF=0	

						0.077821	
	Hamburg	0.000000	0.000000	0.000000	0.000000	0.076305	-
	Kremsmünster	0.000000	0.000000	0.000000	0.000000	0.050831	-
Pumpkins -potatoes used as surrogate crop	Pumpkins; 1 x 60 g a.s./ha; IC 60 %; relative app.date; n.a. interval; BBCH 21						-
						Tier 1; PUF=0	-
	Châteaudun	0.000000	0.000000	0.000000	0.000000	0.035275	-
	Hamburg	0.000000	0.000000	0.000000	0.000000	0.060383	-
	Jokioinen	0.000000	0.000000	0.000000	0.000000	0.000015	-
	Kremsmünster	0.000000	0.000000	0.000000	0.000000	0.047775	-
	Okehampton	0.000000	0.000000	0.000000	0.000000	0.070952	-
	Piacenza	0.000000	0.000000	0.000000	0.000000	0.055738	-
	Porto	0.000000	0.000000	0.000000	0.000000	0.031737	-
	Sevilla	0.000000	0.000000	0.000000	0.000000	0.001687	-
	Thiva	0.000000	0.000000	0.000000	0.000000	0.020005	-
Pumpkins; 1 x 60 g a.s./ha; IC 85%; relative app.date; n.a. interval; BBCH 51							-
Pumpkins -potatoes used as surrogate crop						Tier 1; PUF=0	-
	Châteaudun	0.000000	0.000000	0.000000	0.000000	0.007000	-
	Hamburg	0.000000	0.000000	0.000000	0.000000	0.015485	-
	Kremsmünster	0.000000	0.000000	0.000000	0.000000	0.012258	-
Tomatoes	Tomatoes; 1 x 60 g a.s./ha; IC 50%; relative app.date; n.a. interval; BBCH 11						-
						Tier 1; PUF=0	-
	Châteaudun	0.000000	0.000000	0.000000	0.000000	0.069090	-
	Piacenza	0.000000	0.000000	0.000000	0.000000	0.086314	-
	Porto	0.000000	0.000000	0.000000	0.000000	0.052471	-
	Sevilla	0.000000	0.000000	0.000000	0.000000	0.003410	-
	Thiva	0.000000	0.000000	0.000000	0.000000	0.039122	-
	Tomatoes; 1 x 60 g a.s./ha; IC 70%; relative app.date; n.a. interval; BBCH 20						-
	Châteaudun	0.000000	0.000000	0.000000	0.000000	0.032657	-
Summer OSR	Summer OSR; 1x60 g a.s./ha; IC 80%; relative app.date; n.a. interval; BBCH 30; (spring app.)						-
	Jokioinen	0.000000	0.000000	0.000000	0.000000	0.000001	-
	Okehampton	0.000000	0.000000	0.000000	0.000000	0.030866	-
	Porto	0.000000	0.000000	0.000000	0.000000	0.016574	-
Sunflower; 1x50 g a.s./ha; IC 20%; relative app.date; n.a. interval; BBCH 10							Every other year
Sunflower - Maize used as surrogate crop						Tier 1; PUF=0	Tier 2; PUF=0.5
	Châteaudun	0.000000	0.000000	0.000000	0.000000	0.110642	0.037342

	Hamburg	0.000000	0.000000	0.000000	0.000000	0.156944	0.116863	0.057131
	Kremsmünster	0.000000	0.000000	0.000000	0.000000	0.114022	0.088751	0.041327
Tabacco; 2x25 g a.s./ha; IC 70%; relative app.date; n.a. interval; BBCH 30								-
Tobacco – Vines used as surrogate crop	Châteaudun	0.000000	0.000000	0.000000	0.000000	0.053185		-
	Hamburg	0.000000	0.000000	0.000000	0.000000	0.039809		-
	Kremsmünster	0.000000	0.000000	0.000000	0.000000	0.031057		-
Soybean; 1x60 g a.s./ha; IC 35%; relative app.date. interval; BBCH 11								Every other year
Soybean - Bean - used as surrogate crop	Châteaudun	-	-	-	-	-		-
	Hamburg	0.000000	0.000000	0.000000	0.000000	Tier 1; PUF=0	Tier 2; PUF=0.5	Tier 2; PUF=0.5
						0.147740	0.110452	0.054562
	Kremsmünster	0.000000	0.000000	0.000000	0.000000	0.101968	0.078738	0.037730
Soybean; 1x60 g a.s./ha; IC 35%; relative app.date. interval; BBCH 11								Every other year
Soybean - Peas - used as surrogate crop						Tier 1; PUF=0	Tier 2; PUF=0.5	Tier 2; PUF=0.5
	Châteaudun	0.000000	0.000000	0.000000	0.000000	0.023270	0.017472	0.013016
	Hamburg	0.000000	0.000000	0.000000	0.000000	0.156597	0.113517	0.056410
	Kremsmünster	-	-	-	-	-		-
Opium poppy; 1x30 g a.s./ha; IC 40%; 1 st April ; n.a. interval; BBCH 10								-
Opium poppy- S OSR used as surrogate crop						Tier 1; PUF=0		-
	Châteaudun	0.000000	0.000000	0.000000	0.000000	0.017944		-
	Hamburg	0.000000	0.000000	0.000000	0.000000	0.060876		-
	Kremsmünster	0.000000	0.000000	0.000000	0.000000	0.044180		-

Table 8.8-6: PEC_{gw} FOCUS modelling results - PELMO (v. 5.5.3.)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)				
		Acetamipryd Acetamiprid	Metabolite IC-0	Metabolite IM-1-2	Metabolite IM 1-4	Every year
						Metabolite IM 1-5
Winter OSR; 1x60 g a.s./ha; IC 80%; 1 st March; n.a. interval; BBCH 30; (spring app.)						
Winter oilseed rape (<i>Flax, common hemp, soybean, late appl., sunflower, opium poppy</i>)						Tier 1; PUF=0
	Châteaudun	0.000	0.000	0.000	0.000	0.002
	Hamburg	0.000	0.000	0.000	0.000	0.031
	Kremsmünster	0.000	0.000	0.000	0.000	0.026
	Okehampton	0.000	0.000	0.000	0.000	0.040
	Piacenza	0.000	0.000	0.000	0.000	0.019
	Porto	0.000	0.000	0.000	0.000	0.024
Maize; 1x60 g a.s./ha; IC 75%; relative app.date; n.a. interval; BBCH 51						
Maize						Tier 1; PUF=0
	Châteaudun	0.000	0.000	0.000	0.000	0.015
	Hamburg	0.000	0.000	0.000	0.000	0.032
	Kremsmünster	0.000	0.000	0.000	0.000	0.027
	Okehampton	0.000	0.000	0.000	0.000	0.044
	Piacenza	0.000	0.000	0.000	0.000	0.039
	Porto	0.000	0.000	0.000	0.000	0.022
	Sevilla	0.000	0.000	0.000	0.000	0.000
Thiva	0.000	0.000	0.000	0.000	0.014	
Spring cereals; 1x40 g a.s./ha; IC 80%; relative app.date; n.a. interval; BBCH 30						
Spring cereals	Châteaudun	0.000	0.000	0.000	0.000	Tier 1; PUF=0
						0.000
	Hamburg	0.000	0.000	0.000	0.000	0.012
	Jokioinen	0.000	0.000	0.000	0.000	0.000
	Kremsmünster	0.000	0.000	0.000	0.000	0.010
	Okehampton	0.000	0.000	0.000	0.000	0.019
	Porto	0.000	0.000	0.000	0.000	0.010
Winter cereals; 1x40 g a.s./ha; IC 80%; 1 March; n.a. interval; BBCH 30						
Winter cereals						Tier 1; PUF=0
	Châteaudun	0.000	0.000	0.000	0.000	0.000
	Hamburg	0.000	0.000	0.000	0.000	0.016

	Jokioinen	0.000	0.000	0.000	0.000	0.000
	Kremsmünster	0.000	0.000	0.000	0.000	0.014
	Okehampton	0.000	0.000	0.000	0.000	0.023
	Piacenza	0.000	0.000	0.000	0.000	0.015
	Porto	0.000	0.000	0.000	0.000	0.012
	Sevilla	0.000	0.000	0.000	0.000	0.000
	Thiva	0.000	0.000	0.000	0.000	0.000
Orchards – apple, pear, quince, cherry, peach, plum, hazelnut, walnut, tabaeeo , common osier, purple willow	Orchards; 2 x 25 g a.s./ha; IC 60%; relative app.date; 7 days interval; BBCH 11					
						Tier 1; PUF=0
	Châteaudun	0.000	0.000	0.000	0.000	0.098
	Hamburg	0.000	0.000	0.000	0.000	0.074
	Jokioinen	0.000	0.000	0.000	0.000	0.000
	Kremsmünster	0.000	0.000	0.000	0.000	0.062 0.063
	Okehampton	0.000	0.000	0.000	0.000	0.087
	Piacenza	0.000	0.000	0.000	0.000	0.076
	Porto	0.000	0.000	0.000	0.000	0.047
	Sevilla	0.000	0.000	0.000	0.000	0.039
	Thiva	0.000	0.000	0.000	0.000	0.090
	Orchards; 2 x 25 g a.s./ha; IC 60%; relative app.date; 7 days interval; BBCH 51					
						Tier 1; PUF=0
	Châteaudun	0.000	0.000	0.000	0.000	0.097
	Hamburg	0.000	0.000	0.000	0.000	0.075
	Kremsmünster	0.000	0.000	0.000	0.000	0.062
Orchards (Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations)	Orchards; 1 x 50 g a.s./ha; IC 60%; relative app.date; n.a. interval; BBCH 11					
						Tier 1; PUF=0
	Châteaudun	0.000	0.000	0.000	0.000	0.098
	Hamburg	0.000	0.000	0.000	0.000	0.074
	Jokioinen	0.000	0.000	0.000	0.000	0.000
	Kremsmünster	0.000	0.000	0.000	0.000	0.062
	Okehampton	0.000	0.000	0.000	0.000	0.087
	Piacenza	0.000	0.000	0.000	0.000	0.076
	Porto	0.000	0.000	0.000	0.000	0.047
	Sevilla	0.000	0.000	0.000	0.000	0.039
	Thiva	0.000	0.000	0.000	0.000	0.089
	Orchards; 1 x 40 g a.s./ha; IC 60%; relative app.date; n.a. interval; BBCH 11					
						Tier 1; PUF=0
	Châteaudun	0.000	0.000	0.000	0.000	0.073
	Hamburg	0.000	0.000	0.000	0.000	0.054
	Kremsmünster	0.000	0.000	0.000	0.000	0.046

Pumpkins <i>-potatoes used as surrogate crop</i>	Pumpkins; 1 x 60 g a.s./ha; IC 60%; relative app.date; n.a. interval; BBCH 21						
						Tier 1; PUF=0	
	Châteaudun	0.000	0.000	0.000	0.000	0.024	
	Hamburg	0.000	0.000	0.000	0.000	0.048	
	Jokioinen	0.000	0.000	0.000	0.000	0.000	
	Kremsmünster	0.000	0.000	0.000	0.000	0.042	
	Okehampton	0.000	0.000	0.000	0.000	0.071	
	Piacenza	0.000	0.000	0.000	0.000	0.053	
	Porto	0.000	0.000	0.000	0.000	0.041	
	Sevilla	0.000	0.000	0.000	0.000	0.001	
Thiva	0.000	0.000	0.000	0.000	0.018		
Pumpkins <i>-potatoes used as surrogate crop</i>	Pumpkins; 1 x 60 g a.s./ha; IC 85%; relative app.date; n.a. interval; BBCH 51						
						Tier 1; PUF=0	
	Châteaudun	0.000	0.000	0.000	0.000	0.004	
	Hamburg	0.000	0.000	0.000	0.000	0.011	
	Kremsmünster	0.000	0.000	0.000	0.000	0.010	
Tomatoes	Tomatoes; 1 x 60 g a.s./ha; IC 50%; relative app.date; n.a. interval; BBCH 11						
						Tier 1; PUF=0	
	Châteaudun	0.000	0.000	0.000	0.000	0.037	
	Piacenza	0.000	0.000	0.000	0.000	0.085	
	Porto	0.000	0.000	0.000	0.000	0.054	
	Sevilla	0.000	0.000	0.000	0.000	0.000	
	Thiva	0.000	0.000	0.000	0.000	0.029	
	Tomatoes; 1 x 60 g a.s./ha; IC 70%; relative app.date; n.a. interval; BBCH 20						
	Châteaudun	0.000	0.000	0.000	0.000	0.016	
Summer OSR	Summer OSR; 1x60 g a.s./ha; IC 80%; relative app.date; n.a. interval; BBCH 30; (spring app.)						
	Jokioinen	0.000	0.000	0.000	0.000	0.000	
	Okehampton	0.000	0.000	0.000	0.000	0.032	
	Porto	0.000	0.000	0.000	0.000	0.020	
Sunflower - Maize used as surrogate crop	Sunflower; 1x50 g a.s./ha; IC 20%; relative app.date; n.a. interval; BBCH 10						
						Tier 1; PUF=0	Tier 2; PUF=0.5
	Châteaudun	0.000	0.000	0.000	0.000	0.073	0.042
	Hamburg	0.000	0.000	0.000	0.000	0.128	0.083
	Kremsmünster	0.000	0.000	0.000	0.000	0.105	0.068
Tobacco – Vines used as surrogate crop	Tabacco; 2x25 g a.s./ha; IC 70%; relative app.date; n.a. interval; BBCH 30						
						Tier 1; PUF=0	
Châteaudun	0.000	0.000	0.000	0.000	0.050		

	Hamburg	0.000	0.000	0.000	0.000	0.044
	Kremsmünster	0.000	0.000	0.000	0.000	0.038
Soybean - Bean - used as surrogate crop	Soybean; 1x60 g a.s./ha; IC 35%; relative app.date. interval; BBCH 11					
					Tier 1; PUF=0	Tier 2; PUF=0.5
	Châteaudun	-	-	-	-	-
	Hamburg	0.000	0.000	0.000	0.000	0.120
	Kremsmünster	0.000	0.000	0.000	0.000	0.095
Soybean - Peas - used as surrogate crop	Soybean; 1x60 g a.s./ha; IC 35%; relative app.date. interval; BBCH 11					
					Tier 1; PUF=0	Tier 2; PUF=0.5
	Châteaudun	0.000	0.000	0.000	0.000	0.008
	Hamburg	0.000	0.000	0.000	0.000	0.121
	Kremsmünster	-	-	-	-	-
Opium poppy- S OSR used as surrogate crop	Opium poppy; 1x30 g a.s./ha; IC 40%; 1 st April ; n.a. interval; BBCH 10					
					Tier 1; PUF=0	
	Châteaudun	0.000	0.000	0.000	0.000	0.004
	Hamburg	0.000	0.000	0.000	0.000	0.055
	Kremsmünster	0.000	0.000	0.000	0.000	0.045

Conclusion of PECgw simulations for acetamipryd acetamiprid and metabolites

PECgw simulations for acetamipryd and metabolites (IM-1-2, IM-1-4, IC-0 and IM-1-5) have been conducted with FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 for all important scenarios, inclusive the representative ones for Poland (Hamburg, Kremsmünster & Chateaudun).

The results of the simulations indicate that none of the PEARL and PELMO model scenarios for LEPTOSAR 200 SL for major uses (i.e.: *winter oilseed rape and maize*) and minor uses (i.e.: *oilseed rape, winter & spring cereals, apple, pear, quince, cherry, peach, plum, hazelnut, walnut, tobacco, common osier, purple willow, flax, common hemp, soybean, sunflower, opium poppy, forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations*) of acetamiprid and metabolites (IM-1-2, IM-1-4 & IC-0) not exceed the trigger value of 0.1 µg/L considering the applications performed every year.

The results for application every year for metabolite IM-I-5 were above the trigger value of 0.1 µg/L at application in sunflower (1 x 50 g/ha) and soybean (1 x 60 g/ha) therefore, for these crops (*soybean and sunflower*) additional calculations were performed with consideration of biennial application of LEPTOSAR 200 SL for which unacceptable leaching was demonstrated for applications performed every year. Results obtained for metabolite IM-I-5 were < 0.1 µg/L for applications performed every second year.

Results are presented in tables above.

Taking above information into account, it could be stated that the use of LEPTOSAR 200 SL according to recommendations will not pose a risk of groundwater contamination by acetamipryd and its metabolites

(IM 1-2, IM 1-4, IC 0 and IM 1-5).

Conclusion:

The results presented above indicate that when used as the formulation LEPTOSAR 200 SL according to the proposed representative GAP neither acetamiprid nor its major soil metabolites should pose a serious threat to the groundwater compartment. It shall be pointed out however that typical calcareous soils that are agriculturally used are not common in Poland.

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

zRMS Comments:	The submitted PEC _{sw} and PEC _{sed} calculations were accepted.					
	All used endpoints for active substances and its metabolites were agreed at the EU level or recalculated (geom mean of K _{foc}).					
	Calculations of PEC _{sw} for active substance and its relevant metabolites were provided with PUF = 0, in accordance with LoEP, 2016.					
	The recommended FOCUS models were used: FOCUS Step 1 & 2, Step 3 and Step 4.					
	In Step 4 the SWAN model and VFSmod were used.					
	The maximum width of vegetated buffer zone is 20 m					
	Only scenarios D3, D4 and R1 were taken into consideration, also relevant for Poland.					
	For tomato (*) in greenhouse use, the input data were in accordance with EFSA, 2016. In case of permanent construction – no mitigation measures are required; in case of indoor use – the PEC _{sw} assessment is covered by pumpkin.					
	For field crops the following mitigation measures were proposed.					
	Acetamiprid. Central Zone, proposed mitigation measures based on SWAN or VFSmod modelling					
Crop	Application rate g a.s./ha	No spray buffer m	Nozzle reduction %	Vegetated buffer m	Max PEC _{sw} µg/l	Scenario
Maize	60	20	50	20	0.01634	D4 stream
Winter cereals – spring application	40	20	none	20	0.02006	D4 stream
Winter oilseed rape	60	20	50	20	0.01428	D4 stream
Spring cereals (BBCH13)	40	20	none	none	0.02087	D4 stream
Spring oilseed rape (BBCH 17)	60	30	none	none	0.02180	R1 stream
Pome fruits (BBCH 51)	2 x 25	50	none	20	0.02031	D4 stream
		20	90	20	0.02288	R1 pond
Pome fruits ornamentals	40	30	90	20	0.01381	D4 stream

Pumpkin (potatoes)	60	20	50	20	0.01420	D3 ditch
Soybean (legumes)	60	30	none	none	0.02013	D4 stream
		20	50	none	0.01484	D4 stream
Sunflower	50	20	50	20	0.01303	D4 stream
Opium	30	20	none	none	0.01568	D4 stream

Metabolites of acetamipirid. All relevant metabolites were considered. The max PEC_{sw} and PEC_{sed} values are presented in the table below:

Metabolite	Crop	Step 2	
		PEC _{sw} µg/L	PEC _{sed} µg/kg
IM-1-2	Pome fruits 1x50g as/ha	1.0259	0.4225
IM-1-4	Pome fruits 1x50g as/ha	2.2886	3.6921
IC-0	Pome fruits 1x50g as/ha	1.0641	1.0917
IM-1-5	soybean	0.4005	1.2332
IB-1-1	Pome fruits 1x50g as/ha	1.6844	nr

Formulation. Taking into consideration the drift from formulation use, the following non-spray buffer strips were calculated by the evaluator. The drift exposure was assessed using the Drift Calculator in SWASH model:
 The max PEC_{sw} are presented in the table below.

Crop	Max. application rate (L/ha)	Amount of the product (g/ha)	Buffer strip (m)	PEC _{sw} (µg product /L)
Winter oilseed rape (<i>Flax, common hemp</i>)	0.3	352	1	2.2615
Maize	0.3	352	1	2.2615
Summer oilseed rape	0.3	352	1	2.2615
Spring & winter cereals	0.2	234	1	1.5034
Pumpkin	0.3	352	1	2.2615
Tomato	0.3	352	1	2.2615
Soybean	0.3	352	1	2.2615
Sunflower	0.3	352	1	2.2615
Pome fruits/ orchard (apple, pear,	0.125	146.5	3	12.7549

	quince, cherry, peach, plum, hazelnut, walnut, tobacco, common osier, purple willow)				
	Pome fruits (Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations)	0.2	234.4	3	20.4078

ZRMS is of the opinion, that relevant mitigation measures will be considered at the Member State level.

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In Step 3 and Step 4 the PEC_{sw}/sed assessment in scenarios D3, D4 and R1 was considered. The following mitigation measures were proposed.

Acetamiprid. Step 3.

Crop	Application rate g a.s./ha	Max PEC _{sw} µg/l	Scenario
Maize	1 x 20	0.034	D3 ditch

The relevant mitigation measure will be recommended in ecotoxicological section.

8.9.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints.

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

Table 8.9-1: Input parameters related to application for $PEC_{SW/SED}$ calculations

Plant protection product	LEPTOSAR 200 SL											
Use No.	1-94											
Crop	MaizeG	Winter Cereal	Winter Oilseed rape (Flax, common hemp, soybean, sunflower, opium poppy)	Spring Cereal	Spring Oilseed rape	Tomato (Aerial appln.) (aubergine, paprika)	Pome fruits/ orchard (apple, pear, quince, cherry, peach, plum, hazelnut, walnut, tobacco, common osier, purple willow) (at BBCH51)	Pumpkin (Potatoes) BBCH>50	Pome fruits (Forest and ornamental nurseries plants, restockings, afforestations and forest trees' seed plantations; Christmas trees grown on plantations)	opium poppy as S OSR	Soybean as legumes	Sunflower as maize
Application rate (kg as/ha)	0.06	0.04	0.06	0.04	0.06	0.00006 (0.1 % emission)	0.025	0.06	0.05 0.04	0.03	0.06	0.05
Number of applications/interval (d)	1/n.a.						2/7	1/n.a.				
Application window (step 2)	March-May (spring sprying) No runoff/drainage - tomato crop											
CAM (Chemical application method)	2 - appln foliar linear (in case of R scenario)											
Models used for calculation	Step 1-2 in FOCUS v.3.2, FOCUS SWASH v. 5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN 5.0.1											

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for PEC_{sw/sed} calculations for the application of LEPTOSAR 200 SL (Application dates based on AppDate v. 3.06)

Crop	Scenario	Application window used in modelling		
		Single Application		Multiple Application
		First day	Last day	Last day
Winter oilseed rape 60g/ha BBCH 31 Spring appl. Average crop	D3	2 Mar -	1 - Apr	-
	D4	6 Mar -	5 - Apr	-
	R1	17 Apr -	17 - May	-
Spring oilseed rape 60g/ha BBCH 17 Spring appl. Minimal crop cover	D3	22 April	22 May	-
	D4	10 May	9Jun	-
	R1	21 April	21 May	-
Maize 60g/ha BBCH 51 Full canopy	D3	12 Jul	11 Aug	-
	D4	19 July	18 Aug	-
	R1	10 Jul	9 Aug	-
Sunflower (as Maize) 50g/ha BBCH 10 Minimal crop cover	D3	06 May	06 June	-
	D4	11 May	10 June	-
	R1	04 May	03 June	-
Winter cereals, 40g/ha BBCH 40 Spring appl. Interception (step 2) – full canopy	D3	22 May	21 June	-
	D4	22 Apr	22 May	-
	R1	11 May	10 June	-
Spring cereals, 40g/ha BBCH 13 Spring appl. Interception (step 2) – no interception	D3	6 Apr	6 May	-
	D4	30 Apr	30 May	-
Pome fruits 2 x 25 g/ha Multiple appl.	D3	18 Apr	18 May	25 May
	D4	23 Apr	23 May	30 May

Interval – 7 d BBCH 11 Interception (step 2) – Minimal crop cover	R1	18 Apr	18 May	25 May
Pome fruits 2 x 25 g/ha Multiple appl. Interval – 7 d BBCH 51	D3	26 May	25 June	02 July
	D4	30 May	29 June	06 July
	R1	26 May	25 June	02 July
Pumpkin (potatoes) 60 g/ha Single appl BBCH 21 Interception (step 2) – Intermediate crop cover	D3	30 May	29 June	-
	D4	17 June	17 July	-
	R1	20 May	19 June	-
Pumpkin (potatoes) 60 g/ha Single appl BBCH > 50 Interception (step 2) – full canopy	D3	4-July	03 - Aug	-
	D4	01-Aug	31-Aug	-
	R1	16-Jun	17-Jul	-
Opium poppy (S OSR) 30 g/ha Single appl BBCH 10 Interception (step 2) – Minimal crop cover	D3	11-Apr	11-May	-
	D4	2-May	1-Jun	-
	R1	11-Apr	11-May	-
Soybean (as legumes) 60g/ha BBCH 11 Minimal crop cover	D3	18-Apr	18-May	-
	D4	26-Apr	26-May	-
	R1	18-Apr	18-May	-

8.9.2.1 Acetamiprid and its metabolites

Table 8.9-3: Input parameters related to active substance acetamiprid and metabolite(s) for PEC_{sw/sed} calculations STEP 1/2 and 3(4)

Compound	Acetamiprid Acetamiprid	Metabolite IC-0	Metabolite IM-1-2	Metabolite IM 1-4	Metabolite IM 1-5	Metabolite IB 1-1	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	222.68	157.55	240.69	156.62	197.67	204.23	EFSA Journal 2016;14(11):4610

Compound	Acetamipryd Acetamiprid	Metabolite IC-0	Metabolite IM-1-2	Metabolite IM 1-4	Metabolite IM 1-5	Metabolite IB 1-1	Value in accordance with EU endpoint y/n/ Reference*
Water solubility (g/mol):	2950 mg/l (25 °C); pH 7	1x10 ⁶ (25 °C)	1x10 ⁶ (25 °C)	1x10 ⁶ (25 °C)	1x10 ⁶ (25 °C)	1x10 ⁶ (25 °C)	EFSA Journal 2016;14(11):4610
Saturated vapour pressure (Pa):	1 x 10 ⁻⁶ Pa (25 °C)	1x10 ⁻⁸ (20 °C)	1x10 ⁻⁸ (20 °C)	1x10 ⁻⁸ (20 °C)	1x10 ⁻⁸ (20 °C)	1x10 ⁻⁸ (20 °C)	EFSA Journal 2016;14(11):4610
DT ₅₀ in soil (d)	1.45 (geomean mean normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58)	2.7 (geomean mean)	1.7 (geomean mean)	14.6 (geomean mean)	495 (geomean mean)	1000	EFSA Journal 2016;14(11):4610
DT ₅₀ in water/sediment system (d)	27.0 Geometric mean (n = 2) of total aquatic system	1000					EFSA Journal 2016;14(11):4610
DT ₅₀ in water (d)	27.0 Geometric mean (n = 2) of total aquatic system	1000					EFSA Journal 2016;14(11):4610
DT ₅₀ in sediment (d)	27.0 (Step1,2) 1000 (Step 3)	1000					EFSA Journal 2016;14(11):4610
K _{foc} (mL/g)	102.1 (geomean mean)	106.5 (geomean mean)	41.7 (geomean mean)	167.1 (geomean mean)	307.9 (geomean mean)	0	EFSA Journal 2016;14(11):4610
K _{fom} (mL/g)	59.2	Not required in Step 1 and 2					Calculated from K _{foc} (K _{fom} = K _{foc} /1.724)
1/n	0.86 (arithmetic mean)	Not required in Step 1 and 2					EFSA Journal 2016;14(11):4610
Plant uptake factor	0	Not required in Step 1 and 2					Conservative default
Maximum occ. Observed (% molar basis with respect to parent)	-	w/s:29.5 soil:11.3	w/s:13.4 soil: 55	w/s:43.0 soil:72	w/s: 0 soil:20	w/s: 35 soil:0	EFSA Journal 2016;14(11):4610
Other input data (required for Step 3)							
Temperature correction function Reference temperature [°C] MACRO: [K ⁻¹] PRZM: Q ₁₀ [-]		20 0.095 2.58					FOCUS recommendation EFSA recommendation EFSA recommendation
Moisture correction function Reference moisture [-] PRZM / MACRO: moisture exponent		pF 2 0.7					FOCUS recommendation

Compound	Acetamiprid	Metabolite IC-0	Metabolite IM-1-2	Metabolite IM 1-4	Metabolite IM 1-5	Metabolite IB 1-1	Value in accordance with EU endpoint y/n/ Reference*
[-]							
Temperature correction function							
Reference temperature [°C]		20					FOCUS recommendation
TOXSWA: activation energy [J mol ⁻¹]		65 400					EFSA recommendation
Wash off coefficient							
PRZM: [cm ⁻¹]		0.5					FOCUS recommendation
MACRO: [mm ⁻¹]		0.05					

PEC_{sw/sed}

Table 8.9-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single/multiple application(s) of LEPTOSAR 200 SL to maize (BCH 51)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	---	18.1554	spray drift, runoff, drainage	13.9846	17.9732
Step 2	ditch	0.5866		0.4398	0.5656
Northern Europe	March-May				
Step 3					
D3	ditch	0.3145	spray drift, runoff, drainage	0.01574	0.09335
D4	pond	0.01271		0.009579	0.02306
D4	stream	0.2817		0.002663	0.03166
R1	pond	0.03394		0.02536	0.05942
R1	stream	0.5513		0.01563	0.1571

Table 8.9-5a: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application(s) of LEPTOSAR 200 SL to sunflower (as maize) at BBCH 10

Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
Step 1	---	15.1295	spray drift, runoff, drainage	11.6538	14.9777
Step 2	ditch	0.7273		0.5508	0.7086
Northern Europe	March-May				
Step 3					
D3	ditch	0.2623	spray drift, runoff, drainage	0.0145	0.0830
D4	pond	0.0106		0.0083	0.0208
D4	stream	0.2246		0.000955	0.0133

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
R1	pond	0.0139		0.0113	0.0317
R1	stream	0.2475		0.0080	0.0449

Table 8.9-5: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application(s) of LEPTOSAR 200 SL to winter cereals – spring application

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)*
Step 1	---	12.1036	spray drift, runoff, drainage	9.3231	11.9822
Step 2	ditch	0.4084		0.3066	0.3943
Northern Europe	March-May				
Step 3					
D3	ditch	0.2537	spray drift, runoff, drainage	0.01450	0.08154
D4	pond	0.008746		0.007151	0.01935
D4	stream	0.1993		0.000558	0.008173
R1	pond	0.03650		0.03076	0.07262
R1	stream	0.5768		0.01982	0.1676

Table 8.9-7: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single of LEPTOSAR 200 SL to winter oilseed rape

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)*
Step 1	---	-	spray drift, runoff, drainage	-	-
Step 2	ditch	0.6126		0.4599	0.5915
Northern Europe	March-May				
Step 3					
D3	ditch	0.3793	spray drift, runoff, drainage	0.01511	0.09895
D4	pond	0.01311		0.01080	0.03020
D4	stream	0.2837		0.000543	0.008183
R1	pond	0.01312		0.01091	0.03305
R1	stream	0.2500		0.008948	0.05739

Table 8.9-8: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single of LEPTOSAR 200 SL to spring oilseed rape (BBCH 17)

Scenario	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)*
FOCUS					
Step 1	---	18.1554	spray drift, runoff, drainage	13.9846	17.9732
Step 2	ditch	0.7687		0.5805	0.7468
Northern Europe	Mar-May				
D3	ditch	0.3804		0.02025	0.1153
D4	pond	0.01312		0.01026	0.02558
D4	stream	0.3116		0.001375	0.01892
R1	pond	0.01312		0.01045	0.02789
R1	stream	0.2504		0.002203	0.02712

Table 8.9-9: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single of LEPTOSAR 200 SL to spring cereals (BBCH13)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)*
Step 1	---	12.1036	spray drift, runoff, drainage	9.3231	11.9822
Step 2	ditch	0.6512		0.4943	0.6359
Northern Europe	March-May				
Step 3					
D3	ditch	0.2532	spray drift, runoff, drainage	0.01166	0.07317
D4	pond	0.008747		0.006825	0.01748
D4	stream	0.2073		0.000894	0.01245

Table 8.9-10: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following and multiple applications (2 x 25g as/ha) of LEPTOSAR 200 SL to pome fruits at BBCH 11

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)*
Step 1	---	19.5358	spray drift, runoff, drainage	14.6644	14.9777
Step 2	ditch	3.7573		2.8127	3.2653
Northern	March-May				

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)*
Europe					
Step 3					
D3	ditch	1.671	spray drift, runoff, drainage	0.1909	0.6025
D4	pond	0.1587		0.1275	0.3508
D4	stream	1.690		0.008652	0.1155
R1	Pond	0.1910		0.1532	0.3421
R1	stream	1.340		0.01899	0.1295

Table 8.9-10a: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following and multiple applications (2 x 25g as/ha) of LEPTOSAR 200 SL to pome fruits at BBCH 51

Scenario	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)*
FOCUS					
Step 1	---	19.5358	spray drift, runoff, drainage	14.6644	14.9777
Step 2	ditch	3.7573		2.8127	3.2653
Northern Europe	March-May				
Step 3					
D3	ditch	1.678	spray drift, runoff, drainage	0.2861	0.7902
D4	pond	0.1517		0.1172	0.3178
D4	stream	1.762		0.02292	0.2407
R1	Pond	0.1772		0.1366	0.3071
R1	stream	1.348		0.02252	0.1602

Table 8.9-11: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application (1 x 50g as/ha) of LEPTOSAR 200 SL to pome fruits (ornamentals).

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)*
Step 1	---	19.5358	spray drift, runoff, drainage	14.6644	14.9777
Step 2	ditch	4.8662		3.5933	4.1914

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)*
Northern Europe	March-May				
Step 3					
D3	ditch	3.883	spray drift, runoff, drainage	0.2121	1.030
D4	pond	0.2360		0.1951	0.4230
D4	stream	3.741		0.01006	0.1427
R1	Pond	0.2360		0.1893	0.3932
R1	stream	3.140		0.02526	0.2948

Table 8.9-11a: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application (1 x 40g as/ha) of LEPTOSAR 200 SL to pome fruits (ornamentals).

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)*
Step 1	---	19.5358	spray drift, runoff, drainage	14.6644	14.9777
Step 2	ditch	4.8662		3.5933	4.1914
Northern Europe	March-May				
Step 3					
D3	ditch	3.106	spray drift, runoff, drainage	0.1697	0.8358
D4	pond	0.1888		0.1560	0.3432
D4	stream	2.993		0.008045	0.1146
R1	Pond	0.1888		0.1513	0.3191
R1	stream	2.512		0.02021	0.2377

Table 8.9-12: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of LEPTOSAR 200 SL to potatoes (pumpkin).

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)*
Step 1	—	18.1554	spray drift, runoff, drainage	13.9846	17.9732
Step 2	ditch	0.7166		0.5403	0.6950
Northern Europe	March-May				

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)*
Step 3					
D3	ditch	0.3145	spray drift, runoff, drainage	0.01561	0.09327
D4	pond	0.01270		0.009549	0.02225
D4	stream	0.2456		0.000465	0.007019
R1	Pond	0.04120		0.03137	0.07168
R1	stream	0.4842		0.02133	0.1912

Table 8.9-12a: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of LEPTOSAR 200 SL to pumpkin (potatoes) at BBCH >50.

Scenario	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)*
FOCUS					
Step 1	---	18.1554	spray drift, runoff, drainage	13.9846	17.9732
Step 2	ditch	0.7166		0.5403	0.6950
Northern Europe	March-May				
Step 3					
D3	ditch	0.3146	spray drift, runoff, drainage	0.01619	0.09480
D4	pond	0.0127		0.009656	0.02482
D4	stream	0.2365		0.000385	0.005750
R1	Pond	0.0681		0.05122	0.1161
R1	stream	0.7731		0.03660	0.07653

Table 8.9-13: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of LEPTOSAR 200 SL to tomato.

Scenario	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)*
FOCUS					
Step 1	---	0.0242	spray drift, runoff, drainage	0.0181	0.0180
Step 2	ditch	0.0066		0.0047	0.0039
Northern Europe	No runoff/dranaige				

Table 8.9-14: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of LEPTOSAR 200 SL to opium poppy.

Scenario	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)*
FOCUS					
Step 1	---	9.0777	spray drift, runoff, drainage	6.9923	8.9866
Step 2	ditch	0.3843		0.2903	0.3734
Northern Europe	March-May				
Step 3					
D3	ditch	0.1900	spray drift, runoff, drainage	0.009405	0.05794
D4	pond	0.0066		0.005114	0.01336
D4	stream	0.1558		0.000688	0.009566
R1	Pond	0.0066		0.005209	0.01456
R1	stream	0.1252		0.001101	0.01386

Table 8.9-15: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of LEPTOSAR 200 SL to soybean (as legumes).

Scenario	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)*
FOCUS					
Step 1	---	18.1554	spray drift, runoff, drainage	13.9846	17.9732
Step 2	ditch	0.8727		0.6610	0.8503
Northern Europe	March-May				
Step 3					
D3	ditch	0.3144	spray drift, runoff, drainage	0.01577	0.09351
D4	pond	0.0127		0.01016	0.02553
D4	stream	0.2559		< 1e-6	0.01346
R1	Pond	0.0127		0.008085	0.01247
R1	stream	0.2175		0.001968	0.02422

FOCUS Step 4

Table 8.9-14: Table 8.9-12: Global maximum PEC_{sw} values for acetamiprid, following single application(s) of LEPTOSAR 200 SL to maize according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid			
Nozzle reduction	Vegetative strip (m)	20	20	20	30
	No spray buffer (m)	20	50	20	30
None	D3 ditch	0.02840	0.01176	0.02840	0.01926
50%		0.01420	0.005878	0.01420	
None	D4 pond	0.005452	0.002841	0.005452	0.004154
50%		0.002727	0.001421	0.002727	—
None	D4 stream	0.03270	0.01353	0.03270	0.02216
50%		0.01634	0.006767	0.01634	-
None	R1 pond	0.009102	0.005931	0.005447	0.004147
50%		0.006956	0.003429	0.002724	-
None	R1 stream	0.1309	0.1309	0.02501	0.01695
50%		0.1309	0.1309	0.01250	-

Table 8.9-15: Global maximum PEC_{sw} values for acetamiprid, following single application(s) of LEPTOSAR 200 SL to winter cereals (spring application) according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid		
Nozzle reduction	Vegetative strip (m)	20	20	20
	No spray buffer (m)	20	50	20
None	D3 ditch	0.01895	0.007846	0.01895
50%		0.009475	0.003923	
None	D4 pond	0.003632	0.001892	0.003632
50%		0.001816	0.000946	
None	D4 stream	0.02006	0.008305	0.02006
50%		0.01003	0.004154	
None	R1 pond	0.008973	0.007461	0.003631
50%		0.007395	0.006641	
None	R1 stream	0.1372	0.1372	0.01674
50%		0.1372	0.1372	

Table 8.9-17: Global maximum PEC_{sw} values for acetamiprid, following single application(s) of LEPTOSAR 200 SL to winter oilseed rape according to surface water Step 4

PEC _{sw} (µg/L)	Scenario		STEP 4 acetamiprid		
Nozzle reduction	Vegetative strip (m)	20	20	20	30
	No spray buffer (m)	20	50	20	30
None	D3 ditch	0.02833	0.01173	0.02833	0.01921
		50%	0.01417	0.005864	0.01417
None	D4 pond	0.005447	0.002837	0.005447	0.004147
		50%	0.002723	0.001418	0.002723
None	D4 stream	0.02857	0.01182	0.02857	0.01936
		50%	0.01428	0.005911	0.01428
None	R1 pond	0.005447	0.002837	0.005447	0.004147
		50%	0.002724	0.001541	0.002724
None	R1 stream	0.05109	0.05109	0.02518	0.01706
		50%	0.05109	0.05109	0.01258

Table 8.9-18: Global maximum PEC_{sw} values for acetamiprid, following single application(s) of LEPTOSAR 200 SL to spring cereals according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid	
Nozzle reduction	Vegetative strip (m)	-	-
	No spray buffer (m)	10	20
None	D3 ditch	0.03640	0.01891
None	D4 pond	0.005440	0.003633
None	D4 stream	0.04017	0.02087

Table 8.9-18: Global maximum PEC_{sw} values for acetamiprid, following single application(s) of LEPTOSAR 200 SL to spring oilseed rape according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid	
Nozzle reduction	Vegetative strip (m)	-	-
	No spray buffer (m)	20	30
None	D3 ditch	0.02841	0.01927
None	D4 pond	0.005449	0.004149
None	D4 stream	0.03138	0.02126
None	R1 pond	0.005447	0.004147
None	R1 stream	0.02522	0.02180

Table 8.9-19: Global maximum PEC_{sw} values for acetamiprid, following single application(s) of LEPTOSAR 200 SL to pome fruits at BBCH 51 (2 x 25g as/ha) according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid			
Nozzle reduction	Vegetative strip (m)	20	20	40	50
	No spray buffer (m)	20	20	40	50
None	D3 ditch	0.1970	0.1970	0.03163	0.01749
None	D4 pond	0.03039	0.03039	0.007313	0.004494
None	D4 stream	0.2194	0.2194	0.03521	0.01947
None	R1 pond	0.03662	0.03662	0.008821	0.005422
None	R1 stream	0.2657	0.1740	0.02793	0.01544

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid			
Nozzle reduction	Vegetative strip (m)	20	20	20	20
	No spray buffer (m)	20	80	20	50
None	D3 ditch	0.1979	0.01757	0.1979	0.01757

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid			
Nozzle reduction	Vegetative strip (m)	20	20	20	20
	No spray buffer (m)	20	80	20	50
50%	None	0.09895	0.002511	0.09895	0.008783
90 %		0.01979	0.000503	0.01979	-
None		0.02906	0.004299	0.02906	0.004299
50%	D4 pond	0.01451	0.000736	0.01451	0.002146
90 %		0.002892	0.000147	0.002892	-
None	D4 stream	0.2288	0.02031	0.2288	0.02031
50%		0.1144	0.002902	0.1144	0.01015
90 %		0.02288	0.000580	0.002288	-
None	R1 pond	0.03396	0.005026	0.03396	0.005026
50%		0.01696	0.000860	0.01696	0.002509
90 %		0.003381	0.000306	0.02288 0.00338	-
None	R1 stream	0.1751	0.02501	0.1751	0.01554
50%		0.08754	0.02501	0.08754	0.007768
90 %		0.02501	0.02501	0.003381	-

Table 8.9-20: Global maximum PEC_{sw} values for acetamiprid, following single application(s) of LEPTOSAR 200 SL to pome fruits– ornamental plants (1 x 50g as/ha) according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid			
Nozzle reduction	Vegetative strip (m)	20	40	50	70
	No spray buffer (m)	20	40	50	70
None	D3 ditch	0.4284	0.08248	0.04836	0.02159
None	D4 pond	0.04711	0.01327	0.008592	0.004350
None	D4 stream	0.4513	0.08692	0.05096	0.02275
None	R1 pond	0.04711	0.01327	0.008591	0.004350
None	R1 stream	0.3787	0.07294	0.04276	0.01909

Table 8.9-20a: Global maximum PEC_{sw} values for acetamiprid, following single application(s) of LEPTOSAR 200 SL to pome fruits – ornamental plants (1 x 40g as/ha) according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid VFSmod	
Nozzle reduction	Vegetative strip (m)	50	70
	No spray buffer (m)	50	70
None	D3 ditch	0.03869	0.01727
None	D4 pond	0.006874	0.003480
None	D4 stream	0.04079	0.01820
None	R1 pond	0.006873	0.003480
None	R1 stream	0.03423	0.01527

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid	
Nozzle reduction	Vegetative strip (m)	20	20
	No spray buffer (m)	20	30
None	D3 ditch	0.3428	0.1310
75%		0.08568	0.03276
90 %		0.03428	0.01310
None	D4 pond	0.03769	0.01825
75%		0.009421	0.004561
90 %		0.003768	0.001825
None	D4 stream	0.3611	0.1381
75%		0.09028	0.03452
90 %		0.03611	0.01381
None	R1 pond	0.03769	0.01825
75%		0.009420	0.004560
90 %		0.003768	0.001825
None	R1 stream	0.3030	0.1159
75%		0.07576	0.02897
90 %		0.03030	0.01159

Table 8.9-21: Global maximum PEC_{sw} values for acetamiprid, following single application(s) of LEPTOSAR 200 SL to pumpkin at BBCH>50 according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid		
Nozzle reduction	Vegetative strip (m)	20	20	20 VFS mode
	No spray buffer (m)	20	50	20
None	D3 ditch	0.02841	0.01176	0.0284
50%		0.01420	0.005880	0.01420
None	D4 pond	0.005461	0.002852	0.0055
50%		0.002739	0.001434	0.00275
None	D4 stream	0.02746	0.01137	0.0275
50%		0.01373	0.005694	0.01373
None	R1 pond	0.01604	0.01417	0.0055
50%		0.01409	0.01316	0.003541
None	R1 stream	0.1820	0.1820	0.0253
50%		0.1820	0.1820	0.01266

Table 8.9-22: Global maximum PEC_{sw} values for acetamiprid, following single application(s) of LEPTOSAR 200 SL to sunflower according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid VFSmod	
Nozzle reduction	Vegetative strip (m)	20	30
	No spray buffer (m)	20	30
None	D3 ditch	0.0237	0.0237
None	D4 pond	0.0045	0.0035
None	D4 stream	0.0261	0.0177
None	R1 pond	0.0045	0.0035

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid VFSmod	
Nozzle reduction	Vegetative strip (m)	20	30
	No spray buffer (m)	20	30
None	R1 stream	0.0207	0.0140

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid			
Nozzle reduction	Vegetative strip (m)	-	20	20	20
	No spray buffer (m)	50	20	50	20
None	D3 ditch	0.009809	0.02369	0.009809	0.0237
50%		-	0.01184	0.004903	0.01184
None	D4 pond	0.002365	0.004541	0.002365	0.0045
50%		-	0.002270	0.001183	0.002270
None	D4 stream	0.01079	0.02606	0.01079	0.0261
50%		-	0.01303	0.005393	0.01303
None	R1 pond	0.007671	0.004629	0.002973	0.0045
50%		-	0.002901	0.002075	0.002269
None	R1 stream	0.2475	0.05121	0.05121	0.0207
50%		-	0.05121	0.05121	0.01034

Table 8.9-23: Global maximum PEC_{sw} values for acetamiprid, following single application(s) of LEPTOSAR 200 SL to soybean according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid VFSmod	
Nozzle reduction	Vegetative strip (m)	20	30
	No spray buffer (m)	20	30
None	D3 ditch	0.0284	0.0193
None	D4 pond	0.0054	0.0041
None	D4 stream	0.0297	0.0201
None	R1 pond	0.0054	0.0041
None	R1 stream	0.0253	0.0171

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid	
Nozzle reduction	Vegetative strip (m)	!	!
	No spray buffer (m)	20	30
None	D3 ditch	0.02840	0.01925
50%		0.01420	!
None	D4 pond	0.005448	0.004148
50%		0.002724	!
None	D4 stream	0.02970	0.02013
50%		0.01484	!
None	R1 pond	0.005447	0.004147
50%		0.002724	!
None	R1 stream	0.02525	0.01711
50%		0.01685	!

Table 8.9-24: Global maximum PEC_{sw} values for acetamiprid, following single application(s) of LEPTOSAR 200 SL to pumpkin at BBCH>50 according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid VFSmod	
Nozzle reduction	Vegetative strip (m)	20	30
	No spray buffer (m)	20	30
None	D3 ditch	0.0284	0.0193
None	D4 pond	0.0055	0.0042
None	D4 stream	0.0275	0.0186
None	R1 pond	0.0055	0.0041
None	R1 stream	0.0253	0.0172

Table 8.9-25: Global maximum PEC_{sw} values for acetamiprid, following single application(s) of LEPTOSAR 200 SL to opium according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid VFSmod	
Nozzle reduction	Vegetative strip (m)	10	20
	No spray buffer (m)	10	20
None	D3 ditch	0.0273	0.0142
None	D4 pond	0.0041	0.0027
None	D4 stream	0.0302	0.0157
None	R1 pond	0.0041	0.0027
None	R1 stream	0.0243	0.0126

PEC _{sw} (µg/L)	Scenario	STEP 4 acetamiprid VFSmod	
Nozzle reduction	Vegetative strip (m)	-	-
	No spray buffer (m)	10	20
None	D3 ditch	0.02732	0.01420
None	D4 pond	0.004080	0.002725
None	D4 stream	0.03018	0.01568
None	R1 pond	0.004078	0.002724
None	R1 stream	0.02426	0.01260

Metabolites of acetamiprid

Table.8.9-22 PEC_{sw} for IC-0 calculated with STEPS 1-2 for following application to intended crops

FOCUS crop	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
	Step 1	Step 2	Step 1	Step 2
Miaze	5.1706	0.1570	5.3841	0.1625
Spring Cereals	3.4471	0.1116	3.5894	0.1157
Winter Oilseed rape	10.3413	0.1674	10.7681	0.1735
Spring Oilseed rape	5.1706	0.2299	5.3841	0.2401
Pumpkin	5.1706	0.2091	5.3841	0.2179
Pome fruits 1x50g as/ha	5.2285	1.0641	4.4867	1.0917
Tomato	0.0064	0.0014	0.0054	0.0009
Opium poppy	2.5853	0.1150	2.6920	0.1200
Pumpkin (>BBCH 50)	5.1706	0.1674	5.3841	0.1735
Soybean	14.0875	0.4945	5.8412	0.2055
Sunflower	4.3089	0.2263	4.4867	0.2370

Table.8.9-23 PEC_{sw} for IM 1-2 calculated with STEPS 1-2 for following application to intended crops

FOCUS crop	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
	Step 1	Step 2	Step 1	Step 2
Miaze	14.0875	0.2074	5.8412	0.0858
Spring Cereals	28.1750	0.3006	11.6823	0.1243
Winter Oilseed rape	28.1750	0.2335	11.6823	0.0967
Spring Oilseed rape	28.1750	0.3006	11.6823	0.1243
Pumpkin	14.0894	0.3379	5.8420	0.1403
Pome fruits 1x50g as/ha	12.3795	1.0259	4.8683	0.4225

Tomato	0.0150	0.0010	0.0058	0.0003
Opium poppy	7.0438	0.1950	2.9206	0.0810
Pumpkin (>BBCH 50)	14.0875	0.2335	5.8412	0.0967
Soybean	14.0875	0.4945	5.8412	0.2055
Sunflower	11.7396	0.4121	4.8676	0.1712

Table.8.9-24 PEC_{sw} for IM 1-4 calculated with STEPS 1-2 for following application to intended crops

FOCUS crop	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
	Step 1	Step 2	Step 1	Step 2
Miaze	13.3962	0.5240	22.1062	0.8602
Spring Cereals	8.9308	0.3998	14.7375	0.6579
Winter Oilseed rape	26.7925	0.5998	44.2125	1.6551
Spring Oilseed rape	13.3962	1.6611	22.1062	0.9868
Pumpkin	13.3962	0.9030	22.1062	1.4932
Pome fruits 1x50g as/ha	12.4962	2.2886	18.4219	3.6921
Tomato	0.0152	0.0020	0.0221	0.0019
opium	0.0810	0.5273	11.0531	0.8732
Pumpkin (>BBCH 50)	13.3962	0.5998	22.1062	0.9868
Soybean	13.3962	1.3579	22.1062	2.2527
Sunflower	11.1635	1.1316	18.4219	1.8773

Table.8.9-25 PEC_{sw} for IM 1-5 calculated with STEPS 1-2 for following application to intended crops

FOCUS crop	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
	Step 1	Step 2	Step 1	Step 2
Miaze	2.5173	0.1252	7.7508	0.3854
Spring Cereals	5.0346	0.2989	15.5016	0.9204
Winter Oilseed rape	5.0346	0.1502	15.5016	0.4624
Spring Oilseed rape	2.5173	0.3004	7.7508	0.9249
Pumpkin	2.5173	0.2503	7.7508	0.7707
Pome fruits 1x50g as/ha	2.5173	0.2503	7.7508	0.7707
Tomato	0.0025	0.0000	0.0078	0.0000
opium	1.2587	0.1502	3.8754	0.4624
Pumpkin (>BBCH 50)	2.5173	0.1502	7.7508	0.4624
Soybean	2.5173	0.4005	7.7508	1.2332
Sunflower	2.0978	0.3338	6.4590	1.0277

Table.8.9-26 PEC_{sw} for IB 1-1 calculated with STEPS 1-2 for following application to intended crops

FOCUS crop	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
	Step 1	Step 2	Step 1	Step 2
Miaze	6.5971	0.2241	-	-
Spring Cereals	4.3981	0.1557	-	-
Winter Oilseed rape	13.1943	0.2336	-	-

Spring Oilseed rape	6.5980	0.2905	-	-
Pumpkin	6.5980	0.2715	-	-
Pome fruits (1x50g as/ha)	6.9130	1.6844	-	-
Tomato	0.0086	0.0021	-	-
opium	3.2986	0.1452	-	-
Pumpkin (>BBCH 50)	6.5971	0.2336	-	-
Soybean	6.5971	0.3284	-	-
Sunflower	5.4976	0.2737	-	-

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Acetamiprid
Direct photolysis in air	Not studied - no data requested
Photochemical oxidative degradation in air	DT50 (h): 0.140 derived by the Atkinson model OH (12h) concentration assumed = 1.5×10^6 OH/cm ³
Volatilisation	Vapour pressure (Pa): 1.73-7 Pa at 50°C (expected to be less than 1×10^{-6} Pa at 25 °C) Henry's Law Constant (Pa.m ³ /mol): $< 5.3 \times 10^{-8}$ (25 °C)
Volatilisation from plant surfaces (BBA guideline)	<1% after 24 hours
Volatilisation from soil surfaces (BBA guideline)	<1% after 24 hours
Metabolites	No data

Taking into account acetamiprid vapour pressure $<10^{-5}$ Pa, no unacceptable volatilisation from plant and soil surfaces is anticipated. This was further confirmed in studies performed according to BBA guideline, where volatilisation after 24 hours was <1% from both, soil and plant, surfaces. Air DT50 <2 days indicates that acetamiprid is not persistent in the air and for this reason will not be a subject of the short- or long-term transport. On the basis of available data no unacceptable contamination of the atmosphere is expected following application of LEPTOSAR 200 SL according to the recommended use pattern.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4	Łożuk I.	2021	Calculation of the predicted environmental concentrations of acetamipryd and its metabolites in groundwater after application of LEPTOSAR 200 SL (FOCUS PEARL and FOCUS PELMO) CIECH Sarzyna S.A., Poland RS/04/21 non GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 9.2.4_01	Łożuk I.	2021	Calculation of the predicted environmental concentrations of acetamipryd and its metabolites in groundwater after application of LEPTOSAR 200 SL (FOCUS PEARL and FOCUS PELMO) CIECH Sarzyna S.A., Poland RR/17/21 non GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 9.2.5	Siwiec I.	2021	Calculation of the predicted environmental concentrations of acetamipryd and its metabolites in surface water and water sediment after application of LEPTOSAR 200 SL (STEPS 1-2 in FOCUS, SWASH, SWAN) CIECH Sarzyna S.A., Poland RS/05/21 non GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 9.2.5_01	Siwiec I.	2021	Calculation of the predicted environmental concentrations of acetamipryd and its metabolites in surface water and water sediment after application of LEPTOSAR 200 SL (STEPS 1-2 in FOCUS, SWASH, SWAN)_supplemental appendix CIECH Sarzyna S.A., Poland RS/18/21 non GLP Unpublished	N	CIECH Sarzyna S.A.

Appendix 2 Detailed evaluation of the new Annex II studies

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)