Table A7.5.3.1.2/01-2: Values of reproduction ability in Bobwhite Quail

Par ameter	Mean Measured Dietary Concentration (mg as/kg food)					
<u>-</u>	0 ppm	36 ppm	61 ppm	126 ppm	243 ppm	
Egg production (no. eggs laid/hen in 10 weeks)	42	50	39	44	42	
Percentage of cracked eggs	6	12	9	9	8	
Viability (per cent viable embryos of eggs set)	80	83	87	87	84	
Hatchability (per cent hatching of eggs set)	86	85	81	80	86	
Percentage of hatchings that survive to 14 days	95	92	95	83	96	
Number of 14-day old survivors per hen	22	28	23	26	23	
Eggshell thickness (mm)	0,35	0,35	0.34*	0.34	0.33*	
Mean eg gshell strength (kg)	0.99	0.99	0.91	0,94	1.04	

^{*}statistically significant ($p \le 0.05$), but in the absence of any effect on mean eggshell strength or percentage eggs cracked, the observation was not considered biologically significant

Table A7.5.3.1.2/01-3: Effects of imidacloprid on reproduction of birds

Test substance	Techn. as		
Test object	Bobwhite quail		
Exposure	20 weeks dietary		
Lowest observed effect concentration (LOEC) [mg as/kg feed]	243*		
No observed effect concentration (NOEC) [mg_as/kg_feed]	126*		

^{*} Results are based on body weights of male adults.

 $Table\ A7.5.3.1.2/01\ 4: \quad Calculation\ of\ the\ NOELlt\ (daily\ dietary\ dose)\ in\ avian\ reproduction\ studies\ based\ on\ the\ respective\ NOEClt\ (dietary\ concentration)$

Species	NOEC _{II} based on measured dietary concentration [mg as/kg diet]	Mean food consumption [g/bird/day]	Mean body mass of group animals [g/bird]	Daily amount of as ingested [mg as/bird]	NOEL _{II} based on Daily dietary dose (DDD) [mg as/kg bw/day]
Bobwhite quail	126	17.8	242	2.3	9.3
Mallard duck	128	113	1,240	14.5	11.7

Table A7.5.3.1.2/01-5: Validity criteria for bird reproduction test according to OECD 206

	Fulfilled	Not fulfilled
Mortality of control animals <10%	X	
Average number of 14-day-old survivors per hen in controls ≥ 14, 12 and 24 for mallard duck, bobwhite quail and Japanese quail	X	
Average eggshell thickness for the control group ≥ 0.34, 0.19 and 0.19 mm for mallard duck, bobwhite quail and Japanese quail	X	
Concentration of the test substance in the diet ≥ 80 % of the nominal concentration throughout the test period	X	

Effects on reproduction of birds

One generation reproduction study with mallard ducks

		1 REFERENCE	Official use only
1.1	Reference	PPP monograph: B.9.1.3, IIA 8.1.3/02	3400 0,440
1+1	Authors (year)	(1992)	
	Title	Technical NTN 33893: A one generation reproduction study with mallard ducks	
	Company, report No.	Bayer CropScience AG, Report-No.: 103813-1 BES Ref.: M-006730-02-1	
	Date	1992-09-03, Amended: 1993-06-03	
	Testing facility		
	Dates of work	November 12, 1991 – May 12, 1992	
	Test substance(s)	Molecule(s): imidacloprid Substance(s): Imidacloprid techn, (Batch-No.: 17129/90, 1030010)	
1.2	Data protection	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2			
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	Guideline study	EPA 71-4, OECD 206	
2.2	GLP	Yes (certified laboratory)	
2.3	Deviations	One minor deviation concerning measurement of room temperature	
		3 METHOD	
3.1	Test material	As given in section 2	
3.1.1	Lot/Batch number	Imidaeloprid, purity: 95.8 % (batch no.: 1030010/17129-90);	
3.1.2	2 Specification	Specification as given in section 2; stability guaranteed for the duration of the study.	
3.1.3	Purity		
3.1.4	Composition of Product	Not relevant for a.s.	
3.1.5	Further relevant properties	none	
3.1.6	Method of analysis	HPLC with UV detection, validation reported in A7.5.3.1.3/01	
3.2	Administration of the test substance	In diet, nominal (mean measured) dietary concentrations were 60 (61), 120 (128) and 240 (250) mg as/kg diet	

Effects on reproduction of birds

One generation reproduction study with mallard ducks

3.3	Testing procedure	
3.3.1	Test organisms	See Table A7.5.3.1.3/02-1.
3.3.2	Test system	Imidacloprid was administered in the diet to groups of 15 pairs of young adult Mallard ducks per treatment (22 weeks old at test initiation); nominal (mean measured) dietary concentrations were 60 (61), 120 (128) and 240 (250) mg as/kg diet administered for 20 weeks
3.3.3	Diet	Adult birds Agway Gamebird Ration, Wildlife International formula with test substance; offspring Teklad DU-11 Duck Starter without test substance
3.3.4	Test conditions	Per US EPA 71-4, OECD 206, no significant deviations noted by the RMS of the December 2005 91/414 DAR
3.3.5	Duration of the test	Approx. 29 weeks in 5 phases: 3 week acclimation; 8 week pre- photostimulation; 2 week pre-egg laying; 10 week egg laying; six week final incubation, hatching and 14 day offspring rearing
3.3.6	Test parameter	Feed consumption, body weight, clinical appearance, survival and
3.3.7	Examination / Observation	postmortem findings of the parental generation were monitored; effects on reproduction and first generation offspring were determined by measuring egg production, egg viability, 3-week embryo survival, hatchability and hatchling body weight, 14-day survival and survivor body weight and eggshell strength/thickness; a gross pathology was conducted.
3.3.8	Statistics	Bartlett's test or Levines test of equal variance, ANOVA using F distribution for parametric procedures followed by Dunnett's test as necessary, Kruskal Wallis test for non-parametric procedures followed by Dunn's summed rank test as necessary 4 RESULTS
4.1	Limit Test / Range finding test	Not performed
4.2	Results test substance	
4.2.1	Applied concentrations	nominal (mean measured) dietary concentrations were 60 (61), 120 (128) and 240 (250) mg as/kg diet

Effects on reproduction of birds

One generation reproduction study with mallard ducks

4.2.2 Effect data (Mortality and reproductivity)

There were no treatment-related mortalities and no clinical signs of toxicity. See Table A7.5.3.1.3/02-2 for reproductive parameters. There was a significant decrease in eggshell thickness and strength which became obvious at 250 mg as/kg diet. No treatment-related effects were observed upon the other examined reproductive parameters or on offsprings.

Based on these results, the no-observed-effect concentration (NOEC) for adult Mallard ducks exposed to technical NTN 33893 was 128 mg as/kg diet. The LOEC value was determined as 250 mg as/kg food (see Table A7.5.3.1.3/02-3).

As the endpoints of the chronic bird studies (NOEC) were determined related to the concentrations in avian diet, the diet-related endpoints [mg as/kg diet] had to be converted to endpoints based on the daily dietary dose (NOEL) [mg as/kg bw/day], in order to assess the long-term risk in compliance with SANCO/4145 (2002). This was performed in detail as demonstrated in A7.5.3.1.3/02-4.

- 4.2.3 Body weight
- 4.2.4 Food consumption
- 4.2.5 Results of residue analysis
- 4.2.6 Other effects

A significant decrease in body weight occurred in female adults at 250 mg as/kg diet. No other significant differences between the control group and treatment groups appeared in any parameter.

Gross pathology: Postmortem examination revealed no compound- or treatment-related lesions in any bird.

4.3 Results of controls

4.3.1 Number/
percentage of
animals showing
adverse effects

none

Not performed

4.3.2 Nature of adverse effects

none

5.1 Materials and methods

5 APPLICANT'S SUMMARY AND CONCLUSION

In a one generation reproduction study conducted according to OECD 206 and EPA FIFRA § 71-4, imidacloprid was administered in the diet to groups of 15 pairs of young adult Mallard ducks per treatment (22 weeks old at test initiation); nominal (mean measured) dietary concentrations were 60 (61), 120 (128) and 240 (250) mg as/kg diet administered for 20 weeks; feed consumption, body weight, clinical appearance, survival and postmortem findings of the parental generation were monitored; effects on reproduction and first generation offspring were determined by measuring egg production, egg viability, 3-week embryo survival, hatchability and hatchling body weight, 14-day survival and survivor body weight and eggshell strength/thickness; a gross pathology was conducted.

Effects on reproduction of birds

One generation reproduction study with mallard ducks

5.2 Results and discussion

There were no treatment-related mortalities and no clinical signs of toxicity.

A significant decrease in body weight occurred in female adults at 250 mg as/kg diet. No other significant differences between the control group and treatment groups appeared in any parameter.

Regarding reproduction parameters, a significant decrease in eggshell thickness and strength became obvious at 250 mg as/kg diet. No treatment-related effects were observed upon the other examined reproductive parameters or on offsprings.

Postmortem examination revealed no compound- or treatment-related lesions in any bird.

Based on these results, the no-observed-effect concentration (NOEC) for adult Mallard ducks exposed to technical NTN 33893 was 128 mg as/kg diet. The LOEC value was determined as 250 mg as/kg food.

5.2.1 NOEC

128 mg as/kg food

5.3 Conclusion

In a study meeting the validity criteria, the no observed effect concentration NOEC for Mallard ducks exposed to imidacloprid tech. in the diet was 128 mg as/kg feed.

5.3.1 Reliability

5.3.2 Deficiencies

No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006/11/27
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version is acceptable.
Conclusion	Applicant's version can be adopted.
Reliability	1
Acceptability	acceptable
Remarks	A Miles

Section 7.5.3.1.3/02 Effects on reproduction of birds Annex Point IIIA XIII 1.3

One generation reproduction study with mallard ducks

COMMENTS FROM ... (specify) Date Give date of comments submitted Materials and Methods Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state Results and discussion Discuss if deviating from view of rapporteur member state Conclusion Discuss if deviating from view of rapporteur member state Reliability Discuss if deviating from view of rapporteur member state Acceptability Discuss if deviating from view of rapporteur member state Remarks

Table A7.5.3.1.3/02-1: Test animals

Criteria	Details
Species/strain	Anus platyrhynchos
Source	Whistling wings Inc. Hanover, IL USA
Age (in weeks), sex and initial body weight (bw)	Approx 22 weeks at test initiation, males and females, weight at start of study ranging from approx 1.05-1.25 kg for females and 1.15-1.45 kg for males (control group values)
Age range within the test	Approx 22 to 42 weeks (adult birds sacrificed at end of 20 week adult exposure period)
Breeding population	Approaching first breeding season when received
Amount of food	Ad libitum
Age at time of first dosing	Approx 22 weeks
Health condition / medication	healthy
Pre-treatment	No adverse effects noted

Table A7.5.3.1.3/02-2: Values of reproduction ability in Mallard Duck

	Mean Measured Dietary Concentration (mg as/kg food)					
Parameter						
	0 ppm	61 ppm	128 ppm	250 ppm		
Egg production (no. eggs laid/hen in 10 weeks)	43	49	40	41		
Percentage of cracked eggs	2	5	7*	5		
Viability (per cent viable embryos of eggs set)	96	94	90	94		
Hatchability (per cent hatching of eggs set)	95	94	93	90		
Percentage of hatchings that survive to 14 days	99	99	97	99		
Number of 14-day old survivors per hen	35	38	29	30		
Eggshell thickness (mm)	0.45	0.44	0.44	0,43*		
Mean eggshell strength (kg)	2,94	2.86	2.79	2,68**		

^{*}statistically significant (Dunnett's one-tailed, $p \le 0.05$)

Table A7.5.3.1.3/02-3: Effects of imidacloprid on reproduction of birds

Test substance	Tech. as
Species	Mallard duck
Exposure	20 weeks dietary
Lowest observed effect concentration (LOEC) [mg as/kg feed]	250 *
No observed effect concentration (NOEC) [mg as/kg feed]	128

^{*} Values based on effects on adult ducks and eggshell thickness

Table A7.5.3.1.2/02-4: Calculation of the NOELlt (daily dietary dose) in avian reproduction studies based on the respective NOEClt (dietary concentration)

Species	NOEC _{lt} based on measured dietary concentration [mg as/kg diet]	Mean food consumption [g/bird/day]	Mean body mass of group animals [g/bird]	Daily amount of as ingested [mg as/bird]	NOEL _{lt} based on Daily dietary dose (DDD) [mg as/kg bw/day]
Bobwhite quail	126	17.8	242	2.3	9.3
Mallard duck	128	113	1,240	14.5	11.7

^{**}statistically significant (Dunnett's one-and two-tailed, $p \le 0.05$)

Bayer Environmental Science

	Fulfilled	Not fulfilled
Mortality of control animals <10%	X	
Average number of 14-day-old survivors per hen in controls ≥ 14, 12 and 24 for mallard duck, bobwhite quail and Japanese quail	X	
Average eggshell thickness for the control group ≥ 0.34, 0.19 and 0.19 mm for mallard duck, bobwhite quail and Japanese quail	X	
Concentration of the test substance in the diet ≥ 80 % of the nominal concentration throughout the test period	X	

Bayer Environmental Science	Imidacloprid	April 2006

Section	A7	.5.4	.1/	01
Annex Po	intl	TIA	XП	T.3

Effects on honeybees

Acute toxicity to Apis mellifera

Official use only

REFERENCE

1.1 Reference PPP monograph: B.9.4.1, II A, 8.3.1.1 /01

Authors (year) (1990)

Title The acute oral and contact toxicity to honey bees of compound NTN

33893 technical

Bayer CropScience AG, Report-No.: BAY 158/901384 Company, report No.

BES Ref.: M-006940-02-1

Date 1990-12-28, Amended: 1994-01-06

Testing facility

Dates of work August 21, 1990 - August 25, 1990

Test substance(s)

Molecule(s): imidacloprid

1.2 Data protection Yes

Bayer CropScience AG 1.2.1 Data owner

1.2.3 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s. for the

purpose of its entry into Annex I/IA

GUIDELINES AND QUALITY ASSURANCE 2

2.1 Guideline study United Kingdom Control of Pesticides Regulations 1986 protocol; EPA

guideline 141-1

2.2 GLP Yes(certified laboratory)

2.3 Deviations No

3 MATERIALS AND METHODS

3.1 Test material As given in Section 2

Imidacloprid, batch 890315ELB 01, purity 99.8%. 3.1.1 Lot/Batch number

Specification as given in section 2; stability guaranteed for the duration 3.1.2 Specification

of the study.

3.1.3 Description

3.1.4 Purity

3.1.5 Stability

3.2 Test design

3.2.1 Administration Oral, test substance in sucrose solution offered ad libitum and contact,

test substance dissolved in dimethylformamide (DMF) placed on the

thorax of each bee

oral: 0.025; 0.0125; 0.0063; 0.0031; 0.0015 µg/ bee 3.2.2 Doses

contact: 0.40; 0.20; 0.10: 0.05; 0.025 µg/ bee

tested

3.2.3 Number of organisms 2 X 10 bees (10 bees/ a wire mesh cage)

3.2.4 Test duration 48 h

Bayer	Environmental Scien	ce Imidacloprid	April 2006
Secti	on A7.5.4.1/01	Effects on honeybees	
	x PointIIIAXIII.3	Acute toxicity to Apis mellifera	
225	Defending instantage		
3.2.5	Reference substance Control	Not included	
3.2.6	Control	Oral: untreated sucrose	
207	3.0	Contact: DMF, 1 µl droplet	
3.2.7	Measurements	Mortality at 24 and 48h	
		4 RESULTS	
4.1	Findings	See Table A7.5.4.1/01-1	
		The 48 hour LD50 values were computed from the mortality probit analysis with Abbots correction for control mortality.	data by
		LD50 oral (48h) 0.0037 µg/ bee, LD50 contact (48 h) 0.081	μg/ bee
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5,1	Materials and methods	In a study conducted according to United Kingdom Control of Regulations 1986 protocol; EPA guideline 141-1, honeybees of exposed to imidacloprid orally (via test substance in sucrose solevels of 0, 0.025; 0.0125; 0.0063; 0.0031; 0.0015 µg/ bee) or (imidacloprid dissolved in DMF at levels of 0, 0.40; 0.20; 0.10 0.025 µg/ bee and applied topically). Mortality was assessed of hours.	were olution at r by contact 0: 0.05;
5.2	Results and discussion	Mortalities occurred in every treatment group and in the oral group. The 48 hour LD50 values were computed from the m by probit analysis with Abbots correction for control mortali	ortality data
		LD50 oral (48h) 0.0037 µg/ bee	2/
		LD50 contact (48 h) 0.081 µg/ bee	
5.3	Conclusion	Imidacloprid a.s. is very toxic to bees by both ingestion and	contact.
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	
		Evaluation by Competent Authorities	
		Use separate "evaluation boxes" to provide transparency as views submitted	to the comments and
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		2006/11/27	
Mate	rials and Methods	Applicant's version is acceptable.	
Resul	ts and discussion	Applicant's version is acceptable.	
Conc	lusion	Applicant's version can be adopted.	
Relial	bility	1	
Accep	otability	acceptable	

Remarks

Bayer Environmental Science	Imidacloprid	April 2006
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Section A7.5.4.1/01	Effects on honeybees	
Annex PointIIIAXIII.3	Acute toxicity to Apis mellifera	

	COMMENTS FROM
Date	Give date of the comments submitted
Materials and Methods	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state
Results and discussion	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state

Table A7.5.4.1/01-1 Mortality of bees after oral and contract treatment with imidacloprid

Route	μg/ bee	Number of bees	% mortality 24 hours	% mortality 48 hours
	0.025	20	95	100
	0.0125	20	75	90
Oral	0.0063	20	45	65
	0.0031	20	40	50
	0.0015	20	15	20
	Control	20	5	5
	0.40	20	75	95
	0.20	20	55	80
Contact	0.01	20	35	55
	0.05	20	20	30
	0.025	20	15	20
	Control	20	0	0

Imidacloprid	April 2006
	Imidacloprid

Section A7.5.4.1/02 Annex PointIIIAXIII.3

Effects on honeybees

Acute toxicity to Apis mellifera

Official use only

REFERENCE

1.1 Reference PPP monograph: B.9.4.1, II A, 8.3.1.1 /04

Authors (year) (1999)

Title Laboratory testing for toxicity (acute oral LD50) of NTN 33893 on

honey bees (Apis mellifera L.) (Hymenoptera, Apidae)

Company, report No. Bayer CropScience AG, Report-No.: 6400036

BES Ref.: M-016942-01-1

Date 1999-09-30

Testing facility

Dates of work July 06, 1999 to July 10, 1999 Test substance(s) Molecule(s): imidacloprid

Substance(s): Imidacloprid (Batch-No.: M00680)

1.2 Data protection Yes

1.2.1 Data owner Bayer CropScience AG

1.2.3 Criteria for data Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA protection

GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study EPPO No. 170

2.2 GLP Yes(certified laboratory)

temperature: 29 °C; relative humidity: 50 - 70 % instead of 25 ° C ± 2 ° 2.3 **Deviations**

C and relative humidity of 60 -70 % as indicated in the guideline

MATERIALS AND METHODS 3

3.1 Test material As given in Section 2

Imidaeloprid, batch M00680, purity 99.4%. 3.1.1 Lot/Batch number

Specification as given in section 2; stability guaranteed for the duration 3.1.2 Specification

of the study.

3.1.3 Description

3.1.4 Purity

3.1.5 Stability

3.2 Test design

3.2.1 Administration Single oral dose

40.9; 22.9; 12.2; 6.0; 3.1; 1.5; 0.8 and 0.1 ng/bee 3.2.2 Doses

3.2.3 Number of organisms 3 X 10 bees (10 bees/ a wire mesh cage)

tested

3.2.4 Test duration 48 h, but extended to 96 h

Bayer	Environmental Scien	nce Imidacloprid A	pril 2006
	on A7.5.4.1/02 x PointIIIAXIII.3	Effects on honeybees Acute toxicity to Apis mellifera	
3.2.5	Reference substance	dimethoate	
3.2.6	Control	untreated sucrose	
3.2.7	Measurements	Mortality and behavioural impact at 1, 4, 24, 48, 72 and 96 h	X
		4 RESULTS	
4.1	Findings	See Table A7.5.4.1/02-1	
		No treatment-related mortalities or behavioural impacts were recorded at or below 1.5 ng/bee. Oral doses of 3.1 ng/bee and higher caused mortalities and behavioural impacts such as apathy and un-coordinated movements.	
		In the control, 3 bees died, whereas all bees died in groups treated with the toxic standard dimethoate.	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5,1	Materials and methods	In a study conducted according to EPPO No. 170, fasted honeybees were given a single oral dose of imidacloprid in sucrose solution at levels of 40.9; 22.9; 12.2; 6.0; 3.1; 1.5; 0.8 and 0.1 ng/ bee. Mortality and behavioural impact were monitored at 1, 4, 24, 48, 72 and 96 hours. Dimethoate was tested as the reference standard. Sugar solution was administered as control.	
5.2	Results and discussion	No treatment-related mortalities or behavioural impacts were recorded at or below 1.5 ng/bee. Oral doses of 3.1 ng/bee and higher caused mortalities and behavioural impacts such as apathy and un-coordinated movements.	
		The 48 hour LD50 value was determined to be 0.049 μ g/ bee	
5.3	Conclusion	Imidacloprid a.s. is very toxic to honeybees by ingestion.	
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

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Bayer Environmental Science	lmidaeloprid	April 2006

Section A7.5.4.1/02	Effects on honeybees
Annex PointIIIAXIII3	Acute toxicity to Apis mellifera

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006/11/28
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version is acceptable.
Conclusion	Applicant's version can be adopted.
Reliability	1
Acceptability	acceptable
Remarks	
	COMMENTS FROM
Date	Give date of the comments submitted
Materials and Methods	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state
Results and discussion	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state

Table A7.5.4.1/02-1: Acute oral toxicity of NTN 33893 to honey bees

	LD ₃₀ oral (48 h):	
NTN 33893	0 049 µg bee	
dimethoate	0.14+ µg / bee	
sugar solution	no mortality	

Section A7.5.4.1/03 Annex PointIIIAXIII.3

Effects on honeybees

Field study on the potential impact of residues in plantback crops grown in fields previously treated with imidacloprid to honeybees

Official use only

1 REFERENCE

1.1 Reference PPP monograph: B.9.4.5g

Authors (year) (2002):

Title Imidacloprid (Admire) residue levels following in-furrow application in

potato fields in Prince Edward Island and New Brunswick

Company, report No. Bayer CropScience AG, Report-No.MO-02-006773

BES Ref.: M-061850-01-1

ate 2002

Testing facility

protection

Test substance(s) Molecule(s): imidacloprid, tested as Admire 240 F

1.2 Data protection Yes

1.2.1 Data owner Bayer CropScience AG

1.2.3 Criteria for data Data submitted to the MS after 13 May 2000 on existing a.s. for the

purpose of its entry into Annex I/IA

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study EPA-FIFRA section 40-CFR part 160 (appendix A)

2.2 GLP Yes

2.3 Deviations None noted

3 MATERIALS AND METHODS

3.1 Test material

3.1.1 Lot/Batch number Imidacloprid formulation Admire 240 F (240 g/l a.s.), a.s. content within manufacturing control level

3.1.2 Specification

3.1.3 Description

3.1.4 Purity

3.1.5 Stability

3.2 Test objective for T.
PPP uses its

The aim of the investigations was to detect residues of imidacloprid and its metabolites in replanted crops and in honey and pollen of honeybee colonies foraging on the replanted crops and the possible impact of

these residues on the foraging colonies.

3.2.1 Relevance to BP use The nature of the objective is consistent with the need to understand the

potential risk to bees foraging near grassland treated with or on crops replanted in α arable soil amended with potentially contaminated manure from 0.5% imidacloprid granule biocidal product use in animal houses.

3.2.2 Test design

The aim of the investigations was to detect residues of imidacloprid and its metabolites in replanted orders in honory and realism of honoryhou

its metabolites in replanted crops in honey and pollen of honeybee colonies foraging on the replanted crops and the possible impact of these residues on the foraging colonies. For these investigations in

Section A7.5.4.1/03 Annex PointIIIAXIII.3

Effects on honeybees

Field study on the potential impact of residues in plantback crops grown in fields previously treated with imidacloprid to honeybees

Prince Edward Island 18 and in New Brunswick 5 field locations were chosen. Regarding the application of imidacloprid respectively the development of imidacloprid residues the fields can be divided into 3 categories:

year 1 fields: potato fields with an Admire 240 F in furrow application (850 mL/ha) in spring 2001

year 2 fields: underseeded grain fields with seed treatment of Admire 240 F (850 mL/ha, respectively 1300 mL/ha) in spring 2000

The fields were underseeded with a mixture of *Trifolium pratense*, *Trifolium hybridum* and *Phleum pratense*.

year 3 fields: first and second flowering clover fields with a foliar application of Admire 240 F in spring 1999

The design included 2 untreated fields as control fields.

3.2.3 Test procedure

At each of 4 second bloom clover fields 8 honeybee colonies were placed and another 8 colonies were placed at the control field. At the first assessment (25-27 July) all colonies were equalised (i.e. similar strength, quantities of food stores, brood and adults covering at least 10 frames).

Sampling:

soil: From each of 11 fields composite samples consisting of 160 soil cores were taken. Additional from 7 run off fields composite samples consisting of 20 soil cores were taken.

clover flowers: From each of 8 fields composite samples consisting of 80 clover flowers were collected in Prince Edward Island and on 5 fields in New Brunswick.

clover leaves: From each of 8 fields in Prince Edward Island composite samples of 400 leaves were collected. In New Brunswick composite samples of 160 leaves were collected in 5 fields.

wild flowers: From 7 run off fields composite samples of 20 soil cores were taken near the base of wild flower plants. Moreover from these wild flower species (Solidago canadensis, Epilobium angustifolium, Aster novi-belgii) flower samples of 40 g were taken in each field.

honeybees: On each of the second bloom treated and control clover fields honeybees were collected from late July to early September. Bees were immediately deep frozen on dry ice for transporting to the laboratory. There the bees were sorted according to nectar and pollen loads.

Colony assessments: Two colony assessments were performed, the first on 26.-27. July 2001 and the second on 14.-15. September 2001. The assessment included colony strength, brood status, honey storage, behaviour of the bees, diseases (American foulbrood, European foulbrood, sackbrood, chalkbrood, Varroa)

Section A7.5.4.1/03 Annex PointIIIAXIII.3

Effects on honeybees

Field study on the potential impact of residues in plantback crops grown in fields previously treated with imidacloprid to honeybees

4 RESULTS

4.1 Findings

All colonies placed in the treated clover fields developed normally and did not show any impact of the test product on colony strength, brood status, honey storage and behaviour. Few colonies showed symptoms of chalkbrood, Varroa and European foulbrood.

Residues of imidacloprid were detected in the soils of all treated fields, ranging from <2 ppb (parts per billion) to 38 ppb. Samples from underseeded grain fields (year 2 fields) ranged from 16 to 38 ppb. Samples from first flowering clover fields (year 3 fields) ranged from 16 to 38 ppb (average 24.6 ppb). Samples from second flowering clover fields ranged from 14 to 25 ppb (average 20 ppb). The edges of sloped fields in the first year rotation (i.e. potato fields) exhibited only one case of residue in soil. These fields had residue levels of imidacloprid in clover leaves at just above the LOD.

Otherwise all clover flowers, wildflowers pollen, nectar and uncapped honey did not have any detectable levels of imidacloprid or its hydroxy and olefine metabolites.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

In a study with analysis conducted according EPA-FIFRA section 40-CFR part 160 (appendix A), a field investigation was conducted to determine the level of residues of imidacloprid and its metabolites in replanted crops and in honey and pollen of honeybee colonies foraging on the replanted crops and the possible impact of these residues on the foraging colonies.

5.2 Results and discussion

Residues of imidacloprid were detected in the soils of all treated fields. Soil levels from first and second flowering clover fields were on average between 20 and 24.6 ppb. Therefore, the potential for plant uptake and movement into plant parts foraged by bees was present. Clover leaves were found to have low levels of active substance, but all clover flowers, wildflowers pollen, nectar and uncapped honey did not have any detectable levels of imidacloprid or its hydroxy and olefine metabolites. This suggests a low potential for aged soil residues to move into plants, particularly the flowering parts.

All colonies placed in the treated clover fields developed normally and did not show any impact of the test product on colony strength, brood status, honey storage and behaviour.

The biocidal product PECsoil values (calculated with Tier 1 assumptions, no refinement) for grassland and arable fields spread with manure/manure slurry from animal houses treated with an 0.5% imidacloprid granule product are less than 10 ppb. Therefore, this study demonstrating the lack of adverse impact on honeybees foraging clover fields grown in soils having more than double the worst case soil levels predicted for the biocidal product use indicates no risk is to be expected to bees foraging bee attractive crops grown in arable land that has received manure from the imidacloprid granule treated animal houses.

5.3 Conclusion

No risk is to be expected to bees foraging bee attractive crops grown in arable land that has received manure from the imidacloprid granule treated animal houses.

Bayer Environmental Sci	nce Imidacloprid	April 2006
Section A7.5.4.1/03	Effects on honeybees	
Annex PointIIIAXIII.3	Field study on the potential impact of residues i in fields previously treated with imidacloprid to	
5.3.1 Reliability	1	
532 Deficiencies	No	

	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2007/04/23	
Materials and Methods	Applicant's version is acceptable.	
Results and discussion	Applicant's version can be adopted.	
Conclusion	Applicant's version can be adopted.	
Reliability	1	
Acceptability	acceptable	
Remarks	e . T	
	COMMENTS FROM	
Date	Give date of the comments submitted	
Materials and Methods	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state	
Results and discussion	Discuss if deviating from view of rapporteur member state	
Conclusion	Discuss if deviating from view of rapporteur member state	
Reliability	Discuss if deviating from view of rapporteur member state	
Acceptability	Discuss if deviating from view of rapporteur member state	

Section A7.5.4.1/04 Annex PointIIIAXIII.3

Effects on honeybees

Field study on the potential impact of residues in sunflowers grown in fields previously treated with imidacloprid to honeybees

Official REFERENCE use only

1.1 Reference

PPP monograph: B.9.4.4h

Authors (year)

(1999a)

Title

Residue Levels of Imidacloprid and Imidacloprid Metabolites in Nectar, Blossoms and Pollen of Sunflowers Cultivated on Soils with Different Imidacloprid Residue Levels and Effects of these Residues on Foraging Honeybees. 1999.

Company, report No.

Bayer CropScience AG, Report-No. SXR/AM 007.

BES Ref.: M-016827-01-1

Date

28 September 1999

Testing facility Dates of work

23 July-21 September 1999

Test substance(s)

Molecule(s): imidacloprid

1.2 **Data protection** Yes

1

1.2.1 Data owner

Bayer CropScience AG

1.2.3 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA

GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

No guideline

2.2 GLP Yes

2.3 **Deviations**

Not applicable

MATERIALS AND METHODS 3

3.1 Test material

3.1.1 Lot/Batch number

Imidacloprid Gaucho WS 70 formulations, a.s. content within manufacturing control level

3.1.2 Specification

3.1.3 Description

3.1.4 Purity

3.1.5 Stability

3.2 Test objective for PPP uses

The aim of the investigations was to determine the level of residues of imidacloprid and its metabolites in sunflowers grown in previously treated fields and in honey and pollen of honeybee colonies foraging on the crop and the possible impact of these residues on the foraging colonies.

3.2.1 Relevance to BP use

The nature of the objective is consistent with the need to understand the potential risk to bees foraging near grassland treated with or on crops replanted in arable soil amended with potentially contaminated manure from 0.5% imidacloprid granule biocidal product use in animal houses.

Section A7.5.4.1/04 Annex PointIIIAXIII.3

Effects on honeybees

Field study on the potential impact of residues in sunflowers grown in fields previously treated with imidacloprid to honeybees

3.2.2 Test design

Previous treatments on the plots:

<u>Control plot</u>: untreated grass area since 1996. Drilled with imidacloprid free sunflower seed on 12 May 1999.

<u>Variant "1997":</u> cropped in fall 1997 with Gaucho treated winter wheat (77 g as/ha), sprayed on 24 April 1999 with 71.5 g/ha Gaucho WS 70 (=50 g as/ha imidacloprid; batch no. 233 614 749, 72.5 % imidacloprid according to FAR no. 559-01). Drilled with imidacloprid-free sunflower seed on 12 May 1999.

Variant "1998": cropped in spring 1996 with Gaucho treated sugar beet (111 g ai/ha), followed in fall 1998 by Gaucho treated winter barley (49 g as/ha). Drilled with imidacloprid-free sunflower seed on 12 May 1999. Variant "1998 (2x)": cropped in spring 1998 with Gaucho traeted sugar beet (105 g as/ha), followed by Gaucho treated winter wheat (76 g as/ha). Drilled with imidacloprid-free sunflower seed on 12 May 1999. Variant "1999": untreated grass area since 1996. Drilled with Gaucho WS 70 treated sunflower seed on 12 May 1999 (52 g as/ha).

3.2.3 Test procedure

Small honeybee colonies of about 2000-3000 individuals were caged for 8 days on sunflower plots (plot size about 50 m2). The different imidacloprid treatments in the plots are described above. The assessment criteria included mortality, behavioral anomalies, colony development and brood status.

For residue analysis from all plots the following types of samples had been taken:

- soil sample (0-30 cm depth)
- leaves (produced latest)
- flowers (male/female)
- nectar (sampled from the hive combs)
- pollen (sampled from the hive combs)
- pollen (sampled from the plants)
- honeybees (exposed to the sunflowers)

See Table A7.5.4.1/04-1 for residue limits of analysis.

4 RESULTS

4.1 Findings

No treatment related mortality or impact on the behaviour of the bees x was observed in the test colonies.

While in the soil samples of the variants 1997, 1998 and 1998 (2x) imidacloprid had been detected in levels of 0.016, 0.013 and 0.014 mg/kg, the soil samples of the control plot and variant 1999 were imidacloprid free.

In the leave sample of variant 1999 imidacloprid residues of 0.006 mg/kg were detected. In all other samples the possible residues of imidacloprid were below the limit of detection:

Section A7.5.4.1/04 Annex PointIIIAXIII.3

Effects on honeybees

Field study on the potential impact of residues in sunflowers grown in fields previously treated with imidacloprid to honeybees

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

A field investigation was conducted under GLP to determine the level of residues of imidacloprid and its metabolites in sunflowers grown in previously treated fields and in honey and pollen of honeybee colonies foraging on the crop and the possible impact of these residues on the foraging colonies.

5.2 Results and discussion

Residues of imidacloprid were detected in the soil of 3 plots at levels of 0.013 to 0.016 mg/kg. Therefore, the potential for plant uptake and movement into plant parts foraged by bees was present.

No treatment related mortality or impact on the behaviour of the bees was observed in the test colonies.

2

No residues of imidacloprid were found in sunflower flowers or pollen or in honeybees, nectar or pollen taken from exposed hives.

The biocidal product PECsoil values (calculated with Tier 1 assumptions, no refinement) for grassland and arable fields spread with manure/manure slurry from animal houses treated with an 0.5% imidacloprid granule product are less than 10 ppb. Therefore, this study demonstrating the lack of adverse impact on honeybees foraging sunflowers grown in soils having almost double the worst case soil levels predicted for the biocidal product use indicates no risk is to be expected to bees foraging bee attractive crops grown in arable land that has received manure from the imidacloprid granule treated animal houses.

5.3 Conclusion

No risk is to be expected to bees foraging bee attractive crops grown in arable land that has received manure from the imidacloprid granule treated animal houses.

5.3.1 Reliability

1

5.3.2 Deficiencies

No

Section A7.5.4.1/04 Annex PointIII AXIII.3

Effects on honeybees

Field study on the potential impact of residues in sunflowers grown in fields previously treated with imidacloprid to honeybees

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 2007/04/23

Materials and Methods Applicant's version is acceptable.

Results and discussion Applicant's version can be adopted with the following comment:

Differences in foraging activity and mortality compared to the control were observed for some treatments: foraging activity averaged 143, 61, 116, 48 and 252 honeybees per 100 sunflower heads in the control, test variants "1997", "1998", (1998 (2x)" and "1999". However, the differences observed are most likely attributed to the differences in the number of actually flowering sunflower heads within the different plots. There was no relation between foraging activity and treatment. Mortality figures were 11, 20, 26, 141 and 28 honeybees for the control, test variants "1997", "1998", (1998 (2x)" and "1999". The site-specific peak mortality of variant "1998 (2x)" is most likely due to an earlier exhausting of the sunflowers since this plot has to be equipped prematurely with a bee colony due to earlier peak flowering. There are 4 observations which supports the latter assumption: 1) mortality figures are not related to soil residue levels; 2) there were no detectable residues in either the nectar nor the pollen of the sunflower plants; 3) no behaviour abnormalities were observed; 4) the "1998 (2x)" colony did not show any difference compared to the others during the final check for colony strength and brood development.

In summary it can be concluded that honeybees were not adversely affected by

any of the examined exposure scenarios.

Conclusion Applicant's version can be adopted.

Reliability 1

Acceptability acceptable

Remarks -

COMMENTS FROM

Date Give date of the comments submitted

Materials and Methods Discuss additional relevant discrepancies referring to the (sub)heading numbers

and to applicant's summary and conclusion.

Discuss if deviating from view of rapporteur member state

Results and discussion Discuss if deviating from view of rapporteur member state

Conclusion Discuss if deviating from view of rapporteur member state

Reliability Discuss if deviating from view of rapporteur member state

Acceptability Discuss if deviating from view of rapporteur member state

Table A7.5.4.1/04-1: Residue levels of imidacloprid and imidacloprid metabolites

	rod	LOD
soil samples	0.006 mg/kg	0.002 mg/kg
biological samples	0.005 mg/kg for imidacloprid and hydroxy- metabolite 0.01 mg/kg for olefine-metabolite.	0.0015 mg/kg and 0.003 mg/kg respectively

Section A7.5.4.1/05 Annex PointIIIAXIII.3

Effects on honeybees

Field study on the potential impact of residues in sunflowers grown in fields previously treated with imidacloprid to honeybees

REFERENCE

Official use only

1.1 Reference

PPP monograph: B.9.4.4i

Authors (year)

(1999b)

Title

Residue Levels of Imidacloprid and Imidacloprid Metabolites in Nectar, Blossoms and Pollen of Sunflowers Cultivated on Soils with Different Imidacloprid Residue Levels and Effects of these Residues on Foraging

1999. Honeybees.

Company, report No.

Bayer CropScience AG, Report-No. SXR/AM 006.

BES Ref.: M-016820-01-1

Date

27 September 1999

Testing facility Dates of work

25 July-21 September 1999

Test substance(s)

Molecule(s): imidacloprid

1.2 **Data protection**

Yes

1.2.1 Data owner

Bayer CropScience AG

1.2.3 Criteria for data

protection

Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA

GUIDELINES AND QUALITY ASSURANCE 2

2.1 Guideline study

No guideline

2.2 GLP Yes

2.3 Deviations Not applicable

3 MATERIALS AND METHODS

3.1 Test material

3.1.1 Lot/Batch number

Imidacloprid Gaucho WS 70 formulations, a.s. content within manufacturing control level

3.1.2 Specification

3.1.3 Description

3.1.4 Purity

3.1.5 Stability

3.2 Test objective for PPP uses

The aim of the investigations was to determine the level of residues of imidacloprid and its metabolites in sunflowers grown in previously treated fields and in honey and pollen of honeybee colonies foraging on the crop and the possible impact of these residues on the foraging colonies.

3.2.1 Relevance to BP use

The nature of the objective is consistent with the need to understand the potential risk to bees foraging near grassland treated with or on crops replanted in arable soil amended with potentially contaminated manure from 0.5% imidacloprid granule biocidal product use in animal houses.

Bayer Environmental Scientific Environmental Environmental Scientific Environmental Environmen	nce Imidacloprid	April 200
Section A7.5.4.1/05 Annex PointIIIAXIII.3	Effects on honeybees Field study on the potential impact of residues in sunflowers g	grown in
	fields previously treated with imidacloprid to honeybees	
3.2.2 Test design	Previous treatments on the plots: Control plot: untreated grass area since 1996. Drilled with in free sunflower seed on 10 May 1999. Variant "1997": cropped in fall 1997 with Gaucho treated with (59 g as/ha), sprayed on 30 April 1999 with 71.5 g/ha Gauch (=50 g as/ha imidacloprid; batch no. 233 614 749, 72.5 % in according to FAR no. 559-01). Drilled with imidacloprid-free seed on 10 May 1999. Variant "1998": cropped in fall 1998 with Gaucho treated with (52 g as/ha). Drilled with imidacloprid-free sunflower seed on 1999. Variant "1999": untreated grass area since 1996. Drilled with WS 70 treated sunflower seed on 10 May 1999 (45 g as/ha).	inter wheat sho WS 70 nidacloprid sunflower nter barley on 10 May
3.2.3 Test procedure	Small honeybee colonies of about 2000-3000 individuals wer sunflower plots (plot size about 50 m2). The different in treatments in the plots are discribed above. The assessme included mortality and behavioral anomalies. For residue analysis from all plots the following types of sabeen taken: - soil sample (0-30 cm depth) - leaves (produced latest) - flowers (male/female) - nectar (sampled from the hive combs) - pollen (sampled from the plants) - honeybees (exposed to the sunflowers) See Table A.7.5.4.1/04-1 for analytical limits	nidacloprid ent criteria

RESULTS

4.1 **Findings**

No treatment related mortality or impact on the behaviour of the bees was observed in the test colonies.

Residues of imidacloprid have been detected in the soil samples:

- Variant "1997"; 0.018 mg/kg Variant "1998"; < LOQ Variant "1999"; < LOD

In the leave samples of variant 1999 residues of imidacloprid were detected on the level of 0.007 mg/kg.

Section A7.5.4.1/05 Annex PointIIIAXIII.3

Effects on honeybees

Field study on the potential impact of residues in sunflowers grown in fields previously treated with imidacloprid to honeybees

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

A field investigation was conducted under GLP to determine the level of residues of imidacloprid and its metabolites in sunflowers grown in previously treated fields and in honey and pollen of honeybee colonies foraging on the crop and the possible impact of these residues on the foraging colonies.

5.2 Results and discussion

Residues of imidacloprid were detected in the soil of Vaiant 1997 plot at a 0.018 mg/kg (ppb) level. In the leave samples of variant 1999 residues of imidacloprid were detected on the level of 0.007 mg/kg.

Therefore, the potential for plant uptake and movement into plant parts foraged by bees was present.

No treatment related mortality or impact on the behaviour of the bees was observed in the test colonies.

No residues of imidacloprid were found in sunflower flowers or pollen or in honeybees, nectar or pollen taken from exposed hives.

The biocidal product PECsoil values (calculated with Tier 1 assumptions, no refinement) for grassland and arable fields spread with manure/manure slurry from animal houses treated with an 0.5% imidaeloprid granule product are less than 10 ppb. Therefore, this study demonstrating the lack of adverse impact on honeybees foraging sunflowers grown in soils having almost double the worst case soil levels predicted for the biocidal product use indicates no risk is to be expected to bees foraging bee attractive crops grown in arable land that has received manure from the imidaeloprid granule treated animal houses.

5.3 Conclusion

No risk is to be expected to bees foraging bee attractive crops grown in arable land that has received manure from the imidacloprid granule treated animal houses.

5.3.1 Reliability

1

5.3.2 Deficiencies

No

	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2007/04/23	
Materials and Methods	Applicant's version is acceptable.	
Results and discussion	Applicant's version can be adopted.	
Conclusion	Applicant's version can be adopted.	
Reliability	1	
Acceptability	acceptable	
Remarks	Q = 1	

Bayer Environmental Scientific Environmental Environm	nce Imidacloprio	d April	200
Section A7.5.4.1/05	Effects on honeybees		
Annex PointIIIAXIII.3	Field study on the potential imp fields previously treated with im	act of residues in sunflowers grown in uidacloprid to honeybees	
	COMMENTS FROM		
Date	Give date of the comments subm	nitted	
Materials and Methods	Discuss additional relevant disc and to applicant's summary and Discuss if deviating from view o		vers
Results and discussion	Discuss if deviating from view of	of rapporteur member state	
Conclusion	Discuss if deviating from view of	of rapporteur member state	
Reliability	Discuss if deviating from view of	of rapporteur member state	
Acceptability	Discuss if deviating from view of	of rapporteur member state	

Section A7.5.4.1/06 Annex PointIII AXIII.3

Effects on honeybees

Field study on the potential impact of residues in summer rape grown in fields previously treated with imidacloprid to honeybees

Official use only

1 REFERENCE

1.1 Reference PPP monograph: B.9.4.4j

Authors (year)

Title Residue Levels of Imidacloprid and Imidacloprid Metabolites in Nectar,

Blossoms and Pollen of Summer Rape Cultivated on Soils with

Different Imidacloprid Residue Levels and Effects of these Residues on

(1999c)

Foraging Honeybees. 1999.

Company, report No. Bayer CropScience AG, Report-No. SXR/AM 010.

BES Ref.: M-016842-01-1

Date 28 September 1999

Testing facility

Dates of work

12 July-21 September 1999

Test substance(s) Molecule(s): imidacloprid

1.2 Data protection Yes

1.2.1 Data owner Bayer CropScience AG

12.1 Data owner Buyor Cropocioneo 11

1.2.3 Criteria for data protection Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study No guideline

2.2 GLP Yes

2.3 Deviations Not applicable

3 MATERIALS AND METHODS

3.1 Test material

3.1.1 Lot/Batch number Imidacloprid Gaucho WS 70 formulations, a.s. content within manufacturing control level

3.1.2 Specification

3.1.3 Description

3.1.4 Purity

3.1.5 Stability

3.2 Test objective for PPP uses The aim of the investigations was to determine the level of residues of imidacloprid and its metabolites in summer rape grown in previously treated fields and in honey and pollen of honeybee colonies foraging on the crop and the possible impact of these residues on the foraging colonies.

3.2.1 Relevance to BP use

The nature of the objective is consistent with the need to understand the potential risk to bees foraging near grassland treated with or on crops replanted in arable soil amended with potentially contaminated manure from 0.5% imidacloprid granule biocidal product use in animal houses.

Section A7.5.4.1/06 Annex PointIIIAXIII.3

Effects on honeybees

Field study on the potential impact of residues in summer rape grown in fields previously treated with imidacloprid to honeybees

3.2.2 Test design

Previous treatments on the plots:

<u>Control plot</u>: untreated grass area since 1996. Drilled with imidacloprid free summer rape seed on 11 May 1999.

<u>Variant "1997":</u> cropped in fall 1997 with Gaucho treated winter wheat (59 g as/ha), sprayed on 30 April 1999 with 71.5 g/ha Gaucho WS 70 (=50 g as/ha imidacloprid; batch no. 233 614 749, 72.5 % imidacloprid according to FAR no. 559-01). Drilled with imidacloprid-free summer rape seed on 11 May 1999.

<u>Variant "1998":</u> cropped in fall 1998 with Gaucho treated winter barley (52 g as/ha). Drilled with imidacloprid-free summer rape seed on 11 May 1999.

<u>Variant "1999":</u> untreated grass area since 1996. Drilled with Gaucho WS 70 treated summer rape seed on 11 May 1999 (72 g as/ha).

3.2.3 Test procedure

Small honeybee colonies of about 2000-3000 individuals were caged on flowering summer rape (cage size about 50 m2). The different previous imidacloprid treatments are discribed above.

Testing period lasted from July 12 – 19, 1999.

The assessment criteria included mortality, behavioral anomalies, colony strength and brood status.

For residue analysis from all plots the following types of samples had been taken:

- soil sample (0-30 cm depth)
- leaves (produced latest)
- flowers
- nectar (sampled from flowers)
- pollen (sampled from the hives and bees)
- honeybees (exposed to the summer rape)

See Table A.7.5.4.1/04-1 for analytical limits

4 RESULTS

4.1 Findings

No treatment related mortality or impact on the behaviour of the bees was observed in the test colonies.

Residues of imidacloprid have been detected in the soil samples:

- Variant "1997": 0.018 mg/kg
- Variant "1998": < LOQ
- Variant "1999": < LOD

Residues of imidacloprid in all leave samples, in the pollen samples of variant 1998 and 1998 (2x) and in the nectar sample of variant 1999 were below the limit of quantification.

Section A7.5.4.1/06 Annex PointIIIAXIII.3

Effects on honeybees

Field study on the potential impact of residues in summer rape grown in fields previously treated with imidacloprid to honeybees

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

A field investigation was conducted under GLP to determine the level of residues of imidacloprid and its metabolites in summer rape grown in previously treated fields and in honey and pollen of honeybee colonies foraging on the crop and the possible impact of these residues on the foraging colonies.

5.2 Results and discussion

Residues of imidacloprid were detected in the soil of Variant 1997 plot at a 0.018 mg/kg (ppb) level.

Therefore, the potential for plant uptake and movement into plant parts foraged by bees was present.

No treatment related mortality or impact on the behaviour of the bees was observed in the test colonies.

No quantifiable residues of imidacloprid were found in rape flowers or nectar or in honeybees or pollen taken from exposed hives.

The biocidal product PECsoil values (calculated with Tier 1 assumptions, no refinement) for grassland and arable fields spread with manure/manure slurry from animal houses treated with an 0.5% imidacloprid granule product are less than 10 ppb. Therefore, this study demonstrating the lack of adverse impact on honeybees foraging sunflowers grown in soils having almost double the worst case soil levels predicted for the biocidal product use indicates no risk is to be expected to bees foraging bee attractive crops grown in arable land that has received manure from the imidacloprid granule treated animal houses.

5.3 Conclusion

No risk is to be expected to bees foraging bee attractive crops grown in arable land that has received manure from the imidacloprid granule treated animal houses.

5.3.1 Reliability

1

No

5.3.2 Deficiencies

	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2007/04/23	
Materials and Methods	Applicant's version is acceptable.	
Results and discussion	Applicant's version can be adopted.	
Conclusion	Applicant's version can be adopted.	
Reliability	1	
Acceptability	acceptable	
Remarks	2	

Bayer Environmental Scientific Environmental Environm	nce Imidacloprid	April 2006
Section A7.5.4.1/06	Effects on honeybees	
Annex PointIIIAXIII.3	Field study on the potential impact of resid fields previously treated with imidacloprid	lues in summer rape grown in to honeybees

	COMMENTS FROM
Date	Give date of the comments submitted
Materials and Methods	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state
Results and discussion	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state

Section A7.5.4.1/07 Annex PointIIIAXIII.3

Effects on honeybees

Field study on the potential impact of residues in summer rape grown in fields previously treated with imidacloprid to honeybees

Official use only

1 REFERENCE

1.1 Reference PPP monograph: B.9.4.4k

Authors (year) (1999d)

Title Residue Levels of Imidacloprid and Imidacloprid Metabolites in Nectar,

Blossoms and Pollen of Summer Rape Cultivated on Soils with

Different Imidacloprid Residue Levels and Effects of these Residues on

Foraging Honeybees. 1999.

Company, report No. Bayer CropScience AG, Report-No. SXR/AM 008.

BES Ref.: M-016828-01-1

Date 28 September 1999

Dates of work 12 July-21 September 1999

Test substance(s) Molecule(s): imidacloprid

1.2 Data protection Yes

Testing facility

1.2.1 Data owner Bayer CropScience AG

Dayor Cropocience

1.2.3 Criteria for data protection Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study No guideline

2.2 GLP Yes

2.3 Deviations Not applicable

3 MATERIALS AND METHODS

3.1 Test material

3.1.1 Lot/Batch number Imidacloprid Gaucho WS 70 formulations, a.s. content within

3.1.2 Specification manufacturing control level

3.1.3 Description

3.1.4 Purity

3.1.5 Stability

3.2 Test objective for PPP uses

The aim of the investigations was to determine the level of residues of imidacloprid and its metabolites in summer rape grown in previously treated fields and in honey and pollen of honeybee colonies foraging on the crop and the possible impact of these residues on the foraging colonies.

3.2.1 Relevance to BP use

The nature of the objective is consistent with the need to understand the potential risk to bees foraging near grassland treated with or on crops replanted in arable soil amended with potentially contaminated manure from 0.5% imidacloprid granule biocidal product use in animal houses.

Section A7.5.4.1/07 Annex PointIIIAXIII.3

Effects on honeybees

Field study on the potential impact of residues in summer rape grown in fields previously treated with imidacloprid to honeybees

3.2.2 Test design

Previous treatments on the plots:

<u>Control plot</u>: untreated grass area since 1996. Drilled with imidacloprid free summer rape seed on 12 May 1999.

Variant "1997": cropped in fall 1997 with Gaucho treated winter wheat (77 g as/ha), sprayed on 24 April 1999 with 71.5 g/ha Gaucho WS 70 (= 50 g as/ha imidacloprid; batch no. 233 614 749, 72.5 % imidacloprid according to FAR no. 559-01). Drilled with imidacloprid-free summer rape seed on 12 May 1999.

<u>Variant "1998":</u> cropped in fall 1998 with Gaucho treated sugar beet (111 g as/ha), followed in fall 1998 by Gaucho treated winter barley (49 g as/ha). Drilled with imidacloprid-free summer rape seed on 12 May 1999.

<u>Variant "1999":</u> untreated grass area since 1996. Drilled with Gaucho WS 70 treated summer rape seed on 12 May 1999.

3.2.3 Test procedure

Small honeybee colonies of about 2000-3000 individuals were caged on flowering summer rape (cage size about 50 m2). The different previous imidacloprid treatments are discribed above.

Testing period lasted from July 12 – 19, 1999.

The assessment criteria included mortality, behavioral anomalies, colony strength and brood status.

For residue analysis from all plots the following types of samples had been taken:

- soil sample (0-30 cm depth)
- leaves (produced latest)
- flowers
- nectar (sampled from flowers)
- pollen (sampled from the hives and bees)
- honeybees (exposed to the summer rape)

See Table A.7,5.4.1/04-1 for analytical limits

4 RESULTS

4.1 Findings

No treatment related mortality or impact on the behaviour of the bees x was observed in the test colonies.

Residues of imidacloprid have been detected in the soil samples:

- Variant "1997": 0.016 mg/kg
- Variant "1998": 0.013 mg/kg
- Variant "1998 (2x)": 0.014 mg/kg

Residues of imidacloprid in all leave samples, in the pollen samples of variant 1998 and 1998 (2x) and in the nectar sample of 1999 were below the limit of quantification

Section A7.5.4.1/07 Annex PointIIIAXIII.3

Effects on honeybees

Field study on the potential impact of residues in summer rape grown in fields previously treated with imidacloprid to honeybees

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

A field investigation was conducted under GLP to determine the level of residues of imidacloprid and its metabolites in summer rape grown in previously treated fields and in honey and pollen of honeybee colonies foraging on the crop and the possible impact of these residues on the foraging colonies.

5.2 Results and discussion

Residues of imidacloprid were detected in the soil of 3 plots between a 0.013 and 0.016 mg/kg (ppb) level.

Therefore, the potential for plant uptake and movement into plant parts foraged by bees was present.

No treatment related mortality or impact on the behaviour of the bees x was observed in the test colonies.

No quantifiable residues of imidacloprid were found in rape flowers or nectar or in honeybees or pollen taken from exposed hives.

The biocidal product PECsoil values (calculated with Tier 1 assumptions, no refinement) for grassland and arable fields spread with manure/manure slurry from animal houses treated with an 0.5% imidacloprid granule product are less than 10 ppb. Therefore, this study demonstrating the lack of adverse impact on honeybees foraging sunflowers grown in soils having almost double the worst case soil levels predicted for the biocidal product use indicates no risk is to be expected to bees foraging bee attractive crops grown in arable land that has received manure from the imidacloprid granule treated animal houses.

5.3 Conclusion

No risk is to be expected to bees foraging bee attractive crops grown in arable land that has received manure from the imidacloprid granule treated animal houses.

5.3.1 Reliability

1

5.3.2 Deficiencies

No

Section A7.5.4.1/07 Annex PointIIIAXIII.3

Effects on honeybees

Field study on the potential impact of residues in summer rape grown in fields previously treated with imidacloprid to honeybees

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2007/04/23
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version can be adopted with the following comment:
	Foraging activity was 122, 82, 97, 99 and 134 honeybees per 2 m² summer rape in the control, test variants "1997", "1998", (1998 (2x)" and "1999". However, the differences observed are most likely attributed to the differences in the number of actually flowering summer rape plants within the different plots. Most summer rape plants were emerged and in flower on the control and test variant "1999" which had the highest foraging activity as well. Therefore, it can be concluded that there was no treatment related effect on foraging activity.
Conclusion	Applicant's version can be adopted.
Reliability	1
Acceptability	acceptable
Remarks	ė .
	COMMENTS FROM
Date	Give date of the comments submitted
Materials and Methods	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state
Results and discussion	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A 6.4.1.2. /02*		1989	52-week oral toxicity (feeding) study with NTN 33893 technical in the dog Bayer CropScience AG, Report No.: R4856, Edition Number: M-027093-02-1 Date: 19.10.1989, Amended: 03.03.1992 GLP, unpublished	Yes	BCS
A 7.1.1.1.2. /01	Anderson, C.; Bornatsch, W.; Brauner, A.	1991	Photodegradation of NTN 33893 in water Nitokuno, Ibaraki, Japan Bayer CropScience AG, Report No.: PF3517, Edition Number: M-024286-01-1 Date: 18.07.1988, revised May 14, 1991 GLP, unpublished	Yes	BCS
A 7.2.2.1./03	Anderson, C.; Fritz, R.	1990a	Degradation of [pyridinyl-14C-methylene] NTN 33893 in silt soil Hoefchen under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3322, Edition Number: M-006740-02-1 Date: 19.01.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.4 /03 also filed: A 7.2.2.4 /09	Yes	BCS
A 7.2.2.1. /04	Anderson, C.; Fritz, R.	1990b	Degradation of [pyridinyl-14C-methylene] NTN 33893 in sandy loam Monheim 1 under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3434, Edition Number: M-006728-02-1 Date: 07.12.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.4 /02 also filed: A 7.2.2.4 /08	Yes	BCS

A 7.2.2.4 /02	Anderson, C.; Fritz, R.	1990	Degradation of [pyridinyl-14C-methylene] NTN 33893 in sandy loam Monheim 1 under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3434, Edition Number: M-006728-02-1 Date: 07.12.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.1 /04 also filed: A 7.2.2.4 /08 (Not included in Caddy, as already filed as A7.2.2.1/04)	Yes	BCS
A 7.2.2.4 /03	Anderson, C.; Fritz, R.	1990	Degradation of [pyridinyl-14C-methylene] NTN 33893 in silt soil Hoefchen under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3322, Edition Number: M-006740-02-1 Date: 19.01.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.1 /03 also filed: A 7.2.2.4 /09 (Not included in Caddy, as already filed as A7.2.2.1/03)	Yes	BCS
A 7.2.2.4 /08	Anderson, C.; Fritz, R.	1990	Degradation of [pyridinyl-14C-methylene] NTN 33893 in sandy loam Monheim 1 under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3434, Edition Number: M-006728-02-1 Date: 07.12.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.1 /04 also filed: A 7.2.2.4 /02 (Not included in Caddy, as already filed as A7.2.2.1/04)	Yes	BCS

A 7.2.2.4 /09 Anderson, C.; Fritz, R.	The second secon	1990	Degradation of [pyridinyl-14C-methylene] NTN 33893 in silt soil Hoefchen under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG,	Yes	BCS
		Report No.: PF3322, Edition Number: M-006740-02-1 Date: 19.01.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.1 /03 also filed: A 7.2.2.4 /03 (Not included in Caddy, as already filed as			
A 7.2.2.1./01	Anderson, C.; Fritz, R.; Brauner, A.	1990a	A7.2.2.1/03) Metabolism of (pyridinyl-14C-methylene) NTN 33893 in loamy soil BBA 2.2 under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3321, Edition Number: M-006742-02-1 Date: 15.01.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.4 /04 also filed: A 7.2.2.4 /10	Yes	BCS
A 7.2.2.1. /02	Anderson, C.; Fritz, R.; Brauner, A.	1990b	Metabolism of (pyridinyl-14C-methylene) NTN 33893 in sandy loam under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3433, Edition Number: M-023514-01-1 Date: 14.11.1990 GLP, unpublished also filed: A 7.2.2.4 /05 also filed: A 7.2.2.4 /11	Yes	BCS
A 7.2.2.4 /04	Anderson, C.; Fritz, R.; Brauner, A.	1990	Metabolism of (pyridinyl-14C-methylene) NTN 33893 in loamy soil BBA 2.2 under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3321, Edition Number: M-006742-02-1 Date: 15.01.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.1/01 also filed: A 7.2.2.4 /10 (Not included in Caddy, as already filed as A7.2.2.1/01)	Yes	BCS

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A 7.2.2.4 /05	Anderson, C.; Fritz, R.; Brauner, A.	1990	Metabolism of (pyridinyl-14C-methylene) NTN 33893 in sandy loam under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3433, Edition Number: M-023514-01-1 Date: 14.11.1990 GLP, unpublished also filed: A 7.2.2.1 /02 also filed: A 7.2.2.4 /11 (Not included in Caddy, as already filed as A7.2.2.1/02)	Yes	BCS
A 7.2.2.4 /10	Anderson, C.; Fritz, R.; Brauner, A.	1990	Metabolism of (pyridinyl-14C-methylene) NTN 33893 in loamy soil BBA 2.2 under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3321, Edition Number: M-006742-02-1 Date: 15.01.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.1/01 also filed: A 7.2.2.4 /04 (Not included in Caddy, as already filed as A7.2.2.1/01)	Yes	BCS
A 7.2.2.4 /11	Anderson, C.; Fritz, R.; Brauner, A.	1990	Metabolism of (pyridinyl-14C-methylene) NTN 33893 in sandy loam under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3433, Edition Number: M-023514-01-1 Date: 14.11.1990 GLP, unpublished also filed: A 7.2.2.1 /02 also filed: A 7.2.2.4 /05 (Not included in Caddy, as already filed as A7.2.2.1/02)	Yes	BCS
A 7.5.1.1./01	Anderson, J. P. E.	1988	Influence of NTN 33893 on the microbial mineralization of carbon in soils Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: AJO/54088, Edition Number: M-006978-01-2 Date: 11.04.1988 Non GLP, unpublished	Yes	BCS

A 7.5.1.1. /02	Anderson, J.P.E.	1999	Influence of imidacloprid (tech.) in mineralization of (carboxyl-14C) sodium acetate to 14CO2 in a slurry of soil and water Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: AJO/196699, Edition Number: M-048331-01-1 Date: 29.07.1999 GLP, unpublished	Yes	BCS
A 4.1. /03	Anon.	1997	Imidacloprid 582 CIPAC Bayer CropScience AG, Report No.: CIPAC 582, Edition Number: M-032649-01-1 Date: 01.01.1997 Non GLP, unpublished	Yes	BCS
A VIII. /01	Anon.	2006	Imidacloprid technical insecticide Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-246172-02-1, Edition Number: M-246172-02-1 Date: 18.01.2006 Non GLP, unpublished also filed: A IX. /01	Yes	BCS
A IX. /01	Anon.	2006	Imidacloprid technical insecticide Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-246172-02-1, Edition Number: M-246172-02-1 Date: 18.01.2006 Non GLP, unpublished also filed: A VIII. /01	Yes	BCS
A 4.2.1. /02	Bachlechner, G.	1992	Method for high performance liquid chromatographic determination of residues of the insecticide imidacloprid in soil using a laboratory robotic system Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00270, Edition Number: M-006708-02-1 Method Report No.: RA-139/92 Date: 11.03.1992 Non GLP, unpublished	Yes	BCS

Competent Authority: DE

A 7.2.2.2./01	Bachlechner, G.	1993b	Dissipation of imidacloprid in soil under field conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: RA-2130/91, Report includes Trial Nos.: 10359/4 10360/8 10361/6 10362/4 10363/2 10364/0 Edition Number: M-006700-01-1 Date: 11.03.1993 GLP, unpublished	Yes	BCS
A7,2.2.2./02	Bachlechner, G.	1992	Dissipation of Imidacloprid in soil under field conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: RA-2082/91, Edition Number: M-006704-01-1 Date: 04.11.1992 GLP, unpublished	Yes	BCS
A 7.5.2.1. /03	Bakker, F. M.	1999	An extended laboratory dose-response study to evaluate the effects of imidacloprid tech. on the predaceous mite Hypoaspis aculeifer Canestrini (Acari: Gamasidae) MITOX Stichting Bevordering Duurzame Plaagbestrijding, Amsterdam, Netherlands Bayer CropScience AG, Report No.: B019HAE, Edition Number: M-041284-01-1 Date: 01.04.1999 GLP, unpublished	Yes	BCS
A 6.8.1. /01*	Becker, H.; Vogel, W.; Terrier, C.	1988	Embryotoxicity study (including teratogenicity) with NTN 33893 technical in the rat RCC, Research and Consulting Company AG, Itingen, Switzerland Bayer CropScience AG, Report No.: R5442, Edition Number: M-027900-04-1 Date: 24.11.1988, Amended: 03.03.1992 GLP, unpublished	Yes	BCS

A 6.8.1. /02*	Becker, H.; Vogel, W.; Terrier, C.	1988	Embryotoxicity study (including teratogenicity) with NTN 33893 technical in the rabbit	Yes	BCS
			RCC, Research and Consulting Company AG, Itingen, Switzerland Bayer CropScience AG,		
			Report No.: R5443,		
			Edition Number: M-027920-04-1		
			Date: 24.11.1988, Amended: 03.03.1992 GLP, unpublished		
A 6.12.1. /02	Becker, M.	2006	Occupational, medical experience with imidacloprid gel 2,15 percent Pharma + Veterinaer Produkte, Kiel,	Yes	BCS
			Germany Bayer CropScience AG,		
			Report No.: M-267506-01-1,		
			Edition Number: M-267506-01-1		
			Date: 06.03.2006		
			Non GLP, unpublished		
A 4.2.3. /02 Billesbach, K. S.; Leimkuehler, W. M.; Widmer, S. L.	Leimkuehler, W. M.;	1996	Analytical method for the determination of imidacloprid and the guanidine, olefinic guanidine, and urea metabolites in groundwater by high-performance liquid chromatography tandem mass spectrometry (LC-MS/MS)	Yes	BCS
		Bayer Corporation, Kansas City, MO, USA Bayer CropScience AG, Report No.: 107352, Edition Number: M-012941-01-1 Date: 11.06.1996 GLP, unpublished			
A 6.3.1 *		1987	28-day oral range-finding toxicity (feeding) study with NTN 33893 tech. in the dog, Report No. R4196, RCC Project 084993, Bayer project T 6025018	Yes	BCS
			No GLP, Unpublished		1
A 7.5.1.1. /03	Blumenstock, I.	1988	Influence of NTN 33893 on the microbial mineralization of nitrogen in soils	Yes	BCS
			Bayer CropScience AG, Report No.: BSI/54288, Edition Number: M-006964-01-2 Date: 20.07.1988		
		Non GLP, unpublished	1		

A 3.11	Bogdoll, B.	2009	NTN 33893 - Statements on the Articles A.12. and A.13., Council Directive 67/548/EEC, Annex V Flammability (substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities), A.12. Flammability (solids and liquids) / Pyrophoric properties, A.13. Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: AF09/040, Edition Number: M-347798-01-1 Date: 25.05.2009 Non GLP, unpublished	Yes	BCS
A 6.1.1. /01*		1989	NTN 33893 - Study for acute oral toxicity to rats Bayer CropScience AG, Report No.: 18594, Edition Number: M-025996-01-1 Date: 15.12.1989 GLP, unpublished	Yes	BCS
A 6.1,1./02*		1991	NTN 33893 AMP (proposed c.n.: Imidacloprid) - Study for acute oral toxicity to rats Bayer CropScience AG, Report No.: 20591, Edition Number: M-028854-01-1 Date: 19.08.1991 GLP, unpublished	Yes	BCS
A 6.1.1./03*		1991	NTN 33893 CNS (c.n.: Imidacloprid (proposed) - Study for acute oral toxicity in rats Bayer CropScience AG, Report No.: 20637, Edition Number: M-028901-01-1 Date: 03.09.1991 GLP, unpublished	Yes	BCS
A 6.1.1./04*		1989	NTN 33893 - Study for acute oral toxicity to mice Bayer CropScience AG, Report No.: 18593, Edition Number: M-007509-01-1 Date: 15.12.1989 GLP, unpublished	Yes	BCS

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A 7.4.1.1./02		1990	Acute toxicity of NTN 33893 to rainbow trout (Oncorhynchus mykiss)	Yes	BCS
			Bayer CropScience AG, Report No.: 100349, Edition Number: M-007019-01-1 Date: 12.12.1990 GLP, unpublished		
A 7.4.3.5. /02	Brock, T.C.M.	2005	Evaluation of the report - Biological effects and fate of imidacloprid SL 200 in outdoor microcosm ponds Bayer CropScience AG, Report No.: MO-05-008527, Edition Number: M-251183-01-1 Date: 02.05.2005 Non GLP, unpublished	Yes	BCS
A 7.4.1.1, /03	Bussard, J.	1990	Method validation for the analysis of NTN-33893 in aquatic test water [Tox/Ecotox method] ABC Laboratories, Inc., Columbia, MO, USA Bayer CropScience AG, Report No.: 100090, Edition Number: M-015716-01-1 Method Report No.: 37859 Method Report No US: F45.001-00 Date: 13.03.1990 GLP, unpublished	Yes	BCS
A 4.1. /06	Cichy, M.; Gau, W.	2005	WAK in NTN 33893 AMP W; Assay - HPLC-external standard Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 2005-0002002-92, Edition Number: M-007788-02-3 Date: 24.01.2005 Non GLP, unpublished confidential	Yes	BCS
A 3.17. /01	Cichy, M.; Merheim, P.	2005	Stability of Imidacloprid (NTN 33893/ AE F106464) to normal and elevatedtemperature, metals and metal ions and corrosion characteristics Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: PA05/059, Edition Number: M-255320-01-1 Date: 29.07.2005 GLP, unpublished	Yes	BCS

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A 6.6.3. /03*		1988	Mutagenicity test on NTN 33893 in the rat primary hepatocyte unscheduled DNA synthesis assay Bayer CropScience AG, Report No.: R4631, Edition Number: M-026493-01-1 Date: 21.12.1988 GLP, unpublished	Yes	BCS
A 7.5.4.1. /01	Cole, J. H.	1990	The acute oral and contact toxicity to honey bees of compound NTN 33893 technical Bayer CropScience AG, Report No.: BAY 158/901384, Edition Number: M-006940-02-1 Date: 28.12.1990, Amended: 06.01,1994 GLP, unpublished	Yes	BCS
A 4.1, /12	Dobrat W.; Martijn A.	1995	CIPAC Handbook Volume F Physico-chemical methods for technical and formulated pesticides MT 30 Water 30.1 Karl Fischer method Publisher:Collab. Int. Pest. Anal. Council Ltd., Journal:CIPAC Handbook, Volume:F, Pages:91;93, Year:1995, Report No.: C042873, Edition Number: M-233461-01-1 Date: 01.01.1995 Non GLP, published confidential	No	
A 7.4.1.3, /02	Dorgerloh, M.	2000	Imidacloprid - Influence on the growth of green alga, Selenastrum capricornutum Bayer CropScience AG, Report No.: DOM 20018, Edition Number: M-033262-01-1 Date: 23.05.2000 GLP, unpublished	Yes	BCS
A 7.4.1.2. /02	Dorgerloh, M.; Sommer, H.	2002	Acute toxicity of imidacloprid (tech.) to larvae of Chironomus riparius Bayer CropScience AG, Report No.: DOM 22031, Edition Number: M-058794-01-1 Date: 12.04.2002 GLP, unpublished	Yes	BCS

A 7.4.3.4. /02	Dorgerloh, M.; Sommer, H.	2001a	Influence of imidacloprid (tech.) on development and emergence of larvae of Chironomus riparius in a water-sediment system Bayer CropScience AG, Report No.: DOM 21035, Edition Number: M-075819-01-1 Date: 04.10.2001 GLP, unpublished	Yes	BCS
A 7.4.3.4. /03	Dorgerloh, M.; Sommer, H.	2001Ъ	Influence of imidacloprid-desnitro on development and emergence of larvae of Chironomus riparius in a water-sediment system Bayer CropScience AG, Report No.: DOM 21039, Edition Number: M-081499-01-1 Date: 26.10.2001 GLP, unpublished	Yes	BCS
A 6.5. /02*		1991	NTN 33893 (proposed common name: Imidacloprid) - Chronic toxicity and cancerogenicity studies on Wistar rats (administration in food over 24 months) - supplementary MTD study for two-year study T1025699 Bayer CropScience AG, Report No.: 20541, Edition Number: M-027135-01-1 Date: 19.08.1991 GLP, unpublished also filed: A 6.7. /02	Yes	BCS
A 6.7. /02*		1991	NTN 33893 (proposed common name: Imidacloprid) - Chronic toxicity and cancerogenicity studies on Wistar rats (administration in food over 24 months) - supplementary MTD study for two-year study T1025699 Bayer CropScience AG, Report No.: 20541, Edition Number: M-027135-01-1 Date: 19.08.1991 GLP, unpublished also filed: A 6.5. /02	Yes	BCS

A 6.5. /01*		1991	NTN 33893 (proposed c.n.: Imidacloprid) - Chronic toxicity and cancerogenicity studies on Wistar rats (administration in food over 24 months) Bayer CropScience AG, Report No.: 19925, Edition Number: M-027741-02-1 Date: 25.01.1991 GLP, unpublished also filed: A 6.7, /01	Yes	BCS
A 6.7. /01*		1991	NTN 33893 (proposed c.n.: Imidacloprid) - Chronic toxicity and cancerogenicity studies on Wistar rats (administration in food over 24 months) Bayer CropScience AG, Report No.: 19925, Edition Number: M-027741-02-1 Date: 25.01.1991 GLP, unpublished also filed: A 6.5. /01	Yes	BCS
A 6.4.1.1./01*		1989	NTN 33893 - Subchronic toxicity study on wistar rats (administration in the feed for 96 days) Bayer CropScience AG, Report No.: 18187, Edition Number: M-007967-01-1 Date: 14.07.1989 GLP, unpublished	Yes	BCS
A 5.7.2. /01	Elbert, A.; Bailo- Schleiermacher, I.; Brueggen, K.U.; Nauen, R.; Rogers, D.; Steffens, R.; Denholm, I.	2005	Pflanzenschutz-Nachrichten Bayer 58 - Special edition - Bayer CropScience Guidelines on Resistance Management for Neonicotinoids Publisher:Bayer CropScience, Location:Germany, Journal:Pflanzenschutz Nachrichten Bayer, Volume:58, Issue:76, Pages:1 - 32, Year:2005, Report No.: MO-05-008987, Edition Number: M-252077-01-1 Non GLP, published	No	

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A 7.4.1.2. /03	England, D.; Bucksath, J. D.	1991	Acute toxicity of NTN 33893 to Hyalella azteca Bayer CropScience AG, Report No.: 101960, Edition Number: M-007182-01-1 Date: 09.10.1991	Yes	BCS
A 7.2.2.2./03	Fahl, U.; Leicht, W.	1999	GLP, unpublished Recalculation of imidacloprid half-lives in bare soil (field trials) according to 1st order statistics Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: M10166, Edition Number: M-021684-01-1 Date: 10.11.1999 Non GLP, unpublished	Yes	BCS
A 7.2.2.2./06	Fahl, U.; Leicht, W.	1999	also filed: A 7.2.2.2 /06 Recalculation of imidacloprid half-lives in bare soil (field trials) according to 1st order statistics Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: M10166, Edition Number: M-021684-01-1 Date: 10.11.1999 Non GLP, unpublished also filed: A 7.2.2.2 /03 (Not included in Caddy, as already filed as A7.2.2.2/03)	Yes	BCS
A 7.2.2.4 /06	Fahl, U.; Leicht, W.	2001	Recalculation of imidacloprid half-life in soil (laboratory trials) according to 1st order statistics Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: M10150, Edition Number: M-010575-03-1 Date: 19.04.2001 Non GLP, unpublished	Yes	BCS
A 6.14. /07*		1989	Unscheduled DNA synthesis in primary hepatocytes of male rats in vitro with WAK 3839 Bayer CropScience AG, Report No.: R4746, Edition Number: M-026532-01-1 Date: 24.04.1989 GLP, unpublished	Yes	BCS

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A 6.3.2 /01*	1990	NTN 33893 techn Study for subacute dermal toxicity in the rabbit	Yes	BCS	
			Bayer CropScience AG, Report No.: 19152, Edition Number: M-025976-01-1 Date: 11.06.1990 GLP, unpublished		
A 7.1,3./01	Fritz, R.	1988	Adsorption/desorption of NTN33893 on soils Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3128, Edition Number: M-023859-01-1 Date: 11.11.1988 GLP, unpublished	Yes	BCS
A 7.1.3. /03	Fritz, R.	1993	Adsorption/desorption of imidacloprid on lysimeter soils originated from "Borstel" and "Laacher Hof" Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3978, Edition Number: M-023822-02-2 Date: 24.02.1993, Amended: 01.06.2001 GLP, unpublished	Yes	BCS
A 7.1.3. /04	Fritz, R.	1998	Adsorption/desorption of imidacloprid (NTN 33893) on two light soils at different rates of application Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: MR-319/98, Edition Number: M-023808-01-1 Date: 24.04.1998 GLP, unpublished	Yes	BCS

A 7.1.2.2.2. /04	Fritz, R.; Hellpointner, E.	1991	Degradation of pesticides under anaerobic conditions in the system water/sediment: Imidacloprid, NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3524, Edition Number: M-024093-01-1 Date: 04.06.1991 GLP, unpublished	Yes	BCS
A 7.4.1.1. /01		1988Ь	The acute toxicity of NTN 33893 techn. to rainbow trout (salmo gairdneri) in a static test Bayer CropScience AG, Report No.: FF-210, Edition Number: M-006827-01-2 Date: 03.03.1988 GLP, unpublished	Yes	BCS
A 7.4.1.1. /04		1987	The acute toxicity of NTN 33893 techn. to golden orfe (Leuciscus idus melanotus) in a static test Bayer CropScience AG, Report No.: FO-1042, Edition Number: M-006830-01-2 Date: 26.10.1987 GLP, unpublished	Yes	BCS
A 7.5.3.1.1, /02		1988a	Acute oral LD50 of NTN 33893 to japanese quail Bayer CropScience AG, Report No.: VW-123, Edition Number: M-006710-01-1 Date: 28.01.1988 GLP, unpublished	Yes	BCS
A 7.5.3.1.2. /02		1996	NTN 33893 techn. 5-day-dietary LC50 to japanese quail Bayer CropScience AG, Report No.: GMU / VW-177, Edition Number: M-006792-02-1 Date: 14.03.1996, Amended: 22.01.2002 GLP, unpublished	Yes	BCS

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A 7.4.3.2. /01		2002	Imidacloprid (NTN 33893): Early life-stage toxicity test with rainbow trout (Oncorhynchus mykiss) under flow-through conditions Bayer CropScience AG, Report No.: 1022.016.321, Edition Number: M-049894-01-1 Date: 29.08.2002 GLP, unpublished	Yes	BCS
A 7.5.3.1.1./03		1996	NTN 33893 technical: An acute oral LD50 with mallards Bayer CropScience AG, Report No.: 107354, Edition Number: M-006784-01-1 Date: 20.06.1996 GLP, unpublished	Yes	BCS
A 7.1.2.2.2/07	Hardy, I.A.J., Patel, M.	2007	Imidacloprid: Kinetic modelling analysis of data from a water sediment study and a microcosm study Batelle UK Ltd, Essex, UK, Bayer CropScience AG, Report No.: CX/06/041, Edition Number: M-284318-01-1, Date: 21.02.2007 non GLP, unpublished	Yes	BCS

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A 4.1./02	Haustein, M.	2003	Validation of HPLC-method 2201- 0260401-93 -Determination of the assay in Confidor (Imidacloprid) techn. grade active ingredient- Bayer Industry Services, Dormagen, Germany Bayer CropScience AG, Report No.: VB2-2201-0260401, Edition Number: M-090267-03-1 Date: 25.04.2003 Non GLP, unpublished	Yes	BCS
A 4.1. /04	Haustein, M.	1998	NTN 33893; By-products - Linear Synthesis; HPLC, External Standard Bayer CropScience AG, Report No.: 2201-0308702-98, Edition Number: M-007778-02-2 Date: 04.06.1998 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /05	Haustein, M.	2003	Validation of HPLC-method 2201- 0308702-98 -Determination of the by- products in Confidor (Imidacloprid) techn. grade active ingredient- Germany Bayer CropScience AG, Report No.: VB2-2201-0308702, Edition Number: M-090284-02-1 Date: 28.04.2003 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /07	Haustein, M.	2001	Validation of HPLC-method 2005- 0002002-92 -Determination of WAK 3839 in Confidor (Imidacloprid) techn. grade a.i Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: VB2-2005-0002002, Edition Number: M-046369-02-1 Date: 14.03.2001 Non GLP, unpublished confidential	Yes	BCS
A 6.14. /08*		1989	Chromosome aberration assay in chinese hamster V79 cells in vitro with WAK 3839 Bayer CropScience AG, Report No.: R4849, Edition Number: M-026528-01-1 Date: 27.09.1989 GLP, unpublished	Yes	BCS

A 7.1.2.2.2. /05	Heim, D.; Yan, Z.; Halarnkar, P. P.	1996	Anaerobic aquatic biotransformation of [Pyridinyl-14C-methyl] imidacloprid at 5 °C ABC Laboratories, Inc., Columbia, MO, USA Bayer CropScience AG, Report No.: BR107546, Edition Number: M-024068-01-1 Date: 17.12.1996	Yes	BCS
A 7.4.1.3. /01	Heimbach, F.	1986a	GLP, unpublished Growth inhibition of green algae (Scenedesmus subspicatus) caused by NTN 33893 (technical) Bayer CropScience AG, Report No.: HBF/AL 27, Edition Number: M-006854-01-2 Date: 28.11.1986 GLP, unpublished	Yes	BCS
A 7,5.1.2. /01	Heimbach, F.	1986ь	Acute toxicity of NTN 33893 (techn.) to earth worms Bayer CropScience AG, Report No.: HBF/RG 63, Edition Number: M-006863-01-2 Date: 10.11.1986 GLP, unpublished	Yes	BCS
A 7.5.2.1./01	Heimbach, F.	1999	Influence of low concentrations of imidacloprid (tech.) on the reproduction of earthworms (Eisenia fetida) Bayer CropScience AG, Report No.: HBF/RG 301, Edition Number: M-032798-01-1 Date: 20.05.1999 GLP, unpublished	Yes	BCS
A4.2.2/03	Hellpointner, E.	1999	Confirmatory method for the determination of imidaeloprid in air Bayer AG report no. MR-335/99, method no. 00326-M001, study no. P 625 9 6000 unpublished	Yes	BCS
A 7.1.1.1.2. /02	Hellpointner, E.	1990	Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation of imidacloprid in water Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3422, Edition Number: M-024014-01-2 Date: 06.11.1990 GLP, unpublished	Yes	BCS

A 7.2.2.1. /05	Hellpointner, E.	1999a	Degradation of imidacloprid in lysimeter soil Laacher Hof AXXa	Yes	BCS
			Bayer AG, Leverkusen, Germany		110
			Bayer CropScience AG,		
			Report No.: MR-389/99,		
			Edition Number: M-010737-01-1		
			Date: 02.08.1999		
			GLP, unpublished		
			also filed: A 7.2.2.4 /07		
A 7.2.2.4 /07	Hellpointner, E.	1999	Degradation of imidacloprid in lysimeter soil Laacher Hof AXXa	Yes	BCS
			Bayer AG, Leverkusen, Germany		
			Bayer CropScience AG,		
			Report No.: MR-389/99,		
			Edition Number: M-010737-01-1		
			Date: 02.08.1999		
			GLP, unpublished		
			also filed: A 7.2.2.1 /05		
			(Not included in Caddy, as already filed as		
			A7.2.2.1/05)		
A 7.3.1. /01	Hellpointner, E.	1999	Calculation of the chemical lifetime of	Yes	BCS
			imidacloprid in the troposphere		
			Bayer AG, Leverkusen, Germany		
			Bayer CropScience AG, Report No.: MR-088/99,		
			Edition Number: M-007805-01-1		
			Date: 18.02.1999		
			Non GLP, unpublished		
A 7.1.2.2.2. /03	Henneboele, J.	1998	Aerobic metabolism of imidacloprid, 14C-	Yes	BCS
		100	NTN 33893, in an aquatic model ecosystem		
			Bayer AG, Leverkusen, Germany		
			Bayer CropScience AG,		
			Report No.: PF4337,		
			Edition Number: M-032538-01-1		
			Date: 25.02.1998		
			GLP, unpublished		
A 6.6.1. /01*		1989	NTN 33893 - Salmonella/microsome test to evaluate for point mutagenic effects	Yes	BCS
			Bayer CropScience AG,		
			Report No.: 17577,		
			Edition Number: M-027611-01-1		
			Date: 06.01.1989		
			GLP, unpublished		

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A 6.6.1. /02*	1991	NTN 33893 AMP - Salmonella/microsome test	Yes	BCS
		Bayer CropScience AG, Report No.: 20090, Edition Number: M-025825-01-1 Date: 22.03.1991 GLP, unpublished		
A 6.6.1. /03*	1992	NTN 33893 AMP W - Salmonella/microsome test Bayer CropScience AG, Report No.: 21775, Edition Number: M-029085-01-1 Date: 19.10.1992 GLP, unpublished	Yes	BCS
A 6.6.2. /03*	1989	NTN 33893 - In vitro cytogenetic study with human lymphocytes for the detection of induced clastogenic effects Bayer CropScience AG, Report No.: 18092, Edition Number: M-028377-02-1 Date: 16.06.1989, Amended: 24.08.1989 GLP, unpublished	Yes	BCS
A 6.6.3. /02*	1988	NTN 33893 - Test on S. cerevisiae D7 to evaluate for induction of mitotic recombination Bayer CropScience AG, Report No.: 16832, Edition Number: M-027595-01-1 Date: 27.06.1988 GLP, unpublished	Yes	BCS
A 6.6.4. /01*	1989	NTN 33893 - In vivo cytogenetic study of the bone marrow in chinese hamster to evaluate for induced clastogenic effects Bayer CropScience AG, Report No.: 18557, Edition Number: M-025903-01-1 Date: 24.11.1989 GLP, unpublished	Yes	BCS

A 6.6.4. /02*		1989	NTN 33893 - Sister chromatid exchange in bone marrow of chinese hamsters in vivo	Yes	BCS
			Bayer CropScience AG, Report No.: 18093, Edition Number: M-028379-02-1 Date: 16.06.1989, Amended: 23.11.1993 GLP, unpublished		
A 6.6.5. /01*		1988	NTN 33893 - Micronucleus-test on the mouse to evaluate for clastogenic effects Bayer CropScience AG, Report No.: 16837, Edition Number: M-027591-01-1 Date: 27.06.1988 GLP, unpublished	Yes	BCS
A 6.14, /09*		1989	WAK 3839 - Micronucleus test on the mouse after oral application Bayer CropScience AG, Report No.: 18406, Edition Number: M-025775-01-1 Date: 03.10.1989 GLP, unpublished	Yes	BCS
A 6.14./10*		1989	WAK 3839 or NTN 37571 - Micronucleus test on the mouse after intraperitoneal injection Bayer CropScience AG, Report No.: 18407, Edition Number: M-025706-01-1 Date: 03.10.1989 GLP, unpublished	Yes	BCS
A 3.13. /01	Imre, L.	1993	NTN 33893 - Surface tension Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC319, Edition Number: M-004100-02-1 Date: 03.06.1993 GLP, unpublished	Yes	BCS
A 6.2. /04*		1992	(Pyridinyl-14C-methyl)Imidacloprid: Distribution of the metabolites in some organs at different times following single oral administration to rats Bayer CropScience AG, Report No.: PF3635, Edition Number: M-024164-01-1 Date: 12.03.1992 GLP, unpublished	Yes	BCS

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A 6.15.3. /01		1991	(Pyridinyl-14C-methylene) imidacloprid: Absorption, distribution, excretion and metabolism in a lactating goat	Yes	BCS
			Bayer CropScience AG, Report No.: PF3731, Report includes Trial Nos.: KNO43 KWN63 WBZ144 Edition Number: M-024212-01-1 Date: 18.12.1991 GLP, unpublished		
A 6.8.1/01	Kast, A.	1994	"Wavy ribs". A reversible pathologic finding in rat fetuses Exp. Toxic. Pathol. 46: 203-210 Published	No	Public
A 3.9. /02	Каивтапп, , В.	2003	Determination of the log POW of NTN 33893 - metabolites by HPLC (Analytical note) Bayer CropScience AG, Report No.: MO-03-004358, Edition Number: M-088171-01-1 Date: 31.03.2003 Non GLP, unpublished	Yes	BCS
A 3.4.1 /01	Kaussmann, M.	2001	Spectral Data Set of Imidachloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 156002172, Edition Number: M-032373-01-1 Date: 04.12.2001 GLP, unpublished also filed: A 3.4.2 /01 also filed: A 3.4.3 /01	Yes	BCS
A 3.4.2 /01	Kaussmann, M.	2001	Spectral Data Set of Imidachloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 156002172, Edition Number: M-032373-01-1 Date: 04.12.2001 GLP, unpublished also filed: A 3.4.1 /01 also filed: A 3.4.3 /01 also filed: A 3.4.4 /01	Yes	BCS

A 3.4.3 /01	Kaussmann, M.	2001	Spectral Data Set of Imidachloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 156002172, Edition Number: M-032373-01-1 Date: 04.12.2001 GLP, unpublished also filed: A 3.4.1 /01 also filed: A 3.4.2 /01	Yes	BCS
A 3.4.4 /01	Kaussmann, M.	2001	Spectral Data Set of Imidachloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 156002172, Edition Number: M-032373-01-1 Date: 04.12.2001 GLP, unpublished also filed: A 3.4.1 /01 also filed: A 3.4.2 /01 also filed: A 3.4.3 /01	Yes	BCS
A 6.8.1/01	Khera, K.S.	1981	Common fetal aberrations and their teratologic significance: A review Fund. Appl. Toxicol. 1: 13-18	No	Public
A 6.12.1. /01	Kehrig, B.; Steffens, W.	2004	Occupational medical experiences with Imidacloprid Bayer Industry Services, Dormagen, Germany Bayer CropScience AG, Report No.: MO-05-004265, Edition Number: M-245951-01-1 Date: 05.11.2004 Non GLP, unpublished	Yes	BCS
A 7.5.4.1. /03	Kemp, J. R.; Rogers, R. E. L.	2002	Imidacloprid (Admire) residue levels following in-furrow application in potato fields in Prince Edward Island and New Brunswick Bayer CropScience AG, Report No.: MO-02-006773, Edition Number: M-061850-01-1 Date: 02.05.2002 Non GLP, unpublished	Yes	BCS

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A 6.2. /01*	1987	(14C)-NTN 33893: Biokinetic part of the 'General metabolism study' in the rat	Yes	BCS
		Bayer CropScience AG,		
		Report No.: PF2889, Edition Number: M-024189-01-1		
		Date: 09.11.1987		
		GLP, unpublished		
A 6.2. /06*	1990	Imidacloprid - WAK 3839: Comparison of biokinetic behaviour and metabolism in the rat following single oral dosage and investigation of the metabolism after chronic feeding of imidacloprid to rats and mice	Yes	BCS
		Parray Curus Salamas A.C.		
		Bayer CropScience AG, Report No.: PF3432,		
		Edition Number: M-024174-01-1		
		Date: 17,07.1990		
		GLP, unpublished		
A 6.15.3. /02	1992	[Methylene-14C] Imidacloprid: absorption, distribution, excretion, and metabolism in the liver and kidney of a lactating goat - Amendment to report no. PF3731	Yes	BCS
		Bayer CropScience AG,		
		Report No.: PF3760,		
		Report includes Trial Nos.: KNO56		
		Edition Number: M-024202-01-1		
		Date: 11.10.1992		
1 × 2 /02t	1001	GLP, unpublished	X 7	D.CC
A 6.2. /02*	1991	Imidazolidine-4,5-14C-Imidacloprid: Investigation of the biokinetic behaviour and metabolism in the rat	Yes	BCS
		Bayer CropScience AG,		
		Report No.: PF3629,		
		Edition Number: M-024167-01-1		
		Date: 11.01.1991		
		GLP, unpublished		
		also filed: A 6.2 /05		

A 6.2. /05*	1991	Imidazolidine-4,5-14C-Imidacloprid: Investigation of the biokinetic behaviour and metabolism in the rat	Yes	BCS
		Bayer CropScience AG, Report No.: PF3629, Edition Number: M-024167-01-1 Date: 11.01.1991 GLP, unpublished also filed: A 6.2 /02 (Not included in Caddy, as already filed as A6.2/02)		
A 6.15.3. /03	1990	(Methylene-14C) imidacloprid - Absorption, distribution, excretion and metabolism in laying hens	Yes	BCS
		Bayer CropScience AG, Report No.: PF3558, Report includes Trial Nos.: BNA45 KNO30 Edition Number: M-024187-01-1 Date: 17.09.1990 GLP, unpublished		
A 6.15.3. /04	1992	[Methylene-14C] Imidacloprid: Absorption, distribution, excretion, and metabolism in laying hens - Amendment to report no. PF3558	Yes	BCS
		Bayer CropScience AG, Report No.: PF3759, Edition Number: M-024216-01-1 Date: 16.09.1992 GLP, unpublished		
A 6.2. /03*	1990	Methylene-(14C)-Imidacloprid; Metabolism part of the general metabolism study in the rat	Yes	BCS
		Bayer CropScience AG, Report No.: PF3316, Edition Number: M-024182-01-1 Date: 30.01.1990 GLP, unpublished		

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A 4.2.3. /03	Koenig, T.	1996	Method for the determination of imidacloprid in drinking water by HPLC with on-line solid phase extraction Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00406, Edition Number: M-006837-02-1 Method Report No.: MR-831/95 Date: 09.01.1996 Non GLP, unpublished	Yes	BCS
A 6.1.2 /01*		1989	NTN 33893 (c.n. imidacloprid (proposed) - Study for acute dermal toxicity to rats Bayer CropScience AG, Report No.: 18532, Edition Number: M-025697-01-1 Date: 15.11.1989 GLP, unpublished	Yes	BCS
A 6.14. /11		1992	WAK 3839 - Subchronic toxicological study on rats (twelve-week administration on drinking water) Bayer CropScience AG, Report No.: 21140, Edition Number: M-029731-01-1 Date: 02.03.1992 GLP, unpublished	Yes	BCS
A 3.1.1/01	Krohn, J.	1993	Melting Point of Imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC312, Edition Number: M-004037-01-1 Date: 19.05.1993 GLP, unpublished	Yes	BCS
A 3.1.2 /01	Krohn, J.	1996	Boiling Point of Imidacloprid (NTN 33893) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC1437, Edition Number: M-004039-01-1 Date: 25.09.1996 Non GLP, unpublished	Yes	BCS
A 3.1.3 /02	Krohn, J.	1995	Density of Imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC713, Edition Number: M-004040-01-1 Date: 08.02.1995 GLP, unpublished	Yes	BCS

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A 3.2. /01	Krohn, J.	1993	Vapour Pressure Curve of Imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC313, Edition Number: M-004042-01-1 Date: 30.09.1993 GLP, unpublished	Yes	BCS
A 3.2.1 /01	Krohn, J.	1993	Calculation of the Henry Law Constant of Imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC315, Edition Number: M-004047-01-1 Date: 08.10.1993 Non GLP, unpublished	Yes	BCS
A 3.5. /01	Krohn, J.	1993	Water solubility of Imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC320, Edition Number: M-004109-01-1 Date: 03.03.1993 GLP, unpublished	Yes	BCS
A 3.7. /01	Krohn, J.	1993	Solubility of Imidacloprid in representative organic solvents Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC323, Edition Number: M-004130-01-1 Date: 22.06.1993 Non GLP, unpublished	Yes	BCS
A 3.9. /01	Krohn, J.	1989	Octanol/Water partition coefficient of NTN 33893 Bayer AG, Wuppertal, Germany Bayer CropScience AG, Report No.: PC337, Edition Number: M-004153-02-1 Date: 15.06.1989, Amended: 30.01.1992 GLP, unpublished	Yes	BCS
A 6.6.3. /01*		1989	NTN 33893 - Mutagenicity study for the detection of induced forward mutations in the CHO-HGPRT assay in vitro Bayer CropScience AG, Report No.: 17578, Edition Number: M-027630-01-1 Date: 06.01.1989 GLP, unpublished	Yes	BCS

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A 6.14. /04*	1989	WAK 3839 - Mutagenicity study for the detection of induced forward mutations in the CHO-HGPRT assay in vitro Bayer CropScience AG, Report No.: 17757, Edition Number: M-027645-01-1	Yes	BCS	
			Date: 22.02.1989 GLP, unpublished		
A 6.14. /05*		1989	WAK 3839 - Mutagenicity study for the detection of induced forward mutations in the V79-HGPRT assay in vitro Bayer CropScience AG, Report No.: 18281, Edition Number: M-025757-01-1 Date: 15.08.1989 GLP, unpublished	Yes	BCS
A 3.11. /01	Mix, K. H.	1993	Investigation of safety-relevant parameters of Confidor techn. Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC635, Edition Number: M-004182-01-2 Date: 29.10.1993 GLP, unpublished also filed: A 3.15. /01	Yes	BCS
A 3.15./01	Mix, K. H.	1993	Investigation of safety-relevant parameters of Confidor techn. Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC635, Edition Number: M-004182-01-2 Date: 29.10.1993 GLP, unpublished also filed: A 3.11. /01	Yes	BCS
A 3.1.2 /02	Mix, K. H.; Berg, G.	1988	Thermal stability of the active ingredient NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC339, Edition Number: M-004178-01-2 Date: 28.06.1988 Non GLP, unpublished also filed: A 3.10. /01	Yes	BCS

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A 3.10. /01	Mix, K. H.; Berg, G.	1988	Thermal stability of the active ingredient NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC339, Edition Number: M-004178-01-2 Date: 28.06.1988 Non GLP, unpublished also filed: A 3.1.2 /02	Yes	BCS
A 5.3.1. /03	Mrusek, K.	1997	Biological efficacy of imidacloprid versus the internal standards cyfluthrin and propoxur against flying and crawling insects Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: BES-EH-Mo 1442, Edition Number: M-267636-01-1 Date: 21.05.1997 Non GLP, unpublished	Yes	BCS
A 7.4.1.4. /01	Mueller; Caspers	2001	NTN 33893 - Toxicity to bacteria Bayer CropScience AG, Report No.: 1058 A/00 B, Edition Number: M-036840-01-1 Date: 12.02.2001 GLP, unpublished	Yes	BCS
A 6.14. /02*		1988	NTN 37571 - Acute toxicity study on mice Bayer CropScience AG, Report No.: RS88038, Edition Number: M-028572-01-1 Date: 19.10.1988 Non GLP, unpublished	Yes	BCS
A 6.14. /12*		1991	NTN 38014 - Acute oral toxicity study on rats Bayer CropScience AG, Report No.: RA91018, Edition Number: M-028687-01-1 Date: 18.03.1991 GLP, unpublished	Yes	BCS

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A 5.7.1. /02	Nauen, R., Denholm, I.	2005	Resistance of insect pests to neonicotinoid insecticides: current status and future prospects Publisher: Wiley InterScience, Location: Wiley-Liss, Inc., Journal: Archives of Insect Biochemistry and Physiology, Volume: 58, Issue: 2005, Pages: 200-215, Year: 2005, Report No.: MO-05-007838, Edition Number: M-250577-01-1 Non GLP, published	No	
A 5.7.1. /01	Nauen, R.; Ebbinghaus- Kintscher, U.; Elbert, A.; Jeschke, P.; Tietjen, K.	2001	Acetylcholine receptors as sites for developing neonicotinoid insecticides Publisher:Springer-Verlag Berlin, Location:Heidelberg, Journal:Biochemical Sites of Insecticide Action and Resistance, Pages:77-105, Year:2001, Report No.: MO-01-005653, Edition Number: M-047708-01-1 Non GLP, published	No	
A 5.3.1. /01	Nentwig	1993	Efficacy of NTN 33893 after oral application against flies (Musca domestica, Stomoxys calcitrans) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 930, Edition Number: M-114195-01-1 Date: 24.06.1993 Non GLP, unpublished	Yes	BCS
A 5.3.1. /04	Nentwig, G.	2000	Efficacy of different concentrations of imidacloprid after oral application against the American cockroach (Periplaneta americana) and the German cockroach (Blattella germanica) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: BES-EH-MO 01444, Edition Number: M-267714-01-1 Date: 20.09.2000 Non GLP, unpublished	Yes	BCS

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A 5.3.1. /05	Nentwig, G.	2000	Efficacy of different concentrations of imidacloprid after oral application against the American cockroach (Periplaneta americana), the German cockroach (Blattella germanica) and the housefly (Musca domestica) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: BES-EH-MO 01443, Edition Number: M-267717-01-1 Date: 09.08.2000 Non GLP, unpublished	Yes	BCS
A 6.8.1/01	Nishimura, M., Iizuka, M., Iwaki, S., & Kast, A.	1982	Repairability of drug-induced "wavy ribs" in rat offspring ArzneimForsch./Drug Res. 32 (II), No. 12: 1518-1522	No	Public
A 6.1.5. /01*		1988	NTN 33893 technical - Study for skin sensitising effect on guinea pigs (maximisation test) Bayer CropScience AG, Report No.: 16533, Edition Number: M-027579-01-1 Date: 15.03.1988 GLP, unpublished	Yes	BCS
A 6.14. /01*		1991	WAK 3839 - Acute oral toxicity study on rats Bayer CropScience AG, Report No.: RA91017, Edition Number: M-028685-01-1 Date: 11.03.1991 GLP, unpublished	Yes	BCS
A 6.14. /14*		1991	NTN 35884 - Acute oral toxicity study on rats Bayer CropScience AG, Report No.: RA91039, Edition Number: M-028777-01-1 Date: 29.11.1991 GLP, unpublished	Yes	BCS

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A 6.14. /15*	1991	NTN 35884 - Reverse mutation assay (Salmonella typhimurium and Escherichia coli) Bayer CropScience AG, Report No.: RA91040, Edition Number: M-028781-01-1 Date: 29.11.1991 GLP, unpublished	Yes	BCS
A 6.14./16*	1991	NTN 33519 – Acute oral toxicity study on rats. Bayer CropScience AG, Report No.: RA91023, Edition Number: M-028693-01-1 Date: May 31, 1991 GLP, unpublished	Yes	BCS

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A 6.1.3. /01		1988	NTN 33893 - Study for acute inhalation toxicity in the rat in accordance with OECD guideline no. 403 Bayer CropScience AG, Report No.: 16777, Edition Number: M-027586-01-1 Date: 06.06.1988 GLP, unpublished	Yes	BCS
A 6.1.4. /01*		1988	NTN 33893 - Study for irritant/corrosive potential on the skin (rabbit) according to OECD guideline no. 404 Bayer CropScience AG, Report No.: 16455, Edition Number: M-028272-01-1 Date: 25.02.1988 GLP, unpublished	Yes	BCS
A 6.1.4. /02*		1988	NTN 33893 - Study for irritant/corrosive potential on the eye (rabbit) according to OECD guideline no. 405 Bayer CropScience AG, Report No.: 16456, Edition Number: M-028278-01-1 Date: 25.02.1988 GLP, unpublished	Yes	BCS
A 6.3.3 /01*		1989	NTN 33893 (proposed common name: Imidacloprid) - Subacute inhalation toxicity study on the rat according to OECD guideline no. 412 Bayer CropScience AG, Report No.: 18199, Edition Number: M-026004-01-1 Date: 18.07.1989 GLP, unpublished	Yes	BCS
A 6.12.5. /01	Proenca, P.; Teixeira, H.; Castanheira, F.; Pinheiro, J.; Monsanto, P.V.; Marques, E.P.; Vieira, D.N.	2005	Two fatal intoxication cases with imidacloprid: LC/MS analysis Publisher:Elsevier Ireland Ltd., Location:Anon., Journal:Forensic Science International, Volume:153, Pages:75-80, Year:2005, Report No.: M-256901-01-1, Edition Number: M-256901-01-1 Non GLP, published	No	

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A 6.6.2. /02*	1989	BAY NTN 33893 - Sister chromatid exchange assay in chinese hamster ovary cells Bayer CropScience AG, Report No.: BC1149, Edition Number: M-025499-01-1 Date: 12.09.1989 GLP, unpublished	Yes	BCS
A 6.2. /08*	2005	Confidor OD 200 ([14C]-imidacloprid): Comparative in vitro dermal absorption study using human and rat skin. , on behalf of Bayer AG, Monheim/Germany. Study no. SA 04242, Report amendmend no. 1, Edition Number: M-251756-02-1 Date: 21.02.2005 GLP, unpublished	Yes	BCS

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A 7.1.2.2.2. /06	Ratte, H.T.; Memmert, U.	2003	Biological effects and fate of imidacloprid SL 200 in outdoor microcosm ponds RCC Ltd., Itingen, Switzerland Bayer CropScience AG, Report No.: 811776, Edition Number: M-084035-01-1 Date: 26.02.2003 GLP, unpublished also filed: A 7.4.3.5. /01	Yes	BCS
A 7.4.3.5. /01	Ratte, H.T.; Memmert, U.	2003	Biological effects and fate of imidacloprid SL 200 in outdoor microcosm ponds RCC Ltd., Itingen, Switzerland Bayer CropScience AG, Report No.: 811776, Edition Number: M-084035-01-1 Date: 26.02.2003 GLP, unpublished also filed: A 7.1.2.2.2. /06	Yes	BCS
A 4.2.2. /01	Riegner, K.	1993	Method for the determination of imidacloprid in air Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00326, Edition Number: M-011427-02-1 Method Report No.: RA-357/93 Date: 22.06.1993 GLP, unpublished	Yes	BCS
A 4.2.2. /02	Riegner, K.	1993	Modification of the method 00326 (RA-357/93) for the determination of imidacloprid in air Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00326/M001, Edition Number: M-006843-03-1 Method Report No.: RA-631/93 Date: 22.10.1993 GLP, unpublished	Yes	BCS
A 7.4.1.2. /04	Roney, D. J.; Bowers, L. M.	1996	Acute toxicity of 14C-NTN 33823 to Hyallela azteca under static conditions Report No.: 107315, Edition Number: M-032758-01-1 Date: 26.02.1996 GLP, unpublished	Yes	BCS

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A 3.6. /01	Rosenfeldt, F.	1990	Dissociation constant of NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC317, Edition Number: M-004052-02-1 Date: 12.09.1990, Amended: 30.01.1992 Non GLP, unpublished	Yes	BCS
A 6.4.1.2. /01*		1990	NTN 33893 technical - Subchronic toxicity study on dogs in oral administration (thirteen-week feeding study) Bayer CropScience AG, Report No.: 18732, Edition Number: M-026540-01-1 Date: 02.02.1990 GLP, unpublished	Yes	BCS
A 7.2.2.2. /07	Schad, T.	2001	Calculation of temperature referenced first order DT50 of Imidacloprid based on field dissipation studies conducted in Europe Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: MR-387/01, Edition Number: M-069290-01-1 Date: 20.08.2001 Non GLP, unpublished	Yes	BCS
A7.2.2.2./08	Schad, T.; Zerbe, P.	2005	Kinetic evaluation of the dissipation of imidacloprid under european field conditions Bayer CropScience AG, Report No.: MEF-05/077, Edition Number: M-245946-01-1 Date: 23.02.2005 Non GLP, unpublished	Yes	BCS
A 2.8. /04	Schindler, M.	2006	Results Concerning the Molecular Geometry of Imidacloprid Based on Quantum Chemical Calculations Bayer CropScience AG, Edition Number: M-277468-01-1 Date: 14.09.2006 Non GLP, unpublished confidential	Yes	BCS
A 2.8./05	Schindler, M.	2006	Results Concerning the Molecular Geometry of Imidacloprid Based on Crystal Structure Analysis Bayer CropScience AG, Edition Number: M-277469-01-1 Date: 14.09.2006 Non GLP, unpublished confidential	Yes	BCS

A 7.5.4.1. /02	Schmitzer, S.	1999	Laboratory testing for toxicity (acute oral LD50) of NTN 33893 on honey bees (Apis mellifera L.) (Hymenoptera, Apidae) Report No.: 6400036, Edition Number: M-016942-01-1 Date: 30.09.1999 GLP, unpublished	Yes	BCS
A 7.5.3.1.2. /03		1996	Age-related five day dietary toxicity of Imidacloprid to bobwhite quail Bayer CropScience AG, Report No.: SXR/VB 057, Edition Number: M-006782-01-1 Date: 14.11.1996 GLP, unpublished	Yes	BCS
A 7.5.4.1. /04	Schmuck, R.; Schoening, R.; Schramel, O.	1999a	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of sunflowers cultivated on soils with different imidacloprid residue levels and effects on these residues on foraging honeybees. 1999 Bayer CropScience AG, Report No.: SXR/AM 007, Edition Number: M-016827-01-1 Date: 28.09.1999 GLP, unpublished	Yes	BCS
A 7.5.4.1./05	Schmuck, R.; Schoening, R.; Schramel, O.	1999b	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of sunflowers cultivated on soils with different imidacloprid residue levels and effects of these residues on foraging honeybees. 1999 Bayer CropScience AG, Report No.: SXR/AM 006, Edition Number: M-016820-01-1 Date: 27.09.1999 GLP, unpublished	Yes	BCS

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A 7.5.4.1./06	Schmuck, R.; Schoening, R.; Schramel, O.	1999с	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of summer rape cultivated on soils with different imidacloprid residue levels and effects of these residue on foraging honeybees. 'Hoefchen' 1999 Bayer CropScience AG, Report No.: SXR/AM 010, Edition Number: M-016842-01-1 Date: 28.09.1999 GLP, unpublished	Yes	BCS
A 7.5.4.1./07	Schmuck, R.; Schoening, R.; Schramel, O.	1999d	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of summer rape cultivated on soils with different imidacloprid residue levels and effects of these residues on foraging honeybees. 1999 Bayer CropScience AG, Report No.: SXR/AM 008, Edition Number: M-016828-01-1 Date: 28.09.1999 GLP, unpublished	Yes	BCS
A 2.6. /01	Schneider, U.	2002	Synthesis of Imidacloprid at the BCS production plant Bayer CropScience AG, Report No.: MO-02-018639, Edition Number: M-073725-01-1 Date: 18.11.2002 Non GLP, unpublished confidential	Yes	BCS
A.7.2.2.4 /01	Scholz, K.	1992	Degradation of NTN 33893 in soil with groundcover Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3438, Edition Number: M-006712-02-1 Date: 20.02.1991, Amended: 21.02.1992 GLP, unpublished	Yes	BCS

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A 4.2.1. /01	Schramel, O.	2001	Method 00680 (MR-090/01) for the determination of imidacloprid in soil by HPLC-MS/MS	Yes	BCS
			Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00680,		
			Edition Number: M-082263-01-1 Method Report No.: MR-090/01 Date: 29.10.2001 GLP, unpublished		
A 4.2.1. /03	Schramel, O.	1999	Enforcement-/confirmatiory method 00577 (MR-172/99) for liquid chromatographic determination of imidacloprid in soil Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00577, Edition Number: M-012349-01-1 Method Report No.: MR-172/99 Date: 30.04.1999 GLP, unpublished	Yes	BCS
A 2.8. /01	Schreiber, R.	2003	Material Accountability of Confidor T Bayer CropScience AG, Report No.: MO-03-004124, Edition Number: M-087652-01-1 Date: 16.01.2003 GLP, unpublished confidential	Yes	BCS
A 2.8./02	Schreiber, R.	2003	NTN 33893 - Reanalyzes of the analytical profile of the TOX-batches Bayer CropScience AG, Report No.: DOR/03/003/SBRU, Edition Number: M-088099-01-1 Date: 28.03.2003 Non GLP, unpublished confidential	Yes	BCS
A 4.1, /09	Schroeder, S.	2000	Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: VB1-2005-0000703, Edition Number: M-031957-01-1 Date: 09.05.2000 Non GLP, unpublished confidential	Yes	BCS

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A 4.1./11	Schroeder, S.	2000	Validation report VB1-2005-0009701-99; Karl Fischer water determination Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: VB1-2005-0009701-99, Edition Number: M-031907-01-1 Date: 20.04.2000 Non GLP, unpublished confidential	Yes	BCS
A 7.5.1.3. /01	Seyfried, B.	1999	Terrestrial plants, growth test with imidacloprid Bayer CropScience AG, Report No.: 724915, Edition Number: M-017610-01-1 Date: 11.05.1999 GLP, unpublished also filed: A 7.5.2.2./01	Yes	BCS
A 7.5.2.2. /01	Seyfried, B.	1999	Terrestrial plants, growth test with imidacloprid Bayer CropScience AG, Report No.: 724915, Edition Number: M-017610-01-1 Date: 11.05.1999 GLP, unpublished also filed: A 7.5.1.3. /01	Yes	BCS
A 6.9. /01*		1994	An acute oral neurotoxicity screening study with technical grade imidacloprid (NTN 33893) in rats Bayer CropScience AG, Report No.: BC7221, Edition Number: M-028815-02-1 Date: 16.02.1994, Amended: 07.06.1994 GLP, unpublished	Yes	BCS
A 6.9. /02*		1994	A subchronic dietary neurotoxicity screening study with technical grade Imidacloprid (NTN 33893) in Fischer 344 rats Bayer CropScience AG, Report No.: BC7331, Edition Number: M-027944-01-1 Date: 13.06.1994 GLP, unpublished	Yes	BCS

A 6.9. /03*		2001	A developmental neurotoxicity screening study with technical grade Imidacloprid in Wistar rats	Yes	BCS
			Bayer CropScience AG, Report No.: 110245, Edition Number: M-084646-01-1 Date: 14.09.2001 GLP, unpublished		
A 3.16. /01	Smeykal, H.	2005	Confidor, imidacloprid; NTN 33893 (AE F106464) - Oxidizing properties A.17. Siemens AG, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: 20050628.01, Edition Number: M-255230-01-1 Date: 28.07.2005 GLP, unpublished	Yes	BCS
A 5.3.1. /02	Smith, G.	1994	Efficacy of Imidacloprid over a range of doses as a sugar granule fly bait against flies in a piggery Bayer Ltd., Sydney Australia Bayer CropScience AG, Report No.: MO-03-009113, Edition Number: M-116541-01-1 Date: 11.08.1994 Non GLP, unpublished	Yes	BCS
A 4.2.3. /01	Sommer, H.	1999	Enforcement and confirmatory method for determination of imidacloprid in drinking water and surface water by HPLC Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00576, Edition Number: M-013524-01-1 Method Report No.: MR-173/99 Date: 18.06.1999 GLP, unpublished	Yes	BCS
A 7.2.2.2./04	Sommer, H.	1998a	Dissipation of Confidor 200 SL in soil under field conditions (Italy and Spain) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: RA-2107/96, Edition Number: M-021151-02-1 Date: 24.09.1998, Amended: 29.10.1998 GLP, unpublished	Yes	BCS

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A 7.2.2.2. /05	Sommer, H.	1998b	Dissipation of Confidor 200 SL in soil under field conditions (France and Italy) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: RA-2084/95, Report includes Trial Nos.: R506230 R506249 Edition Number: M-021135-02-1 Date: 02.07.1998, Amended: 10.11.1999 GLP, unpublished	Yes	BCS
A 7.1.2.2.2. /01	Spiteller, M.	1993	Aerobic metabolism of imidacloprid, 14C-NTN 33893, in an aquatic model ecosystem Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3950, Edition Number: M-024398-01-1 Date: 20.10.1993 GLP, unpublished	Yes	BCS
A 2.8./03	Sporenberg, W.	2003	Determination of volatile Nitrosamines Bayer Industry Services, Leverkusen, Gemany Bayer CropScience AG, Report No.: MO-03-006004, Edition Number: M-090994-01-1 Date: 09.05.2003 Non GLP, unpublished confidential	Yes	BCS
A 4.1./13	Sporenberg, W.	2003	Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, Report No.: 2011-0600201-03, Edition Number: M-091031-01-1 Date: 08.05.2003 Non GLP, unpublished confidential	Yes	BCS
A 4.1./14	Sporenberg, W.	2003	Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, Report No.: 2011-0600401-03, Edition Number: M-091023-01-1 Date: 08.05.2003 Non GLP, unpublished confidential	Yes	BCS

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A 4.1./15	Sporenberg, W.	2003		Yes	BCS
			Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG,		
			Report No.: VD-2011-0600201-03, Edition Number: M-091218-01-1		
			Date: 12.05.2003 Non GLP, unpublished confidential		
A 4.1./16	Sporenberg, W.	2003		Yes	BCS
			Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG,		
			Report No.: VD-2011-0600401-03, Edition Number: M-091221-01-1 Date: 12.05,2003		
			Non GLP, unpublished confidential		
A 7.5.3.1.3. /02		1992	Technical NTN 33893: A one generation reproduction study with mallard ducks	Yes	BCS
			Bayer CropScience AG, Report No.: 103813-1,		
			Edition Number: M-006730-02-1		
			Date: 03.09.1992, Amended: 03.06.1993 GLP, unpublished		
			(Caddy complete – total pages 138; Supplement pages 1-39, First report 1-99 (40-138)).		
A 6.12.2. /01	Steffens, W.	2000	Final report on the poisoning incident "Lizetan Kombistäbehen, 30.5.00"	Yes	BCS
			Bayer CropScience AG,		
			Report No.: MO-00-014602,		
			Edition Number: M-023399-01-1 Date: 26.10,2000		
			Non GLP, unpublished		

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A 7.1.2.2.1. /01	Stevens, J.; Halarnkar, P. P.; Leimkuehler, W. M.; Davis, J. S.	1997	Characterization of three degradates of imidacloprid from aerobic aquatic biotransformation study ABC Laboratories, Inc., Columbia, MO, USA Bayer CropScience AG, Report No.: BR107547, Edition Number: M-024427-02-1 Date: 04.12.1996, Amended: 25.09.1997 GLP, unpublished	Yes	BCS
A 3.3.1 /01	Stoecker, R. H.	2001	Appearance of the substance Imidiacloprid Technical Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SKD APP 05/2001, Edition Number: M-041457-01-1 Date: 22.08.2001 Non GLP, unpublished also filed: A 3.3.2 /01 also filed: A 3.3.3 /01	Yes	BCS
A 3.3.2 /01	Stoecker, R. H.	2001	Appearance of the substance Imidiacloprid Technical Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SKD APP 05/2001, Edition Number: M-041457-01-1 Date: 22.08.2001 Non GLP, unpublished also filed: A 3.3.1 /01 also filed; A 3,3.3 /01	Yes	BCS
A 3.3.3 /01	Stoecker, R. H.	2001	Appearance of the substance Imidiacloprid Technical Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SKD APP 05/2001, Edition Number: M-041457-01-1 Date: 22.08.2001 Non GLP, unpublished also filed: A 3.3.1 /01 also filed: A 3.3.2 /01	Yes	BCS
A 6.8.2. /01*	Suter, P.; Biedermann, K.; Luetkemeier, H.; Wilson, J. T.; Terrier, C.	1990	Multiple generation reproduction study with NTN 33893 technical in rats RCC, Research and Consulting Company AG, Itingen, Switzerland Bayer CropScience AG, Report No.: R5097, Edition Number: M-027300-03-1 Date: 21.06.1990, Amended: 03.03.1992 GLP, unpublished	Yes	BCS

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A 6.6.2. /01*	Taalman, M.	1988	Clastogenic evaluation of NTN 33893 in an in vitro cytogenetic assay measuring sister chromatid exchange in chinese hamster ovary (CHO) cells Hazleton Biotechnologies Laboratory, Veenendaal, Netherlands Bayer CropScience AG, Report No.: R4407, Edition Number: M-026488-01-1 Date: 21.04.1988 GLP, unpublished	Yes	BCS
A 7,5,3.1.1./01		1990a	Technical NTN 33893: An acute oral LD50 with Bobwhite quail Bayer CropScience AG, Report No.: 100059, Edition Number: M-006718-01-1 Date: 01.03.1990 GLP, unpublished	Yes	BCS
A 7.5.3.1.2. /01		1990ъ	Technical NTN 33893: A subacute dietary LC50 with mallard ducks Bayer CropScience AG, Report No.: 100238, Edition Number: M-006721-01-1 Date: 22.08.1990 GLP, unpublished	Yes	BCS
A 7.5.3.1.3. /01		1991	Technical NTN 33893: A one generation reproduction study with bobwhite quail Bayer CropScience AG, Report No.: 101203, Edition Number: M-006723-01-1 Date: 25.02.1991 GLP, unpublished	Yes	BCS
A 5.4. /01	Tomizawa, M.; Casida, J. E.	2002	Selective toxicity of neonicotinoids attributable to specificity of insect and mammalian nicotinic receptors Publisher:Annual Reviews, Journal:Annual Review of Entomology, Volume:48, Pages:339 - 364, Year:2003, Report No.: MO-05-004254, Edition Number: M-245942-01-1 Non GLP, published	No	

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A 6.6.6. /01*		1990	Mouse germ-cell cytogenetic assay with NTN 33893	Yes	BCS
			Bayer CropScience AG, Report No.: R5063, Edition Number: M-026551-01-1 Date: 22.05.1990 GLP, unpublished		
A 6.15.3. /05		1992	[Pyridinyl-14C-methyl] NTN 33893 residues in rotational crops Bayer CropScience AG, Report No.: PF3674, Edition Number: M-024386-01-1 Date: 10.08.1992 GLP, unpublished	Yes	BCS
A 2.7./01	Volkmann, T.	2003	Composition Statement - CONFIDOR techn. Bayer CropScience AG, Report No.: MO-03-001628, Edition Number: M-039228-02-1 Date: 11.02.2003 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /08	Wanner, B.	2000	Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 2005-0000703-00, Edition Number: M-031899-03-2 Date: 11.05.2000 Non GLP, unpublished confidential	Yes	BCS
A 4.1./10	Wanner, B.	1999	Analytical procedure for the Karl Fischer water determination Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 2005-0009701-99, Edition Number: M-021975-01-2 Date: 04.11.1999 Non GLP, unpublished confidential	Yes	BCS
A 6.6.1. /04*		1991	NTN 33893 - Reverse mutation assay (Salmonella typhimurium and Escherichia coli) Bayer CropScience AG, Report No.: RA91002, Edition Number: M-028670-01-1 Date: 17.01.1991 GLP, unpublished	Yes	BCS

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A 6.14. /03*	1990	WAK 3839 - Reverse mutation assay (Salmonella tyhimurium and Escherichia coli)	Yes	BCS
		Bayer CropScience AG, Report No.: RA90035, Edition Number: M-028631-01-1 Date: 26.11.1990 GLP, unpublished		
A 6.14, /06	1991	WAK 3839 - Rec-assay with spores in the bacterial system Bayer CropScience AG, Report No.: RA91015, Edition Number: M-028680-01-1 Date: 01.03.1991 GLP, unpublished	Yes	BCS
A 6.14. /13*	1991	NTN 38014 - Reverse mutation assay (Salmonella typhimurium and Escherichia coli) Bayer CropScience AG, Report No.: RA91019, Edition Number: M-028689-02-1 Date: 29.03.1991 GLP, unpublished	Yes	BCS
A 6.14/17*	1991	NTN 33519 – Reverse mutation assay (Salmonella typhimurium and Escherichia coli). Bayer CropScience AG, Report No.: RA91024, Edition Number: M-028770-01-1 Date: July 22, 1991 GLP, unpublished	Yes	BCS

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A 6.5. /04*	1991	NTN 33893 (proposed common name: Imidacloprid) - Carcinogenicity study in B6C3F1 mice (supplementary MTD testing for study T5025710 with administration in diet over a 24-month period)	Yes	BCS
		Bayer CropScience AG, Report No.: 20769, Edition Number: M-026038-01-1 Date: 24.10.1991 GLP, unpublished also filed: A 6.7. /04		
A 6.7. /04*	1991	NTN 33893 (proposed common name: Imidacloprid) - Carcinogenicity study in B6C3F1 mice (supplementary MTD testing for study T5025710 with administration in diet over a 24-month period) Bayer CropScience AG, Report No.: 20769, Edition Number: M-026038-01-1 Date: 24.10.1991 GLP, unpublished also filed: A 6.5. /04	Yes	BCS
A 6.5. /03*	1991	NTN 33893 (proposed common name Imidacloprid) - Carcinogenicity study on B6C3F1 mice (administration in the food for 24 months) Bayer CropScience AG, Report No.: 19931, Edition Number: M-026310-01-1 Date: 28.01.1991 GLP, unpublished also filed: A 6.7. /03	Yes	BCS
A 6.7. /03*	1991	NTN 33893 (proposed common name Imidacloprid) - Carcinogenicity study on B6C3F1 mice (administration in the food for 24 months) Bayer CropScience AG, Report No.: 19931, Edition Number: M-026310-01-1 Date: 28.01.1991 GLP, unpublished also filed: A 6.5. /03	Yes	BCS

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A 3.1.3 /01	Weber	1987	Density of NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC333, Edition Number: M-004041-01-1 Date: 31.07.1987 Non GLP, unpublished	Yes	BCS
A 4.1./01	Werner, T.	1993	Confidor; Assay - HPLC, External Standard Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: 2201-0260401-93, Edition Number: M-005637-01-2 Date: 17.06.1993 Non GLP, unpublished	Yes	BCS
A7.5.2.1./02	Wilhelmy, H.	1999	NTN 33893 - Inhibition of reproduction of collembola (Folsomia candida) Bayer CropScience AG, Report No.: ICR64081, Edition Number: M-031094-01-1 Date: 26.08.1999 GLP, unpublished	Yes	BCS
A 7.1.3. /02	Williams, M. D.; Berghaus, L.; Dyer, D.	1992	Soil/sediment adsorption-desorption of [14C] imidacloprid ABC Laboratories, Inc., Columbia, MO, USA Bayer CropScience AG, Report No.: MR103816, Edition Number: M-023828-01-1 Date: 14.09.1992 GLP, unpublished	Yes	BCS
A 7.1.2.2.2. /02	Wilmes, R.	1990	Aerobic aquatic metabolism of NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3466, Edition Number: M-024098-02-1 Date: 04.12.1990 GLP, unpublished	Yes	BCS
A 7.1.1.1.1./01	Yoshida, H.	1989	Hydrolysis of NTN 33893 Nihon Tokushu Noyaku Seizo K. K., Ibraki, Japan Bayer CropScience AG, Report No.: NR1276, Edition Number: M-024064-01-1 Date: 06.09.1989 GLP, unpublished	Yes	BCS

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Reference List author

A 7.4.3.4. /01	Young, B. M.; Blakemore, G. C.	1990	21-day chronic static renewal toxicity of NTN 33893 to Daphnia magna Bayer CropScience AG, Report No.: 100247, Edition Number: M-006824-01-1 Date: 19.09.1990 GLP, unpublished	Yes	BCS
A 7.4.1.2. /01	Young, B. M.; Hicks, S. L.	1990	Acute toxicity of NTN 33893 to Daphnia magna Bayer CropScience AG, Report No.: 100245, Edition Number: M-006821-01-1 Date: 12.09.1990 GLP, unpublished	Yes	BCS

^{*} key study

Section No / Reference No	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A 2.6./01	Schneider, U.	2002	Synthesis of Imidacloprid at the BCS production plant Bayer CropScience, Bayer CropScience AG, Report No.: MO-02-018639, Edition Number: M-073725-01-1 Date: 18.11.2002 Non GLP, unpublished confidential	Yes	BCS
A.2.7. /01	Volkmann, T.	2003	Composition Statement - CONFIDOR techn. Bayer CropScience AG, Report No.: MO-03-001628, Edition Number: M-039228-02-1 Date: 11.02.2003 Non GLP, unpublished confidential	Yes	BCS
A 2.8./01	Schreiber, R.	2003	Material Accountability of Confidor T Bayer AG Bayer CropScience AG, Report No.: MO-03-004124, Edition Number: M-087652-01-1 Date: 16.01.2003 GLP, unpublished confidential	Yes	BCS
A 2.8. /02	Schreiber, R.	2003	NTN 33893 - Reanalyzes of the analytical profile of the TOX-batches Bayer AG, Bayer CropScience AG, Report No.: DOR/03/003/SBRU, Edition Number: M-088099-01-1 Date: 28.03.2003 Non GLP, unpublished confidential	Yes	BCS
A 2.8. /03	Sporenberg, W.	2003	Determination of volatile Nitrosamines Bayer Industry Services, Leverkusen, Gemany Bayer CropScience AG, Report No.: MO-03-006004, Edition Number: M-090994-01-1 Date: 09.05.2003 Non GLP, unpublished confidential	Yes	BCS
A 2.8./04	Schindler, M.	2006	Results Concerning the Molecular Geometry of Imidacloprid Based on Quantum Chemical Calculations Bayer CropScience AG, Edition Number: M-277468-01-1 Date: 14.09.2006 Non GLP, unpublished confidential	Yes	BCS

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A 2.8. /05	Schindler, M.	2006	Results Concerning the Molecular Geometry of Imidacloprid Based on Crystal Structure Analysis Bayer CropScience AG, Edition Number: M-277469-01-1 Date: 14.09.2006 Non GLP, unpublished confidential	Yes	BCS
A 3.1.1 /01	Krohn, J.	1993	Melting Point of Imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC312, Edition Number: M-004037-01-1 Date: 19.05.1993 GLP, unpublished	Yes	BCS
A 3.1.2 /01	Krohn, J.	1996	Boiling Point of Imidacloprid (NTN 33893) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC1437, Edition Number: M-004039-01-1 Date: 25.09.1996 Non GLP, unpublished	Yes	BCS
A 3.1.2/02	Mix, K. H.; Berg, G.	1988	Thermal stability of the active ingredient NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC339, Edition Number: M-004178-01-2 Date: 28.06.1988 Non GLP, unpublished also filed: A 3.10. /01	Yes	BCS
A 3.1.3 /01	Weber	1987	Density of NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC333, Edition Number: M-004041-01-1 Date: 31.07.1987 Non GLP, unpublished	Yes	BCS
A 3.1.3 /02	Krohn, J.	1995	Density of Imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC713, Edition Number: M-004040-01-1 Date: 08.02.1995 GLP, unpublished	Yes	BCS
A 3.2. /01	Krohn, J.	1993	Vapour Pressure Curve of Imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC313, Edition Number: M-004042-01-1 Date: 30.09.1993 GLP, unpublished	Yes	BCS

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A 3.2,1 /01	Krohn, J.	1993	Calculation of the Henry Law Constant of Imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC315, Edition Number: M-004047-01-1 Date: 08.10.1993 Non GLP, unpublished	Yes	BCS
A 3.3.1 /01	Stoecker, R. H.	2001	Appearance of the substance Imidiacloprid Technical Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SKD APP 05/2001, Edition Number: M-041457-01-1 Date: 22.08.2001 Non GLP, unpublished also filed: A 3.3.2 /01 also filed: A 3.3.3 /01	Yes	BCS
A 3.3.2 /01	Stoecker, R. H.	2001	Appearance of the substance Imidiacloprid Technical Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SKD APP 05/2001, Edition Number: M-041457-01-1 Date: 22.08.2001 Non GLP, unpublished also filed: A 3.3.1 /01 also filed: A 3.3.3 /01	Yes	BCS
A 3.3.3 /01	Stoecker, R. H.	2001	Appearance of the substance Imidiacloprid Technical Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SKD APP 05/2001, Edition Number: M-041457-01-1 Date: 22.08.2001 Non GLP, unpublished also filed: A 3.3.1 /01 also filed: A 3.3.2 /01	Yes	BCS
A 3.4.1 /01	Kaussmann, M.	2001	Spectral Data Set of Imidachloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 156002172, Edition Number: M-032373-01-1 Date: 04.12.2001 GLP, unpublished also filed: A 3.4.2 /01 also filed: A 3.4.3 /01 also filed: A 3.4.4 /01	Yes	BCS

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A 3.4.2 /01	Kaussmann, M.	2001	Spectral Data Set of Imidachloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 156002172, Edition Number: M-032373-01-1 Date: 04.12.2001 GLP, unpublished also filed: A 3.4.1 /01 also filed: A 3.4.3 /01 also filed: A 3.4.4 /01	Yes	BCS
A 3.4.3 /01	Kaussmann, M.	2001	Spectral Data Set of Imidachloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 156002172, Edition Number: M-032373-01-1 Date: 04.12.2001 GLP, unpublished also filed: A 3.4.1 /01 also filed: A 3.4.2 /01 also filed: A 3.4.4 /01	Yes	BCS
A 3.4.4 /01	Kaussmann, M.	2001	Spectral Data Set of Imidachloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 156002172, Edition Number: M-032373-01-1 Date: 04.12.2001 GLP, unpublished also filed: A 3.4.1 /01 also filed: A 3.4.2 /01 also filed: A 3.4.3 /01	Yes	BCS
A 3.5. /01	Krohn, J.	1993	Water solubility of Imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC320, Edition Number: M-004109-01-1 Date: 03.03.1993 GLP, unpublished	Yes	BCS
A 3.6. /01	Rosenfeldt, F.	1990	Dissociation constant of NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC317, Edition Number: M-004052-02-1 Date: 12.09.1990, Amended: 30.01.1992 Non GLP, unpublished	Yes	BCS
A 3.7. /01	Krohn, J.	1993	Solubility of Imidacloprid in representative organic solvents Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC323, Edition Number: M-004130-01-1 Date: 22.06.1993 Non GLP, unpublished	Yes	BCS

Competent Authority: DE

A 3.9. /01	Krohn, J.	1989	Octanol/Water partition coefficient of NTN 33893 Bayer AG, Wuppertal, Germany Bayer CropScience AG, Report No.: PC337, Edition Number: M-004153-02-1 Date: 15.06.1989, Amended: 30.01.1992 GLP, unpublished	Yes	BCS
A 3.9. /02	Каивтапп, , Е.	2003	Determination of the log POW of NTN 33893 - metabolites by HPLC (Analytical note) Bayer CropScience AG, Report No.: MO-03-004358, Edition Number: M-088171-01-1 Date: 31.03.2003 Non GLP, unpublished	Yes	BCS
A 3.10. /01	Mix, K. H.; Berg, G.	1988	Thermal stability of the active ingredient NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC339, Edition Number: M-004178-01-2 Date: 28.06.1988 Non GLP, unpublished also filed: A 3.1.2 /02	Yes	BCS
A 3.11	Bogdoll, B.	2009	NTN 33893 - Statements on the Articles A.12. and A.13., Council Directive 67/548/EEC, Annex V Flammability (substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities), A.12. Flammability (solids and liquids) / Pyrophoric properties, A.13. Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: AF09/040, Edition Number: M-347798-01-1 Date: 25.05.2009 Non GLP, unpublished	Yes	BCS
A 3.11. /01	Mix, K. H.	1993	Investigation of safety-relevant parameters of Confidor techn. Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC635, Edition Number: M-004182-01-2 Date: 29.10.1993 GLP, unpublished also filed: A 3.15. /01	Yes	BCS
A 3.13. /01	Imre, L.	1993	NTN 33893 - Surface tension Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC319, Edition Number: M-004100-02-1 Date: 03.06.1993 GLP, unpublished	Yes	BCS

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A 3.15, /01	Mix, K. H.	1993	Investigation of safety-relevant parameters of Confidor techn. Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC635, Edition Number: M-004182-01-2 Date: 29.10.1993 GLP, unpublished also filed: A 3.11./01	Yes	BCS
A 3.16. /01	Smeykal, H.	2005	Confidor, imidacloprid; NTN 33893 (AE F106464) - Oxidizing properties A.17. Siemens AG, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: 20050628.01, Edition Number: M-255230-01-1 Date: 28.07.2005 GLP, unpublished	Yes	BCS
A 3.17. /01	Cichy, M.; Merheim, P.	2005	Stability of Imidacloprid (NTN 33893/ AE F106464) to normal and elevatedtemperature, metals and metal ions and corrosion characteristics Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: PA05/059, Edition Number: M-255320-01-1 Date: 29.07.2005 GLP, unpublished	Yes	BCS
A 4.1./01	Werner, T.	1993	Confidor; Assay - HPLC, External Standard Bayer CropScience AG, Report No.: 2201-0260401-93, Edition Number: M-005637-01-2 Date: 17.06.1993 Non GLP, unpublished	Yes	BCS
A 4,1./02	Haustein, M.	2003	Validation of HPLC-method 2201- 0260401-93 -Determination of the assay in Confidor (Imidacloprid) techn. grade active ingredient- Germany Bayer CropScience AG, Report No.: VB2-2201-0260401, Edition Number: M-090267-03-1 Date: 25.04.2003 Non GLP, unpublished	Yes	BCS
A 4.1./03	Anon.	1997	Imidacloprid 582 CIPAC Bayer CropScience AG, Report No.: CIPAC 582, Edition Number: M-032649-01-1 Date: 01.01.1997 Non GLP, unpublished	Yes	BCS

A 4.1, /04	Haustein, M.	1998	NTN 33893 ; By-products - Linear Synthesis ; HPLC, External Standard	Yes	BCS
			Bayer CropScience AG, Report No.: 2201-0308702-98, Edition Number: M-007778-02-2 Date: 04.06.1998 Non GLP, unpublished confidential		
A 4.1./05	Haustein, M.	2003	Validation of HPLC-method 2201- 0308702-98 -Determination of the by- products in Confidor (Imidacloprid) techn. grade active ingredient- , Germany Bayer CropScience AG, Report No.: VB2-2201-0308702, Edition Number: M-090284-02-1 Date: 28.04.2003 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /06	Cichy, M.; Gau, W.	2005	WAK in NTN 33893 AMP W; Assay - HPLC-external standard Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 2005-0002002-92, Edition Number: M-007788-02-3 Date: 24.01.2005 Non GLP, unpublished confidential	Yes	BCS
A 4.1./07	Haustein, M.	2001	Validation of HPLC-method 2005- 0002002-92 -Determination of WAK 3839 in Confidor (Imidacloprid) techn. grade a.i Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: VB2-2005-0002002, Edition Number: M-046369-02-1 Date: 14.03.2001 Non GLP, unpublished confidential	Yes	BCS
A 4.1./08	Wanner, B.	2000	Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 2005-0000703-00, Edition Number: M-031899-03-2 Date: 11.05.2000 Non GLP, unpublished confidential	Yes	BCS
A 4.1./09	Schroeder, S.	2000	Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: VB1-2005-0000703, Edition Number: M-031957-01-1 Date: 09.05.2000 Non GLP, unpublished confidential	Yes	BCS

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A 4.1, /10	Wanner, B.	1999	Analytical procedure for the Karl Fischer water determination Bayer AG, Leverkusen, Germany	Yes	BCS
			Bayer CropScience AG, Report No.: 2005-0009701-99, Edition Number: M-021975-01-2 Date: 04.11.1999 Non GLP, unpublished confidential		
A 4.1./11	Schroeder, S.	2000	Validation report VB1-2005-0009701-99; Karl Fischer water determination Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: VB1-2005-0009701-99, Edition Number: M-031907-01-1 Date: 20.04.2000 Non GLP, unpublished confidential	Yes	BCS
A 4.1./12	Dobrat W.; Martijn	1995	CIPAC Handbook Volume F Physico-chemical methods for technical and formulated pesticides MT 30 Water 30.1 Karl Fischer method Publisher:Collab. Int. Pest. Anal. Council Ltd., Journal:CIPAC Handbook, Volume:F, Pages:91;93, Year:1995, Report No.: C042873, Edition Number: M-233461-01-1 Date: 01.01.1995 Non GLP, published confidential	No	
A 4.1./13	Sporenberg, W.	2003	Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, Report No.: 2011-0600201-03, Edition Number: M-091031-01-1 Date: 08.05.2003 Non GLP, unpublished confidential	Yes	BCS
A 4.1./14	Sporenberg, W.	2003	Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, Report No.: 2011-0600401-03, Edition Number: M-091023-01-1 Date: 08.05.2003 Non GLP, unpublished confidential	Yes	BCS

A 4.1,/15	Sporenberg, W.	2003		Yes	BCS
			Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, Report No.: VD-2011-0600201-03, Edition Number: M-091218-01-1 Date: 12.05.2003 Non GLP, unpublished confidential		
A 4.1./16	Sporenberg, W.	2003	Germany Bayer CropScience AG, Report No.: VD-2011-0600401-03, Edition Number: M-091221-01-1 Date: 12.05.2003 Non GLP, unpublished confidential	Yes	BCS
A 4.2.1. /01	Schramel, O.	2001	Method 00680 (MR-090/01) for the determination of imidacloprid in soil by HPLC-MS/MS Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00680, Edition Number: M-082263-01-1 Method Report No.: MR-090/01 Date: 29.10.2001 GLP, unpublished	Yes	BCS
A 4.2.1. /02	Bachlechner, G.	1992	Method for high performance liquid chromatographic determination of residues of the insecticide imidaeloprid in soil using a laboratory robotic system Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00270, Edition Number: M-006708-02-1 Method Report No.: RA-139/92 Date: 11.03.1992 Non GLP, unpublished	Yes	BCS
A 4.2.1. /03	Schramel, O.	1999	Enforcement-/confirmatiory method 00577 (MR-172/99) for liquid chromatographic determination of imidacloprid in soil Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00577, Edition Number: M-012349-01-1 Method Report No.: MR-172/99 Date: 30.04.1999 GLP, unpublished	Yes	BCS

A 4.2,2./01	Riegner, K.	1993	Method for the determination of imidacloprid in air Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00326, Edition Number: M-011427-02-1 Method Report No.: RA-357/93 Date: 22.06.1993 GLP, unpublished	Yes	BCS
A.4.2.2. /02	Riegner, K.	1993	Modification of the method 00326 (RA-357/93) for the determination of imidacloprid in air Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00326/M001, Edition Number: M-006843-03-1 Method Report No.: RA-631/93 Date: 22.10.1993 GLP, unpublished	Yes	BCS
A4.2.2/03	Hellpointner, E.	1999	Confirmatory method for the determination of imidaeloprid in air Bayer AG report no. MR-335/99, method no. 00326-M001, study no. P 625 9 6000 unpublished	Yes	BCS
A.4.2.3. /01	Sommer, H.	1999	Enforcement and confirmatory method for determination of imidacloprid in drinking water and surface water by HPLC Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00576, Edition Number: M-013524-01-1 Method Report No.: MR-173/99 Date: 18.06.1999 GLP, unpublished	Yes	BCS
A.4.2.3. /02	Billesbach, K. S.; Leimkuehler, W. M.; Widmer, S. L.	1996	Analytical method for the determination of imidacloprid and the guanidine, olefinic guanidine, and urea metabolites in groundwater by high-performance liquid chromatography tandem mass spectrometry (LC-MS/MS) Bayer Corporation, Kansas City, MO, USA Bayer CropScience AG, Report No.: 107352, Edition Number: M-012941-01-1 Date: 11.06.1996 GLP, unpublished	Yes	BCS

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A 4.2.3. /03	Koenig, T.	1996	Method for the determination of imidacloprid in drinking water by HPLC with on-line solid phase extraction Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00406, Edition Number: M-006837-02-1 Method Report No.: MR-831/95 Date: 09.01.1996 Non GLP, unpublished	Yes	BCS
A 5,3.1. /01	Nentwig	1993	Efficacy of NTN 33893 after oral application against flies (Musca domestica, Stomoxys calcitrans) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 930, Edition Number: M-114195-01-1 Date: 24.06.1993 Non GLP, unpublished	Yes	BCS
A 5.3.1. /02	Smith, G.	1994	Efficacy of Imidacloprid over a range of doses as a sugar granule fly bait against flies in a piggery Bayer Ltd., Sydney Australia Bayer CropScience AG, Report No.: MO-03-009113, Edition Number: M-116541-01-1 Date: 11.08.1994 Non GLP, unpublished	Yes	BCS
A 5.3.1./03	Mrusek, K.	1997	Biological efficacy of imidacloprid versus the internal standards cyfluthrin and propoxur against flying and crawling insects Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: BES-EH-Mo 1442, Edition Number: M-267636-01-1 Date: 21.05.1997 Non GLP, unpublished	Yes	BCS
A 5.3.1./04	Nentwig, G.	2000	Efficacy of different concentrations of imidacloprid after oral application against the American cockroach (Periplaneta americana) and the German cockroach (Blattella germanica) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: BES-EH-MO 01444, Edition Number: M-267714-01-1 Date: 20.09.2000 Non GLP, unpublished	Yes	BCS

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A 5.3.1. /05	Nentwig, G.	2000	Efficacy of different concentrations of imidacloprid after oral application against the American cockroach (Periplaneta americana), the German cockroach (Blattella germanica) and the housefly (Musca domestica) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: BES-EH-MO 01443, Edition Number: M-267717-01-1 Date: 09.08.2000 Non GLP, unpublished	Yes	BCS
A 5.4. /01	Tomizawa, M.; Casida, J. E.	2002	Selective toxicity of neonicotinoids attributable to specificity of insect and mammalian nicotinic receptors Publisher:Annual Reviews, Journal:Annual Review of Entomology, Volume:48, Pages:339 - 364, Year:2003, Report No.: MO-05-004254, Edition Number: M-245942-01-1 Non GLP, published	No	
A 5.7.1./01	Nauen, R.; Ebbinghaus- Kintscher, U.; Elbert, A.; Jeschke, P.; Tietjen, K.	2001	Acetylcholine receptors as sites for developing neonicotinoid insecticides Publisher:Springer-Verlag Berlin, Location:Heidelberg, Journal:Biochemical Sites of Insecticide Action and Resistance, Pages:77-105, Year:2001, Report No.: MO-01-005653, Edition Number: M-047708-01-1 Non GLP, published	No	
A 5.7.1./02	Nauen, R., Denholm, I.	2005	Resistance of insect pests to neonicotinoid insecticides: current status and future prospects Publisher:Wiley InterScience, Location:Wiley-Liss, Inc., Journal:Archives of Insect Biochemistry and Physiology, Volume:58, Issue:2005, Pages:200-215, Year:2005, Report No.: MO-05-007838, Edition Number: M-250577-01-1 Non GLP, published	No	

A 5.7.2. /01	Elbert, A.; Bailo- Schleiermacher, I.; Brueggen, K.U.; Nauen, R.; Rogers, D.; Steffens, R.; Denholm, I.	2005	Pflanzenschutz-Nachrichten Bayer 58 - Special edition - Bayer CropScience Guidelines on Resistance Management for Neonicotinoids Publisher:Bayer CropScience, Location:Germany, Journal:Pflanzenschutz Nachrichten Bayer, Volume:58, Issue:76, Pages:1 - 32, Year:2005, Report No.: MO-05-008987, Edition Number: M-252077-01-1 Non GLP, published	No	
A 6.1.1. /01*		1989	NTN 33893 - Study for acute oral toxicity to rats Bayer CropScience AG, Report No.: 18594, Edition Number: M-025996-01-1 Date: 15.12.1989 GLP, unpublished	Yes	BCS
A 6.1.1. /02*		1991	NTN 33893 AMP (proposed c.n.: Imidacloprid) - Study for acute oral toxicity to rats Bayer CropScience AG, Report No.: 20591, Edition Number: M-028854-01-1 Date: 19.08.1991 GLP, unpublished	Yes	BCS
A 6.1.1. /03*		1991	NTN 33893 CNS (c.n.: Imidacloprid (proposed) - Study for acute oral toxicity in rats Bayer CropScience AG, Report No.: 20637, Edition Number: M-028901-01-1 Date: 03.09.1991 GLP, unpublished	Yes	BCS
A 6.1.1./04*		1989	NTN 33893 - Study for acute oral toxicity to mice Bayer CropScience AG, Report No.: 18593, Edition Number: M-007509-01-1 Date: 15.12.1989 GLP, unpublished	Yes	BCS
A 6.1.2 /01*		1989	NTN 33893 (c.n. imidacloprid (proposed) - Study for acute dermal toxicity to rats Bayer CropScience AG, Report No.: 18532, Edition Number: M-025697-01-1 Date: 15.11.1989 GLP, unpublished	Yes	BCS

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A 6.1.3. /01	1988	NTN 33893 - Study for acute inhalation toxicity in the rat in accordance with OECD guideline no. 403	Yes	BCS
		Bayer CropScience AG, Report No.: 16777, Edition Number: M-027586-01-1 Date: 06.06.1988 GLP, unpublished		
A 6.1.4. /01*	1988	NTN 33893 - Study for irritant/corrosive potential on the skin (rabbit) according to OECD guideline no. 404 Bayer CropScience AG, Report No.: 16455, Edition Number: M-028272-01-1 Date: 25.02.1988 GLP, unpublished	Yes	BCS
A 6.1.4. /02*	1988	NTN 33893 - Study for irritant/corrosive potential on the eye (rabbit) according to OECD guideline no. 405 Bayer CropScience AG, Report No.: 16456, Edition Number: M-028278-01-1 Date: 25.02.1988 GLP, unpublished	Yes	BCS
A 6.1.5. /01*	1988	NTN 33893 technical - Study for skin sensitising effect on guinea pigs (maximisation test) Bayer CropScience AG, Report No.: 16533, Edition Number: M-027579-01-1 Date: 15.03.1988 GLP, unpublished	Yes	BCS
A 6.2. /01*	1987	(14C)-NTN 33893: Biokinetic part of the 'General metabolism study' in the rat Bayer CropScience AG, Report No.: PF2889, Edition Number: M-024189-01-1 Date: 09.11.1987 GLP, unpublished	Yes	BCS
A 6.2. /02*	1991	Imidazolidine-4,5-14C-Imidacloprid: Investigation of the biokinetic behaviour and metabolism in the rat Bayer CropScience AG, Report No.: PF3629, Edition Number: M-024167-01-1 Date: 11.01.1991 GLP, unpublished also filed: A 6.2 /05	Yes	BCS

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A 6.2. /03*	1990	Methylene-(14C)-Imidacloprid: Metabolism part of the general metabolism study in the rat Bayer CropScience AG, Report No.: PF3316, Edition Number: M-024182-01-1 Date: 30.01.1990 GLP, unpublished	Yes	BCS
A 6.2. /04*	1992	(Pyridinyl-14C-methyl)Imidacloprid: Distribution of the metabolites in some organs at different times following single oral administration to rats Bayer CropScience AG, Report No.: PF3635, Edition Number: M-024164-01-1 Date: 12.03.1992 GLP, unpublished	Yes	BCS
A 6.2. /05*	1991	Imidazolidine-4,5-14C-Imidacloprid: Investigation of the biokinetic behaviour and metabolism in the rat Bayer CropScience AG, Report No.: PF3629, Edition Number: M-024167-01-1 Date: 11.01.1991 GLP, unpublished also filed: A 6.2 /02 (Not included in Caddy, as already filed as A6.2/02)	Yes	BCS
A 6.2. /06*	1990	Imidacloprid - WAK 3839: Comparison of biokinetic behaviour and metabolism in the rat following single oral dosage and investigation of the metabolism after chronic feeding of imidacloprid to rats and mice Bayer CropScience AG, Report No.: PF3432, Edition Number: M-024174-01-1 Date: 17.07.1990 GLP, unpublished	Yes	BCS
A 6.2. /08*	2005	Confidor OD 200 ([14C]-imidacloprid): Comparative in vitro dermal absorption study using human and rat skin. , on behalf of Bayer AG, Monheim/Germany. Study no. SA 04242, Report amendmend no. 1, Edition Number: M-251756-02-1 Date: 21.02.2005 GLP, unpublished	Yes	BCS

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A 6.3.1 *	1987	28-day oral range-finding toxicity (feeding) study with NTN 33893 tech. in the dog, Report No. R4196, RCC Project 084993, Bayer project T 6025018 No GLP, Unpublished	Yes	BCS
A 6.3.2 /01*	1990	NTN 33893 techn Study for subacute dermal toxicity in the rabbit Bayer CropScience AG, Report No.: 19152, Edition Number: M-025976-01-1 Date: 11.06.1990 GLP, unpublished	Yes	BCS
A 6.3.3 /01*	1989	NTN 33893 (proposed common name: Imidacloprid) - Subacute inhalation toxicity study on the rat according to OECD guideline no. 412 Bayer CropScience AG, Report No.: 18199, Edition Number: M-026004-01-1 Date: 18.07.1989 GLP, unpublished	Yes	BCS
A 6.4.1.1./01*	1989	NTN 33893 - Subchronic toxicity study on wistar rats (administration in the feed for 96 days) Bayer CropScience AG, Report No.: 18187, Edition Number: M-007967-01-1 Date: 14.07.1989 GLP, unpublished	Yes	BCS
A 6.4.1.2. /01*	1990	NTN 33893 technical - Subchronic toxicity study on dogs in oral administration (thirteen-week feeding study) Bayer CropScience AG, Report No.: 18732, Edition Number: M-026540-01-1 Date: 02.02.1990 GLP, unpublished	Yes	BCS
A 6.4.1.2. /02*	1989	52-week oral toxicity (feeding) study with NTN 33893 technical in the dog Bayer CropScience AG, Report No.: R4856, Edition Number: M-027093-02-1 Date: 19.10.1989, Amended: 03.03.1992 GLP, unpublished	Yes	BCS

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A 6.5. /01*	1991	NTN 33893 (proposed c.n.: Imidacloprid) - Chronic toxicity and cancerogenicity studies on Wistar rats (administration in food over 24 months) Bayer CropScience AG, Report No.: 19925, Edition Number: M-027741-02-1 Date: 25.01.1991 GLP, unpublished also filed: A 6.7. /01	Yes	BCS
A 6.5. /02*	1991	NTN 33893 (proposed common name: Imidacloprid) - Chronic toxicity and cancerogenicity studies on Wistar rats (administration in food over 24 months) - supplementary MTD study for two-year study T1025699 Bayer CropScience AG, Report No.: 20541, Edition Number: M-027135-01-1 Date: 19.08.1991 GLP, unpublished also filed: A 6.7. /02	Yes	BCS
A 6.5. /03*	1991	NTN 33893 (proposed common name Imidacloprid) - Carcinogenicity study on B6C3F1 mice (administration in the food for 24 months) Bayer CropScience AG, Report No.: 19931, Edition Number: M-026310-01-1 Date: 28.01.1991 GLP, unpublished also filed: A 6.7. /03	Yes	BCS
A 6.5. /04*	1991	NTN 33893 (proposed common name: Imidacloprid) - Carcinogenicity study in B6C3F1 mice (supplementary MTD testing for study T5025710 with administration in diet over a 24-month period) Bayer CropScience AG, Report No.: 20769, Edition Number: M-026038-01-1 Date: 24.10.1991 GLP, unpublished also filed: A 6.7. /04	Yes	BCS
A 6.6.1. /01*	1989	NTN 33893 - Salmonella/microsome test to evaluate for point mutagenic effects Bayer CropScience AG, Report No.: 17577, Edition Number: M-027611-01-1 Date: 06.01.1989 GLP, unpublished	Yes	BCS

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A 6.6.1. /02*	1991	NTN 33893 AMP - Salmonella/microsome test	Yes	BCS
		Bayer CropScience AG, Report No.: 20090, Edition Number: M-025825-01-1 Date: 22.03.1991 GLP, unpublished		
A 6.6.1. /03*	1992	NTN 33893 AMP W -	Yes	BCS
		Salmonella/microsome test Bayer CropScience AG, Report No.: 21775, Edition Number: M-029085-01-1 Date: 19.10.1992 GLP, unpublished		
A 6.6.1. /04*	1991	NTN 33893 - Reverse mutation assay (Salmonella typhimurium and Escherichia coli)	Yes	BCS
		Bayer CropScience AG, Report No.: RA91002, Edition Number: M-028670-01-1 Date: 17.01.1991 GLP, unpublished		
A 6.6.2. /01*	1988	Clastogenic evaluation of NTN 33893 in an in vitro cytogenetic assay measuring sister chromatid exchange in chinese hamster ovary (CHO) cells	Yes	BCS
		Bayer CropScience AG, Report No.: R4407, Edition Number: M-026488-01-1 Date: 21.04.1988 GLP, unpublished		
A 6.6.2. /02*	1989	BAY NTN 33893 - Sister chromatid exchange assay in chinese hamster ovary cells	Yes	BCS
		Bayer CropScience AG, Report No.: BC1149, Edition Number: M-025499-01-1 Date: 12.09.1989 GLP, unpublished		
A 6.6.2. /03*	1989	NTN 33893 - In vitro cytogenetic study with human lymphocytes for the detection of induced clastogenic effects	Yes	BCS
		Bayer CropScience AG, Report No.: 18092, Edition Number: M-028377-02-1 Date: 16.06.1989, Amended: 24.08.1989 GLP, unpublished		

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A 6.6.3. /01*	1989	NTN 33893 - Mutagenicity study for the detection of induced forward mutations in the CHO-HGPRT assay in vitro	Yes	BCS
		Bayer CropScience AG, Report No.: 17578, Edition Number: M-027630-01-1 Date: 06.01.1989 GLP, unpublished		
A 6.6.3. /02*	1988	NTN 33893 - Test on S. cerevisiae D7 to evaluate for induction of mitotic recombination Bayer CropScience AG, Report No.: 16832, Edition Number: M-027595-01-1	Yes	BCS
		Date: 27.06.1988 GLP, unpublished		-
A 6.6.3. /03*	1988	Mutagenicity test on NTN 33893 in the rat primary hepatocyte unscheduled DNA synthesis assay Bayer CropScience AG, Report No.: R4631, Edition Number: M-026493-01-1 Date: 21.12.1988 GLP, unpublished	Yes	BCS
A 6.6.4. /01*	1989	NTN 33893 - In vivo cytogenetic study of the bone marrow in chinese hamster to evaluate for induced clastogenic effects Bayer CropScience AG, Report No.: 18557, Edition Number: M-025903-01-1 Date: 24.11.1989 GLP, unpublished	Yes	BCS
A 6.6.4. /02*	1989	NTN 33893 - Sister chromatid exchange in bone marrow of chinese hamsters in vivo Bayer CropScience AG, Report No.: 18093, Edition Number: M-028379-02-1 Date: 16.06.1989, Amended: 23.11.1993 GLP, unpublished	Yes	BCS
A 6.6.5. /01*	1988	NTN 33893 - Micronucleus-test on the mouse to evaluate for clastogenic effects Bayer CropScience AG, Report No.: 16837, Edition Number: M-027591-01-1 Date: 27.06.1988 GLP, unpublished	Yes	BCS

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A 6.6.6. /01*	1990	Mouse germ-cell cytogenetic assay with NTN 33893	Yes	BCS
		Bayer CropScience AG, Report No.: R5063, Edition Number: M-026551-01-1 Date: 22.05.1990 GLP, unpublished		
A 6.7. /01*	1991	NTN 33893 (proposed c.n.: Imidacloprid) - Chronic toxicity and cancerogenicity studies on Wistar rats (administration in food over 24 months)	Yes	BCS
		Bayer CropScience AG, Report No.: 19925, Edition Number: M-027741-02-1 Date: 25.01.1991 GLP, unpublished also filed: A 6.5. /01		
A 6.7. /02*	1991	NTN 33893 (proposed common name: Imidacloprid) - Chronic toxicity and cancerogenicity studies on Wistar rats (administration in food over 24 months) - supplementary MTD study for two-year study T1025699	Yes	BCS
		Bayer CropScience AG, Report No.: 20541, Edition Number: M-027135-01-1 Date: 19.08.1991 GLP, unpublished also filed: A 6.5. /02		
A 6.7. /03*	1991	NTN 33893 (proposed common name Imidacloprid) - Carcinogenicity study on B6C3F1 mice (administration in the food for 24 months)	Yes	BCS
		Bayer CropScience AG, Report No.: 19931, Edition Number: M-026310-01-1 Date: 28.01.1991 GLP, unpublished also filed: A 6.5. /03		
A 6.7. /04*	1991	NTN 33893 (proposed common name: Imidacloprid) - Carcinogenicity study in B6C3F1 mice (supplementary MTD testing for study T5025710 with administration in diet over a 24-month period)	Yes	BCS
		Bayer CropScience AG, Report No.: 20769, Edition Number: M-026038-01-1 Date: 24.10.1991 GLP, unpublished also filed: A 6.5. /04		

A 6.8,1./01*		1988	Embryotoxicity study (including teratogenicity) with NTN 33893 technical in the rat Bayer CropScience AG, Report No.: R5442, Edition Number: M-027900-04-1 Date: 24.11.1988, Amended: 03.03.1992	Yes	BCS
A 6.8.1./01*	Khera, K.S.	1981	GLP, unpublished Common fetal aberrations and their teratologic significance: A review Fund. Appl. Toxicol. 1: 13-18	No	Public
A 6.8.1. /01*	Nishimura, M., Iizuka, M., Iwaki, S., & Kast, A.	1982	Repairability of drug-induced "wavy ribs" in rat offspring ArzneimForsch./Drug Res. 32 (II), No. 12: 1518-1522	No	Public
A 6.8.1. /01*	Kast, A.	1994	"Wavy ribs". A reversible pathologic finding in rat fetuses Exp. Toxic. Pathol. 46: 203-210 Published	No	Public
A 6.8.1. /02*		1988	Embryotoxicity study (including teratogenicity) with NTN 33893 technical in the rabbit Bayer CropScience AG, Report No.: R5443, Edition Number: M-027920-04-1 Date: 24.11.1988, Amended: 03.03.1992	Yes	BCS
A 6.8.2. /01*		1990	GLP, unpublished Multiple generation reproduction study with NTN 33893 technical in rats Bayer CropScience AG, Report No.: R5097, Edition Number: M-027300-03-1 Date: 21.06.1990, Amended: 03.03.1992 GLP, unpublished	Yes	BCS

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A 6.9. /01*		1994	An acute oral neurotoxicity screening study with technical grade imidacloprid (NTN 33893) in rats Bayer CropScience AG, Report No.: BC7221, Edition Number: M-028815-02-1 Date: 16.02.1994, Amended: 07.06.1994 GLP, unpublished	Yes	BCS
A 6.9. /02*		1994	A subchronic dietary neurotoxicity screening study with technical grade Imidacloprid (NTN 33893) in Fischer 344 rats Bayer CropScience AG, Report No.: BC7331, Edition Number: M-027944-01-1 Date: 13.06.1994 GLP, unpublished	Yes	BCS
A 6.9. /03*		2001	A developmental neurotoxicity screening study with technical grade Imidacloprid in Wistar rats Report No.: 110245, Edition Number: M-084646-01-1 Date: 14.09.2001 GLP, unpublished	Yes	BCS
A 6.12.1. /01	Kehrig, B.; Steffens, W.	2004	Occupational medical experiences with Imidacloprid Bayer CropScience AG, Report No.: MO-05-004265, Edition Number: M-245951-01-1 Date: 05.11.2004 Non GLP, unpublished	Yes	BCS
A 6.12.1./02	Becker, M.	2006	Occupational, medical experience with imidacloprid gel 2,15 percent Bayer CropScience AG, Report No.: M-267506-01-1, Edition Number: M-267506-01-1 Date: 06.03.2006 Non GLP, unpublished	Yes	BCS
A 6.12.2. /01	Steffens, W.	2000	Final report on the poisoning incident "Lizetan Kombistäbchen, 30.5.00" Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: MO-00-014602, Edition Number: M-023399-01-1 Date: 26.10.2000 Non GLP, unpublished	Yes	BCS

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A 6.12.5. /01	Proenca, P.; Teixeira, H.; Castanheira, F.; Pinheiro, J.; Monsanto, P.V.; Marques, E.P.; Vieira, D.N.	2005	Two fatal intoxication cases with imidacloprid: LC/MS analysis Publisher:Elsevier Ireland Ltd., Location:Anon., Journal:Forensic Science International, Volume:153, Pages:75-80, Year:2005, Report No.: M-256901-01-1, Edition Number: M-256901-01-1 Non GLP, published	No	
A 6.14. /01*		1991	WAK 3839 - Acute oral toxicity study on rats Bayer CropScience AG, Report No.: RA91017, Edition Number: M-028685-01-1 Date: 11.03.1991 GLP, unpublished	Yes	BCS
A 6.14. /02*		1988	NTN 37571 - Acute toxicity study on mice Bayer CropScience AG, Report No.: RS88038, Edition Number: M-028572-01-1 Date: 19.10.1988 Non GLP, unpublished	Yes	BCS
A 6.14. /03*		1990	WAK 3839 - Reverse mutation assay (Salmonella tyhimurium and Escherichia coli) Bayer CropScience AG, Report No.: RA90035, Edition Number: M-028631-01-1 Date: 26.11.1990 GLP, unpublished	Yes	BCS
A 6.14. /04*		1989	WAK 3839 - Mutagenicity study for the detection of induced forward mutations in the CHO-HGPRT assay in vitro Bayer CropScience AG, Report No.: 17757, Edition Number: M-027645-01-1 Date: 22.02.1989 GLP, unpublished	Yes	BCS
A 6.14. /05*		1989	WAK 3839 - Mutagenicity study for the detection of induced forward mutations in the V79-HGPRT assay in vitro Bayer CropScience AG, Report No.: 18281, Edition Number: M-025757-01-1 Date: 15.08.1989 GLP, unpublished	Yes	BCS