ANNEX B

Metconazole

B.9 Ecotoxicology

(revised September 2005)

B.9.1 Effects on birds (Annex IIA 8.1; Annex IIIA 10.1)

B.9.1.1 Acute oral toxicity (Annex IIA 8.1.1)

WL 148271 : Acute Oral Toxicity (LD_{50}) to Bobwhite Quail (Hakin B. *et al*., 1992a)
Guidelines :
EPA FIFRA 71-1
GLP :
Yes
Material and Methods :
Test Substance: metconazole (83:17 *cis:trans*), purity: 96.3%, batchn°: 89-01
Test species : Bobwhite quail, *Colinus virginianus*
Sex, weight, age : 5♀ + 5♂ birds/concentration, 189-204 g, more than 16 weeks
Applied concentrations : untreated control, 423, 623, 919, 1356 and 2000 mg a.s./kg body weight;
Type of application : oral intubation in corn oil
Time of exposure : one single application, monitoring during 14 days
Findings :
Mortality : Mortality was 100% at the two highest test concentrations. 80% mortality was observed in the 919 ppm group and only 10% in the 623 ppm group.
Body weight : A treatment related decrease in body weight was observed from day 0 to day 7. During the next observation period (day 7-14) bodyweight increase was higher in all treatment groups with respect to the control group.
Clinical signs : birds were observed to be subdued and showing unsteadiness. Symptoms became worse with increasing dosage. The birds in the lowest treatment group and the control group remained in good health during the whole study period. The birds in the 623 ppm study group recovered on day 2.
Feed consumption : over days 1-7 following dosing, a treatment-related reduction in food consumption was observed in all treatment groups. Starting from day 8 food consumption recovered except or the 1356 and 2000 ppm group due to mortality
Post mortem observations : Birds from the 3 highest treatment groups had a reduced amount of subcutaneous fat.
Conclusions :
Study is acceptable.
LD_{50} = 787 mg a.s./kg bw
NOEL = 423 mg a.s./kg bw

Metconazole 85:15 *cis:trans*, Metconazole 95% *cis*, A Comparative Acute Oral Toxicity (LD_{50}) Study with Northern Bobwhite, (Johnson A.J. et al., 1998).
Guidelines :
EPA FIFRA 71-1
GLP :
Yes
Material and Methods :
Test Substances:

1. Metconazole 84.2:13.7 *cis:trans*, Lot number : AC 10575-61
2. Metconazole 96.7% *cis*, Lot number ST89/324

Test species : Northern bobwhite, *Colinus virginianus*
Sex, weight, age : 5♀ + 5♂ birds/concentration, 185-206 g, ± 13 months
Applied concentrations : untreated control, 450, 630, 882, 1235, 1729 and 2420 mg a.s./kg body weight;
Type of application : the test material was administered to the birds in gelatine capsules directly into the proventriculus or crop.
Time of exposure : one single application, monitoring during 14 days
Findings :
Mortality :

1. All birds died in the 3 highest treatment groups. 6 birds died in the 882 ppm group and 2 birds died in the 630 ppm group.
2. All birds died in the 2 highest treatment groups. 7 birds died in the 1235 ppm group, 4 birds died in the 882 ppm group, 3 birds died in the 630 ppm group and 1 bird died in the 450 ppm group..

Body weight : For both products a clear decrease in body weight was observed for the first observation period (day 0-7). During the next observation period (day 7-14) bodyweight increase was higher in all treatment groups with respect to the control group.
Clinical signs : Subdued behaviour and unsteadiness of gait were observed in all test groups. All surviving birds had recovered for substance 1 after 12 days and for substance 2 after 9 days.
Feed consumption : For both tested products food consumption was lower for all treatment groups from day 0 to 7. Over days 8-14 food consumption was higher than in the control for both tested products.
Post mortem observations : For both test materials, birds had reduced muscle and subcutaneous fat. The intestines were found to be dark in colour at dose levels of 1235 mg/kg and above for substance 1 and at 1729 mg/kg for substance 2.
Conclusions :
Study is acceptable.

1. LD_{50} = 798 mg a.s./kg bw
   NOEL < 450 mg a.s./kg bw
2. LD_{50} = 875 mg a.s./kg bw
   NOEL < 450 mg a.s./kg bw

B.9.1.2 Avian dietary toxicity (5day) (Annex IIA 8.1.2)

Dietary Toxicity (LC_{50}) of WL148271 to the Bobwhite Quail, (Hakin B. *et al.*, 1991a)
Guidelines :
OECD Guidelines for testing of chemicals, 205
GLP :
Yes
Material and Methods :
Test Substance: Metconazole; 83.7:16.3 *cis:trans*; purity : 95.3%; Batchn° : 89-01
Test species : Bobwhite quail, *Colinus virginianus*
Sex, weight, age : 10 birds/test group, 21.9-23.2 g, 14 days at test diet introduction
Applied concentrations : untreated control, 163, 325, 650, 1300, 2600 and 5200 mg/kg feed;
Type of application : dietary application, mean analyzed concentrations were within 6% of nominal concentrations.
Time of exposure : Short-term feeding test (5 days with exposition by the feed + 3 days observations)
Findings :
Mortality : Mortality was observed starting from the 325 ppm treatment group. Mortality increased with increasing test concentration.
Body weight : Bodyweight increase was lower in all treatment groups from day 0 to day 5. After removal of the diets body weight increase was variable.
Clinical signs : Black areas in the liver of 4 birds were observed at the highest treatment level and in one bird of the 1300 ppm group. Two birds of the 5200 ppm group and one of the 2600 ppm group had dark intestines.
Feed consumption : Feed consumption was lower during the treatment period.
Conclusions :
Study is acceptable.
LC_{50} (5d) = 1057 mg a.s./kg feed or 167.85 mg/kg bw/day based on a food consumption of 3.7 g/bird/day and a body weight of 23.3 g
NOEC (5d) < 163 mg a.s./kg feed

Dietary Toxicity (LC_{50}) of WL148271 to the Mallard Duck, (Hakin B. *et al.*, 1991b).
Guidelines :
OECD Guidelines for testing of chemicals, 205
GLP :
Yes
Material and Methods :
Test Substance: Metconazole; 83.7:16.3 *cis:trans*; purity : 95.3%; Batchn° : 89-01
Test species : mallard duck, *Anas platyrhynchos*
Sex, weight, age : 10 birds/test group, 172-213 g, 14 days at test diet introduction

Applied concentrations : untreated control, 163, 325, 650, 1300, 2600 and 5200 mg/kg feed;
Type of application : dietary application, mean analyzed concentrations were within 6% of nominal concentrations.
Time of exposure : Short-term feeding test (5 days with exposition by the feed + 3 days observations)
Findings :
Mortality : four birds were found dead at the highest treatment rate.
Body weight : A weight loss was observed at two highest dose rate during the exposure period. At the highest dose rate the birds continued losing weight during the post treatment period.
Clinical signs : The four birds found dead at the highest treatment rate were all thin but otherwise normal.
Feed consumption : Feed consumption was lower for the highest test concentration during the treatment period.
Conclusions :
Study is acceptable.
LC_{50} (5d) > 5200 mg a.s./kg feed or 537.93 mg a.s./kg bw/day based on a body weight of 174 g and a food consumption of 18 g/bird/day
NOEC (5d) = 1300 mg a.s./kg feed

B.9.1.3 Subchronic and reproductive toxicity (Annex IIA 8.1.3)

WL136184 - Reproduction in the Bobwhite Quail, (Hakin *et al.*, 1992b)
Guidelines :
EPA FIFRA 71-4
GLP :
Yes
Material and Methods :
Test substance : Metconazole 95.2% *cis*, Batch N° : 12
Test species : Bobwhite quail, *Colinus virginianus*
Sex, weight, age : 20 x (1♀ + 1♂) birds/concentration, 187-198 g, 6-7 months old at start of the treatment period
Applied concentrations : untreated control, 10, 60 and 400 mg/kg in the feed
Type of application : dietary application
Time of exposure : Test birds were fed treated diet *ad libitum* during the pre-egg laying period and for the 12-week egg production period. Control birds were fed untreated basal diet throughout.
Findings :
Table B.9.1.3-1 : Major effects of observed during the reproduction study of Bobwhite quail

Endpoints	**Doses (mg/kg feed)**			
	0	**10**	**60**	**400**
Adults				
Mortality (%)	15	7.5	2.5	25
Clinical symptoms	-	-	-	Pale and mottled livers
Body weight	Male group mean bodyweights were significantly lower at 400 ppm. No apparent treatment related effects at the other dose rates.			
Food consumption	Only the 400 ppm treatment group ate significantly less than the control group over the 24-weeks feeding period.			
Reproduction parameters				
No. of eggs laid	895	986	1081	72
No. of eggs laid/female bird	44.7	49.3	54.0	3.6*
Cracked and broken eggs of eggs laid (%)	5.0	6.5	6.1	5.6
Mean egg shell thickness (mm)	0.203	0.217	0.207	-
No. of eggs set	792	837	940	66
No. of viable embryos	745	765	796	27
Viable embryos of eggs set (%)	94.1	91.4	84.7	40.9*
No. of viable 3-week old embryos	736	756	789	24
Viable 3-week old embryos of viable embryos (%)	98.8	98.8	99.1	88.9

Endpoints	Doses (mg/kg feed)			
	0	10	60	400
No. of normal hatchlings	691	704	747	5
Normal hatchlings of live '3-week' embryos (%)	93.9	93.1	94.7	20.8
Normal hatchlings of viable embryos (%)	92.8	92	93.8	18.5
No. of 14-day surviving chicks	633	614	693	2
No. of 14-day surviving chicks/normal hatchlings (%)	91.6	87.2	92.8	40
No. of 14-day surviving chicks/eggs laid (%)	70.7	62.3	64.1	2.7
No. of 14-day surviving chicks/female bird	31.7	30.7	34.7	0.1
Mean body weight of chicks at hatching (g)	6.78	6.89	6.77	-
Mean body weight of chicks 14 days after hatching (g)	20.9	21.6	21.4	-

* Statistically significant (p <0.01)

Remarks :

Control mortality was above 10 %, which means that the validity criteria are not met. The percentage of cracked eggs in the control was too high. Cages were too small.

Conclusions :

Study is not acceptable (see remarks).

The NOEC (24 weeks) is 60 mg a.s./kg feed or 5.6 mg a.s./kg bw/day based on a body weight of 203.5 g and a food consumption of 19 g/bird/day.

WL136184 Reproduction in the Mallard Duck, (Hakin B. *et al*., 1992c).

Guidelines :

EPA FIFRA 71-4

GLP :

Yes

Material and Methods :

Test substance : Metconazole 95.2% *cis*, Batch N° : 12

Test species : Mallard duck, *Anas platyrhynchos*

Sex, weight, age : 6 x (5♀ + 2♂) birds/concentration, 187-198 g, 9-10 months old at start of the pre-treatment period

Applied concentrations : untreated control, 10, 60 and 400 mg/kg in the feed

Type of application : dietary application

Time of exposure : Test birds were fed treated diet *ad libitum* during the pre-egg laying period and for the 12-week egg production period. Control birds were fed untreated basal diet throughout.

Findings :

Table B.9.1.3-2 : Major effects of metconazole observed during the reproduction study of mallard duck

Endpoints	Doses (mg/kg feed)			
	0	10	60	400
Adults				
Mortality	9.5	2.4	14.3	14.3
Clinical symptoms	No treatment related abnormalities observed.			
Body weight	No significant treatment related effects were observed.			
Food consumption	Food consumption was similar in all groups during the entire treatment period.			
Reproduction parameters				
No. of eggs laid	1531	1432	1345	1294
No. of eggs laid/female bird	51	47.7	44.8	43.1
Cracked and broken eggs of eggs laid (%)	2	3	1.6	0.8*
Mean egg shell thickness (mm)	0.33	0.34	0.34	0.33
No. of eggs set	1394	1284	1229	1192
No. of viable embryos	1323	1185	1207	1168
Viable embryos of eggs set (%)	94.9	92.3	98.2	98
No. of viable 3-week old embryos	1254	1095	1133	1072

Endpoints	Doses (mg/kg feed)			
	0	10	60	400
Viable 3-week old embryos of viable embryos (%)	94.8	92.4	93.9	91.8
No. of normal hatchlings	974	824	839	734
Normal hatchlings of live '3-week' embryos (%)	77.7	75.3	74.1	68.5
Normal hatchlings of viable embryos (%)	73.6	69.5	69.5	62.8*
No. of 14-day surviving chicks	944	795	807	685
No. of 14-day surviving chicks/normal hatchlings (%)	96.9	96.5	96.2	93.3*
No. of 14-day surviving chicks/eggs laid (%)	61.7	55.5	60	52.9
No. of 14-day surviving chicks/female bird	31.5	26.5	26.9	22.8*
Mean body weight of chicks at hatching (g)	38	38.7	37.2	37.9
Mean body weight of chicks 14 days after hatching (g)	266	252	272	262

* Statistically significant (log-Rank-test, p≤0.05)

Remarks :

The mean egg shell thickness in the control is slightly too low. The cages were too small. Two males were put in one cage with 5 females instead of one male with 3 females.

Conclusions :

Study is acceptable. The NOEC (22 weeks) is 60 mg a.s./kg feed or 9.33 mg a.s./kg bw/day based on a body weight of 1147.7 g and a food consumption of 178.5 g/bird/day.

Metconazole 85:15 *cis:trans*, Assessment to Determine the Effects on Reproduction in the Northern Bobwhite, (Johnson A.J. & Ahmed S., 1999).

Guidelines :

EPA FIFRA 71-4

GLP :

Yes

Material and Methods :

Test substance : Metconazole 84.2:13.7 *cis:trans*, Lot N° : AC 10575-61

Test species : Bobwhite quail, *Colinus virginianus*

Sex, weight, age : 20 x (1♀ + 1♂) birds/concentration, 173-181g, 18 weeks old at start of the pre-treatment period

Applied concentrations : untreated control, 15, 30, 60 and 120 mg/kg in the feed

Type of application : dietary application

Time of exposure : Test birds were fed treated diet *ad libitum* during 10-week the pre-egg laying period and for the 12-week egg production period. Control birds were fed untreated basal diet throughout.

Findings :

Table B.9.1.3-3 : Major effects of observed during the reproduction study of Bobwhite quail

Endpoints	Doses (mg/kg feed)				
	0	15	30	60	120
Adults					
Mortality (%)	5	2.5	7.5	2.5	7.5
Clinical symptoms	No treatment related abnormalities observed.				
Body weight	The male body weights of the 120 ppm group during the pre-egg laying period were significantly higher than the control..				
Food consumption	No significant treatment related effects were observed.				
Reproduction parameters					
No. of eggs laid	967	1252	1046	1030	819
No. of eggs laid/female bird	53	66.1	58.3	51.5	42.9
No. of cracked eggs	15	28	34	23	18
No. of cracked eggs of eggs laid (%)	1.6	2.2	3.3	2.2	2.2
Mean egg shell thickness (mm)	0.21	0.22	0.22	0.21	0.21
No. of eggs incubated	872	1136	923	931	743

Endpoints	Doses (mg/kg feed)				
	0	**15**	**30**	**60**	**120**
No. of viable embryos	802	869	800	901	641
No. of live 3-week embryos	778	851	753	883	612
Viable embryos of eggs set (%)	92	76.5	86.7	96.8	86.3
Live 3-week embryos of viable embryos (%)	97	97.9	94.1	98	95.5
No. of normal hatchlings	684	768	676	815	473
No. of "dead-in-shell"	94	83	76	68	137
Normal hatchlings of viable embryos (%)	85.3	88.4	84.5	90.5	73.8*
Normal hatchlings of eggs laid (%)	70.7	61.3	64.6	79.1	57.8
No. of 14-day surviving chicks	637	697	649	742	235
No. of 14-day surviving chicks/eggs laid (%)	65.9	55.7	62	72	28.7*
No. of 14-day surviving chicks/ normal hatchlings (%)	93.1	90.8	96	91	49.7*
No. of 14-day surviving chicks/female bird	35.3	36.6	36.2	39.1	12.5*
Mean body weight of chicks at hatching (g)	6.4	6.3	6.4	6.4	5.7*
Mean body weight of chicks 14 days after hatching (g)	25	24	24	24	22*

* Statistically significant (p <0.01)
Remarks : Cages were too small.
Conclusions :
Study is acceptable. The NOEC (22 weeks) is 60 mg a.s./kg feed or 6.19 mg a.s./kg bw/day based on a body weight of 187 g and a food consumption of 19.3 g/bird/day.

B.9.1.4 Acute oral toxicity of the preparations (Annex IIIA 10.1.1)

Not required.

B.9.1.5 Supervised cage or field trials (Annex IIIA 10.1.2)

Not required.

B.9.1.6 Acceptance of bait, granules or treated seeds by birds (palatability test) (Annex IIIA 10.1.3)

Not required

B.9.1.7 Effects of secondary poisoning (Annex IIIA 10.1.4)

Not required. See point B.9.1.8.

B.9.1.8 Summary of effects to birds - exposure and risk assessment for birds (Annex IIIA 10.1)

Tab. B.9.1.8-1 : Summary of effects of Metconazole to birds.

Test species	Test System	Results	References
Bobwhite quail	acute oral toxicity	**LD_{50} = 787 mg a.s./kg bw**	Hakin B. *et al.*, 1992
Northern bobwhite		LD_{50} = 798 mg a.s./kg bw	Johnson A.J. et al., 1998
Bobwhite quail	5-day dietary toxicity	**LC_{50} = 167.85 mg a.s./kg bw/day**	Hakin B. *et al.*, 1991
Mallard duck		LC_{50} > 537.93 mg a.s./kg bw/day	Hakin B. *et al.*, 1991
Mallard duck	reproduction study	NOEC (22 weeks) = 9.33 mg a.s./kg bw/day	Hakin B. *et al.*, 1992
Bobwhite quail		**NOEC (22 weeks) = 6.19 mg a.s./kg bw/day**	Johnson A.J. & Ahmed S., 1999

The risk assessment for birds is based on the new Guidance Document for birds and mammals Under Council Directive 91/414/EEC of November 2002. As a worst-case it was assumed that the birds obtained 100% of their diet in the treated area.

Tab. B.9.1.8-2 : Estimated oral uptake of metconazole by birds and first tier Toxicity Exposure Ratio's (TER's)

Application rate	Bird type	Time scale	FIR/bw	RUD (90%)	MAF	f_{twa}	ETE (mg a.s./kg bw/day)	TER	Annex VI trigger value
2 x 0.090 kg a.s./ha in cereals	Large herbivorous bird	acute	0.44	142	1.2	-	6.75	116.6	10
		short term	0.44	76	1.4	-	4.21	39.87	10
		long term	0.44	76	1.4	0.53	2.23	2.78	5
	Insectivorous bird	acute	1.04	52	-	-	4.87	161.6	10
		short term	1.04	29	-	-	2.71	61.94	10
		long term	1.04	29	-	-	2.71	2.28	5
2 x 0.090 kg a.s./ha in oilseed rape	med. herbivorous bird	Acute	0.76	87	1.2	-	7.1	110	10
		short term	0.76	40	1.4	-	3.8	44.4	10
		long term	0.76	40	1.4	0.53	2.03	3.1	5
	insectivorous bird	Acute	1.04	52	-	-	4.87	161.7	10
		short term	1.04	29	-	-	2.71	61.8	10
		long term	1.04	29	-	-	2.71	2.3	5

The acute and short-term risk for large herbivorous and insectivorous birds is considered acceptable.

The long term risk for large herbivorous and insectivorous birds is not considered acceptable based on the first tier risk assessment.

The notifier presented a detailed tier 2 assessment.

Tier 2 assessment submitted by the notifier (2003)
"There are several reasons to assume that the TER_{lt} would exceed the trigger of 5 when more realistic assumptions are applied in a **Tier 2 Assessment**.

Residues
In Tier 1 the default residue values for plant feed items used are 142 mg a.s./kg for acute exposure and 76 mg a.s./kg for long-term exposure, respectively, to accomplish a worst-case scenario. However, in field trials with metconazole the residues reveal values below these defaults. Treatment and application regime in these studies were comparable to the scheme for the representative formulation.

These residue data are specific for metconazole and will be used in the Tier 2 risk assessment to represent the monocotyledonous plant type.

The data were normalized to an application rate of 1 kg a.s./ha resulting in RUD values which can be directly used in the Tier 2 assessment. Based on Sanco 4145/2000 (rev.6, 25.09.02), the arithmetic mean residue values will be used to refine the long-term risk assessment.

In **cereal green plants** 2 applications with 0.09 kg a.s./ha resulted in a mean initial worst case RUD (covering 2 applications) of **20.75 mg a.s./kg** (n = 20) (see Doc M II, 6.3 or BASF DocIDs MK-730-031, -034, -038, -039, -040, -041, -043, -049, -050). Due to the fact that this RUD covers 2 successive applications, the Multiple Application Factor (MAF) is set to 1.0.

Tab. B.9.1.8-3: Initial residues of metconazole in cereal green plants

Crop	Number of trials	Number of applications	RUD Range [1)] [mg a.s./kg green matter]	RUD Max. [1)] [mg a.s./kg green matter]	RUD Mean [1)] [mg a.s./kg green matter]
Cereal plants	22	2	12.89 - 44.33	44.33	**20.75**

1) Residue unit dose (RUD), corresponding to 1 kg a.s./ha.

Species of concern
The Guidance Document Sanco 4145/2000 (rev.6, 25.09.02) considers indicator species for the Tier 1 risk assessment, which in Tier 2 may need to be refined based on the use pattern specific to the substance in question.

Tab. B.9.1.8-4 Indicator species according to Sanco 4145/2000, rev.6, 25.09.02

Crop	Crop stage	Indicator species	Example
Cereals	Early	Large herbivorous bird - 3000 g	Goose
		Insectivorous bird - 10 g	Wren, tit
	Late	Insectivorous bird - 10 g	Wren, tit

For **herbivorous birds**, Sanco 4145/2000 (rev.6, 25.09.02) identified **geese** grazing cereal shoots as the indicator species for cereals. This is seen relevant in coastal areas where geese may feed on arable fields for the part of the day when the tide is in. Geese thus represent the large herbivorous species of concern for the early crop stages, and thus would potentially be exposed to metconazole from the **first application (BBCH 29)** only.

For **insectivorous birds**, Sanco 4145/2000 (rev.6, 25.09.02) lists the wren and the tit as indicator species. Although both are feeding almost exclusively on insects, these species are not typically found in cereals. Their predominant habitats are hedges, bushes and trees in undisturbed environments, but not intensively managed crop areas. This indicates that the indicator species - selected for their small size and exclusive feeding on insects - do not represent the species of concern to refine the insectivorous long-term risk assessment for metconazole in cereals.

The **Yellowhammer** (*Miliaria citrinella*) prefers dry sunny habitats with fairly rich and varied vegetation, avoiding dense forest, undrained wetlands and towns. Farming enabled this species to extend widely across cultivated land with hedges, plantations or highways flanked by trees and bushes, but stops short of gardens and parks [Cramp, S. 1998. Birds of the western Palearctic. CD-Rom Version]. This species feeds almost exclusively on the ground, and avoids areas with dense vegetation. The short ground vegetation in cereals at **early developmental stages (BBCH 29)**, and hence yellowhammer would make use of such areas when adjacent to

their prime habitats. Thus, the yellowhammer represents the small bird species of concern to refine the risk assessment for Metconazole.

The diet consists predominantly of animal food (mainly large insects) and to a lesser extent of seeds (predominantly cereal grain) [Glutz von Blotzheim, U. N. & Bauer, K. M. 1997. Emberiza citrinella Linnaeus 1758 – Goldammer. pp. 1432-1485. In: Glutz von Blotzheim, U. N. (Ed.). Handbuch der Vögel Mitteleuropas. Bd. 14/III Teil 5; Aula Verlag Wiesbaden]. Based on this reference a spring/summer diet consisting of 65% epigaegic insects, 25% soil inhibiting insects, 8% cereal grain, 2% small seeds (worst case 10% small seeds) is assumed. Animal feed items reach the size of large beetles or grasshoppers, and all seeds are dehusked. Based on this, the portions of diet (**PD**) for the yellowhammer used to refine the risk assessment are 0.65 for epigaeic insects, 0.25 for endogaeic insects, and 0.1 for weed seeds.

The yellowhammer selects food items predominantly from the ground. Therefore, a significant part for the yellowhammer diet consists of soil inhabiting animals (e.g. Tipulidae larvae contribute up to 25% of the diet) and of seeds. Both feed items are not fully exposed to the spray and reveal therefore no risk for the birds (see also Interception Factor).

In the first tier risk assessment it is assumed that the entire dietary is from the treated area. However, exclusive feeding on a treated diet is unlikely to occur. The landscape is scattered with different types of habitats, and a potentially applied field is only one of them. For the yellowhammer the proportion of observations in different habitat elements was determined in a multi-annual study (1982-1984) by recording a total of 837 individuals. The proportion of sightings in arable fields in relation to all habitat elements was 2.0% in spring [Seitz, B.-J. 1989. Beziehungen zwischen Vogelwelt und Vegetation im Kulturland - Untersuchungen im südwestdeutschen Hügelland. Beihefte zu den Veröffentlichungen für Naturschutz und Landschaftspflege in Baden-Württemberg 54: 1-236]. Thus, a realistic estimate of the portion of time spend in the treated area (**PT**) would be a factor of **0.02**.

The **marsh warbler** (*Acrocephalus palustris*) is a typical inhabitant of vertical vegetation structures and may also make use of cereal and sunflower fields in the late developmental stages [a) Cramp, S. 1998. Birds of the western Palearctic. CD-Rom Version. b) Glutz von Blotzheim, U. N. & Bauer, K. M. 1991. Acrocephalus palustris Bechstein 1798 – Sumpfrohrsänger. pp. 377-433. In: Glutz von Blotzheim, U. N. (Ed.). Handbuch der Vögel Mitteleuropas. Bd. 12 II; Aula Verlag Wiesbaden]. This would only apply when small insects like aphids are available on the crop. However, this seems unreasonable to assume as aphids affect the yields quality and quantity and thus would need to be controlled when their number exceeds a threshold.

Nevertheless, for the purpose of refinement it is assumed that cereals could provide potential food sources for the marsh warbler up from the end of inflorescence emergence in cereals (BBCH >59).

The diet of adult marsh warblers covers a broad spectrum of arthropod species that are taken from the air or the vertical plant structures. To refine the risk assessment for metconazole it is assumed that the diet consists of 100% arthropods.

In the first tier risk assessment it is assumed that the entire dietary is taken from the treated area. However, exclusive feeding on a treated diet is unlikely to occur. The landscape is scattered with different types of habitats, and a potentially applied field is only one of them. For the marsh warbler the proportion of observations in different habitat elements was determined in a multi-annual study (1982-1984) by recording a total of 37 individuals. In fields the marsh warbler was only observed during summer, and the proportion of sightings in relation to all habitat elements was 2.7% [Seitz, B.-J. 1989. Beziehungen zwischen Vogelwelt und Vegetation im Kulturland - Untersuchungen im südwestdeutschen Hügelland. Beihefte zu den Veröffentlichungen für Naturschutz und Landschaftspflege in Baden-Württemberg 54: 1-236]. Thus, a realistic estimate of the portion of time spend in the treated area (**PT**) would be a factor of **0.027**.

Interception factor (IF)

SANCO 4145/2000 (rev.6, 25.09.02) assumes no interception in arable crops. However, according to FOCUS [Focus groundwater scenarios in the EU review of active substances, Sanco/321/2000, rev.2] and Linders et al. [Linders, J., H. Mensink, G. Stephenson, D. Wauchope & K. Racke. Foliar interception and retention values after pesticide application. A proposal for standardized values for environmental risk assessment. Pest Manag Sci 58, 313-315 (2002) and Pure Appl. Chem. 72(11): 2199-2218 (2002)] the following interception can be assumed for cereals:

BBCH 10-19 (leave development) with 25% interception (DF (deposition factor) = 0.75).

BBCH 20-39 (tillering and elongation) with 50% interception (DF (deposition factor) = 0.5).
BBCH 40-89 (... flowering ...) with 70% interception (DF (deposition factor) = 0.3).
As metconazole is intended for cereal uses between BBCH 29 and 69, the relevant interception rate of 50% is selected, which would translate into a as a worst case Interception Factor (IF) of 0.75 for the Tier 2 assessment

Refined exposure assessments and the long term TER values for birds in cereals
The exposure assessment taking into account the refinement options described before, and the refined TER long term values are provided in the following table:

Tab. B.9.1.8-5: Estimated oral uptake of metconazole by birds and Tier 2 long term Toxicity Exposure Ratio's (TER's)

Application rate	**Bird type**	**FIR/bw *)**	**Category**	**RUD (mean)**	**PT**	**PD**	**DF**	**f_{twa}**	**MAF**	**ETE (mg a.s./kg bw/day)**	**TER**	**Annex VI trigger value**
2 x 0.09 kg a.s./ha in cereals	Large herbivorous bird (**Goose**)	0.44	cereal green plant	20.75	1	1	1	0.53	1.0	0.44	**14**	5
	Insectivorous bird early (**Yellow-hammer**)	0.78	Arthropodes (soil surface)	29	0.02	0.65	0.5	-	-	0.013	-	-
		0.78	Arthropodes (in soil)	0	0.02	0.25	0.5	-	-	0.0	-	-
		0.78	weed seeds (soil surface)	40	0.02	0.10	0.5	-	-	0.003	-	-
										0.016	**387**	5
	Insectivorous bird late (**Marsh warbler**)	0.98	Foliar insects	29	0.027	1	1	-	-	0.07	**88.4**	5

*) Crocker D.R., Hart A., Gurney J. and McCoy C. (2002): Methods for estimating daily food intake of wild birds and mammals. Central Science Laboratory, Project PN0908.
Final Report. http://www.pesticides.gov.uk/general/ResearchReports/index.htm.

The long term risk for large herbivorous and insectivorous birds is considered acceptable."

Conclusion of the rapporteur :

The RUD estimation that has been performed is based on the whole plant residue analysis just after last spray application. These data are summarized in Chapter B.7. The estimation is considered valid.

PT and PD factors were refined for 3 representative scenarios. We considered these scenarios as plausible, but not sufficient to establish validated PD values. Certainly because we consider the establishment and use of this figures as a precedent.
We consider it necessary that lists of PD-values are established at a EU-level per crop and possible food source for the different bird species. These lists should be available as an annex to the present guidance document on birds and mammals so that every risk evaluation will be established on the same basis.

Interception factors that are presented here were established by the FOCUS group in the framework of the groundwater modeling. The relevance of these factors in the risk assessment for birds should be established at EU level.

The rapporteur considers that the risk for large herbivorous and insectivorous birds is acceptable.
- The first tier assessment indicates acceptable acute and short-term risk
- The first tier assessment (worst case assumptions : 100% contaminated diet; NOEC based on continuous exposure of the birds during 22 weeks) indicates that the long term was 'almost acceptable'. The refinement that has been provided by the notifier indicates that acceptable uses could be identified.
-

Metconazole has a potential for bioaccumulation. The TER_{lt} have therefore been calculated for birds consuming fish and earthworms. Calculations are based on the new Guidance Document for birds and mammals Under Council Directive 91/414/EEC of November 2002 (p 20). PEC water and PEC soil are taken from sections B.8.3 and B.8.6.1

- a.s. concentration in fish = (PEC_{water} x BCF) x 0.21 =(0.0012 mg a.s./L x 129.7) x 0.21 = 0.033 mg a.s./kg bw/day
- a.s. concentration in earthworm = (PEC soil x BCF) x 1.1 = (0.15 mg a.s./kg soil x 3.58) x 1.1 = 0.59 mg a.s./kg bw/day (BCF = (0.84 + 0.01 K_{ow})/(f_{oc} x K_{oc}) = (0.84 + 0.01 x 7079)/(0.02 x 1000.6) = 3.58)
- diet containing 100% contaminated item (fish or earthworm)

Tab. B.9.1.8-3 : Toxicity Exposure Ratio's (TER's) for birds consuming fish and earthworms

Application rate (kg as/ha)	Crop	Category	Time-scale	TER	Annex VI Trigger
2 x 0.09	Cereals	Bird eating earthworms Bird eating fish	Long term Long term	6.19/0.59= 10.5 6.19/0.033=189	5 5

The long term risk for birds consuming contaminated fish or earthworms is considered acceptable.

B.9.2 Effects on aquatic organisms (fish, aquatic invertebrates, algae) (Annex IIA 8.2; Annex IIIA 10.2)

B.9.2.1 Acute toxicity of the active substance and metabolites, degradation or reaction products to fish (Annex IIA 8.2.1)

WL148271 (KNF-S-474m): Acute toxicity to Salmo gairdneri, Daphnia magna and Selenastrum capricornutum, (Toy R., 1990).
Guidelines :
OECD Guideline 203
GLP :
Yes
Material and Methods :
Test substance : metconazole (83:17 *cis:trans*), purity: 96.3%, Batchn°: 89-01
Test species : rainbow trout (*Salmo gairdneri*)
Number of organisms, weight, length : 10 per concentration, 1.2 g, 4.8 cm;
Type of test : semi static
Applied and measured concentrations : solvent control, 0.19, 0.35, 0.6, 1.1, 2.1, 3.7, 6.7 and 12 mg a.s./L.
Measured concentrations ranged from 78-88% of the nominal concentrations.
Test conditions :
temperature : 15.7-16.4°C
pH : 7.4-8.2
oxygen content : above 60% of saturation values
total hardness : 248-280 mg/L as $CaCO_3$
Photoperiod : 16 h light, 8 h dark cycle
Analytical methods : GC
Findings :
Mortality : 50% mortality was observed in the 1.9 ppm group, 70% in the 3.1 ppm group and 100% in the 6.2 and 11 ppm groups.
Behavioral observations : Toxic symptoms (f.e. increased cough frequency, hyperventilation, abnormal swimming) were observed starting from the 0.91 ppm treatment group.
Conclusions :
The study is acceptable.
LC_{50} (72h) = 2.1 mg a.s./L (mean measured concentration)
NOEC (96h) = 0.53 mg a.s./L (mean measured concentration)

WL148271 (KNF-S-474m): 96 h acute toxicity to Pimephales promelas, (Toy R., 1991).
Guidelines :
OECD Guideline 203
GLP :
Yes
Material and Methods :
Test substance : metconazole (83:17 *cis:trans*), purity: 96.3%, Batchn°: 89-01
Test species : fathead minnow (*Pimephales promelas*)
Number of organisms, weight, length : 7 organisms per concentration, 0.04g, 1.7 cm;
Type of test : semi static
Applied and measured concentrations : control, solvent control, 0.18, 0.41, 0.81, 1.8, 3.3 and 7.9 mg a.s./L.
Measured concentrations ranged from 71-95% of the nominal concentrations.
Test conditions :
temperature : 22-26°C
pH :7.0-7.1
oxygen content : above 60% of saturation values
total hardness : 260-272 mg/L $CaCO_3$
Photoperiod : 16 h light, 8 h dark cycle
Analytical methods : GC
Findings :

Mortality : 10% mortality was observed in the 3.3 ppm group and 100% mortality in the 7.9 ppm group.40% mortality was observed in the 0.41 ppm treatment group. This effect is regarded as non treatment related as no effects were observed at the 0.81 and 1.8 ppm treatment groups.
Behavioral observations : Some transient sublethal effects were observed at the 3.3 ppm treatment group. At the highest test concentration the fish died within 24 hours.
Conclusions :
The study is acceptable.
LC_{50} (96h) = 3.9 mg a.s./L (measured concentration)
NOEC (96h) = 1.8 mg a.s./L (measured concentration)

Acute Toxicity of AC 900,768 (metconazole) to Common Carp (*Cyprinus carpio)* Under Flow-Through Test Conditions, (Mitchell G.C. *et al*., 1996a).
Guidelines :
OECD Guidelines 201
Official Journal of the European communities Test C1
US EPA Pesticide Assessment Guidelines
GLP :
Yes
Material and Methods :
Test substance : Metconazole, purity: 97.9% (83.3% *cis*: 14.6% *trans*), Batch-N°:AC 9339-114
Test species : common carp (*Cyprinus carpio*)
Number of organisms, weight, length : 2 x 10 organisms per concentration, 0.52 g, 37 mm;
Type of test : flow-through
Applied and measured concentrations : control, solvent control, 0.53, 0.96, 2.0, 4.0 and 8.0 mg a.s./L. Measured concentrations ranged from 84-119% of the nominal concentrations.
Test conditions :
temperature : 22.5°C ± 0.5°C,
pH : 8.0-8.4
oxygen content : above 60% of saturation values
total hardness : 172 mg/L $CaCO_3$
Photoperiod : 16 h light, 8 h dark cycle with a 15 minute transition period.
Analytical methods : FAMS 058-01 (GC-method)
Findings :
Mortality : 10% mortality was observed in the 0.633 and 0.814 ppm test groups. 25% mortality was observed in the 2.02 ppm test group, 30% in the 3.35 ppm test group and 100% in the 7.32 ppm test group.
Behavioral observations : sublethal effects were observed starting from the 2.02 ppm group.
Conclusions :
The study is acceptable
LC_{50} (96h) = 3.99 mg a.s./L (mean calculated concentrations)
NOEC (96h) = 0.814 mg a.s./L (mean calculated concentrations)

B.9.2.2 Fish early life stage toxicity (Annex IIA 8.2.2.1)

Toxicity of AC 900,768 (metconazole) Technical to Rainbow Trout (*Onchorrhynchus mykiss*) in a Flow-Through Prolonged Toxicity Test, (Mitchell G.C. *et al.*, 1996b).
Guidelines :
OECD Guidelines N° 204
GLP :
Yes
Material and Methods :
Test substance : Metconazole, purity: 97.9% (83.3% *cis*: 14.6% *trans*), Batch-N°:AC 9339-114
Test species : rainbow trout (*Onchorrhynchus mykiss*)
Number of organisms, weight, length : 2 x 10 organisms per concentration, 1.7 g, 55 mm
Type of test : flow-through test

Applied and measured concentrations : control, solvent control, 0.64, 1.2, 2.5, 5.1 and 10 mg a.s./L. Measured concentrations ranging from 79-111 % of the nominal concentrations.
Test conditions :
temperature : 15.5-16°C
pH : 7.9-8.4
oxygen content : above 60% of saturation values
total hardness : 164-168 mg/L $CaCO_3$
Photoperiod : 16 h light, 8 h dark cycle with a 15 minute transition period.
Analytical methods : FAMS 058-01 (GC-method)
Findings :
Mortality : 100% mortality was observed starting from the 2.52 ppm treatment group.
Behavioral observations : sublethal effects were observed starting from the 2.52 ppm treatment group.
Conclusions :
Study is acceptable
LC_{50} (28d) = 1.69 mg a.s./L (mean calculated concentration)
NOEC (28d) = 1.14 mg a.s./L (mean calculated concentration)

B.9.2.3 Fish juvenile growth test (Annex IIA 8.2.2.2)

BAS 555 F – Early Life-Stage Toxicity Test on the Rainbow Trout (*Onchorhynchus mykiss*), (Zok S., 2001).
Guidelines :
OECD 210
(U.S.) EPA-FIFRA 72-4 (a)
GLP :
Yes
Material and Methods :
Test substance : Metconazole, Purity : 97.4% (83.1% *cis*), Batch N°: AC 10925-24B
Test species : rainbow trout (*Onchorhynchus mykiss*)
Number of organisms : 4 x 25 fertilized eggs per concentration
Type of test : flow-through system (95 days exposure)
Applied and measured concentrations : control, 0.001, 0.0032, 0.01, 0.032, 0.1 and 0.32 mg a.s./L. Measured concentrations ranging from 90.9-103.0 % of the nominal concentrations. In addition there was a viability control during the first two weeks.
Test conditions :
temperature : 10°C
pH : 8.0-8.3
oxygen content : above 60% of saturation values
total hardness : 2.13-2.23 mmol/L
Photoperiod : until swim-up the embryos and larvae were kept in the dark, thereafter, until termination of the study, they were exposed to dim light of 78-260 Lux.
Analytical methods : CP371 (HPLC/UV)
Findings :
Viability control : the survival in the viability control after 14 days was 93%
Survival :

Tab. B.9.2.3-1 : Major effects of metconazole observed during the early life-stage toxicity test

	Concentration (mg/L)						
	0	**0.001**	**0.0032**	**0.01**	**0.032**	**0.1**	**0.32**
Embryo survival (0-28d) of eggs set (%)	94	94	93	92	92	93	96
Embryo/larvae survival (28-37d) of 28 d survivors (%)	94.7	96.8	94.6	91.3	97.8	95.7	96.9
Embryo/larvae survival (0-37d) of eggs set (%)	89	91	88	84	90	89	93
Larvae survival (37-62d) of 37 d survivors (%)	96.6	97.8	98.9	97.6	96.7	94.4	95.7

	Concentration (mg/L)						
	0	**0.001**	**0.0032**	**0.01**	**0.032**	**0.1**	**0.32**
Larvae survival (0-62d) of eggs set (%)	86	89	87	82	87	84	89
Young fish survivors (62-95d) of 62 d survivors (%)	98.8	100	98.9	86.6*	78.2*	84.5*	88.8*
Survival at the end from the test of eggs set (%)	85	89	86	71**	68*	71**	79

*Statistically significant (log-Rank-test, p≤0.01)
** Statistically significant (log-Rank-test, p≤0.05)
Day 28 : beginning of hatch; Day 37 : end of hatch; Day 62 : end of swim-up; Day 95 : end of exposure;
A significant difference in survival of young fish (day 62-day 95) was observed starting from the 0.01 ppm test group. Also the overall survival was significantly affected but only for the 0.01, 0.032 and 0.1 mg/L test groups and not for the highest concentration tested.

Time to hatch : The larvae in the control group started hatching on day 30-32 and hatch was completed on day 35. In the treatment groups larvae started hatching on days 28-32 and hatch was completed on day 33-37.

Time to swim-up : The first swim-up in the control groups was observed at days 48-50 and swim-up was completed on days 53-55. In the replicates of the 0.001-0.032 mg/L treatment groups swim-up started during days 46-51 and ended on days 52-56. In the replicates of the concentrations 0.1 and 0.32 mg/L swim-up was delayed as it started on days 53-54 and ended on day 62.

Sublethal effects and abnormalities : Starting from the 0.032 mg/L treatment group, the larvae showed exhibited lateral position, apathy, a reduced body length and, during the final two weeks of the exposure period, tumbling. At the end of the exposure period no vertebral deformations were seen in any fish from the control or the concentration groups.

Body weight and length : At termination of exposure the mean body weight of the lowest treatment group was significantly higher than the control. Starting from the 0.01 mg/L treatment group, the body weights were significantly lower than the control with a clear concentration-related trend. The same results were observed for dry weight as for wet weights. The mean body length was significantly lower than the control starting from the 0.01 ppm treatment group with a clear concentration-related trend.

Conclusions :
Study is acceptable.
NOEC (95d) = 0.00291 mg a.s./L (mean analytically determined concentration) based on body weight and length and survival of young fish.

B.9.2.4 Fish life cycle test (Annex IIA 8.2.2.3)

Not required.

B.9.2.5 Bioaccumulation potential in fish (Annex IIA 8.2.3)

Two studies dealing with the bioaccumulation of metconazole in fish were provided.

CL 900,768 (Metconazole): Bioconcentration and Elimination of [Triazole-3,5-^{14}C]CL 900,768-Derived Residues by Bluegill Sunfish, (Kao M.K., 1996).
Guidelines :
US 40 CFR 158.290 pesticide Assessment Guidelines Subdivision N, Series 165-4
OECD Testing Guidelines, Method 305E
GLP :
Yes
Material and Methods :
Test substance : metconazole; radiopurity : 99.44% (77.4:22.6 *cis:trans*); specific activity : 3.81 µCi/mg
Test species : Bluegill sunfish (*Lepomis macrochirus*)

Number of organisms, weight, length : 120 fish/concentration, 7.04 ± 1.44 g (0.4 mg/L) and 6.32 ± 1.58 g (0.04 mg/L), 61 ± 4.1 mm (0.4 mg/L) and 58 ± 4.2 mm (0.04 mg/L);
Type of test : Bioaccumulation test (28 + 14 days) in a flow-through system
Measured concentrations : Fish were exposed to 0.038 and 0.38 mg/L
Test conditions :
Temperature: 20-21°C; pH : 7.84-8.28; oxygen content : > 60% of saturation; total hardness : 274-300 mg/L as $CaCO_3$; Total organic carbon (dilution water): <1.0-<1.17 mg/L; Suspended solids (dilution water): 0.3-1.3 mg/L
Analytical methods : Total radioactive residues in samples were determined by either direct liquid scintillation counting (LSC) or combustion of aliquots to yield $^{14}CO_2$ that was trapped by an amine and quantified by LSC.
Findings :
Table B.8.2.3-1 Bioaccumulation potential of metconazole in fish

	Water		Fillet (edible part)		Viscera (non-edible part)		Whole fish	
	0.038 mg/L	0.38 mg/L	0.038 mg/L	0.38 mg/L	0.038 mg/L	0.38 mg/L	0.038 mg/L	0.38 mg/L
Mean residue concentration after 28 day exposure period (mg/kg)	0.038	0.38	1.6	25	5.8	59	3.5	41
Residue concentration after 3 days depuration (mg/kg)	-	-	0.10	0.35	0.19	2.8	0.14	1.5
Residue concentration after 14 days depuration (mg/kg)	-	-	0.022	0.099	0.044	0.25	0.032	0.17
BCF_{ss} (Total Radioactive Residues, 28d)	-	-	42.1	65.8	152.6	155.3	92.1	107.8
BCF_k (TRR)							114	119
Depuration half-life (d)	-	-	< 1 d	< 1 d	< 1 d	< 1 d	0.41	0.45

Conclusions :
The study is acceptable. A maximum whole fish BCF_{ss} (TRR) of 123.7 was observed at day 14 for the 0.4 mg/L test group and a maximum of 128.2 was observed at day 14 for the 0.04 mg/L test group.

BAS 555 F (AC 900768, Metconazole): Bioconcentration and Elimination of [*p*-Chlorophenyl-U-^{14}C] AC 900768-Derived Residues by Bluegill Sunfish, (Cenni M., 2002).
Guidelines :
US 40 CFR 158.290 pesticide Assessment Guidelines Subdivision N, Series 165-4
OECD Testing Guidelines, Method 305E
GLP :
Yes
Material and Methods :
Test substance : metconazole; radiopurity : 97.2%; specific activity : 4.37 µCi/mg
Test species : Bluegill sunfish (*Lepomis macrochirus*)
Number of organisms, weight, length : 120 fish/concentration, 6.0155 ± 1.5236 g , 59 ± 4.5 mm;
Type of test : Bioaccumulation test (28 + 14 days) in a flow-through system
Measured concentrations : Fish were exposed to 0.038 and 0.37 mg/L
Test conditions :
Temperature: 20-22°C; pH : 8.0±0.2; oxygen content : > 60% of saturation; total hardness : 274-300 mg/L as $CaCO_3$; Total organic carbon (dilution water): <1.0-<1.17 mg/L; Suspended solids (dilution water): 0.3-1.3 mg/L
Analytical methods : Total radioactive residues in samples were determined by either direct liquid scintillation counting (LSC) or combustion of aliquots to yield $^{14}CO_2$ that was trapped by an amine and quantified by LSC.
Findings :
Table B.8.2.3-1 Bioaccumulation potential of metconazole in fish

	Water		Fillet (edible part)		Viscera (non-edible part)		Whole fish	
	0.038 mg/L	0.37 mg/L	0.038 mg/L	0.37 mg/L	0.038 mg/L	0.37 mg/L	0.038 mg/L	0.37 mg/L
Mean residue concentration after 28 day exposure period (mg/kg)	0.041	0.38	1.1	19	3.2	43	2.1	30
Residue concentration after 3 days depuration (mg/kg)	-	-	0.0	0.04	0.0048	0.092	0.0022	0.064

	Water		Fillet (edible part)		Viscera (non-edible part)		Whole fish	
	0.038 mg/L	0.37 mg/L	0.038 mg/L	0.37 mg/L	0.038 mg/L	0.37 mg/L	0.038 mg/L	0.37 mg/L
Residue concentration after 14 days depuration (mg/kg)	-	-	0.0054	0.022	0.013	0.033	0.0089	0.047
BCF_{ss} (Parent, day 28)	-	-	26.8	50.0	78.0	113.2	51.2	78.9
BCF_{ss} (TRR, day 28)	-	-	44.7	56.7	205.3	164.9	118.4	105.4
BCF_k (Parent)	-	-	-	-	-	-	51	80
BCF_k (TRR)	-	-	-	-	-	-	114	106
BCF_{ss} (Parent, corrected for lipid content, day 21)	-	-	-	-	-	-	896	1179
BCF_{ss} (TRR, corrected for lipid content, day 21)	-	-	-	-	-	-	1845	1466
Depuration half-life (d)	-	-	< 1 d	< 1 d	< 1 d	< 1 d	0.53	0.58

Conclusions :
The study is acceptable. A maximum whole fish BCF_{ss} (TRR) of 110.8 was observed at day 7 for the 0.4 mg/L test group and a maximum of 129.7 was observed at day 7 for the 0.04 mg/L test group.

B.9.2.6 Acute toxicity to invertebrates (Annex IIA 8.2.4)

WL148271 (KNF-S-474m): Acute toxicity to Salmo gairdneri, Daphnia magna and Selenastrum capricornutum, (Toy R., 1990).
Guidelines :
OECD Guideline 202
GLP :
Yes
Material and Methods :
Test substance : metconazole (83:17 *cis:trans*), purity: 96.3%, Batchn°: 89-01
Test species : Daphnia magna
Number of organisms, age : 2 x 10 organisms/concentration, less than 24h old
Type of test : Static toxicity test
Applied and measured concentrations : solvent control, 0.19, 0.35, 0.63, 1.1, 2.1, 3.7, 6.6 and 12.0 mg a.s./L.
Measured concentrations ranging from 72-89% of the nominal concentrations
Test conditions :
temperature : 18-24.3°C
pH : 7.8-8.5
oxygen content : more than 60% of air saturation value
total hardness : 156 mg/L as $CaCO_3$
Analytical methods : HPLC
Findings :
Mortality : Mortality was observed starting from the 4.9 ppm treatment group.
Behavioral observations : /
Conclusions :
Study is acceptable.
LC_{50} (48h) = 4.2 mg a.s./L (measured concentration at t_0)
NOEC (48h) = 3.0 mg a.s./L (measured concentration at t_0)

B.9.2.7 Chronic toxicity to aquatic invertebrates (Annex IIA 8.2.5)

BAS 555 F – Determination of the chronic effect on the reproduction of the water flea *Daphnia magna* STRAUS, (Jatzek, 2002).
Guidelines :
EEC Guideline XI/691/86, Draft 4: "Prolonged toxicity study with *Daphnia magna*: Effects on reproduction".
Deutches Institut für Normung: Bestimmung der biologischen Wirkung von Wasserinhaltstoffen auf Kleinkrebse (Reproduktionstest mit *Daphnia magna*)
OECD Guideline for Testing of Chemicals No. 211
GLP :
Yes
Material and Methods :
Test substance : metconazole, purity: 97.4%, Batchn°: AC 10925-24B
Test species : Daphnia magna
Number of organisms, weight, length, age : 10 x 1 organism per concentration
Type of test : semistatic toxicity test (21 d)
Applied and measured concentrations : control, 0.02, 0.039, 0.078, 0.16, 0.31, 0.63, 1.25 and 2.5 mg a.s./L.
Measured concentrations were above 80% of the nominal concentrations
Test conditions :
temperature : 20.0-20.7°C
pH : 7.0-8.3
oxygen content : more than 60% of air saturation value
total hardness : 2.20-3.20 mmol/L
Photoperiod : 16 hours light, 8 hours darkness
Analytical methods : HPLC-method CP371
Findings :
Table B.9.2.7-1 : Major effects of metconazole observed during the reproduction study of *Daphnia magna*

	Test concentration (mg a.s./L)									
	0	**solvent control**	**0.02**	**0.039**	**0.078**	**0.16**	**0.31**	**0.63**	**1.25**	**2.5**
Total number of surviving parent animals (21 d)	9	10	10	10	10	10	10	9	8	0
First appearance of young (d)	8	8	9	8	9	9	9	12	11	-
Total number of living young per surviving parent (21 d)	153.0	154.5	151.0	165.0	162.1	131.1	24.3	0.0	0.0	-
Total number of dead young per surviving parent (21 d)	0.0	0.0	0.0	0.0	0.1	0.0	61.1	89.0	0.5	-
Total number of aborted subitane eggs per surviving parent (21 d)	1.4	0.8	1.1	0.4	0.9	0.4	0.2	0.4	0.0	-

Conclusions :
Study is acceptable.
NOEC (21d) = 0.16 mg a.s./L

B.9.2.8 Effects on algal growth (Annex IIA 8.2.6)

WL148271 (KNF-S-474m): Acute toxicity to Salmo gairdneri, Daphnia magna and Selenastrum capricornutum, (Toy R., 1990).
Guidelines :
OECD Guideline for Testing of Chemicals: 201, Alga Inhibition Test
GLP :
Yes
Material and Methods :
Test substance : metconazole (83:17 *cis:trans*), purity: 96.3%, Batchn°: 89-01

Test species : Selenastrum capricornutum
Number of organisms : 3 replicates per concentration (6 in the control); 10000 cells/mL at initiation
Type of test : static toxicity test (72 h)
Applied and measured concentrations : control, 0.01, 0.02, 0.05, 0.11, 0.23, 0.51, 1.13, 2.48, 5.45 en 12 mg a.s./L. Measured concentrations ranging from 57-69% of the nominal concentrations. Results are expressed in measured concentrations at t_0. The test product was not stable in the test medium at the lowest test concentration. The test substance was stable in the test medium with respect to t_0-values in the range of the EC_{50}-values.
Test conditions :
temperature : 22.6-23.5°C
pH : 7.9-9.6
Photoperiod : constant illumination
Analytical methods : HPLC
Conclusions :
The study is acceptable.
E_bC_{50} (72h) = 1.7 mg a.s./L
E_rC_{50} (72h) = 2.2 mg a.s./L
NOEC (72h) = 0.38 mg a.s./L

B.9.2.9 Effects on sediment dwelling organisms (Annex IIA 8.2.7)

Effects of AC 900,768 (metconazole) on the Development of Sediment-Dwelling Larvae of *Chironomus riparius* in a Water-Sediment System, (England D.C. *et al.*, 1997).
Guidelines :
- American Society for Testing Materials (1992 : Standard guide for conducting sediment toxicity tests with freshwater invertebrates; Standard guide for collection, storage, characterization and manipulation of sediments for toxicity testing; Standard methods for conducting basic acute toxicity tests with fishes, macroinvertebrates and amphibians;
- Adams W.J. et al. (1985) Aquatic safety assessment of chemicals sorbed to sediments;
- US EPA (1975) Methods for acute toxicity tests with fish, macroinvertebrates and amphibians;
- US EPA (1985) Standard evaluation procedure, acute toxicity test for freshwater invertebrates;
- Dohmen G.P. and Barrett K.L. A proposed test method for the assessment of pesticide impact on sediment dwelling larvae of the midge Chironomus riparius (draft document);

GLP :
Yes
Material and Methods :
Test substance : metconazole, chemical purity : 97.9%, LotN° : #AC 9339-114
Test species : Chironomus riparius
Number of organisms, age : 25 larvae/concentration, first-instar midge larvae
Type of test : Sediment-water chironomid toxicity test using spiked water
Applied and measured concentrations : 0, 0.313, 0.625, 1.25, 2.5 and 5.0 mg a.i./L. Mass balance recoveries on day 28 ranged from 53-82% of nominal concentrations. Results are expressed in measured concentrations.
Test conditions :
temperature : 20.5°C ± 0.2 °C
pH : 7.2 ± 0.8
oxygen content : above 60% of nominal
total hardness : 130-160 mg/L as $CaCO_3$
Photoperiod : 16h light/8h dark with a 30-minute transition period
Analytical methods : FAMS 058-01(GC-method)
Remarks : The study was established with an artificial sediment containing 10% sphagnum peat instead of 5%. The sediment layer had a depth of 1.5 cm and the dilution water had a depth of 15 cm, giving a water:sediment volume ratio of 10:1.
Conclusions :
A decreasing concentration in the water column was observed with a corresponding increase in sediment and interstitial water
LC_{50} (10d) = 3.33 mg a.s./L (based on survival/emergence, measured concentration)
NOEC (10d) = 2.12 mg a.s./L (based on survival/emergence, measured concentration)
LC_{50} (28d) = 3.41 mg a.s./L (based on survival/emergence, measured concentration)

NOEC (28d) = 2.12 mg a.s./L (based on survival/emergence, measured concentration)

B.9.2.10 Effects on aquatic plants (Annex IIA 8.2.8)

Not required.

B.9.2.11 Acute toxicity of the preparations (Annex IIIA 10.2.1)

BAS 555 F 60SL acute toxicity Study on the Rainbow Trout (*Onchorhynchus mykiss)* in a Static System over 96 hours, (Zok S., 2001).
Guidelines :
EPA-Para. 72-1, Oct. 1982
92/69/EEC, Annex V, C1
OECD 203
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g/L SL, Purity : 58.2 g/L, Batch N°. : 162940
Test species : Rainbow trout (*Onchorhynchus mykiss*)
Number of organisms, weight, length, age : 10 fish/concentration, 1.9 g, 6.2 cm, approx. 6 months
Type of test : static system (96 hours)
Applied and measured concentrations : control, 0, 5, 10, 22, 50 and 100 mg formulation/L. Measured concentrations ranging from 87-98 % of the nominal concentrations
Test conditions :
temperature : 12-13°C
pH : 8.2-8.6
oxygen content : above 60% of air saturation value
total hardness : 250 mg/L as $CaCO_3$
Photoperiod : 16 hours light, 8 hours darkness
Analytical methods : CP 371 RP-HPLC with UV-detection
Findings :
Mortality : 100% mortality was observed starting from the 22 mg/L group.
Behavioral observations : Sublethal effects were observed starting from the 10 mg/L group. In the 10 mg/L group effects had disappeared on day 4.
Conclusions :
The study is acceptable.
LC_{50} (96h) = 14.83 mg formulation/L
NOEC (72h) = 5 mg formulation/L
NOEC (96h) = 10 mg formulation/L

Acute Toxicity of AC 900768 (metconazole) 60 g/L SL formulation (SF 09381) to *Daphnia magna* Under Static Test Conditions, (Mitchell G.C. *et al.*, 1998).
Guidelines :
OECD Guideline 203
European Communities Test Method C.2.
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 60.4 g/L, BatchN° : 005
Test species : Daphnia magna
Number of organisms, age : 2 x 10 organisms/concentration, less than 24h old
Type of test : static toxicity test

Applied and measured concentrations : control, 100, 170, 290, 480 and 800 µg formulation/L. Measured concentrations ranging from 85-105 % of the nominal concentrations.
Test conditions :
temperature : 19.7-20.0°C
pH : 7.4
oxygen content : above 60% of air saturation value
total hardness : 180 mg/L as $CaCO_3$
Photoperiod : 16 hours light and 8 hours dark photoperiod with a 15-minutes transition period
Analytical methods : FAMS 058-01 (GC-method)
Findings :
Mortality : Mortality was observed starting from the 490 µg/L group.
Behavioral observations : No sublethal effects were observed.
Conclusions :
The study is acceptable.
EC_{50} (48h) = 420 µg formulation/L (mean calculated concentration)
NOEC (48h) = 270 µg formulation/L (mean calculated concentration)

AC 900768 (metconazole) 60 g/L formulation (SF 09381): Acute Toxicity to *Daphnia magna* in a Static Water System, (Aufderheide J.A. & Mitchell G.C., 1998).
Guidelines :
US EPA Pesticide Assessment Guidelines
OECD Guidelines for the Testing of Chemicals
Official Journal of the European Communities Test C2
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 60.4 g/L, BatchN° : 005
Test species : Daphnia magna
Number of organisms, age : 2 x 10 organisms/concentration, less than 24h old
Type of test : static toxicity test
Applied and measured concentrations : control, 100, 170, 290, 480 and 800 µg formulation/L. Measured concentrations ranging from 70-100 % of the nominal concentrations
Test conditions :
temperature : 19-20.5°C
pH : 7.4-7.9
oxygen content : above 60% of air saturation value
total hardness : 104 mg/L as $CaCO_3$
Photoperiod : 16 hours light and 8 hours dark photoperiod with a 30-minutes transition period
Analytical methods : FAMS 058-01 (GC-method)
Findings :
Mortality : 1 mortality was observed in the 203 µg/L group. 10 mortalities were observed in the 350 µg/L group and 19 mortalities in the 728 µg/L group.
Behavioral observations : Sublethal effects were observed starting from the 203 µg/L group.
Conclusions :
The study is acceptable.
EC_{50} (48h) = 365 µg formulation/L (measured concentration at t_{48})
NOEC (48h) = 121 µg formulation/L (measured concentration at t_{48})

Acute Toxicity of Formulation (SF 09747) to *Daphnia magna* under Static Test Conditions, (Mitchell G.C. *et al.*, 2001).
Guidelines :
OECD Guidelines for the Testing of Chemicals
Official Journal of the European Communities Test Method C2
GLP :
Yes

Material and Methods :
Test substance : Blank formulation (recipe: SF09747)
Test species : Daphnia magna
Number of organisms, age : 2 x 10 organisms/concentration, less than 24h old
Type of test : static toxicity test (48h)
Applied and measured concentrations : control, 100, 170, 290, 480 and 800 µg test product/L.
Test conditions :
temperature : 19.7±0.4°C
pH : 7.4-7.5
oxygen content : above 60% of air saturation value
total hardness : 160 mg/L as $CaCO_3$
Photoperiod : 16 hours light and 8 hours dark photoperiod with a 15-minutes transition period
Findings :
Mortality : No mortality was observed in the control and in the 100 µg/L test group. Mortality was observed in the other treatment groups.
Behavioral observations : No sublethal effects were observed in the control and in the 100 µg/L test group. Sublethal effects were observed at higher test rates.
Conclusions :
Study is acceptable.
LC_{50} (48h) = 140 µg test product/L
NOEC (48h) = 100 µg test product/L

Effects of a AC 900768 (metconazole) 60 g/L SL formulation (SF 09381) on the growth of *Selenastrum capricornutum*, (Mitchell G.C. *et al.*, 1996b).
Guidelines :
OECD Guideline 201
Official Journal of the European Communities Test C3 "Algal Inhibition Test"
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 59.2 g/L, BatchN° : 005
Test species : Selenastrum capricornutum
Number of organisms : 3 replicates per concentration (6 in the control); 10000 cells/mL at initiation
Type of test : static toxicity test (72 h)
Applied and measured concentrations : control, 1.1, 2.3, 4.2, 8.3 and 17 mg formulation/L. Measured concentrations ranging from 88-97 % of the nominal concentrations.
Test conditions :
temperature : 23.6°C ± 0.1 °C
pH : 7.5-10.0
Photoperiod : continuous light of ± 740 foot-candles
Analytical methods : FAMS 058-01(GC-method)
Conclusions :
The study is acceptable.
E_bC_{50} (72h) = 5.13 mg formulation/L
E_rC_{50} (72h) = 8.38 mg formulation/L
NOEC (72h) = 2.23 mg formulation/L

B.9.2.12 Microcosm and mesocosm study (Annex IIIA 10.2.2)

Not required.

B.9.2.13 Residue data in fish (Annex IIIA 10.2.3)

See Point B.9.2.5.

B.9.2.14 Supplementary studies of toxicity to fish and aquatic invertebrates (Annex IIIA 10.2.4)

Toxicity of AC 900,768 (metconazole) 60 g/L SL Formulation (SF09381) to Rainbow Trout (*Onchorhynchus mykiss*) in a Flow-Through Prolonged Toxicity Test, (Mitchell G.C. *et al.*, 1996a).
Guidelines :
OECD Guideline 204
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 59.2 g/L, BatchN° : 005
Test species : Rainbow trout (*Onchorhynchus mykiss*)
Number of organisms, weight, length : 2 x 10 fish/concentration, 1.09 g, 45 mm;
Type of test : flow through prolonged toxicity test (28 d)
Applied and measured concentrations : control, 20, 35, 69, 140 and 280 µg a.s./L. Measured concentrations were above 80% of the nominal concentrations.
Test conditions :
temperature : 14.1-16.0°C
pH : 7.9-8.6
oxygen content : above 60% of air saturation value
total hardness : 160-180 mg/L as $CaCO_3$
Photoperiod : 16 hour light and 8 hour dark period with a 15 minutes transition period.
Analytical methods : FAMS 058-01 (GC-method)
Findings :
Mortality : mortality was observed starting from the 31.1 µg/L test group.
Behavioral observations : Sublethal effects were observed starting from the 31.1 µg/L test group. One fish of the 16.1 µg/L treatment group seemed affected on day 23 but appeared back normal on day 24.
Conclusions :
The study is acceptable.
LC_{50} (28 d) = 33.7 µg a.s./L (measured concentration) or 507 µg/L formulation/L
NOEC (28 d) = 16.1 µg a.s./L or 242 µg formulation/L

Chronic Toxicity of AC 900,768 (metconazole) in a 60 g/L SL Formulation (SF 09381) During the Complete Life-Cycle of *Daphnia magna* Under Static Renewal Test Conditions, (Mitchell G.C. *et al*., 1996c).
Guidelines :
OECD Guidelines for the Testing of Chemicals Test 202 Part B
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 59.2 g/L, BatchN° : 005
Test species : Daphnia magna
Number of organisms, age : 4 x 10 organisms/concentration, less than 24 h old
Type of test : semi-static toxicity test (21d)
Applied and measured concentrations : control, 21, 42, 83, 170 and 330 µg formulation/L. Measured concentrations ranging from 95-100% of the nominal concentrations.
Test conditions :
temperature : 19.5±0.6°C
pH : 8.2±0.3
oxygen content : : above 60% of air saturation value
total hardness : 160-180 mg/L as $CaCO_3$
Photoperiod : 16 hours light and 8 hours dark photoperiod
Analytical methods : FAMS 058-01 (GC-method)

Findings :

Table B.9.2.14-1 : Major effects of metconazole 60 g/L SL formulation observed during the reproduction study of *Daphnia magna*

	Test concentration (µg formulation/L, calculated)					
	0	**20.8**	**42.0**	**80.9**	**161**	**328**
Total number of surviving parent animals (21 d)	39	39	37	26*	19*	0*
First appearance of young (d)	12.0	12.0	12.3	14.0*	>19**	-**
Total number of living young per surviving parent (21 d)	45.3	45.2	18.4*	5.0*	0.05*	-**
Mean dry weight of surviving adults (mg)	0.5	0.5	0.42	0.24*	0.13*	-**
Mean length of surviving adults (mm)	4.0	4.0	3.8*	2.7*	2.1*	-**

*Statistically different from the control (α=0.05)
**Assumed to be different from the control

Conclusions :

Study is acceptable although the first young were born in the controls after 12 days, which is rather late.
EC_{50} (21 d) = 111 µg formulation/L (calculated concentration)
NOEC (21 d) = 20.8 µg formulation/L (calculated concentration)

B.9.2.15 Summary of effects to water organisms (Annex IIA 8.2, Annex IIIA 10.2)

Table B.9.2.15-1 : Summary of effects of Metconazole to waterorganisms

Test species	Test system	Duration of exposure	Results	References
Salmo gairdneri	**semi static**	**72h**	**LC_{50} = 2.1 mg a.s./L**	**Toy R., 1990**
Pimephales promelas	semi static	96h	LC_{50} = 3.9 mg a.s./L	Toy R., 1991
Cyprinus carpio	flow-through	96h	LC_{50} = 3.99 mg a.s./L	Mitchell G.C. *et al.*, 1996a
Onchorrhynchus mykiss	flow-through	28d	NOEC = 1.14 mg a.s./L	Mitchell G.C. *et al.*, 1996b
Onchorhynchus mykiss	**early life-stage toxicity test**	**95d**	**NOEC = 0.00291 mg a.s./L**	**Zok S., 2001**
Lepomis macrochirus	bioaccumulation potential	28d exposure/14d depuration	max BCF = 124 depuration half-life < 1d	Kao M.K., 1996
Lepomis macrochirus	bioaccumulation potential	28d exposure/14d depuration	max BCF = 129.7 depuration half-life < 1d	Cenni M., 2002
Daphnia magna	**Static**	**48h**	**LC_{50} = 4.2 mg a.s./L**	**Toy R., 1990**
Daphnia magna	**semistatic**	**21d**	**NOEC = 0.16 mg a.s./L**	**Jatzek, 2002**
Selenastrum capricornutum	**static**	**72h**	**E_bC_{50} = 1.7 mg a.s./L**	**Toy R., 1990**
Chironomus riparius	**static**	**28d**	**NOEC = 2.12 mg a.s./L**	**England D.C. *et al.*, 1997**

Table B.9.2.15-2 : Summary of effects of Metconazole 60 g/L SL formulation to waterorganisms

Test species	Test system	Duration of exposure	Results (mg formulation/l)	References
Onchorhynchus mykiss	**static**	**96h**	**LC_{50} = 14.83**	**Zok S., 2001**
Daphnia magna	static	48h	EC_{50} = 0.42	Mitchell G.C. *et al.*, 1998
Daphnia magna	**static**	**48h**	**EC_{50} = 0.365**	**Aufderheide J.A. & Mitchell G.C., 1998**
Daphnia magna	static/blank formulation	48h	LC_{50} = 0.140	Mitchell G.C. *et al.*, 2001
Selenastrum capricornutum	**static**	**72h**	**E_bC_{50} = 5.13**	**Mitchell G.C. *et al.*, 1996b**
Onchorhynchus mykiss	**flow through**	**28 d**	**NOEC = 0.242**	**Mitchell G.C. *et al.*, 1996a**
Daphnia magna	**semi-static**	**21 d**	**NOEC = 0.0208**	**Mitchell G.C. *et al.*, 1996c**

B.9.2.16 Exposure and risk assessment for aquatic organisms (Annex IIIA 10.2)

For details of the PEC calculations see point B.8.6.1. The toxicity endpoints were compared to the maximum concentration of 1.2 µg a.s./L found just after the last application (2 x 90 g a.s./ha in cereals) at 1 m distance of the water body.

Table B.9.2.16-1 : Theoretical Exposure Ratio for aquatic organisms exposed to metconazole

Test species	Effect Concentration (mg a.s./L)	Distance (m)	Estimated initial concentration (mg a.s./L)	TER	Annex VI trigger value
Salmo gairdneri	LC_{50} = 2.1	1 m	0.0012	1750	100
Onchorhynchus mykiss	**NOEC = 0.00291**	1 m	0.0012	2.43	10
		5 m	**0.000247**	**11.78**	**10**
Daphnia magna	LC_{50} = 4.2	1 m	0.0012	3500	100
Daphnia magna	NOEC = 0.16	1 m	0.0012	133	10
S. capricornutum	E_bC_{50} = 1.7	1 m	0.0012	1417	10
Chironomus riparius	NOEC = 2.12	1 m	0.0012	1767	10

The NOEC for *Chironomus riparius* in water is 2.12 mg a.s./L (28 d). Given that the water/sediment ratio is 10:1, this results in a NOEC of 21.2 mg a.s./kg sediment. The PEC in sediment is 0.12 mg a.s./kg sediment (plateau average concentration). The TER in sediment is therefore 177.

The risk for aquatic organisms resulting from the use of the active substance metconazole is considered acceptable if a buffer zone of 5 meters next to water bodies is taken into account.

The BCF-values resulting from the 2 studies established are above 100 and as the active substance is not readily biodegradable, a higher tier risk assessment is considered necessary.
An early life stage study was established resulting in a NOEC of 0.00291 mg a.s./L on basis of which the risk is considered acceptable if a buffer zone of 5 meters is taken into account. In addition the depuration half time is less than 1 day. Therefore it is considered that the risk for bioaccumulation of metconazole in fish is low.

Table B.9.2.16-2 : Theoretical Exposure Ratio for aquatic organisms exposed to the formulation metconazole 60 g/L SL

Test species	**Effect Concentration (mg formulation/L)**	**Distance (m)**	**Estimated initial concentration (mg formulation/L)**	**TER**	**Annex VI trigger value**
Onchorhynchus mykiss	LC_{50} = 14.83	1 m	0.0211	702.8	100
Daphnia magna	EC_{50} = 0.365	1 m	0.0211	17.3	100
		5 m	0.004343	84	100
		10 m	0.00221	165	100
S. capricornutum	E_bC_{50} = 5.13	1 m	0.0211	243.13	10
Onchorhynchus mykiss	NOEC = 0.242	1 m	0.0211	11.47	10
Daphnia magna	NOEC = 0.0208	1 m	0.0211	0.986	10
		5 m	0.004343	4.79	10
		10 m	0.00221	9.4	10
		15 m	**0.001524**	**13.65**	**10**

The risk for aquatic organisms resulting from the use of a formulation containing 60 g metconazole/L is considered acceptable if a buffer zone of 15 meters next to water bodies is taken into account.

B.9.3 Effects on other terrestrial vertebrates (Annex IIIA 10.3.1)

The risk assessment for small mammals is based on the following assumptions :

Tab. B.9.3-1 : Summary of effects of Metconazole to mammals.

Test species	Test System	Results	References
Mouse	acute	LD_{50} = 410 mg a.s./kg	Gardner, 1990a
Rabbit	Long term	NOAEL = 4 mg a.s./kg bw/day	Masters, 1991b Masters, 1992a

The risk assessment for mammals is based on the new Guidance Document for birds and mammals Under Council Directive 91/414/EEC of November 2002. As a worst-case it was assumed that the mammals obtained 100% of their diet in the treated area.

Tab. B.9.3-2 : Estimated oral uptake of metconazole by mammals and first tier Toxicity Exposure Ratio's (TER's)

Application rate	Mammal type	Time scale	FIR/bw	RUD (90%)	MAF	f_{twa}	ETE (mg a.s./kg bw/day)	TER	Annex VI trigger value
2 x 0.090 kg a.s./ha in cereals	Small herbivorous mammal	acute	1.39	142	1.2	-	21.32	19.23	10
		long term	1.39	76	1.4	0.53	7.05	0.57	5
	Insectivorous mammal	acute	0.63	14	-	-	0.79	519	10
		long term	0.63	5.1	-	-	0.29	13.8	5
2 x 0.090 kg a.s./ha in oilseed rape	med. herbivorous mammal	acute	0.28	87	1.2	-	2.63	155.1	10
		long term	0.28	40	1.4	0.53	0.75	5.3	5

The acute risk for insectivorous or small herbivorous mammals is considered acceptable.

The long term risk for small herbivorous mammals is not considered acceptable based on the first tier risk assessment. Risk refinement is considered necessary.

"Tier 2 Assessment presented by the notifier
In Tier 1 the default residue values for plant feed items used are 142 mg a.s./kg for acute exposure and 76 mg a.s./kg for long-term exposure, respectively, to accomplish a worst-case scenario. However, in field trials with metconazole the residues reveal values below these defaults. Treatment and application regime in these studies were comparable to the scheme for the representative formulation.

These residue data are specific for metconazole and will be used in the Tier 2 risk assessment to represent the monocotyledonous plant type.

The data were normalized to an application rate of 1 kg a.s./ha resulting in RUD values which can be directly used in the Tier 2 assessment. Based on Sanco 4145/2000 (rev.6, 25.09.02), the arithmetic mean residue values will be used to refine the long-term risk assessment.

In **cereal green plants** 2 applications with 0.09 kg a.s./ha resulted in a mean initial worst case RUD (covering 2 applications) of **20.75 mg a.s./kg** (n = 20) (see Chapter B.7). Due to the fact that this RUD covers 2 successive applications, the Multiple Application Factor (MAF) is set to 1.0.

Tab. B.9.3-3: Initial residues of metconazole in cereal green plants

Crop	Number of	Number of	RUD Range [1)]	RUD Max. [1)]	RUD Mean [1)]

Tab. B.9.3-3: Initial residues of metconazole in cereal green plants

	trials	applications	[mg a.s./kg green matter]	[mg a.s./kg green matter]	[mg a.s./kg green matter]
Cereal plants	22	2	12.89 - 44.33	44.33	**20.75**

1) Residue unit dose (RUD), corresponding to 1 kg a.s./ha.

Refined exposure assessments and the long term TER values for mammals in cereals
The exposure assessment taking into account the refinement options described before, and the refined TER long term values are provided in the following table:

Tab. B.9.3-4: Estimated oral uptake of metconazole by mammals and Tier 2 long term Toxicity Exposure Ratio's (TER's)

Appli-cation rate	**Mammal type**	**FIR/bw *)**	**Category**	**RUD (mean)**	**PT PD MAF**	**f_{twa}**	**ETE (mg a.s./kg bw/day)**	**TER**	**Annex VI trigger value**
2 x 0.09 kg a.s./ha in cereals	Small herbivorous mammal **(Vole)**	1.39	cereal green plant	20.75	1	0.53	1.38	2.9	5

*) Crocker D.R., Hart A., Gurney J. and McCoy C. (2002): Methods for estimating daily food intake of wild birds and mammals. Central Science Laboratory, Project PN0908.
Final Report. http://www.pesticides.gov.uk/general/ResearchReports/index.htm.

Conclusion by the rapporteur :
The risk for large herbivorous and insectivorous mammals is considered acceptable.
- first tier assessment indicates that the acute risk to mammals is acceptable.
- First tier assessment indicates that the long term risk to insectivorous mammals is acceptable
- Refined risk assessment (considering actual residue level in cereal leaves) indicates that the long term TER is 2.9 (lower than 5). No refinement for PD and PT factors has been done. It can be considered that the risk is acceptable.

We consider it necessary that lists of PD-values are established at a EU-level per crop and possible food source for the different mammal species. These lists should be available as an annex to the present guidance document on birds and mammals so that every risk evaluation will be established on the same basis.

Metconazole has a potential for bioaccumulation. The TER long term have therefore been calculated for mammals consuming fish and earthworms. Calculations are based on the new Guidance Document for birds and mammals Under Council Directive 91/414/EEC of November 2002 (p 20). PEC water and PEC soil are taken from sections B.8.3 and B.8.6.1

- a.s. concentration in fish = (PEC_{water} x BCF) x 0.13 = (0.0012 mg a.s./L x 129.7) x 0.13 = 0.020 mg a.s./kg bw/day
- a.s. concentration in earthworm = (PEC soil x BCF) x 1.4 = (0.15 mg a.s./kg soil x 3.58) x 1.4 = 0.75 mg a.s./kg bw/day (BCF = (0.84 + 0.01 K_{ow})/(f_{oc} x K_{oc}) = (0.84 + 0.01 x 7079)/(0.02 x 1000.6) = 3.58)
- diet containing 100% contaminated item (fish or earthworm)

Tab. B.9.3-3 : Toxicity Exposure Ratio's (TER's) for mammals consuming fish and earthworms

Application rate (kg as/ha)	Crop	Category	Time-scale	TER	Annex VI Trigger
2 x 0.09	Cereals	Mammals eating earthworms	Long term	4 /0.75= 5.3	5

		Mammals eating fish	Long term	4/0.02 = 200	5

B.9.4 Effects on bees (Annex IIA 8.3.1; Annex IIIA 10.3.2)

B.9.4.1 Acute toxicity to bees (Annex IIA 8.3.1.1)

WL148271; KNF-S-474m : Acute topical and oral toxicity to the honey bee, Apis mellifera L., (Harrison E.G. & Hillaby J.M., 1991).
Guidelines :
/
GLP :
Yes
Material and Methods :
Test substance : Metconazole; 83.7:16.3 *cis:trans*; purity : 95.3%; Batchn° : 89-01
Test species : Honeybees (*Apis mellifera L.*); worker bees
Number of organisms : 20 bees x 5 replicates/concentration in the contact toxicity test
20 bees x 3 replicates/concentration in the oral toxicity test
Type of test : acute oral and contact toxicity test (96 h)
Applied concentrations : oral test : 0, 3, 6, 12, 25, 50 and 100 µg a.s./bee (nominal); solvent and positive control (ethyl parathion); contact test : 100 µg a.s./bee and solvent control
Exposure route : Contact test : A 1 µL aliquot of test solution was applied to the dorsal thorax of each bee.
Oral test : 0.4 ml of test solution was administered to each test cage (20 bees). The length of time taken for the bees to consume their dose was noted.
Test conditions :
Temperature of 25.7-25.8°C, with a relative humidity of 52-53%.
Findings :
Mortality : No mortality was observed in the contact toxicity test. Mortality was observed in all the concentrations of the oral toxicity test. Mortality increased with increasing test concentration.
Time to consume the dose : Time from start of the test until the test dose was consumed was rather similar in the control and treatment groups. Except for the highest concentration tested which needed more than twice as much time to consume their dose.
Remark : The test substance was not replaced after 6 hours with an uncontaminated sucrose solution during the oral toxicity study.
Conclusion :
The study is acceptable.
LD_{50} (96h) contact > 100 µg a.s./bee (nominal) (highest concentration tested)
NOEL(96h) contact = 100 µg a.s./bee (nominal)
LD_{50} (72h) oral = 85 µg a.s./bee (nominal)
NOEL (72h) oral = 6 µg a.s./bee (nominal)

B.9.4.2 Bee brood feeding test (Annex IIA 8.3.1.2)

Not required.

B.9.4.3 Acute toxicity of the preparations to bees (Annex IIIA 10.4.1)

An acute contact and oral toxicity study with AC 900768 in a 60 g ai/L soluble concentrate (60 SL) formulation (SF 09381) on the honey bee (*Apis mellifera*) based on EPPO Guideline # 170, (Engelhard E.K. *et al*., 1998).
Guidelines :
EPPO Guideline # 170
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 59.2 g/L, BatchN° : 005
Test species : Honeybees (*Apis mellifera L.*); worker bees
Number of organisms : 10 bees X 3 replicates/concentration
Type of test : acute oral and contact toxicity test (72 h)
Applied concentrations : contact test : 200 µg formulation/bee (nominal) and a control which consisted of a 0.1% Etalfix-deionized water solution; oral test : 0, 12.5, 25, 50, 100 and 200 µg formulation/bee (nominal) or 0, 12.5, 24.2, 46.7, 100 and 187 µg formulation/bee (actual ingested doses); Positive control for both tests : Dimethoate; Concentrations were analytically verified for both tests. Measured concentrations were always above 94% of the nominal.
Exposure route : Honeybees were exposed to the test solution, administered topically in a 1 µL droplet to the thorax of each bee in the contact toxicity test. Oral administration to 10 bees of 0.1 ml sucrose solution containing the test product.
Test conditions :
Temperature of 24.5-26.5°C, with a relative humidity of 50-67%.
Findings :
Mortality : No mortality was observed during the contact toxicity test. Average mortalities of 3.3%, 16.7%, 30.0%, 33.3% and 13.3% were observed for the 12.5, 24.2, 46.7, 100 and 187 µg formulation/bee treatments respectively.
Sublethal effects : In both tests at the highest concentrations tested, 6.6-13.3% of the bees were affected.
Conclusion :
Study is acceptable.
LD_{50} (72h) contact > 200 µg formulation/bee (nominal) (highest concentration tested)
NOEL(72h) contact = 200 µg formulation/bee (nominal) based on mortality
LD_{50} (72h) oral > 187 µg formulation/bee (actual ingested dose)
NOEL (72h) oral = 12.5 µg formulation/bee (actual ingested dose) based on mortality

Laboratory Testing for Toxicity (Acute Contact and Oral LD50) of Metconazole (CL 900,768) 60 g a.i./L SL (SF 09381) to Honey Bees (Apis mellifera L.) (Hymenoptera, Apidae), (Schmitzer, 1999b).
Guidelines :
OEPP/EPPO Bulletin 22, 203-215 1992, No. 170
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 59.2 g/L, BatchN° : 005
Test species : Honeybees (*Apis mellifera L.*); worker bees
Number of organisms : 10 bees x 3 replicates/concentration
Type of test : acute oral and contact toxicity test (48 h)
Applied concentrations : contact test : 6.25, 12.5, 25, 50 and 100 µg formulation/bee (nominal), control and solvent control; oral test : 9.9, 19.4, 38.2, 72.8 and 139.7 µg formulation/bee (actual ingested dose), solvent

control; Positive control for both tests : Dimethoate; Concentrations were analytically verified for both tests. Measured concentrations were always above 93% of the nominal.
Exposure route : Honeybees were exposed to the test solution, administered topically in a 5 µL droplet to the thorax of each bee in the contact toxicity test. Oral administration to 10 bees of 0.1 ml sucrose solution containing the test product.
Test conditions :
Temperature of 28±2°C, with a relative humidity of 40-88%.
Findings :
Mortality :
Contact test : Less than 10 mortality was observed at the 2 lowest dose rates. No mortality was observed in the 25 and 50 µg/bee dose rates. 16.7% mortality was observed at the highest concentration tested.
Oral test : No mortality was observed except for one bee at the highest concentration rate.
Remarks : During the contact toxicity tests 5µL drops were applied instead of 1µL drops. Temperature and relative humidity were rather high.
Conclusion :
Study is acceptable.
LD_{50} (48h) contact > 100 µg formulation /bee (nominal) (highest concentration tested)
NOEL(48h) contact = 50 µg formulation /bee (nominal)
LD_{50} (48h) oral > 139.7 µg formulation /bee (actual ingested dose)
NOEL (48h) oral = 139.7 µg formulation /bee (actual ingested dose)

B.9.4.4 effects on bees of residues on crops (Annex IIIA 10.4.2)

Not required.

B.9.4.5 Cage tests (Annex IIIA 10.4.3)

Not required.

B.9.4.6 Field tests to investigate special effects (Annex IIIA 10.4.4)

Not required.

B.9.4.7 Tunnel testing to investigate effects of feeding on contaminated honey (Annex IIIA 10.4.5)

Not required.

B.9.4.8 Exposure and risk assessment for bees (Annex IIIA 10.4)

Table B.9.4.8-1 : Toxicity and risk assessment for bees

Test species	Test system	Results	References
Honeybee *(Apis mellifera L)*	Acute contact and oral toxicity test	LD_{50} (96h) contact > 100 µg a.s./bee NOEL(96h) contact = 100 µg a.s./bee LD_{50} (72h) oral = 85 µg a.s./bee NOEL (72h) oral = 6 µg a.s./bee	Harrison E.G. & Hillaby J.M., 1991
Honeybee *(Apis mellifera L)*	Acute contact and oral toxicity test with a Metconazole 60 g a.s./L SL formulation	LD_{50} (72h) contact > 200 µg formulation/bee NOEL(72h) contact = 200 µg formulation/bee LD_{50} (72h) oral > 187 µg formulation/bee NOEL (72h) oral = 12.5 µg formulation/bee	Engelhard E.K. *et al.*, 1995
Honeybee *(Apis mellifera L)*	Acute contact and oral toxicity test with a Metconazole 60 g a.s./L SL formulation	LD_{50} (48h) contact > 100 µg formulation /bee NOEL(48h) contact = 50 µg formulation /bee LD_{50} (48h) oral > 139.7 µg formulation /bee NOEL (48h) oral = 139.7 µg formulation /bee	Schmitzer, 1999

An application rate of 90 g a.s./ha, with 1-2 applications is intended for all the proposed good agricultural practices. Therefore the risk is calculated for an application rate of 180 g a.s./ha as a worst-case scenario.

The hazard quotients calculated for all use types indicate that the risk of metconazole to honey bees is negligible.

Table B.9.4.8-2 : Hazard quotients for bees

Application rate	Crop	Route	Hazard quotient	Annex VI trigger
2 x 90 g a.s./ha	Winter/spring wheat, winter/spring barley, winter/spring oats, rye, triticale and oilseed rape	Contact	180/100 = 1.8	50
		Oral	180/85 = 2.1	50

B.9.5 Effects on other arthropods species (Annex IIA 8.3.2; Annex IIIA 10.5)

B.9.5.1 Effects of the active substance on non-target terrestrial arthropods (Annex IIA 8.3.2)

Laboratory Contact Toxicity Test with AC900,768 in a 60 g a.i./L Soluble Liquid Formulation on the Ground Beetle, *Poecilus cupreus* (Coleoptera: Carabidae), (Candolfi M.P., 1996).
Guidelines :
IOBC Guidelines of the Working Group "Pesticides and Beneficial Organisms" (Heimbach, 1992)
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 59.2 g/L, BatchN° : 005
Test species : Poecilus cupreus
Number of organisms, age : (3♀+3♂) x 5 replicates/concentration, 7-8 weeks at test initiation
Type of test : laboratory contact toxicity test
Applied and measured concentrations : control, 90 and 180 g a.s./ha, toxic standard : 1 L/ha Afugan 30 EC; Analysis of sand samples resulted in a mean recovery of 72.5-77.2%.
Exposure route : 14 days exposure in containers filled with pure quartz sand.
Test conditions : temperature : 20±3°C; relative humidity : 70 ± 20 %; light regime : 16 h light of 500-1500 Lux; Beetles were fed with *Musca domestica* pupae.
Findings :

Evaluation criteria	Control	Treatment		Toxic standard
		90 g a.s./ha	180 g a.s./ha	
Percentage mortality (14 d)	6.7	0	0	100
Mean feeding rate (average number of fly pupae consumed per beetle)	0.21	0.22	0.22	-

Observations : No abnormal behaviour was observed in the groups treated with the test substance.
Conclusion :
Study is acceptable.
Reduction of beneficial capacity = -4.8%

An extended laboratory test to determine the effects of fresh residues of Metconazole (AC 900768) in a 60 g/L soluble concentrate (60 SL) formulation (SF09381), on spiders of the genus *Pardosa* (Aranea, Lycosidae), (Mead-Briggs M & Strnad S., 1998b).
Guidelines :
Draft BBA Guideline VI, 23-2.1.9
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 60.4 g/L, BatchN° : F004498
Test species : Pardosa
Number of organisms : 15♀+15♂ spiders/concentration
Type of test : extended laboratory toxicity test
Applied and measured concentrations : control, 90 g a.s./ha and 2 x 90 g a.s./ha with a 7d interval; toxic standard : 2.5 g deltamethrine/ha
Exposure route : 14 days exposure in containers filled with standard loam soil (0.05% OC). The spiders were introduced to the test pots which were then treated with the test substance for the first time in case of the 90 g a.s./ha treatment group and for the second time in case of the 2 x 90 g a.s./ha treatment group.
Test conditions : temperature : 19-21°C; relative humidity : 46-64 %; light regime : 16 h light of ca. 775 Lux; Spiders were fed with live aphids.

Findings :

Evaluation criteria	Control	Treatment		Toxic standard
		90 g a.s./ha	2 x 90g a.s./ha	
Percentage mortality (14 d)	7	23	14	100
Mean feeding rate (average number of aphids consumed per beetle)	12.7	11.4	13.8	-

Observations : No abnormal behaviour was observed in the groups treated with the test substance.
Conclusion :
Study is acceptable.
Reduction of beneficial capacity = 25.7% for the 90 g a.s./ha treatment group
Reduction of beneficial capacity = -0.5% for the 2 x 90 g a.s./ha treatment group

Laboratory Contact Toxicity test with AC900,768 in a 60 g ai/L Soluble Liquid Formulation on the Sevenspotted Lady Beetle, *Coccinella septempunctata* L. (Coleoptera, Coccinellidae), (Candolfi M.P. & van er Kolk J., 1996b).
Guidelines :
BBA Guideline VI, 23-2.1.5
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 59.2 g/L, BatchN° : 005
Test species : Coccinella septempunctata L.
Number of organisms : 10 x 5 replicates/concentration. During the reproduction phase groups of ≤ 25 beetles with the sex ratio approximately 1:1 were formed.
Type of test : laboratory contact toxicity test
Applied and measured concentrations : control, 90 and 180 g a.s./ha, toxic standard : 1 L/ha Afugan 30 EC
Exposure route : larvae were exposed during17d confined in an individual cage on a glass plate. During the reproduction phase groups of ≤ 25 beetles with the sex ratio approximately 1:1 were formed and observed during 5 weeks.
Test conditions : temperature : 22-24.5°C; relative humidity : 61-76 %; light regime : 16 h light of >1000 Lux; Beetles were fed with aphids.
Findings :

Evaluation criteria	Control	Treatment		Toxic standard
		90 g a.s./ha	180 g a.s./ha	
Percentage mortality (17d)	20	16	40	100
Average N° of eggs per female per day	8.9	8.0	6.8	-
Mean percent hatching	83.2	57.7	45.7	-
Total N° of viable eggs per female	152	95	68	-

Conclusion :
Study is acceptable.
Reduction of beneficial capacity = 34.4% for the 90 g a.s./ha treatment group
Reduction of beneficial capacity = 66.45% for the 180 g a.s./ha treatment group

An extended laboratory test to determine the effects of fresh residues of Metconazole (AC 900768) in a 60 g/L soluble concentrate (60 SL) formulation (SF09381), on *Coccinella septempunctata* (Coleoptera, Coccinellidae), (Mead-Briggs M & Strnad S., 1998a).
Guidelines :
/
GLP :
Yes

Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 60.4 g/L, BatchN° : F004498
Test species : Coccinella septempunctata
Number of organisms : 50 x 1 replicates/concentration; 37 x 1 replicates in the toxic standard
Type of test : extended laboratory toxicity test
Applied and measured concentrations : control, 90 g a.s./ha and 2 x 90 g a.s./ha with a 10d interval; toxic standard : 340 g dimethoate/ha
Exposure route : The beetle larvae were exposed to fresh residues on spring wheat plants for 18-28 days. There were 5 plants and one beetle larvae per arena. Once the pupae had developed in the arenas, they were transferred to large ventilated plastic boxes. Approximately 3 weeks after most adults had emerged, fecundity assessments were carried out. Therefore one female and one male beetle were placed in a petri dish. The fecundity assessments continued for 4 weeks.
Test conditions : temperature : 17-26°C; relative humidity : 34-92%; light regime : 16 h light of >1000 Lux; Beetles were fed with aphids.
Findings :

Evaluation criteria	**Control**	**Treatment**		**Toxic standard**
		90 g a.s./ha	**2 x 90 g a.s./ha**	
Percentage mortality (larvae to adults)	29	33	44	100
Number of eggs/female/day	3.9	4.7	3.7	-
Egg viability (%)	82	73	85	-

Conclusion :
Study is acceptable.
Reduction of beneficial capacity = -0.3% for the 90 g a.s./ha treatment group
Reduction of beneficial capacity = 22.3% for the 2 x 90 g a.s./ha treatment group

An extended laboratory test to determine the effects of fresh residues of Metconazole (AC 900768), in a 60 g/L soluble concentrate (60 SL) formulation (SF09381), on the plant-active predator *Orius laevigatus* (Heteroptera; Anthocoridae), (Vinall S. & Strnad S., 1998).
Guidelines :
/
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 60.4 g/L, BatchN° : F004498
Test species : Orius laevigatus
Number of organisms : 20 nymphs x 5 replicates/concentration;
Type of test : extended laboratory toxicity test
Applied and measured concentrations : control, 90 g a.s./ha and 2 x 90 g a.s./ha with a 7d interval; toxic standard : 340 g dimethoate/ha
Exposure route : The *Orius* nymphs were exposed to fresh residues on sweet pepper seedlings for 17 days. After the exposure the bugs were transferred to fecundity pots. Where sufficient number of insects were available, 3 replicate arenas containing 5 male and 5 female bugs were set up for each treatment. After 72h the bugs were removed and the number of eggs laid assessed. Egg hatching was observed until 8 days after being laid.
Test conditions : temperature : 19-22°C; relative humidity : 56-87%; light regime : 16 h light of ca. 6666 Lux; Bugs were fed with *Ephestia* eggs and broad bean pollen.
Findings :

Evaluation criteria	**Control**	**Treatment**		**Toxic standard**
		90 g a.s./ha	**2 x 90 g a.s./ha**	
Percentage mortality (10 DAT)	42	46	44	100
Mean number of viable eggs per female	7.3	0.7	6.3	-

Conclusion :
Study is not acceptable due to high control mortality.
Reduction of beneficial capacity = 91% for the 90 g a.s./ha treatment group
Reduction of beneficial capacity = 16.7% for the 2 x 90 g a.s./ha treatment group

Laboratory contact toxicity test with AC 900,768 in a 60 g ai/L soluble liquid formulation on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera: Braconidae), (Candolfi M.P. & van der Kolk J., 1996a).
Guidelines :
Guidelines for testing the effect of pesticides on *Aphidius rhopalosiphi*, Polgar (1988)
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 59.2 g/L, BatchN° : 005
Test species : Aphidius rhopalosiphi
Number of organisms : 10 x 4 replicates/concentration
Type of test : acute laboratory toxicity test
Applied and measured concentrations : control, 90 and 180 g a.s./ha, toxic standard : 0.17 ml Perfektion/ha
Exposure route : 1 day exposure followed by 10 days observation
Test conditions : temperature : 20±2°C; relative humidity : 70±20%; light regime : 16 h light of > 1000 Lux;
Findings :

Evaluation criteria	**Control**	**Treatment**		**Toxic standard**
		90 g a.s./ha	**180 g a.s./ha**	
Percentage mortality (24h)	0	25	85	92.5
N° of mummies per surviving female	4.4	7.4	2.3	-

Observations : Only 17.5% of the wasps appeared healthy in the 90 g/ha treatment group after 24h. None appeared healthy in the 180 g/ha group after 24h while at that moment all the wasps appeared healthy in the control group.
Conclusion :
Study is not acceptable as the exposure period was only 24h and as the wasps in the control group produced less than 5 mummies. It is considered that lower fecundity levels do not allow a meaningful comparison of treatments.
Reduction of beneficial capacity = -26% for the 90 g a.s./ha treatment group
Reduction of beneficial capacity = 92.2% for the 180 g a.s./ha treatment group

An extended laboratory test to determine the effects of fresh residues of metconazole (AC 900768) in a 60 g/L soluble concentrate (60 SL) formulation (SF09381), on *Aphidius rhopalosiphi* (Hymenoptera: Braconidae), (Mead-Briggs M. & Strnad S., 1998c).
Guidelines :
/
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 60.4 g/L, BatchN° : F004498
Test species : Aphidius rhopalosiphi
Number of organisms : 50 wasps/concentration
Type of test : extended laboratory toxicity test
Applied and measured concentrations : control, 90 g a.s./ha and 2 x 90 g a.s./ha with a 7d interval; toxic standard : 340 g dimethoate/ha
Exposure route : Survival and behaviour of adult *Aphidius* was assessed during a period of 48 hours to the test material on spring wheat plants. After 24 h female wasps surviving in the arenas were transferred to pots of barley seedlings. The surviving wasps were allowed to parasitize aphids over 24h. After 10 days their fecundity was assessed.
Test conditions : temperature : 19-22°C; relative humidity : 60-68%; light regime : 16 h light of 1033 Lux

Findings :

Evaluation criteria	Control	Treatment		Toxic standard
		90 g a.s./ha	2 x 90 g a.s./ha	
Percentage mortality (24h)	0	0	0	78
N° of mummies per surviving female	9.3	10.2	13.5	-

Observations : Although no dead wasps were recorded, 3 wasps were missing in the control group, 2 in the 90 g as/ha group, 8 in the 2 x 90 g as/ha group and 11 in the toxic standard group.
Conclusion :
Study is acceptable. Wasps were exposed to the test substance only for 24 hours.
Reduction of beneficial capacity = -9.7% for the 90 g a.s./ha treatment group
Reduction of beneficial capacity = -45.2% for the 2 x 90 g a.s./ha treatment group

Laboratory Contact Toxicity Test with AC900,768 in a 60 g ai/L Soluble Liquid Formulation on the Predacious Mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae), (Candolfi M.P. & van der Kolk J., 1996c).
Guidelines :
Overmeer (1988)
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 59.2 g/L, BatchN° : 005
Test species : Typhlodromus pyri
Number of organisms : 20 x 5 replicates/concentration
Type of test : laboratory contact toxicity test
Applied and measured concentrations : control, 90 and 180 g a.s./ha, toxic standard : 36.14 g parathion/ha
Exposure route : 10 days exposure on glass plates.
Test conditions : temperature : 23.5-26°C; relative humidity : 70-80%; light regime : 16 h light of 1000-1500 Lux
Findings :

Evaluation criteria	Control	Treatment		Toxic standard
		90 g a.s./ha	180 g a.s./ha	
Percentage mortality (10 d)	7.5	100	100	52
Number of eggs per female per day (days 7-10)	0.85	-	-	1.02

Observations : Mortality reached 100% in the treatment groups after 7 days of exposure.
Conclusion :
Study is acceptable.
Reduction of beneficial capacity = 100%

A Laboratory Contact Toxicity Test with Drift Rates of AC 900768 in a 60 g ai/L Soluble Concentrate Formulation (SF09381) on the Predaceous Mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae), (Engelhard E.K. *et al.*, 1998b).
Guidelines :
Overmeer and Van Zon (1982)
Overmeer (1988)
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 59.2 g/L, BatchN° : 005
Test species : Typhlodromus pyri
Number of organisms : 20 x 5 replicates/concentration
Type of test : laboratory contact toxicity test

Applied and measured concentrations : control, 0.54 and 1.1 g a.s./ha, toxic standard : Ethyl Parathion 500 g/L EC applied at 0.36 ml formulation/L
Exposure route : 14 days exposure on glass plates.
Test conditions : temperature : 24-25.5°C; relative humidity : 75-81%; light regime : 16 h light
Findings :

Evaluation criteria	**Control**	**Treatment**		**Toxic standard**
		0.54 g a.s./ha	**1.1 g a.s./ha**	
Percentage mortality (14 d)	6	7	9	61
Average number of eggs per female per day	1.06	1.12	1.02	0.83

Conclusion :
Study is acceptable.
Reduction of beneficial capacity = -4.5% for the 0.54 g a.s./ha treatment group
Reduction of beneficial capacity = 6.85% for the 1.1 g a.s./ha treatment group

An aged-residue extended laboratory test to determine the effects of metconazole (AC 900768), in a 60 g/L SL formulation (BAS 555 00 F), on the predatory mite, *Typhlodromus pyri* (Acari: Phytoseiidae), (Taruza S. & Strnad S., 2002).
Guidelines :
/
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 59.2 g/L, BatchN° : 005
Test species : Typhlodromus pyri
Number of organisms : 20 x 5 replicates/concentration
Type of test : extended laboratory toxicity test
Applied and measured concentrations : control, 90 g a.s./ha and 2 x 90 g a.s./ha with a 7d interval; toxic standard : 40 g dimethoate/ha
Exposure route : 7 days exposure on bean leaves in petri dishes. The bioassay was initiated one day after treatment of the bean plants.
Test conditions : temperature : 22-27°C; relative humidity : 64-83%; light regime : 16 h light of 400 Lux
Findings :

Evaluation criteria	**Control**	**Treatment**		**Toxic standard**
		90 g a.s./ha	**2 x 90 g a.s./ha**	
Percentage mortality (7 d)	9	20	11	54
Mean number of eggs per female	8.5	9.7	8.4	not assessed

Conclusion :
Study is acceptable.
Reduction of beneficial capacity = -0.4% for the 90 g a.s./ha treatment group
Reduction of beneficial capacity = 3.4% for the 2 x 90 g a.s./ha treatment group

B.9.5.2 Effects of the formulations on non-target terrestrial arthropods (laboratory, semi-field tests) Annex IIIA 10.5.1)

See point B.9.5.1.

B.9.5.3 Effects of the formulations on non-target terrestrial arthropods (field tests) Annex IIIA 10.5.2)

Not required.

B.9.5.4 Summary of effects, exposure and risk assessment for non-target terrestrial arthropods

Table B.9.5.4-1 : Summary of effects of Metconazole 60 g/L SL to non-target terrestrial arthropods

Test species	Test system	Dose rate	Results	Risk Assessment	References
Poecilus cupreus	Lab test	180 g a.s./ha	E = -4.8%	Harmless	Candolfi M.P., 1996
Pardosa	Extended lab test	2 x 90 g a.s./ha	E = -0.5%	Harmless	Mead-Briggs M & Strnad S., 1998b
Coccinella septempunctata	Lab test	180 g a.s./ha	E = 66.45%	Slightly harmful	Candolfi M.P. & van er Kolk J., 1996b
Coccinella septempunctata	Extended lab test	2 x 90 g a.s./ha	E = 22.3%	Harmless	Mead-Briggs M & Strnad S., 1998a
Aphidius rhopalosiphi	Extended lab test	2 x 90 g a.s./ha	E = -45.2%	Harmless	Mead-Briggs M. & Strnad S., 1998c
Typhlodromus pyri	Lab test	180 g a.s./ha	E = 100%	Harmful	Candolfi M.P. & van der Kolk J., 1996c
Typhlodromus pyri	Lab test	1.1 g a.s./ha	E = 6.85%	Harmless	Engelhard E.K. *et al.*, 1998b
Typhlodromus pyri	Extended lab test	2 x 90 g a.s./ha	E = 3.4%	Harmless	Taruza S. & Strnad S., 2002

The risk from metconazole for non-target arthropods is considered acceptable. No further studies are considered necessary.

B.9.6 Effects on earthworms (Annex IIA 8.4; Annex IIIA 10.3.6)

B.9.6.1 Acute toxicity to earthworms (Annex IIA 8.4.1)

WL136184 (KNF-S-474c): Toxicity to the earthworm, *Eisenia foetida*, in a 14-day artificial soil test, (Hillaby J.M. & Harrison E.G., 1991).
Guidelines :
OECD Guideline 207
EEC Guideline C8
GLP :
Yes
Material and Methods :
Test substance : Metconazole, 95.2 % *cis*, 0.1% *trans*, Batch N° 12; F900250
Test species : Earthworms (*Eisenia foetida*);
Number of organisms, weight : 10 worms x 5 replicates/concentration, 300-600 mg;
Type of test : acute toxicity test (14 days)
Applied concentrations : 1000 mg a.s./kg (nominal); water control, positive control : chloroacetamide
Soil type and test conditions :
test substrate : 10% sphagnum peat, 20% kaolin clay, 70% sand, 0.5% $CaCO_3$
water content : 30-31% dry weight
temperature : 19.9°C
light regime : continuous light of 740-850 Lux
Findings :
Mortality : 2% mortality in the tested dose rate
Observations : no significant difference between the percentage weight loss of the control and the treatment.
Conclusion :
Study is acceptable.
LC_{50} (14d) > 1000 mg a.s./kg substrate
NOEC (14d) = 1000 mg a.s./kg substrate

B.9.6.2 Sublethal effects on earthworms (Annex IIA 8.4.2)

A Chronic Toxicity and reproduction Test Exposing the Earthworm *Eisenia fetida* to AC 900768 Technical material in OECD Artificial Soil, Following the ISO-draft (ISO/DIS 11268-2), (Engelhard E. *et al*., 1998a).
Guidelines :
ISO/DIS 11268-2
GLP :
Yes
Material and Methods :
Test substance : Metconazole 85/15 cis/trans, Purity : 98.3%, Lot Number : AC10575-61
Test species : Earthworms (*Eisenia foetida*);
Number of organisms, weight, age : 10 worms x 4 replicates/concentration, 568-590 mg, 11-12 months;
Type of test : chronic toxicity test (56 days)
Applied concentrations : 90, 180, 450, 900 and 1350 mg a.s./ha (nominal); water control, solvent control, positive control : benomyl; Concentrations were analyzed and were above 90% of the nominal.
Soil type and test conditions :
Test substrate : 10% sphagnum peat, 20% kaolin clay, 70% sand
water content : 63.7-80.4%
Temperature : 19.0-24.0°C
Light regime : 16 hours light
Findings :
Mortality : No treatment related mortalities were observed.
Observations : No significant differences between the control and the treatment groups were observed concerning biomass increase and reproduction.

Conclusion :
Study is acceptable.
LC_{50} (56d) > 1350 mg a.s./ha or 1.8 mg a.s./kg soil
NOEC (56d) = 1350 mg a.s./ha or 1.8 mg a.s./kg soil

B.9.6.3 Acute toxicity of the formulations to earthworms (Annex IIIA 10.6.1.1)

AC 900768 in a 60 g ai/L Soluble Liquid Formulation (SF09381): 14-Day Acute toxicity Test with the Earthworm (*Eisenia fetida*) Based on OECD Guideline # 207, (Candolfi M. & Ott U., 1996).
Guidelines :
OECD Guideline # 207
GLP :
Yes
Material and Methods :
Test substance : Metconazole 60 g a.s./L SL, Purity : 59.2 g/L, BatchN° : SF 09381
Test species : Earthworms (*Eisenia foetida*);
Number of organisms, weight, age : 10 worms x 4 replicates/concentration, 378-394 mg, at least 2 months;
Type of test : acute toxicity study (14 days)
Applied concentrations : 62.5, 125, 250, 500 and 1000 mg formulation/kg (nominal); water control, positive control : 2-chloracetamide. Concentrations were analyzed and were above 100% of the nominal.
Soil type and test conditions :
Test substrate : 10% sphagnum peat, 20% kaolin clay, 70% sand
water content : 36.8-38.8% dry weight
temperature : 19-20.5°C
light regime : continuous light
Findings :
Mortality : No treatment related mortalities were observed.
Observations : Burrowing time in the 1000 ppm group was longer than the control. No significant difference between the weight gain of the control and the treatment
Conclusion :
Study is acceptable.
LC_{50} (14d) > 1000 mg formulation/kg substrate or 59.2 mg a.s./kg substrate
NOEC (14d) = 500 mg formulation/kg substrate

B.9.6.4 Sublethal effects of the formulation on earthworms (Annex IIIA 10.6.1.2)

Not required.

B.9.6.5 Field tests - residue content of earthworms (Annex IIIA 10.6.1.3)

Not required.

B.9.6.6 Summary and risk assessment for earthworms (Annex III, 10.6.1.1)

Table B.9.6.6-1 : Summary of effects on earthworms

Test product *(cis/trans)*	Test system	Duration of exposure	Results (mg test product/kg soil)	References
Metconazole (95.2/0.1)	Acute toxicity	14 days	LC_{50} > 1000 NOEC = 1000	Hillaby J.M. & Harrison E.G., 1991
Metconazole (85/15)	Long term toxicity	56 days	LC_{50} > 1.8 NOEC = 1.8	Engelhard E. *et al*., 1998a
Metconazole 60 g a.s./L SL	Acute toxicity	14 days	LC_{50} > 1000 NOEC = 500	Candolfi M. & Ott U., 1996

The risk is calculated for the following scenario : an annual application of 180 g a.s./ha in monoculture (practical worst case), mean crop interception of 60%, worst-case scenario with a plateau maximum PEC of 0.15 mg a.s./kg soil.

Results were divided by 2 as the $LogP_{OW}$ exceeds 2.

Table B.9.6.6-2 : Risk assessment for the earthworms

Test species	Effect concentration (mg a.s. kg soil)	Estimated initial concentration (mg a.s. /kg soil)	TER	Annex VI trigger
Earthworm *(Eisenia foetida)*	LC_{50} > 1000 mg a.s./kg soil	0.15	>1000/(2 x 0.15) = 3333	10
	NOEC = 1.8 mg a.s./kg soil	0.15	=1.8/(2 x 0.15) = 6	5
	LC_{50} > 59.2 mg a.s./kg soil	0.15	>59.2/(2 x 0.15) = 197	10

The acute and long term risk for earthworms resulting from the application of metconazole or the tested 60 SL metconazole formulation, is considered acceptable. No further studies are required at the moment.

B.9.7 Effects on other soil non-target macro-organisms (Annex IIIA 10.6.2)

A field evaluation of the effects of metconazole (AC 900768) in a 60 g/L suspended liquid (SL) formulation (SF 09381) on the degradation of buried leaf material, (Walker H.M. *et al.*, 2001a).

Guidelines :

/

GLP :

Yes

Material and Methods :

Test substance : metconazole 60 g/L suspended liquid, purity : 58.2 g/L, Batch N°: 162940

Type of test : litter bag test

Applied concentrations : control, 90 g a.s./ha; toxic standard: methylbromide (113 g/m²)

Test methodology :

Number of litter bags, amount and type of litter per bag, burial depth : 4 replicates x 6 sets of bags/sampling time (3 sets of 3 bags a mesh size of 0.025, 0.5 and 3.36 mm and 3 sets of 2 bags with a mesh size of 0.025 and 0.5 mm), 0.2 g of dried *Castanea sativa* leaves, 5-10 cm;

Trial site : plots of 5 m x 2.5 m with a discard of 2.5m between adjacent plots and 3 m between rows. The soil was characterized as a clay loam. The site received one application with glyphosate and was hand cleared of all vegetation shortly before the start of the study.

Introduction time : 6 June 2000

Application time : 7 June 2000 and 13 June 2000

Sampling times: 5 September 2000 and 7 December 2000

Findings :

	Mesh size	Control	2 x 90 g a.s./ha	Toxic reference
3 months after application leaves degraded (% of input)	0.025 mm	42.4	42.2	42.6
	0.5 mm	37.9	41.9	41.2
	3.36 mm	56.2	55.6	43.4
6 months after application leaves degraded (% of input)	0.025 mm	49.8	51.8	48.3
	0.5 mm	54.1	51.3	52.4

Conclusion :

Study is acceptable. No significant difference was observed between the treatment plots and the control plots.

B.9.8 Effects on soil non-target micro-organisms (Annex IIA 8.5; Annex IIIA 10.7)

The Effects of AC 900,768 in a 60 g a.i./L Soluble Liquid Formulation on the Respiration and Nitrification of Soil Microflora, (van der Kolk J., 1996).

Guidelines :

Guidelines for the Official Examination of Plant Protection Products, Part VI, 1-1 (2. Edition), Effects on the Activity of Soil Microflora (BBA, 1990).

GLP :

Yes

Material and methods :

Test Substance: metconazole 60 g/L suspended liquid, purity : 59.2g/L, Batch N°: 005

Soils : a loamy sand and a sandy loam soil

Applied concentrations : 0.12 and 1.2 mg a.s./kg soil, equivalent to 90 and 900 g a.s./ha, related to a soil depth of 5 cm and a soil density of 1.5 kg/dm³ and no crop interception. 3 replicates/concentration/soil for soil respiration and nitrification.

Type of test : respiration and nitrogen turnover tests

Test conditions :

Soil moisture : 50-55% of its water holding capacity

Soil samples were incubated at 20°C ± 2°C in plastic bottles

Sampling scheme : 0, 14 and 28 days after treatment samples for soil respiration and nitrification were taken

Findings :

Table 9.8-1 Influence of metconazole on soil respiration

Incubation (days)	O_2 - Consumption Rates (mg O_2/100 g dry soil) and % of Control				
	0 (mg a.s./kg dry soil)	0.12 (mg a.s./kg dry soil)		1.2 (mg a.s./kg dry soil)	
	(mg O_2/12 h/100 g)	(mg O_2/12 h/100 g)	(%)	(mg O_2/12 h/100 g)	(%)
Loamy sand (0.9%OC, pH 7, 133 mg microbial carbon/100g soil)					
0	17.12	18.67	9	19.27	12.6
14	11.95	13.95	16.7	15.40	28.9
28	14.06	14.72	4.7	13.63	-3.2
Sandy loam (1.7%OC, pH 7.2, 74.8 mg microbial carbon/100g soil)					
0	16.14	16.89	4.6	17.55	8.7
14	17.29	17.32	0.2	18.61	7.6
28	18.73	18.25	-2.6	17.88	-4.5

Table 9.8-2 Influence of metconazole on soil nitrification

Incubation (days)	Mean Total-N (mg N/kg dry soil) and % of Control				
	0 (mg a.s./kg dry soil)	0.12 (mg a.s./kg dry soil)		1.2 (mg a.s./kg dry soil)	
	(mg/100g)	(mg/100g)	(%)	(mg/100g)	(%)
Loamy sand (0.9%OC, pH 7, 133 mg microbial carbon/100g soil)					
0	3.66	3.68	0.5	3.61	-1.4
14	5.45	5.32	-2.4	5.18	-5
28	5.39	5.11	-5.2	5.2	-3.5
Sandy loam (1.7%OC, pH 7.2, 74.8 mg microbial carbon/100g soil)					
0	2.97	3.06	3.0	2.97	0
14	5.37	4.76	-11.4	4.84	-9.9
28	4.62	4.26	-7.8	4.01	-13.2

Conclusions :

The study is acceptable. The modifications of soil respiration and nitrification were lower than 25% after 28 days.

B.9.9 Effects on other non-target organisms (flora and fauna) believed to be at risk (Annex IIA 8.6; Annex IIIA 10.8)

Effect of Metconazole (AC 900768) 60 g/L SL (SF09381) on the Seedling Emergence and Growth of Selected Non-Target Terrestrial Plants, (Aufderheide J. *et al*., 2000b).

Guidelines :

OECD Method 208

GLP :

Yes

Material and Methods :

Test substance : metconazole 60 g/L SL, chemical purity : 61.4 g/L, LotN°: F0100899

Test species : sugar beet (*Beta vulgaris*), lettuce (*Lactuca sativa*), radish (*Raphanus sativus*), soybean (*Glycine max*), onion (Allium cepa) and oat (*Avena sativa*)

Soil :: loamy clay, pH 5.4, 1.8% organic matter ; All species were fertilized with a commercial 20-20-20 fertilizer.

Number of organisms : 10 seeds per replicate and 4 replicates per treatment

Type of test : seedling emergence study

Applied and measured concentrations : 0, 0.75, 1.5, 3.0, 6.0, 12, 23, 45 and 90 g a.s./ha. All measured concentrations were above 100% of the nominal. The test substance was sprayed over the test pots. Results are expressed in calculated application rates.

Test conditions :

RH : 28.0 – 93.3%

Temperature : 14.85 - 42.46°C

Light intensity : 16h/day supplemental lighting. Average light intensity ranged from 260-840 $\mu Em^{-2}s^{-1}$ as measured on day 19 of the study.

Analytical methods : HPLC

Findings:

Table B.8.9-1 : Endpoints of a seedling emergence study

	Sugar beet (g as/ha)	**Lettuce (g as/ha)**	**Radish (g as/ha)**	**Soybean (g as/ha)**	**Onion (g as/ha)**	**Oat (g as/ha)**
Emergence and survival	NOEC = 96	NOEC = 96	NOEC = 96	NOEC = 96	NOEC = 96	NOEC = 96
Shoot length	EC_{50} > 96 NOEC = 96	EC_{50} > 96 NOEC = 96	EC_{50} > 96 NOEC = 96	EC_{50} > 96 NOEC = 96	EC_{50} > 96 NOEC = 96	EC_{50} > 96 NOEC = 96
Plant dry weight	EC_{50} > 96 NOEC = 96	EC_{50} > 96 NOEC = 96	EC_{50} > 96 NOEC = 96	EC_{50} > 96 NOEC = 96	EC_{50} > 96 NOEC = 96	EC_{50} > 96 NOEC = 96
Phytotoxicity ratings	NOEC = 96	NOEC = 96	NOEC = 96	NOEC = 96	NOEC = 96	NOEC = 96

Conclusions :

The study is acceptable.

Effect of Metconazole (AC 900768) 60 g/L SL (SF 09381) on the Vegetative Vigor of Selected Non-Target Terrestrial Plants, (Aufderheide *et al.*, 2000a).

Guidelines :

OECD Method 208

GLP :

Yes

Material and Methods :

Test substance : metconazole 60 g/L SL, chemical purity : 61.4 g/L, LotN°: F0100899

Test species : sugar beet (*Beta vulgaris*), lettuce (*Lactuca sativa*), radish (*Raphanus sativus*), soybean (*Glycine max*), onion (Allium cepa) and oat (*Avena sativa*)

Soil :: loamy clay, pH 5.4, 1.8% organic matter ; All species were fertilized with a commercial 20-20-20 fertilizer.

Number of organisms : 10 plants per replicate for oat, soybean and onion, 12 plants per replicate for lettuce, radish and sugar beet and 4 replicates per treatment

Type of test : vegetative vigor non-target phytotoxicity study

Applied and measured concentrations : 0, 25, 50, 75 and 100 g a.s./ha for lettuce radish and soybean ; 0 and 90 g a.s./ha for sugar beet, onion and oat. All measured concentrations were above 100% of the nominal. Results are expressed in calculated application rates.
Test conditions :
RH : 15.8-90.9 %
Temperature : 14.5-39.2°C
Light intensity : 16h/day supplemental lighting. Average light intensity ranged from 160-880 $\mu Em^{-2}s^{-1}$ as measured on day 13 of the study (day 9 of the oat re-test).
Analytical methods : HPLC
Findings:
Table B.8.9-1 : Endpoints of a vegetative vigor non-target phytotoxicity study

	Sugar beet (g as/ha)	**Lettuce (g as/ha)**	**Radish (g as/ha)**	**Soybean (g as/ha)**	**Onion (g as/ha)**	**Oat (g as/ha)**
Percent survival	NOEC = 95	NOEC = 110	NOEC = 110	NOEC = 110	NOEC = 95	NOEC = 94
Shoot length	EC_{50} > 95 NOEC = 95	EC_{50} > 110 NOEC = 110	EC_{50} > 110 NOEC = 110	**EC_{50} >110** **NOEC = 27**	EC_{50} > 95 NOEC = 95	EC_{50} > 94 NOEC = 94
Shoot dry weight	EC_{50} > 95 NOEC = 95	EC_{50} > 110 NOEC = 110	EC_{50} > 110 NOEC = 110	EC_{50} > 110 NOEC = 110	EC_{50} > 95 NOEC = 95	EC_{50} > 94 NOEC = 94
Phytotoxicity ratings	NOEC = 95	NOEC = 110	NOEC = 110	NOEC = 80	NOEC = 95	NOEC < 94

Conclusions :
The study is acceptable.

First tier risk assessment :
Data have been submitted on 6 non target plants (seedling emergence, vegetative vigor). The risk is considered acceptable since less than 50% effects were observed at the maximum application rate (NOEC at 90 g a.s./ha). (SANCO/10329/2002)

B.9.10 Effects on biological methods of sewage treatment (Annex IIA 8.7)

Metconazole (AC 900768): Activated Sludge, Respiration Inhibition Test, (Heim D. & Yan Z., 1999).
Guidelines :
OECD Guideline 209
GLP :
Yes
Material and Methods :
Test substance : metconazole, chemical purity : 98.1%, LotN°: AC12140-17
Test design : The inhibitory effect of metconazole on the oxygen consumption of activated sludge suspension (3.9 g suspended solids/L) was determined. The applied a.s. concentrations used were 0 and 1000 mg a.s./L. Incubation at 20 ± 2°C for 3 hours.
Findings and conclusions :
The study is acceptable.
EC_{50} (3h) > 1000 mg a.s./L (nominal)

B.9.11 References relied on

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
II A 8.1.1/1	Hakin B. et al.	1992	WL 148271: Acute oral toxicity (LD50) to bobwhite quail Huntingdon Research Centre; Huntingdon; United Kingdom MK-505-001 Yes unpublished	N	BASF
II A 8.1.1/2	Johnson A. et al.	1998	Metconazole 85:15 cis:trans, Metconazole 95% cis, A comparative acute oral toxicity (LD50) study with northern bobwhite Huntingdon Life Sciences Ltd.; Huntingdon Cambridgeshire PE28 4HS; United Kingdom MK-505-007 Yes unpublished	N	BASF
II A 8.1.2/1	Hakin B. et al.	1991a	Dietary toxicity (LC50) of WL148271 to the bobwhite quail Huntingdon Research Centre; Huntingdon; United Kingdom MK-505-002 Yes unpublished	N	BASF
II A 8.1.2/2	Hakin B. et al.	1991b	Dietary toxicity (LC50) of WL148271to the mallard duck Huntingdon Research Centre; Huntingdon; United Kingdom MK-505-003 Yes unpublished	N	BASF
II A 8.1.3/1	Hakin B.et al.	1992	WL136184 Reproduction in the bobwhite quail Huntingdon Research Centre; Huntingdon; United Kingdom MK-505-005 Yes unpublished	N	BASF
II A 8.1.3/2	Hakin B.et al	1992	WL136184 Reproduction in the mallard duck Huntingdon Research Centre; Huntingdon; United Kingdom MK-505-004 Yes unpublished	N	BASF
II A 8.1.3/3	Johnson A.J.,Ahmed S.	1999	Metconazole 85:15 cis:trans, assessment to determine the effects on reproduction in the northern bobwhite Huntingdon Life Sciences; East Millstone, New Jersey 08875-2360; United States of America MK-505-010 Yes unpublished	N	BASF
II A 8.2.1/1	Toy R.	1990	WL148271 (KNF-S-474m): Acute toxicity to Salmo gairdneri, Daphnia magna and Selenastrum capricornutum Sittingbourne Research Centre; Kent ME9 8AG; United Kingdom MK-510-001 Yes unpublished	N	BASF
II A 8.2.1/2	Toy R.	1991	WL148271 (KNF-S-474m): 96 h acute toxicity to Pimephales promelas Sittingbourne Research Centre; Kent ME9 8AG; United Kingdom MK-511-001 Yes unpublished	N	BASF
II A 8.2.1/3	Mitchell G. et al.	1996a	Acute toxicity of AC 900,768 (metconazole) to common carp (Cyprinus carpio) under flow-through test conditions T. R. Wilbury Laboratories, Inc.; Marblehead, Massachusetts 01945; United States of America MK-511-002 Yes unpublished	N	BASF

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
II A 8.2.2.1/1	Mitchell G. et al.	1996b	Toxicity of AC 900,768 (metconazole) technical to rainbow trout (Oncorhynchus mykiss) in a flow-through prolonged toxicity test T. R. Wilbury Laboratories, Inc.; Marblehead, Massachusetts 01945; United States of America MK-513-001 Yes unpublished	N	BASF
II A 8.2.2.2/1	Zok S.	2001	BAS 555 F - Early life-stage toxicity test on the rainbow trout (Oncorhynchus mykiss) BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. MK-512-002 Yes unpublished	Y	BASF
II A 8.2.3/1	Kao M.L.	1996	CL 900,768 (Metconazole): Bioconcentration and elimination of [Triazole-3,5-14c] CL 900,768-derived residues by bluegill sunfish ABC Laboratories Inc.; Columbia, Missouri 65202; United States of America MK-519-002 Yes unpublished	N	BASF
II A 8.2.3/2	Cenni M.	2002	BAS 555 F (AC 900768, Metconazole): Bioconcentration and elimination of p-chlorophenyl-U-14C] AC 900768-derived residues by bluegill sunfish ABC Laboratories Inc.; Columbia, Missouri 65202; United States of America MK-519-003 Yes unpublished	Y	BASF
II A 8.2.4/1	Toy R.	1990	WL148271 (KNF-S-474m): Acute toxicity to Salmo gairdneri, Daphnia magna and Selenastrum capricornutum Sittingbourne Research Centre; Kent ME9 8AG; United Kingdom MK-510-001 Yes unpublished	N	BASF
II A 8.2.5/1	Jatzek H.-J.	2002	BAS 555 F - Determination of the chronic effect on the reproduction of the water flea Daphnia magna STRAUS BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. MK-523-002 Yes unpublished	Y	BASF
II A 8.2.6/1	Toy R.	1990	WL148271 (KNF-S-474m): Acute toxicity to Salmo gairdneri, Daphnia magna and Selenastrum capricornutum Sittingbourne Research Centre; Kent ME9 8AG; United Kingdom MK-510-001 Yes unpublished	N	BASF
II A 8.2.7/1	England D.C. et al.	1997	Effects of AC 900,768 (metconazole) on the development of sediment-dwelling larvae of chironomus riparius in a water-sediment system ABC Laboratories Inc.; Columbia, Missouri 65202; United States of America MK-549-006 Yes unpublished	N	BASF
II A 8.3.1.1/1	Harrison E.G.,Hillaby J.M.	1991	WL148271;KNF-S-474m : Acute topical and oral toxicity to the honey bee, Apis mellifera L. Sittingbourne Research Centre; Kent ME9 8AG; United Kingdom MK-541-001 Yes unpublished	N	BASF

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
II A 8.3.2/1	Candolfi M.P.	1996	Laboratory contact toxicity test with AC 900,768 in a 60 g a.i./L soluble liquid formulation on the ground beetle Poecilus cupreus (Coleoptera: carabidae) Springborn Laboratories (Europe) AG; Horn; Switzerland MK-549-002 Yes unpublished	N	BASF
II A 8.3.2/2	Mead-briggs M.,Strnad S.	1998b	An extended laboratory test to determine the effects of fresh residues of metconazole (AC 900768) in a 60 g/L soluble concentrate (60 SL) formulation (SF09381), on spiders of the genus Pardosa (Araneae, lycosidae) Agrochemical Evaluation Unit; Southampton SO16 7PX; United Kingdom MK-549-009 Yes unpublished	N	BASF
II A 8.3.2/3	Candolfi M.,van der Kolk J.	1996b	Laboratory contact toxicity test with AC 900,768 in a 60 g ai/L soluble liquid formulation on the sevenspotted lady beetle Coccinella septempunctata L. (Coleoptera, coccinellidae) Springborn Laboratories (Europe) AG; Horn; Switzerland MK-549-003 Yes unpublished	N	BASF
II A 8.3.2/4	Mead-briggs M.,Strnad S.	1998a	An extended laboratory test to determine the effects of fresh residues of metconazole (AC 900768) in a 60 g/L soluble concentrate (60 SL) formulation (SF09381), on Coccinella septempunctata (Coleoptera, coccinellidae) Agrochemical Evaluation Unit; Southampton SO16 7PX; United Kingdom MK-549-008 Yes unpublished	N	BASF
II A 8.3.2/5	Vinall S.,Strnad S.	1998	An extended laboratory test to determine the effects of fresh residues of metconazole (AC 900768) in a 60 g/L soluble concentrate (60 SL) formulation (SF09381), on the plant-active predator Orius laevigatus (Heteroptera; Anthocoridae) Agrochemical Evaluation Unit; Southampton SO16 7PX; United Kingdom MK-560-009 Yes unpublished	N	BASF
II A 8.3.2/6	Candolfi M.,van der Kolk J.	1996a	Laboratory contact toxicity test with AC 900,768 in a 60 g ai/L soluble liquid formulation on the parasitic wasp, Aphidius rhopalosiphi (Hymenoptera: braconidae) Springborn Laboratories (Europe) AG; Horn; Switzerland MK-549-001 Yes unpublished	N	BASF
II A 8.3.2/7	Mead-briggs M.,Strnad S.	1998c	An extended laboratory test to determine the effects of fresh residue of metconazole (AC 900768) in a 60 g/L soluble concentrate (60 SL) formulation (SF09381), on Aphidius rhopalosiphi (Hymenoptera, braconidae) Agrochemical Evaluation Unit; Southampton SO16 7PX; United Kingdom MK-549-010 Yes unpublished	N	BASF
II A 8.3.2/8	Candolfi M.,van der Kolk J.	1996c	Laboratory contact toxicity test with AC 900,768 in a 60 g ai/L Soluble Liquid Formulation on the predacious mite, Typhlodromus pyri scheuten (Acari, Phytoseiidae) Springborn Laboratories (Europe) AG; Horn; Switzerland MK-549-004 Yes unpublished	N	BASF

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
II A 8.3.2/9	Engelhard E.K. et al.	1998b	A laboratory contact toxicity test with drift rates of AC 900768 in a 60g ai/L soluble concentrate formulation (SF09381) on the predaceous mite, Typhlodromus pyri scheuten (Acari, phytoseiidae) Springborn Laboratories (Europe) AG; Horn; Switzerland MK-549-007 Yes unpublished	N	BASF
II A 8.3.2/10	Taruza S.,Strnad S.	2002	An aged-residue extended laboratory test to determine the effects of Metconazole (AC 900768), in a 60 g/L SL formulation (BAS 555 00 F), on the predatory mite, Typhlodromus pyri (Acari: phytoseiidae) Mambo-Tox Ltd.; Southampton; United Kingdom MK-560-020 Yes unpublished	Y	BASF
II A 8.4.1/1	Hillaby J.M.,Harrison E.G.	1991	WL136184 (KNF-S-474c) : Toxicity to the earthworm, Eisenia foetida, in a 14 day artificial soil test Sittingbourne Research Centre; Kent ME9 8AG; United Kingdom MK-531-001 Yes unpublished	N	BASF
II A 8.4.2/1	Engelhard E.K. et al.	1998a	A chronic toxicity and reproduction test exposing the earthworm Eisenia fetida to AC 900768 technical material in OECD artificial soil, following the ISO-draft (ISO/DIA 11268-2) Springborn Laboratories (Europe) AG; Horn; Switzerland MK-534-001 Yes unpublished	N	BASF
II A 8.5/1	van der Kolk J.	1996	The effects of AC 900,768 in a 60 g a.i./L soluble liquid formulation on the respiration and nitrification of soil microflora Springborn Laboratories (Europe) AG; Horn; Switzerland MK-625-003 Yes unpublished	N	BASF
II A 8.6/1	Aufderheide J. et al.	2000b	Effect of metconazole (AC 900768) 60 g/L SL (SF 09381) on the seedling emergence and growth of selected non-target terrestrial plants ABC Laboratories Inc.; Columbia, Missouri 65202; United States of America MK-540-002 Yes unpublished	N	BASF
II A 8.6/2	Aufderheide J. et al.	2000a	Effect of metconazole (AC 900768) 60 g/L SL (SF 09381) on the vegetative vigor of selected non-target terrestrial plants ABC Laboratories Inc.; Columbia, Missouri 65202; United States of America MK-540-001 Yes unpublished	N	BASF
II A 8.7/1	Heim D.,Yan Z.	1999	Metconazole (AC 900768): Activated sludge, respiration inhibition test ABC Laboratories Inc.; Columbia, Missouri 65202; United States of America MK-690-005 Yes unpublished	N	BASF
III A 10.2.1/1	Zok S.	2001	Acute toxicity study on the rainbow trout (Oncorhynchus mykiss) in a static system over 96 hours BASF AG; Ludwigshafen/Rhein; Germany Fed.Rep. MK-560-019 Yes unpublished	Y	BASF

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
III A 10.2.1/2	Mitchell G.C. et al.	1998	Acute toxicity of AC 900768 (metconazole) 60 g/l SL formulation (SF09381) to Daphnia magna under static test conditions T. R. Wilbury Laboratories, Inc.; Marblehead, Massachusetts 01945; United States of America MK-560-007 Yes unpublished	N	BASF
III A 10.2.1/3	Aufderheide J.A.,Mitchell G.C.	1998	AC900768 (metconazole) 60 g/l SL formulation (SF09381): Acute toxicity to Daphnia magna in a static water system ABC Laboratories Europe; Coleraine; Northern Ireland MK-560-008 Yes unpublished	N	BASF
III A 10.2.1/4	Mitchell G.C. et al.	1996b	Effects of a AC 900768 (metconazole) 60 g/l SL formulation (SF09381) on the growth of Selenastrum capricornutum T. R. Wilbury Laboratories, Inc.; Marblehead, Massachusetts 01945; United States of America MK-560-004 Yes unpublished	N	BASF
III A 10.2.1/5	Mitchell G.C. et al.	2001	Acute toxicity of formulation SF 09747 to Daphnia magna under static test conditions T. R. Wilbury Laboratories, Inc.; Marblehead, Massachusetts 01945; United States of America MK-560-018 Yes unpublished	Y	BASF
III A 10.2.4/1	Mitchell G.C. et al.	1996a	Toxicity of AC 900,768 (metconazole) 60 g/l SL formulation (SF09381) to rainbow trout (Oncorhynchus mykiss) in a flow-through prolonged toxicity test T. R. Wilbury Laboratories, Inc.; Marblehead, Massachusetts 01945; United States of America MK-560-003 Yes unpublished	N	BASF
III A 10.2.4/2	Mitchell G.C. et al.	1996c	Chronic toxicity of AC 900,768 (metconazole) in a 60 g/l SL formulation (SF09381) during the complete life-cycle of Daphnia magna under static renewal test conditions T. R. Wilbury Laboratories, Inc.; Marblehead, Massachusetts 01945; United States of America MK-560-005 Yes unpublished	N	BASF
III A 10.4.1/1	Engelhard E.K. et al.	1998	An acute contact and oral toxicity study with AC 900768 in a 60 g ai/L soluble concentrate (60 SL) formulation (SF 09381) on the honey bee Apis mellifera based on EPPO guideline # 170 Springborn Laboratories (Europe) AG; Horn; Switzerland MK-560-006 Yes unpublished	N	BASF
III A 10.4.1/2	Schmitzer S.	1999b	Laboratory testing for toxicity (acute contact and oral LD50) of metconazole (CL 900,768) 60 g a.i./L SL (SF 09381) to honey bees (Apis mellifera L.) (Hymenoptera, apidae) Institut für Biologische Analytik und Consulting IBACON GmbH; Rossdorf; Germany Fed.Rep. MK-541-008 Yes unpublished	N	BASF
III A 10.6.1.1/1	Candolfi M.P.,Ott U.	1996	AC 900,768 in a 60 g ai/L soluble liquid formulation (SF09381): 14-day acute toxicity test with the earthworm (Eisenia foetida) based on OECD guideline # 207 Springborn Laboratories (Europe) AG; Horn; Switzerland MK-560-002 Yes unpublished	N	BASF

Annex point(s)	Author(s)	Year	Title Source BASF Document No. GLP or GEP status Published or not	Data Protection Claimed Y/N	Owner
III A 10.6.2/1	Walker H.M. et al.	2001a	A field evaluation of the effects of metconazole (AC 900768) in a 60 g/L suspended liquid (SL) formulation (1027) on the degradation of buried leaf material Ecotox Ltd; Tavistock Devon PL19 0YU; United Kingdom MK-560-015 Yes unpublished	N	BASF
III A 10.6.2/2	Walker H.M. et al.	2001b	A field evaluation of the effects of metconazole (AC 900768) in a 60 g/L suspended liquid (SL) formulation (SF 09381) on the degradation of buried leaf material Ecotox Ltd; Tavistock Devon PL19 0YU; United Kingdom MK-560-017 Yes unpublished	N	BASF