ANNEX B

Thiram

B.7 Environmental fate and behaviour

B.7.1 Route and rate of degradation in soil (Annex IIA 7.1.1; Annex IIIA 9.1.1)

B.7.1.1 Route of degradation (Annex IIA 7.1.1.1)

B.7.1.1.1 Aerobic degradation in soil (Annex IIA 7.1.1.1.1)

^{14}C-Thiram : Degradation and metabolism in one soil incubated under aerobic conditions (Morgenroth U., 1995a)
Guidelines :
(U.S.) EPA 540/9-82-021 : Pesticide Assessment Guidelines, subdivision N: Section 162-1
GLP :
Yes
Material and Methods :
Test substance : thiram labelled with ^{14}C at both thiocarbonyl positions of the molecules, Radiochemical purity: 100 %. Specific radioactivity: 18.1 mCi/mMol
Soil :
Table B.7.1.1.1-1 : Characteristics of the soil used in the aerobic degradation study

Soil type	Origin	pH	CEC (meq/100g)	OC content (%)	field capacity (1/3 bar moisture %)	Clay content (%)	Silt content (%)	Sand content (%)
sandy loam	New York	6.7	14.44	2.41	19.24	14.8	29.6	55.6

Test conditions :
Aerobic incubation at 20± 1°C, 75% maximum water holding capacity, in the dark. Application rate was 20.3 mg a.s./kg soil (equivalent to 18.3 kg a.s./ha distributed in the top 6 cm of the soil of density 1.5 g/cm^3). Experiment was performed in duplicate.
Analytical methods :
Extraction was performed with chloroform, acetonitrile, acetonitrile/water (1/1), water. The main part of the radioactivity was recovered in the chloroform fraction
Thiram was recovered in chloroform (~ 90%) and acetonitrile/water fractions.
Humin, humic acids and fulvic acids fractionation was performed.

Radioactivity measured by LSC.
Identification of metabolites by TLC and HPLC.
Tetramethylthiuram monosulphide (TMTM), Dimethyldithiocarbamic acid sodium salt dihydrate (DMDTC), Dimethyldithiocarbamic acid methyl ester (DMDTC-ME), Carbon disulfide, (CS_2) 1,1,3,3-tetramethylurea (TMU), 1,1,3,3-tetramethyl-2-thiourea (TMTU) and N,N-dimethylthioformamide (DMTFA) were researched.
Characterization of unknown metabolites by GC/MS and LC/MS.

Findings :
Table B.7.1.1.1-2 : Balance and recovery of radioactivity - aerobic degradation at 20°C in the lab (% of applied radioactivity; 20.3 mg/kg = 100%)

	Sampling time (days)										
	0	1	2	4	7	14	21	42	84	128	205
^{14}C-CO_2 (KOH) (*)	-	3.7	9.0	21.8	35.6	46.1	54.7	59.6	65.9	67.7	74.9
Other volatiles (polyetylene glycol)	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Extractable	103.1	69.8	56.3	38.9	21.9	5.7	3.4	1.8	1.1	0.8	0.6
Thiram (in chloroform and acetonitrile/water)	103.1	65.9	46.7	29.9	15.2	2.9	1.6	0.2	0.1	< 0.1	<0.1
Carbamo (thioperoxoic) acid, dimethyl- (Metabolite 6.5)	n.d.	2.2	4.9	8.7	4.2	1.6	0.8	0.4	0.2	0.1	0.1
Bound residue	-	23.7	31.1	36.5	39.1	47.6	45.1	40.7	36.1	32.8	30.9
Total recovery	107.2	97.2	96.5	97.2	96.6	99.4	103.2	102.1	103.1	101.4	106.4

- : not performed
(*) up to day 4, a total of 2.1% of applied radioactivity was considered as CS_2 (not precipitated by barium carbonate)

Conclusions :
The a.s and 11 metabolites were detected in the extractable residue.
- Thiram was rapidly mineralized, resulting in high amounts of CO_2 (DT_{50} = 2 days; DT_{90} = 7 days)
- The major metabolite (Carbamo (thioperoxoic) acid, dimethyl-) was recorded at doses always lower than 8.7 % of the recovered radioactivity. (DT_{50} = 3 days; DT_{90} = 14 days)
- Other metabolites were recorded at low levels (‘not detected’ to ‘<1% radioactivity applied’).
- After 84 days , 36.1% of applied radioactivity was found as non extracted radioactivity which was further mineralized.

B.7.1.1.2 Anaerobic degradation in soil (Annex IIA 7.1.1.1.2)

Not submitted. It is not expected that thiram will be exposed to anaerobic conditions (application on crop foliage; application on seeds sown in the top layer of the soil)

B.7.1.1.3 Soil photolysis (Annex IIA 7.1.1.1.2)

Photodegradation study of ^{14}C-thiram on soil (Burri R., 1995)
Guidelines :
(U.S.) EPA 540/9-82-021, Pesticide Assessment Guidelines, Subdivision N, Section 161-3
GLP :
Yes
Material and Methods :
Test substance : thiram labelled with ^{14}C at both thiocarbonyl positions of the molecules, Radiochemical purity: ^{3}98.9% %. Specific radioactivity: 75.1 µCi/mg
Soil :

Table B.7.1.1.3.-1 : Characteristics of the soil used in the photodegradation study

Soil type	Origin	pH	CEC (meq/100g)	OC content (%)	field capacity (1/3 bar moisture %)	Clay content (%)	Silt content (%)	Sand content (%)
sandy loam	New York	6.7	14.44	2.41	19.24	14.8	29.6	55.6

Test conditions :
Soil treated with a.s. was exposed to artificial light (Suntest apparatus with xenon lamp which approximates sunlight spectrum, UV filter edge 290 nm)) using a 12 hour light/dark cycle during 21 days.
Incubation at 20.0 ± 1.0°C. Spectral energy in the range 300-800 nm was 412.8 W/m2 or 1893 µmol. s-1. m-2
Application rate was 18.3 mg a.s./kg
Analytical methods :
Extraction of soil by chloroform, acetonitrile and acetonitrile/water.
Tetramethylthiuram disulphide, tetramethylthiuram monosulphide (TMTM), Dimethyldithiocarbamic acid sodium salt dihydrate (DMDTC), Dimethyldithiocarbamic acid methyl ester (DMDTC-ME), Carbon disulfide, (CS_2) 1,1,3,3-tetramethylurea (TMU), 1,1,3,3-tetramethyl-2-thiourea (TMTU) and N,N-dimethylthioformamide (DMTFA) were researched by HPLC and TLC.
Radioactivity measured by LSC.
Findings :
Table B.7.1.1.3-2 : Balance and recovery of radioactivity in soil photolysis study (% applied radioactivity)

	Sampling time (days)					
	0	1	3	7	14	21
	Illuminated samples					
Volatiles (*)	n.p.	9.8	25.1	38.7	51.8	57.4
CO_2	n.p.	5.6	13.1	22.8	32.7	36.9
CS_2	n.p.	4.2	12.0	15.9	19.1	20.5
Extractable (**)	92.8	68.0	47.0	30.6	17.2	11.1
Thiram	90.8	51.2	34.4	18.3	6.3	1.3
Unknown metabolite M3	-	9.6	-	2.5	-	-
Unknown metabolite M5	-	-	2.5	1.6	4.7	4.7
Unknown metabolite M6	-	6.2	8.4	6.7	5.0	4.1
Bound residue	11.0	29.2	35.2	34.5	35.8	30.7
Balance : (volatiles + extractable + bound residue)	103.8	107.0	107.3	103.8	104.8	99.2

(*) KOH-trapped volatiles were characterized by means of barium carbonate precipitation (CO_2 precipitated, CS_2 remained in the supernatant)
(**) : A water fraction accounting for ~ 1-2% of applied radioactivity and not further analyzed explains the divergences in the balance of extractable

	Sampling time (days)					
	0	**1**	**3**	**7**	**14**	**21**
	Dark samples					
Volatiles (*)	n.p.	2.4	5.6	7.3	9.1	11.1
CO_2	n.p.	0.9	2.7	3.4	3.8	5.6
CS_2	n.p.	1.5	2.9	3.9	5.3	5.5
Extractable (**)	92.8	76.4	67.7	64.6	64.1	55.7
Thiram	90.8	70.5	60.2	51.5	47.7	29.8
Unknown metabolite M3	-	-	2.0	-	1.1	5.8
Unknown metabolite M5	-	-	-	-	0.5	-
Unknown metabolite M6	-	4.7	4.3	10.3	11.5	15.2
Bound residue	11.0	24.4	30.9	31.4	32.8	33.4
Balance : (volatiles + extractable + bound residue)	103.8	103.2	104.2	103.3	106.0	100.2

(*) KOH-trapped volatiles were characterized by means of barium carbonate precipitation (CO_2 precipitated, CS_2 remained in the supernatant)
(**) : A water fraction accounting for ~ 1-2% of applied radioactivity and not further analyzed explain the divergences in the balance of extractable

Metabolite M6 consisted of at least 6 subfractions. One of them was considered to be identical to dimethylcarbamo (thioperoxoic)acid.

Conclusions :
DT_{50} (in the dark) = 15.9 days
DT_{50} (12 h dark/12 h light) = 3.7 days

B.7.1.2 Rate of degradation (Annex IIA 7.1.1.2.1; Annex IIIA 9.1.1.1.1)

B.7.1.2.1 Aerobic degradation

Study for 1 soil, described under point B.7.1.1

B.7.1.2.2 Anaerobic degradation

Not submitted. It is not expected that thiram will be exposed to anaerobic conditions (application on crop foliage; application on seeds sown in the top layer of the soil)

B.7.1.3 Field studies (Annex IIA 7.1.1.2.2; Annex IIIA 9.1.1.2)

B.7.1.3.1 Soil dissipation testing

Not submitted

B.7.1.3.2 Soil residue testing - soil accumulation testing

Not submitted

B.7.2 Adsorption, desorption and mobility in soil (Annex IIA 7.1.2 and 7.1.3; Annex IIIA 9.1.2)

B.7.2.1 Adsorption and desorption of the active substance and relevant metabolites (Annex IIA 7.1.2)

Adsorption/desorption of ^{14}C-thiram on four soils (Morgenroth U., 1995b)
Guidelines :
(U.S.) EPA 540/9-82-021, Pesticide Assessment Guidelines, Subdivision N, Section 163-1
OECD guideline N°106
GLP :
Yes
Material and Methods :
Test substance : thiram labelled with ^{14}C at both thiocarbonyl positions of the molecules, Radiochemical purity: 97% %. Specific radioactivity: 285.2 µCi/mg
Soils :
Table B.7.2.1-1 : Characteristics of the soils used in the adsorption/desorption study

Soil type	Origin	pH	CEC (meq/100g)	OC content (%)	Clay content (%)	Silt content (%)	Sand content (%)
sandy loam	New York	6.7	14.4	2.41	14.8	29.6	55.6
loamy sand	Illinois	4.8	7.4	0.61	7.5	9.4	83.1
silt loam	Illinois	6.7	12.6	1.06	16.8	59.1	24.1
loam	Iowa	7.3	31.0	2.04	25.2	33.6	41.2

Test conditions :
5 g soil and 25 g 0.01M CaCl2 were shaken at 20°C for 4 hours (equilibrum reached after 4 h. Partial degradation of the a.s. was observed; therefore, in order to avoid futher degradation, an absorption time of 4 hours was chosen).
Four different concentrations were taken : 1.07; 0.20; 0.04 and 0.01 mg a.s. /l aqueous calcium chloride solution.
Desorption was determined after 4 hours shaking time.
Analytical methods :
Radioactivity in the soil and the supernatant were determined by LSC and HPLC.
A balance of the radioactivity recovered in the soil (chloroform extract + residue after combustion) and the supernatant amounts for 94.10-96.70 % of applied radioactivity.

Findings :
Table B.7.2.1-2 : Adsorption/desorption constants Ka, Koc, 1/n of thiram

Soil	**Adsorption**			**Desorption**		
	Ka	**Koc**	**1/n**	**K'a**	**K'oc**	**1/n'**
sandy loam	54.10	2245	1.0362	781.17	32414	1.2713
loamy sand	149.61	24526	1.1486	1762.10	288869	1.2641
silt loam	67.40	6359	1.1041	841.44	79381	1.2250
loam	263.14	12899	1.1258	1679.73	82340	1.1562

Conclusions :
The Freundlich adsorption constants showed that thiram is moderatly mobile to immobile in soil (Koc = 2245-24526)

B.7.2.2 Column leaching studies with the active substance and relevant metabolites (Annex IIA 7.1.3.1; Annex IIIA 9.1.2.1)

Not submitted

B.7.2.3 Aged residue column leaching (Annex IIA 7.1.3.2; Annex IIIA 9.1.2.1)

Not submitted

B.7.2.4 Lysimeter and field leaching studies (Annex IIA 7.1.3.3; Annex IIIA 9.1.2.2)

Not submitted

B.7.3 Summary of behaviour in soil and predicted environmental concentration in soil (PECs) Annex IIIA 9.1.3)

The studies which were submitted do not allow to fully assess the fate and behaviour of thiram and its metabolites in soil. Further information is required (see level 4 of the report)

Table B.7.3-1 : Summary of behaviour in soil

Test soil				**Test system**	**Results**	**References**
Soil type	**Soil $pH_{(KCl)}$**	**CEC**	**Organic matter content (%)**			
Sandy loam	6.7	14.44	2.41	Aerobic degradation at 20° C	DT_{50} = 2 days DT_{90} = 7 days important mineralization (65.9% radioactivity as CO_2 at day 84)	Morgenroth U., 1995a
Sandy loam	6.7	14.44	2.41	Photolysis at 20°C	DT_{50} (12 h dark/12 h light) = 3.7 days DT_{50} (in the dark) = 15.9 days	Burri R., 1995
Sandy loam	6.7	14.4	2.41	Adsorption/desorption	Koc = 2245	Morgenroth U., 1995b
Loamy sand	4.8	7.4	0.61		Koc = 24526	
Silt loam	6.7	12.6	1.06		Koc = 6359	
Loam	7.3	31.0	2.04		Koc = 12899	

PEC soil :
PEC were calculated for the seed treatment applications and for the foliar applications in orchard.

The following assumptions were made to calculate the PEC for seed treatment applications :
- DT_{50} of 2 days was taken. The degradation was calculated according to first order kinetics. No other value was available at this stage. The accuracy of the PEC is therefore questionable. More information on rate of degradation is needed.
- First order dissipation PEC and TWA PEC were calculated for the 'worst case' situation : peas at the highest sowing rate.
- Several major crops were taken into account.
- soil layer of 5 cm and soil density of 1.5 g/cm3
- sowing rates according to the ATD Guide to the International Seed Business, Agritech Decision, (1991) and to Station of Phytopharmacy , Gembloux
-' Worst cases' were the application rates of formulations containing thiram only.

Table B.7.3-2 : PEC soil of thiram in mg a.s./kg soil - seed treatment

Crop	**Sowing rate (kg seed/ha)**	**Application rate (g a.s./100 kg seed)**	**Initial PECsoil (mg a.s./kg soil)**
Barley	120-155	200	0.320 - 0.413
Oat	120-130	150	0.240 - 0.260
Rye	115-150	200	0.307 - 0.400
Wheat	170-200	160	0.363 - 0.427
Pea	100-220	200	0.267 - 0.587
Maize	20-25	200	0.053 - 0.067
Sugar beet	40-50	480	0.256 - 0.320
Oilseed rape	2-5	440	0.012 - 0.029

Table B.7.3-3 : PEC soil of thiram in mg a.s./kg soil - Seed treatment

Time after application (days)	Sowing of peas 220 kg seed , 200 g a.s./100 kg seed	
	first order dissipation PEC	TWA PEC
0	0.587	
1	0.415	0.496
2	0.293	0.423
4	0.147	0.317
7	0.052	0.220
14	0.004	0.120
21	0.0004	0.081
28	0	0.060
50	0	0.034
100	0	0.017

The following assumptions were made to calculate the PEC for foliar applications :

- DT_{50} of 2 days was taken. The degradation was calculated according to first order kinetics. No other value was available at this stage. The accuracy of the PEC is therefore questionable. More information on rate of degradation is needed.
- TWA PECs were calculated according to the recommendations of the FOCUS group (Doc 7617/VI/96 - Feb. 97)

- 50 % of the a.s. reached the soil.
- soil layer of 5 cm and soil density of 1.5 g/cm3
- Two scenarios were chosen :
  strawberries, 3.2 kg a.s./ha, 4 applications/season, at 7 days interval
  orchard, 2.4 kg a.s./ha, 6 applications/season, 7 days interval

Table B.7.3-4 : PEC soil of thiram in mg a.s./kg soil - foliar application - single application

Time after application (days)	Strawberries 3.2 kg a.s./ha 50% a.s. reaching the soil	Orchard 2.4 kg a.s./ha 50% a.s. reaching the soil
0	2.133	1.600
1	1.508	1.131
2	1.067	0.800
4	0.533	0.400
7	0.189	0.141
14	0.017	0.012
21	0.001	0.001
28	0	0
50	0	0
100	0	0

Table B.7.3-5 : TWA PEC soil of thiram in mg a.s./kg soil - foliar applications - repeated applications

	Strawberries 3.2 kg a.s./ha 4 applications 7 days interval 50% a.s. reaching the soil	Orchard 2.4 kg a.s./ha 6 applications 7 days interval 50% a.s. reaching the soil
TWA PEC once the plateau is reached	0.879	0.660

PEC groundwater :
No evaluation can be made in the absence of data on the mobility of the a.s. Nevertheless, due to its quick degradation and its high Koc it would be improbable that thiram would be found in groundwater.

B.7.4 Fate and behaviour in water (Annex IIA 7.2.1; Annex IIIA 9.2)

B.7.4.1 Hydrolysis rate of relevant metabolites, degradation and reaction products (Annex IIA 7.2.1.1)

The study 'Determination of the hydrolysis of ^{14}C-thiram (Norris K., 1991)
The method is described under point B.2.1.1.5
Findings and conclusions :
Thiram rapidly breaks down in alkaline and neutral solutions.
DT_{50} (pH 5) = 68.5 days
DT_{50} (pH 7) = 3.5 days
DT_{50} (pH 9) = 6.9 hours
The major metabolite was CS_2 which is volatile.

No data on metabolites of thiram is required

B.7.4.2 Direct phototransformation of relevant metabolites, degradation and reaction products in water (Annex IIA 7.2.1.2)

Identification of the aqueous photodegradation products of ^{14}C-thiram (Mc Manus J., 1990)
The method is described under point B.2.1.1.6
Findings and conclusions :
Thiram is rapidly photodegraded.
DT_{50} (pH 5) = 8.8 hours
The major metabolite was CS_2 which is volatile.

No data on metabolites of thiram is required

B.7.4.3 Ready biodegradability of the active substance (Annex IIA 7.2.1.3.1)

Not submitted.

B.7.4.4 Water/sediment study (Annex IIA 7.2.1.3.2)

Degradation and metabolism of thiram in aquatic systems (Wyss-Benz M., 1992)
Guidelines :
BBA Richtlinien Teil IV : 5-1
GLP :
Yes
Material and Methods :
Test substance : thiram labelled with ^{14}C at both thiocarbonyl positions of the molecule, Radiochemical purity: 99.7 %. Specific radioactivity: 17 mCi/mMol
Water and sediment :
Waters and sediments were collected in the Rhine river and in the Judenweiher pond, both located in Switzerland (Aargau)

Table B.7.4.4-1 : Characteristics of water from Rhine river and Judenweiher pond

Parameter	**Rhine**	**Judenweiher**
Temperature (°C)		
at surface	17.1	12.8
5 cm above sediment	17.1	12.8
pH		
at surface	7.90	> 7
5 cm above sediment	7.85	-
Redox potential (mV)		
at surface	247	215
5 cm above sediment	239	168
O_2-content (mg/l/%)		
at surface	8.4	1.9
5 cm above sediment	8.4	1.9
Total N (mg/l)	2.05	0.94
Total P (mg/l)	0.08	0.07
TOC (mg C/l)	8.6	79.6
Water hardness	10	21

Table B.7.4.4-2 : Characteristics of sediments from Rhine river and Judenweiher pond

Parameter	**Rhine**	**Judenweiher**
USDA soil classification	loamy sand	loam
Particle size distribution (%)		
Clay	4.5	18.4
Silt	16.2	33.6
Sand	79.3	48.0
Organic C (%)	0.62	3.18
CEC (mVal N/100 g soil)	4.48	13.73
pH (KCl)	7.31	7.08
Redox potential (mV)	-114	-417
Total N (g/kg dry soil)	0.74	1.63
Total P (g/kg dry soil)	0.30	0.41
Biomass (mg microbial C/ 100g dry soil)	26.8	173.1
Dry mass (kg dry soil/kg fresh sediment)	0.67	0.58

Test conditions :
1.195 mg a.s./l water was applied to the flasks containing 220 ml of river water and 93.8 g of river sediment (dry weight) .
1.378 mg a.s./l water was applied to the flasks containing 220 ml of pond water and 91.6 g of pond sediment (dry

weight) .
Duplicate samples for river and pond were incubated at 20 ± 2 °C in the dark.
pH, oxygen concentration and redox potential were monitored during the acclimation period and during the incubation period.
Analytical methods :
- Several water samples were collected at each sampling date. Some of them were immediately analyzed by HPLC in order to avoid degradation of compounds during storage. Some of them were acidified and immediately analyzed by HPLC in order to avoid degradation of some metabolites.
- The sediments were extracted by chloroform and by methanol.
- The following compounds were researched by HPLC in water and extractable fractions of the sediments : Thiram, Tetramethylthiuram monosulphide (TMTM), Dimethyldithiocarbamic acid sodium salt dihydrate (DMDTC), Dimethyldithiocarbamic acid methyl ester (DMDTC-ME), Carbon disulfide, (CS_2) 1,1,3,3-tetramethylurea (TMU), 1,1,3,3-tetramethyl-2-thiourea (TMTU) and Carbonyl sulfide (COS).
- Radioactivity was measured by LSC.
Findings :
Table B.7.4.4-3 : Distribution of radioactivity and balance in the Rhine river water/sediment system (% of applied radioactivity)

	Sampling time (days)									
	0	**0.25**	**1**	**2**	**4**	**7**	**14**	**30**	**57**	**101**
Volatiles : KOH and polyethylene glycol traps	n.p.	0.1	0.2	0.7	2.8	5.2	15.2	37.0	59.7	65.8
Water	107.5	99.0	95.8	94.9	84.6	72.5	47.5	32.3	12.8	6.5
Unknown metabolite 1	-	-	12.31	15.49	22.69	27.63	20.68	14.48	4.69	5.02
Unknown metabolite 2	-	-	-	-	1.26	4.44	7.37	7.12	4.10	1.51
Unknown metabolite 3	-	-	-	1.26	3.18	5.11	14.48	-	4.02	-
Unknown metabolite 4	-	-	-	-	2.09	3.18	-	1.51	-	-
Unknown metabolite 5	-	-	-	-	-	-	-	3.27	-	-
Unknown metabolite 6	-	-	-	-	-	-	-	3.01	-	-
Dimethyldithiocarbamic acid methyl ester	-	-	1.76	1.84	6.36	4.86	4.94	2.85	-	-
Thiram	107.50	99.04	61.20	60.78	26.96	8.04	-	-	-	-
CS_2	-	-	5.27	1.84	6.11	4.10	-	-	-	-
Unknown metabolite 10	-	-	5.69	-	4.60	12.98	-	-	-	-
Unknown metabolite 11	-	-	9.71	13.73	11.30	-	-	-	-	-
Unknown metabolite 12	-	-	-	-	-	2.26	-	-	-	-
Sediment	0.3	2.0	0.5	5.8	6.1	16.3	29.6	22.5	17.8	15.6
Extractable	n.p.	n.p.	n.p.	0.27	0.59	1.39	2.03	2.04	1.61	0.99
Bound residue	n.p.	n.p.	n.p.	5.4	4.86	9.34	27.08	22.93	14.67	15.12
Balance (volatiles + water + sediment)	107.8	101.1	96.5	101.4	93.5	93.9	92.2	91.7	90.2	87.8

n.p. : not performed
- : not detected

Table B.7.4.4-4 : Distribution of radioactivity and balance in the Judenweiher pond water/sediment system (% of applied radioactivity)

	Sampling time (days)									
	0	**0.25**	**1**	**2**	**4**	**7**	**14**	**30**	**57**	**101**
Volatiles : KOH and polyethylene glycol traps	n.p.	0.1	0.3	0.5	3.8	5.2	24.3	42.3	60.3	60.8
Water	107.5	102.6	98.1	89.1	80.6	70.1	43.9	21.3	13.8	6.1
Unknown metabolite 1	-	-	4.94	15.23	22.92	25.68	21.83	10.96	9.29	5.02
Unknown metabolite 2	-	-	-	-	7.70	6.02	15.06	2.34	-	1.00
Unknown metabolite 3	-	-	-	-	-	4.02	-	1.76	-	-
Unknown metabolite 4	-	-	-	-	0.92	0.67	3.26	-	-	-
Unknown metabolite 5	-	-	-	-	-	-	-	4.10	4.52	-
Unknown metabolite 6	-	-	-	-	-	-	-	-	-	-
Dimethyldithiocarbamic acid methyl ester	-	-	3.60	1.17	5.52	3.76	3.68	2.09	-	-
Thiram	107.50	102.48	75.21	62.99	24.93	2.51	-	-	-	-
CS_2	-	-	3.85	1.25	7.19	8.70	-	-	-	-
Unknown metabolite 10	-	-	5.69	-	7.86	12.80	-	-	-	-
Unknown metabolite 11	-	-	4.94	8.45	3.43	5.86	-	-	-	-
Unknown metabolite 12	-	-	-	-	-	-	-	-	-	-
Sediment	0.3	3.1	5.7	10.5	9.9	22.9	25.4	34.7	24.3	23.9
Extractable (*)	n.p.	0.07	0.13	0.39	0.80	1.33	1.80	3.89	1.97	1.28
Bound residue (*)	n.p.	3.39	6.58	11.32	9.4	13.71	19.66	27.83	21.55	30.23
Balance (volatiles + water + sediment)	107.8	105.8	104.0	100.0	94.2	98.1	93.5	98.2	98.4	90.7

n.p. : not performed
- : not detected
(*) : Recovery was in the range 64-153%

Conclusions :
^{14}C thiram which was only detected in the water phase of both systems degraded very rapidly.
River system : DT_{50} = 46.07 hours; DT_{90} = 153.03 hours
Pond system : DT_{50} = 31.78 hours; DT_{90} = 105.57 hours

Two known metabolites (dimethyldithiocarbamic acid methyl ester and CS_2) were detected in the water phase; Several unknown metabolites were detected at arate higher than 10% during the incubation period. Identification of these metabolites of concern is necessary.

Release of CO_2 was important in both systems.
The main part of the sediment radioactivity was constituted of bound residue unextractable by chloroform and

methanol.
Thiram degraded very rapidly to dimethyldithiocarbamic acid sodium salt dihydrate and then to CS_2. After a period of about 7 days, remaining metabolites in the water as well as in the sediment are metabolized mainly to CO_2 (mainly in the river system)
A metabolic pathway of thiram in water/sediment system was proposed (Figure B.7.4.4-1)

^{14}C-Thiram: Degradation and metabolism in an anaerobic aquatic system (Wyss-Benz M., 1995)
Guidelines :
(U.S.) EPA 540/9-82-021: Pesticide Assessment Guidelines, Subdivison N: Section 162-3
GLP :
Yes
Material and Methods :
*Test substance:*thiram labelled with ^{14}C at both thiocarbonyl positions of the molecule, Radiochemical purity: 100.0 %. Specific radioactivity: 18.1 mCi/mMol
Water and sediment :
Water and sediment sampled from a pond located in Alabama known to be submitted to discharges of near human activity. Water was screened for major pesticides (all below limit of detection)

Table B.7.4.4-5 : Characteristics of water from Alabama pond

Parameter	**Alabama**
Temperature (°C)	15.5
pH	5.62
Redox potential (mV)	n.d.
O_2-content (mg/l)	7.9
Total N (mg/l)	0.05
Total P (mg/l)	0.09
TOC (mg C/l)	4.3
Water hardness (°dH)	<1

Table B.7.4.4-6 : Characteristics of sediment from Alabama pond

Parameter	**Alabama**
USDA soil classification	Clay loam
Particle size distribution (%)	
Clay	39.2
Silt	31.6
Sand	29.2
Organic C (%)	1.72
CEC (mVal N/100 g soil)	13.39
pH (KCl)	5.3
Redox potential (mV)	n.d.
Total N (g/kg)	2.188
Total P (g/kg)	0.518

Biomass (mg microbial C/ 100g dry soil)	115.8
Dry mass (kg dry soil/kg fresh sediment)	0.47

Test conditions :
12.2 mg a.s./l water was applied to the flasks containing 530 ml of pond water and 150 g of pond sediment (dry weight) .
Duplicate samples were incubated at 20 ± 2 °C in the dark.
Anaerobic conditions in water maintained by ventilation of water with N2 stream without disturbing the sediment. pH, oxygen concentration and redox potential were monitored during the acclimation period and during the incubation period.
Analytical methods :
- Extraction of water and sediment by chloroform.
- The following compounds were researched by HPLC in water and extractable fractions of the sediments : Thiram, Tetramethylthiuram monosulphide (TMTM), Dimethyldithiocarbamic acid sodium salt dihydrate (DMDTC), Dimethyldithiocarbamic acid methyl ester (DMDTC-ME), Carbon disulfide, (CS_2) 1,1,3,3-tetramethylurea (TMU), 1,1,3,3-tetramethyl-2-thiourea (TMTU) and Carbonyl sulfide (COS).
- TLC was used for the confirmation of thiram only..
- Radioactivity was measured by LSC.
Findings :
Table B.7.4.4-7 : Distribution of radioactivity and balance in a pond water/sediment system under anaerobic conditions (% of applied radioactivity)

	Sampling time (days)										
	0	**1**	**2**	**4**	**7**	**14**	**21**	**42**	**84**	**168**	**252**
Volatiles : KOH and polyethylene glycol traps	n.p.	0.3	1.0	11.5	23.6	70.4	71.9	81.1	77.9	79.8	93.3
CS_2 (*)	n.p.	0.2	2.4	17.7	33.7	71.0	74.4	75.9	76.8	77.3	77.5
CO_2 (*)	n.p.	-	-	-	-	7.9	9.6	10.4	11.5	14.0	15.8
Water	99.0	82.0	81.4	63.6	45.0	8.4	8.1	2.8	3.0	2.3	1.4
Thiram	95.95	77.40	74.70	48.55	23.30	0.30	4.15	1.00	1.45	0.90	-
CS_2	-	1.80	4.85	11.40	17.20	5.00	-	-	-	-	-
Unknown metabolite M9	2.00	-	-	0.90	1.65	1.10	1.90	1.20	1.00	0.25	-
Unknown metabolite M6	-	-	-	-	-	-	0.6	-	-	-	-
Unknown metabolite M8	-	-	-	-	-	-	-	-	-	0.15	-
Sediment (extractable + bound)	3.0	16.2	16.1	21.1	23.3	19.4	20.0	16.1	15.8	18.9	5.3
Extractable	1.15	9.95	7.25	11.30	12.00	9.30	10.90	7.50	5.00	11.70	1.35
- Thiram	1.10	6.30	2.00	2.10	2.25	2.30	5.05	2.65	2.45	5.85	-
- CS_2	-	1.70	3.40	6.25	7.30	4.10	1.30	1.45	0.00	1.30	-
-Unknown metabolite M9	0.10	1.95	1.85	2.90	2.40	2.75	4.40	3.35	2.50	4.00	-
Bound residue	1.80	6.25	8.85	9.80	11.25	10.10	9.10	8.60	10.80	7.25	4.00

	Sampling time (days)										
	0	**1**	**2**	**4**	**7**	**14**	**21**	**42**	**84**	**168**	**252**
Balance (volatiles + water + sediment)	102.0	98.5	98.5	96.2	91.8	98.2	100.0	100.0	96.7	101.0	100.0

n.p. : not performed
- : not detected
(*) : The contributions of CO_2 and CS_2 do not give the right sum for volatile compounds. Nevertheless the evolution pattern of both compounds is correct.

Conclusions :
Thiram is rapidly degraded in water/sediment system under anaerobic conditions. Main part of a.s. is present in water phase.
DT_{50} (whole system) = 4 days
DT_{90} (whole system) = 22 days
The main metabolite was CS_2 which appeared very fast mainly within the first 14 days and then reached 77.5% applied radioactivity after 252 days. Another important metabolite was CO_2 which appeared after day 7 and reached 15.8% at day 252.
Three other unindentified metabolites (M6, M8, M9) were of minor importance.

B.7.4.5 Degradation in the saturated zone of active substance, metabolites, degradation and reaction products (Annex IIA 7.2.1.4)

Not submitted. Not required. It is not expected that the active substance or its metabolites will be found in the saturated zone.

B.7.5 Impact on water treatment procedures (Annex IIIA 9.2.2)

Not submitted. More information is required.

B.7.6 Summary of behaviour in water and predicted environmental concentrations in surface water and in ground water (PECsw, PECgw) (Annex IIIA 9.21, 9.2.3)

B.7.6-1 : Summary of behaviour of thiram in water

Test medium (soil, sediment, water)				**Test system**	**Results**	**References**
Medium type	**pH**	**CEC**	**Organic carbon content (%)**			
Buffer solutions	5 7 9	-	-	Hydrolysis at 25°C in the dark	DT_{50} (pH5) = 68.5 days DT_{50} (pH 7) = 3.5 days DT_{50} (pH 9) = 6.9 hours	Norris K., 1991
Buffer solution	5	-	-	Photolysis at 25°C (12 hours light/12 hours dark)	DT_{50} (pH5) = 8.8 hours	Mc Manus J., 1990
Rhine river water/ sediment	 7.85 7.31	 - 4.48	 - 0.62	Water/sediment study at 20°C in the dark, under aerobic conditions	DT_{50} = 46.07 hours (*) DT_{90} = 153.03 hours (*)	Wyss-Benz M., 1992

Judenweiher pond water/ sediment	>7 7.08	- 13.73	- 3.18		DT_{50} = 31.78 hours (*) DT_{90} = 105.57 hours (*)	
Alabama pond Water/ sediment	5.62 5.3	- 13.39	- 1.72	Water/sediment study at 20°C in the dark, under anaerobic conditions	DT_{50} = 4 days (*) DT_{90} = 22 days (*)	Wyss-Benz M., 1995

(*) : DT for whole system; the main part of thiram is found in the water phase.

PECsw :

The estimations of the PECsw were calculated for foliar spray applications assuming that :

- DT_{50} = 4 days : (water/sediment study under anaerobic conditions). The degradation rate was calculated according to first order kinetics. A DT_{50} reflecting the actual rate of degradation of thiram cannot be easily determined. The rate of degradation is depending upon the pH of water (degradation is slower under acidic conditions) , the temperature (lab tests at 20-25°C; natural conditions : 10-15°C).

First order dissipation PECsw and TWA PECsw were calculated according to the recommendations of the FOCUS group (Doc 7617/VI/96 - Feb. 97)

- water layer : 30 cm
- the spray drift scenarios are determined according to Ganzelmeier (1995)
- Two scenarios were chosen :
  - strawberries, 3.2 kg a.s./ha, 4 applications/season, at 7 days interval
  - orchard, 2.4 kg a.s./ha, 6 applications/season, 7 days interval

Table B.7.6-2 : PEC_{sw} for foliar spray applications (mg a.s./l water) - first order kinetics

Time after applications (days)	strawberries 3.2 kg a.s./ha		Orchard 2.4 kg a.s./ha	
	direct application (drift = 100 %) (*)	application at 1 m of the surface water (drift = 5%)	direct application (drift = 100 %) (*)	application at 5 m of the surface water (drift = 20%)
0	1.066	0.053	0.800	0.160
1	0.897	0.045	0.673	0.1345
2	0.754	0.038	0.566	0.113
4	0.533	0.027	0.400	0.080
7	0.317	0.016	0.238	0.048
14	0.094	0.005	0.071	0.014
21	0.028	0.001	0.021	0.004

28	0.008	0.0004	0.006	0.001
42	0.0007	-	0.0006	0.0001

(*) : overspray situation; given only to help the reader

Table B.7.6-3 : TWA PECsw of thiram in mg a.s./l water - foliar applications - repeated applications

	Strawberries 3.2 kg a.s./ha 4 applications 7 days interval		Orchard 2.4 kg a.s./ha 6 applications 7 days interval	
	Overspray situation 100% drift (*)	1 m spray drift 5% drift	Overspray situation 100% drift (*)	5 m spray drift 20% drift
TWA concentration once plateau is reached	0.88	0.043	0.660	0.132

(*) : overspray situation; given only to help the reader

Calculation of PEC for the relevant metabolites is required in order to evaluate the risk resulting from the presence of these compounds.

B.7.7 Fate and behaviour in air (Annex IIA, 7.2.2; Annex IIIA 9.3)

Not submitted.

B.7.8 Summary of behaviour in air and predicted environmental concentrations in air (PECa) (Annex IIIA 9.3)

Not submitted.

B.7.9 Definition of the residue (Annex IIA 7.3)

Major metabolites of thiram are CS_2 and CO_2.
It should be necessary to identify the other major metabolites which were recovered in the water/sediment study.
The residue is therefore defined as the sum of thiram and the major metabolites.

B.7.10 References relied on

See Annex A.

ANNEX B

Thiram

B.8 Ecotoxicology

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

B.8.1.1 Acute oral toxicity (Annex IIA 8.1.1)

No study submitted

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

No study submitted

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

No study submitted

B.8.1.4 Acute oral toxicity of the preparations (Annex IIIA 10.1.1)

No study submitted

B.8.1.5 Supervised cage or field trials (Annex IIIA 10.1.2)

No study submitted

B.8.1.6 Acceptance of bait, granules or treated seeds by birds (palatability test) (Annex IIIA 10.1.3)

Repellency study of VITAVAX 200FF on common pheasant (*Phasianus colchicus*) (Hadhazy A., 1990)
Guidelines :
BBA-Richtlinie 25-1 zur Prüfung von Pflanzenbehandlungsmitteln auf Vogelgefahrdung
GLP :
no
Material and Methods :
Test substance: VITAVAX 200FF (containing 170 g/l carboxin and 170 g/l thiram)
Test species : Common pheasant *(Phasianus colchicus)*
Sex, weight, age : female birds, more than 16 weeks
Experimental design :
10 female birds receiving 50% treated maize seeds (application rate of 2 l formulation/T ; 340 mg thiram/kg maize and 340 mg carboxin/kg maize) and 50% untreated maize seeds and were free to choose their food. (60 g seed/bird/d)

2 controls :
5 female birds receiving 50% untreated seeds (30 g seed/bird/d)
5 female birds receiving 100% untreated seeds (60 g seed/bird/d)

After 7 days of acclimation the birds were fed for 7 days with treated maize seeds
Weather conditions were recorded during the test.
Findings :
Mortality : No
Food consumption : The birds of the treated group consumed 7.77% treated seeds and 92.0% untreated seeds
Bodyweigth : Bodyweights and bodyweight changes were in accordance with food uptake.
Clinical symptoms : No gross pathological changes.
Conclusions :
Birds can detect the presence of formulation VITAVAX 200FF in their diet. This study gives no indication of the own palatibility of thiram (thiram alone in the formulation).

B.8.1.7 Effects of secondary poisoning (Annex IIIA 10.1.4)

No study submitted

B.8.1.8 Summary of effects to birds - exposure and risk assessment for birds (Annex IIIA 10.1)

One palatability study performed with formulation VITAVAX 200FF (thiram + carboxin) showed repellency effects on pheasant.

According to literature data provided by the notifier the most sensitive avian species are :

Table B.8.1.8-1 : Literature data on the toxicity of thiram

Test species	Test system	Duration of exposure	Results	References
Japanese quail	Acute oral test	single exposure	LD50 = 695 mg a.s./kg	Gruen et al., 1982
Bobwhite quail	Short-term dietary	5 days	LC50 = 3950 mg a.s./kg	Hill et al. 1975

The evaluation of the acute and short-term risk in the case of seed treatment

The risk assessment is based on the following assumptions :
- The application rate on maize or pea was chosen (200 g a.s./100 kg seed or 2000 mg a.s./kg food)
- The 'nominal' rate of application was taken into account assuming that no degradation of the a.s. occurred just after sowing.
- Scenarios for small birds (30% food consumption) and large birds (10% food consumption) were evaluated.

The evaluation which was made (TER acute and short term between 1 and 3) may be considered as a worst case situation since it does not take into account the possible degradation of thiram in the soil or at its surface. Nevertheless this evaluation showed that valid toxicity data are required.

The evaluation of long-term effects was not performed due to the absence of a subchronic toxicity study.

Tab. B.8.1.8-2 : Toxicity exposure ratios (TER's) for birds exposed to thiram - Seed treatment

Bird type	food consumed	Effect concentration	Estimated Theorical Exposure	Type of TER	Toxicity Exposure Ratio
small bird (<100g bw)	pea or maize	695 mg a.s./kg bw	600 mg a.s./kg bw	LD_{50}/ETE	1
		3950 mg a.s./kg feed	2000 mg a.s./kg feed	LC_{50}/ETE	2
large bird (>100 g bw)	pea or maize	695 mg a.s./kg bw	200 mg a.s./kg bw	LD_{50}/ETE	3
		3950 mg a.s./kg feed	2000 mg a.s./kg feed	LC_{50}/ETE	2

The evaluation of the acute and short-term risk in the case of foliar spray in orchard and vineyard

The risk assessment is based on the following assumptions :
- The application rate of 3.2 kg a.s./ha in vineyard was taken as 'worst case' situation.
- The initial concentration of thiram in the food was estimated according to Hoerger and Kenaga (1972)
- Scenarios for small birds (30% food consumption) and large birds (10% food consumption) were evaluated.

The evaluation of acute TER (23-70) and short-term TER (40) showed that the risk resulting from the use of thiram in vineyard and orchard is low.
The evaluation of long-term effects was not performed due to the absence of subchronic toxicity study.

Table B.8.1.8-3 : Estimated initial concentration of thiram in potential feed of birds - Foliar application

Target crop	**Application rate (g a.s./ha)**	**Estimated initial residues (mg a.s. kg food)**		
		Leaves and leafy crops	**Small seeds and small insects**	**Large insects**
Vineyard	3200 g a.s./ha	99.2	92.8	8.64

Table B.8.1.8-4 : Estimated oral uptake of thiram by birds - Foliar application

Target crop	**Bird type**	**food consumed**	**food consumption (% bw)**	**Max. daily intake (mg a.s./kg bw / day)**
Vineyard	small bird (< 100g bw)	Leaves and leafy crops	30	29.76
		Small seeds and small insects	30	27.84
		Large insects	30	2.59
Vineyard	large bird (>100g bw)	Leaves and leafy crops	10	9.92
		Small seeds and small insects	10	9.28
		Large insects	10	0.86

Table B.8.1.8-5 : Toxicity exposure ratios (TER's) for birds exposed to thiram - Foliar applications - worst cases

Bird type	**food consumed**	**Effect concentration**	**Estimated Theorical Exposure**	**Type of TER**	**Toxicity Exposure Ratio**
small bird	Leaves and leafy crops	695 mg a.s./kg bw	29.76mg a.s./kg bw	LD_{50}/ETE	23
		3950 mg a.s./kg feed	99.2 mg a.s./kg feed	LC_{50}/ETE	40

large bird	Leaves and leafy crops	695 mg a.s./kg bw	9.92 mg a.s./kg bw	LD_{50}/ETE	70
		3950 mg a.s./kg feed	99.2 mg a.s./kg feed	LC_{50}/ETE	40

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

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

Fish toxicity - 96 hour toxicity study on rainbow trout (*Salmo gairdneri*) (He/Ko, 1977)
Guidelines :
Not mentioned.
GLP :
No
Material and Methods :
Test substance : Thiram Technical (Purity: 96,7%) (no indication on origin)
Test species : Rainbow trout (*Salmo gairdneri*)
Number of organisms, weight, length, age : 10 fishes per 15 l of water in each aquarium, loading : 0,6-0,8 g/l solution, 4 - 5.6 cm
Type of test : Acute toxicity test (96 hours, static)
Applied and measured concentrations : 0.13, 0.14, 0.15, 0.17, 0.19 and 0.20 mg/l and a solvent control
Concentrations were not measured during the test.
Test conditions :
temperature : 16 °C,
pH : 6.8 - 8.0
oxygen content : 10.0 mg O_2 /l (0 h) to 7.0 - 9.4 mg O_2 /l (96 h)
total hardness : 2.13 ± 0.04 mmole Ca^{2+}
Photoperiod : -
Analytical methods : not realized
Findings :
Mortality : The fishes predominantly died during the first 24 hours.
Behavioral observations : Slight symptoms at the lowest concentration. In the other concentrations, mean or severe symptoms (no clear definition of these levels)
Endpoints :
LC_{50} (96h) = 0.16 (0.15 - 0.18) mg a.s./l
Conclusions :
Thiram is very toxic to rainbow trout.
The study is not accepted due to its poor quality (no information on the fishes used, no analytical data, no description of symptoms...)

Thiram: Acute toxicity to sheepshead minnow (*Cyprinodon variegatus*) (Croudace C., 1992)
Guidelines :
U.S. EPA FIFRA, Subdivision E, Guideline 72-3
GLP :
Yes
Material and Methods :
Test substance : Thiram Technical, a.s. as manufactured, purity: 99% (pre-analyses) and 98;3 % (re-analyses), lot # V614/0801 AC.
Test species : Sheepshead minnow *(Cyprinodon variegatus*)
Number of organisms, weight, length, age : 20 test organisms/concentration and solvent and dilution water controls
; 1.17 g (0.71 - 1.76 g), 33 mm (28-38 mm)

Type of test : 96 hours dynamic (flow-through) test
Applied and measured concentrations : 0, 0.056, 0.10, 0.18, 0.32, 0.56 and 1 mg a.s. /l, and solvent control
measured concentrations ranging from 90 to 96% of the nominal concentrations
Test conditions :
Dissolved oxygen, pH and temperature were measured daily.
temperature : 22 ± 1°C
pH : 8.18 - 8.23
oxygen content : 6.6 - 6.8 mg O_2 /l (0 h) to 6.2 - 6.4 mg O_2 /l (96 h)
total hardness : -
Photoperiod : -
Analytical methods : Test solutions were analyzed by HPLC method (ICI Group Environmental Laboratory standard operating procedure AL245, version 02 and AL200, version 02) at 0, 24, 48, 72 and 96 hours.
Findings :
Mortality : The majority of the fishes died during the first 24 hours of the test (25% at 0.56 mg/l and 80% at 1.0 mg/l)
Behavioral observations : Significant effects (quiescent, surfacing, sounding and dark discolouration) were observed at the concentrations 0.18 to 1.0 mg/l
Endpoints :
LC_{50} (96h) = 0.54 mg a.s./l (95% confidence limits : 0.485 - 0.62)
NOEC (96h) = 0.09 mg a.s./l
Conclusions :
Thiram is very toxic to *Cyprinodon varieagatus*.

B.8.2.2 Fish early life stage toxicity (Annex IIA 8.2.2.1)

Not submitted.

B.8.2.3 Fish juvenile growth test (Annex IIA 8.2.2.2)

Not submitted. Required (one test under point IIA 8.2.2.1, IIA 8.2.2.2 or IIA 8.2.2.3)

B.8.2.4 Fish life cycle test (Annex IIA 8.2.2.3)

Not submitted.

B.8.2.5 Bioaccumulation potential in fish (Annex IIA 8.2.3)

Not submitted. Based on the value of log Pow (1.72), thiram is not bioconcentrated.

B.8.2.6 Acute toxicity to invertebrates (Annex IIA 8.2.4)

Acute toxicity to *Daphnia magna* (Bell G., 1994)
Guidelines :
OECD Guideline for Testing of Chemicals No. 202, Part I "*Daphnia* Acute Immobilisation Test",
and EEC method C2
GLP :
Yes
Material and Methods :
Test substance : Thiram Technical, a.s. as manufactured, purity: 98.8%, Batch #V620/0801 AC.
Test species : Waterflea (*Daphnia magna)*
Number of organisms, age : 20 animals/ test group; young waterfleas <24 hours.

Type of test : Static immobilisation test (48 hours)
Applied and measured concentrations :
0, 1.0, 2.0, 4.0, 8.0, 16, 32 and 64 µg a.s. /l
Measured concentrations were in the range 25.2 - 92.7 % (0 h) and 0 - 42.6 % (48 h) of nominal concentrations.
Test conditions :
pH (0 and 48 hours) , dissolved oxygen (0 and 48 hours) and temperature (0, 24 and 48 hours) were recorded
temperature : 22 °C
pH : 7.0 - 7.2 (0 hour) and 7.5 - 7.7 (48 hours)
oxygen content 8.7 mg O_2 /l (0 hour) and 7.9 - 8.2 mg O_2 /l (48 hours)
total hardness : -
Photoperiod : 16 hours light/8 hours dark
without supplementary aeration or feeding during the 48 hours exposure period.
Analytical methods :
Test solutions were analyzed by HPLC at 0 and 48 h
Findings :
Endpoints :
EC_{50} (24 h) = 0.026 mg a.s./l (95% confidence limits : 0.022 - 0.031) (nominal concentrations)
EC_{50} (48 h) = 0.011 mg a.s./l (95% confidence limits : 0.009 - 0.013) (nominal concentrations)
EC0 (48h) = 0.001 mg a.s./l (nominal concentrations)
Conclusions :
Thiram is very toxic to *Daphnia magna.*

B.8.2.7 Chronic toxicity to aquatic invertebrates (Annex IIA 8.2.5)

Not submitted. Required.

B.8.2.8 Effects on algal growth (Annex IIA 8.2.6)

Thiram: Algal growth inhibition (Douglas M., 1993)
Guidelines :
OECD Guideline No. 201 “Alga, Growth Inhibition Test”,
EEC Method and
EPA Pesticide Assessment Guidelines, Subdivision J, Sections 122-2 and 123-2
GLP :
Yes
Material and Methods :
Test substance : Thiram Technical, a.s. as manufactured, purity: 99% (pre-analyses) and 98.3 % (re-analyses), white powder, lot # V614/0801 AC.
Test species : Green alga *(Selenastrum capricornutum),* Strain No. CCAP 278/4
Type of test : Static test (120 hours)
Applied and measured concentrations :
nominal concentrations: 0.0125, 0.025, 0.050, 0.10, 0.20 and 0.40 mg/l
Measured concentrations were in the range 65-86 % (0 h) and 0-15 % (48 h) of nominal concentrations.
Test conditions :
pH (at 0 and 120 h) and temperature (at 0, 24, 48, 72, 96 and 120 h) were recorded.
temperature : 24°C ± 1°C
pH : 8.1 - 8.2 (0 h), 8.3 - 9.7 (120 h)
oxygen content : -
total hardness : -
Photoperiod : continuous illumination
Analytical methods :
Test solutions were analyzed by a HPLC method at 0 and 120 hours
Findings :
Endpoints :
E_bC_{50} (72 h) = 0.065 mg a.s./l (95% confidence limits = 0.059-0.070)

E_bC_{50} (120 h) = 0.076 mg a.s./l (95% confidence limits = 0.069-0.083)
E_rC_{50} (0-24 h) = 0.12 mg a.s./l (95% confidence limits = 0.11-0.13)
NOEC (120h) = 0.0057 mg a.s./l
Conclusions :
Thiram is very toxic to *Selenastrum capricornutum.*

B.8.2.9 Effects on the organisms of the sediments (Annex IIA 8.2.7)

Not submitted. Not required : In the water/sediment study, thiram mainly remains in the water phase of the system.

B.8.2.10 Effects on aquatic plants (Annex IIA 8.2.8)

Not submitted.

B.8.2.11 Acute toxicity of the preparations (Annex IIIA 10.2.1)

Not submitted. Required.

B.8.2.12 Microcosm and mesocosm study (Annex IIIA 10.2.2)

Not submitted. Required.

B.8.2.13 Residue data in fish (Annex IIIA 10.2.3)

Not submitted. Not required : the substance is not bioaccumulated.

B.8.2.14 Supplementary studies of toxicity to fish and aquatic invertebrates (Annex IIIA 10.2.4)

Not submitted.

B.8.2.15 Summary of effects to water organisms - Exposure and hazard assessment for aquatic organisms (Annex IIIA 10.2)

Table B.8.2.15-1 : Summary of effects of thiram to water organisms

Test species	Test system	Duration of exposure	Results	References
Cyprinodon variegatus	Flow-through test	96 hours	LC_{50} = 0.54 mg a.s./l NOEC = 0.09 mg a.s./l	Croudace C., 1992
Daphnia magna	Static test	48 hours	EC_{50} = 0.011 mg a.s./l	Bell G., 1994
Selenastrum capricornutum	Static test	120 hours	E_bC_{50} (72h) = 0.065 mg a.s./l	Douglas M., 1993

Acute risk for aquatic organisms :
Exposure of water surface is mainly due to spray drift resulting from application in orchard and vineyard . We assumed that the contribution of other routes of contamination is small in comparison with the drift (20% of applied dose at 5 m of water surface)

The following assumptions were made to assess the acute risk for water organisms :
- water layer : 30 cm
- the spray drift scenarios are determined according to Ganzelmeier (1995) : orchard early growth stage
- Initial PEC were taken into account.
- application in orchard at the highest application rate of 2.4 kg a.s./ha.

The TERacute (all were far below the threshold values of 100 for fish and aquatic invertebrate and 10 for alga) show that an acute risk for the aquatic organisms is existing. (Table B.8.2.15-2)

Chronic risk to aquatic organisms :
Repeated or continuous exposure of aquatic organisms has to be taken into account in the evaluation of the risk. GAP recommend 2-4 applications at 7-14 days interval in orchard and grapes.

In absence of chronic toxicity tests it is impossible to evaluate the TER long term at this stage.

Acute and chronic risk resulting from the presence of metabolites :
Information is required. In absence of information on the identity of the metabolites and their toxicity, no assessment can be made.

Table B.8.2.15-2 : Theoretical Exposure Ratio for aquatic organisms exposed to thiram - Drift scenarios in orchard

Target crop	**Distance (m)**	**Test species**	**Effect concentration**	**Estimated initial concentration (mg a.s./l)**	**TER**
orchard (2.4 kg a.s./ha)	0	*Cyprinodon variegatus*	0.54 mg a.s./l	0.800	0.7 (*)
	5			0.160	3
	10			0.088	6
	20			0.032	17
	30			0.016	34
	50			0.0016	338
	0	*Daphnia magna*	0.011 mg a.s./l	0.800	0.01 (*)
	5			0.160	0.07
	10			0.088	0.1
	20			0.032	0.3
	30			0.016	0.7
	50			0.0016	7
	0	*Selenastrum capricornutum*	0.065 mg a.s./l	0.800	0.08 (*)
	5			0.160	0.4
	10			0.088	0.7
	20			0.032	2

	30			0.016	4
	50			0.0016	40

(*) : overspray situation. This situation is not taken into account in the risk assessment

B.8.3 Effects on other terrestrial vertebrates (Annex IIIA 10.3.1)

The evaluation of the acute risk in the case of seed treatment

The risk assessment is based on the following assumptions :
- LD_{50} (rat) = 1800 mg/kg bw
- The application rate on maize or pea was chosen (200 g a.s./100 kg seed or 2000 mg a.s./kg food)
- The 'nominal' rate of application was taken into account assuming that no degradation of the a.s. occurred just after sowing.
- Scenario for small mammal (30% food consumption) was evaluated.

A high acute risk was identified for small mammals eating treated seeds. More information on the effects of thiram is required (unpalatability,...)

Table B.8.3-1 : Toxicity Exposure Ratio's for mammals exposed to thiram.

Mammal type	**food consumed**	**Effect concentration**	**Estimated Theorical Exposure**	**Type of TER**	**Toxicity Exposure Ratio**
small mammal (<100g bw)	pea or maize	1800 mg a.s./kg bw	600 mg a.s./kg bw	LD_{50}/ETE	3

The evaluation of the acute risk in the case of foliar spray in orchard and vineyard

The risk assessment is based on the following assumptions :
- LD_{50} (rat) = 1800 mg/kg bw
- The application rate of 3.2 kg a.s./ha in vineyard was taken as 'worst case' situation.
- The initial concentration of thiram in the food was estimated according to Hoerger and Kenaga (1972)
- Scenarios for small mammals (30% food consumption) and large mammals (10% food consumption) were evaluated.

The evaluation of acute TER for small mammals eating leafy crops or small insects (TER= 60) or large mammals eating grass (TER = 50) showed that the acute risk resulting from the use of thiram in vineyard and orchard is low.

Table B.8.1.8-2 : Estimated initial concentration of thiram in potential feed of mammals - Foliar application

Target crop	**Application rate (g a.s./ha)**	**Estimated initial residues (mg a.s. /kg food)**		
		Leaves and leafy crops	**Small seeds and small insects**	**Range grass**
Vineyard	3200 g a.s./ha	99.2	92.8	358.4

Table B.8.1.8-3 : Estimated oral uptake of thiram by mammals - Foliar application

Target crop	**Bird type**	**food consumed**	**food consumption (% bw)**	**Max. daily intake (mg a.s./kg bw / day)**
Vineyard	small mammal (< 100g bw)	Leaves and leafy crops	30	29.76
		Small seeds and small insects	30	27.84
		Range grass	30	107.52
Vineyard	large mammal (>100g bw)	Leaves and leafy crops	10	9.92
		Small seeds and small insects	10	9.28
		Range grass	10	35.84

Table B.8.1.8-4 : Toxicity exposure ratios (TER's) for mammals exposed to thiram - Foliar applications in vineyard - worst cases

Species	**food consumed**	**Effect concentration**	**Estimated Theorical Exposure**	**Type of TER**	**Toxicity Exposure Ratio**
small mammal	Leaves and leafy crops	1800 mg a.s./kg bw	29.76mg a.s./kg bw	LD_{50}/ETE	60
	Range grass	1800 mg a.s./kg bw	107.52 mg a.s./kg bw	LD_{50}/ETE	17
large mammal	Leaves and leafy crops	1800 mg a.s./kg bw	9.92 mg a.s./kg bw	LD_{50}/ETE	181
	Range grass	1800 mg a.s./kg bw	35.84 mg a.s./kg bw	LD_{50}/ETE	50

The evaluation of the short term risk in the case of seed treatment and foliar spray

The risk assessment is based on a comparison of the estimated initial residues on the food of the small mammals and the NOAEL of the 28 day mouse study (300 ppm) and the 28 day dog study (125 ppm).

Table B.8.1.8-5 : short term TER for mammals exposed to thiram

Food	**Estimated initial residue (mg a.s./kg food)**	**Short term NOAEL (mg a.s./kg food)**	**Short term TER**
Maize or pea seed	2000 mg a.s./kg food (= application rate)	125	0.06
Leaves and leafy crops	99.2 (*)	125	1.3
Small seeds and small insects	92.8 (*)	125	1.3
Range grass	358.4 (*)	125	0.34
Maize or pea seed	2000 mg a.s./kg food (= application rate)	300	0.15
Leaves and leafy crops	99.2 (*)	300	3.0
Small seeds and small insects	92.8 (*)	300	3.2
Range grass	358.4 (*)	300	0.83

(*) : See table B.8.1.8-2

An evaluation of the short term TER (1.3-3.2 < 10) showed the existence of a risk for mammals. The risk is particularly important for the mammals feeding on treated seeds. (TER = 0.06-0.15)

B.8.4 Effects on bees (Annex IIA 8.3.1; Annex IIIA 10.3.2)

B.8.4.1 Acute toxicity to bees (Annex IIA 8.3.1.1)

Not submitted.

B.8.4.2 Bee brood feeding test (Annex IIA 8.3.1.2)

Not submitted.

B.8.4.3 Acute toxicity of the preparations to bees (Annex IIIA 10.4.1)

Not submitted.

B.8.4.4 effects on bees of residues on crops (Annex IIIA 10.4.2)

Not submitted.

B.8.4.5 Cage tests (Annex IIIA 10.4.3)

Not submitted.

B.8.4.6 Field tests to investigate special effects (Annex IIIA 10.4.4)

Not submitted.

B.8.4.7 Tunnel testing to investigate effects of feeding on contaminated honey (Annex IIIA 10.4.5)

Not submitted.

B.8.4.8 Exposure and risk assessment for bees (Annex IIIA 10.4)

The effects of thiram on bees were not investigated. These informations are required.

No risk assessment performed.

B.8.5 Effects on other arthropods species (Annex IIA 8.3.2; Annex IIIA 10.5)

B.8.5.1 Effects of the active substance on non-target terrestrial arthropods (Annex IIA 8.3.2)

Test en tour de Potter *Neoseïlus californicus* (Adulte) (Bourgouin B., 1992)
Guideline:
Not mentioned.
GLP :
No
Material and Methods :
Test substance : Thiram (no indication on purity or type of formulation)
Test species : *Neoseïlus californicus* adult Phytoseiidae (4 different strains)
Number of organisms : 20 adults / treatment
Type of test : laboratory test
Applied concentrations : thiram at 400 g a.s./ha, methidathion and water as positive and negative references.
Exposure route : 5 days of exposure in boxes
Test conditions : -
Findings :
Corrected percentage of mortality are 0, 8.5, 22.5 and 39.5 % respectively for each strain.
Conclusions :
This test shows that thiram is not toxic to adult Phytoseiidae. The description of the test is limited. This test is not realized on the most sensitive stage of the organism

B.8.5.2 Effects of the formulations on non-target terrestrial arthropods (laboratory, semi-field tests) Annex IIIA 10.5.1)

Not submitted.

B.8.5.3 Effects of the formulations on non-target terrestrial arthropods (field tests) Annex IIIA 10.5.2)

Toxicity of thiram to *Typhlodromus pyri* (Research Station of Gorsem, 1993)
Guideline:
IOBC/Working group “Pesticides and beneficial organisms”
GLP :
No
Material and Methods :
Test substance :
Formulation THIANOSAN containing 800 g/kg thiram
Test species :
The trials were realized in orchards with a sufficient number of *Typhlodromus pyri*, at least a mean value of 1 predatory mite on 2 leaves is required. All the predatory mites in the testing orchards are from the same origin, an organophosphates and carbamates resistant strain from the Netherlands.
Experimental design :
- 2 field trials in orchard were performed in 1993; the trials were designed as randomized blocks with 4 replications of 8 trees. Formulations containing captan, mancozeb were tested.
- In each object 4 times 50 leaves were examined with binocular. The Henderson-Tilton formula was applied on these results. Henderson-Tilton criteria < +25% means that the product is harmless
- Maximum and minimum temperatures, sunshine, rainfall, phenological stages of the crop were recorded .
Findings :
Table B.8.5.3-1 : Overview of 2 trials in orchard evaluating the effects of THIANOSAN on *Typhlodromus pyri*

Location	Zelk (Belgium)	Kozen (Belgium)
Crop	apple Jonagold	apple Jonagold
Experimental design	4 replicates/treatment 8 trees/object	4 replicates/treatment 8 trees/object
Number of applications	4 applications on 06/07/93 16/07/93 23/07/93 02/08/93	4 applications on 20/07/93 29/07/93 04/08/93 11/08/93
Application rate	2400 g a.s/ha 1500 l water/ha	2400 g a.s./ha 1500 l water/ha
Henderson-Tilton coefficient	E(after 2 appl.) = 0.9% E(after 4 appl.) = **29.9 %**	E(after 2 appl.) = - 12 % E(after 4 appl.) = 24.8 %

bold : E = 25-49 % slightly harmful; E= 50-74 % moderately harmful; E ³ 75% harmful

Conclusions :
Thiram can be classified after 4 applications as harmless to slightly harmful for *Typhlodromus pyri* according to the IOBC classification for field tests.

Effects of thiram on beneficial insects (Sterk G., et al., 1992)

Guideline:

Method on total fauna in orchard developed by the IOBC/Working group 'Integrated Protection in Orchards'

GLP :

No

Material and Methods :

Test substance :

WP containing 800 g thiram /kg

Test species :

The effects of thiram were studied on the arthropod fauna living on *Carpinus betulus* (beneficials are more abundant on this species than on apple or pear trees)

Experimental design :

The study was performed with 3 replicates. 3 applications of thiram were made.

Directly after spraying plastic sails were placed under the trees. Fallen insects were sampled 1 hour, 1 day, 2 days, 4 days and 7 days after the treatments and were determined. At the end of the experiment 'inventory' was carried out with dichlorvos.

The effects of the a.s. were calculated with the Steiner formula.

Table B.8.5.3-2 : Overview of a field trial on *Carpinus betulus* evaluating the effects of thiram on a wide range of beneficial arthropods

Location	Gembloux (Belgium)
Crop	*Carpinus betulus*
Experimental design	3 replicates/treatment
Number of applications	3 applications
Application rate	160 g a.s./hl sprayed until runoff

Findings :

TableB.8.5.3-3 : Main results of a field trial on *Carpinus betulus* evaluating the effects of thiram on a wide range of beneficial arthropods

Beneficial arthropods		**Steiner coefficient**
Heteroptera	larvae	E = -14.01
	adults	E = -3.44
	total	E = -4.69
Dermaptera	adults	E = 1.01
Chrysopidae	adults	E = -1.16
	larvae	E = -10.02
Coccinellidae	adults	E = 3.97
	larvae	E = -17.35
Syrphidae	adults	E = -0.03
Hymenoptera	adults (parasitica, parasitoid)	E = -7.96

bold : E = 25-49 % slightly harmful

Conclusions :
This experiment showed that thiram is harmless for several groups of beneficial arthropods after 3 applications in *Carpinus betulus* mimicking an orchard situation with important arthropod populations. The report of the study did not contain all the raw data (wheather conditions, timing of applications, individual data, clear indication of the application rate...) The effects on the ground dwelling arthropods are not taken into account by this study.

B.8.5.4 Summary of effects, exposure and risk assessment for non-target terrestrial arthropods

3 studies were performed. they were generally not performed under the 'worst case' GAP conditions, namely apple and pear, 6 treatments/season, 2.4 kg a.s./ha, 240 g a.s./hl
wine grapes, 3 treatments/season , 3.2 kg a.s./ha, 320 g a.s./hl

Due to the fact that the intended uses are mainly in fruit crops where the presence of non-target arthropods is particularly important, studies according to the worst case GAPs are necessary.

Studies of the effects on the ground dwelling arthropods are required to evaluate the risk resulting from foliar spray uses and seed treatment uses

Table B.8.5.4-1 : Summary of effects of thiram on non-target arthropods

Test species	**Test system**	**Results**	**References**
Neoseïlus californicus adult Phytoseiidae (4 strains)	Labo test 400 g a.s./ha	E = 0, 8.5, 22.5 and 39.5 % (quality of the study is questionable)	Bourgouin B., 1992
Typhlodromus pyri	Field test in apple 4 applications 2400 g a.s/ha 1500 l water/ha	E(after 2 appl.) = 0.9% E(after 4 appl.) = **29.9 %**	Research Station of Gorsem, 1993
	Field test in apple 4 applications 2400 g a.s/ha 1500 l water/ha	E(after 2 appl.) = - 12 % E(after 4 appl.) = 24.8 %	
Heteroptera (larvae, adults) Dermaptera (adults) Chrysopidae (larvae, adults) Coccinellidae (larvae, adults) Syrphidae (adults) Hymenoptera (adults)	Field test (*Carpinus betulus*) 3 applications (160 g a.s./hl)	E = -17 to 4% depending on taxa	Sterk G., et al., 1992

B.8.6 Effects on earthworms (Annex IIA 8.4; Annex IIIA 10.3.6)

B.8.6.1 Acute toxicity to earthworms (Annex IIA 8.4.1)

The acute toxicity of Thiram technical to earthworm (*Eisenia foetida*) (Handley J., 1991)
Guidelines :
OECD Guideline 207
GLP :
Yes
Material and Methods :
*Test substance :*Thiram Technical, a.s. as manufactured. Purity: 99.0 %, greyish-powder, major impurities: sodium sulfate and water, Batch No. 0801 AC/V 614.
Test species : Earthworms (*Eisenia foetida*)
Number of organisms, weight, age : 10 worms X 4 replicates/ dose level; 0.40 g (SD 0.08g)
Type of test : Acute toxicity test in artificial soil (14 days)
Applied concentrations : 56.25, 112.5, 225, 450, 900 and 1800 mg a.s./kg (nominal); water control, positive control
Soil type and test conditions :
Test substrate : composed of 69% quartz sand, 20% kaolinite clay, 10% sphagnum peat and 1% $CaCO_3$
water content : 32 % of dry weight of basic substrate for day 0 and 28 % on day 14.
Temperature : 21 °C
Light regime : continuous illumination at 650 Lux
Findings :
Mortality :
8% mortality in the control (<10%)
Observations :
No observed behavioural reactions to exposure
No effect on worm weight
Endpoints :
LC_{50} (14d) = 540 mg a.s./kg substrate (95% confidence limits : 460 - 630)
NOEC = 225 mg a.s./kg ; on the basis that no significant mortalities occurred in this group (i.e. less than 10% mortalities in this test group after 14 days)
Conclusion :
LC_{50} (14d) = 540 mg a.s./kg substrate

B.8.6.2 Sublethal effects on earthworms (Annex IIA 8.4.2)

Not submitted. Not required.

B.8.6.3 Acute toxicity of the formulations to earthworms (Annex IIIA 10.6.1.1)

VITAVAX 200FF - Acute toxicity (LC_{50}) to the earthworm (*Eisenia foetida*) (Johnson A., 1994)
Guidelines :
OECD Guideline 207
GLP :
Yes
Material and Methods :
Test substance : formulation VITAVAX 200FF (FS containing 17.4% carboxin and 17.1% thiram)
Test species : Earthworms (*Eisenia foetida*)
Number of organisms, weight, age : 10 worms X 4 replicates/ dose level; 0.439-0.523 g
Type of test : Acute toxicity test in artificial soil (14 days)
Applied concentrations : 62.5, 125, 250, 500, 1000 mg formulation/kg (nominal); water control, positive control
Soil type and test conditions :
Test substrate : composed of 70% quartz sand, 20% kaolinite clay, 10% sphagnum peat and $CaCO_3$ (pH 5.7)
water content : 34-35% of dry weight of basic substrate for day 0 and 29-31% on day 14.

Temperature : 19-21 °C
Light regime : continuous illumination at 440 Lux
Findings :
Mortality :
0% mortality in control and 500 mg/kg
3-5% mortality at concentrations 62.5, 125, 250 and 1000 mg/kg
Observations :
Weight loss in control and treatments (1-6%)was not dose-related
Endpoints :
LC_{50} (14d) > 1000 mg formulation/kg substrate
NOEC = 1000 mg formulation/kg
Conclusion :
LC_{50} (14d) > 1000 mg formulation/kg substrate

B.8.6.4 Sublethal effects of the formulation on earthworms (Annex IIIA 10.6.1.2)

Not submitted. Not required.

B.8.6.5 Field tests - residue content of earthworms (Annex IIIA 10.6.1.3)

Not submitted. Not required.

B.8.6.6 Summary and hazard assessment for earthworms (Annex III, 10.6.1.1)

Table B.8.6.6-1 : Summary of effects of thiram for earthworms

Test species	**Test system**	**Duration of exposure**	**Results (mg/kg soil)**	**References**
Earthworm *(Eisenia foetida)*	Acute toxicity test in artificial soil	14 days	Thiram technical LC_{50} = 540 mg a.s/kg	Handley J., 1991
Earthworm *(Eisenia foetida)*	Acute toxicity test in artificial soil	14 days	VITAVAX 200 FF LC_{50} > 1000 mg/kg	Johnson A., 1994

The following assumptions were made to assess the acute risk for earthworms :
Soil layer of 5 cm and soil density of 1.5 g/cm^3
Two scenarios were taken into account :
- The application of thiram as seed treatment. The 'worst case' situation was found in pea with a soil concentration of 0.587 mg a.s./ kg soil (sowing rate of 220 kg seed/ha; 200 g a.s./100 kg seed)
- The application of 3.2 kg a.s./ha in vineyard (50% of the a.s. reaching the soil) leading to a concentration of 2.133 mg a.s./kg in soil was considered as 'worst case' situation.

TER acute of 920 and 253 were calculated for these two 'worst case' situations, indicating a low acute risk to earthworm.
Sublethal effects are not expected since DT90 of the a.s. is << 100 days and TERacute are >> 10.

Table B.8.6.6-2 : Risk assessment for the earthworms

Test species	Effect concentration (mg a.s. kg soil)	Estimated initial concentration (mg a.s. /kg soil)	TER
Earthworm *(Eisenia foetida)*	LC_{50} = 540	0.587	920
Earthworm *(Eisenia foetida)*	LC_{50} = 540	2.133	253

B.8.7 Effects on other soil non-target macro-organisms (Annex IIIA 10.6.2)

Not submitted. Required.

B.8.8 Effects on soil non-target micro-organisms (Annex IIA 8.5; Annex IIIA 10.7)

B.8.8.1 Impact of the active substance on soil microbial activity (Annex IIA 8.5)

Not submitted. Required.

B.8.8.2 Impact of the formulations on soil microbial activity (laboratory) (Annex IIIA 10.7.1)

Not submitted. Required.

B.8.8.3 Further laboratory, glasshouse of field testing to investigate impact on soil microbial activity (Annex IIIA 10.7.2)

Not submitted. Required.

B.8.8.4 Summary of studies on non-target micro-organisms - exposure and hazard assessment for non-target micro-organisms

No data submitted

No risk assessment performed.

B.8.9 Effects on other non-target organisms (flora and fauna) believed to be at risk (Annex IIA 8.6; Annex IIIA 10.8)

Not submitted. Not required.

B.8.10 Effects on biological methods of sewage treatment (Annex IIA 8.7)

Not submitted. More information is required

B.8.11 References relied on

See Annex A.

ANNEX B

Thiram

B.9 Proposals for classification and labelling

B.9.1 Proposals for the classification and labelling of the active substance (Annex IIA 10)

Classification and labelling of thiram made by the Rapporteur

Classification:	Xn, R20/22, Xi, R36/37, R43, N, R50/53	
Labelling:		
Hazard symbol:	Xn, N	
Indication of danger:	Harmful, dangerous for the environment	
Risk phrases:	R 20/22	harmful by inhalation and if swallowed
	R36/37	irritating to eyes and respiratory system
	R43	may cause sensitization by skin contact
	R50/53	very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Safety phrases:	S2	keep out of reach of the children
	S24	avoid contact with skin
	S26	in case of contact with eyes, rinse immediatly with plenty of water and seek medical advice
	S36/37	wear suitable protective clothing and gloves
	S60	This material and its container must be disposed of as hazardous waste
	S61	Avoid release to the environment. Refer to special instructions safety data sheets

Table B.9.1-1 : Justification for the proposal made by the Rapporteur concerning the classification and labelling of thiram

Proposal	**Justification**
Xn, R20/22	oral LD50 < 2000 mg/kg bw and LC50 inhalation <5mg kg bw for an aerosol
Xi, R36/37	irritating to eyes and respiratory system
R43	skin sensitizer in the Split Adjuvant Test
N, R50/53	LC_{50} (*Cyprinodon variegatus*) = 0.54 mg a.s./l EC_{50} (*Daphnia magna*) = 0.011 mg a.s./l E_bC_{50} *(Selenastrum capricornutum*, 72h) = 0.065 mg a.s./l No indication on ready biodegradability of the a.s.

B.9.2a Proposals for the classification and labelling of VITAVAX 200 FF (Annex IIIA 12.3)

Classification and labelling of VITAVAX 200 FF made by the Rapporteur

Classification:	-	
labelling:	S2-13-20/21-36/37	
Hazard symbol	-	
Indication of danger:	-	
Risk phrases:	-	
Safety phrases:	S2	keep out of reach of the children
	S13	keep away from food, drink and animal feedingstuffs
	S20/21	when using do not drink, eat or smoke
	S36/37	wear suitable protective clothing and gloves

B.9.2b Proposals for the classification and labelling of THIRAM 80 WG (Annex IIIA 12.3)

Classification and labelling of THIRAM 80 WG made by the Rapporteur

Classification:	Xi, R43	
labelling:		
Hazard symbol	Xi	irritant
Indication of danger:		
Risk phrases:	R43	may cause sensitization by skin contact
Safety phrases:	S2	keep out of reach of the children
	S13	keep away from food, drink and animal feedingstuffs
	S20/21	when using do not drink, eat or smoke
	S24	avoid contact with skin
	S36/37	wear suitable protective clothing and gloves

Table B.9.2b-1 : Justification for the proposal made by the Rapporteur concerning the classification and labelling of THIRAM 80 WG

Proposal	**Justification**
Xi, R43	skin sensitizer in the Split Adjuvant Test

B.9.3 References relied on

See Annex A.

ANNEX B

Thiram

Appendix E : Standard Terms and Abbreviations

Part 1 Technical Terms

A	ampere
ACH	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADP	adenosine diphosphate
AFID	alkali flame-ionization detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD_{50}	approximate median lethal dose, 50%
AOEL	acceptable operator exposure level
AMD	automatic multiple development
approx.	approximate
as	active substance
at. wt.	atomic weight
ATP	adenosine triphosphate
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
b.p.	boiling point
BSP	bromosulfophthalein
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10^{-2})
°C	degree celsius (centigrade)
CAD	computer aided design
cd	candela
CDA	controlled drop(let) application
CEC	cation exchange capacity
cf	confer, compare to
ChE	cholinesterase
cm	centimetre
CNS	central nervous system
CoC	code of conduct
COD	chemical oxygen demand
cu	cubic

cv	coefficient of variation
Cv	ceiling value
cyt	cytogenetic analysis
d	day
DL	racemic (optical configuration, a mixture of dextro- and laevo-; preceding a
dlt	dominant lethal test
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic Acid
dnd	DNA-damage
dni	DNA-inhibition
dnr	DNA-repair
dns	unscheduled DNA-synthesis
DO	dissolved oxygen
DOC	dissolved organic carbon
DT	disappearance time
DTH	delayed-type hypersensitivity
EC	effective concentration
ECD	electron capture detector
ELISA	enzyme linked immunosorbent assay
EMDI	estimated maximum daily intake
EP	end-use product
ERL	extraneous residue limit
F_0	parental generation
F_1	filial generation, first
F_2	filial generation, second
FID	flame ionization detector
f.p.	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram
GAP	good agricultural practice
GC-EC	gas chromatography with electron capture detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice

GFP	good field practice
G.I.	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GPC	gel-permeation chromatography
GPPP	good plant protection practice
h	hour(s)
ha	hectare
Hb	haemoglobin
HCG	human chorionic gonadotropin
hl	hectolitre
hma	host-mediated assay
HPLC	high pressure liquid chromatography or high performance liquid
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
Ht	haematocrit
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilization concentration
i.d.	internal diameter
ID	ionization detector
i.m.	intramuscular
inh	inhalation
i.p.	intraperitoneal
IPM	integrated pest management
IR	infrared
i.v.	intravenous
k	kilo
K	Kelvin
kg	kilogram
l	litre
LBC	loosely bound capacity
LC	lethal concentration

LC	liquid chromatography
LC_{50}	lethal concentration, median
LCA	life cycle analysis
LC_{Lo}	lethal concentration low
LD_{50}	lethal dose, median; dosis letalis media
LD_{Lo}	lethal dose low
LOAEL	lowest observable adverse effect level
LOD	limit of determination
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LT	lethal threshold
m	metre
M	molar
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
µg	microgram
mg	milligram
min	minute(s)
ml	millilitre
MLD	minimum lethal dose
mm	millimetre
mma	microsomal mutagenicity test
mmo	mutation in microorganisms
mnt	micronucleus test
mo	month(s)
mol	Mol
m.p.	melting point
MP	manufacturing-use product
mrc	gene conversion and mitotic recombination
MRE	maximum residue expected
MRL	maximum residue level
msc	mutation in mammalian somatic cells
MSDS	material safety data sheet
MTD	maximum tolerated dose

n	normal (defining isomeric configuration)
NAEL	no adverse effect level
n.d.r.	not dose-related
NEDI	no effect daily intake (mg/kg body wt/day)
NEL	no effect level
NERL	no effect residue level
NMR	nuclear magnetic resonance
no.	number
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
nse	non standard exposure
o	ortho (indicating position in a chemical name)
ODP	ozone-depleting potential
OP	organophosphorous pesticide
otr	oncogenic transformation
p	para (indicating position in a chemical name)
Pa	pascal
2-PAM	2-pralidoxime
PC	paper chromatography
PCV	haematocrit (packed corpuscular volume)
PD	position document
PEC	predicted environmental concentration
PED	plasma-emissions-detector
pH	pH-value
PHI	pre-harvest interval
pic	phage inhibition capacity
PNEC	predicted no effect concentration
p.o.	by mouth
P_{ow}	partition coefficient between n-octanol and water
ppb	parts per billion
ppm	parts per million
ppq	parts per quadrillion
ppt	parts per trillion

PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	prothrombin time
PTT	partial thromboplastin time
RAC	raw agriculture commodity
RBC	red blood cell
Rf	ratio of fronts
RL_{50}	residual lifetime
RNA	ribonucleic acid
rns	rinsed
RPM	reversed phase material
RRT	relative retention time
s.c.	subcutaneous
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SBLC	shallow bed liquid chromatography
sce	sister chromatid exchange
SD	standard deviation
SE	standard error
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
sin	sex chromosome loss and nondisjunction
slt	specific locus test
sp/spp.	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
sp gr	specific gravity
spm	sperm morphology
sq	square
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
SVAT	soil-vegetation-atmosphere transfer

t	tonne (metric ton)
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TC_{Lo}	toxic concentration, low
TD	thermionic detector, alkali flame detector
TD_{Lo}	toxic dose low
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGAI	technical grade of the active ingredient
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TOC	total organic carbon
trn	heritable translocation test
TWA	time weighted average
UDS	unscheduled DNA synthesis
ULV	ultra low volume
UV	ultraviolet
v/v	volume ratio (volume per volume)
WBC	white blood cell
wk	week
wt	weight
wt/vol	weight per volume
w/w	weight per weight
yr	year
<	less than
£	less than or equal to
>	greater than
3	greater than or equal to

Part 2 Organisations and Publications

BA	Biological Abstracts (Philadelphia)
CA	Chemical Abstracts
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCPR	Codex Committee on Pesticide Residues
CIPAC	Collaborative International Pesticides Analytical Council Ltd
COREPER	Comite des Representants Permanents
EC	European Commission
ECCA	European Crop Care Association
ECPA	European Crop Protection Association
EHCD	Environmental Health Criteria Document
EINECS	European Inventory of Existing Commercial Chemical Substances
EPPO	European and Mediterranean Plant Protection Organization
EU	European Union
FAO	Food and Agriculture Organization of the UN
FJCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
GATT	General Agreement on Tariffs and Trade
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques
IARC	International Agency for Research on Cancer
IBT	Industrial Bio-Test Laboratories
IMO	International Maritime Organisation
IOBC	International Organization for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IR-4	Interregional Research Project No 4
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JECFA	FAO/WHO Joint Expert Committee on Food Additives
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)

NATO	North Atlantic Treaty Organisation
NCI	National Cancer Institute (USA)
NCTR	National Center for Toxicological Research (USA)
NGO	non-governmental organization
OECD	Organization for Economic Cooperation and Development
PAN	Pesticide Action Network
RNN	Re-registration Notification Network
SCPH	Standing Committee on Plant Health
SI	Systeme International d'Unites
SITC	Standard International Trade Classification
UN	United Nations
UNEP	United Nations Environment Programme
WHO	World Health Organization
WTO	World Trade Organization
WWF	World Wildlife Fund

ANNEX B

Thiram

Appendix F : Preparation (Formulation) Types and Codes

Preparation (Formulation) Types and Codes*

Code	Description	Definition
AB	Grain bait	Special forms of bait.
AE	Aerosol dispenser	A container-held preparation which is dispersed generally by a propellant as fine droplets/particles upon actuation of a valve.
AL	Other liquids to be applied undiluted	Self defining.
BB	Block baits	Special forms of bait.
BR	Briquette	Solid block designed for controlled release of active substance into water.
CB	Bait concentrate	A solid or liquid intended for dilution before use as a bait.
CG	Encapsulated granule	A granule with a protective or release controlling coating.
CS	Capsule suspension	A stable suspension of capsules in a fluid normally intended for dilution with water before use.
DC	Dispersible concentrate	A liquid homogeneous preparation to be applied as a solid dispersion after dilution in water.
DP	Dustable powder	A free-flowing powder suitable for dusting.
DS	Powder for dry seed treatment	A powder for application in the dry state directly to seed.
EC	Emulsifiable concentrate	A liquid, homogeneous preparation to be applied as an emulsion after dilution in water.
ED	Electrochargeable liquid	Special liquid preparation for electrostatic (electrodynamic) spraying.
EO	Emulsion, water in oil	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of pesticide in water in a continuous organic liquid phase.
ES	Emulsion for seed treatment	A stable emulsion for application to the seed either directly or after dilution.
EW	Emulsion, oil in water	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of pesticide in an organic liquid in a continuous water phase.
FD	Smoke tin	Special form of smoke generator.
FG	Fine granule	A granule in the particle size range from 300 to 2500 µ.
FK	Smoke candle	A smoke generator in the form of a candle.
FP	Smoke cartridge	Special form of smoke generator.
FR	Smoke rodlet	Special form of smoke generator.
FS	Flowable concentrate for seed treatment	A stable suspension for application to the seed either directly or after dilution.
FT	Smoke tablet	Special form of smoke generator.
FU	Smoke generator	A combustible preparation generally solid, which upon ignition releases the active substances in the form of a smoke.

Code	Description	Definition
FW	Smoke pellet	Special form of smoke generator.
GA	Gas	A gas packed in pressure bottle or pressure tank.
GB	Granular bait	Special forms of bait.
GE	Gas generating product	A preparation which generates a gas by chemical reaction.
GG	Macrogranule	A granule in the particle size range from 2000 to 6000 µ.
GP	Flo-dust	Very fine dustable powder for pneumatic application in glass-houses.
GR	Granule	A free-flowing solid preparation of a defined granule size range ready for use.
GS	Grease	Very viscous preparation based on oil or fat.
HN	Hot fogging concentrate	A preparation suitable for application by fogging equipment either directly or after dilution.
KN	Cold fogging concentrate	A preparation suitable for application by cold fogging equipment, either directly or after dilution.
LA	Lacquer	A solvent based film-forming preparation.
LS	Solution for seed treat-ment	A solution for application to the seed either directly or after dilution.
MG	Microgranule	A granule in the particle size range from 100 to 600 µ.
OF	Oil miscible flowable (=oil active substances in a miscible suspension)	A stable suspension of concentrate fluid intended for dilution in an organic liquid before use.
OL	Oil miscible liquid	A liquid, homogenous preparation to be applied as a homogenous liquid after dilution in an organic liquid.
OP	Oil dispersible powder	A powder preparation to be applied as a suspension after dispersion in an organic liquid.
PA	Paste	A water based film forming preparation.
PB	Plate bait	Special forms of bait.
PC	Gel or paste concentrate	A solid preparation to be applied as a gel or a paste after dilution with water.
PR	Plant rodlet	A small rodlet, usually a few centimetres in length and a few millimetres in diameter containing active substance.
PS	Seed coated with a pes-ticide	Self defining.
RB	Bait (ready for use)	A preparation designed to attract and be eaten by the target species.
SB	Scrap bait	Special forms of bait.
SC	Suspension concentrate	A stable suspension of active substance(s) in a fluid (= flowable con-centrate) intended for dilution with water before use.
SE	Suspo-emulsion	A fluid, heterogeneous preparation consisting of a stable dispersion of active substance(s) in the form of solid particles and of fine globules in a

Code	Description	Definition
		continuous water phase.
SG	Water soluble granules	A preparation consisting of granules to be applied as a true solution of active substance after dissolution in water but may contain insoluble inert ingredients.
SL	Soluble concentrate	A liquid homogenous preparation to be applied as a true solution of the active substance after dilution with water.
SO	Spreading oil	A preparation designed to form a surface layer on application to water.
SP	Water soluble powder	A powder preparation to be applied as a true solution of the active substance after solution in water but which may contain insoluble inert ingredients.
SS	Water soluble powder for seed treatment	A powder to be dissolved in water before application to the seed.
SU	Ultra low volume (ULV) suspension	A suspension ready for use through ULV equipment.
TB	Tablet	Solid preparation in the form of small, flat plates for dissolution in water.
TP	Tracking powder	A rodenticidal contact preparation in powder form.
UL	Ultra low volume (ULV) liquid	A homogenous liquid ready for use through ULV equipment.
VP	Vapour releasing product	A preparation containing one or more volatile ingredients, the vapours of which are released into the air. Evaporation rate normally is controlled by using suitable preparations and/or dispensers.
WG	Water dispersible granule	A preparation granule consisting of granules to be applied after disintegration and dispersion in water.
WP	Wettable powder	A powder preparation to be applied as a suspension after dispersion in water.
WS	Water dispersible powder for slurry seed treatment	A powder to be dispersed at high concentration in water before application as a slurry to the seed.
XX	Others	

*based upon the catalogue of Pesticide Formulation types and International Coding Systems, developed by GIFAP in co-operation with the German working group on documentation questions. (Arbeitsgruppe EDV Pflanzenschutz Versuchswesen). GIFAP Technical Monograph No 2. 1989.