ANNEX B

Thiram

B.1 Identity

B.1.1 Identiy of the active substance (Annex IIA 1)

B.1.1.1 Name and address of applicant(s) for inclusion of the active substance in Annex I (Annex IIA 1.1)

The main dossier was submitted by the following task force :

UCB SA
Pantserschipstraat, 207
9000 Gent - Wondelgem
Belgium

Mia Laget
tel: + (32) 9 254 14 11
fax: + (32) 9 254 14 10

Uniroyal Chemical Limited
Kennet House
4, Langley Quay
Slough, Berkshire
SL6 3EH
United Kingdom

Dr. P. R. Pritchard
tel: + (44) 1753 603000
fax: + (44) 1753 603077

A second dossier was submitted by :

FMC Foret S.A.
Córcega 293
08008 Barcelona
Spain
Person to contact : Ignacio Portabella
Tel : 34 3 416 74 00
Fax : 34 3 416 74 03

This dossier was incomplete and not further evaluated.

B.1.1.2 Manufacturer of the active substance (Annex IIA 1.2)

Manufacturer and contact point:

UCB S.A. 326, avenue Louise B-1050 Brussels Belgium	Uniroyal Chemical Co. Inc. World Headquarters Middlebury Connecticut 06749 USA

Location of plant:

UCB N.V. Pantserschipstraat 207 B-9020 Wondelgem (Gent) Belgium	Uniroyal Chemical Co. Inc. World Headquarters Middlebury Connecticut 06749 USA

B.1.1.3 ISO common name and synonyms (Annex IIA 1.3)

Thiram

B.1.1.4 Chemical name (Annex IIA 1.4)

IUPAC: tetramethylthiuram disulfide or bis (dimethylthiocarbamoyl)-disulfide

CA: tetramethylthioperoxydicarbonic diamide

B.1.1.5 Manufacturer's development code number (Annex IIA 1.5)

none

B.1.1.6 CAS, EEC and CIPAC numbers (Annex IIA 1.6)

CAS number :	137-26-8
EEC number :	205-286-2
CIPAC number :	24

B.1.1.7 Molecular formula, molecular mass and structural formula (Annex IIA 1.7)

Molecular formula: $C_6H_{12}N_2 S_4$

Structural formula:

```
H3C        S     S        CH3
    \      ½     ½     ¤
       N -C-S-S-C-N
    ¤                  \
H3C                        CH3
```

Molecular mass: 240.4 g/ml

B.1.1.8 Method or methods of manufacture (Annex IIA 1.8)

Confidential information, see Annex C

B.1.1.9 Specification of the purity of the active substance (Annex IIA 1.9)

Additional information is required to be able to clearly specify the purity of the active substance.
Confidential information, see also Annex C

B.1.1.10 Identity of inactive isomers, impurities and additives (Annex IIA 1.10)

Additional information is required to be able to clearly specify the impurity profile of the active substance.
Confidential information, see also Annex C

B.1.1.11 Analytical profile of batches (Annex IIA 1.11)

Confidential information, see Annex C

B.1.2a Identity of the plant protection product VITAVAX 200FF (Annex IIA 3.1; Annex IIIA 1)

B.1.2.1a Current, former and proposed trade names and development code numbers (Annex IIIA 1.3)

VITAVAX 200 FF

B.1.2.2a Manufacturer or manufacturers of the plant protection product (Annex IIIA 1.2)

Uniroyal Chimica SRL
via Delle Industrie 40
04013 Latina Scalo
Italy

B.1.2.3a Type of the preparation and code (Annex IIIA 1.5)

Physical state : Flowable concentrate for seed treatment (FS)

B.1.2.4a Function (Annex IIIA 1.6)

Seed treatment

B.1.2.5a Composition of the preparation (Annex IIIA 1.4)

FS containing 200 g thiram/l and 200 g carboxin/l

Other components : Confidential information, see Annex C

B.1.2b Identity of the plant protection product THIRAM 80 WG (Annex IIA 3.1; Annex IIIA 1)

B.1.2.1b Current, former and proposed trade names and development code numbers (Annex IIIA 1.3)

THIRAM 80 WG

B.1.2.2b Manufacturer or manufacturers of the plant protection product (Annex IIIA 1.2)

UCB N.V.
Pantserschipstraat 207
B-9020 Wondelgem (Gent)
Belgium

B.1.2.3b Type of the preparation and code (Annex IIIA 1.5)

Physical state : Water dispersible granule (WG)

B.1.2.4b Function (Annex IIIA 1.6)

Fungicide

B.1.2.5b Composition of the preparation (Annex IIIA 1.4)

WG containing 800 g thiram/kg

Other components : Confidential information, see Annex C

B.1.3 References relied on

See Annex A.

ANNEX B

Thiram

B.2 Physical and chemical properties

B.2.1 Physical and chemical properties of the active substance (Annex IIA 2)

Table B.2.1-1 : Physical and chemical properties of thiram

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.1 Melting point, freezing point or solidification point (IIA 2.1.1)	- GRL-SOP-1035 GRL-SOP-157 (Ernst Leitz MP apparatus) - The study is GLP	a.s. 99.1 % pure : melting point range = 144 - 146 °C	- Applicant's statement : the method used is comparable to EEC A1 - The study is acceptable.	Riggs, 1994g (Uniroyal)
B.2.1.2 Boiling Point (IIA 2.1.2)			- Not applicable (not a low melting substance)	
B.2.1.3 Temperature of decomposition or sublimation (IIA 2.1.3)			- Not applicable	
B.2.1.4 Relative density (IIA 2.2)	- GRL-SOP-1068 GRL-SOP-144 (Multivolume helium pycnometer) - The study is GLP	a.s. (TC), *97.8% pure (applicant's statement)* : density at 20 °C : 1.36 g/cm³ (RSD = 0.95 %)	- The method is equivalent to EEC A3, but the density was determined using the technical compound instead of the purified a.s. - The study is acceptable	Tutty, 1993a (Uniroyal)
B.2.1.5 Vapour pressure (IIA 2.3.1)	- OECD-guideline 104 (gas saturation method with HPLC-detection) - No GLP-compliance stated	pure a.s., > *99% pure (applicant's statement)* : at 25 °C : p = 2.4 10^{-3} Pa (test 1) = 1.8 10^{-5} mmHg p = 2.2 10^{-3} Pa (test 2) = 1.6 10^{-5} mmHg	- The method is equivalent to EEC A4. - The study is acceptable	Lemal, 1985 (UCB)

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.6 Volatility, Henry's law constant (IIA 2.3.2)	- Calculation	at 25°C : vapour pressure = 1.7 10^{-5} mmHg solubility in water = 1.65 10^{-5} g/ml Þ H = 3.3 10^{-7} atm.m³/mol = 3.3 10^{-2} Pa.m³/mol	- The report is acceptable	Pierce, 1995
B.2.1.7 Physical state (IIA 2.4.1)	- GRL-SOP-1027 (Visual test) - The study is GLP	a.s. 99.1 % pure : at 20 °C : solid fine crystals a.s. (TC), purity not specified : at 20 °C : solid powder that does not readily form an airborne dust	- The study is acceptable	Riggs, 1994c Riggs, 1994d (Uniroyal)
B.2.1.8 Colour (IIA 2.4.1)	- GRL-SOP-1028 (Visual test using Pantone color formula guide) - The study is GLP	a.s. 99.1 % pure : white a.s. (TC), purity not specified : slightly off-white beige	- The study is acceptable	Riggs, 1994a Riggs, 1994b (Uniroyal)
B.2.1.9 Odour (IIA 2.4.2)	- GRL-SOP-1029 - The study is GLP	a.s. 99.1 % pure : at room temperature : no detectable odour a.s. (TC), purity not specified : at room temperature : no detectable odour	- The study is acceptable	Riggs, 1994e Riggs, 1994f (Uniroyal)
B.2.1.10 Spectra of the active substance (IIA 2.5.1)	- GRL-SOP-1078 (UV/VIS) (diode-array spectrophotometer) - GRL-SOP-129 (IR)	a.s. 99.1 % pure : **UV/VIS** : at 23.4 °C; in methanol; under neutral, acidic and basic conditions; recorded from 190 to 820 nm :	- The study is acceptable, although the MS-spectrum was provided for technical thiram and	Tutty, 1994 Forbes, 1995 (< doc J) Penny, 1995 (Uniroyal)

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	- The study is GLP	214 nm : pH 7 ε = 21884 $1.mol^{-1}.cm^{-1}$ pH 2 ε = 21873 $1.mol^{-1}.cm^{-1}$ pH 10 ε = 22275 $1.mol^{-1}.cm^{-1}$ 278 nm : pH 7 ε = 11342 $1.mol^{-1}.cm^{-1}$ pH 2 ε = 11393 $1.mol^{-1}.cm^{-1}$ pH 10 ε = 13781 $1.mol^{-1}.cm^{-1}$ Þ spectra under neutral and acidic conditions are the same and different from spectra under basic conditions a.s. 98.51 % pure (TC) : **MS** : provided a.s., *purity not specified* : **IR** : the spectrum is consistent with the literature spectra for thiram a.s., 97% pure : **NMR** : published spectrum provided; 1 singlet	the NMR-spectrum was taken from the Aldrich Library of NMR-spectra.	Pouchert, 1983
B.2.1.11 Spectra for impurities (IIA 2.5.2)	- The study is GLP	1) tetramethylthiuramtetrasulfide, purity not specified : **MS** : provided in document J (confidential) **NMR, IR, UV/VIS** : not provided 2) tetramethylthiuramhexasulfide, purity not specified **MS** : provided in document J (confidential) **NMR, IR, UV/VIS** : not provided	- The study is acceptable.	Forbes, 1995 (< doc. J) (Uniroyal)
B.2.1.12 Solubility in water (IIA 2.6)	- OECD-guideline 105 (flask method + HPLC-analysis) - The study is GLP	a.s. 99.1% pure : solubility in pure water at 20 ± 1 °C : 0.0165 g/l (RSD : 3.24 %)	- The method is equivalent to EEC- A6 (slight adjustments) - The study is acceptable, but the effect of the pH is not addressed	Tutty, 1993b (Uniroyal)

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.13 Solubility in organic solvents (IIA 2.7)	-OECD-guideline 105 (flask method + HPLC-analysis) - The study is GLP	a.s. 99.1% pure : solubility at 20 ± 1 °C in hexane : 0.093 g/l (RSD = 0.54%) xylene : 8.30 g/l (RSD = 0.55%) methanol : 1.91 g/l (RSD = 0.10%) acetonitrile : 18.58 g/l (RSD = 0.43%)	- The study is acceptable.	Tutty, 1993c (Uniroyal)
	-OECD-guideline 105 (flask method)	a.s. *99% pure (applicant's statement)* : solubility at 25 °C in dichloromethane : 199 g/l acetone : 69.7 g/l chloroform : 204.7 g/l	- The study is acceptable.	Danschutter, 1985 (UCB)
		a.s. 99.8% pure : solubility at 22°C in ethylacetate : 13 g/l	- The study is acceptable.	Baele et al., 1997 (UCB)
B.2.1.14 Partition coefficient n-octanol/water (IIA 2.8)	- OECD-guideline 107 (Shaking flask method + HPLC-analysis) - no GLP-compliance stated	a.s. 100.04 % pure : log P_{ow} = 1.73 (determined using distilled water)	- The method is equivalent to EEC A8. - The study is acceptable, but the effect of the pH is not addressed	Lemal, 1983 (UCB, THIRAM Task Force)
B.2.1.15 Hydrolysis rate at pH 4, 7 and 9 under sterile conditions in the absence of light (IIA 2.9.1)	- in-house method, in compliance with US-EPA-161-1 - The study is GLP	a.s. ^{14}C-labelled - > 98 % radiochemical purity : at 25 °C in the dark : <u>pH 5 (acetate buffer)</u> : k = - 0.01011 d^{-1}; $t_{1/2}$ = 68.5 d <u>pH 7 (phosphate buffer)</u> : k = - 0.19931 d^{-1}; $t_{1/2}$ = 3.5 d <u>pH 9 (borate buffer)</u> : k = - 0.10092 h^{-1}; $t_{1/2}$ < 1 d Þ rapid breakdown in neutral or alkaline aqueous solution (major breakdown product = CS_2; other breakdown products : same as those isolated from photolysis samples (see B.2.1.16)	- Method equivalent to EEC C7; pH 5 instead of pH 4 is not relevant - The study is acceptable.	Norris, 1991 (THIRAM Task Force)

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.16 Direct phototransformation of purified a.s. in water using artificial light under sterile conditions (IIA 2.9.2)	- US-EPA-161-2 (natural sunlight photodegradation apparatus, cut-off < 290 nm) - The study is GLP	a.s. ^{14}C-labelled - > 98 % radiochemical purity : at 25 °C, buffered at pH 5 (acetate buffer) : 1) photochemical half-life : 8.8 h (k = - 0.07833 h^{-1}) 2) mass balance (distribution of radioactivity) after 10 h 29.2 % volatiles (=CS_2) 9.07 % remaining in aqueous phase 53.20 % chloroform extract, consisting of 41.58 % thiram 3 minor degradation products (resp. 1.04 %, 1.40 % and 5.45 %) 3) identity of breakdown products : major product : CS_2 minor products : DMDTC (dimethyldithiocarbamic acid) DMATMS (dimethylaminothioxomethane-sulfenic acid) which were both converted to : methyl DMDTC (methyl dimethyldithio-carbamate)	- Method concurs with the SETAC-procedures , except for the use of natural sunlight. - The study is acceptable (for orientation)	McManus, 1990 (Uniroyal, THIRAM Task Force)
B.2.1.17 Quantum yield of direct phototransformation (IIA 2.9.3)	- OECD draft test guideline : "Phototransformation of Chemicals in Water" (Suntest irradiation apparatus, Xenon burner, 290 nm filter) - The study is GLP	a.s. ^{14}C-labelled - 96.5 % radiochemical purity : at 20 ± 2 °C, buffered at pH 7 (phosphate buffer) : 1) quantum yield PHI = 2.97 10^{-3} (calculated using program QUANTAUS Vers. 1.10, based on results of HPLC characterization of radioactivity) 2) DT_{50} = 4.1 h (HPLC)	- Method concurs with the SETAC-procedures - The study is acceptable	Knoch, 1994 (UCB)
B.2.1.18 Dissociation in water of purified active	- Conductance studies (in 1,4 dioxane/water 89:11 V/V)	a.s., purity not specified : estimated K < 10^{-6} mol/l a.s. is believed to behave as a weak base	- As is mentioned in the study report itself, the reproducibility of the	Van Beylen, 1985 (UCB)

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
substance (IIA 2.9.4)	- no GLP-compliance stated		results obtained is poor, so that a reasonable value for the dissociation constant could not be obtained. - The study is not acceptable.	
	- OECD-guideline 112 (spectrophotometric method) - The study is GLP	a.s. 99.1% pure : at 25°C : pK_a (BH^+) = 8.19	- The study is acceptable.	Thomson, 1995 (Uniroyal)
B.2.1.19 Estimated photo chemical oxidative degradation (IIA 2.10)	- Calculation according to Atkinson method	estimated gas phase hydroxyl radical rate constant : k = 10.2 10^{-9} $cm^3.molecule^{-1}.sec^{-1}$	- The estimation is acceptable (no report, calculation mentioned in summary)	
B.2.1.20 Flammability (IIA 2.11.1)		not tested	- Extra study required	
B.2.1.21 Auto-flammability (IIA 2.11.2)		not tested	- Extra study required	
B.2.1.22 Flash point (IIA 2.12)			- Not applicable (melting point > 40 °C)	

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.23 Explosive properties (IIA 2.13)	- in house method of Westphalian Mining Trade Union Bank, Institute for Explosion Safety and Technology - no GLP compliance stated	a.s., purity not specified : for grain size distribution of 99% < 23 mm : 1) lower explosion limit for dust (= dust concentration above which dust/air mixtures are explosive) : 30 g/m³ 2) ignition temperature of dust cloud (= lowest temperature at which the dust/air mixture still burns with closed flame) : 270°C	- The method is not equivalent to EEC A14 - The study is not acceptable	Beylingstr, 1982 (UCB)
	- Applicant's statement	"The chemical structure of thiram contains no reactive groups that would invoke rapid decomposition with extreme heat formation and liberate large gas volumes. Thiram has been produced many years without occurrence of explosions. Thiram is thus being considered as not sensible to heat, shock or friction." "In normal handling conditions for thiram, and wherever the creation of dust is avoided, no explosion danger is to be expected."	- Acceptable	
B.2.1.24 Surface tension (IIA 2.14)		not tested	- Extra study required	
B.2.2.25 Oxidizing properties (IIA 2.15)	- Applicant's statement	"Examination of the chemical structure of thiram established that the active substance is incapable of reacting exothermically with a combustible material. The structure of thiram contains no highly oxidized groups that would lead to oxidizing properties."	- Acceptable	

B.2.2 Physical and chemical properties of the plant protection products (Annex IIIA 2)

Table B.2.2-1 : Physical and chemical properties of **VITAVAX 200FF** (Flowable concentrate for seed treatment : thiram + carboxin) (UNIROYAL)

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.1 Physical state (IIIA 2.1)	- GRL-SOP-1027 (Visual test) - The study is GLP	at 25 °C : heterogeneous suspension mixture of a solid in a liquid	- The study is acceptable	Tutty, 1993c
B.2.2.2 Colour (IIIA 2.1)	- GRL-SOP-1028 GRL-SOP-154 (Visual test) - The study is GLP	red/pink	- The study is acceptable	Tutty, 1994a
B.2.2.3 Odour (IIIA 2.1)	- GRL-SOP-1029 - The study is GLP	strong and sweet odour	- The study is acceptable	Tutty, 1994b
B.2.2.4 Explosive properties (IIIA 2.2.1)	- OECD-guideline 113 (DSC and TGA) - The study is GLP	no exothermic decomposition in air or nitrogen below 150°C Þ material is stable at room temperature	- The method is not equivalent to EEC A14, so the study is not acceptable. - Additional study, according to EEC A14, is on the way (report expected by 31/12/97).	Charlton, Plain & Macnab, 1994
B.2.2.5 Oxidizing	- in house method (temperature recording)	at 20 ± 1 °C : VITAVAX 200FF shows no tendency to act as an	- The study is acceptable.	Thomson, 1993

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
properties (IIIA 2.2.2)	- The study is GLP	oxidizing or reducing agent when exposed to : distilled water monoammoniumphosphate potassiumpermanganate zinc granules		
B.2.2.6 Flash point (IIIA 2.3)	- GRL-SOP-1050 (Pensky-Martens semi-automatic closed cup flash point tester) - The study is GLP	flash point > 95 °C	- The method is equivalent to EEC A9 - The study is acceptable - The product is not flammable	Tutty, 1993b
B.2.2.7 Flammability (IIIA 2.3)			- Not applicable (substance is a liquid)	
B.2.2.8 Auto-flammability (IIIA 2.3)	- EEC-method A15 - The study is GLP	no auto-ignition temperature below 400 °C (atmospheric pressure : 101.11 - 102.17 kPa)	- The study is acceptable	Tremain & Bartlett, 1994
B.2.2.9 Acidity or alkalinity and pH value (IIIA 2.4.1)	- US-EPA-63-12 - The study is GLP	at 25 °C : pH = 7.86 (COV : 0.29 %)	- The method is equivalent to CIPAC MT 75 - The study is acceptable	Tutty, 1993a
B.2.2.10 pH of a 1 % aqueous dilution, emulsion or dispersion (IIIA 2.4.2)			- Not applicable (formulation is not to be applied as a dilute mixture)	

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.11 Kinematic viscosity (IIIA 2.5.1)	- CIPAC MT 22 (reverse flow viscometer) - The study is GLP	at 20 °C, 5 batches of VITAVAX 200FF : kinematic viscosity : 73.3 cSt 76.6 cSt 66.3 cSt 65.4 cSt 65.2 cSt P.S. each result is the average from 3 replicate determinations. The limit of 0.6 % for the repeatability was not always obtained, due to the compromise that had to be made between making sure the suspension was homogeneous and not entrapping any air in the product. Dynamic viscosity : 85.9 cP 89.2 cP 77.6 cP 76.3 cP 76.3 cP	- The method is comparable to OECD 114. - The study is acceptable.	Parsons, 1994b
B.2.2.12 Viscosity (III 2.5.2)			- Not applicable.	
B.2.2.13 Surface tension (IIIA 2.5.3)		Not available	- Additional study, according to EEC A5, is on the way (report expected by 31/12/97)	
B.2.2.14 Relative density (IIIA 2.6.1)	- EEC-method A3.1.4.4. (Oscillating density meter) - The study is GLP	At 20 °C : density = 1.157 g/cm³	- The study is acceptable.	McKelvie & Harpum, 1994
B.2.2.15			- Not applicable (liquid	

Study Bulk or tap density (IIIA 2.6.2)	**Guidelines and GLP**	**Findings**	**Evaluation and conclusion** preparation)	**References**
B.2.2.16 Stability after storage for 14 days at 54 °C (IIIA 2.7.1)	- CIPAC MT 46 - The study is GLP	<u>after 4 weeks at 50 ± 2 °C</u> : 1) no change in carboxin content max. difference in thiram content of - 1.5 % (from 17.4 % to 15.9 %) = - 8.6 % relative 2) darkened colour 3) bleed (4.7 %) reconstituted within 10 invertions 4) pH (6.8 initial to 7.1 final) and wet sieve values (< 1 % retained on 45 µ) remain stable	- 4 weeks at 50 °C instead of 2 weeks at 54 °C, without a justification being stated - The study is nevertheless acceptable (see also B.2.2.17)	Harpum & McKelvie, 1993
B.2.2.17 Stability after storage for other periods and temperatures (IIIA 2.7.1)	- CIPAC MT 46 - The study is GLP	<u>after 8 weeks at 40 ± 2 °C</u> (5 batches tested): 1) max. difference in carboxin content = - 0.3 % = - 1.7 % relative max. difference in thiram content = - 1.6 % = - 8.8 % relative 2) no colour change 3) bleed (max. 12.7 %) reconstituted within 10 inverts 4) no drastic change in wet sieve values (from < 0.05 % retained on 45 µ (initially) to max. 0.2 % retained (finally)) 5) max difference in pH = - 1.1 pH unit (final pH between 6.2 and 6.4)	- The study is acceptable.	Harpum, 1994b
B.2.2.18 Minimum content after heat stability testing (IIIA 2.7.1)		See B.2.2.16 : min. thiram content after 4 weeks at 50 °C = 15.9% See B.2.2.17 : min. thiram content after 8 weeks at 40 °C = 16.6%	- The information is required since the content of thiram decreases with > 5 % relative. - Characterization of degradation products is not provided	

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.19 Effect of low temperature on stability (IIIA 2.7.2)	- The study is GLP	after 8 weeks at 0 ± 2 °C (5 batches tested) : 1) max. difference in carboxin content = - 0.3 % = - 1.7 % relative max difference in thiram content = - 0.7 % = - 3.8 % relative 2) no colour change 3) bleed (max. 5.1 %) reconstituted within 10 inverts 4) no drastic change in wet sieve values (from < 0.05 % retained on 45 µ (initially) to max. 0.1 % retained (finally)) 5) max. difference in pH = - 1.2 pH unit (final pH between 6.1 and 6.3)	- The method is not equivalent to CIPAC MT 39. - The study is nevertheless acceptable.	Harpum, 1994b
B.2.2.20 Shelf life (IIIA 2.7.3)	- GLP-compliance is not claimed	after 25 months storage at ambient temperature in high density polyethylene container : 1) initial active substance content : 17.5 % carboxin 17.1 % thiram final active substance content : 17.0 % carboxin 16.4 % thiram 2) product fully homogeneous and without lumpy matter or sediment after 10 gentle invertions of the sample container 3) pH 7.1 (normal limits : 6.5 - 8.5) 4) wet sieve retained on 45 µm : < 1 % (max. 2 %) Þ shelf life : at least 2 years	- The method is equivalent to GIFAP n° 17. - The study is acceptable.	Harpum, 1994a
B.2.2.21 Wettability (IIIA 2.8.1)			- Not applicable (not a solid)	
B.2.2.22			- Not applicable (not	

Study	**Guidelines and GLP**	**Findings**	**Evaluation and conclusion**	**References**
Persistent foaming (IIIA 2.8.2)			diluted with water for use)	
B.2.2.23 Suspensibility (IIIA 2.8.3)	- CIPAC MT 161 - The study is GLP	using standard water C at 30 °C, at 1 % total active substance level (5 batches tested in duplicate) : suspensibility of thiram : 90.7 % 92.1 % 91.0 % 91.4 % 90.2 % suspensibility of carboxin : 86.9 % 87.6 % 85.9 % 87.0 % 85.7 %	- The study is not required (product is not diluted with water for use)	Parsons, 1994a
B.2.2.24 Spontaneity of dispersion (IIIA 2.8.3)			- Not applicable (product is not diluted with water for use)	
B.2.2.25 Dilution stability (IIIA 2.8.4)			- Not applicable (suspension, not an aqueous solution)	
B.2.2.26 Dry sieve test and wet sieve test (IIIA 2.8.5)	- CIPAC MT 59.3 - The study is GLP	Wet sieve of 45 µm : < 0.05 % retained (0.05 % to 0.2 % after 8 weeks of storage)	- The study is acceptable	Harpum, 1994b
B.2.2.27 Size distribution of	- EM 6020 (Laser particle sizer)	volume mean diameter : 4.79 µm 50 % of all particles < 3.91 µm	- The study is not required (product is not	Harpum & McKelvie, 1994a

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
particles - Nominal size range of particles (IIIA 2.8.6.1)	- The study is GLP	90 % of all particles < 9.65 µm	a powder, nor a granule)	
B.2.2.28 Dust content and particle size of dust (IIIA 2.8.6.2)			- Not applicable (not a granular preparation)	
B.2.2.29 Friability and attrition characteristics of granules (IIIA 2.8.6.3)			- Not applicable (not a granular preparation)	
B.2.2.30 Emulsifiability, emulsion stability, re-emulsifiability (IIIA 2.8.7.1)			- Not applicable (product forms no emulsions)	
B.2.2.31 Stability of emulsions (IIIA 2.8.7.2)			- Not applicable (product forms no emulsions)	
B.2.2.32 Flowability (IIIA 2.8.8.1)			- Not applicable (not a granular preparation)	
B.2.2.33 Pourability (including rinsed resi-	- CIPAC MT 148 (high density PE containers)	after a standing period of 24 h (mean of 5 samples) : residue (% w/w) = 0.82 % rinsed residue (% w/w) = 0.14 %	- The study is acceptable	Harpum & McKelvie, 1994b

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
due) (IIIA 2.8.8.2)	- The study is GLP			
B.2.2.34 Dustability following accelerated storage (IIIA 2.8.8.3)			- Not applicable (not a dustable powder)	
B.2.2.35 Physical compatibility of tank mixes (IIIA 2.9.1)			- Not applicable (product is not used in tank mixes)	
B.2.2.36 Chemical compatibility of tank mixes (IIIA 2.9.2)			- Not applicable (product is not used in tank mixes)	
B.2.2.37 Distribution and adhesion (IIIA 2.10)		not available	- A study is underway (evaluation of distribution and adhesion of VITAVAX 200 FF to wheat seed directly after treatment and after storage). Final report is anticipated in november 1998.	

Table B.2.2-2 : Physical and chemical properties of **THIRAM 80 WG** (water dispersible granule : thiram) (UCB)

Study	**Guidelines and GLP**	**Findings**	**Evaluation and conclusion**	**References**
B.2.2.1 Physical state (IIIA 2.1)		granules	- Acceptable (no report, findings mentioned in Tier I)	
B.2.2.2 Colour (IIIA 2.1)		pale brown	- Acceptable (no report, findings mentioned in Tier I)	
B.2.2.3 Odour (IIIA 2.1)		faint odour, comparable to caramel	- Acceptable (no report, findings mentioned in Tier I)	
B.2.2.4 Explosive properties (IIIA 2.2.1)	- Applicant's statement	"The active substance, as well as the formulants, show no explosion sensitivity to shock, friction or elevated temperature." "The MSDS of the formulants state that the formation of dust is to be avoided. The use of water dispersible granules instead of powders was introduced to avoid the presence of dust when handling the product."	- Acceptable	
B.2.2.5 Oxidizing properties (IIIA 2.2.2)	- Applicant's statement	"The MSDS of the formulants do not indicate any danger for oxidation reactions, nor do they mention any chemical incompatibility with other compounds. Together with the knowledge that the active substance does not have oxidizing properties, we conclude that THIRAM 80 WG is not an oxidizing product."	- Acceptable	
B.2.2.6 Flash point (IIIA 2.3)			- Not applicable (not a liquid)	

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.7 Flammability (IIIA 2.3)		not tested	- Extra study required : solid preparation (EEC A10)	
B.2.2.8 Auto-flammability (IIIA 2.3)		not tested	- Extra study required (EEC A16)	
B.2.2.9 Acidity or alkalinity and pH value (IIIA 2.4.1)			- Not applicable (preparation is not acidic (pH < 4) or alkaline (pH > 10))	
B.2.2.10 pH of a 1 % aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	- CIPAC MT 75 - No GLP-compliance stated	1% dispersion in water : pH = 7.6	- The study is accep-table, although not GLP.	Van de Putte, 1995
B.2.2.11 Kinematic viscosity (IIIA 2.5.1)			- Not applicable (product not intended for ULV-use)	
B.2.2.12 Viscosity (III 2.5.2)			- Not applicable (not a liquid)	
B.2.2.13 Surface tension (IIIA 2.5.3)			- Not applicable (not a liquid)	

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.14 Relative density (IIIA 2.6.1)			- Not applicable (not a liquid)	
B.2.2.15 Bulk or tap density (IIIA 2.6.2)	- CIPAC MT 159 (rotation of 90° instead of 10°) - The study is GLP	tap density of **THIRAM 75 WG** (mean of 5 batches, 100 taps) = 0.668 ± 9.23 10^{-3} g/ml (95 % confidence interval)	- The study is acceptable, although the test was performed using THIRAM 75 WG instead of THIRAM 80 WG. Both formulations have the same physical properties (same nominal size of granules) and the difference in a.s. content has no significant influence on the tap density.	Hogg, 1992
B.2.2.16 Stability after storage for 14 days at 54 °C (IIIA 2.7.1)	- CIPAC MT 46	after storage for 14 days at 54 ± 2°C : 1) a.s. content : 78.7% (initial : 79.1%) Þ no significant degradation of a.s. 2) pH of 1% dispersion : 7.9 (initial : 7.6) 3) wet sieve residue on 75 µm sieve : 0.05% (initial : 0.03%) 4) suspensibility : 86.9% (initial : 93.5%)	- The study is acceptable.	Van de Putte, 1995
B.2.2.17 Stability after storage for other periods and temperatures (IIIA 2.7.1)			- Not applicable (product is not heat sensitive)	

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.18 Minimum content after heat stability testing (IIIA 2.7.1)		see B.2.2.16	- Information not required (a.s. content did not decrease by more than 5 % in heat stability testing)	
B.2.2.19 Effect of low temperature on stability (IIIA 2.7.2)			- Not applicable (not a liquid)	
B.2.2.20 Shelf life (IIIA 2.7.3)	- No guideline specified	after storage <u>for 3 years at ambient temperature in the dark in closed PE containers</u>: 1) a.s. content : 80.7% (initial : 81.8%) Þ no significant degradation of a.s. 2) water content : 2.35% (initial : 1.72%) 3) suspensibility : 95.7% 4) dustiness : 10.5 mg 5) flowability : 99.96%	- Method concurs with GIFAP n° 17. - The study is acceptable.	Van de Putte & Demuynck, 1997a
B.2.2.21 Wettability (IIIA 2.8.1)	- CIPAC MT 53.3.1	in tap water : wetting time = 2 seconds (without swirling)	- The study is acceptable (test is not influenced by the use of tap water instead of standard water D).	Van de Putte, 1995
B.2.2.22 Persistent foaming (IIIA 2.8.2)	- CIPAC MT 47	1 ml foam after 1 min	- The study is acceptable.	Van de Putte, 1995

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.23 Suspensibility (IIIA 2.8.3)	- CIPAC MT 168	1% suspension in standard water D : suspensibility after 30 min = 93.5%	- The study is acceptable.	Van de Putte, 1995
B.2.2.24 Spontaneity of dispersion (IIIA 2.8.3)	- CIPAC MT 174	dispersibility in standard water D = 100% (mean of 5 batches)	- The study is acceptable.	Janssens, Van de Putte & Demuynck, 1997
B.2.2.25 Dilution stability (IIIA 2.8.4)			- Not applicable (not a water soluble product)	
B.2.2.26 Dry sieve test and wet sieve test (IIIA 2.8.5)	- CIPAC MT 167	wet sieve residue on 75 µm sieve = 0.03%	- The study is acceptable.	Van de Putte, 1995
B.2.2.27 Size distribution of particles - Nominal size range of granules (IIIA 2.8.6.1)	- CIPAC MT 170 - No GLP-compliance stated	residue on 1 mm sieve : 0% residue on 0.105 mm sieve : 95.37% residue on 0.045 mm sieve : 4.38% residue in receiver pan : 0.25% (results : average of 17 samples)	- The study is acceptable, although not GLP. Also, it would have been better if the test had included 1 or 2 additional sieve sizes between 1 and 0.105 mm.	Van de Putte & Demuynck, 1997b
B.2.2.28 Dust content and par-	- CIPAC MT 171 (gravimetric method)	collected dust = 2.5 mg Þ the preparation is nearly dust-free	- The study is acceptable, although not	Van de Putte, 1995

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
ticle size of dust (IIIA 2.8.6.2)	- No GLP-compliance stated		GLP.	
B.2.2.29 Friability and attrition characteristics of granules (IIIA 2.8.6.3)			- Not applicable (no internationally agreed method available at the time).	
B.2.2.30 Emulsifiability, emulsion stability, stability of emulsions (IIIA 2.8.7.1)			- Not applicable (product does not form emulsions)	
B.2.2.31 Stability of emulsions (IIIA 2.8.7.2)			- Not applicable (product does not form emulsions)	
B.2.2.32 Flowability (IIIA 2.8.8.1)	- CIPAC MT 170	100% passes 5 mm test sieve after storage for 3 years at ambient temperature in the dark in closed PE containers : 99.96% passes 5 mm test sieve	- The test was not performed according to CIPAC MT 172 (no heat test under pressure) - The study is nevertheless acceptable (for orientation).	Van de Putte, 1995 Van de Putte & Demuynck, 1997a
B.2.2.33			- Not applicable :	

Study	**Guidelines and GLP**	**Findings**	**Evaluation and conclusion**	**References**
Pourability (including rinsed residue) (IIIA 2.8.8.2)			product is not a suspension	
B.2.2.34 Dustability following accelerated storage (IIIA 2.8.8.3)			- Not applicable : product is not a dustable powder	
B.2.2.35 Physical compatibility of tank mixes (IIIA 2.9.1)	- Applicant's statement	"The only known incompatibility is with copper containing compounds (through existing combinations and tank mixes in practice)"	- Acceptable	
B.2.2.36 Chemical compatibility of tank mixes (IIIA 2.9.2)	- Applicant's statement	"The only known incompatibility is with copper containing compounds (through existing combinations and tank mixes in practice)"	- Acceptable	
B.2.2.37 Distribution and adhesion (IIIA 2.10)			- Not applicable : preparation is not intended for seed treatment.	

The dossier also contained some studies performed with another water dispersible granule, THIRAM 75 WG, the results of which are summarized in table B.2.2-3. The data package with respect to the physical, chemical and technical properties of this formulation is however not complete.

Table B.2.2-3 : Physical and chemical properties of **THIRAM 75 WG** (water dispersible granule : thiram) (UCB)

Study	**Guidelines and GLP**	**Findings**	**Evaluation and conclusion**	**References**
B.2.2.1 pH of a 1 % aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	- US-EPA-63-12 (pH-meter with glass electrode) - The study is GLP	pH of a **4 %**-dispersion in water at 20 °C (mean of 5 batches) = 8.95 ± 3.73 10^{-2} (95% confidence interval)	- The method is equivalent to CIPAC MT 75, but a 4 % dispersion was used instead of a 1 % dispersion. - The study is acceptable.	Else, 1992a
B.2.2.2 Bulk or tap density (IIIA 2.6.2)	- CIPAC MT 159 (rotation of 90° instead of 10°) - The study is GLP	tap density (mean of 5 batches, 100 taps) = 0.668 ± 9.23 10^{-3} g/ml (95 % confidence interval)	- The study is acceptable.	Hogg, 1992
B.2.2.3 Stability after storage for 14 days at 54 °C (IIIA 2.7.1)	- CIPAC MT 46 (applied pressure of 25 g/cm²) - The study is GLP	initial content of a.s. (5 batches) : 75.0 % ± 0.54 % (95% confidence interval) final content of a.s. (5 batches) : 74.4 % ± 0.76 % (95% confidence interval) Þ no significant degradation of thiram after 2 weeks of storage at 54 °C	- The study is acceptable, but relevant physico-chemical properties were not tested after storage.	Else, 1992b
B.2.2.4	- US-EPA-63-17	after storage <u>for 12 months at ambient temperature in its</u>	- Method does not	Else, Mullee &

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
Shelf life (IIIA 2.7.3)	- The study is GLP	commercial container in the dark (5 batches tested) : 1) no change in appearance 2) no sign of leakage or corrosion of containers 3) initial content of a.s. : 75 % ± 0.54 % (95% confidence interval) final content of a.s. : 74.8 % ± 0.29 % (95% confidence interval) Þ no significant degradation of a.s. after 12 months storage at ambient temperature	concur with GIFAP n° 17 : storage at ambient temperature should take at least 2 years + relevant physico-chemical properties were not tested after storage.	Bartlett, 1993

B.2.4 References relied on

See Annex A.

ANNEX B

Thiram

B.3 Data on application and further information

B.3.1 Data on application relevant to the active substance (Annex IIA 3.1 to 3.6)

B.3.1.1 Function (Annex IIA 3.1)

Fungicide (seed treatment, foliar spray), bird and game repellent

B.3.1.2 Effects on harmful organisms (Annex IIA 3.2.1)

Fungitoxic action,
Inhibition of numerous enzymes in the fungus resulting in subsequent inhibition of spore germination and mycelial growth.

B.3.1.3 Translocation in plants (Annex IIA 3.2.2)

not systemic

B.3.1.4 Fields of use (Annex IIA 3.3)

Agriculture, orchards, horticulture, forests

B.3.1.5 Pests controlled and crops protected (Annex IIA 3.4.1, 3.4.2)

The following table indicates the uses (crops protected and pest controlled) of products registered in the EU.

Table B.3.1.5-1 : List of existing uses of thiram in the EU

Crops protected	**Pests controlled**
Seed treatment	
(Uses supported by the notifers) Potato Beans Grass Lupin Oats Vetch Wheat Maize Radish Barley Peas Rye Linseed Cucumber Poppy Alfalfa Cabbage Celery Lettuce Onion Parsley Spinach Oilseed rape Turnip Beet (leaf beet, sugar beet) Leek Soya Triticale Sorghum Rice Cotton	*Aspergillus spp.* *Penicillium spp.* *Fusarium spp* including *F. nivale* *Tilletia caries* *Ascochyta spp* *Phoma spp.* *Pythium spp.* *Phytophtora spp* *Pyrenophora spp.* *Rhizoctonia spp.* *Botrytis spp.*
(Uses not supported by the notifers) Chichpea Cantaloupe Pumpkin Watermelon Lentil Millet Sunflower Aubergine Tomato Clover Medicinal herbs Carrots Pepper	

Crops protected	**Pests controlled**	
Fruit - Foliar spray (Uses supported by the notifiers)		
Pome fruit	Locoluascomycetes	*Venturia spp.* (*Gloeosporium* - storage rot)
	Discomycetes	*Monilinia spp.* *Septoria species* *Stemphylium*
Stone fruit	Hemiascomycetes	*Taphrina deformans*
	Hemiascomycetes	*Taphrina wiesneri*
	Discomycetes	*Monilinia spp.*
	Coelomycetes	*Coryneum beijerinckii (= Stigmina carpophila)*
	Coelomycetes	*Coryneum microstictum*
	Coelomycetes	*Fussicoccum amygdali*
Tree nuts	Discomycetes	*Monilinia spp.*
	Coelomycetes	*Coryneum*
Berries and small fruit Strawberries		*Mycosphaerella* *Botrytis* Cane spot Spur blight
Vineyard	Coelomycetes	*Colletotrichum* *Botrytis cinerea*
Ornamentals- Foliar spray (Uses supported by the notifiers)		
Ornamentals (outdoor, indoor)		*Botrytis*
Ornamentals (bulbs)		*Sclerotinia*
Peony		*Botrytis*
Vegetables - Foliar spray (Uses not supported by the notifiers)		
Bulb vegetables		*Botrytis*
Tomatoes	Oomycetes	*Peronospora sp.*
	Coelomycetes	*Botrytis cinerea*
Cucurbits	Coelomycetes	*Colletotrichum sp.*
	Oomycetes	*Peronospora*
	Coelomycetes	*Botrytis*
		Pythium

Crops protected	**Pests controlled**	
Cabbage	Oomycetes	*Peronospora parasitica*
	Coelomycetes	*Botrytis*
Lettuce (use supported by the notifiers)	Coelomycetes	*Botrytis* *Colletotrichum*
Celery leaves	Coelomycetes	*Colletotrichum*
French beans	Coelomycetes	*Colletotrichum*
Pea	Coelomycetes	*Colletotrichum*
Asparagus		*Fusarium* *Botrytis*
Potato		*Rhizoctonia*
Endive		*Botrytis*
Game repellent (Uses not supported by the notifiers)		
Trees (orchards, forests, ornamentals)		mice, rabbit, hares, game
Soil treatment (Uses not supported by the notifiers)		
soil treatment		Soil diseases

B.3.1.6 Effects achieved - mode of action (Annex IIA 3.4.3, 3.5.1)

'Thiram inhibits the respiration by a specific reaction with thiol groups of the enzyme pyruvatedhydrogenase which has a major function in the conversion of pyruvic acid in acetyl CoA.

The thiram binding opens and the thiol groups get bound to the disulfide binding of thiram. This results in the formation of a new symmetric disulfide compound and free dithiocarbamate ions.'

B.3.1.7 Information relative to the formation of active metabolites and degradation products (Annex IIA 3.5.2, 3.5.3)

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B.3.1.8 Information relative to the possible occurrence of the development of resistance or cross-resistance (Annex IIA 3.6)

'See Vonk J.W. 1983. Metabolism of fungicides in plants; in : Progress in pesticide biochemistry and toxicology; volume 3; edited by Hutson D.H. and Roberts T.R. 111-118) and Sisler H.D. 1982. Biodegradation of agricultural fungicides; in : Biodegradation of pesticides; edited by Matsumura F. and Krishna M. 140-142).
With respect to the resistance risk thiram may be classified as low risk fungicide because of the multisite fungitoxic effect.
As a matter of fact for preventing or delaying build up of resistant pathogens, specific site inhibitors are preferentially applied in mixtures with multisite inhibitors like thiram (Bahadir M. et al. (1990). Controlled release. Biochemical Effets of Pesticides, Inhibition of Plant Pathogenic Fungi. page 271).

No field resistance reported.'

B.3.2a Data on application relevant to the plant protection products - seed treatment (Annex IIIA 3)

B.3.2.1a Fields of use (Annex IIIA 3.1)

Agriculture, horticulture (seed treatment)

B.3.2.2a Nature of the effects on harmful organisms (Annex IIIA 3.2)

Fungitoxic action, inhibition of numerous enzymes in the fungus resulting in subsequent inhibition of spore germination and mycelial growth.

B.3.2.3a Pests controlled and crops protected (Annex IIIA 3.3)
Rate of application (Annex IIIA 3.4)
Concentration of active substance in material used (Annex IIIA 3.5)
Description of the method of application, type of equipment used and type and volume of diluent per unit of area or volume (Annex IIIA 3.6)
Number and timing of applications and duration of protection afforded (Annex IIIA 3.7)

- UCB submitted intended uses for seed treatment based on formulations containing thiram alone.

- UNIROYAL submitted the list of registered uses of VITAVAX 200FF (containing 200 g/l thiram and 200 g/l carboxin) to support the seed treatment uses . The dose of thiram is in this case lower than for UCB formulations due to the presence of another fungicide in the formulation.
The notifier declared that ” in the case of small grain cereals and maize, the rates used in South Europe are in practice the same as those in North Europe”.

The intended uses submitted by UCB were taken into account to assess the risk to human health, environment and non target organisms since they represent the “worst case situation”.

Table B.3.2.3a-1 : List of intended uses for seed treatment - based on the uses supported by UCB (formulations containing thiram alone)

Crop	Pest - Disease	Country	Maximum rate (g a.s./100 kg seed)
Potato	soil / seed borne fungi	All Europe	80
Beans	soil / seed borne fungi	All Europe	150
Grass	soil / seed borne fungi	All Europe	150
Lupin	soil / seed borne fungi	All Europe	150
Oats	soil / seed borne fungi	All Europe	150
Vetch	soil / seed borne fungi	All Europe	150
Wheat	soil / seed borne fungi, bird repellency	All Europe	160
Maize	soil / seed borne fungi, bird repellency	All Europe	197
Radish	soil / seed borne fungi	All Europe	197
Barley	soil / seed borne fungi, bird repellency	All Europe	200
	soil / seed borne fungi,		

Crop	Pest - Disease	Country	Maximum rate (g a.s./100 kg seed)
Peas	bird repellency	All Europe	200
Rye	soil / seed borne fungi	All Europe	200
Linseed	soil / seed borne fungi	All Europe	300
Cucumber	soil / seed borne fungi	All Europe	326
Poppy	soil / seed borne fungi	All Europe	394
Alfalfa	soil / seed borne fungi	All Europe	400
Cabbage	soil / seed borne fungi	All Europe	400
Celery	soil / seed borne fungi	All Europe	400
Lettuce	soil / seed borne fungi	All Europe	400
Onion	soil / seed borne fungi	All Europe	400
Parsley	soil / seed borne fungi	All Europe	400
Spinach	soil / seed borne fungi	All Europe	400
Oilseed rape	*Phoma sp*, Damping off	All Europe	440
Turnip	soil / seed borne fungi	All Europe	440
Beet (leaf beet, sugar beet)	soil / seed borne fungi	All Europe	480
Leek	soil / seed borne fungi	All Europe	5600

Table B.3.2.3a-2 : List of intended uses for seed treatment - based on the uses supported by Uniroyal (VITAVAX 200FF : FS containing 200 g/l thiram and 200 g/l carboxin)

Crop	Pest - Disease	Country	Maximum rate (g a.s./100 kg seed)
Wheat	soil / seed borne fungi	North Europe South Europe	60 90
Peas	soil / seed borne fungi	North Europe	50
Barley	soil / seed borne fungi	North Europe South Europe	60 100
Maize	soil / seed borne fungi	North Europe South Europe	50 90
Soya	soil / seed borne fungi	North Europe South Europe	50 60
Oats	soil / seed borne fungi	North Europe South Europe	60 90
Rye	soil / seed borne fungi	North & South Europe	60
Triticale	soil / seed borne fungi	North Europe	60
S. Beet	soil / seed borne fungi	South Europe	120
Sorghum	soil / seed borne fungi	South Europe	80
Rice	soil / seed borne fungi	South Europe	100
Cotton	soil / seed borne fungi	South Europe	90

B.3.2.4a Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops - Limitations on choice of succeeding crops (Annex IIIA 3.8)

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B.3.2.5a Proposed instructions for use as printed, or to be printed, on labels (Document C)

Table B.3.2.5a-1 : List of labels submitted in the documents C of the notifier(s) - Registrations in the EU

Crop/uses	Formulation name	Formulation type	Country
Peas /seed treatment	VITAVAX PRO 200	SC 198 g/l Thiram, 198 g/l Carboxin	France
Corn, sweet corn /seed treatment	VITAVAX PRO 200	SC 198 g/l Thiram, 198 g/l Carboxin	France
Oilseed rape /seed treatment	VITAVAX RS	FS 45 g/l Carboxin 90 g/l Thiram 67.5 g/l Lindane	United Kingdom
Wheat, barley, peas /seed treatment	VITAVAX 20 DUST	20% Carboxin 40% Thiram	Greece

B.3.2b Data on application relevant to the plant protection products - foliar uses (Annex IIIA 3)

B.3.2.1b Fields of use (Annex IIIA 3.1)

orchards, horticulture, ornamentals

B.3.2.2b Nature of the effects on harmful organisms (Annex IIIA 3.2)

Contact action, fungitoxic action, repulsive effect on bird and game

B.3.2.3b Pests controlled and crops protected (Annex IIIA 3.3)
Rate of application (Annex IIIA 3.4)
Concentration of active substance in material used (Annex IIIA 3.5)
Description of the method of application, type of equipment used and type and volume of diluent per unit of area or volume (Annex IIIA 3.6)
Number and timing of applications and duration of protection afforded (Annex IIIA 3.7)

The intended uses of thiram as foliar spray are restricted to fruit crops and ornamentals.

Table.3.2.3b-1 Intended uses of thiram - foliar spray formulations

Crop **Disease**	**Country**	**Maximum rate per application (kg a.s./ha)**	**Maximum rate per season (kg a.s./ha)**	**Spray concentration (g/hl)**	**Maximum number of applications per season**	**spray interval in days**	**Pre-harvest interval in days**
				Fruit			
Apple *Venturia inaequalis* (Scab) *Stemphylium*	All Europe	2.4	14.4	100 to 240	6 (treatments against *Monilia* and *Gloeosporium* included)	7-14 days - First application on young leaves	14
Apple *Monilia*	All Europe	2.4	-	160 to 240	2	7-14 days - First application before flowering	14
Apple *Gloeosporium*	All Europe	2.0	-	160 to 200	4	7-14 days - First application half June	14
Pear *Venturia pirina* (Scab)	All Europe	2.4	14.4	100 to 240	6 (treatments against *Monilia* and *Gloeosporium* included)	7-14 days - First application on young leaves	14
Pear *Monilia*	All Europe	2.4	-	160 to 240	2	7-14 days - First application before flowering	14
Pear *Gloeosporium*	All Europe	2.00	-	160 to 200	4	7-14 days - First	14

Crop **Disease**	**Country**	**Maximum rate per application (kg a.s./ha)**	**Maximum rate per season (kg a.s./ha)**	**Spray concentration (g/hl)**	**Maximum number of applications per season**	**spray interval in days**	**Pre-harvest interval in days**
						application half June	
Cherry *Monilia spp.* *Coryneum*	All Europe	2.4	7.2	160 to 240	3	7-14 days - First application before/during flowering	10
Plum *Monilia spp.* *Coryneum*	All Europe	2.4	7.2	160 to 240	3	7-14 days - First application before/during flowering	10
Almond *Monilia spp.* *Coryneum*	South-Europe	2.4	7.2	60 to 240	3	7-14 days - First application before/during disease occurrence	14
Apricot *Coryneum beijerinckii* *Monilia spp.*	South-Europe	2.4	9.6	160 to 240	4	7-14 days - First application before/during disease occurrence	14
Peach *Monilia spp.*	All Europe	2.4	9.6	160 to 240 (300 to 400 g a.s./hl for low volume spray at 500 l/ha)	4	7-14 days - First application before/during flowering	14
Peach *Taphrina deformans*	All Europe	2.4	4.8	160 to 240 (300 to 400 g a.s./hl for low volume spray at 500 l/ha)	2	7-14 days - Winter treatment	14
Peach *Coryneum beijerincki (Stigmina carpophila)* *Fusicoccum amygdali*	All Europe	2.4	4.8	160 to 240 (300 to 400 g a.s./hl for low volume spray at 500 l/ha)	2	- Autumn/winter treatment after harvest	14
Wine grapes *Botrytis* *Colletotrichum*	All Europe	3.2 kg/ha	9.6 kg/ha	160 to 320	3	- First application during flowering	28-35

Crop Disease	Country	Maximum rate per application (kg a.s./ha)	Maximum rate per season (kg a.s./ha)	Spray concentration (g/hl)	Maximum number of applications per season	spray interval in days	Pre-harvest interval in days
Field crops (changes and additions were brought by the applicant very lately during the review process. No evaluation of the risk to the operator and to the environment was done for these uses. These points should be addressed properly by the notifier.)							
Strawberry *Botrytis* *Mycosphaerella* *Colletotrichum*	All Europe	1.6-2.5	7.5	120 to 320	3	- During flowering - Repeat every 7-14 days if necessary	7
Lettuce *Botrytis*	All Europe indoor	8.0	16	0.8	2	Last treatment when leaves cover the row	42
	All Europe outdoor	2.0	4	0.2	1	Last treatment when leaves cover the row	28
	All Europe indoor	10.0	20	dusting	2	Last treatment when leaves cover the row	42
Ornamentals							
Ornamentals (outdoor) *Botrytis*	All Europe	3.2	-	200 to 320	as needed	7 days	-
Ornamentals (indoor) *Botrytis*	All Europe	3.2	-	200 to 300	as needed	7 days	-
Ornamental bulbs *Sclerotinia*	All Europe	3.2	-	320	as needed	7-10 days after flowering	-
Peony *Botrytis*	All Europe	-	-	1500 (root soaking)	1	-	-

B.3.2.4b Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops - Limitations on choice of succeeding crops (Annex IIIA 3.8)

Not relevant for perennial crops.

B.3.2.5b Proposed instructions for use as printed, or to be printed, on labels (Document C)

Several labels were proposed in Document C.

B.3.3 Summary of data on application

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B.3.4 Further information on the active substance (Annex IIA 3.7 to 3.9)

B.3.4.1 Recommended methods and precautions relating to handling, warehouse storage, user level storage, transport, fire (Annex IIA 3.7)

This information is presented under the form of a safety data sheet pursuant to Article 27 of Council Directive 67/548/EEC.

B.3.4.2 Procedures for destruction or decontamination of the active substance

B.3.4.2.1 Controlled incineration - Pyrolitic behaviour under controlled conditions at 800°C (Annex IIA 3.8.1)

Possible combustion products include oxides of carbon, nitrogen and sulfur.
There is no halogen in the molecule.

B.3.4.2.2 Methods other than controlled incineration for disposal of the active substance, contaminated packaging and contaminated materials (Annex IIA 3.8.2)

No other method specified.

B.3.4.3 Methods for decontamination of water in the case of accident (Annex IIA 3.9)

No method specified.

B.3.5 Further information on the plant protection product VITAVAX 200FF - Seed treatment (Annex IIIA 4)

B 3.5.1 Packagings, suitability of the packaging material to its content (Annex IIIA 4.1)

B.3.5.1.1 Description and specification of the packaging and materials used in packaging, size, capacity, size of openings, types of closure and seal (Annex IIIA 4.1.1)

No information on the packagings. (The notifier mentioned the use of drums of 20, 25 or 200 l)

B.3.5.1.2 Suitability of the packaging and closures (Annex IIIA 4.1.2)

No information.

B.3.5.1.3 Resistance of the packaging material to its contents (Annex IIIA 4.1.3)

No information

B.3.5.2 Procedures for cleaning application equipment and protective clothing (Annex IIIA 4.2)

No information.

B.3.5.3 Re-entry intervals, waiting periods and other precautions to protect man and animals

B.3.5.3.1 Pre-harvest intervals, re-entry intervals or withholding periods to minimize residues in crops, plants, plant products, treated areas or spaces (Annex IIIA 4.3.1)

Pre-harvest and re-entry periods for seed treatment formulations

Pre-harvest interval (in days) for each relevant crop :	Not relevant
Re-entry period (in days) for livestock to areas to be grazed :	Not relevant
Re-entry period (in hours or days) for man to crops, buildings or spaces treated :	Re-entry period to fields recently sowned is not relevant
Withholding period (in days) for animal feedingstuffs :	Not relevant.
Waiting period (in days) between application and handling treated products :	Not relevant
Waiting period (in days) between last application and sowing or planting succeeding crops :	Not necessary. Residues in soil resulting from sowing treated seeds are expected to be very low and transient

B.3.5.3.2 Information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used (Annex IIIA 4.3.2)

Not applicable

B.3.5.4 Recommended methods, precautions and handling procedures to minimize the risks relating to warehouse storage, user level storage, transport, fire - Detailed procedures for use in the event of an accident during transport, storage or use (Annexes IIIA 4.4 and 4.5)

This information is presented under the form of a safety data sheet pursuant to Article 27 of Council Directive 67/548/EEC.

B.3.5.5 Procedures for destruction or decontamination of the formulation VITAVAX 200FF and its packaging

B.3.5.5.1 Neutralization procedures for use in the event of accidental spillages (Annex IIIA 4.6.1)

No specific recommendations

B.3.5.5.2 Controlled incineration - Pyrolytic behaviour of the active substance under controlled conditions at 800° C (Annex IIIA 4.6.2)

Possible combustion products include oxides of carbon, nitrogen and sulfur.
There is no halogen in the formulation.

B.3.5.5.3 Methods other than controlled incineration for disposal of the plant protection product, contaminated packaging and contaminated materials (Annex IIIA 4.6.3)

No specific recommendations

B.3.5b Further information on the plant protection product THIRAM 80WG - Foliar spray (Annex IIIA 4)

B 3.5.1b Packagings, suitability of the packaging material to its content (Annex IIIA 4.1)

B.3.5.1.1b Description and specification of the packaging and materials used in packaging, size, capacity, size of openings, types of closure and seal (Annex IIIA 4.1.1)

Table B.3.5.1.1b-1 : Description of the receptacles of THIRAM 80WG

Contents	Package material	Dimensions
1 kg	Paper bag with inner polyethylene layer attached in a cardboard	115 x 75 x 250 mm
2.5 kg	Paper bag with inner polyethylene layer attached in a cardboard	184 x 106 x 283 mm
5 kg	Paper bag with inner polyethylene layer attached in a cardboard	237 x 111 x 362 mm
20 kg	Polyethylene bag in cardboard box	385 x 280 x 390 mm

The bags are sealed and the boxes are closed with glue (hot melt).
The package is opened by pulling a lid on one of the upper corners of the box along a provisional edge. This liberates a tip of the internal bag. This tip can be torn off. Then the product can be poured. (By following the method, no cutting tool whatever is required).

B.3.5.1.2b Suitability of the packaging and closures (Annex IIIA 4.1.2)

Keuringen van kartonnen dozen (4G) bestemd voor het vervoer van gevaarlijke goederen van de gevarengroepen I, II en III (Wittebolle M., 1995)

Table B.3.5.1.2-1 : Suitability of the receptacles of THIRAM 80WG

Formulation Receptacle type Capacity	Test method	Test conditions	Findings and conclusions	References
paper bag (4G) 1.3 kg content	ADR 3552 Drop test	5 samples 1.8 m fall	no break of the box or loss of its content	G-95.042
	ADR 3555	3 samples height of the pile : 3 m equivalent to 15 kg pressure during 24 hours	no deformation which could affect the strength of the box or the stability of the pile	
paper box (4G) 6.4 kg content	ADR 3552 Drop test	5 samples 1.8 m fall	no break of the box or loss of its content	G-95.043
	ADR 3555	3 samples height of the pile : 3 m equivalent to 50 kg pressure during 24 hours	no deformation which could affect the strength of the box or the stability of the pile	
paper box (4G) 3.5 kg content	ADR 3552 Drop test	5 samples 1.8 m fall	no break of the box or loss of its content	G-95.041
	ADR 3555	3 samples height of the pile : 3 m equivalent to 35 kg pressure during 24 hours	no deformation which could affect the strength of the box or the stability of the pile	
paper box (4G) 20 kg content	ADR 3552 Drop test	5 samples 1.8 m fall	no break of the box or loss of its content	G-95.040
	ADR 3555	3 samples height of the pile : 3 m equivalent to 185 kg pressure during 24 hours	no deformation which could affect the strength of the box or the stability of the pile	

B.3.5.1.3b Resistance of the packaging material to its contents (Annex IIIA 4.1.3)

No study available.
The notifier declared that ‘no signs of interaction between product and package have been observed’
Information on the resistance of the packaging must be provided.

B.3.5.2b Procedures for cleaning application equipment and protective clothing (Annex IIIA 4.2)

The equipment is cleared by rinsing several times with water. The rinsing water can be sprayed onto field.

B.3.5.3b Re-entry intervals, waiting periods and other precautions to protect man and animals

B.3.5.3.1b Pre-harvest intervals, re-entry intervals or withholding periods to minimize residues in crops, plants, plant products, treated areas or spaces (Annex IIIA 4.3.1)

Pre-harvest and re-entry periods of foliar spray formulations

Pre-harvest interval (in days) for each relevant crop :	See point B.6.10
Re-entry period (in days) for livestock to areas to be grazed :	Not relevant It is not expected that livestock would be present in the orchards during the growing season.
Re-entry period (in hours or days) for man to crops, buildings or spaces treated :	Exposure of the operator/ worker/ bystander was considered as unacceptable. This point must be addressed by the notifiers
Withholding period (in days) for animal feedingstuffs :	Not relevant
Waiting period (in days) between application and handling treated products :	See B.6.10
Waiting period (in days) between last application and sowing or planting succeeding crops :	Not relevant Thiram is applied on perennial crops which are not subjected to crop rotation

B.3.5.3.2b Information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used (Annex IIIA 4.3.2)

Do not use thiram with formulations containing copper or immediately after a treatment with copper formulation.

B.3.5.4b Recommended methods, precautions and handling procedures to minimize the risks relating to warehouse storage, user level storage, transport, fire - Detailed procedures for use in the event of an accident during transport, storage or use (Annexes IIIA 4.4 and 4.5)

This information is presented under the form of a safety data sheet pursuant to Article 27 of Council Directive 67/548/EEC.

B.3.5.5b Procedures for destruction or decontamination of the formulation THIRAM 80WG and its packaging

B.3.5.5.1b Neutralization procedures for use in the event of accidental spillages (Annex IIIA 4.6.1)

No specific recommendations

B.3.5.5.2b Controlled incineration - Pyrolytic behaviour of the active substance under controlled conditions at 800° C (Annex IIIA 4.6.2)

No specific recommendations

No halogen in the formulation.

B.3.5.5.3b Methods other than controlled incineration for disposal of the plant protection product, contaminated packaging and contaminated materials (Annex IIIA 4.6.3)

No specific recommendations

B.3.6 Summary of further information

Packaging :
Information about the packagings characteristics of seed treatment formulations was not submitted.
Description and suitability tests were provided for the formulation THIRAM 80 WG.

Procedures for cleaning application equipment and protective clothing :
In the case of foliar spray formulations, the equipment is cleaned by rinsing several times with water. The rinsing water can be sprayed onto the field.

Re-entry intervals, waiting periods and other precautions to protect man and animals

1) Pre-harvest and re-entry periods for foliar spray formulations
PHI : See point B.6.10
Reentry periods : Exposure of the operator/ worker/ bystander was considered as unacceptable. This point must be addressed by the notifiers

2) Pre-harvest and re-entry periods for seed treatment formulations : not relevant

Recommended methods, precautions and handling procedures to minimize the risks relating to warehouse storage, user level storage, transport, fire :

- Handling precautions : handle and open container with care. Avoid contact with skin, eyes and mucous membranes. In confined areas and during spraying wear suitable respiratory equipment. Wear suitable protective clothing. Wear safety goggles and wear suitable gloves.
Wash contaminated clothing before reuse.

- Storage : store in a cool dry place, away from foodstuffs and acids.

- Transport: See Material Safety Data Sheets (Appendix B in Annex B)

- Fire-fighting measures:

Flash point :	not applicable
Auto-flammability :	no information available
Explosive properties :	no information available
Extinguishing media :	foam, waterspray, CO_2, dry chemical
Specific hazards :	Combustible but moderately inflammable. Combustion causes toxic and irritant fumes. Decomposes in presence of acids.

Special protective equipment for firefighters: wear breathing apparatus.

- First-aid measures :
See points B.5.9.4 and B.5.9.5

Procedures for use in the event of an accident during transport, storage or use :

In case of leak or spill, keep all non-essential personnel away from the area. Warn everybody of toxic hazard.
Do not repack. Collect spillages for recovery.
Sweep up into separate containers. Do not contaminate unspilled material. Sweep up into containers for disposal.
Do not contaminate waterways with waste product or container. Avoid discharge into environment.

Procedures for destruction or decontamination of the formulations and their packaging :

This material and/or its container must be disposed of as hazardous waste. Do not discharge into drains or the environment, dispose to an authorised waste collection point or burn only in special, controlled high temperature incinerator.

Thiram does not contain halogen compounds, therefore no information concerning the pyrolitic behaviour is required.

B.3.7 References relied on

See Annex A.

ANNEX B

Thiram

Appendix A : Authorizations - Registrations

A part of the thiram produced by UCB is formulated by other companies. UCB considers that the list of the authorizations granted to its customers is trade secret. Confidential information - See also Annex C.

Table 1 : Authorizations and Registrations in the EU - Seed treatment formulations of Uniroyal

Country	Type of authorization	Crops/uses	Authorization details
UK	**Commercial**	**Oilseed rape**	**Vitavax RS carboxin 45 g/l thiram 90 g/l lindane 675 g/l FS seed treatment App. No. 06029 Iss. 3/12/93 Exp. 25/7/03**
France	**Provisional Commercial**	**Peas wheat barley bird repellent maize soya**	**Vitavax 200 FF carboxin 200 g/l thiram 200 g/l FS seed treatment App. No.8800011 Iss. 01/06/88 Exp.**
France	**Provisional**	**peas wheat**	**Vitavax Pro 200 carboxin 198 g/l thiram 198 g/l App. No. 9200127 Iss. 01/04/92**
	Commercial	**wheat maize soya bird repellent**	
France	**Provisional**	**wheat barley**	**Vitavax rouge carboxin 198 g/l thiram 198 g/l App. No. 9400148 Iss. 01/04/94**
	Commercial	**wheat barley bird repellent**	
France	**Provisional**	**wheat**	**Semevax carboxin 198 g/l thiram 198 g/l App. No. 920015 Iss. 01/04/92**
	Commercial	**wheat barley oats rye bird repellent**	
France	**Provisional**	**sugarbeet wheat anti-corbeau oilseed rape linseed maize onion**	**Gustafson 42S thiram 480 g/l FS seed treatment App. No. 9200548 Iss. 03/94**
Greece	**Commercial**	**wheat barley chickpea**	**Vitavax 2T carboxin 20 % thiram 40 %**

Table 1 : Authorizations and Registrations in the EU - Seed treatment formulations of Uniroyal

Country	Type of authorization	Crops/uses	Authorization details
			WS seed treatment **App. No. 6063** **Iss. 17/7/80** **Exp. 31/12/96**
Italy	**Commercial**	**maize** **cantaloupe** **cucumber** **marrow** **pumpkin** **watermelon** **flax** **wheat** **barley** **rye** **rice** **clover** **legumes** **sorghum** **millet** **pea** **lentil** **bean** **soyabean** **grass** **carrot** **salad** **lettuce** **pepper** **red salad** **spinach** **sunflower** **cabbage** **eggplant** **onion** **tomato** **leaf beet** **sugarbeet**	**Thiram 30** **thiram 300 g/l** **FS seed treatment** **App. No. 7324** **Iss. 16/212/87** **Exp. none**
Italy	**Commercial**	**(crops as Thiram 30)**	**Thiram 42S** **thiram 480 g/l** **FS seed treatment** **App. No. 7312** **Iss. 10/12/87** **Exp. None**
Italy	**Commercial**	**wheat** **barley** **rye** **oats** **corn** **sorghum** **rice**	**Vitaflo** **carboxin 149 g/l** **thiram 132 g/l** **FS seed treatment** **App. No. 7107** **Iss. 17/06/87** **Exp. none**

Table 1 : Authorizations and Registrations in the EU - Seed treatment formulations of Uniroyal

Country	Type of authorization	Crops/uses	Authorization details
		sugarbeet **soyabean** **bean**	
Italy	**Commercial**	**wheat** **barley** **oats** **corn** **sorghum** **rice**	**Vitavax 30 T** **carboxin 300 g/kg** **thiram 300 g/kg** **WS seed treatment** **App. No. 2615** **Iss. 2/7/77** **Exp. none**
Italy	**Commercial**	**wheat** **barley** **oats** **corn** **sorghum**	**Vitavax T** **carboxin 194 g/kg** **thiram 392 g/kg** **WS seed treatment** **App. No. 4229** **Iss. 13/3/81** **Exp. none**
Italy	**Commercial**	**wheat** **barley** **rye** **oats** **sorghum** **rice** **sugarbeet** **soyabean** **beans**	**Vitavax Flo** **carboxin 200 g/l** **thiram 200 g/l** **WS seed treatment** **App. No. 7106** **Iss. 17/6/87** **Exp. none**
Spain	**Commercial**	**wheat** **barley** **oats** **corn** **cotton** **rice**	**Vitavax Flo** **carboxin 200 g/l** **thiram 200 g/l** **WS seed treatment** **App. No. 16308/96** **Iss. 15/12/93** **Exp. 30/6/96**
Spain	**Commercial**	**wheat** **barley** **oats** **corn** **cotton**	**Vitavax T-PM** **carboxin 37.5 %** **thiram 37.5 %** **App. No. 16309/96** **Iss. 13/12/93** **Exp. 31/10/96**

Table 2 : Authorizations and Registrations in the EU - Formulations of UCB

Country	Type of authorization	Crops/uses	Authorization details
Austria	Commercial UCB	Fruit trees, corn, leguminous plants	Pomarsol Forte WP 80 % Reg. No : 563

Table 2 : Authorizations and Registrations in the EU - Formulations of UCB

Country	Type of authorization	Crops/uses	Authorization details
Austria	Commercial	Seed treatment (pea, bean, maize, root crops)	Alentiram WG 50 % Reg. No : 647
Belgium	Commercial UCB	seed treatment (maize, beet)	Thiram 80 WP WP 80 % Reg. No : 6019/B Issue Date : 25/8/96 Exp. Date : 25/8/2006
Belgium	Commercial UCB	Apple, pear, lettuce, endive, tomato, cucumber, other cucurbitaceae, asparagus, strawberry, currant, raspberry, blackberry, cherry, plum, peach ornamentals (peony, bulb desinfection, soil desinfection)	Thianosan Express WG 80 % Reg. No : 7591/B Issue Date : 1/8/96 Exp. Date : 1/8/2006
Belgium	Commercial UCB	Apple, pear, lettuce, endive, tomato, cucumber, other cucurbitaceae, asparagus, strawberry, currant, raspberry, blackberry, cherry, plum, peach ornamentals (peony, bulb desinfection, soil desinfection)	Hermosan 80 WP WP 80 % Reg. No : 7593/B Issue Date : 1/8/96 Exp. Date : 1/8/2006
Belgium	Commercial UCB	Apple, pear, lettuce, endive, tomato, cucumber, other cucurbitaceae, asparagus, strawberry, currant, raspberry, blackberry, cherry, plum, peach ornamentals (peony, bulb desinfection, soil desinfection)	Pomarsol WG WG 80 % Reg. No : 7651/B Issue Date : 1/2/97 Exp. Date : 11/2/2007
Belgium	Commercial UCB	Seed treatment (maize, pea)	TMTD 98 % Satec WP 98 % Reg. No : 8408/B Issue Date : 11/8/94 Exp. Date : 30.7/2002
France	Commercial UCB	Apple, pear, peach, grape, bean lettuce	Thianosan Ultra Dispersible WG 80 % Reg. No : 8500023 Issue Date : 28/2/85 Exp. Date : 28/2/95
Italy	Commercial UCB	Grape, pomefruit, stonefruit, vegetables, industrial crops, ornamentals, soil desinfection, seed treatment, bulb desinfection	Thianosan Instantaneo WG 50 % Reg. No : 8004 Issue Date : 24/1/92
Portugal	Commercial UCB	Apple, pear, plum, apricot, almond, peach, cherry, morello cherry,	Thianosan WG 80 % WG 80 %

Table 2 : Authorizations and Registrations in the EU - Formulations of UCB

Country	Type of authorization	Crops/uses	Authorization details
		strawberry	Reg. No : 2112 Issue Date : 11/3/94 Exp. Date : 31/7/95
Spain	Commercial UCB	Fruit trees, grapes, strawberries vegetables, seed treatment	TMTD 80 % PM WP 80 % Reg. No : 16469/97 Issue Date : 10/9/92 Exp. Date : 9/97
Spain	Commercial UCB	Fruit trees, grapes, strawberries vegetables, seed treatment	Thianosan Expres WG 80 % Reg. No : 17386/96 Issue Date : 15/11/93 Exp. Date : 30/9/96
Spain	Commercial UCB	Fruit trees (pomefruit, stonefruit, fig trees), grapes, strawberries, vegetables, seed treatment	Polyxane WG 50 % Reg. No : 18094/96 Issue Date : 15/3/95 Exp. Date : 30/3/2005
The Netherlands	Commercial	Apple, pear, strawberries, lettuce, endive, seed treatment, radish, plum, cherry, peach, blackberry, raspberry, currant, tomato, cucumber, asparagus, ornamentals	Thianosan Ultra Dispergeerbaar WG 80 % Reg. No : 10172N Issue Date : 5/7/93 Exp. Date : 1/1/96

ANNEX B

Thiram

Appendix B : Material Safety Data Sheets

List of Material Safety Data Sheets submitted by the notifiers

Thiram a.s.

VITAVAX 200 FF (seed treatment formulation)

THIRAM WG (foliar spray formulation)

ANNEX B

Thiram

B.4 Methods of analysis

B.4.1 Analytical methods for active substance and formulation analysis

B.4.1.1 Analytical methods for the determination of pure active substance in the active substance as manufactured (Annex IIA 4.1.1)

- Control test AC-1139 : Determination of Thiram and impurities in Thiram technical (author and date of report not specified) (UNIROYAL)

GLP :
No GLP-compliance stated
Principle of the method :
After dissolution of Thiram technical in methanol, Thiram and its impurities are separated by gradient HPLC on a reversed phase Spherisorb phenyl analytical column (5 µ, 250 x 4.6 mm, acetonitrile/water gradient). Determination by UV detection at 254 nm using an external standard.
Findings :
Specificity - interferences : no interferences were mentioned
Linearity : a correlation coefficient of 0.9998 was obtained on a 3-point standard curve ranging from 0.05 to 1 mg/ml. The standard curve was non-linear at 2 mg/ml.
Further information regarding the calibration curve (e.g. equation of the standard curve, number of measurements per concentration) was not provided.
Accuracy : not discussed
Repeatability : COV of 1 % (8 repetitive injections)
Conclusions :
The method is applicable for the determination of thiram, but additional validation (e.g. accuracy) is required.
A CIPAC-method (24/TC/M3/3) is available, however the applicability of this method was not discussed by the notifier.

B.4.1.2 Analytical methods for the determination of isomers, impurities and additives in the active substance as manufactured (Annex IIA 4.1.2)

- Determination of impurities in Thiram Phyto (author : not specified, 1994) (UCB)

For description of the method : see Annex C - confidential information (point [B.1.1.11b])

Conclusions :
Additional validation of the method for determination of impurities in thiram technical is required.
Methods for the determination of the additives in thiram technical are also required.

B.4.1.3 Analytical methods for the determination of pure active substance in plant protection products (Annex IIIA 5.1.1)

no methods were submitted; the notifier refers to the data that were presented under Annex IIA 4.1.1.

Conclusion :
The data submitted under Annex IIA 4.1.1 contain no validation data concerning plant protection products. Consequently, analytical methods for the determination of a.s. in formulations (foliar spray formulations and seed treatment formulations) with full validation are necessary.

For formulations such as VITAVAX 200FF, a combined method for the determination of thiram and carboxin should be provided.
CIPAC-methods are available for WP (24/WP/M3/3), DS (24/DS/M3/3) and LS (24/LS/M3/3), however the applicability of these methods was not discussed by the notifier.

B.4.1.4 Analytical methods for the determination of isomers, impurities, additives and formulants in plant protection products (Annex IIIA 5.1.2)

no methods were submitted; the notifier refers to the data that were presented under Annex IIA 4.1.2.

Conclusion :
No methods required since the impurities, additives and formulants in the plant protection products are not considered to be relevant.

B.4.2 Analytical methods (residue) for food and feed (Annex IIA 4.2.1; Annex IIIA 5.2.1)

Two types of methods were presented for the determination of Thiram residues in food and feed.
The first type of methods determine Thiram in fruit matrices and fruit derived products (such as wine and pomace) through HPLC, while the second type of methods determine respectively Thiram and one metabolite in fruit, vegetables and fish as CS_2 through analysis by GC.

HPLC

- Selective method for the determination of residues of Thiram in crops (Roland L. et al, 1992) (UCB)
- Validation of the HPLC method for the determination of residues of Thiram in vine (grapes and wine) (Weber H., 1993) (UCB)
- Validation of the HPLC method for the determination of residues of Thiram in vine (wet and dry pomace, must) (Weber H., 1994) (UCB)

GLP :
The validation studies are GLP.
Principle of the method :
Parent method (as described for crops): Because of the rapid degradation of Thiram in presence of grinded crops, it is essential to keep the samples as intact as possible when assuming the representativity of the subsample. The sampling method of the quarters is used.
Thiram is immediately extracted by dichloromethane or acetonitrile depending on the matrix (shaking for 2 minutes) : dichloromethane for crops with a high water content and a low content of lipidic material (strawberries, cherries, peaches, grapes, plums) and acetonitrile for apples and pears. After filtration, the extract is immediately evaporated and the dry residue is dissolved in a mixture methanol/water (10/90).
After purification on a microcolumn of C18 (elution with acetonitrile/water 40/60), determination of Thiram is carried out by HPLC on a Nucleosil C18 column (5 µ, 10 cm, mobile phase : methanol/phosphoric acid 0.1% 50/50 or acetonitrile/phosphoric acid 0.1% 40/60) with UV detection at 280 nm.
Method transfer (for grapes, wine, pomace, must) : Thiram is extracted with dichloromethane (for wine and must : extracted twice) and the organic phases are evaporated. The dry residue is dissolved in a mixture water/acetonitrile.
HPLC conditions : RP-18 column (5µ, 250 x 4 mm, mobile phase : water/acetonitrile 60/40)

Findings :

Specificity : the method has been set up to provide a selective determination of Thiram towards the other dithiocarbamates based on its solubility in organic solvents, but experimental proof of this selectivity is not given in these studies.

Table B.4.2-1 : Validation of the HPLC method (Roland et al, 1992)

Matrix	**Analyte**	**Fortification level (mg/ kg commodity)**	**Recovery**			
			Number of samples	**Mean (%)** ***individual values**	**Standard Deviation (%)**	**Coefficient of variation (%)**
Recovery trial - parent method (Roland L. et al, 1992)						
strawberries	thiram	0.20 0.50 1.00 2.00	1 1 1 1	96* 94* 97* 97* (mean = 96)	- (1.41)	- (1.47)
apple	thiram	0.20 0.50 1.00 2.00	1 1 1 1	80* 95* 93* 90.4* (mean = 89.6)	- (6.67)	- (7.45)
Validation of the method in an independent laboratory (grapes and wine) (Weber H., 1993)						
grapes	thiram	0.1 10	4 4	99	9.5	10
wine	thiram	0.1 10	4 4	61 98	7.0 2.0	11 2
Validation of the method in an independent laboratory (pomace and must) (Weber H., 1994)						
wet pomace	thiram	0.10 0.20 0.50 1.0	1 1 1 1	108	10	9.3
dry pomace	thiram	0.10 0.20 0.50 1.0	1 1 1 1	78	8.3	11
must	thiram	0.10 0.20 0.50 1.0	1 1 1 1	90	8.2	9.1

() = mean recovery, standard deviation and coefficient of variation : calculated, not given as such in the study

Limit of determination : in the parent method, a limit of determination of 0.05 mg/kg is stated, but this value was apparently not substantiated with recovery trials at the corresponding concentration level. Based on the recovery trials that were submitted, a value of 0.20 mg/kg seems appropriate for strawberries and apple.

For grape and wine matrices, a limit of determination of 0.1 mg/kg is stated, although the recoveries at the 0.1 mg/kg level in wine are low (range 54 - 69 %). This is due to the rapid degradation of Thiram at low concentrations in matrix-loaded sample solutions.

For wet and dry pomace and must matrices, a limit of determination of 0.1 mg/kg is stated.

Conclusions :

In terms of LOQ (0.2 mg/kg for strawberries and apple; 0.1 mg/kg for grapes, wine, wet and dry pomace and must), of accuracy (mean recoveries between 70 and 110 %) and of precision (SDs and CVs lower than 20 %), the method developed is suitable for residue analysis in the above-mentioned matrices. However, sample preparation requires special attention because of the rapid degradation of Thiram in presence of grinded crops.

For residue analysis in wine matrices, the recovery at the 0.1 mg/kg level is lower (61 %) due to the rapid breakdown of Thiram at low concentrations in matrix-loaded sample solutions.

Interferences from other dithiocarbamates were not discussed.

- Determination of residues of Thiram on plums, pears, peaches, cherries and apples in compliance with Good Laboratory Practice regulations - Liquid Chromatography method (Gatti G., 1992a) (UCB)

GLP :

The study is GLP

Principle of the method :

The samples are cut into portions according to the method of the quarters for the preparation of subsamples.

Thiram is immediately extracted from the samples with dichloromethane (plums, peaches, cherries) or acetonitrile (apples, pears) depending on the matrix (homogenized for 30 seconds with mixer). After filtration, the extract is evaporated and the dry residue is dissolved in a mixture methanol/water.

After purification on a microcolumn of C18 (elution with acetonitrile/water 50/50), the determination of Thiram is carried out by HPLC on a Erbasil C18 column (5 µ, 15 cm x 4.6 mm, mobile phase : acetonitrile/water 50/50) with UV detector (280 nm).

Findings :

Specificity : interferences with other crop protectants were not discussed

Limit of determination : a value of 0.020 mg/kg was stated, but the recovery obtained at this concentration level was not provided. Based on the recovery trials that were submitted, a value of 0.1 mg/kg seems appropriate.

Linearity of instrumental response of Thiram : r = 0.99964

Conclusions :

In terms of LOQ (0.1 mg/kg), of accuracy (recoveries between 70 and 110 %) and of precision (SDs and CVs lower than 20 %), the method is suitable for residue analysis in the above mentioned matrices. However, sample preparation requires special attention because of the rapid degradation of Thiram in presence of grinded crops.

Interferences from other dithiocarbamates were not discussed.

Table B.4.2-2 : Validation of the HPLC method (Gatti G., 1992a)

Matrix	Analyte	Fortification level (mg/ kg commodity)	Recovery			
			Number of samples	Mean (%) *individual values	Standard Deviation (%)	Coefficient of variation (%)
plum	thiram	0.1 4.0	1 1	87.5* 98.2* (mean = 92.85)	- (7.57)	- (8.15)
pear	thiram	0.1 4.0	1 1	92.0* 91.9* (mean = 91.95)	- (0.07)	- (0.08)
peach	thiram	0.1 4.0	1 1	84.8* 91.1* (mean = 87.95)	- (4.46)	- (5.07)
cherry	thiram	0.1 4.0	1 1	90.4* 85.9* (mean = 88.15)	- (3.18)	- (3.61)
apple	thiram	0.1 4.0	1 1	97.0* 97.3* (mean = 97.15)	- (0.21)	- (0.22)

() = mean recovery, standard deviation and coefficient of variation : calculated, not given as such in the study

<u>CS_2 determination by GC</u>

- Determination of residues of Thiram on plums, pears, peaches, cherries and apples in compliance with Good Laboratory Practice regulations - CS_2 headspace detection method (Gatti G., 1992b) (UCB)

<u>GLP :</u>

The study is GLP.

<u>Principle of the method :</u>

Thiram is determined as CS_2. The partially defrozen sample is rapidly cut in little portions and homogenized, after which the reagents (4 % $SnCl_2$ in concentrated HCl) are added to the weighed homogenate in a headspace bottle and the sample is hydrolyzed in a boiling water bath for 2 hours.

The headspace containing the CS_2 produced by the Thiram on the sample is then analysed by GC on a Supelco Chromosil 330 column (Teflon 8' x 1/8") with a Flame Photometric Detector (FPD, S-filter).

<u>Findings :</u>

Specificity : analysis of blanks does not evidence the presence of interferences.
Interferences with other crop protectants were not discussed, but it is clear that this method determines all dithiocarbamate residues and not just Thiram.

Limit of determination : a value of 0.030 mg/kg was stated, but the recovery obtained at this concentration was not discussed. Based on the recovery trials that were submitted, a value of 0.1 mg/kg seems appropriate.

Linearity of instrumental response of Thiram (as CS_2) : polynomial regression (r = 0.9987605).

Conclusion :

The method allows no selective determination of Thiram since all dithiocarbamate residues are measured.

Table B.4.2-3 : Validation of the CS_2 headspace GC method (Gatti G., 1992b)

Matrix	**Analyte**	**Fortification level (mg/ kg commodity)**	**Recovery**			
			Number of samples	**Mean (%)** ***individual values**	**Standard Deviation (%)**	**Coefficient of variation (%)**
plum	thiram	0.1 4.0	1 1	90.2* 98.6* (mean = 94.40)	- (5.94)	- (6.29)
pear	thiram	0.1 4.0	1 1	94.6* 104.1* (mean = 99.35)	- (6.72)	- (6.76)
peach	thiram	0.1 4.0	1 1	98.4* 97.9* (mean = 98.15)	- (0.35)	- (0.36)
cherry	thiram	0.1 4.0	1 1	95.2* 99.6* (mean = 97.40)	- (3.11)	- (3.19)
apple	thiram	0.1 4.0	1 1	94.3* 103.7* (mean = 99.00)	- (6.65)	- (6.71)

() = mean recovery, standard deviation and coefficient of variation : calculated, not given as such in the study

- Determination of residues of dithiocarbamate pesticides in foodstuffs by a Headspace Gas Chromatographic

method (Blundstone, 1991) (UNIROYAL)
GLP :
No GLP-compliance stated
Principle of the method :
The dithiocarbamate pesticide residues are reduced by a $SnCl_2$-reagent (in concentrated HCl) to CS_2 in capped bottles at 80 °C for 1 hour. The CS_2 released is measured in the headspace by GC on a Chromasil 310 column (Teflon 6' x 1/8") with Flame Photometric Detection (FPD, S mode). Results are expressed in terms of mg CS_2 released per kg of test sample.
This method can be used for the determination of total dithiocarbamate pesticide residues on fruit, vegetables, plant material and beverages.
Findings :
Specificity : this method determines all dithiocarbamate residues and not just Thiram.
Limit of determination : a value of 0.04 mg/kg (expressed as CS_2) is stated
Recovery : in lettuce the average recovery is 80.94 % (n = 249, COV = 10.5 %), without indication of the relevant fortification levels
Conclusion :
The method allows no selective determination of Thiram since all dithiocarbamate residues are measured.
The method was poorly validated.

- Gas Chromatographic determination of Thiram by carbon disulfide (CS_2) evolution (no author, 1988) (UNIROYAL, THIRAM TASK FORCE I).
GLP :
No GLP-compliance stated
Principle of the method :
Thiram is quantitatively decomposed to CS_2 by refluxing the sample for 1 hour in dilute HCl in the presence of $SnCl_2$. The evolved CS_2 is swept through an adsorption and purification system by a stream of air and absorbed in ethanol at dry ice temperature. The CS_2 is measured by GC (Tenax 60-80 mesh, 6' x 4 mm) using a Flame Photometric Detector (S mode).
Findings :
Specificity : Interferences with other crop protectants were not discussed, but it is clear that this method determines all dithiocarbamate residues and not just Thiram.
Limit of determination (sensitivity) : not determined
Precision : not determined
Accuracy (recovery): not determined
Conclusion :
The method allows no selective determination of Thiram since all dithiocarbamate residues are measured.
The method has not been validated.

- Gas Chromatographic determination of Dithioglucoside by carbon disulfide (CS_2) evolution (no author, 1988) (UNIROYAL, THIRAM TASK FORCE I).
GLP :
No GLP-compliance stated
Principle of the method :
Dithioglucoside is extracted with 1.0 N HCl, after which Thiram and other non-water soluble CS_2 generators are removed by extracting with chloroform. The aqueous extract is subsequently quantitatively decomposed to CS_2 by refluxing the sample in dilute HCl in the presence of $SnCl_2$. The evolved CS_2 is swept through an adsorption and purification system by a stream of air and absorbed in ethanol at dry ice temperature. The CS_2 is measured by GC (Tenax 60-80 mesh, 6' x 4 mm) using a Flame Photometric Detector (S mode).
Findings :
Specificity : Interferences with other crop protectants were not discussed
Limit of determination (sensitivity) : not determined
Precision : not determined
Accuracy (recovery) : not determined
Conclusion :
The method has not been validated.

- Determination of Thiram in fish (no author, 1988) (UNIROYAL).

GLP :

No GLP-compliance stated

Principle of the method :

After grinding of the frozen sample, the Thiram present is converted to CS_2 during reaction with $HCl/SnCl_2$-reagent for 1 hour at 100 °C in a sealed reaction flask. An aliquot of the headspace is analysed by GC (6' x 1/4" o.d. glass column packed with 28 % Pennwalt 223 + 4 % KOH on 80/100 Gas Chrom R) with Flame Photometric Detection (FPD, S mode).

Findings :

Specificity : Interferences with other crop protectants were not discussed, but it is clear that this method determines all dithiocarbamate residues and not just Thiram.

Limit of detection : a value of 0.05 mg/kg is stated, but the origin of this value is not clear.

Precision : not determined

Accuracy (recovery) : not determined

Conclusion :

The method allows no selective determination of Thiram since all dithiocarbamate residues are measured.
The method has not been properly validated.

B.4.3 Analytical methods (residue) in soil, water, air (Annex IIA 4.2.2 to 4.2.4; Annex IIIA 5.2.2 to 5.2.4)

B.4.3.1 Analytical methods for soil and water (Annex IIA 4.2.2 and 4.2.3; Annex IIIA 5.2.2 and 5.2.3)

- Determination of Thiram in water and soils by Cathodic Stripping Voltammetry based on adsorptive accumulation (Procopio J.R. et al, 1988)

GLP :

No GLP-compliance stated

Principle of the method :

Thiram is quantitatively extracted from water samples using Sep-Pak C18 cartridges (elution with methanol), while soil samples are extracted 3 times with chloroform. After drying of the extract, the residue is dissolved in methanol and diluted with water prior to the analysis through Cathodic Stripping Voltammetry.
Stripping and cyclic voltammograms are obtained with a Metrohm model 646 VA-processor, equipped with a 647 VA-stand. A hanging mercury drop electrode (0.6 mm² surface area), a Ag/AgCl (3 mol/l KCl) reference electrode and a glassy carbon wire auxiliary electrode are used, with a 0.075 mol/l ammonia solution as supporting electrolyte. The accumulation potential (- 0.2 V) is applied to the working electrode while the solution is stirred and 20 seconds after the stirring is stopped, the voltammogram is recorded by applying a negative scan at 5 mV/s and a pulse amplitude of - 100 mV. The scan is terminated at - 0.8 V.

Findings :

Specificity : interferences with other crop protectants are not discussed.

Linearity of instrumental response : at concentrations of Thiram between 0.1 and 5 ng/ml, the peak current is linear with the concentration.
for 120 s accumulation : slope = 1.91 $nA/ng.ml^{-1}$; r = 0.9999
for 600 s accumulation : slope = 15.32 $nA/ng.ml^{-1}$; r = 0.9998

Limit of determination : limits of detection of 0.3 µg/l (120 s accumulation) and 0.03 µg/l (600 s accumulation) are stated.
Based on the recovery trials that were submitted, limits of determination of 0.001 mg/l for water samples and 1 mg/kg for soil samples seem appropriate.

Repeatability : 10 successive measurements yielded a RSD of 1.5 % for 3 µg/l (120 s accumulation)
RSD of 3.5 % for 0.5 µg/l (600 s accumulation)

Conclusions :

The method requires equipment that is not commonly available in most control laboratories. Moreover, the LOQ for water samples (0.001 mg/l, based on the recovery trials that were submitted) is higher than the drinking water limit of 0.1 µg/l. A more adequate method should thus be provided.

Table B.4.3.1-1 : Validation of the Cathodic Stripping Voltammetry method (Procopio J.R. et al, 1988)

Matrix	Analyte	Fortification level (mg/ kg commodity) (* mg/l commodity)	Recovery			
			Number of samples	Mean (%)	Standard Deviation (%)	Coefficient of variation (%)
water	thiram	0.005 *	not given	95.7	2.5	-
		0.001 *	not given	88.4	2.2	-
soil	thiram	20	not given	91.3	1.7	-
		10	not given	89.0	1.8	-
		1	not given	93.4	2.1	-

B.4.3.2 Analytical methods for air (Annex IIA 4.2.4; Annex IIIA 5.2.4)

no methods submitted

Conclusion :
Seed treatment formulations are applied in closed buildings. The calculation of the potential exposure showed that the main route of exposure of the workers is by inhalation and that the exposure trigger values can be exceeded if no protection is proposed.
Therefore analytical methods for the determination of a.s. in air are required.

B.4.4 Analytical methods (residue) wildlife and for use in support of diagnostic and therapeutic regimes (Annex IIA 4.2.5; Annex IIIA 5.2.5)

no methods submitted

Conclusion :
No methods required since the active substance is not toxic.

B.4.5 Evaluation and assessment

B.4.5.1 Evaluation and assessment of analytical methods for technical active substance and formulation analysis

Table B.4.5.1-1 : Summary of analytical methods for technical active substance and formulation analysis

Matrix	Analyte	Type of method	Validation	References
technical active substance	thiram as pure a.s.	gradient HPLC with UV detection	specificity, linearity and repeatability	Test AC-1139 (?, ?) (UNIROYAL)
technical active substance	impurities	gradient HPLC with UV detection	specificity	(?, 1994) (UCB)

Evaluation :
The methods submitted allow to determine the purity and the impurities of the technical a.s., although some additional validation is required. Methods for the determination of the additives in Thiram technical are also required.
Analytical methods for the determination of a.s. in foliar spray formulations (WG) and seed treatment formulations (FS) need to be provided.

CIPAC-methods are available for the determination of Thiram in the technical compound, as well as in formulations (WP, DS and LS), but the applicability of these methods was not discussed by the notifier.

B.4.5.2 Evaluation and assessment of the analytical methods (residue) in food and feed

Table B.4.5.2-1a : Summary of analytical methods (residue) in food and feed

Matrix	Analyte	Type of method	Method range	Validation	References
strawberries apple grapes wine wet/dry pomace must	thiram	HPLC with UV detection	0.2 to 2 mg/kg commodity 0.1 to 10 mg/kg commodity 0.1 to 1 mg/kg commodity	full validation	(Roland L. et al, 1992) (UCB)
plum pear peach cherry apple	thiram	HPLC with UV detection	0.1 to 4 mg/kg commodity	specificity not discussed, no validation by an independent laboratory	(Gatti G., 1992a) (UCB)

Table B.4.5.2-1b : Summary of analytical methods (residue) in food and feed

Matrix	Analyte	Type of method	Method range	Validation	References
plum pear peach cherry apple	thiram (as CS_2)	GC with FPD	0.1 to 4 mg/kg commodity	no validation by an independent laboratory	(Gatti G., 1992b) (UCB)
lettuce	dithiocarbamate (as CS_2)	GC with FPD	not given (LOQ : 0.04 mg/kg expressed as CS_2)	no validation by an independent laboratory	(Blundstone, 1991) (UNIROYAL)
various crops	thiram (as CS_2)	GC with FPD	not given	no validation	(?, 1988) (UNIROYAL, THIRAM TASK FORCE I)
various crops	dithioglucoside (as CS_2)	GC with FPD	not given	no validation	(?, 1988) (UNIROYAL, THIRAM TASK FORCE I)
fish	thiram (as CS_2)	GC with FPD	not given (LOQ : 0.05 mg/kg)	no validation	(?, 1988) (UNIROYAL)

Evaluation :
The HPLC method provided (Roland L. et al, 1992) allows the determination of Thiram in food matrices of plant origin. However, sample preparation requires special attention due to the rapid degradation of Thiram in presence of grinded crops.

The CS_2 - GC methods on the other hand measure all dithiocarbamate residues and thus allow no selective determination of Thiram. None of these methods has been properly validated.

Methods for the determination of residues in food matrices of animal origin are not required since residues of Thiram are not expected in animal products for human consumption.

B.4.5.3 Evaluation and assessment of the analytical methods (residue) in soil, water and air

Table B.4.5.3-1 : Summary of analytical methods (residue) in soil and water

Matrix	Analyte	Type of method	Method range	Validation	References
water soil	thiram	Cathodic Stripping Voltammetry	0.001 to 0.005 mg/l water 1 to 20 mg/kg soil	full validation	(Procopio J.R. et al, 1988)

Evaluation :
The method provided for the determination of Thiram residues in water and soil matrices requires equipment that is not commonly available in most control laboratories. Moreover, the LOQ for water samples (0.001 mg/l) is higher than the drinking water limit of 0.1 µg/l, so that more adequate methods allowing the determination of a.s. and relevant metabolites in soil and water are necessary.

Methods that allow the determination of Thiram residues in air also need to be submitted.

B.4.5.4 Evaluation and assessment of analytical methods (residue) wildlife and for use in support of diagnostic and therapeutic regimes

no methods were submitted

Evaluation :
No methods required since the active substance is not toxic.

B.4.6 References relied on

see Annex A