ANNEX B

Ziram

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 a task-force, constituted by the 2 following notifiers :

Name	**ELF ATOCHEM AGRI SA**	**UCB SA**
Address	1, Rue des Frères Lumière Bp 9 - 78373 - Plaisir Cedex France	Pantserschipstraat, 207 9000 Gent - Wondelgem Belgium
Person to contact	B. SORNIN, Anne Marie JEAN	Mia LAGET
Telephone n°	+ (33) 1 30 81 73 00	+ (32) 9 254 14 11
Fax n°	+ (33) 1 30 81 72 51	+ (32) 9 254 14 10

Two other dossiers were 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

Bakelite Italia S.p.A;
Via G. Mazzini 104,
21058 Solbiate Olona
Italy
Person to contact: Dr. Alberto Coglio
Tel : 39-331-355225
Fax : 39-331-376390

These 2 dossiers were incomplete. The available information was evaluated in the relevant sections (some toxicological data)

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

Manufacturer and contact point	
Elf Atochem Agri S.A. 1 rue des frères Lumière - 78373 Plaisir France	UCB S.A. Avenue Louise, 326 - 1050 Brussels Belgium
Location of plants	
1 Tankhoofd 10 3196 KE Rotterdam The Netherlands	UCB Gent Pantserschipstraat 207 - 9000 Ghent Belgium
2 Aparto n°. 20 22660 Sabiñanigo - Huesca Spain	

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

Ziram

B.1.1.4 Chemical name (Annex IIA 1.4)

IUPAC: Zinc bis (dimethyldithiocarbamate)
CA: (T-4) - bis (dimethyldithiocarbamato-S,S') zinc

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

none

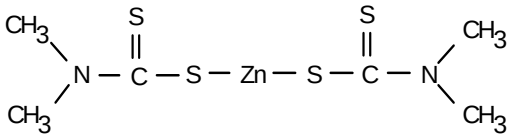
B.1.1.6 CAS, EEC and CIPAC numbers (Annex IIA 1.6)

CAS number : [137-30-4]
EEC number : 205-288-3
CIPAC number : 31

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

Molecular formula: $C_6 H_{12}N_2 S_4 Zn$

Structural formula:



Molecular mass: 305.81

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

It can be stated that the information submitted by the notifiers is not sufficient to establish purity limits and profile of impurities of technical ziram unequivocally. Additional information, including a complete analytical profile of batches, is required.

The minimum purity as stated by the notifiers within the task-force varies between 970 and 980 g/kg.
The minimum purity as stated in the FAO-specification for ziram technical (CP/82) equals 950 g/kg.

Confidential information, see Annex C

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

Confidential information, see Annex C

B.1.2 Identity of the plant protection products TRISCABOL 76 WG - ZIRAM 76 WG (Annex IIA 3.1; Annex IIIA 1)

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

Trade name : TRISCABOL 76 WG (Elf Atochem)
ZIRAM 76 WG (UCB)

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

Manufacturer and contact point	
Elf Atochem Agri S.A. **1 rue des frères Lumière - 78373 Plaisir** **France**	**UCB S.A.** **Avenue Louise, 326 - 1050 Brussels** **Belgium**

Location of plants		
1	**Tankhoofd 10** **3196 KE Rotterdam** **The Netherlands**	**UCB Gent** **Pantserschipstraat 207 - 9000 Ghent** **Belgium**
2	**Aparto n°. 20** **22660 Sabiñanigo - Huesca** **Spain**	

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

Physical state : Water dispersible granule (WG)

B.1.2.4 Function (Annex IIIA 1.6)

Fungicide, game and bird repellent

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

WG containing 760 g Ziram/kg

Other components : Confidential information, see Annex C

B.1.3 References relied on

Identity

Identity of the active substance - Elf Atochem (Annex IIA 1; Annex IIIA 1, 3.1 to 3.4)

Annex point(s) Dir 91/414/EEC	Author(s)	Title Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file No. of submitting company Date of report for publication: reference	GLP GEP	Published Protected
IIA 1.8	Anonymous	Manufacturing process of Ziram Statement generated by : Elf Atochem Agri S.A. Submitted by : Elf Atochem Agri S.A. (< doc. J) Company file N° : - Date of report : -	no	unpublished protected
IIA 1.9 IIA 1.10	Kool P.	Confidential statement of formula - Triscabol technical Statement generated by : Elf Atochem Agri B.V. Submitted by : Elf Atochem Agri S.A. (< doc. J) Company file N° : - Date of report : August 15, 1994	no	unpublished protected
IIA 1.11	Diepenhorst P.C.	PH-M 227.1.1* Generated by : Pennwalt Holland (Elf Atochem Agri B.V.) Submitted by : Elf Atochem Agri S.A. (< doc. J) Company file N° : PH-M 227.1.1 Date of report : July 24, 1987a	no	unpublished protected
IIA 1.11	Diepenhorst P.C.	Triscabol technical : determination of impurities by HPLC Generated by : Pennwalt Holland (Elf Atochem Agri B.V.) Submitted by : Elf Atochem Agri S.A. (< doc. J) Company file N° : PH-M 227.2.1 Date of report : June 25, 1987b	no	unpublished protected
IIA 1.11	Diepenhorst P.C.	PH-M 227.4.1* Generated by : Pennwalt Holland (Elf Atochem Agri B.V.) Submitted by : Elf Atochem Agri S.A. (< doc. J) Company file N° : PH-M 227.4.1 Date of report : June 27, 1987c	no	unpublished protected
IIA 1.11	Diepenhorst P.C.	SOP DLA-M 026.2* Generated by : Elf Atochem Agri B.V. Submitted by : Elf Atochem Agri S.A. (< doc. J) Company file N° : SOP DLA-M 026.2 Date of report : July 21, 1993	no	unpublished protected

* full title not indicated (mentions name of impurity or additive, see Annex C)

Identity of the active substance - UCB (Annex IIA 1; Annex IIIA 1, 3.1 to 3.4)

Annex point(s) Dir 91/414/EEC	Author(s)	Title Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file No. of submitting company Date of report for publication: reference	GLP GEP	Published Protected
IIA 1.8	Anonymous	Ziram - Manufacturing process Statement generated by : UCB S.A. Submitted by : UCB S.A. (< doc. J) Company file N° : - Date of report : -	no	unpublished protected
IIA 1.9 IIA 1.10 IIA 1.11	Anonymous	Identity of isomers, impurities and additives Statement generated by : UCB S.A. Submitted by : UCB S.A. (< doc. J) Company file N° : - Date of report : -	no	unpublished protected

Identity of the active substance - FMC Foret (Annex IIA 1; Annex IIIA 1, 3.1 to 3.4)

Annex point(s) Dir 91/414/EEC	Author(s)	Title Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file No. of submitting company Date of report for publication: reference	GLP GEP	Published Protected
IIA 1.8	Anonymous	Operations manual Diziram plant - Vinaros factory Generated by : FMC Foret Submitted by : FMC Foret (< doc. J) Company file N° : FORET-MPI-802 Date of report : February, 1995	no	unpublished protected

Identity of the active substance - Bakelite (Annex IIA 1; Annex IIIA 1, 3.1 to 3.4)

Annex point(s) Dir 91/414/EEC	Author(s)	Title Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file No. of submitting company Date of report for publication: reference	GLP GEP	Published Protected
IIA 1.8	Anonymous	Method of manufacture (synthesis pathway) of Ziram Statement generated by : Bakelite Italia S.p.A. Submitted by : Bakelite Italia S.p.A. (< doc. J) Company file N° : - Date of report : -	no	unpublished protected
IIA 1.9 IIA 1.10	Anonymous	Identity of isomers, impurities and additives Statement generated by : Bakelite Italia S.p.A. Submitted by : Bakelite Italia S.p.A. Company file N° : - Date : November 18, 1994	no	unpublished protected
IIA 1.11	Anonymous	Analysis certificates Generated by : Bakelite Italia S.p.A. Submitted by : Bakelite Italia S.p.A. (< doc. J) Company file N° : - Date of report : October 12-13, 1994	no	unpublished protected

Identity of the formulation TRISCABOL 76 WG - Elf Atochem (Annex IIIA 1, 3.1 to 3.7, 3.9 and 12.1)

Annex point(s) Dir 91/414/EEC	Author(s)	Title Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file No. of submitting company Date of report for publication: reference	GLP GEP	Published Protected
IIIA 1.4	Kool P.	Confidential statement of formula - Triscabol 76 WG Statement generated by : Elf Atochem Agri B.V. Submitted by : Elf Atochem Agri S.A. (< doc. J) Company file N° : - Date of report : August 18, 1994	no	unpublished protected

Identity of the formulation ZIRAM 76 WG - UCB (Annex IIIA 1, 3.1 to 3.7, 3.9 and 12.1)

Annex point(s) Dir 91/414/EEC	Author(s)	Title Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file No. of submitting company Date of report for publication: reference	GLP GEP	Published Protected
IIIA 1.4	Anonymous	Composition of the preparation : content and identity of formulants Statement generated by : UCB S.A. Submitted by : UCB S.A. (< doc. J) Company file N° : - Date of report : March, 1995	no	unpublished protected

ANNEX B

Ziram

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 Ziram

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.1 Melting point, freezing point or solidification point (IIA 2.1.1)	- Data taken from literature	purified a.s. : melting point = 246 °C technical a.s. : melting point = between 240 and 244 °C	- Not acceptable (data from literature : only summary results which can't be evaluated because quality of data can't be checked)	Pesticide Manual, 10th Edition, 1994
B.2.1.2 Boiling Point (IIA 2.1.2)			- Not applicable (not a low melting substance)	
B.2.1.3 Temperature of decom-position or sublimation (IIA 2.1.3)			- Not applicable	
B.2.1.4 Relative density (IIA 2.2)	- Data taken from literature	a.s., purity not specified : 1.66 at 25 °C	- Not acceptable (data from literature : only summary results which can't be evaluated because quality of data can't be checked)	Pesticide Manual, 10th Edition, 1994
B.2.1.5 Vapour pressure	- Modified Watson correlation method	technical a.s. : vapour pressure < 10^{-5} Pa	- Not acceptable (no full report, only	Diepenhorst, 1987

Study (IIA 2.3.1)	**Guidelines and GLP** - No GLP-compliance stated	**Findings**	**Evaluation and conclusions** summary results which can't be evaluated because quality of data can't be checked)	**References**
B.2.1.6 Volatility, Henry's law constant (IIA 2.3.2)		H < 1.9 10^{-5} atm.m³.mol^{-1} (< 1.9 Pa.m³.mol^{-1}) (can not be determined precisely)	- Not acceptable (see B.2.1.5)	
B.2.1.7 Physical state (IIA 2.4.1)	- Data taken from literature	a.s., purity not specified : powder	- Acceptable, but description of both purified a.s. and technical a.s. is required	Pesticide Manual, 10th Edition, 1994
B.2.1.8 Colour (IIA 2.4.1)	- ASTM D 1535-68 (Munsell color system)	technical a.s., 98% pure : Munsell color notation = 4.13Y 9.46/0.49 Ziram is specified to be a colourless powder (Pesticide Manual)	- Acceptable, but additional information is required (colour of purified a.s.)	De Lange & Verberckt, 1986
B.2.1.9 Odour (IIA 2.4.2)		technical a.s. : no characteristic odour	- Acceptable (no report, findings mentioned in Tier I), but additional information is required (odour of purified a.s.)	
B.2.1.10		a.s., purity not specified :	- Not acceptable : no	UV/VIS : no author,

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
Spectra of the active substance (IIA 2.5.1)	-No GLP-compliance stated	**UV/VIS** : in methanol, resp. water/methanol (3/7); recorded from 190 to 820 nm **MS** **IR**	NMR-spectrum + reports on other spectra contain insufficient data (e.g. no specification of purity of samples, no mention of molar extinction coefficients at relevant wavelengths (UV/VIS), no table of signal characteristics, needed for interpretation of the spectra (IR, MS))	1989 IR : no author, 1984 MS : no author or date specified
B.2.1.11 Spectra for impurities (IIA 2.5.2)		no data	- Spectra of impurities that are considered to be of toxicological significance (e.g. tetramethylthiourea) are required.	
B.2.1.12 Solubility in water (IIA 2.6)	- OECD-guideline 105 (flask method + atomic absorption analysis)	technical a.s., purity not further specified : average solubility in distilled water at 20 °C = 18.3 ± 7.2 ppm (mean of 9 batches)	- Not acceptable (solubility is determined using	Danschutter, 1985

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	- No GLP-compliance stated		technical a.s. instead of purified a.s. and the purity of the samples is not further specified) - The method used for determination of a.s. concentration in the supernatant is not specific for Ziram (also measures zinc containing impurities)	
	- OECD-guideline 105 (flask method + atomic absorption spectrometry) - No GLP-compliance stated	technical a.s., purity not further specified : average solubility in distilled water at 20 °C = 3.35 ± 0.22 ppm (mean of 10 batches)	- Not acceptable (same reasons as mentioned above). Moreover, the result differs from the result obtained in the above-mentioned study, although the method used was comparable.	Christiaens & Verberckt, 1987
	- OECD-guideline 105 (modified flask method) - No GLP-compliance stated	purified a.s., purity not further specified in the report *(in Tier I : 99.7%):* average solubility in water at 20 °C = 1.58 mg/l (RSD = 5.4%)	- Not acceptable (no full report, only summary results which can't be evaluated because quality of data can't be checked)	Diepenhorst, 1987
	- ASTM E70-74	technical a.s., purity not further specified :	- Not relevant; the	Vandevelde &

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	- No GLP-compliance stated	average pH of a 4% aqueous suspension in distilled water at 20 °C = 7.29 ± 0.34 (mean of 12 batches)	aspect "effect of pH on solubility in water" is not addressed.	Verberckt, 1986
B.2.1.13 Solubility in organic solvents (IIA 2.7)	- OECD-guideline 105 (modified flask method)	technical a.s., purity not further specified : solubility at 20 °C in acetone : 0.288 g/100 g methanol : 0.022 g/100 g toluene : 0.233 g/100 g solvent naphta : 0.109 g/100 g n-hexane : 0.007 g/100 g	- Not acceptable (no full report, only summary results which can't be evaluated because quality of data can't be checked)	Diepenhorst, 1987
	- Data taken from literature	a.s., purity not specified : soluble in : chloroform and carbon disulfide moderately soluble in : acetone almost insoluble in : ethanol and diethyl ether	- Not acceptable (data from literature : only summary results which can't be evaluated because quality of data can't be checked)	Pesticide Manual, 10th Edition, 1994
B.2.1.14 Partition coefficient n-octanol/water (IIA 2.8)	- OECD-guideline 107 - No GLP-compliance stated	purified a.s., purity not further specified : at 20 °C : log P_{ow} = 1.23	- Not acceptable (no full report, only summary results which can't be evaluated because quality of data can't be checked)	Diepenhorst, 1987
B.2.1.15	- US EPA N-161-1	a.s. ^{14}C-labelled - radiochemical purity : 95.2 - 97%	- Not acceptable : the	Daly & Cranor, 1987

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
Hydrolysis rate at pH 4, 7 and 9 under sterile conditions in the absen-ce of light (IIA 2.9.1)	- GLP-compliance stated	at 25 °C in the dark (sterile conditions) : pH 5 (acetate buffer) : $t_{½}$ = 25 d pH 7 (Tris-HCl buffer) : $t_{½}$ = 8 d pH 9 (borate buffer) : $t_{½}$ = 45 d pH 9 (glycine-NaOH buffer) : $t_{½}$ = 191 d No characterization of the hydrolysis products. Based on the structural formula, it is postulated that dimethylamine, carbondisulfide and possibly carbonyl sulfide or carbondioxide are the most likely hydrolysis products of Ziram.	scientific basis of the study is questionable (half-life calculation is based on the decline of total ^{14}C-residues within the test solution, rather than on measurement of the actual rate of decline of parent compound + hydrolysis degradates were not characterized).	
B.2.1.15 (cont.)	- US EPA N-161-1	a.s. ^{14}C-labelled - radiochemical purity : > 98%	- Method equivalent to	Heasook, 1995

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	- GLP-compliance stated	at 25 °C in the dark (sterile conditions, acetone as cosolvent) : pH 5 (acetate buffer) : $t_{½}$ = 10.4 min pH 7 (Tris-HCl buffer) : $t_{½}$ = 17.67 h pH 9 (borate buffer) : $t_{½}$ = 6.31 d In pH 5 and pH 7 buffered solutions, the major degradate was identified as CS_2. In pH 9 buffered solutions the major degradate was identified as dimethyldithiocarbamic acid (DDC). CS_2 was also observed, but as a minor degradate. Other minor degradates were carbon oxysulfide, isothiocyanic acid or thiocyanic acid and N,N-dimethylformamide.	EEC C7; pH 5 instead of pH 4 is not relevant. - Acceptable	
B.2.1.16 Direct phototransformation of purified a.s. in water using artificial light under sterile conditions (IIA 2.9.2)	- US EPA N-161-2 (Type RS® Sunlamp) - GLP-compliance stated	a.s. ^{14}C-labelled - radiochemical purity : > 90% pH 9 buffered solution : nonsensitized exposed system : $t_{½}$ = 7.84 d nonsensitized dark system : $t_{½}$ = 6.04 d	- Not acceptable : the scientific basis of the study is questionable (no thermostatic control + the activity balance obtained in the test systems varies over a wide range + the correlation coefficients of the degradation curves used for $t_{½}$-estimation are low).	Carpenter, 1985
B.2.1.16 (cont.)	- US EPA N-161-2 (Heraeus SUNTEST CPS xenon arc lamp with UV filter for λ<290 nm)	a.s. ^{14}C-labelled - radiochemical purity : 96.54% at 25 °C (sterile conditions, acetonitrile as cosolvent) in a pH 9 buffered solution (phosphate buffer) : 1) photochemical half-life : 8.7 h 2) mass balance (distribution of radioactivity) after	- Method concurs with SETAC-procedures - Acceptable	Heasook, 1996

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	- GLP-compliance stated	24 h : 15.11% Ziram 26.83% degradate A 20.98% degradate B 20.59% degradate E 15.28% degradate F 1.22% minor degradates (C, D and H) total radioactivity in test solution represents 92.74% of initially applied radioactivity (average total ^{14}C-recovery in test solutions throughout duration of study was 97.73% for irradiated samples and 103.18% for dark controls) 3) <u>identity of major degradates</u> : A and E = N,N-dimethylformamide B : composed of several degradates, B-1 = N,N-dimethylthioformamide B-2 = N,N-dimethyl-N-formyl sulfinic acid B-3 = N,N-dimethyl-N-thioformyl sulfinic acid B-4 = N,N-dimethyl-N-thioformyl sulfonic acid B-5 = N,N-dimethyl-N-thioformyl-O-sulfonic acid B-6 = unknown B-7 = dimethyldithiocarbamic acid F = N,N-dimethylthioformamide		
B.2.1.17 Quantum yield of direct phototransformation (IIA 2.9.3)		no data	- Study on quantum yield is required	
B.2.1.18 Dissociation in water of purified active	- OECD-guideline 108 (Differential Pulse Polarography)	conditional stability constant at pH 9.15 : $\log \beta_2 = 6.4 \pm 0.5$	- Study describes the determination of the stability constant of	Fischer & Vandegans, 1987

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
substance (IIA 2.9.4)	- No GLP-compliance stated		Ziram, but does not address the aspect "dissociation in water" (pKa).	
B.2.1.19 Estimated photo chemical oxidative degradation (IIA 2.10)		no data	- Estimation of photochemical oxidative degradation is required (e.g. Atkinson method)	
B.2.1.20 Flammability (IIA 2.11.1)	- EEC-method A13 - No GLP-compliance stated	technical a.s., purity not further specified : Ziram does not ignite in contact with air at 25 °C	- Not acceptable (method used does not correspond with EEC-method A10)	Diepenhorst, 1987
B.2.1.21 Auto-flammability (IIA 2.11.2)	- EEC-method A16 - No GLP-compliance stated	technical a.s., purity not further specified : Ziram is not autoflammable	- Not acceptable (no full report, only summary results which can't be evaluated because quality of data can't be checked)	Diepenhorst, 1987
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)	- EEC-method A14(*) - Recommendations on the transport of dangerous goods, Part I (**) - ASTM E-487 (***) - No GLP-compliance stated	technical a.s., purity not further specified : shock sensibility (BAM-shocktest) : > 50 Nm (*) friction sensibility : > 360 N (*) Koenen test : < 1 mm (**) thermal explodability : DSC (***) - endotherm 236-271 °C, 114-133 kJ/kg (melting effect) - exotherm 289-343 °C, 440-533 kJ/kg - no self-heating observed under 180 °C Þ no explosive properties	- Not acceptable (no full report, only summary results which can't be evaluated because quality of data can't be checked)	Diepenhorst, 1987
B.2.1.24 Surface tension (IIA 2.14)		no data	- Study on surface tension according to EEC A5 is required	
B.2.1.25 Oxidizing properties (IIA 2.15)	- EEC-method A12 (*) - EEC-method A13 (**) - Federal register Vol. 44-No.53-page 16267-A-3.67 section B (***), section C (Ù), section E (ÙÙ), section D (ÙÙÙ) - No GLP-compliance stated	technical a.s., purity not further specified : - with water : negative (*) - with diatomite : negative (**) - with carbondioxide : negative (***) - with iron : negative (Ù) - with potassiumpermanganate : limited temperature increase (± 8 °C) (ÙÙ) - with terpentine : negative (ÙÙÙ) Þ no oxidizing/reducing properties	- Not acceptable (methods used do not correspond with EEC-method A17 + report contains only summary results which can't be evaluated because quality of data can't be checked).	Diepenhorst, 1987

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

The Annex III dossier submitted by the Task Force concerns a water dispersible granule containing 76% Ziram. It is however not clear whether the formulation with which the tests were performed (ZIRAM 76 WDG) corresponds with TRISCABOL 76 WG (composition presented by ELF Atochem) or with ZIRAM 76 WG (composition presented by UCB).

Table B.2.2-1 : Physical and chemical properties of ZIRAM 76 WDG (water dispersible granule : Ziram)

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.1 Physical state (IIIA 2.1)	- Visual inspection	granules	- Acceptable (no report, findings mentioned in Tier I)	
B.2.2.2 Colour (IIIA 2.1)	- Visual inspection	light brown	- Acceptable (no report, findings mentioned in Tier I)	
B.2.2.3 Odour (IIIA 2.1)		no specific odour	- Acceptable (no report, findings mentioned in Tier I)	
B.2.2.4 Explosive properties (IIIA 2.2.1)	- Applicant's statement	"Ziram is not explosive and therefore ZIRAM 76 WDG is not explosive as well"	- Not acceptable (submitted Annex II study regarding explosive properties of Ziram was considered to be not acceptable)	
B.2.2.5	- Applicant's statement	"Ziram is corrosive to iron and copper"	- Statement is	

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
Oxidizing properties (IIIA 2.2.2)			contradictory to information given in response to point IIA 2.15 (see B.2.1.25); study on oxidizing properties according to EEC A17 is required.	
B.2.2.6 Flash point (IIIA 2.3)			- Not applicable (formulation is not a liquid)	
B.2.2.7 Flammability (IIIA 2.3)	- Applicant's statement	"Although the product does not pose any known fire risk, it should be regarded as weakly flammable"	- Statement is not sufficient; study on flammability according to EEC-method A10 is required	
B.2.2.8 Auto-flammability (IIIA 2.3)		no data	- Study on autoflammability according to EEC-method A16 is required	
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	- CIPAC MT 75	5% dispersion in CIPAC water D :	- Not acceptable (report	Kool, 1990

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
pH of a 1 % aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	- No GLP-compliance stated	pH = 5.5 - 8.5	gives no explanation for the very broad pH-range found + water D was used instead of distilled water).	
	- ASTM E70-74 - No GLP-compliance stated	4% dispersion in distilled water at 20 °C : pH = 5.29 (mean of 10 batches; 95% confidence limits : 5.06 - 5.52)	- Method equivalent to CIPAC MT 75, but a 4% dispersion was used instead of a 1% dispersion. - Acceptable	Van Dorpe & Verberckt, 1986
B.2.2.11 Kinematic viscosity (IIIA 2.5.1)			- Not applicable (formulation is not a liquid intended for ULV-use)	
B.2.2.12 Viscosity (III 2.5.2)			- Not applicable (formulation is not a liquid)	
B.2.2.13 Surface tension (IIIA 2.5.3)			- Not applicable (formulation is not a liquid)	
B.2.2.14 Relative density (IIIA 2.6.1)			- Not applicable (formulation is not a liquid)	
B.2.2.15	- Method not specified	bulk density = 0.65 kg/l	- Not acceptable :	Van Beijnen, 1990

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
Bulk or tap density (IIIA 2.6.2)			report contains insufficient information (e.g. method used is not specified) and apparently states only "provisional" results.	
B.2.2.16 Stability after storage for 14 days at 54 °C (IIIA 2.7.1)	- CIPAC MT 46 - No GLP-compliance stated	after storage for 14 days at 54 °C : 1) a.s. content : 79% (initial : 79%) 2) suspensibility : 95% (initial : 95%) Þ no variations in the characteristics of the formulation	- Not acceptable : not all relevant physico-chemical properties were determined (e.g. no data on pH and wet sieve residue) + report contains insufficient information (e.g. no specification of methods used)	Kool, 1990
B.2.2.17 Stability after storage for other periods and temperatures (IIIA 2.7.1)			- Not applicable (product is not heat sensitive)	
B.2.2.18 Minimum content after heat stability testing (IIIA 2.7.1)			- Not applicable (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 (formulation is not a liquid)	

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.20 Shelf life (IIIA 2.7.3)	- No guideline specified	after storage for 17 months at warehouse conditions in glazed cardboard boxes with paper lining (mean of 5 batches): a.s. content : 76.34% ± 0.74% (95% confidence interval) initial a.s. content : 76.42% ± 0.64% (95% confidence interval)	- Not acceptable : method does not concur with GIFAP n° 17 (storage at ambient temperature should take at least 2 years + relevant physico-chemical properties were not tested) and report does not mention the storage temperature.	Christiaens & Matthijs, 1987
B.2.2.21 Wettability (IIIA 2.8.1)	CIPAC MT 53.3.1	wetting time = 1.5 min (without swirling)	- Not acceptable (findings mentioned in Tier I are not substantiated with a report)	
B.2.2.22 Persistent foaming (IIIA 2.8.2)		no data	- Study on persistent foaming according to CIPAC MT 47 is required.	
B.2.2.23 Suspensibility (IIIA 2.8.3)	CIPAC MT 15.1	suspensibility = 95%	- Not acceptable : report contains insufficient information (e.g. no mention of suspension concentration that was tested or type of water used; method used was only indicated in Tier I)	Kool, 1990

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.24 Spontaneity of dispersion (IIIA 2.8.3)		no data	- Study on dispersibility according to CIPAC MT 174 is required.	
B.2.2.25 Dilution stability (IIIA 2.8.4)			- Not applicable (formulation is not a water soluble product)	
B.2.2.26 Dry sieve test and wet sieve test (IIIA 2.8.5)	- Method not specified	wet sieve residue on 45 µm filter = 0	- Not acceptable : findings mentioned in Tier I are not substantiated with a report.	
B.2.2.27 Size distribution of particles - Nominal size range of particles (IIIA 2.8.6.1)	- CIPAC MT 170 - No GLP-compliance stated	99% of particles : < 600 µm 90% of particles : between 105 and 500 µm	- Not acceptable : report contains insufficient information (e.g. method used was only indicated in Tier I) and apparently states only “provisional” results.	Van Beijnen, 1990
B.2.2.28 Dust content and particle size of dust (IIIA 2.8.6.2)	- CIPAC MT 171 - No GLP-compliance stated	dust content : max. 0.5%	- Not acceptable : report contains insufficient information (e.g. method used was only indicated in Tier I) and apparently states only “provisional” results.	Van Beijnen, 1990

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
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)		no data available	- Study on flowability according to CIPAC MT 172 is required	
B.2.2.33 Pourability (including rinsed residue) (IIIA 2.8.8.2)			- Not applicable (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	- Applicant's statement	"ZIRAM 76 WDG is compatible with most of the other	- Acceptable	no author specified,

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
Physical compatibility of tank mixes (IIIA 2.9.1)		pesticides (insecticides and fungicides). It is incompatible with formulations containing iron, copper, mercury, TEPP, lime and calcium arsenate.”		1990
B.2.2.36 Chemical compatibility of tank mixes (IIIA 2.9.2)	- Applicant’s statement	“ZIRAM 76 WDG is compatible with most of the other pesticides (insecticides and fungicides). It is incompatible with formulations containing iron, copper, mercury, TEPP, lime and calcium arsenate.”	- Acceptable	no author specified, 1990
B.2.2.37 Distribution and adhesion (IIIA 2.10)			- Not applicable (product is not intended for seed treatment)	

B.2.3 References relied on

Physical and chemical properties

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

Annex point(s) Dir 91/414/EEC	Author(s)	Title Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file No. of submitting company Date of report for publication: reference	GLP GEP	Published Protected
IIA 2.1.1 IIA 2.2 IIA 2.4.1 IIA 2.7	Anonymous	The Pesticide Manual 10th edition 1994	no	published -
IIA 2.9.2	Carpenter M.	Determination of photodegradation of Ziram in aqueous solutions Submitted by : Ziram Task Force Company file N° : ABC Labs Inc. Report #33369 Date of report : October 3, 1985	yes	unpublished -
IIA 2.16	Christiaens P. Matthijs G.	Ziram technical : stability Submitted by : Ziram Task Force Company file N° : UCB Report WLZA n° 05/87 Date of report : March 3, 1987	no	unpublished -
IIA 2.6	Christiaens P. Verberckt J.	Ziram technical : Water solubility Submitted by : Ziram Task Force Company file N° : UCB Report WL ZT n° 01/87 Date of report : November 4, 1987	no	unpublished -
IIA 2.9.1	Daly D. Cranor W.	Determination of hydrolysis rate with ^{14}C-Ziram Submitted by : Ziram Task Force Company file N° : ABC Labs Inc. Report #33363 Date of report : November 18, 1987	yes	unpublished -
IIA 2.6	Danschutter J.	Ziram technical : Water solubility Submitted by : Ziram Task Force Company file N° : UCB Report WL n° 08/85 Date of report : May 31, 1985	no	unpublished -
IIA 2.4.1	De Lange R. Verberckt J.	Ziram 98 % agricultural grade : color Submitted by : Ziram Task Force Company file N° : UCB Report WLZA n° 03/86 Date of report : December 19, 1986	no	unpublished -
IIA 2.3.1 IIA 2.6 IIA 2.7 IIA 2.8 IIA 2.11.1 IIA 2.11.2 IIA 2.13 IIA 2.15	Diepenhorst P.C.	Product chemistry - Ziram technical Submitted by : Ziram Task Force Company file N° : - Date of report : August 20, 1987	no	unpublished -
	Fischer M.	Determination of the stability constant of		unpublished

Annex point(s) Dir 91/414/EEC	Author(s)	Title Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file No. of submitting company Date of report for publication: reference	GLP GEP	Published Protected
IIA 2.9.4	Vandegans J.	Zinc-bis (N,N, dimethyldithiocarbamate) or Ziram Submitted by : Ziram Task Force Company file N° : - Date of report : May 25, 1987	no	-
IIA 2.1, 2.2, 2.3, 2.4, 2.5	Flack, I.	Ziram - Physical and chemical properties Submitted by : Ziram Task Force Company file N° : Huntingdon Life Sciences. Report N° FCC 150/953136 Date of report : June 14, 1996 (not evaluated due to very late submission date)	yes	unpublished protected
IIA 2.9.1	Heasook K.-K.	Hydrolysis of [^{14}C] Ziram in water at pH 5, 7 and 9 Submitted by : Ziram Task Force Company file N° : Xenobiotic Labs Inc. Report N° RPT00213 Date of report : November 13, 1995	yes	unpublished protected
IIA 2.9.2	Heasook K.-K.	Aqueous photolysis of [^{14}C] Ziram Submitted by : Ziram Task Force Company file N° : Xenobiotic Labs Inc. Report N° RPT00223 Date of report : August 15, 1996	yes	unpublished protected
IIA 2.5.1	Not specified	Ziram - Mass spectrum Submitted by : Ziram Task Force Company file N° : - Date of report : not specified	no	unpublished -
IIA 2.5.1	Not specified	Ziram - IR Spectrum Submitted by : Ziram Task Force Company file N° : - Date of report : April 2, 1984	no	unpublished -
IIA 2.5.1	Not specified	Ziram - UV/Vis spectrum Submitted by : Ziram Task Force Company file N° : - Date of report : April 7, 1989	no	unpublished -
IIA 2.6	Vandevelde F. Verberckt J.	Ziram agricultural grade : pH Submitted by : Ziram Task Force Company file N° : UCB Report WLZA n° 02/86 Date of report : December 10, 1986	no	unpublished -

Physical and chemical properties of the formulation ZIRAM 76 WDG (Annex IIIA 2)

Annex point(s) Dir 91/414/EEC	Author(s)	Title Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file No. of submitting company Date of report for publication: reference	GLP GEP	Published Protected
IIIA 2.7.3	Christiaens P. Matthijs G.	Ziram 76 % WDG : storage stability Submitted by : Ziram Task Force Company file N° : UCB Report WLZWG n° 04/87 Date of report : March 5, 1987	No	unpublished protected
IIIA 2.4.2 IIIA 2.7.1 IIIA 2.8.3	Kool P.	Ziram 76 DG Submitted by : Ziram Task Force Company file N° : - Date of report : July 30, 1990	No	unpublished -
IIIA 2.9.1 IIIA 2.9.2	Not specified	Triscabol technical Submitted by : Ziram Task Force Company file N° : - Date of report : July 26, 1990	No	unpublished -
IIIA 2.6.2 IIIA 2.8.6.1 IIIA 2.8.6.2	Van Beijnen A.	Ziram 76 DG Submitted by : Ziram Task Force Company file N° : - Date of report : February 22, 1990	No	unpublished -
IIIA 2.4.2	Van Dorpe F. Verberckt J.	Ziram 76 WDG : pH Submitted by : Ziram Task Force Company file N° : UCB Report WLZWG n° 01/86 Date of report : December 18, 1986	No	unpublished -

ANNEX B

Ziram

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, game and bird repellent

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

Contact action, 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)

Orchards, horticulture (ornamentals), game and bird repellent

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

Data to support the uses of Ziram as game repellent (trees and ornamentals) and as bird repellent (maize seed) were not submitted by the notifiers. Therefore the evaluation was restricted to foliar spray on fruit crops and ornamentals.

Table B.3.1.5-1 : List of crops protected and pest controlled (Intended uses)

Crops protected	**Pests controlled**	
Fruits - foliar spray		
Citrus	Coelomycetes	*Deuterophoma tracheiphila*
Pome fruit	Loculoascomycetes Teliomycetes Coelomycetes	*Venturia spp.* *Gymnosporangium spp.* *Pezicula spp.* *(Gloeosporium-storage rot)*
Stone fruit	Teliomycetes Hemiascomycetes Hemiascomycetes Discomycetes Coelomycetes Coelomycetes Coelomycetes	*Tranzschelia pruni-spinosae* *Taphrina deformans* *Taphrina wiesneri* *Monilinia spp.* *Coryneum beijerinckii* *=Stigmina carpophila* *Coryneum microstictum* *Fusicoccum amygdali*
Ornamentals - foliar spray		
Ornamentals	Teliomycetes Teliomycetes Coelomycetes Hyphomycetes	*Puccinia sp.* *Phragmidium sp.* *Septoria spp.* *Alternaria spp.*
Game and bird repellent		
trees, ornamentals		hare, rabbit, bird, wild game
maize seed treatment		birds

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

‘Ziram is a dimethyl dithiocarbamate. These fungicides are fairly unstable compounds which form free dithiocarbamic ions. These ions form water soluble 1:1 and water insoluble 1:2 complexes with Cu^{2+} and it is suggested that these complexes are the toxic agents which may interfere with some specific sites of respiration. The anion also acts as an inhibitor of many essential enzymes containing either Cu ions, such as polyphenoloxidase, and ascorbic acid oxidase or SH groups (e.g. glucose-6-phosphate dehydrogenase). Finally, the anion also binds to redox compounds such as glutathion and cystein. This indicates that Ziram is a multisite inhibitor in fungal cells. ‘

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

See B.3.1.6

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

Ziram has a multisite fungitoxic effect. The risk of occurrence of resistance is therefore lower.

B.3.2 Data on application relevant to the plant protection product TRISCABOL 76 WG / ZIRAM 76 WG (Annex IIIA 3)

B.3.2.1 Fields of use (Annex IIIA 3.1)

See B.3.1.4

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

See B.3.1.2

B.3.2.3 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)

Data to support the uses of Ziram as game repellent (trees and ornamentals) and as bird repellent (maize seed) were not submitted by the notifiers. Therefore the evaluation was restricted to foliar spray on fruit crops and ornamentals.

Table B.3.2.3-1 : List of intended uses of Ziram

Crop **Disease**	**Country**	**Maximum rate per application (kg a.s./ha)**	**Maximum rate per season (kg a.s./ha)**	**Spray concen-tration (g a.s./hl)**	**Maxi mum num-ber of applications per season**	**spray interval in days**	**Pre-harvest interval in days**
Apple Scab *(Venturia inaequalis)*	All Europe	2.70	16.20	94 to 270	6 (treatments against *Gloeosporium* included)	7-14 days - First application on young leaves	14
Apple *Gloeosporium*	All Europe	1.18	(rate already taken into account in the Venturia applica-tions)	75 to 118	4	7-14 days - First application half June	14
Pear Scab *(Venturia pirina)*	All Europe	2.70	16.20	94 to 270	6 (treatments against *Gloe-osporium* included)	7-14 days - First application on young leaves	14
Pear *Gloeosporium*	All Europe	1.18	(rate already taken into account in the Venturia applica-tions)	75 to 118	4	7-14 days - First application half June	14
Medlar Scab *(Venturia inaequalis*)	All Europe	2.35	7.05	235	3	7-14 days - First application just before	28

Crop **Disease**	**Country**	**Maximum rate per application (kg a.s./ha)**	**Maximum rate per season (kg a.s./ha)**	**Spray concen-tration (g a.s./hl)**	**Maxi mum num-ber of applications per season**	**spray interval in days**	**Pre-harvest interval in days**
						blooming	
Cherry *Stigmina carpophila, Monilinia spp. Venturia cerasi*	All Europe	3.04	9.12	133 to 304	3	7-14 days - First application before/during flowering	10
Plum Rust *(Tranzschelia pruni-spinosa*) *Stigmina carpophila* *Monilia spp.*	All Europe	3.04	9.12	114 to 304	3	7-14 days - First application before/during flowering	10
Almond *Taphrina deformans*	South-Europe	1.78	5.34	133 to 178	3	7-14 days - Winter/Spring treatment; First application on very young foliage	14
Almond *Fusicoccum amygdali*	South-Europe	1.78	5.34	133 to 178	3	7-14 days - Autumn/ Winter treatment after harvest	14
Almond *Monilinia spp.* *Coryneum*	South-Europe	2.70	8.1	133 to 270	3	7-14 days - First application when disease occurs	14
Apricot *Monilia*	South-Europe	2.70	10.80	152-270	4	7-14 days Winter/Spring treatment; First application on young foliage;	14
Apricot *Coryneum beijerinckii*	South-Europe	1.52	6.08	114 to 152	4	Autumn/ Winter treatment after harvest	-
Peach *Taphrina deformans* *Stigmina carpophila*	All Europe	3.04	9.12	133 to 304	3	7-14 days Winter/Spring treatment; First application on	14

Crop Disease	Country	Maximum rate per application (kg a.s./ha)	Maximum rate per season (kg a.s./ha)	Spray concen-tration (g a.s./hl)	Maxi mum num-ber of applications per season	spray interval in days	Pre-harvest interval in days
Monilinia spp.						young foliage NL: Application before flowering. ?	
Peach *Coryneum beijerinckii (Stigmina carpophila) Fusicoccum amygdali*	All Europe	3.04	6.08	114 to 532	2	Autumn / Winter treatment after harvest	-
Ornamentals Outdoor Rust (*Puccinia spp,Uromyces dianthii*) Black spot (*Diplocarpon rosae*)	All Europe	1.60		179 to 225	as needed	7 days - First application when disease occurs	-
Game and bird repellent							
Trees Hare-Rabbit-Wildgame repellent	-	-	-	160 to 320	1	Brush over trunk of the trees	-
Ornamentals Birds-Rabbit-Hare repellent	-	3.00	-	10 to 15	as needed	-	-
Maize Bird repellent	-	0.200	0.200	-	1	seed treatment	-

B.3.2.4 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 applicable for orchard trees.

B.3.3 Summary of data on application

See B.3.2.3

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 safety data sheets pursuant to Article 27 of Council Directive 67/548/EEC. (See Appendix : Material Safety Data Sheets)

Hazard identification
Flammable and toxic gases may be released under effect of heating.
May cause sensitisation by inhalation and skin contact.
May cause severe irritation to eyes.
Prolonged and repeated exposure may cause skin irritation, conjunctivitis and bronchitis.

Handling and storage

Technical protective measure :	Keep the product in the original container, away from food, animal foodstuffs and out of the reach of children. Do not breathe the dust. Do not eat, drink or smoke during application. After treatment, wash and change clothes prior to anything else like eating, drinking or smoking.
Handling :	Handle container tightly closed. Anti-dust mask may be desirable when emptying bags. Wear suitable protective clothing and gloves, as well as eye/face protection.
Storage :	Store in dry, cool, well-ventilated area. Avoid exposure to direct sunlight. Do not pile higher than 3 pallets.

Transport

RID/ADR :	Class 6.1-76°a) - label 6.1
ICAO/IATA :	Class 6.1 - group I - label 6.1 (RPB) - Packing instruction 607
IMO/IMDG code :	Class 6.1 - group I - label 6.1 (POISON)
UN N° (proper shipping name) :	UN 2771. DITHIOCARBAMATE PESTICIDE, SOLID, TOXIC, N.O.S.

Fire-fighting measures
Suitable extinguishing media : carbon dioxide, dry chemicals, foam. Do not use water, except in case of an important fire. Contain fire fighting water to protect the environment.
Thermal decomposition may release toxic fumes. In case of an important fire, use a self contained respiratory apparatus and protective clothes.
Keep away from sources of ignition. No smoking.

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)

No specific recommendations.

Information on pyrolytic behaviour is not required due to the absence of any halogens in this a.s.

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 specific recommendations.

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

No information provided

B.3.5 Further information on the plant protection product TRISCABOL 76 WG / ZIRAM 76 WG (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 : materials used, manner of construction, size, capacity, size of openings, types of closure and seal (Annex IIIA 4.1.1)

Following types of packaging are available.

Table B.3.5.1.1-1 : Description of packaging material for plant protection product

Package material	Content	Dimensions
Paper bag with inner polyethylene layer attached in a cardboard	1 kg	115 x 75 x 250 mm
	2.5 kg	184 x 106 x 283 mm
	5 kg	237 x 111 x 362 mm
Polyethylene bag in cardboard box	20 kg	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, which can then be torn off allowing the product to be poured (by following this method, no cutting tool whatever is required).

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

- Keuring van kartonnen dozen (4G) bestemd voor het vervoer van gevaarlijke goederen van de gevarengroepen I, II en III (Wittebolle & Van Dael, 1995)

The adequacy of the packaging has been tested by the “Belgisch Verpakkingsinstituut”, using the tests prescribed by the following guidelines : UN Part 9
IMDG Annex 1
ICAO Part 7
ADR-RID Annex A5 (V)

Table B.3.5.1.2-1 : Suitability of packaging material for plant protection product

Receptacle type Capacity	Test method	Test conditions	Findings and conclusions	References
cardboard box (4G) 6 kg content gross weight 6.4 kg	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 Pile test	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	
cardboard box (4G) 1 kg content gross weight 1.3 kg	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 Pile test	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	
cardboard box (4G) 3 kg content gross weight 3.5 kg	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 Pile test	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	
cardboard box (4G) 6 x 3 kg content gross weight 20 kg	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 Pile test	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.3.5.1.3 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 ever been observed’.

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

The equipment is cleaned by rinsing several times with water. The rinsing water can be sprayed onto field.
No specific recommendations regarding the cleaning of protective clothing.

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

B.3.5.3.1 Pre-harvest intervals, re-entry periods 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 TRISCABOL 76 WG / ZIRAM 76 WG

Pre-harvest interval (in days) for each relevant crop :	Apple : 14 d Pear : 14 d Medlar : 28 d Cherry : 10 d Plum : 10 d Almond : 14 d Apricot : 14 d Peach : 14 d
Re-entry period (in days) for livestock to areas to be grazed :	Not relevant (orchard)
Re-entry period (in hours or days) for man to crops, buildings or spaces treated :	The point ‘ worker exposure’ has to be addressed by the notifier
Withholding period (in days) for animal feedingstuffs :	Not relevant
Waiting period (in days) between application and handling treated products :	The point ‘ worker exposure’ has to be addressed by the notifier
Waiting period (in days) between last application and sowing or planting succeeding crops :	Not relevant (perennial crop)

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)

Do not use Ziram with formulation containing copper or immediately after treatment with copper formulation.

B.3.5.4 Recommended methods and precautions concerning 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 (Annex 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.3.5.4.1 Handling, storage, transport, fire (Annex IIIA 4.4)

<u>Hazard identification</u>
Flammable and toxic gases may be released under effect of heating.
May cause sensitisation by inhalation and skin contact.
May cause severe irritation to eyes.
Prolonged and repeated exposure may cause skin irritation, conjunctivitis and bronchitis.

Handling and storage

Technical protective measure : Keep the product in the original container, away from food, animal foodstuffs and out of the reach of children.
Do not breathe the dust. Do not eat, drink or smoke during application. After treatment, wash and change clothes prior to anything else like eating, drinking or smoking.

Handling : Handle container tightly closed.
Anti-dust mask may be desirable when emptying bags. Wear suitable protective clothing and gloves, as well as eye/face protection.

Storage : Store in dry, cool, well-ventilated area.
Avoid exposure to direct sunlight.
Do not pile higher than 3 pallets.

Transport

RID/ADR :	Class 9.12 C) - Label 9
ICAO/IATA :	Class 9 - Group III
IMO/IMDG code :	Class 9 - Group III - marine pollutant
UN N° (proper shipping name) :	UN 3077, environmentally hazardous substance, SOLID, N.O.S.

Fire-fighting measures

Suitable extinguishing media : carbon dioxide, dry chemicals, foam. Do not use water, except in case of an important fire. Contain fire fighting water to protect the environment.
Thermal decomposition may release toxic fumes. In case of an important fire, use a self contained respiratory apparatus and protective clothes.
Keep away from sources of ignition. No smoking.

B.3.5.4.2 Emergency measures in case of an accident (Annex IIIA 4.5)

Personal precautions : Avoid contact with eyes and skin. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. In case of contact with skin, wash immediately thoroughly with soap and water.
In case of ingestion, give plenty of water and induce vomiting. In case of inhalation, move to fresh air, sit in half upright position and loosen clothes.

Environmental precautions : Stop any eventual leakage. Do not reject spilled product into sewers or natural water. Sweep up or vacuum to collect product without dust and incinerate according to regulation or recycle.

B.3.5.5 Procedures for destruction or decontamination of the formulation TRISCABOL 76 WG / ZIRAM 76 WG 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 formulation under controlled conditions at 800° C (Annex IIIA 4.6.2)

No specific recommendations.

Information on pyrolytic behaviour is not required due to the absence of any 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.3.6 References relied on

Data on application and further information

Annex point(s) Dir 91/414/EEC	Author(s)	Title Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file No. of submitting company Date of report for publication: reference	GLP GEP	Published Protected
IIIA 4.1.2	Wittebolle M. Van Dael S.	Keuring van kartonnen dozen (4G) bestemd voor het vervoer van gevaarlijke goederen van de gevarengroepen I, II et III Submitted by : Ziram Task Force Company file N° : B.V.I. Rapport Nr. SVD/as/G-95.043/0269 Date of report : March 6, 1995	No	unpublished -

ANNEX B

Ziram

Appendix A : Authorizations - Registrations

COUNTRY	TYPE OF AUTHORIZATION	CROPS/USES	AUTHORIZATION DETAILS
Austria	Commercial UCB	Bird repellent (mais)	Avistop-Agro SC 21.6% Reg. No : 2364
Belgium	Commercial UCB	Apple/Pear	Thionic Express WG 76% Reg. No : 7594/B Issue Date : 1/8/96 Exp. Date : 1/8/2006
France	Commercial UCB	Apple, peach	Thionic Ultradispersible WG 90% Reg. No : 8500022 Issue Date : 28/2/85 Exp. Date : 95
France	Commercial UCB	Apple, peach	Thionic Ultradispersible WG 76% Reg. No : 8500412 Issue Date : 25/10/85 Exp. Date : 95
France	Commercial Elf Atochem Agri	Apple Peach	Triscabol DG WG 90% Reg N° 8900302 Iss. Date Expiry date : 1999
Greece	Commercial Elf Atochem Agri	Apple/pear Peach Plum Cherry	Zirafin 76 WG WG 76% Reg N° 6571 Iss. Date 08/04/1993 Expiry date :
Italy	Commercial UCB	Apple, pear, peach, plum, apricot, cherry, tomato, onion potato, peas, beans, grapes, oranges, lemons, strawberries, ornamentals	Thionic instantaneo WG 76% Reg. No : 8301 Issue Date : 4/6/93
Italy	Commercial Elf Atochem Agri	Apple/pear Peach Plum Cherry	Triscabol DG WG 76% Reg N° 3486 Iss. Date 7/02/1980 Expiry date :
Netherlands	Commercial Elf Atochem Agri	Apple/pear Peach Bramble	Triscabol spuitpoeder WP 75 % Reg N° 5491 N Expiry date: 17/12/2000
Portugal	Commercial UCB	Bean, melon, cucumber, ornamentals (pink, rose, chrysanthemum), apple, pear, medlar, peach, almond, apricot, prune, cherry, olive, garlic,	Thonic WG WG 76% N· 2420 Issue Date : Exp. Date :

COUNTRY	TYPE OF AUTHORIZATION	CROPS/USES	AUTHORIZATION DETAILS
		onion, peas	
Spain	Commercial UCB	Fruit trees, grapes, strawberries, lettuce and other leafy vegetables Ornamentals	Ziram 90PM WP 90% Reg. No : 16151/97 Issue Date : 09/92 Exp. Date : 09/97
Spain	Commercial UCB	To be used in formulations	Ziram Technico WP 98% Reg. No 16468/97 Issue Date : 10/9/92 Exp. Date : 9/97
Spain	Commercial UCB	Fruit trees, grapes, strawberries, lettuce and other leafy vegetables Ornamentals	Pomarsol Z WG WG 76% Reg. No : 17966/99 Issue Date : 11/10/94 Exp. Date : End 1999

ANNEX B

Ziram

Appendix B : Material Safety Data Sheets

List of Material Safety Data Sheets submitted by the notifiers
Active Substance
Ziram (UCB)
Ziram TC (Elf Atochem)
Formulations
Ziram WG
Ziram 76

ANNEX B

Ziram

B.4 Methods of analysis

B.4.1 Analytical methods for formulation analysis

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

- SOP DLA-012.1 : Carbon disulphide determination in dithiocarbamates by the "Sulphuric acid method" (Diepenhorst, 1993a)

GLP :
No GLP-compliance stated.
Principle of the method :
The sample, dissolved or dispersed in tetrasodium EDTA solution, is decomposed by boiling with sulphuric acid into the corresponding amine sulphate and carbon disulphide. The latter is carried by a stream of air through scrubbers containing lead acetate solution to remove hydrogen sulphide and then into an absorber containing methanolic potassium hydroxide, to afford potassium methylxanthate. This xanthate solution is neutralized with dilute acetic acid and titrated with standard iodine solution on starch indicator.
Findings :
No validation data were presented.
Conclusions :
The method described is the officially accepted CIPAC 61/1/M/1.2 method, with only some minor modifications to the apparatus and reagents. The method is applicable for the determination (via the carbon disulphide content) of the active substance of technical dithiocarbamates (including Ziram) and their formulations, provided that high levels of interfering redox or complex forming ions like copper are absent.
As the method is not specific for Ziram, it should be taken into consideration that CS_2-containing impurities, if present in the technical Ziram, are also measured by this method, possibly leading to an overestimation of the a.s. content. In these cases the content of the impurities in question, determined using another method, can be subtracted from the result obtained using CIPAC 61/1M/1.2. in order to get the correct a.s. content.

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

- PH-M 227.3.1 : Triscabol technical - determination of water soluble zinc by AAS (Diepenhorst, 1987)

GLP :
No GLP-compliance stated.
Principle of the method :
The sample of Ziram technical is dispersed in Milli-Q water and after stirring for 10 minutes at 20 °C, part of the suspension is filtered over a 0.45 µm filter. Any unreacted zinc present in the sample as zinc chloride dissolves in water and the dissolved zinc is measured on an atomic absorption spectrometer (AAS) in an air/acetylene flame, using a zinc standard calibration line.
The contribution of dissolved Ziram to the zinc chloride concentration results obtained under these conditions, will be 0.0014%, based on a solubility of 1.58 mg/kg Ziram in water at 20 °C.
Findings :
No validation data were presented.
Conclusions :
The method presented essentially complies with A.O.A.C Official Method of Analysis (1984) 2.126-2.130.

- The other methods for determination of impurities and additives in the active substance as manufactured are described as part of the confidential information (see Annex C - point [B.1.1.11]).

Conclusions :
Methods are available for the determination of all significant and/or relevant impurities and additives in the technical a.s.. For relevant impurities, additional validation of the methods is required.

B.4.1.3 Analytical methods for the determination of pure active substance in plant protection products

(Annex IIIA 5.1.1)

- SOP DLA-M 227.5 : Triscabol 76 WG - determination of active ingredient (Diepenhorst, 1993b)
GLP :
No GLP-compliance stated.
Principle of the method :
Same as for SOP DLA-012.1 (see B.4.1.1), except that the sample is dissolved in water instead of in tetrasodium EDTA solution. Pre-grinding of the sample is not required.
Findings :
No validation data were presented.
Conclusions :
The method described is the officially accepted CIPAC 31/WG/M/3 method, with only some minor modifications to the apparatus and reagents.
The comment made with respect to the specificity of method CIPAC 61/1M/1.2 (SOP DLA-012.1) also applies to this method.

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

The notifier refers to the methods for determination of impurities and additives that were submitted as part of document J (see Annex C - point [B.1.1.11])

Conclusions :
Methods are available for the determination of relevant impurities in technical a.s.. Validation data demonstrating the applicability of these methods to plant protection products were however not submitted.

No methods are required for the determination of formulants in the plant protection products, since none of the formulants are considered to be of toxicological or environmental significance.

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

The determination of residues of Ziram in plants is based on the carbon disulphide evolution method.

- PH-M 027.7.1 : Ethylenebis(dithiocarbamates) - spectrophotometric determination of residue on crops (range between 0.02 and 10 mg/kg) (Kool, 1989)
GLP :
No GLP-compliance stated.
Principle of the method :
The sample material, adequately cut or chopped, is boiled in hydrochloric acid, in presence of tin-(II)-chloride, decomposing the 1,2-ethylenebisdithiocarbamate to its diamine salt and carbondisulphide. The latter is carried by a stream of nitrogen through absorbers containing lead acetate solution to remove hydrogen sulphide and then into an absorber containing Cullens reagent, being a solution of copper- (II)-acetate and diethanolamine in ethanol.
The quantity of the evolved carbondisulphide is determined by spectrometry, measuring the absorbance at 435 nm of the formed copper-(II)-dithiocarbamate complex, using CS_2-standard calibration.
Findings :
No validation data were presented.
Conclusions :
The report provides no validation data demonstrating the applicability of the method for the determination of Ziram residues on crops.

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 (Annex IIA 4.2.2; Annex IIIA 5.2.2)

No methods were submitted

Conclusion :
Analytical methods for the determination of Ziram and/or relevant metabolites in soil are required.

B.4.3.2 Analytical methods for water (Annex IIA 4.2.3; Annex IIIA 5.2.3)

- Spectrophotometric determination of Ziram (dithiocarbamate fungicide) by thiocyanate and rhodamine 6G method (Lata et al., 1995)
GLP :
No GLP-compliance stated. The report is a published article.
Principle of the method :
To an aliquot of the water sample, 2 ml conc. HCl is added followed by 1 ml acetate buffer, after which the pH is adjusted to 4. The estimation of Ziram is based on the determination of zinc by formation of a ternary complex with potassium thiocyanate and rhodamine 6G at pH 4. The pink coloured complex is stabilized by gelatin and the absorbance of the solution is measured spectrophotometrically at 570 nm against a reagent blank. Quantification by external standard calibration.
Findings :
Specificity - interferences : the method is free from interferences from similar dithiocarbamate fungicides containing Mn^{2+} and Fe^{3+} -ions
Calibration line : the colour system showed linear absorbance in the range of 0 to 1 µg/ml.
Recovery - precision : for polluted water (from agricultural fields) at a fortification level of 0.2 mg/l, the recovery equals 95.2% (mean of 3 replicate analyses). The RSD is not mentioned in the report, nor can it be calculated (individual recoveries are not listed).
Limit of determination (LOQ) : not discussed
Conclusions :
The method has not been properly validated. The data provided in the publication do not allow to ascertain if for drinking water a LOQ of at least 0.1 µg/l (= EU drinking water limit) can be obtained.

B.4.3.3 Analytical methods for air (Annex IIA 4.2.4; Annex IIIA 5.2.4)

- Gas chromatographic determination of dithiocarbamate fungicides in workroom air (Maini & Boni, 1986)
GLP :
No GLP-compliance stated. The report is a published article.
Principle of the method :
Workroom air sampling is performed by means of pre-weighed microporous filtering membranes, with an air flow rate of about 20 l/min (as the vapour pressure of dithiocarbamates is practically zero, they are only present as dust in workroom air). After weighing, the filtering membrane is introduced into a screw-cap test tube. The filter is wetted slightly with 4-5 drops of distilled water, after which 5 ml of 2,2,4-trimethylpentane (isooctane) are added, followed by a reagent containing 3% $SnCl_2$ in 37% HCl, filling it up to the rim. The test tube is immediately and tightly capped and placed in an oven at 80 °C for 1 h with periodical shaking every 10-15 min. After cooling to room temperature, an aliquot of the solvent layer is diluted with isooctane to a suitable concentration for the detector linearity range. Care should be taken to avoid CS_2 volatilization from the solvent. Residues are determined as CS_2 by gas chromatography with an electron capture detector.
Findings :
Specificity - interferences : the method determines all dithiocarbamate residues and thus is not specific for Ziram.
The method is reported to be free from interferences from the coformulants of dithiocarbamate fungicides and from other active substances that are commonly formulated in mixture with dithiocarbamates, such as sulphur, copper oxychloride, cymoxanil, carboxin and carbendazim.
Recovery - precision : recovery was tested with several different dithiocarbamates. The overall mean recovery was 88.3% (N = 36; RSD = 12.5%), while for Ziram formulations the mean recovery was 93.5% (N = 6; weighed amount between 1.3 and 4.1 mg; RSD = 10%). The

corresponding fortification levels (expressed as mg/m³) were however not clearly indicated in the report.

Limit of determination (LOQ) : the notifier states the LOQ to be 0.003 mg/m³, but the recovery obtained at this concentration level was not mentioned in the report

Conclusions :
The method allows no selective determination of Ziram since all dithiocarbamate residues are measured.
The validation data provided in the publication are insufficient.

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)

- Ziram : nature of the residue in lactating goats (Bodden, 1993) : "Analysis for Ziram and/or other CS_2 generators in milk, urine and tissues"

GLP :
The study is GLP.

Principle of the method :
The method is derived from the CS_2-evolution method of Keppel (1971). The sample (25 g) is refluxed for 60 min with HCl in the presence of stannous chloride, leading to decomposition of the dithiocarbamates present. The evolved CS_2 is swept by a stream of air through an absorption system consisting of Mallcosorb®, then lead acetate and finally cupric acetate - diethanolamine and the resulting cupric salt has a yellow colour that absorbs at 435 nm. Ziram and/or other dithiocarbamates are quantified spectrophotometrically from a standard curve established using Ziram as a standard.

Findings :

Specificity - interferences : the method is not specific for Ziram; all dithiocarbamates (CS_2-generating compounds) are detected.

Recovery - precision : the recovery was 74.1% for feces, 86.8% for omental fat, 88.3% for urine, 92.3% for milk, 92.5% for liver and 93.0% for muscle. The corresponding fortification levels were however not specified in the report, nor the number of samples for each matrix either.

Limit of determination (LOQ) : the detection limit for this analysis is stated to be approximately 1 ppm (Ziram equivalents) when using a 25 g sample size, but the report does not mention the recovery obtained at this concentration level.

Conclusions :
The method allows no selective determination of Ziram since all dithiocarbamate residues are measured.
The validation data provided in the report are insufficient.

B.4.5 Evaluation and assessment

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

Evaluation :
The analytical methods submitted for the determination of pure active substance in the technical a.s. and in WG formulations (resp. CIPAC 61/1/M/1.2 and CIPAC 31/WG/M/3) are based on the determination of the CS_2-content, which implies that they are not specific for Ziram. It should therefore be taken into consideration that CS_2-containing impurities, if present, are also measured, possibly leading to an overestimation of the a.s. content.

Analytical methods were submitted for the determination of significant and/or relevant impurities and additives in the technical a.s., but for relevant impurities, additional validation of the methods is required. Validation data demonstrating the applicability of these methods to plant protection products (WG formulations) also remain to be provided (see also Annex C, Confidential information).

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

Matrix	Analyte	Type of method	Validation	References
technical a.s.	dithiocarbamates	CS_2-evolution method + iodometry	officially accepted CIPAC 61/1/M/1.2	SOP DLA-012.1 (Diepenhorst, 1993a)
formulation WG	dithiocarbamates	CS_2-evolution method + iodometry	officially accepted CIPAC 31/WG/M/3	SOP DLA-M 227.5 (Diepenhorst, 1993b)
technical a.s.	water soluble zinc (< impurities)	Atomic Absorption Spectrometry (AAS)	A.O.A.C. (1984) 2.126-2.130	PH-M 227.3.1 (Diepenhorst, 1987)
technical a.s. formulation WG	other impurities additives	see Confidential information (Annex C, point [B.1.1.11])		

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

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

Matrix	Analyte	Type of method	Method range	Validation	References
crops	dithiocarbamates	CS_2-evolution + spectrophotometry	0.02 to 10 mg/kg com-modity	no validation data	PH-M 027.7.1 (Kool, 1989)

Evaluation :
The analytical method submitted for the determination of Ziram residues on crops, being based on CS_2-evolution, measures all dithiocarbamate residues and thus allows no selective determination of Ziram. Validation data were not provided.
A selective method of analysis is needed as Ziram has a particular low ADI in comparison with other dithiocarbamates, thus requiring specific residue levels.

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

Table B.4.5.3-1 : Analytical methods (residue) in soil, water and air

Matrix	Analyte	Type of method	Method range	Validation	References
water	Ziram	Zn-complexation + spectrophotometry	0.2 to 1 mg/l	insufficient validation data	(Lata et al., 1995)
air	dithiocarbamates	CS_2-evolution + GC with ECD	not specified	insufficient validation data	(Maini & Boni, 1986)

Evaluation :
The method submitted for water analysis allows the selective determination of Ziram residues, although additional validation is required in order to ascertain, among other things, if for drinking water a LOQ of at least 0.1 µg/l (= EU drinking water limit) can be obtained.

The analytical method submitted for the determination of Ziram residues in air, being based on CS_2-evolution, measures all dithiocarbamate residues and thus allows no selective determination of Ziram. Additional validation data (e.g. recovery at LOQ) are required.

Validated analytical methods that allow the determination of Ziram and/or relevant metabolites in soil 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

Table B.4.5.4-1 : Analytical methods (residue) wildlife and for use in support of diagnostic and therapeutic regimes

Matrix	Analyte	Type of method	Method range	Validation	References
milk, urine, tissues, feces	dithiocarbamates	CS_2-evolution + spectrophotometry	not specified	insufficient validation data	(Bodden, 1993)

Evaluation :
The analytical method submitted for the determination of Ziram residues in body fluids and tissues, being based on CS_2-evolution, measures all dithiocarbamate residues and thus allows no selective determination of Ziram. Additional validation data (e.g. LOQ) remain to be provided.

B.4.6 References relied on

Methods of analysis (Annex IIA 4, IIIA 5)

Annex point(s) Dir 91/414/EEC	Author(s)	Title Generated by (company or organisation), Submitted by (company(ies) or organisation), Report/file No. of submitting company Date of report for publication: reference	GLP GEP	Published Protected
IIA 4.2.5	Bodden R.M.	Analysis of CS_2 generators in milk, urine and tissues See study "Nature of the residue in Lactating Goats" Cross ref. : 6.2/01 Submitted by : Ziram Task Force Company file N° : Hazelton Labs America Inc. HLA 6225-101 Date of report : June 16, 1993	Yes	unpublished protected
IIA 4.1.2	Diepenhorst P.C.	Triscabol technical : Determination of water soluble zinc by AAS Submitted by : Ziram Task Force Company file N° : Pennwalt Holland PH-M 227.3.1 Date of report : June 26, 1987	No	unpublished protected
IIA 4.1.1	Diepenhorst P.C.	Carbon disulfide : determination in dithiocarbamates by the "sulfuric acid method" Submitted by : Ziram Task Force Company file N° : Elf Atochem SOP DLA-012.1 Date of report : September 10, 1993a	No	unpublished protected
IIIA 5.1.1	Diepenhorst P.C.	Triscabol 76 WG : determination of active ingredient Submitted by : Ziram Task Force Company file N° : Elf Atochem SOP DLA-M 227.5 Date of report : September 9, 1993b	No	unpublished protected
IIA 4.2.1	Kool P.	Ethylenebisdithiocarbamates : spectrophotometric determination of residue on crops (range between 0.02 and 10 mg/kg) Submitted by : Ziram Task Force Company file N° : Elf Atochem PH-M 027.7.1 Date of report : June 16.1989	No	unpublished protected
IIA 4.2.3	Lata M. Prasada Rao T. Iyer C.S.P. Damodaran A.D.	Spectrophotometric determination of Ziram (dithiocarbamate fungicide)by thiocyanate and rhodamine 6G method Talanta, Vol 42, N° 1, pp 41-43, 1995	No	published -
IIA 4.2.4	Maini P. Boni R.	Gas chromatographic determination of dithiocarbamate fungicide in workroom air Bull. Environ. Contam. Toxicol., 37, pp 931-937, 1986	No	published -