10.2	**Certifying authority**	not applicable
10.3	**GLP**	no
10.4	**Justification**	GLP regulations were not yet introduced at the time when the study was conducted.
11.1	**GEP**	not applicable
11.2	**Type of facility (official or officially recognised)**	[redacted]
11.3	**Justification**	not applicable

12 Test system

Animal species: Rat, Tif:RAIf, Mouse Tif:MAGf
Source: [redacted]
Dose levels: 0, 20, 80, 160 and 320 mg/kg
Group size: 6 mice and 6 rats per dose group.
Age/weight: Young adult, mean body weight rats 190 g, mice 26 g:
Administration: Oral by gastric intubation
Study duration: 14 consecutive days
General study Design: Daily treatment (10 ml/kg) for 14 consecutive days.
Mortality: Daily
Clinical signs: Daily

Post mortem examinations:
Livers were weighed, and chilled on ice. The tissue was then homogenized. Microsomal and cytosolic fractions were prepared by centrifugation. Microsomal fractions were suspended and recentrifuged to produce washed microsomal fractions. In addition, a small part of each rat liver homogenate was used to prepare a 50 g supernatant.

Biochemical determinations:
Protein concentrations were estimated in homogenates, 50 g supernatants of rat livers, microsomes and cytosolic fractions by standard methods. The DNA concentration was determined fluorimetrically in liver homogenates of control and high dosage group animals. In the microsomal or cytosolic fractions, the following parameters were evaluated:
phospholipid
Cytochrome P-450
Activities of ethoxycoumarin 0-deethylase in presence or absence of monooxygenase inhibitors
Epoxide hydrolase
UDP-glucuronosyltransferase
Glutathione S-transferase with 1-chloro-2,4-dinitrobenzene as substrate
Glutamyltranspeptidase activity was measured in rat liver 50 g supernatants.
All analyses were done according to publsished standard methods.

Electron microscopy:
Livers from 2 rats and 2 mice from the control groups and 2 rats and 3 mice from the highest dosage groups (320 mg/kg) were dissected into small blocks and fixed with 3 % glutaraldehyde. Following post-fixation with 1 % osmium tetroxide, the tissue was dehydrated and embedded in Epon. Thin sections were double-stained with uranyl acetate and lead citrate. In general one tissue block per animal was examined.

13 Findings

Mortality: No unscheduled deaths occurred.

Body weight: The body weight remained unaffected in all groups.

Liver weight: A dose-related increase in the liver to body weight ratios was noted in rats and mice in all treated groups.

Biochemical studies: The results are outlined inthe following table: If not indicated otherwise, enzyme activities are given as nMol/min/g liver.

Enzyme induction profile of propiconazole in the rodent liver					
Parameter / Dose [mg/kg]	Control	Propiconazole			
	0 mg/kg	20	80	160	320
RATS					
Liver weight	8.24	9.30	8.87	10.52	12.53
Liver DNA content	30.6	-	-	-	36.1
Microsomal Protein [mg/l]	8.96	8.74	14.1	13.3	16.7
Microsomal Phospholipid [mg/l]	5.84	5.24	7.68	9.03	11.9
Cytochrome P-450	11.9	11.3	21.5	27.9	39.6
EROD	5.22	4.30	9.38	17.2	31.2
Epoxide hydrolase	154	132	300	579	852
Glutathione S-transferase	1.19	1.08	1.78	3.36	3.87
UDP-glucurono-syltransferase	87.4	76.9	98.8	175	269
g-Glutamyl Transpeptidase	18.2	22.1	24.3	17.0	40.7
MICE					
Liver weight [g]	1.27	1.36	1.35	1.59	1.89
Liver DNA content	4.69	-	-	-	7.12
Microsomal Protein [mg/l]	10.7	8.82	11.9	18.0	21.0
Microsomal Phospholipid [mg/l]	7.05	7.07	8.74	11.5	13.9.
Cytochrome P-450	15.7	14.8	27.8	49.4	62.7
EROD	19.0	24.0	23.4	30.7	54.5
Epoxide hydrolase	62.6	51.4	70.5	160	212
UDP-glucurono-syltransferase	619	404	664	890	1'080
Glutathione S-transferase	290	301	380	421	422

Morphological studies: The ultrastructural organisation of the hepatocytes of mice and rats treated with 320 mg/kg propiconazole showed a marked proliferation of the smooth surfaced endoplasmic reticulum membranes. In addition, the number of autophagic vacuoles was increased in both species. In rats, increased numbers of lysosomes were noted while mice frequently showed lipid droplets in the cytoplasm. The structure of other organelles was apparently not altered by the treatment.

Conclusion: The repeated oral administration of propiconazole to male rats and male mice caused a marked liver enlargement and an induction of the activity of several hepatic enzymes which are involved in the metabolism of foreign compounds. The profile of enzyme induction was similar to that of phenobarbital. In both species the observed effects were dose dependent. A simultaneous proliferation of smooth-surfaced endoplasmic reticulum was revealed by electron microscopic investigations.

14	**Statistics**	Body and organ weights and enzyme activities were analysed by analysis of variance (ANOVA) followed by Student's t-Test
15 (published)	**References**	none
16 data	**Unpublished**	none
17 Indicator	**Reliability**	1

Data Protection Claim	Yes

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	5.8.2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

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

98/8 Doc IIIA section No.	6.11	Studies on other routes of administration (parental routes)

[redacted]

[redacted]

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	8.8.2005
Conclusion	
Acceptability	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

98/8 Doc IIIA section No.	**6.12.1/01**	**Medical surveillance data on manufacturing plant personnel if available**
Annex Point addressed	**II 5.9.1 / 01**	Medcal surveillance on manufacturing plant personnell

1.2	**Title**	Industrial Health Record CGA 64'250 Propiconazole
1.3	**Report and/or project N° Syngenta File N° (SAM)**	none 64250 / 2172
1.4	**Lab. Report N°**	none
1.5	**91/414 Cross Reference to original study / report**	5.9.1 / 01
1.6	**Authors**	Report: [redacted] Summary: [redacted]
1.7	**Date of report**	October 1991
1.8	**Published / owner**	unpublished / SYNGENTA Ltd. Basle, Switzerland
2.1	**Production facility**	[redacted]
2.2	**Time period covered**	1980 to 1991
3.	**Objectives**	Compilation of Industrial Health Records from production plant personnel involved in the production pf propiconazole.
4.1	**Substance**	CGA 64'250, technical grade active ingredient
7.1	**Test method**	Regular, general medical examination once per year. Documentation of accidents and / on conplaints of personnel.
13	**Findings**	No adverse impact on health related to the contact with propiconazole was reported in production workers nor in any other person who has been working with the compound.
14	**Reliability Indicator**	2

Data Protection Claim	Yes

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	8.8.2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

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

98/8 Doc IIIA section No.	6.12.1/ 02	Direct observation, e.g. clinical cases, poisoning incidents if available
Annex	II	Medical data
Point addressed	5.9.1 / 02	Medical surveillance on manufacturing plant personnel

1.2	Title	Medical Data
1.3	Report and/or project N° Syngenta File N° (SAM)	none 64250 / 2941
1.4	Lab. Report N°	none
1.5	91/414 Cross Reference to original study / report	5.9.1
1.6	Authors	Report: [redacted]
1.7	Date of report	16.10.1995
1.8	Published / owner	unpublished / SYNGENTA Ltd. Basle, Switzerland
2.1	Production facility	[redacted]
2.2	Time period covered	January 1988 until December 1994.
3.	Objectives	to update the industrial health record for propiconazole
4.1	Substance	CGA 64'250, technical grade active ingredient
7.1	Test method	In order to update the industrial health record for propiconazole, a questionnaire was sent to manufacturing and formulation plants concerned with the production of propiconazole and its formulations. The documents cover the period from January 1988 until December 1994.

13 Findings

General:

Manufacturing employees in Switzerland are medically examined by a company physician at the beginning of their employment and then routinely once a year according to the criteria of the Swiss Accident Insurance Institution (SUVA).

Routine medical examinations include:

Anamnesis,

Physical examination,

Blood analysis: hemoglobin, erythrocytes, leukocytes, thrombocytes, complete blood count, blood sedimentation rate, blood sugar, blood pressure, cholesterol, triglycerides, ALT, AST, alkaline phosphatase, bilirubin, creatinine, uric acid,

Urine analysis

Data from persons exposed in manufacturing:

Propiconazole is manufactured in continuous production in our facility at Monthey (Switzerland). Formulation and packaging is located in Montey and Aigues Vives (France).

Questionnaires have been sent to the responsible heads of production and formulation sites and company physicians. The following response was obtained:

Production: Propiconazole is in continiuous production. In total, 27 workers are involved in production and 3 persons in the laboratory are in charge with quality checks in the laboratory.

Formulation and packaging: Formulation in Montey is done in 4 - 5 campaingns each of which has a duration of 3 - 5 days. A total of 20 - 25 workers are involved.

In the formulation plant Aigues Vives, formulation of propiconazole is done in two campaigns per year, each of 3 months duration. Here, 30 persons are involved.

In Dielsdorf, formulation of metalaxyl-containing products is done in 3 campaigns each of which has a duration of 1 to 2 months. The campaigns are run by 20 workers.

No findings with regard to human health have been reported.

14 Reliability 1

Indicator

Data Protection Claim	Yes

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	8.8.2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

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

98/8 Doc IIIA section No.	6.12.1/ 03	Direct observation, e.g. clinical cases, poisoning incidents if available
Annex	II	Medical data
Point addressed	5.9.1 / 03	Medical surveillance on manufacturing plant personnel

1.2	Title	Medical Data - Overview/summary data of: Medical surveillance on manufacturing plant personnel Direct observations, e.g. clinical cases and poisoning incidents Diagnosis of poisoning First aid measures
1.3	Report and/or project N° Syngenta File N° (SAM)	64250/4358
1.4	Lab. Report N°	Not applicable
1.5	91/414 Cross Reference to original study / report	5.9.1 /03
1.6	Authors	Report: [redacted]
1.7	Date of report	14.09.2000
1.8	Published / owner	unpublished / SYNGENTA Ltd. Basle / Switzerland
2.1	Testing facility	[redacted]
2.2	Dates of experimental work	Review of data from 1982 to 2000
3.	Objectives	Assessment of medical data available on propiconazole
4.1	Test substance	Not applicable
4.2	Specification	[redacted]
4.3	Storage stability	Not applicable
4.4	Stability in vehicle	Not applicable.
4.5	Homogeneity in vehicle	not applicable
4.6	Validity	Not applicable
5	Vehicle / solven	Not applicable
6	Physical form	Not applicable
7.1	Test method	Not applicable
7.2	Justification	Not applicable
7.3	Copy of method	Not applicable
8	Choice of method	Not applicable
9	Deviations from EC-Directive 87/302	Not applicable
10.1	Certified laboratory	Not applicable

10.2 authority	**Certifying**	Not applicable
10.3	**GLP**	Not applicable
10.4	**Justification**	not applicable
11.1	**GEP**	not applicable
11.2 (official or officially recognised)	**Type of facility**	[redacted]
11.3	**Justification**	not applicable
12	**Test system**	Manufacturing employees are medically examined routinely once a year. Data are available of adverse findings on active substance and formulation plants between 1982 to 2000 at various sites. Case reports; there are four case reports of adverse incidents reported to Syngenta, one with the active substance and three with the formulation Diagnosis of Poisoning – unspecific signs Details of First Aid Measures are detailed
13	**Findings**	4 adverse incidents have been recorded at the formulation plant at Aigues Vives in France, between 1995-1999. A contribution of formulation ingredients to the effects could not be discounted. A total of 139 employees have worked with the active substance or formulation from 1982 – 2000. The reported cases of poisoning incidents gave no evidence for sensitisating potential. However, a few individuals may experience chest pains or local skin reactions when exposed to the formulation, TILT ® by direct contact. No cases of serious poisoning with propiconazole, or with formulations containing propiconazole have been reported to Syngenta, or found in the public literature.
14	**Statistics**	Not applicable
15 (published)	**References**	A literature search was conducted for the period 1975 to 2000. There were 20 hits, most of which did not refer to human data. There were 5 references (detailed in the report) for occupational exposure, which did not report any adverse findings.
16 data	**Unpublished**	none
17 Indicator	**Reliability**	1

Data Protection Claim	Yes

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	8.8.2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

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

98/8 Doc IIIA section No.	**6.12.2**	**Direct observation, e.g. clinical cases, poisoning incidents if available**
Annex Point addressed	**II 5.9.2 / 01**	Direct observations

1.2	**Title**	Epicutaneous Test with propiconazole in 20 human volunteers.
1.3	**Report and/or project N° Syngenta File N° (SAM)**	none 64250 / 2173
1.4	**Lab. Report N°**	none
1.5	**91/414 Cross Reference to original study / report**	5.9.2 / 01
1.6	**Authors**	Letter: [redacted] Summary: [redacted]
1.7	**Date of report**	August 1, 1991
1.8	**Published / owner**	[redacted]
2.1	**Production facility**	[redacted]
2.2	**Time period covered**	1980 to 1991
3.	**Objectives**	Compilation of Industrial Health Records from production plant personnel involved in the production pf propiconazole.
4.1	**Substance**	propiconazole, technical grade active ingredient
7.1	**Test method**	20 human volunteers were dermally tested with propiconazole suspended in vaseline at concentration levels of 0.1, 0.5 and 1%.
13	**Findings**	No dermal reactions were noted in any of the exposed persons. Further experimental details were not reported.
14	**Reliability Indicator**	1

Data Protection Claim	Yes

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	8.8.2005
Materials and Methods	As presented in the summary by applicant
Results and discussion	As presented in the summary by applicant
Conclusion	See Remarks
Reliability	3
Acceptability	Not acceptable
Remarks	This "study" is a letter in german from a physician, probably a dermatologist, describing in two sentences an epicutaneous test in 20 volunteers of unknown age, sex, health status and life-style habits with three doses of "Propiconazol". No evidence of sensitisation or dermal irritation is reported. No further details of the study are given. In IUCLID, the whole section under Point 5.10. (Exposure Experience) should be revised and updated.

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

98/8 Doc IIIA section No.	**6.12.2**	**Direct observation, e.g. clinical cases, poisoning incidents if available**
Annex	**II**	Direct observations
Point addressed	**5.9.2 / 02**	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	8.8.2005 27.3.2007
Conclusion	[redacted]
Acceptability/Remarks	[redacted]

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

98/8 Doc IIIA section No.	6.12.8	Prognosis following poisoning

In animal studies, symptoms of acute intoxication were unspecific and transient only. The same can be expected for humans, however, no cases of intoxication with propiconazole have yet been observed. Following ingestion, nausea, vomiting, diarrhoea and abdominal pain may occur.

98/8 Doc IIIA section No.	6.13	Toxic effects on lifestocks and pets

Several metabolism studies on chickens, hens, lactating goats and cows were carried out :

In one study, two chickens were orally dosed--one with phenyl- and one with triazole-^{14}C labeled propiconazole--for 16 consecutive days at 54.2 ppm and 48.0 ppm, respectively.

In a second study, four laying hens were dosed daily with 10 mg of ^{14}C-propiconazole (67 ppm in feed based on 150 g feed/day intake) in a gelatin capsule for 8 consecutive days.

In an other study, ninety mature white leghorn hens were acclimated 21 days before CGA 64250 feeding began. Prior to start sixty hens were selected based on optimal egg production and grouped as above (15 hens in each group), and fed CGA 64250 in feed of 0, 7.5, 37.5 and 75 ppm levels.

Then, the metabolism of [triazole-^{14}C]propiconazole was determined utilizing [redacted]. A lactating goat was dosed daily with -+5 mg of [triazole-^{14}C]propiconazole (4.53 ppm in feed based on averaged feed/day intake) in a gelatin capsule for 10 consecutive days.

The metabolism of [phenyl-^{14}C]propiconazole was also investigated; Two lactating goats were dosed daily with 125 mg of [phenyl-^{14}C]propiconazole (62-92 ppm in feed based on averaged feed/day intake) in a gelatin capsule for 4 consecutive days.

Finally, lactating dairy cows were dosed with CGA 64250 at levels equivalent to 15, 75 and 150 ppm in their feed. Milk samples for analysis were taken from all test treatments at 0, 1, 4, 7, 12, 14, 21 and 28 days and samples of liver, kidney, fat and muscle were collected for residue analysis after the following number of treatment days:

0 ppm - 14, 28 days
15 ppm - 14, 21, 28 days
75 ppm - 14, 21, 28 days
150 ppm - 14, 21, 28 days

Animals receiving 15 ppmof CGA 64250 were dosed by adding the compound to their feed, whereas animals receiving 75 and 150 ppm were dosed orally via gelatin capsules or intra-rumen injection.

In all these studies, propiconazole had not effect on feed consumption, body weight, milk production, and/or the general health of the animals.

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	10.8.2005
Conclusion	[redacted]
Acceptability	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

98/8 Doc IIIA section No.	6.14	Other test(s) related to the exposure of humans

Not applicable

[redacted]

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	7.2.2011
Conclusion	[redacted]
Acceptability	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

98/8 Doc IIIA section No.	6.15	Food and feedingstuffs

98/8 Doc IIIA section No.	6.17	If the active substance is to be used in products for action against plants then tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals shall be required

Not applicable

[redacted]

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	15.8.2005
Conclusion	[redacted]
Acceptability	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

98/8 Doc IIIA section No.	6.18	Summary of mammalian toxicology and conclusions

Summary is covered by Document IIA.

PROPICONAZOLE

Dossier for Directive 98/8/EC
Document IIIA

Section 7.1 : Fate and Behaviour in Water

Section 7.2 : Fate and Behaviour in Soil

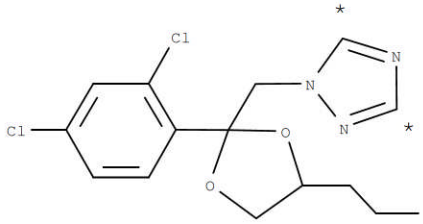
Section 7.3 : Fate and Behaviour in Air

From
Tier I - Section 5 - Annex II
of 91/414 dossier

98/8 Doc IIIA section No.	7.1.1.1.1/01	Hydrolysis as a function of pH and identification of breakdown products

91/414 Annex II -7.2.1.1 /01

General Information	
Title of the study:	**Rate of Hydrolysis of CGA-64250 under Laboratory Conditions**
Report and /or project number: Author: Syngenta File Number (SAM):	Project Report 07/80 N. Burkhard 64250/241
Name and address of testing facility:	Ciba - Geigy Ltd., Basle/Switzerland
Study period:	not reported
Date of report:	January 30, 1980
Compliance with GLP	Yes [ ] No, but complies with sound scientific standards [X]
Test guideline(s) used :	not mentioned
Deviations from test guideline :	-

Test substance 1	
Test substance (code number):	Propiconazole (CGA 64250)
Batch:	[redacted]
14-C-labeled test substance :	Yes [X] No [ ]
if yes, give specific activity	[redacted]
Position of labeling:	Triazole
Purity of test substance: *1)*	[redacted]
Structural formula: (* = Position of labeling)	
Test substance 2	
Test substance (code number)	
Batch:	
14-C-labeled test substance :	Yes [ ] No [ ]
if yes, give specific activity	MBq/mg (= µCi/mg)
Position of labeling	
Purity of test substance:	% (w/w)
Structural formula: (Position of labeling)	
Formulation used for study : Type of formulation (if used):	Yes [ ] No [X]
Solvent for application (if used):	Dichloromethane

1) not in original report, taken from raw data.

Test system	
Test concentration (mg/L)	10
Water solubility (mg/L)	110
pH-values and temperatures tested	pH 1 (0.1N HCl) ..... at 70°C pH 5 .....at 70°C pH 7 .....at 70°C pH 9 .....at 70°C pH 13 (0.1N NaOH) at 70°C
Number of sampling intervals	5 at each pH
Test duration	28 days
Absence of light	Yes [X] No [ ]
Sterilisation of test system:	Yes [ ] No [X]
Test buffer concentration < 0.02M	Yes [ ] No [X]
Buffer systems used	pH 5: Phthalate pH 7: Phosphate pH 9: Borate
Cosolvent used if Yes : identity and concentration	Yes [ ] No [X]

Test results				
Calculated First Order Parameters				
	70°C		°C	
pH	k[s^{-1}]	Half-life t_{50}	k [s^{-1}]	Half-life t_{50}
1	not calculated	>> 28 days		
5	not calculated	>> 28 days		
7	not calculated	>> 28 days		
9	not calculated	>> 28 days		
13	not calculated	>> 28 days		
Identification of hydrolysis products performed	Yes ( ) No (X)			

Summary of findings

The chemical hydrolysis of CGA-64250 in different aqueous media with pH-values ranging from 1 to 13 and at a concentration of 10 ppm was investigated. No significant hydrolysis of CGA-64250 occurred at each pH-value at 70°C over a period of 28 days.

Reliability indicator	1
Data Protection Claim	Yes

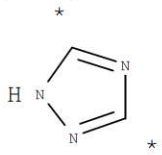
AK/PP2.54/April 25, 1994

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*15 February 2005*
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

98/8 Doc IIIA section No.	7.1.1.1.1/02	Hydrolysis as a function of pH and identification of breakdown products

91/414 Annex II -7.2.1.1 /02

General Information	
Title of the study:	**Determination of the Hydrolysis Rate Constants of 1,2,4-H-Triazole**
Report and /or project number: Author of the study: Author of the summary: Syngenta File Number (SAM):	Project Number 83-E-074 W.C. Spare A. Keller 71019/18
Name and address of testing facility:	Biospheric Inc., Rockville, Maryland 20852 / USA
Period(s) of experimental work:	Not mentioned
Date of report:	September 20, 1983
Publication status:	Final Report
Objectives:	--
Test guideline(s) used :	Not mentioned
Rationale for choice of test method:	--
Deviations form the test guideline:	--
Compliance with GLP	Yes [X] No, but complies with sound scientific standards [ ]

Test substance 1	
Test substance (code number):	1,2,4-H-Triazole (Metabolite of Propiconazole)
Batch:	[redacted]
14-C-labeled test substance :	Yes [X] No [ ]
if yes, give specific activity	[redacted]
Position of labeling:	U-Ring-14C
Purity of test substance:	[redacted]
Structural formula: (* = Position of labeling) 2kaiti4	
Test substance 2	
Test substance (code number)	
Batch:	
14-C-labeled test substance :	Yes [ ] No [ ]
if yes, give specific activity	MBq/mg (= µCi/mg)
Position of labeling	
Purity of test substance:	% (w/w)
Structural formula: (Position of labeling)	
Formulation used for study : Type of formulation (if used):	Yes [ ] No [X]
Solvent for application (if used):	Water, deionized

Test system	
Test concentration (mg/L)	10
Water solubility (mg/L)	630 000
pH-values and temperatures tested	pH 5 and 25°C pH 7 and 25°C pH 9 and 25°C
Number of sampling intervals	6
Test duration	30 days
Absence of light	Yes [X] No [ ]
Sterilisation of test system:	Yes [X] No [ ]
Test buffer concentration < 0.02M	Yes [X] No [ ]
Buffer systems used	pH 5: sodium acetate adjusted with acetic acid pH 7: NaH2PO4 + K2PO4 pH 9: Na2B4O7 adjusted with acetic acid
Cosolvent used if Yes : identity and concentration	Yes [ ] No [X]

Test results				
Calculated First Order Parameters				
	25°C		°C	
pH	k[s^{-1}]	Half-life t_{50}	k [s^{-1}]	Half-life t_{50}
1		--		
5	not calculated	> 30 days		
7	not calculated	> 30 days		
9	not calculated	> 30 days		
13		--		
Identification of hydrolysis products performed		Yes ( ) No (X)		

Summary of findings

At all three tested pH values 5, 7 and 9 1,2,4-H-Triazole was found to be stable for 30 days at 25°C.

Reliability indicator	1
Data Protection Claim	Yes

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*15 February 2005*
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

AK/PP 2.54/July 11, 1994