United States Environmental Protection Agency

Office of Prevention, Pesticides and Toxic Substances (7505P)



SEPA Pesticide **Fact Sheet**

Name of Chemical: **Epoxiconazole New Chemical Reason for Issuance:**

Tolerances Established

Date Issued: August 2006

Description of Chemical

Generic Name: *rel*-1-[[(2*R*,3*S*)-3-(2-chlorophenyl)-2-(4-fluorophenyl)

oxiranyl]methyl]-1*H*-1,2,4-triazole

Common Name: Epoxiconazole

Opal® 7.5 EC Fungicide Trade Name in

OPUS® Fungicide Foreign Countries:

Chemical Class: Triazole

EPA Chemical Code: 123909

Chemical Abstracts

Service (CAS) Number: 135319-73-2

Registration Status: Not Registered, Import Tolerances Established

Pesticide Type: Fungicide

U.S. Producer: **BASF** Corporation

> Agricultural Product Division 26 Davis Drive, P.O. Box 13528 Research Triangle Park, NC 27709

Tolerances Established

Import tolerances were established in the 40 CFR §180.619 for bananas at 0.5 ppm and coffee at 0.05 ppm.

Use Pattern and Formulations in Foreign Countries

Epoxiconazole is produced by BASF Corporation and is a triazole fungicide proposed for control of Black Sigatoka (*Mycosphaerella fijiensis*) and Yellow Sigatoka (*Mycosphaerella musicola*) in bananas and Coffee Rust (*Hamileia vastatrix*) in coffee. It acts as an inhibitor of ergosterol biosynthesis, thereby interfering with fungal cell membrane synthesis. Epoxiconazole is formulated as an emulsifiable concentrate (EC), Opal[®] 7.5 EC Fungicide and as a flowable concentrate (FIC), OPUS[®] 125 g/L, intended for use in the banana-producing countries of Central and South America. The EC formulation is proposed for broadcast foliar/fruit applications at a target rate of 1 liter per ha (equivalent to 75 g ai per ha), and the FIC formulation is proposed for broadcast foliar/fruit applications at a target rate of 1 liter per ha (equivalent to 125 g ai per ha). At present, there are no registered or proposed uses of epoxiconazole in the United States.

Science Findings

Available product chemistry and toxicology data supporting the proposed uses are summarized below.

Table 1 Nomenclature and Pl	nysicochemical Properties of Epoxiconazole
Physical/Chemical Structure	CI N N
Common Name	Epoxiconazole
Company Experimental names	BASF 480 F
Molecular Weight	329.76
IUPAC Name	(2RS,3SR)-1-[3-(2-chlorophenyl)-2,3-epoxy-2-(4-fluorophenyl) propyl]-1 <i>H</i> -1,2,4-triazole)
CAS Name	<i>rel</i> -1-[[(2 <i>R</i> ,3 <i>S</i>)-3-(2-chlorophenyl)-2-(4-fluorophenyl)oxiranyl] methyl]-1 <i>H</i> -1,2,4-triazole
CAS#	135319-73-2 (formerly 106325-08-0)
Empirical Formula	$C_{17}H_{13}CIFN_3O$
PC Code Number	123909
Water Solubility	8.42 ppm, @ 20°C
Log K _{ow}	3.58 @ 25℃

Table 2 Physicochemical Properties of the Technical Grade Epoxiconazole

Parameter	Value	
Melting Point	134 °C	
рН	7.3	
Relative Density at 20° C	$D^{20}_{4} = 1.374$	
Water Solubility at 20° C	8.42 mg/L	
Solvent Solubility (g/L) at 20° C	Solvent	g/100 mL (20° C)
	acetone	14.4
	acetonitrile	7.0
	dichloromethane	29.1
	ethyl acetate	9.8
	n-heptane	0.046
	isopropyl alcohol	1.2
	methanol	2.8
	n-octanol	1.1
	toulene	4.4
Vapor Pressure	4.5 x 10 ⁻⁷ at 20°C	
Octanol/water partition coefficient $Log(K_{ow})$	$Log P_{ow} = 3.58 (25^{\circ} C)$	

TOXICOLOGY SUMMARY

Table 3 Acute toxicity for Epoxiconazole				
Guideline No.	Study Type	MRID No.	Results	Toxicity Category
81-1	Acute Oral - Rat	44335002	LD ₅₀ : $M = 3160 \text{ mg/kg}$ F = >5000 mg/kg	Ш
81-2	Acute Dermal - Rat	44335003	$LD_{50} = > 2000 \text{ mg/kg}$	IV
81-3	Acute Inhalation - Rat	44335004	$LD_{50} = > 5.3 \text{ mg/L}$	IV
81-4	Primary Eye Irritation - Rabbit	44335005	Irritation clear by 72 hours	III
81-5	Primary Skin Irritation - Rabbit	44335006	No irritation observed	IV
81-6	Dermal Sensitization – Guinea Pigs	44335039	Non-sensitizer	N/A

Table 4 Subchronic, Chronic and Other Toxicity Profile		
Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.3100a 90-Day oral toxicity (rat)	No. 44401604 (1991) Acceptable Doses: 0, 30, 90, 270, 800 ppm [0, 3, 8, 21, 63 mg/kg/d]	NOAEL = Male - none; Female - 8 mg/kg/day LOAEL = Female: 21 mg/kg/day based on histopathological effects on the liver. Male: Significant decreases in adrenal weights seen at all dose levels.
870.3100b 90-Day oral toxicity (mouse)	No. 44335009 (1991) Acceptable Doses: 0, 7.5, 125, 250, 500, 1000 ppm [0, 2, 32, 67, 123, 264 mg/kg/day	NOAEL = 2 mg/kg/day LOAEL = M & F: 32 mg/kg/day, based on hepatic toxicity (increased absolute & relative liver weights, decreased serum cholesterol and triglycerides, hepato-cellular hypertrophy).
870.3150 90-Day oral toxicity (dog)	No. 44335008 (1990) Acceptable Doses: 0, 50, 200, 800 ppm (Males 0, 1.8, 6.8, 28.2 mg/kg/day) (Females 0, 1.9, 7.8, 32.4 mg/kg/day)	NOAEL = [Male: 6.8; Female: 7.8 mg/kg/day] LOAEL = [Male: 28.2 mg/kg/day, based on increased inflammatory cell foci in the liver and decreased serum cholesterol and total protein. Female: 32.4 mg/kg/day, based on increased liver weights and serum alkaline phosphatase.
870.3200 21/28-Day dermal toxicity (rat)	No. 44335013 (1992) Acceptable 0, 100, 400 and 1000 mg/kg/day	NOAEL = 400 mg/kg/day LOAEL = 1000 mg/kg/day based on decrease in red blood cells and hematocrit in males; increased absolute mean liver weights in both sexes; centrilobular liver cell hypertrophy in males; and increased absolute mean kidney weight in females.
870.3700a Prenatal developmental in rats	No. 44335020 (1990) Acceptable Doses: 0, 5, 15 and 45, mg/kg/day	Maternal NOAEL = 15 mg/kg/day LOAEL = 45 mg/kg/day based on reduced body weight gain and reduced food consumption during the treatment period. Developmental NOAEL = 5 mg/kg/day LOAEL = 15 mg/kg/day based on an increased incidence of skeletal variations in the litters in the mid- and high-dose groups.
870.3700b Prenatal developmental in rabbits	No. 44335021 (1990) Acceptable Doses: 0, 5, 20 or 80 mg/kg/day	Maternal NOAEL = 5 mg/kg/day LOAEL = 20 mg/kg/day based on reduced body weight gains. Developmental NOAEL = 20 mg/kg/day LOAEL = 80 mg/kg/day based on increased early resorptions.

Table 4 Subchronic, Chronic and Other Toxicity Profile		
Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.3800 Reproduction and fertility effects in rats	No. 44335024 (1992) Acceptable (Doses: 0, 10, 25 and 250 ppm [0, 0.85, 2.17, or 22.12 mg/kg/day for F ₀ and F ₁ generations combined - males; 0, 0.95, 2.41, 31.85 mg/kg/day for F ₀ and F ₁ combined - females].	Parental/Systemic NOAEL = Male: 2.17 mg/kg/day; Female: 2.41 mg/kg/day LOAEL = Male: 22.12 mg/kg/day and Female 31.85 mg/kg/day. For males: based on reduced body weight gain, food consumption, and body weight during pre-mating period; and decreased adrenal weights. For females: based on mortality (three deaths), increase in vaginal hemorrhaging during gestation, and increase in liver weights (F1 parents). For males and females: increase in pre-coital interval. Reproductive NOAEL = Male: 2.17 mg/kg/day; Female: 2.41 mg/kg/day LOAEL = Male: 22.12 mg/kg/day and Female 31.85 mg/kg/day. Both based on increases in stillborn pups and decreases in percent live born pups and viability index. Offspring NOAEL = Male: 2.17 mg/kg/day; Female: 2.41 mg/kg/day LOAEL = Male: 22.12 mg/kg/day and Female 31.85 mg/kg/day. Based on decreases in pup body weight (F2) and an increase in poor general health immediately after birth
870.4100b Chronic toxicity (dog)	Main Study No. 44335015 (1992) Acceptable Doses: 0, 50, 500 or 1500 ppm [0, 1.5, 14.4 46.1 mg/kg/day for males and 0, 1.6, 16.3 or 51.4 mg/kg/day for females] Suppl. Study No. 44401605 (1992) Doses: 0, 20, 30, 40 ppm (males only) [0, 0.3, 0.6, 0.9, 1.1 mg/kg/day]	NOAEL = Male: 1.1, Female: 1.6 mg/kg/day LOAEL = Male: 50 ppm (1.5 mg/kg/day), Female: 500 ppm (16.3 mg/kg/day) based on decreases of hematologic parameters indicative of hypochromic anemia.
870.4200 Chronic Toxicity/ Carcinogenicity (rat)	No. 44335017 (1992) Acceptable Doses: 0, 30, 150, 750, 1500 ppm or 0, 2, 7, 40, 80 mg/kg/day	NOAEL = Male:7, Female:2 mg/kg/day LOAEL = Male:40 mg/kg/day based on decreased body weight and increased liver foci., Female:7 mg/kg/day based on increased incidences of adrenal histopathological findings and increased incidences of ovarian cysts. There was evidence of carcinogenicity.

Table 4 Subchronic, Chronic and Other Toxicity Profile		
Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.4300 Carcinogenicity (mouse)	No. 44335018 (1992) Acceptable Doses: 0, 7.5, 125, 250, 500, 1000 ppm or 0, 2, 32, 67, 123, and 264 mg/kg/day.	NOAEL = Male & Female: 2 mg/kg/day LOAEL = Male & Female: 32 mg/kg/day based on hepatic toxicity as indicated by increased relative and absolute liver weights, and hepato-cellular hypertrophy in the males. There was evidence of carcinogenicity.
870.5100 Bacterial system, mammalian activation gene mutation	No. 44335025 (1989) Acceptable Doses: 0, 20, 100, 500, 2500, and 5000 <u>ug</u> /plate	There was no evidence of induced mutant colonies over background.
870.5300 In vitro Mammalian Cell Gene Mutation	44335029 (1990) acceptable Doses 0.05 to 1.0 mg/mL	The test material was not mutagenic in this test system.
870.5375 In vitro mammalian chromosome aberration	44335041 (1989) Acceptable Doses: 10 to 140 μg/mL, at 7, 24, 30 h	Epoxiconazole is not mutagenic in this <i>in vitro</i> aberration assay.
870.5395 Mammalian Erythrocytes Micronucleus Test	44335028 (1991) Acceptable Doses of 0, 200, 1000, and 5000 mg/kg.	There was no significant increase in the frequency of micro nucleated polychromatic erythrocytes in bone marrow at any treatment time following epoxiconazole exposure.
870.5500 Other Genotoxicity DNA damage (Adduct formation)	44335030 (1992) Acceptable Doses: 131 mg/kg (2.55 x 10 ⁹ dpm/kg) - rats and 27.8 mg/kg (2.82 x 10 ⁹ dpm/kg - mice	There is no indication of DNA adduct formation in rat or mouse treated <i>in vivo</i> with epoxiconazole.
870.5550 Other Genotoxicity Unscheduled DNA Synthesis	44335040 (1991) Acceptable 0, 0.15, 0.5, 1.5, 5.0, 15.0, 50.0, or 150.0 μg/mL	There was no evidence that unscheduled DNA synthesis, as determined by radioactive tracer procedures [nuclear silver grain counts] were induced at any concentration in either trial.
870.6200a Acute neurotoxicity screening battery	No. 44335007 (1996) Unacceptable/ upgradeable Dose: 0, 500, 1,000, 2,000 mg/kg.	Tentative NOAEL: 500 mg/kg (M) and 1000 mg/kg (F) Tentative LOAEL: 1000 mg/kg (M) based on decreased motor activity and 2000 mg/kg (F) based on decreased body weight gain, piloerection, and decreased motor activity.

Table 4 Subchronic, Chronic and Other Toxicity Profile		
Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.6200b Subchronic neurotoxicity screening battery	No. 44335014 (1996) Unacceptable/ upgradeable Doses; males: 0, 16, 50, 133; females: 0, 20, 59, 227 mg/kg/day	Tentative NOAEL: 50 mg/kg/day (M) and 59 mg/kg/day (F) Tentative LOAEL: 133 mg/kg/day (M) and 227 mg/kg/day (F) based on changes in body weight and food consumption. No significant signs of neurotoxicity were observed.
870.7485 Metabolism and pharmacokinetics (rat)	No. 44335032 & 44401609 Acceptable Doses: 3 or 100 mg/kg (single oral dose) or 3 mg/kg/day for 14 days.	Epoxiconazole is rapidly absorbed, metabolized and excreted. Plasma half-lives are five hours (single low dose) or 30 hours (single high dose). Approximately 30 metabolites have been identified (see Appendix for detailed metabolic map). Metabolites were detected in feces, bile, and the urine. Parent compound was only detected in the feces and only at the high, single dose (suggesting saturation of absorption).
870.7600 Dermal penetration (rat)	No. 44335031 (1991) Acceptable Doses: 3 and 30 mg/kg	Dermal absorption factor = 7.81% at 72 hrs
Special studies	No. 44335019 (1995) Acceptable/Nonguideline	A variety of <i>in vitro</i> hormone studies were performed in cultured rat, human, and pig cells. Results showed that epoxiconazole was a potent inhibitor of aromatase activity (an enzyme responsible for converting androstenedione to estrogen) and also a moderate inhibitor of 17-hydroxylase activity (responsible for cortisol production).

TOXICOLOGICAL ENDPOINTS:

Table 5 Summary of	Table 5 Summary of Toxicological Doses and Endpoints for Chemical for Use in Human Risk Assessments			
Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects	
Acute Dietary (females 13-49)	NOAEL= 5 UF = 100 Acute RfD = 0.05 mg/kg/day	Special FQPA SF = 1X aPAD = 0.05 mg/kg/day	Developmental toxicity-Rat: LOAEL of 15 mg/kg/d based on increased incidence of skeletal variations	
Acute Dietary (general population)	An appropriate dose/endpoint attributable to a single dose was not available from the oral toxicity studies including the developmental toxicity studies.			
Chronic Dietary (all populations)	NOAEL = 2 UF = 100 Chronic RfD = 0.02 mg/kg/day	Special FQPA SF = 1X cPAD = 0.02 mg/kg/day	2-year Rat Carcinogenicity: LOAEL of 7 mg/kg/d based on increased incidences of ovarian cysts and adrenal histopathological findings in females	
Cancer (oral, dermal, inhalation)	Classification: Likely human carcinogen with a Q_1^* (mg/kg/day) ⁻¹ of 3.04 x 10^{-2} .			

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no-observed-adverse-effect-level, LOAEL = lowest-observed-adverse-effect-level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose

Food Quality Protection Act Considerations:

FQPA Safety Factor:

There is a complete toxicity database for epoxiconazole and exposure data are complete or are estimated based on data that reasonably account for potential exposures. There is no evidence of susceptibility following *in utero* and/or postnatal exposure in the rabbit developmental toxicity and in the 2-generation rat reproduction study. There is low concern for the susceptibility seen in the rat developmental toxicity study and no residual uncertainty for pre- and/or post-natal toxicity. There is no evidence of significant neurotoxicity, as indicated by both the acute and subchronic neurotoxicity studies. Acute and chronic dietary food exposure estimates are based on conservative (Tier 1) assumptions, and will not underestimate exposure/risk. There is no potential for drinking water or residential exposure. Based on these data and conclusions, there are no FQPA uncertainty factors and the FQPA Safety Factor can be reduced to 1X.

Exposure Assessment:

Epoxiconazole is proposed for use only on imported coffee and banana commodities. The sole anticipated exposure route for the US population is via dietary (food) exposure. There is no

expectation that epoxiconazole residues would occur in surface or ground water sources of drinking water. Therefore, no aggregate nor occupational exposure is expected. There are no registered uses of epoxiconazole in the United States.

<u>Acute</u>: The acute dietary exposure assessment for the only population subgroup of concern, females 13-49 years old, assumed 100% crop treated and tolerance level residues. It is estimated that dietary (food only) exposure to epoxiconazole will utilize < 2% of the aPAD and is below the Agency's level of concern.

<u>Chronic</u>: The chronic dietary exposure assessment for the most highly exposed population subgroup, children 1-2 years old, assumed 100% crop treated and tolerance level residues. It is estimated that dietary (food only) exposure for children 1-2 years old will utilize 4.6% of the cPAD and is below the Agency's level of concern. The chronic dietary exposure estimate for the U.S. general population and all other population subgroups was lower.

<u>Cancer</u>: The cancer dietary exposure estimate for the U.S. population (total) is 3×10^{-5} mg/kg/day. This is equivalent to a risk of 9.03×10^{-7} which is below the Agency's level of concern (generally in the range of 1×10^{-6})

SUMMARY OF DATA GAPS

The registrant will provide the following:

- 1. Additional data to upgrade the acute neurotoxicity study
- 2. Additional data to upgrade subchronic neurotoxicity study
- 3. A coffee metabolism study
- 4. A radiovalidation of the enforcement method
- 5. A description of BASF Method 536/0

Contact person at USEPA

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DISCLAIMER: The information in this Pesticide Fact Sheet is for information only and is not to be used to satisfy data requirements for pesticide registration. The information is believed to be accurate as of the date on the document.

APPENDIX I:

GLOSSARY OF TERMS AND ABBREVIATIONS

ADNT Acute delayed neurotoxicity

a.i. Active Ingredient

aPAD Acute Population Adjusted Dose

ARI Aggregate Risk Index
BCF Bioconcentration Factor
CAS Chemical Abstracts Service

ChE Cholinesterase

ChEI Cholinesterase inhibition

cPAD Chronic Population Adjusted Dose

%CT Percent crop treated DAT Days after treatment

DEEM-FCID Dietary Exposure Evaluation Model - Food Consumption Intake Database

DNA Deoxyribonucleic acid DNT Developmental neurotoxicity

DIT Developmental immunotoxicity
DWLOC Drinking Water Level of Comparison.
EC Emulsifiable Concentrate Formulation

EEC Estimated Environmental Concentration. The estimated pesticide concentration in

an environment, such as a terrestrial ecosystem.

EPA U.S. Environmental Protection Agency

FQPA Food Quality Protection Act GLC Gas Liquid Chromatography

GLN Guideline Number

LC₅₀ Median Lethal Concentration. A statistically derived concentration of a substance

that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l,

mg/kg or ppm.

LD₅₀ Median Lethal Dose. A statistically derived single dose that can be expected to

cause death in 50% of the test animals when administered by the route indicated

(oral, dermal, inhalation). It is

expressed as a weight of substance per unit weight of animal, e.g.,

mg/kg.

LOAEL Lowest Observed Adverse Effect Level

LOAEC Lowest Observed Adverse Effect Concentration

LOC Level of Concern
LOD Limit of Detection
LOQ Limit of quantitation

mg/kg/day Milligram Per Kilogram Per Day

mg/L Milligrams Per Liter MOE Margin of Exposure

MRID Master Record Identification (number), EPA's system of recording and tracking

studies submitted

MTD Maximum tolerated dose

NA Not Applicable

NOEC No Observable Effect Concentration

NOEL No Observed Effect Level

NOAEL No Observed Adverse Effect Level

NOAEC No Observed Adverse Effect Concentration
NPDES National Pollutant Discharge Elimination System

OP Organophosphate

OPP EPA Office of Pesticide Programs

OPPTS EPA Office of Prevention, Pesticides and Toxic Substances

PAD Population Adjusted Dose
PAG Pesticide Assessment Guideline
PAM Pesticide Analytical Method
PHED Pesticide Handler's Exposure Data

PHI Preharvest Interval ppb Parts Per Billion

PPE Personal Protective Equipment

ppm Parts Per Million

PRZM/

EXAMS Tier II Surface Water Computer Model

RAC Raw Agriculture Commodity

RBC Red Blood Cell

RED Reregistration Eligibility Decision

REI Restricted Entry Interval

RfD Reference Dose

SCI-GROW Tier I Ground Water Computer Model

SF Safety Factor

TGAI Technical Grade Active Ingredient

UF Uncertainty Factor

μg micrograms

 $\mu g/L$ Micrograms Per Liter $\mu L/g$ Microliter per gram

USDA United States Department of Agriculture

WPS Worker Protection Standard

APPENDIX II

Citations Considered to be Part of the Data Base Supporting the Registration of Epoxiconazole.

MRID	Citation
44335000	BASF Corp. (1997) Submission of Product Chemistry, Toxicology, Metabolism, and Residue Data in Support of Import Tolerance Petition for Epoxiconazole in/on Bananas. Transmittal of 41 Studies.
44335001	Nelsen, T. (1997) The Physical Chemical Properties Registration No. 205259 (Epoxiconazole) Technical Grade Active Ingredient: Lab Project Number: 97/5255: PCF 01810: 97/10578. Unpublished study prepared by BASF Aktiengesellschaft. 99 p.
44335002	Kirsch, P. (1988) Report on the Acute Oral Toxicity Reg. No. 205259 (Epoxiconazole) on the Rat: Lab Project Number: 88/0107: 10A0035/871003. Unpublished study prepared by BASF Aktiengesellschaft. 15 p.
44335003	Kirsch, P. (1988) Report on the Acute Dermal Toxicity Reg. No. 205259 (Epoxiconazole) on the Rat: Lab Project Number: 88/0108: 11A0035/871004. Unpublished study prepared by BASF Aktiengesellschaft. 14 p.
44335004	Klimisch, J. (1988) Report on the Acute Inhalation Toxicity Reg. No. 205259 (Epoxiconazole) as a Dust Aerosol in Rats; 4 Hour Exposure: Lab Project Number: 88/0081: 13I0265/877027. Unpublished study prepared by BASF Aktiengesellschaft. 22 p.
44335005	Kirsch, P. (1988) Report on the Acute Irritation to the Eye of the White Rabbit with Reg. No. 205259 (Epoxiconazole): Lab Project Number: 88/0110: 13H0035/872008. Unpublished study prepared by BASF Aktiengesellschaft. 11 p.
44335006	Kirsch, P. (1988) Report on the Acute Irritation/Corrosivity to the Intact Dorsal Skin of the White Rabbit with Reg. No. 205259 (Epoxiconazole): Lab Project Number: 88/0109: 14H0035/872007. Unpublished study prepared by BASF Aktiengesellschaft. 12 p.
44335007	Mellert, W.; Kaufmann, W.; Hildebrand, B. (1996) Reg. No. 205 259Acute Oral Neurotoxicity Study in Wistar Rats: Lab Project Number: 20S0195/91174: 96/10736. Unpublished study prepared by BASF Aktiengesellschaft. 361 p.
44335008	Hellwig, J. (1990) Report on the Study of the Toxicity of Reg. No. 205259 (Epoxiconazole) in Beagle Dogs Administration via the Diet over Three Months: Lab Project Number: 90/0411: 31D0265/87106. Unpublished study prepared by BASF Aktiengesellschaft. 487 p.
44335009	Schilling, K. (1991) Study of the of the (sic) Oral Toxicity of Reg. No. 205259 (Epoxiconazole) in C57BL/6Ncr1BR Mice Administration via the Diet for Three Months: Lab Project Number: 97/10908: 53S0265/87113. Unpublished study prepared by BASF Aktiengesellschaft. 371 p.
44335010	Schilling, K. (1991) Study of the of the (sic) Oral Toxicity of Reg. No. 205259

MRID	Citation
	(Epoxiconazole) inB6C3F1/Cr1BR (sic) Mice Administration via the Diet over Three Months: Lab Project Number: 91/10855: 53S0265/87029. Unpublished study prepared by BASF Aktiengesellschaft. 295 p.
44335011	Schilling, K. (1991) Study of the Oral Toxicity of Reg. No. 205259 (Epoxiconazole) inB6C3F1/Cr1BR (sic) Mice Administration in the Diet Over Three Months: Lab Project Number: 91/10856: 53S0265/87078. Unpublished study prepared by BASF Aktiengesellschaft. 293 p.
44335012	Schilling, K. (1991) Supplementary Study on the Oral Toxicity of Reg. No. 205259 (Epoxiconazole) for the Selection of the MTD in Thge (sic) Subsequent Long Term Study in the Rat Administration in the Diet for Three Months: Lab Project Number: 91/10837: 31S0265/87100: 91/10836. Unpublished study prepared by BASF Aktiengesellschaft. 311 p.
44335013	Kirsch, P. (1992) Study of the Dermal Toxicity of Reg. No. 205259 (Epoxiconazole) in Wistar Rats: Applications to the Intact Skin Over 3 Weeks: Lab Project Number: 92/10691: 37H0959/88113. Unpublished study prepared by BSF Aktiengesellschaft. 255 p.
44335014	Mellert, W.; Kaufmann, W.; Hildebrand, B. (1996) Reg. No. 205 259Subchronic Oral Neurotoxicity Study in Wistar Rats: Administration in the Diet for 3 Months: Lab Project Number: 96/10713: 50S0195/91170. Unpublished study prepared by BASF Aktiengesellschaft. 487 p.
44335015	Mellert, W. (1992) Report on the Study of Reg. No. 205259 (Epoxiconazole) in Beagle Dogs: Administration via the Diet over Twelve Months: Lab Project Number: 33D0959/88068: 92/10687. Unpublished study prepared by BASF Aktiengesellschaft. 974 p.
44335016	Mellert, W. (1992) Study on the Chronic Toxicity of Reg. No. 205259 (Epoxiconazole) in Wistar Rats: Administration via the Diet over 24 Months: Lab Project Number: 92/10685: 71S0959/88065. Unpublished study prepared by BASF Aktiengesellschaft. 1621 p.
44335017	Mellert, W. (1992) Study of the Potential Carcinogenicity of Reg. No. 205259 (Epoxiconazole) (in) Wistar Rats: Administration via the Diet over 24 Months: Lab Project Number: 92/10686: 71S0959/88066. Unpublished study prepared by BASF Aktiengesellschaft. 2027 p.
44335018	Mellert, W. (1992) Study of the Potential Carcinogenicity of Reg. No. 205259 (Epoxiconazole) (in) C57BL Mice: Administration via the Diet for 78 Weeks: Lab Project Number: 92/10699: 80S0959/88082. Unpublished study prepared by BASF Aktiengesellschaft. 2238 p.
44335019	Wuttke, W. (1995) Registration No. 205259 (Epxiconazole (sic))in vitro Investigation into the Effects of Triazole on the Production of Ovarian and Adrenal Steroids and the Pituitary Hormone Prolactin: Lab Project Number: 95/11234. Unpublished study prepared by Georg-August University. 27 p.
44335020	Hellwig, J. (1990) Study of the Prenatal Toxicity of Reg. No. 205259 (Epoxiconazole) in

MRID	Citation
	Rats after Oral Administration: Lab Project Number: 90/0214: 30R0959/88073. Unpublished study prepared by BASF Aktiengesellschaft. 276 p.
44335021	Hellwig, J. (1990) Study of the Prenatal Toxicity of Reg. No. 205259 (Epoxiconazole) in Rabbits after Oral Administration: Lab Project Number: 90/0213: 40R0959/88085. Unpublished study prepared by BASF Aktiengesellschaft. 213 p.
44335022	Hellwig, J. (1993) Study of the Prenatal Toxicity of Reg. No. 205259 (Epoxiconazole) in Rats after Dermal Administration: Lab Project Number: 93/10151: 34R0959/88121. Unpublished study prepared by BASF Aktiengesellschaft. 273 p.
44335023	Hellwig, J. (1992) First, Discontinued Reproduction Study with Reg. No. 205259 (Epoxiconazole) in Rats: Continuous Dietary Administration over 1 Generation: Lab Project Number: 92/10688: 70R0959/88076. Unpublished study prepared by BASF Aktiengesellschaft. 399 p.
44335024	Hellwig, J. (1992) Reproduction Study with Reg. No. 205259 (Epoxiconazole) in Rats: Continuous Dietary Administration over 2 Generations: Lab Project Number: 92/10689: 70R0959/88098. Unpublished study prepared by BASF Aktiengesellschaft. 1203 p.
44335025	Gelbke, H. (1989) Report on the Study of Reg. No. 205 259 (Epoxiconazole) in the Ames Test: (Standard Plate Test and Preincubation Test with Salmonella typhimurium): Lab Project Number: 89/0028: 40M0959/884316: 884316. Unpublished study prepared by BASF Aktiengesellschaft. 29 p.
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