

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PESTICIDE FACT SHEET

Name of Chemical: Tembotrione

Reason for Issuance: Conditional Registration

Date Issued: September 2007

I. DESCRIPTION OF CHEMICAL

CHEMICAL NAME: Tembotrione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-(trifluoroethoxy)methyl]benzoyl]-1,3-cyclohexanedione

COMMON NAME: Tembotrione

CHEMICAL FORMULA:

EPA PC CODE: 012801

CHEMICAL ABSTRACTS SERVICE (CAS) NUMBER: 335104-84-2

YEAR OF INITIAL REGISTRATION: 2007

PESTICIDE TYPE: Herbicide

CHEMICAL CLASS: Triketone

US PRODUCER: Bayer CropScience LP

II. USE PATTERNS AND FORMULATIONS

Application Sites: Tembotrione is registered as a selective, post-emergence herbicide developed for the control of a broad spectrum of broadleaf and grassy weeds in corn.

Type of Formulations: Technical grade manufacturing use product (96.2% tembotrione) and liquid end use product (34.5% tembotrione)

Application Methods and Rates: The application rate is 0.082 lbs a.i./acre (0.092 kg a.i./ha) followed 14 days later by a second treatment at the same application rate, if needed. Applications take place between crop emergence to the V8 (more than 8 visible leaves) developmental stage of corn. Tembotrione is broadcast applied using flat-fan nozzles that provide medium to coarse spray droplets.

Description	Value
Melting point	117 °C
pH @ 24 °C	3.63
Density (g/mL @ 20 °C)	1.56
Water solubility (mg/L @ 20 °C)	0.22 at pH 4 28.3 at pH 7 29.7 at pH 9
Solvent solubility (g/L at 20	29.7 at pH 9
°C) DMSO Methylene Chloride Acetone Ethyl Acetate Toluene Hexane Ethanol Vapor pressure (Torr, 20 °C)	>600 >600 300-600 180.2 75.7 47.6 8.2 8.25 x 10 ⁻¹¹
Dissociation constant (pK _a)	3.2
Octanol/water partition coefficient (P _{ow} @ 23 °C) (P _{ow} @ 24 °C) (P _{ow} @ 23 °C)	0.0430 at pH 9.0 0.0807 at pH 7.0 144.9 at pH 2.0
UV/visible absorption spectrum (nm)	Primary: 205 Secondary: 284 Tertiary: 240

III. PHYSICAL AND CHEMICAL PROPERTIES

IV. HUMAN HEALTH RISK ASSESSMENT

A. Toxicity

1. Acute Toxicity: Tembotrione has low acute toxicity via the oral, dermal and inhalation routes of exposure (Toxicity category III or IV). It is a dermal sensitizer but not an eye or dermal irritant. The acute toxicity findings are summarized below:

Summary of	Summary of Acute Toxicity of Tembotrione.					
Guideline	Study Type	Results	Toxicity Category			
870.1100	Acute Oral – rat	LD ₅₀ > 2000 mg/kg	III			
870.1200	Acute Dermal - rat	LD ₅₀ > 2000 mg/kg	III			
870.1300	Acute Inhalation - rat	LC ₅₀ > 5.03 mg/L	IV			
870.2400	Primary Eye Irritation – rabbit	Formulation is moderately irritating to the eye	III			
870.2500	Primary Skin Irritation – rabbit	Not an irritant to the skin	IV			
870.2600	Dermal sensitization - guinea pig	Not a dermal sensitizer	N/A			

2. Subchronic/ChronicToxicity: The primary target organs were the eyes, liver and kidneys. In subchronic and chronic oral toxicity studies, corneal opacity, neovascularization, edema of the cornea, and keratitis of the eye were observed in the rat and dog. Liver effects (increased weight, hypertrophy, hyperplasia) were seen in the rat, mouse and dog. In the kidney, increased weight, and papillary mineralization were observed in the rat and mouse following chronic exposure. The dog appeared to be more sensitive to hematological effects. In the subchronic and chronic dog toxicity studies hematological changes indicative of anemia were seen [decreased mean corpuscular hemoglobin (MCH) and mean corpuscular volume (MCV)]. Similar hematological effects were also observed in the chronic toxicity study in the mouse. Certain changes in multiple organs seen in the subchronic, chronic, dermal, and reproduction studies (e.g., microscopic changes in the thyroid gland, adrenal gland, and pancreas; increased number of corpora lutea in the ovary, and delayed preputial separation) may be due to various mechanisms including possible liver-pituitary-thyroid homeostatic disruption or inhibition of steroid synthesis.

- **3. Carcinogenicity:** Tembotrione is classified as "Suggestive Evidence of Carcinogenicity", based on increased incidences of thyroid adenomas and squamous cell carcinomas of the cornea in male rats at the highest doses tested (200 and 800 ppm) in the chronic toxicity/carcinogenicity study in rats. These results were considered to be a result of the keratitis of the eye. No evidence of carcinogenicity was observed in the mouse chronic toxicity/carcinogenicity study. The chronic RfD of 0.0004 mg/kg/day, based on the rat chronic toxicity/carcinogenicity study would be protective of both non-cancer and potential cancer precursor effects. Therefore, quantifications of separate cancer risk were not required.
- 4. Prenatal and Postnatal Sensitivity: There is evidence of increased susceptibility in rabbit and rat fetuses to in utero exposure to tembotrione compared to the doses for the effects found in maternal animals. In a developmental toxicity study in rabbits, the NOAEL of 1 mg/kg bw/day was based on decreased growth and/or delayed development of the skeleton and increased incidences of skeletal variations and anomalies in fetuses seen at a LOAEL of 10 mg/kg/day. This LOAEL is ten-fold lower than the dose resulting in maternal toxicity (100 mg/kg/day, few or no feces, late abortion, decreased body weight and food consumption). In a rat developmental toxicity study, increased skeletal variations (e.g., delayed ossifications) and other fetal effects (decreased fetal body weights and an increased number of runts) occurred at a dose of 25 mg/kg/day (the lowest dose tested), which is lower than the 125 mg/kg bw dose that caused marginal maternal toxicity (decreased body-weight gains and food consumption). In a rat developmental neurotoxicity study (DNT), decreased post-weaning body weight (males), decreased acoustic startle response and brain morphometric changes were seen in rat fetuses at a dose of 0.8 mg/kg/day (the lowest dose tested) which was lower than the dose of 16.3 mg/kg/day at which maternal toxicity occurred (cornel opacity during lactation).

Although, these studies provide evidence of increased susceptibility following preand post-natal exposures, the concern for increased susceptibility is low for several reasons. First, a well characterized NOAEL (with a sufficient margin from the LOAEL) protecting fetuses has been established in the rabbit prenatal study. Also, the prenatal developmental NOAELs or LOAELs for both the rabbit and rat studies are approximately 12 to 30-fold higher than the LOAEL used for the acute RfD. Although there were some marginal effects reported in the offspring in the rat 2generation reproduction study at 1.4 mg/kg/day (the lowest dose tested), these parameters (ocular, decreased absolute brain weight, preputial separation) were also evaluated at the lower dose in the rat DNT study but were not found at the low dose tested (0.8 mg/kg/day). Therefore, a NOAEL has been identified for these effects. Other effects indicative of neurotoxicity (altered brain morphometrics, decrease in auditory startle response) were seen in the rat developmental neurotoxicity study at the lowest dose tested. The response for brain morphometrics seen at termination is considered to be marginal or equivocal since the changes were small and no clear dose response was observed. The decreased acoustic startle response was not found in young pups (postnatal day 22) but only observed in adult rats (post natal day 60)

and was statistically significant at the mid and high dose but not at the lowest dose tested.

- **5. Metabolism:** Rat metabolism data indicate that tembotrione is well absorbed. More than 96% of the administered dose was recovered in urine and feces in 24 hours. Minor sex differences were observed in the routes of excretion. The primary routes of elimination were the urine in females and the urine and feces in males. The highest concentrations of radioactivity were found in the skin followed by the liver, kidneys, stomach (and contents) and carcass. Males had higher mean blood, plasma maximum concentrations (Cmax) and area under the concentration-time curves (AUC) values than females. The primary step in the metabolism of tembotrione is the hydroxylation (oxidative pathway) of the cyclohexyl ring of the molecule.
- 6. Mutagenicity: Tembotrione was negative for mutations and chromosomal aberrations across four in vitro/in vivo genotoxicity studies and was considered not to pose a mutagenic concern.

	Subchronic, Chronic and Other Toxicity Profile for Tembotrione				
Guideline	Study Type	MRID	Results		
No.		No./Doses			
870.3100	90-Day oral toxicity (rat)	46695638 0, 1.25, 75, 1500, 7000 ppm M: 0, 0.07, 4.45, 86.4, 413 mg/kg/day F: 0, 0.09, 5.59, 107.2, 465 mg/kg/day	NOAEL=M/F: 0.07/0.09 mg/kg/day LOAEL=M/F: 4.45/5.59 mg/kg/day based on neovascularization and opacity of the cornea and increased urinary ketones in both sexes; increased cholesterol, absolute liver weights, and diffuse centrilobular hepatocellular hypertrophy in males; and decreased absolute and relative thymus weights in females.		
870.3100	90-Day oral toxicity (rat)	466995639 0, 6, 20, 40 ppm M: 0, 0.30, 0.98, 2.20 mg/kg/day F: 0, 0.35, 1.18, 2.68 mg/kg/day	NOAEL =M/F: 0.30/0.35 mg/kg/day LOAEL = M/F: 0.98/1.18 mg/kg/day based on snowflake-like corneal opacity and keratitis of the eyes in males and corneal opacity, neovascularization and edema of the cornea in females.		
870.3100	90-Day oral toxicity (rat)	466995640 0, 35, 350, 3500, 7000 ppm M: 0, 5.9, 64, 631, 1317 mg/kg/day F: 0, 7.3, 75.6, 783, 1833 mg/kg/day	NOAEL =M/F: 64/75.6 mg/kg/day LOAEL =M/F: 631/783 mg/kg/day based on decreased uterine weights and increased corpora lutea in the ovary in females and serum alanine aminotransferase activity, liver weights, hepatocellular hypertrophy, dark livers, macroscopic erosive/ulcerative lesion in the stomach and/or dark intestinal content in both sexes.		

7. Toxicology Profile: The toxicological profile is discussed in the table below:

870.3150	90-Day oral toxicity (dog)	46695643 0, 125, 750, 4500/2250 ppm M: 0, 4.5, 26.7, 124/111 mg/kg/day F: 0, 4.5, 28.5, 124/111 mg/kg/day	NOAEL =M/F: 26.7/28.5 mg/kg/day LOAEL = 124/111 mg/kg/day based on clinical signs of toxicity including uncoordinated movement, disturbance in locomotion, decreased body weights and body-weight gains, effects on hematology and clinical chemistry, increased liver weights, and microscopic effects on the liver and peripheral nerves in both sexes; vacuolation of the adrenal glands in males, bilateral corneal opacity in males, and decreased food consumption in females.
870.3200	21/28-Day dermal toxicity (rat)	46695644 0, 250, 500, 1000 mg/kg/day	. NOAEL was not established LOAEL = 250 mg/kg/day based on colloid alterations and hypertrophic follicular epithelium in the thyroid gland; and degenerative changes in the pancreas in both sexes and increased proteinacious material in the Rathke pouch in the pituitary and basophilic tubules in the kidneys of males.
870.3200	21/28-Day dermal toxicity (rat)	46695645 0, 50, 250, 1000 mg/kg/day	NOAEL was not established in males; NOAEL=F: 50 mg/kg/day LOAEL = M: 50 mg/kg/day based on colloid alterations in the thyroid gland and degenerative changes in the pancreas. LOAEL=F: 250 mg/kg/day based on degenerative changes in the pancreas.
870.3700a	Prenatal developmental in (rat)	46695646 and 46695647 0, 25, 125, 500 mg/kg/day	Maternal NOAEL = 25 mg/kg/day LOAEL = 125 mg/kg/day based on decreased body- weight gains and food consumption. Developmental NOAEL was not established. LOAEL = 25 mg/kg/day based on increased skeletal variations including delayed ossifications and decreased growth and developmental as indicated by decreased fetal body weights and an increased number of runts.
870.3700b	Prenatal developmental in (rabbit)	46695703 0, 1, 10, 100 mg/kg/day	Maternal NOAEL = 10 mg/kg/day LOAEL = 100 mg/kg/day based on mortality, clinical signs of toxicity (i.e., few or no feces), abortion, decreased body weight and food consumption. Developmental NOAEL = 1 mg/kg/day LOAEL = 10 mg/kg/day based on decreased or delayed growth and/or development of the skeleton and increased incidences of other skeletal variations and anomalies.

870.3800	Reproduction and fertility effects (rat)	46695704 0, 20, 200, 1500 ppm M: 0, 1.4, 13.3, 100.4 mg/kg/day F: 0, 1.6, 15.8, 119.3 mg/kg/day	Parental/Systemic NOAEL was not established. LOAEL = M/F: 1.4/1.6 mg/kg/day based on effects on the eyes, including corneal opacity, acute inflammation, and neovascularization. Reproductive NOAEL = M/F 100.4/119.3 mg/kg/day LOAEL was not established. Offspring NOAEL was not established. LOAEL = M/F: 1.4/1.6 mg/kg/day based on effects on the eyes, including corneal opacity, acute inflammation, and neovascularization; increased incidences of minimal extramedullary hematopoeisis in the spleen, delayed preputial separation, and decreased absolute brain weight.
870.4100b	Chronic toxicity (dog)	46695705 0, 75, 300, or 1200 ppm M: 0, 2.5, 9.0, 37.8 mg/kg/day F: 0, 2.5, 10.2, 41.6 mg/kg/day	NOAEL was not established in males. LOAEL= M: 2.5 mg/kg/day based on the increased number of digestion chambers of the sciatic nerve. NOAEL=F: 10.2 mg/kg/day LOAEL= F: 41.6 mg/kg/day based on decreases in MCH and MCV, increased platelet counts, changes in erythrocyte morphology and pigmentation of the thyroid gland.
870.4300	Chronic/ Carcinogenicity (mouse)	46695706 0, 30, 300, 1000, or 3000 ppm M: 0, 4, 43, 146, 440 mg/kg/day F: 0, 5, 54, 179, 552 mg/kg/day	NOAEL was not established. LOAEL =M/F: 4/5 mg/kg/day based on based on gallstones, eosinophilic cytoplasmic alteration, subepithelial mixed cell infiltrate, and dilatation in/of the gallbladder; hepatocellular vacuolation, hepatocellular hypertrophy, and increased liver weight in males and females; and papillary mineralization of the kidney and changes in hematological parameters indicative of anemia in females. No evidence of carcinogenicity.
870.4300	Chronic/ Carcinogenicity (rat)	46695707 0, 0.10, 1.05, 134, 280 mg/kg/day	NOAEL =F: 0.10 mg/kg/day LOAEL = F: 1.05 mg/kg/day based on keratitis of the eye and biliary hyperplasia/fibrosis. No evidence of carcinogenicity.
870.4300	Chronic/ Carcinogenicity (rat)	46695708 0, 20, 200, or 800 ppm M: 0, 0.04, 0.79, 8.3, 31.7 mg/kg/day	NOAEL=M: 0.04 mg/kg/day LOAEL =M: 0.79 mg/kg/day based on neovascularization and edema of the cornea and snow flake-like corneal opacity, unilateral or bilateral keratitis of the eye, decreased mean body weight and mean body-weight gain, increased total cholesterol, higher ketone levels and lower pH values, higher protein levels, increased kidney weight, kidney to body weight and kidney to brain weight ratios, chronic nephropathy and atrophy of the sciatic nerve. Evidence of carcinogenicity: There was a slight increase in neoplastic lesions; i.e., squamous cell carcinoma of the cornea in the 200 and 800 ppm groups (7% and 3%, respectively), when compared to controls (0%). This change was considered to be a result of the keratitis of the eye.

870.5100	In vitro Bacterial	46695709	There was no evidence of induced mutant colonies
	Gene Mutation	0, 50, 150, 500, 1500 and 5000 ug/plate	over background.
870.5300	In vitro Gene mutation in Chinese Hamster V79	46695713 0, 250, 500, 1000, 1400, 1500, 1600 ug/mL	There was no evidence of induced mutant colonies over background.
870.5375	In vitro Mammalian Cytogenetics chromosomal aberration assay Human Lymphocytes	46695717 0, 0.08, 0.16, 0.31, 0.63, 1.25, 2.5, 5, 10 mM	Equivocal because structural aberrations and polyploidy observed in the absence of excessive cytotoxicity at 3306 ug/mL with metabolic activation was not reproduced.
870.5395	In Vivo Mammalian Cytogenetics - Erythrocyte Micronucleus assay in mice	46695721 500, 1000 and 2000 mg/kg	There was no increase in the frequency of micronucleated immature erythrocytes in mouse bone marrow.
870.5550	Other Effects: Unscheduled DNA Synthesis in primary rat hepatocytes/mammal ian cell cultures	46695722 0, 1000 and 2000 mg/kg	There was no increase in the frequency of micronucleated immature erythrocytes in mouse bone marrow.
870.6200a	Acute neurotoxicity screening battery	46695723 0, 200, 500, 2000 mg/kg	NOAEL was not established in males LOAEL=M: 200 mg/kg based on decreased arousal (sluggish with some exploratory movement) in the open field on day 0 NOAEL= F: 200 mg/kg LOAEL= F: 500 mg/kg based on urine staining, red nasal discharge, decreased body temperature on day 0, decreased motor and locomotor activity on day 0.
870.6200b	Subchronic neurotoxicity screening battery (rat)	46695724 0, 20, 250, 2500 ppm M: 0, 1.33, 16.4, 160 mg/kg/day F: 0, 1.75, 21.0, 224 mg/kg/day	NOAEL= M/F: 16.4/21.0 mg/kg/day LOAEL= M/F: 160/224 mg/kg/day based on decreased body weight and body-weight gain in both sexes.
870.6300	Developmental neurotoxicity (rat)	46695725 0, 10, 200, or 1500 ppm 0, 0.8, 16.3, and 118 mg/kg/day	Maternal NOAEL= 0.8 mg/kg/day Maternal LOAEL=16.3 mg/kg/day based on corneal opacity during lactation. Offspring NOAEL was not established. Offspring LOAEL= 0.8 mg/kg/day based on decreased post-weaning body weight (males), decreased acoustic startle response on PND 60 (males), and brain morphometric changes on PND 75 (males and females).
870.7485	Metabolism and pharmacokinetics (rat)	46695726 5 and 1000 mg/kg	Tembotrione was rapidly absorbed, extensively metabolized, and excreted. Total excretion of tembotrione was 96.3-102.7% by 24 hours regardless of dose level or position of radiolabel. Sex differences were observed in the routes of excretion. The primary routes of elimination were the urine in

			females and the urine and feces in males. Males excreted up to 24.4% and 70.4% and females up to 79.1% and 20% of the administered dose in the urine and feces, respectively, at the low dose. Females excreted up to 63.7% and 28.5% and males up to 44.2 % and 49.1% of the dose in the urine and feces, respectively, at the high dose. The highest mean levels of radioactivity were extracted from the liver (1.7-3.5%) and kidneys (0.14-0.26%) at the low dose. At the high dose, the mean levels of radioactivity were extracted from the skin/fur (0.22-0.33%) and carcass. The highest concentrations of radioactivity were found in the skin followed by the liver, kidneys, stomach (and contents) and carcass. There was no evidence of bioaccumulation. The parent molecule and 11 metabolites were identified & isolated. Metabolic profiles were qualitatively similar for both radiolabeled forms; however, profiles for the high and low doses were not the same and differences were noted between sexes. Females excreted the greatest quantity of the parent molecule in urine (44.1-59.4%). While low and high dose males eliminated 1.9-3.0% and 33.8%, respectively, in the urine. The metabolites found in the greatest quantities were 4-hydroxy tembotrione and 5- hydroxytembotrione. Other identified metabolites found at <5% were the 4,5- dihydroxy, benzylic alcohol, dihydroxy-bezophenone, 4-hydroxy-benzylic alcohol, and ketohydroxy- hexanoic acid ([cyclohexyl-UL-14C] only). Males excreted greater quantities of both metabolites than females; except, at the high dose where 4-hydroxy tembotrione was eliminated in approximately equal amounts in both sexes. The primary step in the metabolism of tembotrione is the hydroxylation
870.7600	Dormal population	46695730	(oxidative pathway) of the cyclohexyl ring of the molecule.
870.7000	Dermal penetration (rat)	40095730 6.6, 66, 660 ug/cm2	Dermal absorption is 15%
	Effects on blood coagulation parameters with and without vitamin K1	46695731 1000 mg/kg 1000 mg/kg and 10 mg/kg vitamin K1	Alterations in clotting parameters were mediated by effects on vitamin K1 clotting factors.
	Effect on blood tyrosine levels in pregnant rabbits	46695732 0, 10 mg/kg/day	Blood tyrosine levels in treated animals were significantly elevated relative to controls for all intervals measured during treatment.
	Inhibition of 4- Hydroxyphenylpyruv ate Dioxygenase in Rats and In Vitro	46695733 and 46695734 In vivo: 0, 10 mg/kg In vitro: 0, 30, 60, 120 uM	In vivo: AE0172747 increased plasma tyrosine levels by 20-fold, AE1417286 increased plasma tyrosine levels by 5- fold, AE0456148 and AE1392936 did not affect plasma tyrosine levels relative to controls. In vitro: Rank of species by their ability to produce 4- HPLA after inhibition of HPPDase in (from most to least produced): mouse, human, rabbit, rat and dog.

9. FQPA Hazard Considerations:

- i. FQPA Safety Factor for Infants and Children. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:
- The toxicity database for tembotrione is adequate to assess chronic risk.
- Despite evidence of sensitivity in pre- and post-natal studies, the chronic RfD • based on an adult animal study (chronic rat study) is considered to be protective of the chronic offspring toxicity found in the rat DNT and 2-generation reproduction studies. The 2-generation reproduction study did not identify a NOAEL for the chronic effects seen on brain weight and preputial separation but a NOAEL can be characterized from the DNT, as discussed above, at 0.8 mg/kg/day. The NOAEL used to set the chronic RfD is 20-fold lower than this 0.8 mg/kg/day dose and is not based on an effect as to which the data have raised sensitivity concerns. Similarly, the chronic rat study and the NOAEL from that study are protective of the chronic effects seen in the DNT study and the other chronic effects found in the 2-generation reproduction study. The endpoints of concern for the chronic RfD are based on ocular toxicity, body weight decreases, kidney toxicity, and changes in the clinical chemistry parameters. Target organ toxicity such as ocular toxicity, kidney toxicity, body weight changes and nervous system effects were assessed in the young through pre- and post- natal exposure to tembotrione in the 2-generation reproduction study and the DNT study. In those studies, these effects were observed at higher doses in the young than in the adults in the chronic rat study Therefore, the chronic RfD is considered to be protective of effects in the young. As noted, the NOAEL (0.04 mg/kg/day) selected for the chronic RfD is 20-fold lower than the dose at which developmental and neurological effects were observed in any study; it is also 20fold lower than the NOAEL for other chronic effects seen in the young.
- There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100%CT and tolerance-level residues.

ii. FQPA Safety Factors for General Population. Given the data described above under the section for Prenatal and Postnatal Sensitivity, the only significant uncertainty concerns the acute RfD due to the failure to identify a NOAEL for the brain morphometric alterations found in the rat DNT. The LOAEL in the DNT is lower than the NOAEL and LOAEL from the rabbit and rat developmental studies, and thus is the lowest dose reflective of potential acute effects. Because of the uncertainty as to the NOAEL for the acute effects (brain morphometric alterations) seen at 0.8 mg/kg/day in the DNT, EPA has retained the additional 10X FQPA safety

factor in calculating the acute RfD. This is a conservative step given the equivocal nature of the brain morphometric alterations seen at the LOAEL in the DNT.

Summary of Toxic	Summary of Toxicological Doses and Endpoints for Tembotrione					
Exposure/ Scenario	Point of Departure	Uncertainty /FQPA SFs	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects		
Acute Dietary (General Population, including Infants and Children)	NOAEL<0. 8 mg/kg	$UF_{A} = 10X$ $UF_{H} = 10X$ $FQPA SF = 10X$ (includes $UF_{L} = 10X$)	Acute RfD = 0.0008 mg/kg aPAD = 0.0008 mg/kg	Developmental neurotoxicity Offspring NOAEL was not established. Offspring LOAEL = 0.8 mg/kg/day based on decreased acoustic startle response on PND 60 (males), and brain morphometric changes on PND 75 (males and females).		
Chronic Dietary (All Populations)	NOAEL=0. 04 mg/kg/day	$UF_{A} = 10X$ $UF_{H} = 10X$ $FQPA SF = 1X$	Chronic RfD = 0.0004 mg/kg/day cPAD = 0.0004 mg/kg/day	Chronic/Carcinogenicity LOAEL = 0.79 mg/kg/day based on neovascularization and edema of the cornea and snow flake-like corneal opacity, unilateral or bilateral keratitis of the eye, decreased mean body weight and mean body-weight gain, increased total cholesterol, higher ketone levels and lower pH values, higher protein levels, increased kidney weight, kidney to body weight and kidney to brain weight ratios, chronic nephropathy and atrophy of the sciatic nerve.		
Incidental Oral Short- and Intermediate-Term (1-30 days and 1-6 months)	NOAEL<0. 8 mg/kg	$UF_{A} = 10X$ $UF_{H} = 10X$ $FQPA SF = 10X$ (includes $UF_{L} = 10X$)	Residential LOC for MOE = 1000	Developmental neurotoxicity Offspring NOAEL was not established. Offspring LOAEL = 0.8 mg/kg/day based on decreased acoustic startle response on PND 60 (males), and brain morphometric changes on PND 75 (males and females).		
Dermal Short- and Intermediate-Term (1-30 days and 1-6 months)	NOAEL<0. 8 mg/kg	$UF_{A} = 10X$ $UF_{H} = 10X$ $FQPA SF = 10X$ (includes) $UF_{L} = 10X$ Dermal-absorption	Residential and Occupation al LOC for MOE = 1000	Developmental neurotoxicity Offspring NOAEL was not established. Offspring LOAEL = 0.8 mg/kg/day based on decreased acoustic startle response on PND 60 (males), and brain morphometric changes on PND 75 (males and females).		

10. Toxicological Endpoints: A summary of the toxicological endpoints are shown below:

Summary of Toxicological Doses and Endpoints for Tembotrione					
Exposure/ Scenario	Point of Departure	Uncertainty /FQPA SFs	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects	
		rate = 15%			
Dermal Long-Term (> 6 months)	NOAEL=0. 04 mg/kg/day	$UF_{A} = 10X$ $UF_{H} = 10X$ $FQPA SF = 1X$ $Dermal-absorption$ $rate = 15\%$	Residential and Occupation al LOC for MOE = 100	Chronic/Carcinogenicity LOAEL = 0.79 mg/kg/day based on neovascularization and edema of the cornea and snow flake-like corneal opacity, unilateral or bilateral keratitis of the eye, decreased mean body weight and mean body-weight gain, increased total cholesterol, higher ketone levels and lower pH values, higher protein levels, increased kidney weight, kidney to body weight and kidney to brain weight ratios, chronic nephropathy and atrophy of the sciatic nerve.	
Inhalation Short- and Intermediate-Term (1-30 days and 1-6 months)	NOAEL<0. 8 mg/kg	$UF_{A} = 10X$ $UF_{H} = 10X$ $FQPA SF = 10X$ (includes) $UF_{L} = 10X$ Inhalation- absorption rate = 100%	Residential and Occupation al LOC for MOE = 1000	Developmental neurotoxicity Offspring NOAEL was not established. Offspring LOAEL = 0.8 mg/kg/day based on decreased acoustic startle response on PND 60 (males), and brain morphometric changes on PND 75 (males and females).	
Inhalation Long-Term (> 6 months)	NOAEL=0. 04 mg/kg/day	$UF_{A} = 10X$ $UF_{H} = 10X$ $FQPA SF = 1X$ Inhalation- absorption rate=100%	Residential and Occupation al LOC for MOE = 100	Chronic/Carcinogenicity LOAEL = 0.79 mg/kg/day based on neovascularization and edema of the cornea and snow flake-like corneal opacity, unilateral or bilateral keratitis of the eye, decreased mean body weight and mean body-weight gain, increased total cholesterol, higher ketone levels and lower pH values, higher protein levels, increased kidney weight, kidney to body weight and kidney to brain weight ratios, chronic nephropathy and atrophy of the sciatic nerve.	
Cancer (oral, dermal, inhalation)	Classification: "Suggestive Evidence of Carcinogenic Potential" based on the observance of squamous cell carcinomas in a rat carcinogenicity study. Quantification of cancer risk is not required.				

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no-observed adverse-effect level. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. FQPA SF = FQPA Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose.

B. Dietary Exposure and Risk

- **1. Dietary Exposure from Food:** As to residues in food, EPA relied upon tolerance level residues and assumed 100% crop treated for all commodities for both acute and chronic exposures.
- 2. Dietary Exposure from Water: In both acute and chronic dietary assessments, drinking water was incorporated into the dietary assessment. For the acute dietary risk assessment, the entire distribution of estimated daily exposure values from the PRZM (Pesticide Root Zone Model)-EXAMS (Exposure Analysis Modeling System) was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the highest estimate of chronic surface water exposure (1.05 ppb) was used to assess the contribution to drinking water.
- **3.** Aggregate Exposure Risk Assessments: There are no uses of tembotrione that are expected to result in residential exposures. Therefore, the aggregate exposure assessment takes into consideration dietary food + water exposure only. The acute and chronic dietary estimates represent aggregate risk. The RfD will be protective of cancer effects (please refer to the section above for Carcinogenicity).
- **4.** Acute Aggregate Risk: The resulting acute dietary (food + water) risk estimates were 32% of the aPAD for the general U.S. population and 77% of the aPAD for all infants.
- 5. Chronic Aggregate Risk: The chronic dietary risk assessment shows that for all included commodities, the chronic dietary risk estimates are not of concern (i.e., <100% cPAD). For the U.S. population the exposure for food and water utilized 22% of the cPAD. The chronic dietary risk estimate for the highest reported exposed population subgroup, children 3-5 years old, is 48% of the cPAD.</p>
- 6. Cancer Aggregate Risk: Tembotrione is classified as "Suggestive Evidence of Carcinogencity". However, for the reasons stated above in the Section for Carcinogencity, it was determined that separate quantifications of cancer risks are not required, and the chronic Rfd will be protective of cancer and non-cancer effects.

A summary of the dietary exposure risks for tembotrione are shown in the table below:

Summary of Dietary (Food and Drinking Water) Exposure Risk for Tembotrione.						
Population Subgroup	Acute Dietary (95 th Percentile)	Chronic Dietary				

	Exposure % aPAD Expo		Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.000255	32	0.000090	22
All Infants (<1 year old)	0.000618	77	0.000159	40
Children 1-2 years old	0.000445	56	0.000172	43
Children 3-5 years old	0.000444	55	0.000192	48
Children 6-12 years old	0.000335	42	0.000141	35
Youth 13-19 years old	0.000261	33	0.000104	26
Adults 20-49 years old	0.000192	24	0.000075	19
Adults 50+ years old	0.000147	18	0.000056	14
Females 13-49 years old	0.000197	25	0.000075	19

Cumulative Risk: Tembotrione, belongs to a class of herbicides (including mesotrione, pyrasulfotole, isoxaflutole and topramezone) that inhibit the liver enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD). As discussed above, EPA has concluded that the ocular effects caused by these herbicides has limited relevance to humans. Nonetheless, as a worst case scenario, EPA has assessed aggregate exposure to tembotrione based on ocular effects in rats. For similar reasons, a semiquantitative screening cumulative assessment was conducted using the rat ocular effects and 100% crop treated information. The results of this screening analysis did not indicate a concern. In the future, assessments of HPPD-inhibiting herbicides will consider more appropriate models and cross species extrapolation methods.

C. Handler and Worker Risk Assessments

1. Occupational Exposure/Risk to Mixer/Loader and Applicators: Tembotrione is applied by ground equipment only (aerial application is prohibited on the label). The most highly exposed occupational pesticide handlers are likely to be: 1) Mixer/loader

using open-pour loading of liquids for groundboom applications 2) Applicators using open-cab groundboom sprayer. Most exposure durations will be short-term (1-30 days). It is possible for commercial applicators to be exposed to intermediate-term exposure durations (1-6 months). In addition, the short- and intermediate-term toxicological endpoints are the same; therefore, the estimates of risk for short-term duration exposures are protective of those for intermediate-term duration exposures. Long-term exposures are not expected; therefore, a long-term assessment was not conducted. The estimates of exposure to pesticide handlers are based upon surrogate study data available in the PHED (Ver 1.1, 1998) Surrogate Exposure Guide (August 1998). The proposed product label directs applicators and other handlers to wear a long-sleeved shirt and long pants; socks, shoes and chemical-resistant gloves. There are no risks of concern associated with the groundboom applicator scenario at baseline. However, risks of concern (i.e., MOEs <1000) are associated with the mixer/loader scenarios at baseline with the use of gloves, as directed by the proposed label. If an extra layer of clothing is worn (i.e., a double layer), then the MOE is 910; and, if a closed mixing/loading system is utilized (i.e., engineering control), then the MOE is 1,400. EPA has determined that, after noting the highly conservative nature of the exposure assumptions, a double layer of clothing would be protective for workers, and the requirement of engineering controls is unwarranted. Therefore, a double layer of clothing (i.e., coverall) will be required on the labeling under the personal protective equipment (PPE) requirements for handlers. A summary of the occupational exposures and risks to mixers/loaders and applicators are discussed in the table below:

Tembotrione	Tembotrione Occupational Dermal and Inhalation Exposures and Risks.						
Exposure Scenario	Crop or Target	App Rate (lb ai/acre) a	Area Trea ted Dail y (acre s) ^b	Unit Exposures Dermal and Inhalation (mg/lb ai)	Doses (mg/kg/day) ^c	Short-and Intermediate- term MOEs	Combined MOEs ^d
	Mixer/Loader						
Mixing/ Loading Liquids Concentrates for Groundboom Applications (open pour)	Field and silage corn, seed corn, sweet corn, popcorn	0.082	200	$\begin{tabular}{c} \hline \underline{Dermal} \\ Baseline^e: \\ 2.9 \\ PPE - SL \\ w/gloves^g: \\ 0.023 \\ PPE - DL \\ w/gloves^h: \\ 0.017 \\ Engineering \\ control^i: \\ 0.0086 \\ \end{tabular}$	Dermal Baseline: 0.1 PPE – SL w/gloves: 0.00081 PPE – DL w/gloves: 0.0006 Engineering control: 0.0003	Dermal Baseline: 7.8 PPE – SL w/gloves: 990 PPE – DL w/gloves: 1,300 Engineering control: 2,600	Baseline Dermal and Inhalation: 7.8 PPE – SL w/gloves + Baseline Inhalation: 730 PPE – DL w/gloves + Baseline Inhalation: 910

Tembotrione Occupational Dermal and Inhalation Exposures and Risks.							
Exposure Scenario	Crop or Target	App Rate (lb ai/acre) a	Area Trea ted Dail y (acre s) ^b	Unit Exposures Dermal and Inhalation (mg/lb ai)	Doses (mg/kg/day) ^c	Short-and Intermediate- term MOEs	Combined MOEs ^d
				<u>Inhalation</u> Baseline ^f : 0.0012	<u>Inhalation</u> Baseline: 0.00028	Inhalation Baseline: 2,800	Engineering control + Baseline Inhalation: 1,400
				Applicator			
Applying Sprays via Ground-boom	Field and silage corn, seed corn,	0.082	200	Dermal Baseline: 0.014 Inhalation	Dermal Baseline: 0.00049 Inhalation	Dermal Baseline: 1,600 Inhalation	Baseline Dermal + Inhalation:
Equipment (open cab)	sweet corn, popcorn		1	Baseline: 0.00074	Baseline: 0.00017	Baseline: 4,600	1,200

a. Application rate = maximum application rate from label (0.082 lb ai/acre).

b. Amount handled per day values are HED estimates of acres treated per day based on Exposure SAC SOP #9 "Standard Values for Daily Acres Treated in Agriculture," industry sources, and HED estimates.

c. Dose (mg/kg/day) = Unit exposure(mg/lb ai) x App Rate (lb ai/acre) x Area Treated (acres/day) x %Absorption

(15% dermal and 100% inhalation) / Body weight (70 kg).

d. Combined MOE = NOAEL or LOAEL (mg/kg/day) / (Dermal + Inhalation Dose (mg/kg/day))

e. Baseline Dermal: Long-sleeve shirt, long pants, and no gloves.

f. Baseline Inhalation: no respirator.

g. PPE - SL w/ gloves: Single layer plus chemical-resistant gloves.

h. PPE – DL w/gloves: Double layer plus chemical-resistant gloves.

i. Engineering control: closed mixing/loading system

2. Postapplication Handler Risk Assessment: Postapplication exposure will occur since tembotrione is applied as a foliar spray. There is a potential for agricultural workers to have post-application exposure to pesticides during the course of typical agricultural activities in corn. Short-term exposures are expected for hand-weeding, scouting, and irrigation activities. Risks are not of concern (i.e., MOEs >1000) on day 0 (REI = 12 hours) only for hand-weeding activities. Scouting activities have a risk of concern, with an MOE of 630 on the day of application. Chemical-specific dislodgeable foliar data would be needed to further refine these estimates. Currently, the label requires a 12-hour REI. If a 5-day REI is observed for scouting activities, the MOE's are greater than 1000 and are no longer of concern. Therefore, a 5-day REI will be required on the labeling for scouting activities. A summary of the occupational postapplication risks are discussed in the table below:

Summary of Occupational Postapplication Risks for Tembotrione.				
Crop Grouping (11	Application rate	n TC (cm ² /hr)	Restricted Entry Interval	MOE
	(lb ai/acre)		LOC = 1000	

Summary of Occupational Postapplication Risks for Tembotrione.				
Crop Grouping	Application rate	TC (cm^2/hr)	Restricted Entry Interval	MOE
	(lb ai/acre)		LOC = 1000	
Corn	0.082	100 (Hand Weeding)	12 Hours	2500
Com		400 (Scouting)	5 Days	>1000

3. Residential Exposure: Currently there are no proposed residential uses for tembotrione.

V. ENVIRONMENTAL RISK ASSESSMENT

- A. Environmental Fate Characterization: Tembotrione is not persistent in the environment except when present in loamy sands, degrading primarily through biodegradation in soil and water. Tembotrione appears to be stable to hydrolysis at environmental pH (pH range 5–9) but may be susceptible to photolysis in soil and water. Due to its vapor pressure and Henry's Law constant, volatilization from water and soil is not expected to be an important environmental fate process. Tembotrione has a high mobility in soil and the potential to leach into ground water. However, its relatively rapid rate of biodegradation may attenuate this process. To address concerns with the potential leaching of tembotrione that may result from the persistence and mobility described above, label language will be required in the form of surface water advisories that stress the potential of runoff after treatment, describe conditions that may promote leaching to groundwater, and suggest practices that may reduce contamination of water. This label language is described in more detail in Section IV of this memo.
- **B.** Potential Risks to Non-Target Plants: For the aquatic assessment, estimated environmental concentrations (EECs) in surface water were calculated using the Tier II PRZM/EXAMS models and employing maximum proposed application rates for tembotrione usage on corn crops. Eleven PRZM scenarios were used to simulate tembotrione use in different types of regions with various types of soil, weather patterns, and crop cultural practices (CA corn; FL sweet corn; IL corn; MS corn; NC (east) corn; ND corn; OH corn; OR sweet corn; PA corn; TX corn). LOCs were exceeded for listed aquatic non-vascular plants (RQ = 1-3.2 depending on scenario). LOCs were exceeded for non-listed (dicot RQ = 12.62) and listed terrestrial plants (dicot RQ = 27.33). LOCs were exceeded for non-listed (monocot RQ = 3.8; dicot RQ = 232.33) semi-aquatic plants. Terrestrial dicots are also at risk from drift (non-listed dicot RQ = 2.1; listed dicot RQ = 2.48). Mitigative language on the label reduces theses risks.

The Agency's strategy to mitigate these risks involves label language that is intended to keep the pesticide on the intended treatment area, and therefore reducing the potential for exposure to non-target plants. For example, spray drift management language will be required on the labeling, which advises users of applicator responsibilities and offers specific techniques to reduce the possibility of spray drift. In addition, the use of vegetative buffer strips is required in the surface water advisory language, which may further reduce possible exposure to non-target plants.

C. Potential Risks to Non-Target Animals: Acute LOCs were exceeded for non-listed and listed estuarine/marine invertebrates for the Florida corn scenario. There are no listed estuarine/marine species in Florida that could be impacted. Chronic LOCs were exceeded for non-listed and listed estuarine/marine invertebrates in the Florida, North Carolina, Mississippi, and Texas scenarios (there are no listed estuarine/marine species in these states). There is concern for chronic exposure only to non-listed invertebrates in coastal regions. LOCs were exceeded for chronic risk to mammals based on body weight gain and corneal opacity data. No adverse reproductive effects were observed. The level of severity for decrease in body weight gain and corneal opacity are low and occurred under continuous exposure, which is an unlikely scenario in the field due to the chemical's propensity to degrade quickly, the number of applications per season, and the proposed interval between applications. Therefore, tembotrione is not expected to result in direct effects to listed mammals. Because there are direct effects to plants, any listed species depending on these taxa may experience indirect effects.

Mitigating the risks to non-target animals involves label language that is intended to keep the pesticide on the intended treatment area (see Potential Risk to Non-Target Plants).

IV. REGULATORY DECISION

- **A. Conditional Registration:** A conditional registration is issued for tembotrione for use as a selective herbicide for control of specific weeds in corn.
 - 1. Conditional Data (Confirmatory)
 - 72-4(b) Life cycle of estuarine/marine invertebrates
 - Submission of an analytical reference standard for tembotrione and its metabolite M5 to the National Pesticide Standards Repository
 - Enforcement methods, LC/MS/MS Methods AE/03/01 for plant commodities and 00967 for livestock commodities must be revised to include a calculation for the conversion of residues of the metabolite(s) to parent equivalents for quantitation. Separate confirmatory methods for Method AE/03/01 will not be requested

provided that two ion transitions are monitored during MS/MS analysis for each analyte.

- 875.2100 Chemical-specific dislodgeable foliar residue data
- **2. Public Interest Finding:** A conditional registration under FIFRA Section 3(c)(7)(C) may be granted only if EPA determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

B. Tolerances

1. Tolerance Levels: The proposed uses and the submitted data support the following permanent tolerances for the combined residues of tembotrione and its metabolite M5 expressed as tembotrione equivalents, in/on the following corn commodities:

Corn, field, grain	0.03 ppm
Corn, field, forage	0.60 ppm
Corn, field, stover	0.45 ppm
Corn, sweet, kernel plus cob with husks removed	0.04 ppm
Corn, sweet, forage	1.0 ppm
Corn, sweet, stover	1.2 ppm
Corn, pop, grain	0.02 ppm
Corn, pop, stover	0.35 ppm

The proposed uses and the submitted data support the following tolerances for the combined residues of tembotrione and its metabolite M5, expressed as tembotrione equivalents in the following livestock commodities:

Cattle, liver	0.40 ppm
Cattle, meat byproducts, except liver	0.07 ppm
Goat, liver	0.40 ppm
Goat, meat byproducts, except liver	0.07 ppm
Horse, liver	0.40 ppm
Horse, meat byproducts, except liver	0.07 ppm
Sheep, liver	0.40 ppm
Sheep, meat byproducts, except liver	0.07 ppm
Poultry, liver	0.07 ppm

- **2. International MRLs:** There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) established for residues of tembotrione in crops or livestock commodities.
- **C. Required Label Statements:** End use products containing tembotrione as an active ingredient will be required to add the following protective language on the product

labeling:

- **1.** Add coveralls to the PPE requirements for handlers.
- **2.** Change the REI to 13 days.
- **3.** Environmental Hazards: "Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinseate."
- 4. Ground Water Advisory: "Tembotrione is known to leach through soil into ground water under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination."
- **5.** Surface Water Advisory: "This product may contaminate water through drift of spray in wind. This product has a high potential for runoff after application. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product. A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours. Sound erosion control practices will reduce this product's contribution to surface water contamination."

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DISCLAIMER: The information presented in this Pesticide Fact Sheet is for informational purposes only and may not be used to fulfill data requirements for pesticide registration and

reregistration.

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MRID	Citation Reference
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161-3 Pho	otodegradation-soil
MRID	Citation Reference
46695412	Hellpointner, E. (2004) (Phenyl-UL-(Carbon 14))AE 0172747: Phototransformation on Soil. Project Number: 200764, A7082101. Unpublished study prepared by Bayer Corp and Bayer Cropscience Gmbh and Agvise Inc. 82 p.
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162-2 An	aerobic soil metabolism
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100 I $100 I$ $100 I$ $100 I$ $100 I$ $100 I$	163-1	Leach/	adsorp	/desor	ption
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MRID	Citation Reference
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830.1550	Product Identity and composition
MRID	Citation Reference
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830.1600	Description of materials used to produce the product
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830.1650	Description of formulation process
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830.1670	Discussion of formation of impurities
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830.6303	Physical state
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830.6304	Odor
MRID	Citation Reference
46695402	Folsom, B. (2005) Product Chemistry of AE 0172747 Technical. Project Number: BR/2423, PA03/060, 20040750/03. Unpublished study prepared by Siemens Axiva GmbH & Co. KG. 266 p.
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830.6313 ions	Stability to sunlight, normal and elevated temperatures, metals, and metal
MRID	Citation Reference
MRID 46695402	Citation Reference Folsom, B. (2005) Product Chemistry of AE 0172747 Technical. Project Number: BR/2423, PA03/060, 20040750/03. Unpublished study prepared by Siemens Axiva GmbH & Co. KG. 266 p.
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830.6316	Explodability
MRID	Citation Reference
46695402	Folsom, B. (2005) Product Chemistry of AE 0172747 Technical. Project Number: BR/2423, PA03/060, 20040750/03. Unpublished study prepared by Siemens Axiva GmbH & Co. KG. 266 p.
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830.6317	Storage stability of product
MRID	Citation Reference
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830.6319	Miscibility
MRID	Citation Reference
47070309	Mitchell, H. (2007) Product Chemistry of SC 547 Herbicide. Project Number: BR/2553. Unpublished study prepared by Bayer Corp. 237 p.
830.6320	Corrosion characteristics
MRID	Citation Reference
46695403	Frank, J. (2005) Product Chemistry of AE 0172747 02 SC 52 A1. Project

	Number: BR2419, 201258, 201307. Unpublished study prepared by Bayer Corp. 50 p.
47070309	Mitchell, H. (2007) Product Chemistry of SC 547 Herbicide. Project Number: BR/2553. Unpublished study prepared by Bayer Corp. 237 p.
830.6321	Dielectric breakdown voltage
MRID	Citation Reference
47070309	Mitchell, H. (2007) Product Chemistry of SC 547 Herbicide. Project Number: BR/2553. Unpublished study prepared by Bayer Corp. 237 p.
830.7000	pH of water solutions or suspensions
MRID	Citation Reference
46695402	Folsom, B. (2005) Product Chemistry of AE 0172747 Technical. Project Number: BR/2423, PA03/060, 20040750/03. Unpublished study prepared by Siemens Axiva GmbH & Co. KG. 266 p.
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830.7100	Viscosity
MRID	Citation Reference
46695403	Frank, J. (2005) Product Chemistry of AE 0172747 02 SC 52 A1. Project Number: BR2419, 201258, 201307. Unpublished study prepared by Bayer Corp. 50 p.
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830.7200	Melting point/melting range
MRID	Citation Reference
46695402	Folsom, B. (2005) Product Chemistry of AE 0172747 Technical. Project Number: BR/2423, PA03/060, 20040750/03. Unpublished study prepared by

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830.7840	Water solubility: Column elution method, shake flask method
MRID	Citation Reference
46695402	Folsom, B. (2005) Product Chemistry of AE 0172747 Technical. Project Number: BR/2423, PA03/060, 20040750/03. Unpublished study prepared by Siemens Axiva GmbH & Co. KG. 266 p.
835.1220	Sediment and soil absorption /desorption isotherm
MRID	Citation Reference
46695404	Mathew, A.; Desmarteau, D. (2003) Adsorption/Desorption of (Phenyl-UL- (Carbon 14))AE 0172747 in Six Soils and a Sediment. Project Number: 200375, A7182101. Unpublished study prepared by Bayer Corp. 102 p.
835.1230	Sediment and soil absorption/desorption for parent and degradates
MRID	Citation Reference
46695409	Mills, E. (2005) (Carbon 14)AE 1392936: Adsorption to and Desorption from Four Soils. Project Number: CX/04/044, MEAEX070. Unpublished study prepared by Battelle Agrifood, Ltd. 86 p.
835.2120	Hydrolysis of parent and degradates as a function of pH at 25 C
MRID	Citation Reference
46695410	Fliege, R. (2003) Abiotic Hydrolysis of (Carbon 14) - AE 0172747 in Buffered Aqueous Solutions at pH 4, pH 7, and pH 9. Project Number: CP/02/020, MEF/083/03. Unpublished study prepared by Bayer Cropscience Gmbh. 37 p.
835.2240	Direct photolysis rate of parent and degradates in water
000.2240	
MRID	Citation Reference

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835.2410	Photodegradation of parent and degradates in soil
MRID	Citation Reference
46695412	Hellpointner, E. (2004) (Phenyl-UL-(Carbon 14))AE 0172747: Phototransformation on Soil. Project Number: 200764, A7082101. Unpublished study prepared by Bayer Corp and Bayer Cropscience Gmbh and Agvise Inc. 82 p.
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835.4100	Aerobic soil metabolism
MRID	Citation Reference
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46695417	Roohi, A. (2005) (Carbon 14)-AE 0941989: Rate of Degradation in Three Soils at 20 Degrees Celcius. Project Number: CX/04/043. Unpublished study prepared by Battelle Agrifood, Ltd. 122 p.

46695418	Simmonds, M. (2005) (Carbon 14)-AE 1392936: Rate of Degradation in Three Soils at 20 Degrees Celcius. Project Number: CX/04/046 Unpublished study prepared by Battelle Agrifood, Ltd. 88 p.
835.4200	Anaerobic soil metabolism
MRID	Citation Reference
46695419	Desmarteau, D.; Mathew, A. (2005) (Cyclohexyl-UL-(Carbon 14))AE 0172747: Anaerobic Soil Metabolism. Project Number: A07042104. Unpublished study prepared by Bayer Corp. 71 p.
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46695428	Kley, C. (2005) Kinetic Evaluation of the Aerobic Aquatic Metabolism of AE 0172747 and its Metabolite in Water/Sediment Systems by Inverse Modelling Using TOXSWA, PEST and MatLab. Project Number: MEF/05/255, MEAEX096. Unpublished study prepared by Bayer Cropscience LP. 68 p.
835.4300	Aerobic aquatic metabolism
MRID	Citation Reference
46695421	Nicolaus, B. (2004) (Cyclohexyl-U-(Carbon 14))-and (Phenyl-U-(Carbon 14))- AE 0172747 Aerobic Aquatic Metabolism in a Fine Sediment System. Project Number: CB02/008, MEF/390/03. Unpublished study prepared by Bayer Cropscience Gmbh. 164 p.
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835.4400	Anaerobic aquatic metabolism
MRID	Citation Reference
46695423	Mathew, A.; Desmarteau, D. (2005) (Phenyl-UL-(Carbon 14))AE 0172747: Anaerobic Aquatic Metabolism. Project Number: A7042401, 201110. Unpublished study prepared by Bayer Corp. 69 p.
46695424	Desmarteau, D.; Mathew, A. (2005) (Cylohexyl-UL-(Carbon 14))AE 0172747: Anaerobic Aquatic Metabolism. Project Number: A7042402, 03MEAEY004. Unpublished study prepared by Bayer Corp. 71 p. - 41 -

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46695430	Sowig, P. (2002) Acute Toxicity to Daphnia magna (Waterflea) Under Static Testing Conditions AE 0172747; Substance, Technical. Project Number: CE02/023. Unpublished study prepared by Bayer Cropscience Gmbh. 30 p.
850.1025	Oyster acute toxicity test (shell deposition)
MRID	Citation Reference
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850.1035	Mysid acute toxicity test
MRID	Citation Reference
46695434	Lima, W. (2003) AE 0172747 - Acute Toxicity to Mysids (Americamysis bahia) Under Flow-Through Conditions. Project Number: 13798/6102, 35401. Unpublished study prepared by Springborn Smithers Laboratories. 52 p.
850.1075	Fish acute toxicity test, freshwater and marine
MRID	Citation Reference
46695435	Lima, W. (2003) AE 0172747 - Acute Toxicity to Sheepshead Minnow (Cyprinodon variegatus) Under Static-Renewal Conditions. Project Number: 13798/6109. Unpublished study prepared by Springborn Smithers Laboratories. 50 p.
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46695437	Dorgerloh, M. (2003) Acute Toxicity of AE 0172747 Technical Substance to Fish (Oncorhynchus mykiss) (Product code AE 0172747 00 1C97 0001). Project Number: DOM/23034, E/280/2423/1. Unpublished study prepared by Bayer Cropscience Gmbh. 35 p.
46695439	Nieden, D. (2005) Acute Toxicity of AE 0456148 to Fish (Oncorhynchus mykiss) Under Static Conditions (Product Code: AE 0456148 00 1B99 0002).

Project Number: EBAEP092, E/280/2958/4. Unpublished study prepared by Bayer Cropscience Gmbh. 45 p.

850.1300	Daphnid chronic toxicity test
MRID	Citation Reference
46695440	Dorgerloh, M. (2003) Influence of AE 0172747 (tech.) on Development and Reproductive Output of the Waterflea daphnia magna in a Static Renewal Laboratory Test System. Project Number: E/321/2371/9, DOM/23002. Unpublished study prepared by Microquim S.A. 53 p.
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850.1350	Mysid chronic toxicity test
MRID	Citation Reference
46695442	Lima, W. (2004) AE 0172747 - Life-Cycle Toxicity Test with Mysids (Americamysis bahia). Project Number: 13798/6160, EBAEX072. Unpublished study prepared by Springborn Smithers Laboratories. 83 p.
850.1400	Fish early-life stage toxicity test
MRID	Citation Reference
46695443	Dorgerloh, M. (2005) Early-Life Stage Toxicity of AE 0172747 Technical Substance to Fish (Pimephales promelas) (Product Code AE 0172747 00 1C94 0003). Project Number: DOM/22076, E/284/2349/2. Unpublished study prepared by Bayer Cropscience Gmbh. 60 p.
850.2100	Avian acute oral toxicity test
MRID	Citation Reference
46695501	Gallagher, S.; Grimes, J.; Beavers, J. (2002) An Acute Oral Toxicity Study with the Northern Bobwhite: AE 0172747; Subatance, Technical; Product Code: AE 0172747 00 1C97 0001. Project Number: 512/119, 35384. Unpublished study prepared by Wildlife International, Ltd. 46 p.
850.2200	Avian dietary toxicity test
MRID	Citation Reference - 43 -

46695502	Gallagher, S.; Grimes, J.; Beavers, J.; et. al. (2002) A Dietary LC50 Study with the Mallard: AE 0172747; Substance Technical; Product Code: AE 0172747 00 1C94 0002. Project Number: 149/183, 35391. Unpublished study prepared by Wildlife International, Ltd. 55 p.
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850.2300	Avian reproduction test
MRID	Citation Reference
46695504	Frey, L.; Martin, K.; Beavers, J.; et. al. (2004) AE 0172747; Substance Technical; Product Code: AE 0172747 00 1C94 0002: Final Report. Project Number: 149/193. Unpublished study prepared by Wildlife International, Ltd. 159 p.
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850.3020	Honey bee acute contact toxicity
MRID	Citation Reference
46695507	Waltersdorfer, A. (2002) Contact Toxicity (LD50) to Honey Bees (Apis mellifera L.): Substance Technical: AE 0172747 00 1C95 0001. Project Number: CW02/047, C/027324. Unpublished study prepared by Aventis Crop Science. 18 p.
46695508	Waltersdorfer, A. (2002) Oral Toxicity (LD50) to Honey Bees (Apis mellifera L.): Substance Technical: AE 0172747. Project Number: CW/02/013, C/027322. Unpublished study prepared by Aventis Crop Science. 18 p.

46695509	Waltersdorfer, A. (2005) Contact Toxicity to Honey Bees (Apis mellifera L.): AE 0172747. Project Number: CW05/019. Unpublished study prepared by Aventis Crop Science. 18 p.
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850.4225	Seedling emergence, Tier II
MRID	Citation Reference
46695511	Christ, M.; Lam, C. (2005) Tier II Seedling Emergence: Nontarget Plant Study Using AE 0172747 SC52. Project Number: A7451401. Unpublished study prepared by Bayer Corp. 70 p.
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MRID	Citation Reference
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MRID	Citation Reference
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860.1300	Nature of the residue - plants, livestock

MRID	Citation Reference
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46695530	Brueckner, H.; Haas, M. (2004) Metabolism of [phenyl-UL-(Carbon 14)]-AE 0172747 in Corn (Zea mays) after Treatment with an Application Rate of 100 g a.i./ha and 200 g a.i./ha in Presence of Safener (Inert Ingredient). Project Number: 36050, CM/01/014, MEF/220/03. Unpublished study prepared by Aventis Crop Science and Bayer Ag, Institute of Product Info. & Residue Anal. 229 p.
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860.1340	Residue analytical method

860.1340 Residue analytical method

MRID	Citation Reference
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860.1380	Storage stability data
MRID	Citation Reference
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860.1480

Meat/milk/poultry/eggs

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870.1100	Acute oral toxicity
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860.1900	Field accumulation in rotational crops
46695612	Rupprecht, J. (2005) The Accumulation of [U-(Carbon 14)-phenyl]-AE 0172747 in Confined Rotational Crops. Project Number: MEAEX007. Unpublished study prepared by Bayer Corp. 85 p.
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860.1850	Confined accumulation in rotational crops
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870.1200	Acute dermal toxicity
MRID	Citation Reference
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870.1300	Acute inhalation toxicity
MRID	Citation Reference
46695626	Wesson, C. (2003) AE 0172747 001C95 0002: Acute Inhalation Toxicity (Nose Only) Study in the Rat. Project Number: 17021005, 1702/005. Unpublished study prepared by Safepharm Laboratories, Ltd. 46 p.
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47070312	Durando, J. (2007) SP102000016695 (636+747+(Inert Ingredient) SC): Acute Inhalation Toxicity Study in Rats - Limit Test: (SC 547 Herbicide). Project Number: 21165, P330, M/284727/01/1. Unpublished study prepared by Product Safety Laboratories. 22 p.
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870.2400	Acute eye irritation
MRID	Citation Reference
46695628	Rees, P. (2003) Eye Irritation to the Rabbit: AE 0172747. Project Number: AES/115/023773, TOX/NG/35587. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 25 p.
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46695630	Schungel, M. (2005) AE 0456148: Acute Eye Irritation on Rabbits. Project Number: AT01860, T/8074430, T8074430. Unpublished study prepared by Bayer Ag Inst. of Toxicology. 20 p.

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870.2500	Acute dermal irritation
MRID	Citation Reference
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870.2600	Skin sensitization
MRID	Citation Reference
46695634	Coleman, D. (2003) Guinea-Pig Skin Sensitization Study (Magnussen & Kligman Method): AE 0172747. Project Number: AES/116/023862, TOX/NG/35589. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 30 p.
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MRID	Citation Reference - 54 -
870.3200	21/28-day dermal toxicity
46695643	Kennel, P. (2004) AE 0172747: 90-Day Toxicity Study in the Dog by Dietary Administration. Project Number: SA/02162. Unpublished study prepared by Bayer Cropscience. 389 p.
MRID	Citation Reference
870.3150	90-day oral toxicity in nonrodents
46695642	Eiben, R. (2005) AE 1417268: Study on Subchronic Toxicity in Rats (Administration in the Diet for 3 Months): Including Amendment 1. Project Number: AT02191, T9074684, 04/294/CK. Unpublished study prepared by Bayer Ag Inst. of Toxicology. 505 p.
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870.3700	Prenatal developmental toxicity study
MRID	Citation Reference
46695647	Wason, S. (2003) AE 0172747: Developmental Toxicity Study in the Rat by Gavage. Project Number: SA/02226. Unpublished study prepared by Bayer Cropscience. 203 p.
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MRID	Citation Reference
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MRID	Citation Reference
46695704	Kennel, P. (2005) AE 0172747: Chronic Toxicity Study in the Dog by Dietary Administration. Project Number: SA/03352. Unpublished study prepared by Bayer Cropscience. 613 p.
870.4200	Carcinogenicity
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MRID	Citation Reference
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MRID	Citation Reference
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MRID	Citation Reference
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870.6300	Developmental neurotoxicity study
MRID	Citation Reference
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870.7600 Dermal penetration

MRID	Citation Reference
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850.1790	Chironomid Sediment Toxicity Test
MRID	Citation Reference
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850.7100	Data reporting for environmental chemistry methods
MRID	Citation Reference
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