

United States
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
(7505P)



Pesticide Fact Sheet

Name of Chemical: Saflufenacil
Reason for Issuance: New Chemical
Tolerances Established
Date Issued: August 2009

I. DESCRIPTION OF CHEMICAL

Description of Chemical

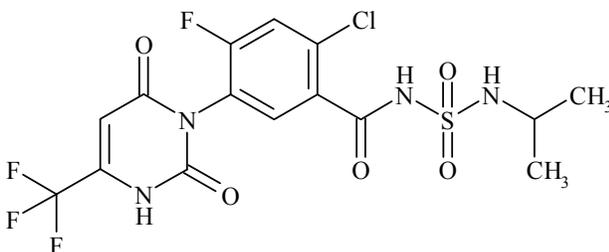
Generic Name: (N[']-[2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)benzyl]-N-isopropyl-N-methylsulfamide)

Common Names: Saflufenacil; Benzamide

Trade Names Used: Kixor® Herbicide

Chemical Class: LDPH, PPO inhibitor

Chemical Structure:



EPA Chemical Code: 118203

Chemical Abstracts
Service (CAS) Number: 372137-35-4

Registration Status: Conditionally registered

Pesticide Type: Herbicide

U.S. Producer: BASF Corporation
Agricultural Product Division
26 Davis Drive, P.O. Box 13528
Research Triangle Park, NC 27709

Tolerances Established

Tolerances were established in the 40 CFR §180.649 for the following commodities:

Table 1. Tolerance Summary for Saflufenacil.			
Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Correct Commodity Definition/Comments
Vegetable, legume, group 06	0.03	0.03	Vegetable, legume, group 6
Vegetable, foliage of legume, group 07	0.1	0.10	Vegetable, foliage of legume, group 7
Fruit, citrus, group 10	0.03	0.03	
Fruit, pome, group 11	0.03	0.03	
Fruit, stone, group 12	0.03	0.03	
Nut, tree, group 14	0.03	0.03	
Pistachio	-	0.03	Translated from tree nuts
Almond, hulls	0.2	0.10	
Grain, cereal, group 15	0.03	0.03	
Grain, cereal, forage, fodder and straw group 16	0.1	0.10	
Sorghum stover	0.1	-	Included in crop group 16
Cotton, undelinted seed	0.03	0.03	
Cotton, gin byproducts	0.03	0.10	
Sunflower, seed	0.7	1.0	
Grape	0.03	0.03	
Animal - Kidney	0.02	-	Individual tolerances required

Table 1. Tolerance Summary for Saflufenacil.			
Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Correct Commodity Definition/Comments
Animal - Liver	0.8	-	for each species
Milk	-	0.01	
Cattle, meat	-	0.01	
Cattle, fat	-	0.01	
Cattle, liver	-	0.80	
Cattle, meat byproducts, except liver	-	0.02	
Goat, meat	-	0.01	
Goat, fat	-	0.01	
Goat, liver	-	0.80	
Goat, meat byproducts, except liver	-	0.02	
Hog, meat	-	0.01	
Hog, fat	-	0.01	
Hog, liver	-	0.80	
Hog, meat byproducts, except liver	-	0.02	
Sheep, meat	-	0.01	
Sheep, fat	-	0.01	
Sheep, liver	-	0.80	
Sheep, meat byproducts, except liver	-	0.02	
Horse, meat	-	0.01	
Horse, fat	-	0.01	
Horse, liver	-	0.80	
Horse, meat byproducts, except liver	-	0.02	

II. USE PATTERNS AND FORMULATIONS

Application Sites: Saflufenacil is registered as a selective herbicide, developed for the control of broadleaf weeds by pre-plant and pre-emergence applications to cereal small grains, corn, chickpeas, cotton, edible beans, edible peas, lentils, lupine, sorghum, soybeans and sunflowers; post-emergence applications to fruit tree orchards, nut tree orchards, and vineyards; and fallow croplands and non-agricultural areas, including pine plantations, rights-of-way, and bare ground. Additionally, saflufenacil is used as a desiccant and/or defoliant on sunflowers.

Type of Formulations: Technical grade manufacturing use product (97.4% saflufenacil) and five end-use products:

Product name	% saflufenacil	Co-active ingredients	form	use
Optill™	17.8	Imazethapyr (50.2%)	Water-dispersible granule	Clearfield® corn Legumes
Treevix™	70.0	n/a	Water-dispersible granule	Fruit trees Nut trees Grape vines
Sharpen™	29.74	n/a	Suspension concentrate	Field and row crops
Integrity™	6.24	Dimethenamid (55.04%)	Emulsifiable concentrate	Field corn Popcorn Sweet corn Grain sorghum
BAS 800 02/03 H	12.27	n/a	Emulsifiable concentrate	Noncropland

Application Methods and Rates:

III. PHYSICAL AND CHEMICAL PROPERTIES

Description	Value
Melting point	189.9°C, with a peak maximum of 193.4°C. BAS 800 H (PAI) is also stable under nitrogen up to 220°C
pH @ 25 °C	4.426
Density @ 20 °C	1.595 g/cc (PAI)
Water solubility (g/100 mL) @ 20 °C	PAI: 0.0014 at pH 4 0.0025 at pH 5 0.21 at pH 7 Could not be determined at pH 9 due to degradation

Description	Value
Solvent solubility (g/100 mL at 20 °C)	TGAI/MUP 95.4%
Acetonitrile	19.4
Dichloromethane	24.4
N,N-DMF	55.4
Acetone	27.5
Ethyl acetate	6.55
THF	36.2
Butyrolactone	35.0
Methanol	2.98
Isopropyl alcohol	0.25
Toluene	0.23
Olive oil	0.01
1-octanol	<0.01
n-heptane	<0.005
Vapor pressure (Pa, 20 °C)	PAI 4.5 x 10 ⁻¹⁵
Dissociation constant (pK _a)	4.41 ± 0.025
Octanol/water partition coefficient	Kow 368.3 log Kow 2.6
UV/visible absorption spectrum (nm)	271.8 at pH 1.12 271.4 at pH 6.94 309.4 at pH 11.69
Henry's Law Constant	4.01 x 10 ⁻²⁰ atm/m ³ /mol

IV. HUMAN HEALTH RISK ASSESSMENT

A. Toxicity

- Acute Toxicity:** Saflufenacil has low acute toxicity via the oral, dermal and inhalation routes of exposure (Toxicity category III or IV). It is slightly irritating to the eye (Toxicity category III). It is neither a dermal irritant nor sensitizer. The acute toxicity findings are summarized below:

Guideline No.	Study Type	MRID(s)	Results	Toxicity Category	Purity
870.1100	Acute oral [rat]	47128101	LD50 was >2000 mg/kg bw	III	93.8%

870.1200	Acute dermal [rat]	47128102	LD ₅₀ >2000 mg/kg	III	93.8%
870.1300	Acute inhalation [rat]	47128103	LC ₅₀ >5.3 mg/L	IV	93.8%
870.2400	Acute eye irritation [White New Zealand rabbit]	47128105	minimal irritation	III	93.8%
870.2400	Acute eye irritation [White New Zealand rabbit]	47128104	minimal irritation	III	93.8%
870.2500	Acute dermal irritation [rabbit]	47128106	slightly irritating	IV	93.8%
870.2600	Skin sensitization [Guinea Pig]	47128107	not a sensitizer	N/A	93.8%

2. Subchronic/Chronic Toxicity: The primary target organ is the hematopoietic system. PPO inhibition in mammals may disrupt heme synthesis, which in turn causes anemia. In the submitted studies, decreased hematological parameters [decreased red blood cells (RBC), decreased hematocrit (Ht), decreased mean corpuscular hemoglobin concentration (MCHC), and mean corpuscular volume (MCV)] were observed at about the same dose level across species, with the exception of the dog, where effects were observed at a slightly higher dose. These effects occurred around the same dose level from short- through long-term exposures, without increasing in severity. Effects were also seen in the liver (increased weight, centrilobular fatty change, lymphoid infiltrate) in mice, the spleen (increased spleen weight and extramedullary hematopoiesis) in rats, and in both these organs (increased iron storage in the liver and extramedullary hematopoiesis in the spleen) in dogs. These effects also occurred around the same dose level from short- through long-term exposures, without increasing in severity. No dermal toxicity was seen at the limit dose in a 28-day dermal toxicity study in rats.

3. Carcinogenicity: Saflufenacil is classified as “Not Likely Carcinogenic to Humans”, based on no evidence of increased incidence of tumors at the tested doses in rats and mice. Saflufenacil is weakly clastogenic in the *in vitro* chromosomal aberration assay in V79 cells in the presence of S9 activation; however, the response was not evident in the absence of S9 activation.

4. Prenatal and Postnatal Sensitivity: There was evidence of increased susceptibility in rabbit and rat developmental toxicity studies and in the 2-generation reproduction study in the rat. Developmental effects such as decreased fetal body weights and increased skeletal variations occurred at doses that were not maternally toxic in the rat developmental study, indicating increased quantitative susceptibility. In rabbits, developmental effects, such as increased liver porphyrins were observed at doses that were not maternally toxic, indicating increased quantitative susceptibility. In the 2-generation reproduction study in rats, offspring effects such as increased number of stillborn pups, decreased viability and lactation indices, decreased pre-weaning body weight and/or body weight gain, and changes in hematological parameters were observed at a dose resulting in less severe maternal toxicity (decreased food intake,

body weight/weight gain and changes in hematological parameters and organ weights indicative of anemia), indicating increased qualitative susceptibility.

In the acute neurotoxicity study, a decrease in motor activity was observed on the first day of dosing at the limit dose in males only. The finding was not accompanied by any other neuropathological changes and was considered a reflection of a mild and transient general systemic toxicity and not a substance-specific neurotoxic effect. In the subchronic neurotoxicity study, systemic toxicity (anemia) was seen at 1000 (66.2 mg/kg/day) and 1350 (101 mg/kg/day) ppm in males and females, respectively. There was no evidence of neurotoxicity or neuropathology in either study due to treatment..

- 5. Metabolism:** Rat metabolism data indicate that saflufenacil is well absorbed and rapidly excreted. The maximum concentration of saflufenacil in blood and plasma was reached within 1 hour (h) of dosing and declined rapidly after 24 h. Excretion of orally dosed saflufenacil was essentially complete within 96 h, with the majority eliminated within the first 24 to 48 h. There was a sex-dependent difference in the excretion of orally administered saflufenacil. The main route of elimination in male rats was via the feces, while urinary excretion was the major route of elimination in females. The sex-dependent excretion was more pronounced at the low-dose level than at the high-dose level. Also, males had significantly higher biliary excretion of saflufenacil residues than females. Exhalation was not a relevant excretion pathway of saflufenacil. At 168 h after dosing, saflufenacil residues remaining in tissues were very low and occurred mainly in carcass, liver, skin, and gut contents.

The parent molecule and 3 major metabolites (M800H01, M800H03, and M800H07) were identified and isolated from urine and feces. Minor metabolites that were identified include M800H05, M800H16, M800H17, M800H18, M800M19, and M800M20. There were no significant gender differences in metabolic profiles. Saflufenacil was metabolized by three major transformation steps, which were demethylation of the uracil ring system, degradation of the *N*-methyl-*N*-isopropyl group to NH₂, and cleavage of the uracil ring, forming a sulfonamide group.

- 6. Mutagenicity:** Saflufenacil was neither mutagenic in bacterial cells nor clastogenic in rodents *in vivo*, and was considered not to pose a mutagenic concern.

- 9. Toxicology Profile:** The toxicological profile is discussed in the table below:

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.3100 28-Day Oral Toxicity feeding-mice	47128110 (2007) Acceptable/non-guideline 0, 50, 150, 450, 1350, or 4050 ppm	LOAEL = 36.6 mg/kg bw/day (males) based on increased alanine aminotransferase, aspartate aminotransferase, urea and total bilirubin, decreased hemoglobin and Ht and

	M\F: 0, 12.8/17.9, 36.6/63.4, 112/153.1, 335/446, 882/1630 mg/kg bw/day.	increased liver weight and centrilobular fatty change. NOAEL = 12.8 mg/kg bw/day. LOAEL = 153.1 mg/kg bw/day (females) based on moderate centrilobular fatty change in the liver. NOAEL = 63.4 mg/kg bw/day.
870.3100 28-Day Oral Toxicity feeding-rat	47128108 (2007) Acceptable/non-guideline 0, 50, 150, 450, 1350, or 4050 ppm M = 0, 4.5, 13.4, 39.2, 117, 357; F = 0, 5.0, 15.9, 43.6, 130.4, 376 mg/kg bw/day.	LOAEL = 39.2 mg/kg bw/day (males) based on decreased Hb, MCV, and MCH. NOAEL = 13.4 mg/kg bw/day. LOAEL = 130.4 mg/kg bw/day (females) based on decreased Hb, Ht, MCV, and MCH. NOAEL = 43.6 mg/kg bw/day.
870.3100 90-Day Oral Toxicity feeding-mice	47128111 (2007) Acceptable/guideline 0, 15 (males only), 50, 150, 450, and 1350 (females only) ppm M = 0, 3.6, 12.4, 36.7, 109.1; F = 0, 17.6, 51.8, 156.6, 471.2 mg/kg bw/day	LOAEL = 36.7mg/kg bw/day (males) based on multiple hematological changes, liver weight increases with centrilobular fatty change and lymphoid infiltrate in males. NOAEL = 12.4mg/kg bw/day. LOAEL = 156.6 mg/kg/day (females) based on increased liver weight with centrilobular fatty change and lymphoid infiltrate. NOAEL = 51.8 mg/kg/day.
870.3100 90-Day Oral Toxicity feeding-rat	47128109 (2007) Acceptable/guideline 0, 50, 150, 450 (males), 1350, or 4050 (females) ppm M = 0, 3.5, 10.5, 32.3, 94.7 F = 0, 4.3, 12.6, 110.5, 344.7 mg/kg bw/day.	LOAEL = 32.3 mg/kg bw/day (M) and 110.5 mg/kg bw/day (F) based on multiple hematological effects and increased spleen weight and extramedullary hematopoiesis. NOAEL = 10.5 (M), 12.6 mg/kg bw/day (F).
870.3150 28-Day Oral Toxicity feeding-dog	47128112 (2005) Acceptable/non-guideline 0, 30, 100, or 300 mg/kg bw/day.	LOAEL = 100 mg/kg bw/day based decreased mean corpuscular volume, MCH, and MCHC, bone marrow hyperplasia, increased iron storage in the liver and extramedullary hematopoiesis in the spleen. NOAEL = 30 mg/kg bw/day.
870.3150 90-Day Oral Toxicity feeding-dog	47128113 (2006) Acceptable/guideline 0, 10, 50, or 150 mg/kg bw/day	LOAEL = 50 mg/kg bw/day based on lower MCV and MCH values in both sexes. NOAEL = 10 mg/kg bw/day.
870.3200 21/28-Day dermal toxicity (rat)	47128114 (2006) Acceptable/guideline 0, 100, 300, or 1000 mg/kg	LOAEL was not established. NOAEL = 1000 mg/kg bw/day.
870.3700a Prenatal developmental in (rat)	47128115 (2007) Acceptable/guideline 0, 5, 20, or 60mg/kg/day	Maternal NOAEL = 20 mg/kg/day LOAEL = 60 mg/kg/day based on decrease hemoglobin and Ht, mean corpuscular volume and MCH.

		Developmental NOAEL = 5 mg/kg/day LOAEL = 20 mg/kg/day based on based on decreased fetal body weights and increase skeletal variations.
870.3700b Prenatal developmental in (rabbit)	47128116 (2006) Acceptable/guideline 0, 50, 200, or 600 mg/kg/day	Maternal NOAEL = 200 mg/kg bw/day LOAEL = 600 mg/kg bw/d based on mortality and increased necropsy findings. Developmental NOAEL = 50 mg/kg/day LOAEL = 200 mg/kg/day based on increased liver porphyrins.
870.3800 Reproduction and fertility effects (rat)	47128117 (2007) acceptable/guideline 0, 5, 15, or 50 mg/kg bw/day	Parental Systemic NOAEL = 15 mg/kg/day Parental Systemic LOAEL = 50 mg/kg/day based on decreased food intake, body weight, body weight gain and changes in hematological parameters and organ weights indicative of anemia. Reproduction NOAEL = M/F 50 mg/kg/day Reproduction LOAEL was not established. Offspring NOAEL = 15 mg/kg/day Offspring LOAEL = 50 mg/kg/day based on decreased number of live born pups, increased number of stillborn pups, decreased viability and lactation indices, decreased pre-weaning body weight and/or body weight gain and changes in hematological parameters.
870.4300b Chronic Toxicity (dog)	47128118 (2007) Acceptable/guideline 0, 5, 20, or 80 mg/kg bw/day	LOAEL = 80 mg/kg bw/day based on decreased albumin, MVH, and MCH. NOAEL = 20 mg/kg bw/day.
870.4300 Chronic/Carcinogenicity (rat)	47128120 (2007) Acceptable/guideline 0, 20, 100, 250 (males), 500 or 1000 (females) ppm M = 0, 0.9, 4.8, 12.0, 24.2 F = 0, 1.3, 6.2, 31.4, 63.0 mg/kg bw/day.	LOAEL = 31.4 mg/kg bw/day (females) based on decreased hemoglobin, Ht, MCV and MCH. NOAEL = 6.2 mg/kg bw/day (females). LOAEL was not established in males. NOAEL = 24.2 mg/kg bw/day. No evidence of carcinogenicity
870.4300 Chronic/Carcinogenicity (mouse)	47128119 (2007) Acceptable/guideline 0, 1 (males), 5, 25, 75, or 150 (females) ppm M = 0, 0.2, 0.9, 4.6, 13.8 F = 0, 1.2, 6.4, 18.9, 38.1 mg/kg bw/day. satellite groups: M = 0, 14.2	NOAEL = 4.6 mg/kg bw/day (males) and 18.9 mg/kg bw/day (females). LOAELs = 13.8 mg/kg bw/day (males) and 38.1 mg/kg bw/day (females) based on decreased red blood cells, hemoglobin, and Ht and porphyria observed in the satellite group. No evidence of carcinogenicity

	F = 0, 39.0 mg/kg bw/d	
Gene Mutation 870.5100 <i>In vitro</i> Bacterial Gene Mutation	47128121 (2005) Acceptable/guideline 0, 20, 100, 500, 2500, or 5000 µg/plate (saflufenacil hydrate)	There was no evidence of induced mutant colonies over background.
Gene Mutation 870.5100 <i>In vitro</i> Bacterial Gene Mutation	47128122 (2005) Acceptable/guideline 0, 20, 100, 500, 2500, or 5000 µg/plate (saflufenacil anhydrate)	There was no evidence of induced mutant colonies over background.
Gene Mutation 870.5300 <i>In vitro</i> Mammalian Cells Gene Mutation (Chinese Hamster Ovary Cells)	47128123 (2005) Acceptable/guideline 0, 312.5, 625, 1250, 2500, or 5000 µg/mL	There was no evidence of induced mutant colonies over background.
Cytogenetics 870.5375 <i>In vitro</i> Mammalian Cytogenetics chromosomal aberration assay-V79 cells	47128124 (2005) Acceptable/guideline 0, 5, 10, and 20 ug/ml without S9 activation 0, 10, 20, and 40 ug/ml with S9 activation	Saflufenacil was considered clastogenic in vitro in V79 cells in the presence of S9 metabolic activation. Saflufenacil was not clastogenic in the absence of metabolic activation.
Cytogenetics-other 870.5395 <i>In Vivo</i> Mammalian Cytogenetics - Erythrocyte Micronucleus assay in mice	47128125 (2005) Acceptable/guideline 0, 500, 1000, or 2000 mg/kg bw.	There was no increase in the frequency of micronucleated immature erythrocytes in mouse bone marrow.
870.5550 Other Genotoxicity- <i>In vivo</i> unscheduled DNA synthesis (rat)	47128126 (2005) Acceptable/guideline single oral dose of 1000, or 2000 mg/kg bw	Negative
870.6200a Acute neurotoxicity battery (rat)	47128127 (2007) Acceptable/Guideline 0, 125, 500, or 2000 mg/kg bw	Systemic LOAEL was 2000 mg/kg bw (males) based on the decreased motor activity representing mild and transient systemic toxicity. Systemic LOAEL was not established for females. Systemic NOAEL = 500 (M) and 2000 (F) mg/kg bw. There was no evidence of neurotoxicity.
870.6200b Subchronic neurotoxicity (rat)	47128128 (2007) Acceptable/Guideline 0, 50, 250, 1000 (males), or 1350 (females) ppm M = 0, 3.3, 16.6, 66.2 F = 0, 3.9, 19.4, 101.0 mg/kg bw/d.	Systemic NOAEL = 16.6 (males), 19.4 (females) mg/kg bw/day. Systemic LOAEL = 66.2 (males) and 101 (females) mg/kg bw/day based on decreased hemoglobin, Ht, mean corpuscular volume and MCH. There was no evidence of neurotoxicity.
870.7485 Metabolism and pharmacokinetics (rat)	47128130, 47128129 (2007) 4, 20, or 100 mg/kg bw (single oral dose) 5 or 100 mg/kg bw (single dose) 100 mg/kg for 14 days	Saflufenacil was rapidly absorbed, distributed, and excreted. Regardless of the dose administered, maximum concentration of saflufenacil in blood and plasma was reached within 1 h of dosing and declined rapidly after 24 h.

		<p>Excretion of orally dosed saflufenacil was essentially complete within 96 h; the majority was eliminated within the first 24 to 48 h. Demonstrating that the majority of the saflufenacil residues occurred in the plasma and was not bound to cellular elements of the blood. There was a sex-dependent difference in the excretion of orally administered saflufenacil. Following single low- and high-dose administration or a repeat high-dose administration, the main route of elimination in male rats was via the feces, while urinary excretion was the major route of elimination in females. There was significantly higher biliary excretion of saflufenacil residues in males than in females. Exhalation was not a relevant excretion pathway of saflufenacil. At 168 h after dosing, saflufenacil residues remaining in tissues were very low, and occurred mainly in carcass, liver, skin, and gut contents. Saflufenacil was metabolized by three major transformation steps: demethylation of the uracil ring system, degradation of the <i>N</i>-methyl-<i>N</i>-isopropyl group to NH₂, and cleavage of the uracil ring, forming a sulfonamide group. The predominant metabolites were M800H01, M800H03, M800H07 and the parent compound. Other minor metabolites were M800H05, M800H16, M800H17, M800H18, M800M19, and M800M20. There were no significant sex differences in metabolic profiles.</p>
870.7600 Dermal penetration (rat)	47128214 (2007) Acceptable/guideline 1.1723 mg/cm ² , 0,1172 mg/cm ² and 0.0117 mg/cm ² 11.723, 1.172 and 0.117 mg/rat	Dermal absorption is 3%.
Comparative Bioavailability/Toxicity Study (rat)	47128133 (2005) Acceptable/non-guideline 0 or 1350 ppm	The bioavailability and toxicity potential of the hydrated and anhydrated forms of saflufenacil were similar.
Mechanistic study – total porphyrin analysis in rat	47128132 (2006) Acceptable/non-guideline 0, 10, 50, or 1000 ppm (♂ = 0, 0.8, 4.1, 80.6; ♀ = 0, 0.9, 4.6, 89.5 mg/kg bw/day, respectively)	Total porphyrins in feces and liver provided the most reliable and sensitive data. Statistically significant effects on porphyrin metabolism could be detected at exposure concentrations well below those associated with adverse hematological effects. NOAEL= 4.1 mg/kg/day LOAEL = 80.6 mg/kg/day based on

		decreased hemoglobin, Ht, MCV, MCH, and MCHC.
Mechanistic study-porphyrin analysis supplementary (rat)	47128131 (2005) Acceptable/non-guideline 0, 1, 5, or 25 ppm (♂ = 0, 0.1, 0.4, 2.0; ♀ = 0, 0.1, 0.5, 2.3 mg/kg bw/day	Dietary administration of saflufenacil at 25 ppm caused an increase in porphyrin in feces of male (237%) and female (61%) rats, while saflufenacil at 5 ppm caused an increase in fecal porphyrin only in males. There were no effects on hematology parameters.

10. 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 toxicology database is adequate to assess the pre- and postnatal toxicity of saflufenacil. In accordance with Part 158 Toxicology Data requirements, an immunotoxicity study (870.7800) is required for saflufenacil. In the absence of specific immunotoxicity studies, EPA has evaluated the available saflufenacil toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. An increase in spleen weight, an organ of the immune system, was seen in rats in the 90-day oral toxicity study. This effect is attributable to an increased clearance of defective RBCs (i.e., defective hemoglobin synthesis) and is thus an indication of toxicity to the hematopoietic system rather than to the immune system. There were no other effects on immune system organs observed in toxicity studies with saflufenacil, and saflufenacil does not belong to a class of chemicals (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Based on these considerations, EPA does not believe that conducting immunotoxicity testing will result in a point of departure lower than those already selected for saflufenacil, and an additional database uncertainty factor is not needed to account for the lack of this study.
- There is no indication that saflufenacil is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- There is evidence of increased quantitative and qualitative susceptibility of offspring in the developmental and reproduction studies for saflufenacil; however, the degree of concern is low and the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of saflufenacil. The degree of concern is low and there are no residual uncertainties for the increased susceptibility since: 1) clear NOAELs/LOAELs were established for the developmental effects seen in rats and rabbits as well as for the offspring effects seen in the two-generation reproduction study; 2) dose-response relationships for the effects of concern are well characterized; 3) none of the effects in the developmental or reproduction

studies were attributable to a single exposure and, therefore, are not of concern for acute risk assessment; 4) the dose used to evaluate chronic dietary risks (4.6 mg/kg/day) is lower than the NOAELS for fetal/offspring effects in the developmental and reproduction studies (5 mg/kg/day in the rat developmental study, 50 mg/kg/day in the rabbit developmental study, and 15 mg/kg/day in the rat reproduction study) and is, therefore, protective of the developmental and offspring effects observed in these studies; and 5) residential exposures are not expected, since there are no residential uses proposed for saflufenacil.

- There are no residual uncertainties with respect to exposure data:
 - The dietary food exposure assessment utilizes proposed tolerance-level residues and 100% crop treated (CT) information for all proposed commodities. By using this screening-level assessment, the acute and chronic exposures/risks will not be underestimated.
 - The dietary drinking water assessment utilizes values generated by model and associated modeling parameters which are designed to provide conservative, health-protective, high-end estimates of water concentrations.
 - There are no registered or proposed uses of saflufenacil which would result in residential exposure.

b. FQPA Safety Factors for General Population - An UF of 100 was applied to acute and chronic RFD calculations to account for interspecies extrapolation (10X) and intraspecies variation (10X). The acute population-adjusted dose (aPAD) and chronic PAD (cPAD) are equal to the acute and chronic RFDs, respectively, divided by the FQPA SF (1X).

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

Table . Summary of Toxicological Doses and Endpoints for Saflufenacil for Use in Dietary Human-Health Risk Assessments.				
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) ¹	NOAEL = 500 mg/kg bw	UF _A = 10X UF _H = 10X FQPA SF = 1X	Acute RfD = 5.0 mg/kg aPAD = 5.0 mg/kg	Acute Neurotoxicity Study NOAEL = 500 (M) and 2000 (F) mg/kg bw. LOAEL was 2000 mg/kg bw (males) based on the decreased motor activity representing mild and transient systemic toxicity.

Table . Summary of Toxicological Doses and Endpoints for Saflufenacil for Use in Dietary Human-Health Risk Assessments.

				LOAEL was not established for females.
Chronic Dietary (All Populations) ²	NOAEL = 4.6 mg/kg/day	UF _A = 10X UF _H = 10X FQPA SF = 1X	Chronic RfD = 0.046 mg/kg/day cPAD = 0.046 mg/kg/day	Chronic/Carcinogenicity (mouse) NOAEL = 4.6 mg/kg bw/d (males) and 18.9 mg/kg bw/d (females). LOAELs = 13.8 mg/kg bw/d (males) and 38.1 mg/kg bw/day (females) based on decreased red blood cells, hemoglobin, and Ht and porphyria observed in the satellite group.
Cancer (oral, dermal, inhalation)	Classification: Not likely carcinogenic to humans based on the lack of tumors in the mouse and rat carcinogenicity studies and lack of mutagenicity.			

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). FQPA SF = FQPA Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose.

1 Not harmonized with Canada and Australia

2 Harmonized with Canada and Australia.

B. Dietary Exposure and Risk

- 1. Dietary Exposure and Risk 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 1-in-10-year peak ground water concentration generated by the Tier II PRZM (Pesticide Root Zone Model)-GW (ground water) model (180 ppb) was used to assess the contribution to drinking water. For the chronic dietary risk assessment, drinking water was incorporated directly into the dietary assessment using the 1-in-10-year annual mean ground water concentration generated by the Tier II PRZM (Pesticide Root Zone Model)-GW (ground water) model (173 ppb).
- 3. Aggregate Exposure Risk Assessments:** There are no uses of saflufenacil that are expected to result in residential exposures. Therefore, the aggregate exposure assessment takes into consideration dietary food + water exposure only. A cancer aggregate-risk assessment was not performed because saflufenacil is not a carcinogen and cancer risk is therefore not a concern.
- 4. Acute Aggregate Risk:** The resulting acute dietary (food + water) risk estimates were < 1% of the aPAD for the general U.S. population and <1% of the aPAD for the most highly exposed population subgroup, all infants (<1 year old).

- 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 8.8% of the cPAD. The chronic dietary risk estimate for the highest reported exposed population subgroup, all infants (<1 year old), is 28% of the cPAD.
- 6. Cancer Aggregate Risk:** Saflufenacil is classified as “not likely carcinogenic to humans.” Therefore, cancer risk is not a concern for this chemical.

Table 4. Summary of Dietary (Food and Drinking Water) Exposure Risk for Saflufenacil.

Population Subgroup	Acute Dietary (95 th Percentile)		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.010051	<1	0.004043	8.8
All Infants (<1 year old)	0.036991	<1	0.012951	28
Children 1-2 years old	0.016375	<1	0.006895	15
Children 3-5 years old	0.014835	<1	0.006176	13
Children 6-12 years old	0.010181	<1	0.004141	9.0
Youth 13-19 years old	0.008192	<1	0.003002	6.5
Adults 20-49 years old	0.009009	<1	0.003672	8.0
Adults 50+ years old	0.008151	<1	0.003821	8.3
Females 13-49 years old	0.009122	<1	0.003659	8.0

*The values for the highest exposed population for each type of risk assessment are bolded.

7. Cumulative Risk: Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to saflufenacil and any other substances, and saflufenacil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that saflufenacil has a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA’s website at

C. Handler and Worker Risk Assessments

- 1. Occupational Exposure/Risk to Mixer/Loader and Applicators:** Saflufenacil can be applied by aerial, chemigation, groundboom and rights-of-way equipment. In addition, applications can be made via dry bulk fertilizer. Based upon the proposed use pattern, EPA expects handler exposure and risk from open mixing/loading liquids and dry flowables for aerial, chemigation, groundboom, and rights-of-way applications; impregnating liquids onto dry bulk fertilizer in commercial and on-farm settings; applying sprays via aerial, groundboom, and rights-of-way applications; applying impregnated dry bulk fertilizer with commercial equipment or with grower-owned equipment; and open mixing/loading/applying via low-pressure handwand.

Handler exposure is expected to be short- or intermediate-term based on information provided on product labels. 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.

No chemical-specific data were available to assess potential exposure to pesticide handlers. The estimates of exposure to pesticide handlers are based upon surrogate study data available in the Pesticide Handler's Exposure Database (PHED) Surrogate Exposure Guide (August, 1998). The saflufenacil product labels direct applicators and other handlers to wear: long-sleeve shirt, long pants, chemical-resistant gloves, shoes plus socks and protective eyewear.. There are no data to assess impregnating liquids onto dry bulk fertilizer in commercial settings. The assumptions that the amount of saflufenacil handled per day in commercial settings (500–960 tons) make it unlikely that open mixing/loading is used. Therefore, as a reasonable surrogate for impregnation of dry bulk fertilizer in commercial settings, unit exposure values from PHED for engineering controls (closed mixing/loading) are used.

The Agency has determined that there are no risks of concern for occupational handlers associated with the use of saflufenacil, **provided workers wear protective gloves as recommended on the label.**

Table 5. Occupational Handler Dermal and Inhalation Exposures and Risks.					
Exposure Scenario	Application rate ^a (lb ai/acre)	Dermal and Inhalation Unit Exposures (mg/lb ai)	Area Treated Daily (acres) ^b	Combined Doses (mg/kg/day) ^c	Total MOE ^d

Table 5. Occupational Handler Dermal and Inhalation Exposures and Risks.					
Exposure Scenario	Application rate ^a (lb ai/acre)	Dermal and Inhalation Unit Exposures (mg/lb ai)	Area Treated Daily (acres) ^b	Combined Doses (mg/kg/day) ^c	Total MOE ^d
<i>Mixer/Loaders</i>					
Mixing/Loading Liquids for Aerial Applications (PHED)	0.35		1,200	Baseline Dermal + Baseline Inhalation: 0.6200 Single layer w/gloves dermal + Baseline Inhalation: 0.013	Baseline Dermal + Baseline Inhalation: 8.1 Single layer w/gloves dermal + Baseline Inhalation: 380
Mixing/Loading Liquids for Chemigation Applications (PHED)	0.111		350	Baseline Dermal + Baseline Inhalation: 0.0570 Single layer w/gloves dermal + Baseline Inhalation: 0.0012	Baseline Dermal + Baseline Inhalation: 88 Single layer w/gloves dermal + Baseline Inhalation: 4,200
Mixing/Loading Liquids for Groundboom Applications (PHED)	0.35		200	Baseline Dermal + Baseline Inhalation: 0.100 Single layer w/gloves dermal + Baseline Inhalation: 0.0022	Baseline Dermal + Baseline Inhalation: 49 Single layer w/gloves dermal + Baseline Inhalation: 2,300
Mixing/Loading Liquids to Support Rights of Way	0.35		80	Baseline Dermal + Baseline Inhalation: 0.041	Baseline Dermal + Baseline Inhalation: 120
Mixing/Loading Liquids for Commercial Impregnation of Dry Bulk Fertilizers (PHED eng control for M/L liquids)	1.34 lb ai/ton	<u>Dermal</u> Engineering control: 0.0086 <u>Inhalation</u> Engineering control: 0.000083	960 tons	Engineering control dermal + inhalation: 0.0073	Engineering control dermal + inhalation: 680
Mixing/Loading Liquids for Commercial Impregnation of Dry Bulk Fertilizers (PHED eng control for M/L liquids)	1.34 lb ai/ton	<u>Dermal</u> Engineering control: 0.0086 <u>Inhalation</u> Engineering control: 0.000083	500 tons	Engineering control dermal + inhalation: 0.0038	Engineering control dermal + inhalation: 1,300
Mixing/Loading Liquids for On-farm Impregnation of Dry Bulk Fertilizers (PHED M/L liquids)	0.134	<u>Dermal</u> Baseline: 2.9 (HC) ⁱ <u>Inhalation</u> Baseline: 0.0012 (HC)	160	Baseline Dermal + Baseline Inhalation: 0.032	Baseline Dermal + Baseline Inhalation: 160

Table 5. Occupational Handler Dermal and Inhalation Exposures and Risks.					
Exposure Scenario	Application rate ^a (lb ai/acre)	Dermal and Inhalation Unit Exposures (mg/lb ai)	Area Treated Daily (acres) ^b	Combined Doses (mg/kg/day) ^c	Total MOE ^d
Mixing/Loading Liquids for On-farm Impregnation of Dry Bulk Fertilizers (PHED M/L liquids)	0.134	<u>Dermal</u> Baseline: 2.9 (HC) ⁱ <u>Inhalation</u> Baseline: 0.0012 (HC)	80	Baseline Dermal + Baseline Inhalation: 0.016	Baseline Dermal + Baseline Inhalation: 320
Mixing/Loading Dry Flowables for Aerial Applications (PHED)	0.022	<u>Dermal</u> Baseline: 2.9 (HC) ⁱ <u>Inhalation</u> Baseline: 0.0012 (HC)	1,200	Baseline Dermal + Baseline Inhalation: 0.0012	Baseline Dermal + Baseline Inhalation: 4,100
Mixing/Loading Dry Flowables for Groundboom Applications (PHED)	0.044	<u>Dermal</u> Baseline: 2.9 (HC) ⁱ <u>Inhalation</u> Baseline: 0.0012 (HC)	80	Baseline Dermal + Baseline Inhalation: 0.0002	Baseline Dermal + Baseline Inhalation: 31,000
Applicators					
Applying Sprays via Aerial Equipment (PHED)	0.35	<u>Dermal</u> Eng control ^h : 0.005 (MC) <u>Inhalation</u> Eng control ^h : 0.000068 (MC)	1,200	Eng control Dermal + Inhalation: 0.0015	Eng control Dermal + Inhalation: 3,300
Applying Sprays via Groundboom Equipment (PHED)	0.35	<u>Dermal</u> Baseline: 0.014 (HC) <u>Inhalation</u> Baseline: 0.00074 (HC)	200	Baseline Dermal + Baseline Inhalation: 0.0014	Baseline Dermal + Baseline Inhalation: 3,700
Applying Sprays via Rights of Way Equipment (PHED)	0.35	<u>Dermal</u> Baseline: 1.3 (LC) <u>Inhalation</u> Baseline: 0.0039 (HC)	80	Baseline Dermal + Baseline Inhalation: 0.02	Baseline Dermal + Baseline Inhalation: 250
Commercial Application of Dry Bulk Fertilizers (PHED tractor-drawn granular spreader data)	0.134	<u>Dermal</u> Baseline: 0.0099 (LC) <u>Inhalation</u> Baseline: 0.0012 (LC)	320	Baseline Dermal + Baseline Inhalation: 0.0011	Baseline Dermal + Baseline Inhalation: 4,700
			160	Baseline Dermal + Baseline Inhalation: 0.0005	Baseline Dermal + Baseline Inhalation: 9,300
On-farm Applications of Dry Bulk Fertilizers (PHED tractor-drawn granular spreader data)	0.134	<u>Dermal</u> Baseline: 0.0099 (LC) <u>Inhalation</u> Baseline: 0.0012 (LC)	160	Baseline Dermal + Baseline Inhalation: 0.0005	Baseline Dermal + Baseline Inhalation: 9,300
			80	Baseline Dermal + Baseline Inhalation: 0.0003	Baseline Dermal + Baseline Inhalation: 19,000
Flaggers					

Table 5. Occupational Handler Dermal and Inhalation Exposures and Risks.					
Exposure Scenario	Application rate ^a (lb ai/acre)	Dermal and Inhalation Unit Exposures (mg/lb ai)	Area Treated Daily (acres) ^b	Combined Doses (mg/kg/day) ^c	Total MOE ^d
Flagging for Aerial Sprays Applications (PHED)	0.35	<u>Dermal</u> Baseline: 0.011 (HC) <u>Inhalation</u> Baseline: 0.00035 (HC)	350	Baseline Dermal + Baseline Inhalation: 0.0014	Baseline Dermal + Baseline Inhalation: 3,600
Mixer/Loader/Applicators					
Mixing/Loading/ Applying Liquids with Low Pressure Handwand (PHED)	0.35	<u>Dermal</u> Baseline: 100 (LC) <u>Inhalation</u> Baseline: 0.03 (MC)	2	Baseline Dermal + Baseline Inhalation: 0.0350	Baseline Dermal + Baseline Inhalation: 140

a. Application rates based on proposed uses on labels for saflufenacil. Units = lb ai/acre unless noted otherwise.

b. ExpoSAC Policy # 9.1.

c. Combined Dose (mg/kg/day) = Dermal + Inhalation doses. Dose = daily unit exposure (mg/lb ai) x application rate (lb ai/acre) x acres treated x absorption factor (dermal: 3%; inhalation: 100%) / body weight (60-kg adult female).

d. Total MOE = NOAEL (5 mg/kg/day) / Combined Dose (mg/kg/day).

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

f. Baseline Inhalation: no respirator.

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

h. Engineering control for applying sprays via aerial equipment: enclosed cockpit.

i. Data confidence: HC = high confidence; MC = medium confidence; LC = low confidence

2. Postapplication Handler Risk Assessment: Most of the proposed uses for saflufenacil are soil-directed preplant or preemergent uses where no crop foliage is present. The proposed labels indicate that crop injury will result if the products are applied postemergent (over the top) to any crop. Currently, HED has no transfer coefficients or other data to assess postapplication dermal exposures to soil by occupational workers. In general, such exposures are considered to be negligible. Therefore, for the proposed soil-directed uses, postapplication dermal exposures and risks to occupational workers were not assessed. For the use on sunflowers as a dessicant, postapplication exposure is expected to be minimal since harvesting of sunflowers is typically done by machine.

The proposed labels have 12- and 24-hour REIs. The technical material has a Toxicity Category III for acute oral, acute dermal, and acute eye irritation. It has a Toxicity Category IV for acute inhalation and acute dermal irritation. Per the Worker Protection Standard (WPS), a 12-hour REI is required for chemicals classified under Toxicity Categories III and IV. Technical-grade Imazethapyr and Dimethenamid, which are used in conjunction with saflufenacil in the Optill™ and Integrity™ formulations, respectively, also have REI's of 12 hours. Therefore, an REI of 12 hours is in compliance with the WPS for all products.

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

V. ENVIRONMENTAL RISK ASSESSMENT

- A. Environmental Fate Characterization:** Saflufenacil is nonvolatile, hydrophilic, and mobile to highly mobile in soil. The solubility of the compound is pH-dependent; at environmentally relevant pH values, saflufenacil is expected to be ionic. The compound dissipates in the environment through both abiotic and biotic degradation and by leaching. It is not expected to persist in aerobic soils (half-life 1 - 5 weeks) or alkaline water bodies (half-life < 1 week), but may be moderately persistent in acidic to neutral water bodies (half-life 4 – 10 weeks). Terrestrial field dissipation study results are relatively consistent with those of the laboratory studies, showing that the chemical dissipates by degradation and leaching, with dissipation half-lives ranging from 1 to 36 days.
- B. Ecological Effects Characterization:** Saflufenacil is classified as practically non-toxic to fish and freshwater invertebrates, and moderately toxic to estuarine/marine invertebrates on an acute exposure basis. No sublethal effects were observed in any of the acute aquatic animals studies for saflufenacil. Available acute toxicity data for the BAS 781 02H formulation (“Integrity” herbicide), which is a co-formulation with dimethenamid-p, show that it is 3 – 7 times more toxic than saflufenacil technical to freshwater fish, invertebrates, and aquatic vascular and non-vascular plants. Available data indicate that this increase in toxicity is due to the dimethenamid-p. Chronic exposure to saflufenacil resulted in a 5% reduction in embryo survival in fish and decreased parental survival (30% reduction) and growth (5% reduction) of invertebrates. Sediment toxicity testing indicates that the compound does not partition to sediment, but remains associated with the water column. Exposure of benthic invertebrates resulted in a 17% reduction in emergence rate. All available aquatic toxicity data show that the M07 and M08 degradates are less toxic to aquatic animals and plants than parent saflufenacil.

Saflufenacil is practically non-toxic to avian species on an acute oral and subacute dietary basis. The lowest NOAEC in an avian reproduction study (96 mg a.i./kg diet) was based on a reduction in bobwhite quail hatchling body weight. Saflufenacil is also practically non-toxic to mammals on an acute oral basis. A two-generation reproduction study in rats resulted in a NOAEL of 15 mg a.i./kg-bw/day based on increased pup mortality, reduced weight gain, and anemia. No sublethal effects were observed in any of the acute terrestrial animal studies; however it is important to note that sublethal effects, including anemia and hematologic effects, which are consistent with the light-dependent peroxidizing herbicide (LDPH) mode of action, were observed in the chronic mammalian study. Saflufenacil is classified as practically non-toxic to non-target terrestrial insects.

Results of Tier II terrestrial plant studies indicate that dicot plant species are more sensitive to saflufenacil than monocots, but both do exhibit adverse effects when

treated with saflufenacil formulations.

C. Exposure Modeling: 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 saflufenacil usage on non-crop areas. This was the only use pattern modeled, as it resulted in the highest estimated aquatic exposure of all proposed uses, and the resulting risk estimates were low, precluding the need for further modeling. The California rights-of-way scenario was used to model the non-agricultural use pattern because, based on a comparison of results, it was the most vulnerable of the nine available non-agricultural PRZM/EXAMS scenarios.

For the terrestrial animal assessment, the T-REX model was used to calculate dietary and dose-based EECs of saflufenacil residues on food items via broadcast spray applications for mammals and birds. The model simulates a 1-year time period for exposure to birds and mammals, using different feeding strategies and size classes. The non-agricultural areas maximum single-application rate (0.356 lb a.i./A) was used.

Exposure to terrestrial plants was estimated using the TerrPlant model, which estimates exposure to plants in areas near the application area. Exposure calculations are based on the amount of pesticide present in soil as a function of drift, and loading via drift to dry, non-target adjacent areas is assumed to occur from one acre of treatment to one acre of the non-target area. Spray drift is also considered as a source of loading to non-target areas.

D. Potential Risks to Non-Target Plants: LOCs were not exceeded for listed or non-listed aquatic plants. LOCs were exceeded for non-listed (dicot RQ = 1.52 to 40.9, depending on formulation; monocot 1.93 to 25.4, depending on formulation) and listed terrestrial plants (dicot RQ = 6.60 to 178, depending on formulation; monocot 73.3 to 1978, depending on formulation) in dry areas. LOCs were exceeded for non-listed (dicot RQ = 12.9 to 225, depending on formulation; monocot RQ = 8.01 to 140, depending on formulation) and listed (dicot RQ = 56.1 to 979 depending on formulation; monocot RQ = 623 to 10,878, depending on formulation) terrestrial plants in semi-aquatic areas. Terrestrial plants are also at risk from drift (non-listed dicot RQ = 2.20 to 178, depending on formulation; non-listed monocot RQ 1.61 to 12.7, depending on formulation; listed dicot RQ = 3.33 to 270, depending on formulation; listed monocot RQ 12.2 to 989 depending on formulation). Mitigative language on the label reduces these 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. Buffer zones are also required, and are dependent upon application method and rate. 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.

- D. Potential Risks to Non-Target Animals:** No acute LOCs were exceeded for terrestrial or aquatic animals. Chronic LOCs were exceeded for certain categories of non-listed and listed mammals for the non-agricultural use scenario, which uses the highest application rate (0.356 lb a.i./A) (RQs that exceed the LOC range from 1.13 to 2.47). The LOC exceedances were based on a reproductive NOAEL of 15 mg a.i./kg-bw/day; increased stillborn pups, increased pup mortality, reduced pup weight, and anemia were observed at the next highest treatment level. Chronic RQs associated with application rates ≤ 0.143 lb a.i./A are below the LOC. 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). The maximum allowable application rate (0.356) for non-crop areas was lowered to 0.143 lb ai/A for most use sites, and the maximum rate is now only for selective stem applications to wilding pine. This greatly reduces the exposure of nontarget mammals and plants, and brings the chronic RQs for mammals below the LOC for most non-crop uses.

VI. PROPOSED REGULATORY DECISION

- A. Conditional Registration:** A conditional registration is recommended for saflufenacil.

1. Conditional Data (Confirmatory)

- Fish early-life stage toxicity for LDPH chemicals; BASF is a member of the LDPH task force which is currently developing a protocol for this study, which will evaluate the potential effect of UV light on the toxicity of surrogate LDPH chemicals. Based on the results of this study, an appropriate toxicity adjustment factor will be derived and applied to risk assessments for LDPH chemicals. For the saflufenacil risk assessment, an adjustment factor of 29X was applied, based on data from a study on the LDPH oxyfluorfen. The resulting risk estimates were below the Agency's Level of Concern.
- Submission of an analytical reference standard for saflufenacil and its metabolites M800H11 and M800H35 to the National Pesticide Standards Repository [Note: This has been completed].
- 850.3020: Honeybee acute contact study using the BAS 781 02H formulation

(“Integrity” herbicide). [Note: This study has been submitted to the Agency and is currently under review (MRID #477962-01).]

- 860.1500: (Crop field trial on sunflower conducted with the SC formulation as bridging data for earlier field trials conducted with WG formulation.

2. Data Requirements for Future New Uses

- 850.2100: Avian acute oral toxicity using a passerine species. This is a new requirement under 40 CFR Part 158. Due to the low avian risk assessed for the currently proposed uses, this study is not required as a condition of this registration, but will be required for future uses of saflufenacil. A protocol for conducting the study should be approved by the Agency prior to study initiation.
- 870.7800: Immunotoxicity study. This is a new requirement under 40 CFR Part 158.

3. 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 saflufenacil, including its metabolites and degradates, in or on the commodities in the table below:

Table 6. Tolerance Summary for Saflufenacil.			
Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Correct Commodity Definition/Comments
Vegetable, legume, group 06	0.03	0.03	Vegetable, legume, group 6
Vegetable, foliage of legume, group 07	0.1	0.10	Vegetable, foliage of legume, group 7
Fruit, citrus, group 10	0.03	0.03	
Fruit, pome, group 11	0.03	0.03	
Fruit, stone, group 12	0.03	0.03	
Nut, tree, group 14	0.03	0.03	
Pistachio	-	0.03	Translated from tree nuts
Almond, hulls	0.2	0.10	

Table 6. Tolerance Summary for Saflufenacil.			
Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Correct Commodity Definition/Comments
Grain, cereal, group 15	0.03	0.03	
Grain, cereal, forage, fodder and straw group 16	0.1	0.10	
Sorghum stover	0.1	-	Included in crop group 16
Cotton, undelinted seed	0.03	0.03	
Cotton, gin byproducts	0.03	0.10	
Sunflower, seed	0.7	1.0	
Grape	0.03	0.03	
Animal - Kidney	0.02	-	Individual tolerances required for each species
Animal - Liver	0.8	-	
Milk	-	0.01	
Cattle, meat	-	0.01	
Cattle, fat	-	0.01	
Cattle, liver	-	0.80	
Cattle, meat byproducts, except liver	-	0.02	
Goat, meat	-	0.01	
Goat, fat	-	0.01	
Goat, liver	-	0.80	
Goat, meat byproducts, except liver	-	0.02	
Hog, meat	-	0.01	
Hog, fat	-	0.01	
Hog, liver	-	0.80	
Hog, meat byproducts, except liver	-	0.02	
Sheep, meat	-	0.01	
Sheep, fat	-	0.01	
Sheep, liver	-	0.80	
Sheep, meat byproducts, except liver	-	0.02	
Horse, meat	-	0.01	
Horse, fat	-	0.01	
Horse, liver	-	0.80	
Horse, meat byproducts,	-	0.02	

Table 6. Tolerance Summary for Saflufenacil.			
Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Correct Commodity Definition/Comments
except liver			

2. International MRLs: There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) established for residues of saflufenacil in crops or livestock commodities. The residue definition and proposed tolerances were harmonized with Canada and Australia.

C. REQUIRED LABEL STATEMENTS: End use products containing saflufenacil as an active ingredient will be required to have the following protective language on the product labeling:

1. Environmental Hazards:

- a. Ground Water Advisory: “This chemical has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow.”
- b. Surface Water Advisory: “This product may impact surface water due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. This product is classified as having high potential for reaching surface water via runoff for several weeks after application. 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 loading of this chemical from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall is forecast to occur within 48 hours.”

D. Contact Person at EPA

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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.

VII. BIBLIOGRAPHY

61-1 Chemical Identity

MRID	Citation Reference
47127802	Genari, G. (2007) Product Identity and Composition of BAS 800 H. Project Number: 2007/1022324. Unpublished study prepared by BASF Aktiengesellschaft. 194 p.

61-2 Description of Beginning Materials and Manufacturing Proces

MRID	Citation Reference
47127802	Genari, G. (2007) Product Identity and Composition of BAS 800 H. Project Number: 2007/1022324. Unpublished study prepared by BASF Aktiengesellschaft. 194 p.

62-1 Preliminary Analysis

MRID	Citation Reference
47127803	Genari, G. (2007) Preliminary Analysis of Five Batches BAS 800 H TGAI. Project Number: 2007/1022325, 132476/1. Unpublished study prepared by BASF Aktiengesellschaft. 40 p.
47127804	Dotzer, R. (2007) Identification of Active Substance BAS 800 H (Reg. No. 4054449) and Minor Components in Technical-Grade Material. Project Number: 2007/1057829. Unpublished study prepared by BASF Aktiengesellschaft. 24 p.

62-2 Certification of limits

MRID	Citation Reference
47127806	Brunt, S.; Genari, G. (2007) BAS 800 H Technical Grade Active Ingredient: Composition and Certified Limits. Project Number: 2007/7013642. Unpublished study prepared by BASF Corporation and BASF Aktiengesellschaft. 27 p.

62-3 Analytical Method

MRID	Citation Reference
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47128403	Walker, A. (2007) Validation of Analytical Method AFL 0747/01 for the Determination of BAS 800 H in BAS 800 04 H. Project Number: MX070191, 2007/1035712. Unpublished study prepared by Battelle UK Ltd. 29 p.
47128602	Polowy, K. (2007) GLP Validation of Analytical Method AFR0067/01 and Certification of BAS 804 00 H: Formulation Lot Number 1641-22: Final Report. Project Number: 2007/7012430, F200711. Unpublished study prepared by BASF Agro Research. 61 p.

63-2 Color

MRID	Citation Reference
47127812	Yacoub, R. (2007) BAS 800 H (MP): Determination of Oxidation/Reduction, Physical State, pH, Bulk Density, Explodability, and Odor: Amended Final Report. Project Number: 132485, 2007/7009479. Unpublished study prepared by BASF Corporation. 14 p.

47128404 Kroehl, T. (2007) Physical and Chemical Properties of BAS 800 04 H (BAS 800 H 342 g/L SC) - Accelerated Storage Stability up to 2 Weeks at 54 Degrees Celsius. Project Number: 313821/1, 2007/1039740. Unpublished study prepared by BASF Aktiengesellschaft, Ecology and Environmental Analytics. 19 p.

63-3 Physical State

MRID	Citation Reference
47127812	Yacoub, R. (2007) BAS 800 H (MP): Determination of Oxidation/Reduction, Physical State, pH, Bulk Density, Explodability, and Odor: Amended Final Report. Project Number: 132485, 2007/7009479. Unpublished study prepared by BASF Corporation. 14 p.
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63-4 Odor

MRID	Citation Reference
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63-7 Density

MRID	Citation Reference
47127812	Yacoub, R. (2007) BAS 800 H (MP): Determination of Oxidation/Reduction, Physical State, pH, Bulk Density, Explodability, and Odor: Amended Final Report. Project Number: 132485, 2007/7009479. Unpublished study prepared by BASF Corporation. 14 p.
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63-9 Vapor Pressure

MRID	Citation Reference
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63-12 pH

MRID	Citation Reference
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63-14 Oxidizing/Reducing Action

MRID	Citation Reference
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63-15 Flammability

MRID	Citation Reference
47128404	Kroehl, T. (2007) Physical and Chemical Properties of BAS 800 04 H (BAS 800 H 342 g/L SC) - Accelerated Storage Stability up to 2 Weeks at 54 Degrees Celsius. Project Number: 313821/1, 2007/1039740. Unpublished study prepared by BASF Aktiengesellschaft, Ecology and Environmental Analytics. 19 p.

63-16 Explodability

MRID	Citation Reference
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63-18 Viscosity

MRID	Citation Reference
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71-1 Avian Single Dose Oral Toxicity

MRID	Citation Reference
47127911	Zok, S. (2006) BAS 800 H - Acute Toxicity in the Bobwhite Quail (<i>Colinus virginianus</i>) After Single Oral Administration (LD50). Project Number: 11W0414/015141, 2005/1029868. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxicologie. 52 p.
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47127929	Holmes, C.; Jackson, S. (2008) BAS 800 H: Screening Level Ecological Risk Assessment for Wildlife, Aquatic Organisms, Nontarget Aquatic Plants, and

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MRID	Citation Reference
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71-4 Avian Reproduction

MRID	Citation Reference
47127915	Zok, R. (2006) BAS 800 H - 1-Generation Reproduction Study on the Bobwhite Quail (<i>Colinus virginianus</i>) by Administration in the Diet. Project Number: 71W0414/015148, 2006/1035447. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxicologie. 349 p.
47127916	Zok, R. (2006) BAS 800 H - 1-Generation Reproduction Study on the Mallard Duck (<i>Anas platyrhynchos</i>) by Administration in the Diet. Project Number: 72W0414/015149, 2006/1035448. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxicologie. 343 p.
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72-1 Acute Toxicity to Freshwater Fish

MRID	Citation Reference
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- 47127904 Jatzek, R. (2005) Acute Toxicity Study on the Rainbow Trout (*Oncorhynchus mykiss*) in a Static System over 96 hours. Project Number: 12F0414/015146, 2005/1029784. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxicologie. 40 p.
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72-2 Acute Toxicity to Freshwater Invertebrates

MRID	Citation Reference
47127901	Bergtold, M.; Janson, G. (2006) Acute Toxicity of BAS 800 H to <i>Daphnia magna</i> Straus in a 48 Hour Static Test: Final Report. Project Number: 132860, 2006/1004506. Unpublished study prepared by BASF Aktiengesellschaft. 20 p.

72-3 Acute Toxicity to Estuarine/Marine Organisms

MRID	Citation Reference
47127929	Holmes, C.; Jackson, S. (2008) BAS 800 H: Screening Level Ecological Risk Assessment for Wildlife, Aquatic Organisms, Nontarget Aquatic Plants, and Nontarget Insects. Project Number: 2007/7013913. Unpublished study prepared by BASF Corp. 20 p.

72-4 Fish Early Life Stage/Aquatic Invertebrate Life Cycle Study

MRID	Citation Reference
47127907	Weltje, L.; Bergtold, M. (2007) Chronic Toxicity of BAS 800 H to <i>Daphnia magna</i> Straus in a 21-Day Semi-Static Test (Including Amendment No. 1). Project Number: 132863, 2007/7013579. Unpublished study prepared by BASF Ag Research Station. 33 p.
47127908	Zok, S. (2007) BAS 800 H - Early Life-Stage Test on the Fathead Minnow (<i>Pimephales promelas</i>) in a Flow Through System (Including Amendment No.1). Project Number: 51F0414/015150, 2007/7002034. Unpublished study

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81-1 Acute oral toxicity in rats

MRID	Citation Reference
47128101	Leibold, E.; Gamer, A. (2005) BAS 800 H - Acute Oral Toxicity Study in Rats. Project Number: 10A0414/011124, 2005/1014960, RTP/NC/27709. Unpublished study prepared by BASF Aktiengesellschaft. 21 p.
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47128306	Rokh, N. (2007) BAS 800 02 H - Acute Oral Toxicity Study in Rats: "Acute Toxic Class Method". Project Number: 10A0812/059038, 2007/1035031. Unpublished study prepared by Centre International de Toxicologie. 40 p.
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47128506	Gamer, A.; Landsiedel, R. (2007) BAS 781 02 H: Acute Oral Toxicity Study in Rats. Project Number: 10A0520/071058, 2007/1053309. Unpublished study prepared by BASF Aktiengesellschaft. 24 p.
47128606	Wolf, T. (2007) BAS 804 00 H - Acute Oral Toxicity Study with Rats (Acute Toxic Class Method). Project Number: BAS17, 10A0174/069081. Unpublished study prepared by Austrian Research Center (ARC). 38 p.

81-2 Acute dermal toxicity in rabbits or rats

MRID	Citation Reference
47128102	Gamer, A.; Leibold, E. (2005) BAS 800 H - Acute Dermal Toxicity Study in Rats. Project Number: 11A0414/011125, 2005/1014961, RTP/NC/27709. Unpublished study prepared by BASF Aktiengesellschaft. 24 p.
47128108	Kaspers, U.; Strauss, V.; Kaufmann, W. et al. (2007) BAS 800 H - Range Finding Study in Wistar Rats Administration in the Diet 4 Weeks. Project

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- 47128407 Wolf, T. (2007) BAS 800 04 H: Acute Dermal Toxicity Study with Rats. Project Number: 11A0175/069087, BAS22, 2007/1044695. Unpublished study prepared by Austrian Research Center (ARC). 28 p.
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- 47128607 Wolf, T. (2007) BAS 804 00 H - Acute Dermal Toxicity Study with Rats. Project Number: BAS18, 11A0174/069080, 2007/1044693. Unpublished study prepared by Austrian Research Center (ARC). 28 p.

81-3 Acute inhalation toxicity in rats

MRID	Citation Reference
47128103	Ma-Hock, L.; Leibold, E. (2005) BAS 800 H - Acute Inhalation Toxicity Study in Wistar Rats. Project Number: 1310414/017021, 2005/1016432, RTP/NC/27709. Unpublished study prepared by BASF Aktiengesellschaft. 23 p.
47128210	Hock, L.; Landsiedel, R. (2007) BAS 800 01 H -Acute Inhalation Toxicity Study in Wistar Rats 4-hour Dust Exposure. Project Number: 1310320/067021, 2007/1039534. Unpublished study prepared by BASF Aktiengesellschaft, Experimental Toxicology and Ecology. 33 p.
47128308	Ma-Hock, L.; Landsiedel, R. (2007) BAS 800 02 H - Acute Inhalation Toxicity Study in Wistar Rats: 4-Hour Liquid Aerosol Exposure. Project Number: 13I0812/057024, 2007/1016466. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxikologie. 73 p.
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81-4 Primary eye irritation in rabbits

MRID	Citation Reference
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47128105	Remmele, M.; Landsiedel, R. (2007) BAS 800 H - Acute Eye Irritation in Rabbits. Project Number: 11H0414/012309, 2007/1011575, RTP/NC/27709. Unpublished study prepared by BASF Aktiengesellschaft. 25 p.
47128211	Remmele, M.; Landsiedel, R. (2007) BAS 800 01 H - Acute Eye Irritation in Rabbits. Project Number: 11H0320/062236, 2007/1020186. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxicologie. 23 p.
47128309	Remmele, M.; Landsiedel, R. (2007) BAS 800 02 H - Acute Eye Irritation in Rabbits. Project Number: 11H0812/052187, 2005/1029892. Unpublished study prepared by BASF Aktiengesellschaft, Experimental Toxicology and Ecology 23 p.
47128409	Remmele, M.; Landsiedel, R. (2007) BAS 800 04 H: Acute Eye Irritation in Rabbits. Project Number: 11H0175/062291, 2007/1053323. Unpublished study prepared by BASF Aktiengesellschaft, Experimental Toxicology and Ecology. 23 p.
47128509	Remmele, M.; Landsiedel, R. (2007) BAS 781 02 H: Acute Eye Irritation in Rabbits. Project Number: 11H0520/072105, 2007/1050806. Unpublished study prepared by BASF Aktiengesellschaft. 24 p.
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81-5 Primary dermal irritation

MRID	Citation Reference
47128106	Remmele, M.; Leibold, E. (2005) BAS 800 H - Acute Dermal Irritation / Corrosion in Rabbits. Project Number: 18H0414/102293, 2005/1005766,

- RTP/NC/27709. Unpublished study prepared by BASF Aktiengesellschaft. 21 p.
- 47128212 Remmele, M.; Landsiedel, R. (2007) BAS 800 01 H - Acute Dermal Irritation/Corrosion in Rabbits. Project Number: 18H0320/062235, 2007/1020185. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxicologie. 21 p.
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- 47128410 Remmele, M.; Landsiedel, R. (2007) BAS 800 04 H: Acute Dermal Irritation/Corrosion in Rabbits. Project Number: 18H0175/062290, 2007/1053325. Unpublished study prepared by BASF Aktiengesellschaft, Experimental Toxicology and Ecology. 21 p.
- 47128510 Remmele, M.; Landsiedel, R. (2007) BAS 781 02 H: Acute Dermal Irritation/Corrosion in Rabbits. Project Number: 2007/1057258, 18H0520/072139. Unpublished study prepared by BASF Aktiengesellschaft. 21 p.
- 47128610 Remmele, M.; Landsiedel, R. (2007) BAS 804 00 H: Acute Dermal Irritation/Corrosion in Rabbits. Project Number: 18H0174/062284, 2007/1052011. Unpublished study prepared by BASF Aktiengesellschaft. 22 p.

81-6 Dermal sensitization

MRID	Citation Reference
47128107	Gamer, A.; Leibold, E. (2005) BAS 800 - Maximization Test in Guinea Pigs. Project Number: 30H0414/012302, 2005/1014962, RTP/NC/27709. Unpublished study prepared by BASF Aktiengesellschaft. 37 p.
47128213	Remmele, M.; Landsiedel, R. (2007) BAS 800 01 H - Modified Buehler Test (9 Inductions) in Guinea Pigs. Project Number: 33H0320/062237, 2007/1020187. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxicologie. 33 p.
47128311	Rokh, N. (2007) BAS 800 02 H - Skin Sensitization Test in Guinea Pigs (Modified Buehler Test: 9 Inductions). Project Number: 33H0812/059041, 2007/1035034. Unpublished study prepared by Centre International de Toxicologie. 40 p.
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- 47128511 Gamer, A.; Landsiedel, R. (2007) BAS 781 02 H: Modified Buehler Test (9 Inductions) in Guinea Pigs. Project Number: 2007/1057259, 33H0520/072140. Unpublished study prepared by BASF Aktiengesellschaft. 32 p.
- 47128611 Gamer, A.; Landsiedel, R. (2007) BAS 804 00 H: Modified Buehler Test (9 Inductions) in Guinea Pigs. Project Number: 33H0174/062286, 2007/1052013. Unpublished study prepared by BASF Aktiengesellschaft. 33 p.

81-8 Acute neurotoxicity screen study in rats

MRID	Citation Reference
47128127	Kaspers, U.; Kaufmann, W.; Van Ravenzwaay, B. (2007) BAS 800 H - Acute Oral Neurotoxicity in Wistar Rats: Administration Via Gavage (Including Amendment No. 1). Project Number: 61S0414/01208, 2007/7009438. Unpublished study prepared by BASF Aktiengesellschaft. 391 p.
47128128	Kaspers, U.; Strauss, V.; Kaufmann, W.; et al. (2007) BAS 800 H - Repeated Dose 90-day Oral Neurotoxicity Study in Wistar Rats: Administration in the Diet. Project Number: 63S0414/01198, 2006/1024382. Unpublished study prepared by BASF Aktiengesellschaft. 510 p.

82-1 Subchronic Oral Toxicity: 90-Day Study

MRID	Citation Reference
47128109	Kaspers, U.; Strauss, V.; Kaufmann, W.; et al. (2007) BAS 800 - Repeated Dose 90-Day Oral Toxicity in Wistar Rats - Administration in the Diet. Project Number: 2005/1012914, RTP/NC/27709. Unpublished study prepared by BASF Aktiengesellschaft. 390 p.
47128111	Kaspers, U.; Strauss, V.; Kaufmann, W.; et al. (2007) BAS 800 H - Repeated Dose 90-day Oral Toxicity Study in C57BL/6NCrI Mice Administration in the Diet. Project Number: 51S0414/01161, 2005/1015755, RTP/NC/27709. Unpublished study prepared by BASF Aktiengesellschaft. 297 p.

82-2 21-day dermal-rabbit/rat

MRID	Citation Reference
47128110	Kaspers, U.; Strauss, V.; Kaufmann, W.; et al. (2007) BAS 800 H - Range Finding Study in C57BL/6NCrL Mice - Administration in the Diet for 4 Weeks. Project Number: 31S0414/01148, 2005/1011556, RTP/NC/27709. Unpublished study prepared by BASF Aktiengesellschaft. 231 p.

47128114 Kaspers, U.; Strauss, V.; Kaufmann, W.; et al. (2006) Repeat Dose 28-days Dermal Toxicity Study in Wistar Rats. Project Number: 33S0414/01193, 2006/1022422, RTP/NC/27709. Unpublished study prepared by BASF Ag Research Station. 311 p.

83-1 Chronic Toxicity

MRID	Citation Reference
47128118	Hempel, K.; Strauss, V.; Kaufmann, W.; et al. (2007) BAS 800 H - Chronic Oral Toxicity in Beagle Dogs: Administration Via Gelatin Capsules for 12 Months. Project Number: 43D0414/01196, 2007/1032051. Unpublished study prepared by BASF Aktiengesellschaft. 523 p.

83-2 Oncogenicity

MRID	Citation Reference
47128119	Kamp, H.; Strauss, V.; Kuttler, K.; et al. (2007) BAS 800 H - Carcinogenicity Study in C57BL/6NCrI Mice: Administration Via the Diet Over 18 Months. Project Number: 87C0414/01177, 2007/1005067. Unpublished study prepared by BASF Aktiengesellschaft. 2172 p.

83-3 Teratogenicity -- 2 Species

MRID	Citation Reference
47128115	Schneider, S.; Strauss, V.; Fabian, E.; et al. (2007) BAS 800 H - Prenatal Developmental Toxicity Study in Wistar Rats Oral Administration (Gavage) . Project Number: 30R0414/01178, 2007/1008481, RTP/NC/27709. Unpublished study prepared by BASF Ag Research Station. 380 p.
47128116	Schneider, S.; Deckardt, K.; Hellwig, J.; et al. (2006) BAS 800 H - Prenatal Developmental Toxicity Study in Himalayan Rabbits Oral Administration (Gavage). Project Number: 40R0414/01173, 2005/1029151, RTP/NC/27709. Unpublished study prepared by BASF Ag Research Station. 319 p.

83-4 2-generation repro.-rat

MRID	Citation Reference
47128117	Schneider, S.; Strauss, V.; Kuettler, K.; et al. (2007) BAS 800 H - Two-

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84-2 Interaction with Gonadal DNA

MRID	Citation Reference
47128121	Engelhardt, G.; Leibold, E. (2005) Salmonella typhimurium / Escherichia coli Reverse Mutation Assay (Standard Plate Test and Preincubation Test) with BAS 800 H. Project Number: 40M0414/014210, 2005/1006704. Unpublished study prepared by BASF Aktiengesellschaft. 53 p.
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47128126	Engelhardt, G.; Liebold, E. (2005) In vivo Unscheduled DNA Synthesis (USD) Assay with BAS 800 H in Rat Hepatocytes: Single Oral Administration. Project Number: 2005/1020111, 80M0414/014212. Unpublished study prepared by BASF Aktiengesellschaft. 50 p.

85-1 General metabolism

MRID	Citation Reference
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122-2 Aquatic plant growth

MRID	Citation Reference
47127923	Hoffmann, F. (2007) Effect of BAS 800 H (Reg. No. 4054449) on the Growth of the Green Alga <i>Pseudokirchneriella subcapitata</i> (Including Amendment No. 1): Final Report. Project Number: 132848, 2007/7013577. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxicologie. 34 p.
47127925	Hoffmann, F. (2007) Effect of BAS 800 H (Reg. No. 405449) on the Growth of the Blue-Green Alga <i>Anabaena flos-aquae</i> (Including Amendment No. 1): Final Report. Project Number: 132851, 2007/7013576. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxicologie. 36 p.

123-1 Seed germination/seedling emergence and vegetative vigor

MRID	Citation Reference
47127929	Holmes, C.; Jackson, S. (2008) BAS 800 H: Screening Level Ecological Risk Assessment for Wildlife, Aquatic Organisms, Nontarget Aquatic Plants, and Nontarget Insects. Project Number: 2007/7013913. Unpublished study prepared by BASF Corp. 20 p.
47560308	Stromel, C.; Brockman, A.; Teresiak, H. (2008) Effect of Metabolite of BAS 800 H, M800H08 with Incorporation into Soil on Seedling Emergence and Seedling Growth of Ten Species of Terrestrial Plants. Project Number: 2008/1036946/US/OCR, AC/BASF/08/12, 31/44/69. Unpublished study prepared by Agro-Check. 132 p.

123-2 Aquatic plant growth

MRID	Citation Reference
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141-1 Honey bee acute contact

MRID	Citation Reference
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47445903	Kling, A. (2008) Assessment of Side Effects of BAS 800 01 H to the Honey Bee, <i>Apis mellifera</i> L. in the Laboratory. Project Number: 2008/1000141, 317342, 20071545/S1/BLEU. Unpublished study prepared by Eurofins - GAB GmbH. 26 p.

161-1 Hydrolysis

MRID	Citation Reference
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161-2 Photodegradation-water

MRID	Citation Reference
47127824	Ta, C.; Trollinger, J. (2007) Aqueous Photolysis of (Carbon 14)-BAS 800 H: Final Report. Project Number: 2007/7009413, 132683. Unpublished study prepared by BASF Corporation. 126 p.
47699901	Ta, C.; Trollinger, J. (2009) Aqueous Photolysis of (Carbon 14)-BAS 800 H: Final Report. Project Number: 2009/7000140/OCR, SUBNO/200711/09/02, 132683. Unpublished study prepared by BASF Agro Research. 141 p.

161-3 Photodegradation-soil

MRID	Citation Reference
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162-1 Aerobic soil metabolism

MRID	Citation Reference
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162-2 Anaerobic soil metabolism

MRID	Citation Reference
47611201	Pyles, A.; Panek, M. (2008) Anaerobic Soil Metabolism of 14C-BAS 800 H: Final Report. Project Number: 2008/7015021, 812/05/01//US/332554, 332554. Unpublished study prepared by BASF Corporation. 124 p.

162-3 Anaerobic aquatic metab.

MRID	Citation Reference
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162-4 Aerobic aquatic metab.

MRID	Citation Reference
47127827	Malinsky, D. (2008) Aerobic Aquatic Metabolism of (Carbon 14) BAS 800 H Under Dark and Light Conditions. Project Number: 133487, 2007/7009863. Unpublished study prepared by BASF Corporation and Agvise Laboratories. 205 p.

163-1 Leach/adsorp/desorption

MRID	Citation Reference
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47127830	Ta, C. (2007) Adsorption/Desorption of the Major Metabolites (M800H01, M800H02, M800H07, M800H08, M800H15, and M800H22) of BAS 800 H on Soils: Final Report. Project Number: 2007/7009870, 132677. Unpublished study prepared by BASF Corporation. 243 p.

164-1 Terrestrial field dissipation

MRID	Citation Reference
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164-2 Aquatic field dissipation

MRID	Citation Reference
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165-1 Confined rotational crop

MRID	Citation Reference
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165-4 Bioaccumulation in fish

MRID	Citation Reference
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171-4B Residue Analytical Methods

MRID	Citation Reference
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171-4A1 Characterization of Total Terminal Residue

MRID	Citation Reference
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830.1000 Background for product properties test guidelines

MRID	Citation Reference
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830.1550 Product Identity and composition

MRID	Citation Reference
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- 47128202 Cannan, T. (2008) BAS 800 01 H Group A - Product Identity, Composition, and Analysis. Project Number: FR0739, 2007/7013548, AFR0064/01. Unpublished study prepared by BASF Corporation. 74 p.
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- 47128501 Aldridge, T. (2008) BAS 781 02 H (68 g/L BAS 800 H + 600 g/L Dimethenamid-P EC): Group A - Product Identity, Composition and Analysis. Project Number: FR0744, 2007/7013645, AFR0068/01. Unpublished study prepared by BASF Corporation. 101 p.
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830.1600 Description of materials used to produce the product

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830.1620 Description of production process

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47128401	Cannan, T. (2008) BAS 800 04 H: Group A - Product Identity, Composition, and Analysis. Project Number: FR0741, 2007/7013550. Unpublished study prepared by BASF Corporation. 102 p.
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830.1650 Description of formulation process

MRID	Citation Reference
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47128401	Cannan, T. (2008) BAS 800 04 H: Group A - Product Identity, Composition, and Analysis. Project Number: FR0741, 2007/7013550. Unpublished study prepared by BASF Corporation. 102 p.
47128501	Aldridge, T. (2008) BAS 781 02 H (68 g/L BAS 800 H + 600 g/L Dimethenamid-P EC): Group A - Product Identity, Composition and Analysis. Project Number: FR0744, 2007/7013645, AFR0068/01. Unpublished study prepared by BASF Corporation. 101 p.
47128601	Cannan, T. (2008) BAS 804 00 H: Group A - Product Identity, Composition, and Analysis. Project Number: 2007/7013549, FR0740, AFR0067/01. Unpublished study prepared by BASF Corporation. 77 p.

830.1670 Discussion of formation of impurities

MRID	Citation Reference
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Project Number: FR0744, 2007/7013645, AFR0068/01. Unpublished study prepared by BASF Corporation. 101 p.

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830.1700 Preliminary analysis

MRID	Citation Reference
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47128301	Aldridge, T. (2008) SHARPEN Herbicide (120 g/L BAS 800 H EC): Group A - Product Identity, Composition and Analysis. Project Number: FR0742, 2007/7013630. Unpublished study prepared by BASF Corporation. 83 p.
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47128601	Cannan, T. (2008) BAS 804 00 H: Group A - Product Identity, Composition, and Analysis. Project Number: 2007/7013549, FR0740, AFR0067/01. Unpublished study prepared by BASF Corporation. 77 p.

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830.1750 Certified limits

MRID	Citation Reference
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47127806	Brunt, S.; Genari, G. (2007) BAS 800 H Technical Grade Active Ingredient: Composition and Certified Limits. Project Number: 2007/7013642. Unpublished study prepared by BASF Corporation and BASF Aktiengesellschaft. 27 p.
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47128301	Aldridge, T. (2008) SHARPEN Herbicide (120 g/L BAS 800 H EC): Group A - Product Identity, Composition and Analysis. Project Number: FR0742, 2007/7013630. Unpublished study prepared by BASF Corporation. 83 p.
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47128501	Aldridge, T. (2008) BAS 781 02 H (68 g/L BAS 800 H + 600 g/L Dimethenamid-P EC): Group A - Product Identity, Composition and Analysis. Project Number: FR0744, 2007/7013645, AFR0068/01. Unpublished study prepared by BASF Corporation. 101 p.
47128601	Cannan, T. (2008) BAS 804 00 H: Group A - Product Identity, Composition, and Analysis. Project Number: 2007/7013549, FR0740, AFR0067/01. Unpublished study prepared by BASF Corporation. 77 p.

830.1800 Enforcement analytical method

MRID	Citation Reference
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47128301	Aldridge, T. (2008) SHARPEN Herbicide (120 g/L BAS 800 H EC): Group A - Product Identity, Composition and Analysis. Project Number: FR0742, 2007/7013630. Unpublished study prepared by BASF Corporation. 83 p.
47128302	Polowy, K.; Hartman, M. (2007) Validation of Analytical Method AFR0064/01 and GLP Certification of BAS 800 01 H Formulation Lot 1641-87 and BAS 800 02 H Lot 1631-22: Final Report. Project Number: F200717, 2007/7012410. Unpublished study prepared by BASF Corporation. 63 p.
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830.6302 Color

MRID	Citation Reference
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830.6303 Physical state

MRID	Citation Reference
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830.6304 Odor

MRID	Citation Reference
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830.6313 Stability to sunlight, normal and elevated temperatures, metals, and metal ions

MRID	Citation Reference
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830.6314 Oxidizing or reducing action

MRID	Citation Reference
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830.6315 Flammability

MRID	Citation Reference
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830.6316 Explodability

MRID	Citation Reference
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830.6317 Storage stability of product

MRID	Citation Reference
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830.6320 Corrosion characteristics

MRID	Citation Reference
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830.7000 pH of water solutions or suspensions

MRID	Citation Reference
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830.7050 UV/Visible absorption

MRID	Citation Reference
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830.7100 Viscosity

MRID	Citation Reference
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830.7200 Melting point/melting range

MRID	Citation Reference
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830.7300 Density/relative density

MRID	Citation Reference
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830.7370 Dissociation constant in water

MRID	Citation Reference
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830.7570 Partition coefficient (n-octanol/water), estimation by liquid chromatography

MRID	Citation Reference
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830.7840 Water solubility: Column elution method, shake flask method

MRID	Citation Reference
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830.7950 Vapor pressure

MRID	Citation Reference
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835.0001 Background for Environmental Fate, Transport, and Drift

MRID

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835.1230 Sediment and soil absorption/desorption for parent and degradates

MRID

Citation Reference

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835.1240 Soil column leaching

MRID

Citation Reference

47127830 Ta, C. (2007) Adsorption/Desorption of the Major Metabolites (M800H01, M800H02, M800H07, M800H08, M800H15, and M800H22) of BAS 800 H on Soils: Final Report. Project Number: 2007/7009870, 132677. Unpublished study prepared by BASF Corporation. 243 p.

835.2120 Hydrolysis of parent and degradates as a function of pH at 25 C

MRID

Citation Reference

47127823 Panek, M. (2006) Hydrolysis of (Carbon 14)-BAS 800 H: Final Report. Project Number: 2005/7004259, 132680. Unpublished study prepared by BASF Corporation. 155 p.

835.2210 Direct photolysis rate in water by sunlight

MRID

Citation Reference

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835.2410 Photodegradation of parent and degradates in soil

MRID	Citation Reference
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835.4100 Aerobic soil metabolism

MRID	Citation Reference
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835.4200 Anaerobic soil metabolism

MRID	Citation Reference
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835.4300 Aerobic aquatic metabolism

MRID	Citation Reference
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835.4400 Anaerobic aquatic metabolism

MRID	Citation Reference
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835.6100 Terrestrial field dissipation

MRID	Citation Reference
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835.6200 Aquatic field dissipation

MRID	Citation Reference
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835.7100 Ground water monitoring

MRID	Citation Reference
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47699903	Saha, M. (2009) Method Validation of BASF Analytical Method D0502 Entitled: "The Determination of Residues of BAS 800 H and its Metabolites in Water Using LC-MS/MS: Final Report. Project Number: 2009/7000172/OCR, US/132692. Unpublished study prepared by BASF Agro Research. 197 p.

850.1010 Aquatic invertebrate acute toxicity, test, freshwater daphnids

MRID	Citation Reference
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47127901	Bergtold, M.; Janson, G. (2006) Acute Toxicity of BAS 800 H to <i>Daphnia magna</i> Straus in a 48 Hour Static Test: Final Report. Project Number: 132860, 2006/1004506. Unpublished study prepared by BASF Aktiengesellschaft. 20 p.
47127929	Holmes, C.; Jackson, S. (2008) BAS 800 H: Screening Level Ecological Risk Assessment for Wildlife, Aquatic Organisms, Nontarget Aquatic Plants, and Nontarget Insects. Project Number: 2007/7013913. Unpublished study prepared by BASF Corp. 20 p.

850.1025 Oyster acute toxicity test (shell deposition)

MRID	Citation Reference
47127902	Palmer, S.; Kendall, T.; Krueger, H.; et al. (2007) BAS 800 H: A 96-Hour Shell Deposition Test with the Eastern Oyster (<i>Crassostrea virginica</i>). Project Number: 147A/214, 132884, 2007/7009823. Unpublished study prepared by Wildlife International, Ltd. 41 p.
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850.1035 Mysid acute toxicity test

MRID	Citation Reference
47127903	Blankinship, A.; Kendall, T.; Krueger, H.; et al. (2007) BAS 800 H: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysid (<i>Americamysis bahia</i>). Project Number: 147A/212C, 132881, 2007/7009955. Unpublished study prepared by Wildlife International, Ltd. 43 p.
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47560303	Minderhout, T. ; Kendall, T.; Krueger, H.; Holmes, C. (2008) BAS 800 H Metabolite M07: A 96-Hour Static Acute Toxicity Test with the Saltwater Mysid (<i>Americamysis bahia</i>). Project Number: 2008/7015130/OCR, 147A/246, 356246. Unpublished study prepared by Wildlife International Ltd. 38 p.

850.1075 Fish acute toxicity test, freshwater and marine

MRID	Citation Reference
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47127906	Palmer, S.; Kendall, T.; Krueger, H.; et al. (2007) BAS 800 H: A 96-Hour Static Acute Toxicity Test with the Sheepshead Minnow (<i>Cyprinodon variegatus</i>). Project Number: 147A/213, 132878, 2007/7009824. Unpublished study prepared by Wildlife International, Ltd. 38 p.
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850.1300 Daphnid chronic toxicity test

MRID	Citation Reference
47127907	Weltje, L.; Bergtold, M. (2007) Chronic Toxicity of BAS 800 H to <i>Daphnia magna</i> Straus in a 21-Day Semi-Static Test (Including Amendment No. 1). Project Number: 132863, 2007/7013579. Unpublished study prepared by BASF Ag Research Station. 33 p.
47127929	Holmes, C.; Jackson, S. (2008) BAS 800 H: Screening Level Ecological Risk Assessment for Wildlife, Aquatic Organisms, Nontarget Aquatic Plants, and Nontarget Insects. Project Number: 2007/7013913. Unpublished study prepared by BASF Corp. 20 p.

850.1350 Mysid chronic toxicity test

MRID	Citation Reference
47127929	Holmes, C.; Jackson, S. (2008) BAS 800 H: Screening Level Ecological Risk Assessment for Wildlife, Aquatic Organisms, Nontarget Aquatic Plants, and Nontarget Insects. Project Number: 2007/7013913. Unpublished study prepared

by BASF Corp. 20 p.

850.1400 Fish early-life stage toxicity test

MRID	Citation Reference
47127908	Zok, S. (2007) BAS 800 H - Early Life-Stage Test on the Fathead Minnow (<i>Pimephales promelas</i>) in a Flow Through System (Including Amendment No.1). Project Number: 51F0414/015150, 2007/7002034. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxicologie. 107 p.
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850.1730 Fish BCF

MRID	Citation Reference
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850.2100 Avian acute oral toxicity test

MRID	Citation Reference
47127911	Zok, S. (2006) BAS 800 H - Acute Toxicity in the Bobwhite Quail (<i>Colinus virginianus</i>) After Single Oral Administration (LD50). Project Number: 11W0414/015141, 2005/1029868. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxicologie. 52 p.
47127912	Zok, S. (2006) BAS 800 H - Acute Toxicity in the Mallard Duck (<i>Anas platyrhynchos</i>) After Single Oral Administration. Project Number: 13W0414/015145, 2005/102866. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxicologie. 54 p.
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850.2200 Avian dietary toxicity test

MRID	Citation Reference
47127913	Zok, R. (2006) BAS 800 H - Avian Dietary LC50 Test in Chicks of the Bobwhite Quail (<i>Colinus virginianus</i>). Project Number: 31W0414/015139, 2005/1029867. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxicologie. 45 p.
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850.2300 Avian reproduction test

MRID	Citation Reference
47127915	Zok, R. (2006) BAS 800 H - 1-Generation Reproduction Study on the Bobwhite Quail (<i>Colinus virginianus</i>) by Administration in the Diet. Project Number: 71W0414/015148, 2006/1035447. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxicologie. 349 p.
47127916	Zok, R. (2006) BAS 800 H - 1-Generation Reproduction Study on the Mallard Duck (<i>Anas platyrhynchos</i>) by Administration in the Diet. Project Number: 72W0414/015149, 2006/1035448. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer Oekotoxicologie. 343 p.
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850.3020 Honey bee acute contact toxicity

MRID	Citation Reference
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850.4100 Terrestrial plant toxicity, Tier 1 (seedling emergence)

MRID	Citation Reference
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850.4150 Terrestrial plant toxicity, Tier 1 (vegetative vigor)

MRID	Citation Reference
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850.4225 Seedling emergence, Tier II

MRID	Citation Reference
47127918	Porch, J.; Krueger, H.; Martin, K.; et al. (2007) BAS 800 02 H: A Toxicity Test to Determine the Effects of the Test Substance on Seedling Emergence of Ten Species of Plants. Project Number: 147/228, 147485, 2007/7012423. Unpublished study prepared by Wildlife International, Ltd. 114 p.
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850.4250 Vegetative vigor, Tier II

MRID	Citation Reference
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47127921	Porch, J.; Krueger, H.; Martin, K.; et al. (2007) BAS 800 01 H: A Toxicity Test to Determine the Effects of the Test Substance on Vegetative Vigor of Ten Species of Plants. Project Number: 147/227, 147482, 2007/7013633. Unpublished study prepared by BASF Aktiengesellschaft, Labor fuer

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850.4400 Aquatic plant toxicity test using Lemna spp. Tiers I and II

MRID	Citation Reference
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47560302	Porch, J.; Kendall, T.; Krueger, H.; Holmes, C. (2008) BAS 800 H Metabolite M07: A 7-Day Toxicity Test with Duckweed (Lemna gibba G3). Project Number: 2008/7013852/OCR, 147A/243, 355549. Unpublished study prepared by Wildlife International Ltd. 50 p.
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850.5400 Algal toxicity, Tiers 1 and II

MRID	Citation Reference
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860.1300 Nature of the residue - plants, livestock

MRID	Citation Reference
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860.1340 Residue analytical method

MRID	Citation Reference
47127831	Saha, M. (2007) Method Validation of BASF Analytical Method D0503 Entitled: "The Determination of Residues of BAS 800 H and its Metabolites in Soil Using LC/MS/MS": Final Report. Project Number: 132659, 2005/5000071. Unpublished study prepared by BASF Agro Research. 197 p.
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47128008	Nejad, H. (2007) Method Validation of BASF Analytical Method D0603/02: Residue Enforcement Method for Determination of Residues BAS 800 H and Its Metabolites M800H11 and M800H35 in Plant Matrices Using LC/MS/MS: Final Report. Project Number: 132590, 2007/7009778. Unpublished study prepared by BASF Agro Research. 144 p.
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860.1360 Multiresidue 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

MRID	Citation Reference
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860.1500 Crop field trials

MRID	Citation Reference
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47128217	Sotack, G. (2008) BAS 800 00H: Tank Mix Uniformity of a WG formulation in a Simulated Spray Tank: Final Report. Project Number: F200713, 2007/7007878. Unpublished study prepared by BASF Corporation. 19 p.
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860.1520 Processed food/feed

MRID

Citation Reference

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860.1550 Proposed tolerances

MRID	Citation Reference
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860.1850 Confined accumulation in rotational crops

MRID	Citation Reference
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860.1900 Field accumulation in rotational crops

MRID	Citation Reference
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870.1100 Acute oral toxicity

MRID	Citation Reference
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870.1200 Acute dermal toxicity

MRID	Citation Reference
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870.1300 Acute inhalation toxicity

MRID	Citation Reference
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870.2400 Acute eye irritation

MRID	Citation Reference
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870.2500 Acute dermal irritation

MRID	Citation Reference
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870.2600 Skin sensitization

MRID	Citation Reference
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870.3100 90-Day oral toxicity in rodents

MRID	Citation Reference
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870.3150 90-day oral toxicity in nonrodents

MRID	Citation Reference
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870.3200 21/28-day dermal toxicity

MRID	Citation Reference
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870.3700 Prenatal developmental toxicity study

MRID	Citation Reference
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870.3800 Reproduction and fertility effects

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870.4100 Chronic toxicity

MRID

Citation Reference

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870.4200 Carcinogenicity

MRID

Citation Reference

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870.4300 Combined chronic toxicity/carcinogenicity

MRID

Citation Reference

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870.5100 Bacterial reverse mutation test

MRID

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870.5300 In vitro mammalian cell gene mutation test

MRID Citation Reference

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870.5375 In vitro mammalian chromosome aberration test

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870.5550 Unscheduled DNA synthesis in mammalian cells in culture

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870.6200 Neurotoxicity screening battery

MRID Citation Reference

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870.7485 Metabolism and pharmacokinetics

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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850.1735 Whole sediment: acute freshwater invertebrates**MRID****Citation Reference**

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870.3050 Repeated dose 28-day oral toxicity in rodents**MRID****Citation Reference**

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850.7100 Data reporting for environmental chemistry methods**MRID****Citation Reference**

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850.6200 Earthworm subchronic toxicity test

MRID	Citation Reference
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