United States
Environmental Protection
Agency

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

Pesticide Fact Sheet

Name of Chemical: Flufenoxuron
Reason for Issuance: New Chemical
Tolerances Established
Date Issued: September 2006

Description of Chemical

Generic Name:	N-[[[4-[2-clair-4-(trifluoromethyl)phenoxy]-2-fluorophenyl]amino]carbonyl]-2,6-difluorobenzamide
Common Name:	Flufenoxuron
Trade Name in Foreign Countries:	Cascade
Chemical Type:	Benzoylurea
EPA Chemical Code:	108203
Chemical Abstracts Service (CAS) Number:	101463-69-8
Registration Status:	Not Registered, Import Tolerances Established
Pesticide Type:	Insecticide/Acaricide
U.S. Producer:	BASF Corporation 26 Davis Drive, PO Box 13528 Research Triangle Park 27709-3528

Tolerances Established

Import tolerances were established in the 40 CFR §180.XXX in or on apple (0.50 ppm); grape (0.70 ppm); grape, raisin (2.0 ppm); cattle, meat (0.10 ppm); cattle, fat (4.5 ppm); cattle, meat byproducts (0.50 ppm); goat, meat (0.10 ppm); goat, fat (4.5 ppm); goat, meat byproducts (0.50 ppm); horse, meat (0.10 ppm); horse, fat (4.5 ppm); horse, meat byproducts (0.50 ppm); sheep, meat (0.10 ppm); sheep, fat (4.5 ppm); sheep, meat byproducts (0.50 ppm); milk (0.20 ppm); milk, fat (4.0 ppm); orange (0.30 ppm); orange, oil (60 ppm); and pear (0.50 ppm).

Use Pattern and Formulations

Flufenoxuron is a benzoylurea type insecticide/acaricide which inhibits chitin biosynthesis (MOA Group 15) in nymphal mites and Lepidopteran larvae. There are currently no food/feed uses or tolerances for flufenoxuron in the U.S. BASF Corporation is supporting the use of flufenoxuron on apples, grapes and oranges grown for export to the U.S. in selected European and South American countries. Flufenoxuron is formulated as 50 and 100 g/L EC, DC or FlC under the trade name Cascade®. Depending on the crop and the country of use, these formulations are proposed for one to four foliar applications per season to the above crops at rates equivalent to 40-250 g ai/ha/application (0.036-0.22 lb ai/A/application).

Science Findings

Available product chemistry data supporting the use of flufenoxuron are summarized below in Tables 1 and 2.

Table 1 Nomenclature and Physiochemical Properties of Flufenoxuron

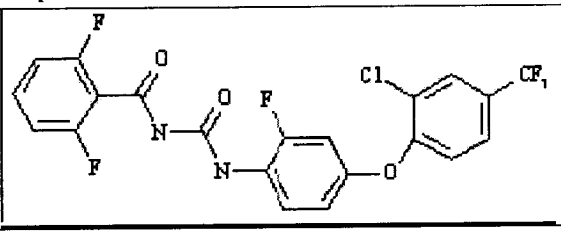
Physical Chemical Structure	
Common Name	Flufenoxuron
Company Experimental Names	CL 811,678 WL 115110
Molecular Weight	488.77
IUPAC Name	1-[4-(2-chloro-á,á,á-trifluoro-*p*-tolyloxy)-2-fluorophenyl]-3-(2,6-difluorobenzoyl)urea
CAS Name	N-[[[4-[2-clair-4-(trifluoromethyl)phenoxy]-2-fluorophenyl]amino]carbonyl]-2,6-difluorobenzamide
CAS #	101463-69-8
Empirical Formula	$C_{21}H_{11}ClF_6N_2O_3$
PC Code Number	108203
Water Solubility	1.36×10^{-6} g/L
Log (K_{ow})	4.01

Table 2 Physiochemical Properties of Technical Grade Flufenoxuron		
Parameter	**Value**	
Melting Point	169-172° C	
pH	6.1	
Relative Density at 20° C	1.57 g/mL	
Water Solubility at 25° C	1.36 x 10^{-6} g/L	
Solvent Solubility (g/L) at 20° C	Solvent	g/100 mL (20° C)
	Hexane	0.012
	Octan-1-ol	1.12
	Methanol	3.55
	Dicloromethane	18.7
	Cyclohexane	96.4
	Dimethyl sulfoxide	287
	Dimethyl formamide	287
	Acetone	73.6
Vapor pressure at 20°C	6.52 x 10^{-12} Pa	
Dissociation constant (pK)	10.1	
Octanol/water partition coefficient Log(KOW) at 25° C	4.01	
Density	1.57 g/mL	

TOXICOLOGY SUMMARY

The Registrant submitted the studies listed in Tables 3 and 4, which include a number of toxicity studies and summaries published in the public literature. These include the usual acute studies for flufenoxuron technical. The Registrant has also submitted oral, dermal and inhalation studies as well as chronic, carcinogenicity and developmental studies as shown in Table 4.

Table 3 Acute Toxicity of Flufenoxuron			
Guideline No.	**Study Type**	**Results (LD50/LC50)**	**Toxicity Category**
870.1100 (81-1)	Acute Oral (rat)	50LD > 5000 mg/kg (M) LD50 > 5000 mg/kg (F)	IV
870.1200 (81-2)	Acute Dermal	NA	NA
870.1300 (81-3)	Acute Inhalation (rat)	NA	NA
870.2400 (81-4)	Primary Eye Irritation	NA	NA
870.2500 (81-5)	Primary Skin Irritation	NA	NA
87.2600 (81-6)	Dermal Sensitization (guinea pig)	NA	NA

Table 4 Subchronic, Chronic, and Other Toxicity Profile		
Guideline No./ Study Type	**MRID No. (year)/ Classification/Doses**	**Results**
870.3100a 90-Day oral toxicity rodents (rat)	MRID 44448406 (1987) **Acceptable/guideline** Doses: 0, 50, 500, 5,000, 50,000 ppm M & F: 0, 2.5, 25, 250, 500, 2500 mg/kg/day	NOAEL = 25 mg/kg/day (M/F) LOAEL = 250 mg/kg/day (M/F), based on decreased hemoglobin levels and hematocrit levels, and red cell counts in females and decreased erythroid:myeloid ratios in males.
870.3100b 90-Day oral toxicity rodents (mouse)	MRID 44448408 (1991) **Acceptable/Guideline** Doses: 0, 50, 500, 5,000, 50,000 ppm (Limit dose) M& F: 0, 7.5, 75, 750, 1500, 7500 mg/kg/day	NOAEL = 7500 mg/kg/day (M/F) LOAEL was not established.
870.3150 90-Day oral toxicity in nonrodents (dog)	MRID 44448409 (1987) **Acceptable/Guideline in conjunction with the chronic dog study (MRID 44448411)** Doses: 0, 0.05% (500 ppm), 0.5% (5000 ppm), 5% (50,000 ppm) in the diet 0, 38, 375, 3750 (3.5x Limit dose) mg/kg/day	NOAEL = 7.5 mg/kg/day (M/F; based on chronic toxicity study in dog). LOAEL = 38 mg/kg/day (M/F), based on decreased hemoglobin, hematocrit levels, and erythrocyte counts in males and increased absolute liver weights, bone marrow hyperplasia and methemoglobinemia in males and females.
870.3200 21/28-Day dermal toxicity (rat)	NA[1]	NA
870.3250 90-Day dermal toxicity	NA	NA
870.3465 90-Day inhalation toxicity	NA	NA
870.3700a Pre-natal developmental in rodents (rat)	MRID 44448415 (1991) **Unacceptable/Guideline, upgradeable upon review of stability and certain fetal external examination data.** Doses: 0, 10, 100, 1000 mg/kg/day (Limit dose) GD 6 - 16, inclusive	Maternal NOAEL = 1000 mg/kg/day LOAEL was not observed. Developmental NOAEL = 1000 mg/kg/day LOAEL was not observed.
870.3700b Pre-natal developmental in nonrodents (rabbit)	MRID 44448416 (1991) **Acceptable/Guideline** Doses: 0, 10, 100, 1000 mg/kg/day (Limit dose) GD 6-18, inclusive	Maternal NOAEL 1000 mg/kg/day LOAEL was not established. Developmental NOAEL = 100 mg/kg/day LOAEL = 1000 mg/kg/day, based on delayed fetal growth.
870.3800 Reproduction and fertility effects (rats)	MRID 44448417 (1991) **Acceptable/Guideline** Doses: 0, 50, 190, 710, 10,000 ppm M: 0, 3.75, 14.33,53.64, 771.6 mg/kg/day F: 0, 4.26, 16.0, 60.98, 907.4 mg/kg/day	Parental Toxicity NOAEL = 771.6/907.4 mg/kg/day (M/F) LOAEL was not established. Rep. Toxicity NOAEL = 771.6/907.4 mg/kg/day (M/F) LOAEL was not established. Offspring Toxicity NOAEL = 3.75/4.26 mg/kg/day (M/F) LOAEL = 14.33/16.0 mg/kg/day, based on lower pup body weight.

Table 4 (continued) Subchronic, Chronic, and Other Toxicity Profile		
Guideline No./ Study Type	**MRID No. (year)/ Classification/ Doses**	**Results**
870.4100b Chronic toxicity dogs	MRID 44448411 (1989) **Acceptable/Guideline** Doses: 0, 10, 100, 500, 50,000 ppm M & F: 0, 0.75, 7.5, 37.5, 3750 mg/kg/day	NOAEL = 7.5 mg/kg/day (M/F) LOAEL = 37.5 mg/kg/day (M/F), based on decreased erythrocyte counts, and mean hemoglobin concentration and increased mean cell volume, platelet counts in males, methemoglobinemia and sulfhemoglobinemia in males and females.
870.4200 Combined chronic toxicity/carcinogenicity rodents (rat)	MRIDs 44448410 & 44448412 (1990) **Acceptable/Guideline** Doses: Chronic phase: 0, 1, 5, 50, 500, 5000, 50000 (> Limit dose) ppm M: 0, 0.044, 0.226, 2.21, 22.03, 232.5, 2470.6 mg/kg/day F: 0, 0.05, 0.279, 2.82, 28.33, 301.0, 3205.6 mg/kg/day Carcinogenicity phase: 0, 500, 5000, 50000 (> Limit dose) ppm M: 0, 21.57, 217.5, 2289.8 mg/kg/day F: 0, 25.92, 276.4, 2900.9 mg/kg/day	NOAEL = 22.03/28.33 mg/kg/day (M/F) LOAEL = 232.5/301 mg/kg/day (M/F), based on decreased body weight and weight gain. No evidence of carcinogenicity.
870.4300 Carcinogenicity mice	MRID 44448414 (1992) **Acceptable/Guideline** Doses: 0, 500, 5,000, 50,000 (> Limit dose) ppm M: 0, 56, 559, 7356 mg/kg/day F: 0, 73, 739, 7780 mg/kg/day 6 3 1B C F strain	NOAEL = 559/73 mg/kg/day (M/F) LOAEL = 7356/739 (M/F), based on decreased body weight and body weight gain and liver lesions in males and females and spleen lesions in males. Dosing was adequate (> 7.5x the limit dose). Total incidence of vascular tumors (combined hemangiosarcomas of the liver and spleen) among high-dose females (16%) was significantly increased over controls (0%) and was slightly outside the published data for historical controls (mean: 3.7%; range: 0%-14%). The overall increase in splenic hemangiosarcomas in high-dose females (14%, $p<0.01$) and the increase in total vascular tumors in the liver of high-dose males (20% vs 12% in controls) occurred at doses that exceeded the limit dose.
870.4300 Carcinogenicity mice	MRID 44448413 (1996) **Acceptable/Guideline** Doses: 0, 100, 1,000, 10,000 (> limit dose) ppm M: 0, 15.3, 152, 1592 mg/kg/day F: 0, 17.4, 187, 1890 mg/kg/day 6 3 1B C F strain	NOAEL = 1592/187 mg/kg/day (M/F) LOAEL = 1890 mg/kg/day (F), based on decreased body weight and body weight gains. LOAEL for males not established. No evidence of carcinogenicity
Gene Mutation 870.5100 reverse gene mutation assay in bacteria	44448419 (1991) **Unacceptable/guideline** *Salmonella typhimurium strains* TA98, TA100, TA1535, and TA1538; Escherichia coli strain WP2 were exposed to flufenoxuron at doses 0, 31.25, 62.5, 125, 250, 500, 1000, 2000, and 4000 µg/plate. Inappropriate positive controls for strains TA1535 and WP2 with +S9 and TA100, TA1537, TA1538, and TA98 -S9.	No evidence of induced mutant colonies over background.

Table 4 (continued) Subchronic, Chronic, and Other Toxicity Profile		
Guideline No./ Study Type	**MRID No. (year)/ Classification/ Doses**	**Results**
Gene Mutation 870.5300 forward gene mutation assay in mammalian cells	46607201 (1986) **Acceptable/guideline** CH V79 cells exposed to flufenoxuron at concentrations up to 1350 µg/mL (±S9)	There was no evidence that flufenoxuron induced mutant colonies over background in the ± S9 activation.
Cytogenetics 870.5375 *in vitro mammalian cytogenetic* assay	46607202 (1987) **Acceptable/guideline** CHO cells exposed to flufenoxuron at doses up to 150 µg/mL (±S9).	No evidence of increased chromosomal aberrations in the presence of S9.
Cytogenetics 870.5375 *in vitro mammalian cytogenetic* assay	46607204 (1988) **Unacceptable/guideline** Rat liver epithelioid cells exposed to flufenoxuron at doses up to 450 µg/mL (-S9) and/or 160 µg/mL (+S9).	Not clastogenic with or without S9 activation, at any dose tested; however, the negative results were not followed-up experiment with a much longer harvest time and in the absence of S9.
870.5375 *in vitro mammalian cytogenetic* assay	46607205 (1992) **Acceptable/guideline** Human lymphocytes cultures exposed to flufenoxuron at doses up to 160 µg/mL (±S9)	No evidence of increased chromosomal aberrations in the ±S9 activation.
Cytogenetics 870.5385 in vivo mammalian cytogenetic assay	46607206 (1986) **Acceptable/guideline** CD rats oral dosed with flufenoxuron at doses up to 4000 mg/kg (>limit dose)	No increase in aberrant cells was seen in the bone marrow chromosomal aberration assay.
Other Effects 870.5395 in vivo mammalian cytogenetic assay	46607208 (1993) **Acceptable/guideline** Doses: 0, 500, 1000, and 2000 mg/kg (limit dose)	Did not induce micronucleated polychromatic erythrocytes (PMCEs) in bone marrow at any dose
Other Genotoxic Effects 870.5550 UDS synthesis in mammalian cell culture	46607207 (1988) **Unacceptable/guideline** Doses: 0, 188, 375, 750, and 1500 mg/kg oral gavage. No justification for upper dose tested.	Did not induce UDS at any dose
Other Genotoxic Effects 870.5575 Mitotic gene conversion in *Saccharomyces cerevisiae*	44448419 (1991) **Acceptable/guideline** Doses: 0, 0.01, 0.1, 0.25, 0.5, and 1.0 mg/mL ± S9.	No increase in the mitotic gene conversion at either histidine or tryptophan loci ± S9.
Non-guideline Replicative DNA synthesis in rat hepatocytes	46607209 (1992) **Unacceptable/non-guideline** Doses: 0, 2000 and 4000 mg/kg oral gavage. No positive control data.	No increased in the incidence replicative DNA synthesis over untreated controls.
870.6200a Acute neurotoxicity screening battery	NA	NA

Table 4 (continued) Subchronic, Chronic, and Other Toxicity Profile		
Guideline No./ Study Type	**MRID No. (year)/ Classification/ Doses**	**Results**
870.6200b 4-Week Subchronic neurotoxicity screening battery	46482203 (2003) **Acceptable/non-guideline because of duration** Doses: 0, 1000, 5000, 20000 ppm M: 0, 88.3, 435.4, 1774.6 mg/kg/day F: 0, 94.9, 474.5, 1934.4 mg/kg/day	NOAEL= 88.3/94.9 mg/kg/day (M/F) LOAEL = 435.4/474.5 mg/kg/day (M/F), based on decreased body weight and body weight gains in males.
870.6300 Developmental neurotoxicity	NA	NA
870.7485 Metabolism and pharmacokinetics (rat)	44448422 (1992) **Acceptable/guideline** Doses: M & F: 3.5 or 350 mg/kg single oral dose (labeled the aniline and difluorobenzene ring) , -single gavage dose of 5 mg/kg for 14 days followed by labeled 5 mg/kg,-in bile duct cannulated, single dose of 5 mg/kg	Metabolic fate of flufenoxuron was determined using two label positions (aniline and difluorobenzene ring). At the high dose, saturated absorption was observed. Approximately 86% of the low dose and 1% of the high dose was absorbed in 168 hours; the majority of which occurred within 48 hours. For the low dose ring, urine (9-27%) was major route of excretion (much less was in the urine at the high dose). Conversely, 93-102% of the high dose and 4-19% of the low dose was eliminated in feces. Elimination via expired air was insignificant. Biliary excretion using the aniline ring label showed that all the radioactivity in the feces of females and 40% of that in males are the biliary excretion products. Accumulation of radioactivity in muscle and adipose tissue 4 hours post dosing with 3.5 mg/kg benzyl label was 30% and 42%, respectively. At 168 hours post dose, these values were 6% and 19%, respectively, suggesting an accumulation in the adipose tissue. High doses of both labels resulted in negligible tissue burden (<0.3%), indicating saturation absorption. Urinary samples showed 10 urinary metabolites and parent accounted for ~5% of the dose in the urine and was considered non-significant. Fecal analysis indicated that parent compound accounting for the greatest portion of radioactivity. Most fecal metabolites represented < 1% of the administered dose. The results of the metabolism characterization studies with both label positions suggest that metabolism of flufenoxuron proceeds via hydrolysis to a benzoic acid metabolite, a phenyl urea metabolite (4-[2-chloro, α, α, α-trifluoro-p-tolyoxy]-2-fluorophenyl urea), an aniline metabolite (4-[2-chloro, α, α, α-trifluoro-p tolyoxy]-2-fluoroaniline), and subsequently several minor components.
870.7600 Dermal penetration	NA	NA

[1] NA = not applicable.

Toxicological Endpoints

Table 5. Summary of Toxicological Dose and Endpoints for Flufenoxuron for Use in Human Risk Assessment1			
Exposure Scenario	**Dose Used in Risk Assessment, UF**	**FQPA SF and Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietary (females 13-50 years of age)	An endpoint of concern attributed to single dose effect was not identified in the database. Quantification of acute risk to general population including infants and children is not required.		
Acute Dietary (general population including infants and children)	An endpoint of concern attributed to single dose effect was not identified in the database. Quantification of acute risk to general population including infants and children is not required.		
Chronic Dietary (all populations)	NOAEL= 3.75 mg/kg/day UF = 100 Chronic RfD = 0.0375 mg/kg/day	FQPA SF = 1X cPAD = (chronic RfD/ FQPA SF) = 0.0375 mg/kg/day	2-Generation Reproduction Toxicity - Rat LOAEL =14.33/16.0 (M/F) mg/kg/day, based on decreased body weights during lactation days 4-21.
Oral - All Durations[2] (Residential)	NOAEL = 3.75 mg/kg/day	Residential LOC for MOE = 100	2-Generation Reproduction Toxicity - Rat LOAEL = 14.33/16.0 (M/F) mg/kg/day, based on decreased body weights during lactation days 4-21.
Dermal - All Durations[2] (Occupational/ Residential)	oral NOAEL= 3.75 mg/kg/day (dermal absorption rate = 100%)	Occupational LOC for MOE = 100 Residential LOC for MOE = 100	2-Generation Reproduction Toxicity - Rat LOAEL = 14.33/16.0 (M/F) mg/kg/day, based on decreased body weights during lactation days 4-21.
Inhalation - All Durations[2] (Occupational/ Residential)	oral NOAEL= 3.75 mg/kg/day (inhalation absorption rate = 100%)	Occupational LOC for MOE = 100 Residential LOC for MOE = 100	2-Generation Reproduction Toxicity - Rat LOAEL = 14.33/16.0 (M/F) mg/kg/day, based on decreased body weights during lactation days 4-21.
Cancer (oral, dermal, inhalation)	"not likely to be carcinogenic to humans"		

[1] UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure.

[2] As there are no registered or proposed domestic uses of flufenoxuron, residential or occupational exposure assessments were not conducted. However, if in the future domestic uses are proposed that would result in occupational and/or residential exposure to flufenoxuron, these endpoints will be applicable.

Food Quality Protection Act Considerations

FQPA Safety Factor

The EPA selected endpoints for risk assessment and evaluated the potential for increased susceptibility of infants and children from exposure to flufenoxuron according to the February 2002 OPP 10X guidance document. The FQPA safety factor (SF) was reduced to 1x by the EPA based on the following toxicological considerations:

- There is no evidence of increased susceptibility in the developmental study in rats.
- In the rabbit developmental study, there is evidence of increased susceptibility; however, the effects are well characterized and clear NOAELs and LOAELs are established. Since the effects occurred at the limit dose, the delayed fetal growth may be considered a high dose effect.

- In the 2-generation reproduction study in rat, there is evidence for the increased susceptibility; however, the effects were well characterized, clear NOAELs and LOAELs were established for offspring toxicities, and the endpoints were used for risk assessment. Therefore, there is no residual uncertainty for pre- and/or post-natal susceptibility.
- The toxicological database is complete for FQPA assessment.
- The chronic dietary food exposure assessment utilizes proposed tolerance level residues and assumes 100% CT information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.

Risk assessments were conducted for the chronic dietary exposure scenario only. The chronic reference dose (cRfD) was calculated by dividing the no-observed-adverse-effect-level (NOAEL) by 100 (10X for interspecies extrapolation, 10X for intraspecies variation). Since the FQPA SF has been reduced to 1X, the chronic population adjusted dose (cPAD) is equal to the cRfD.

Exposure Assessment

Dietary-Exposure Assessment: An unrefined, chronic dietary exposure assessment was performed for the general U.S. population and various population subgroups assuming tolerance level residues and 100% crop treated (%CT) for all commodities. As there are no proposed domestic uses of flufenoxuron, drinking water was not incorporated into the dietary assessment. The chronic dietary exposure estimates are below HED's level of concern (<100% cPAD) for the general U.S. population (14% cPAD) and all population subgroups (Table 6). The most highly-exposed population subgroup is children 1-2 years old at 63% cPAD.

Table 6. Summary of Dietary Exposure and Risk for Flufenoxuron.

Population Subgroup	Chronic Dietary		
	cPAD (mg/kg/day)	Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.0375	0.005262	14
All Infants (< 1 yr)		0.008469	23
Children 1-2 yrs		0.023448	63
Children 3-5 yrs		0.016271	43
Children 6-12 yrs		0.008996	24
Youth 13-19 yrs		0.004562	12
Adults 20-49 yrs		0.003334	8.9
Adults 50+ yrs		0.002961	7.9
Females 13-49 yrs		0.003227	8.6

Water Exposure/Risk Pathway

As there are currently no registered or proposed domestic uses for flufenoxuron, a drinking water assessment was not conducted.

Residential (Non-Occupational) Exposure/Risk Pathway

As there are currently no registered or proposed residential uses for flufenoxuron, a residential exposure assessment was not conducted.

Occupational Exposure/Risk Pathway

As there are currently no registered or proposed domestic uses for flufenoxuron, an occupational exposure assessment was not conducted.

ADDITIONAL CONFIRMATORY DATA

A. Toxicology

1. Confirmatory data on external fetal observations from the developmental toxicity study in rat should be submitted.

B. Analytical Methods[1]

1. The proposed tolerance enforcement method for plant commodities (HPLC/UV Method SAMS 432-3) should be revised to include an alternate confirmatory analysis using LC/MS/MS, which has been shown to adequately detect and quantify flufenoxuron in BASF Method 544/0.
2. The proposed tolerance enforcement method for milk (HPLC/UV Method SAMS 486-1) should be revised to include an alternate confirmatory analysis that is distinct from the primary analytical method.
3. To support the use of Method SAMS 457-2 as an enforcement method, an ILV trial should be conducted with this method using samples of liver and muscle fortified at the method LOQ and the recommended tolerances for meat byproducts (0.8 ppm) and meat (0.2 ppm). Any proposed HPLC/UV method must also be revised to include a confirmatory analysis using an analytical method that is distinct from the primary analytical method. In addition, radiolabeled method validation data are requested for the proposed enforcement method using tissue samples from the goat metabolism study.
4. Completion of adequate Primary Method of Validation by the Analytical Chemistry Branch.

C. Repository Standard

1. The EPA National Pesticide Standards Repository has requested that additional reference standard be submitted for flufenoxuron.

D. Revised Section F

1. Based on submitted data, current commodity definitions, and protective tolerance expressions, HED-recommended tolerances for apple (0.50 ppm); grape (0.70 ppm); grape, raisin (2.0 ppm); cattle, meat (0.10 ppm); cattle, fat (4.5 ppm); cattle, meat byproducts (0.50 ppm); goat, meat (0.10 ppm); goat, fat (4.5 ppm); goat, meat byproducts (0.50 ppm); horse, meat (0.10 ppm); horse, fat (4.5 ppm); horse, meat byproducts (0.50 ppm); sheep, meat (0.10 ppm); sheep, fat (4.5 ppm); sheep, meat byproducts (0.50 ppm); milk (0.20 ppm); milk, fat (4.0 ppm); orange (0.30 ppm); orange, oil (60 ppm); and pear (0.50 ppm).

E. Additional residue data needed to support registrant requested petitioned tolerances[2]**:**

1. To support the available grape and apple processing studies, data are requested demonstrating the stability of flufenoxuron in frozen samples of

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[1] An adequate HPLC/ultraviolet (UV) method (SAMS 432-3) and liquid chromatography (LC)/mass spectrometry (MS)/MS method (BASF Method 544/0) are available for collecting data on flufenoxuron residues in/on plant commodities. Adequate HPLC/UV methods are also available for collecting data on flufenoxuron residues in milk (Method SAMS 486-1) and livestock tissues (Method SAMS 457-2).

[2] BASF originally petitioned the Agency for tolerances in or on apple at 1 parts per million (ppm), pear at 1 ppm, orange at 0.3 ppm, orange oil at 60 ppm, grape at 0.2 ppm, raisin at 0.8 ppm, meat at 0.3 ppm, cattle, meat by-products at 1.5 ppm, cattle, fat at 6 ppm, milk at 0.6 ppm, and milk, fat at 3 ppm.

juice (apple, grape or orange), wet apple pomace, raisins, dried pulp and orange oil for up to 9 months.

2. Three additional pear field trials should be conducted in Argentina (2 trials) and Chile (1 trial) using the appropriate formulation at the maximum seasonal rate being proposed for the given country. Duplicate samples of whole fruit should be collected from each trial at the minimum PHI.
3. New orange field trials are requested. Based on the amount of orange products (fresh fruit and juice) imported from each country, and the type of formulation, maximum seasonal use rate and PHI being proposed for each country, a total of 12 field trials should be conducted, with the trials being distributed between Brazil (6 trials), Spain (4 trials) and Greece (2 trials). These trials should be conducted at the maximum seasonal rate being proposed for a given country and use the appropriate formulation (e.g. EC in Brazil). Duplicate samples of whole fruit should be collected from each trial at the minimum PHI.
4. Processing data on dried pulp and finished orange oil are requested.

F. Foreign labels:

1. The most recent versions of foreign BASF flufenoxuron labels should be submitted along with English translations.

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APPENDIX I

GLOSSARY OF TERMS AND ABBREVIATIONS

ADNT	Acute delayed neurotoxicity
a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
ARI	Aggregate Risk Index
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
ChE	Cholinesterase
ChEI	Cholinesterase inhibition
cPAD	Chronic Population Adjusted Dose
%CT	Percent crop treated
DAT	Days after treatment
DEEM-FCID	Dietary Exposure Evaluation Model - Food Consumption Intake Database
DNA	Deoxyribonucleic acid
DNT	Developmental neurotoxicity
DIT	Developmental immunotoxicity
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EPA	U.S. Environmental Protection Agency
FQPA	Food Quality Protection Act
GLC	Gas Liquid Chromatography
GLN	Guideline Number
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEL	Lowest Observed Adverse Effect Level
LOAEC	Lowest Observed Adverse Effect Concentration
LOC	Level of Concern
LOD	Limit of Detection
LOQ	Limit of Quantitation
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure

MRID	Master Record Identification (number), EPA's system of recording and tracking studies submitted
MTD	Maximum tolerated dose
NA	Not Applicable
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NOAEC	No Observed Adverse Effect Concentration
NPDES	National Pollutant Discharge Elimination System
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
TGAI	Technical Grade Active Ingredient
UF	Uncertainty Factor
µg	micrograms
µg/L	Micrograms Per Liter
µL/g	Microliter per gram
USDA	United States Department of Agriculture
WPS	Worker Protection Standard

APPENDIX II

Citations Considered Part of the Data Base Supporting the Establishment of Flufenoxuron Import Tolerances.

MRID	Citation	Receipt Date
44448400	American Cyanamid Co. (1997) Submission of Product Chemistry, Toxicology and Residue Data in Support of the Petition for Tolerance of Flufenoxuron on Apples, Pears, Oranges, Grapes, Meat and Milk Products. Transmittal of 36 Studies.	09-Dec-1997
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44448402	Gorter de Vries, R.; Wong, G. (1997) Flufenoxuron: Product Identity, Description of Beginning Materials, Manufacturing Process, and Discussion and Formation of Impurities: Lab Project Number: CFS 1996-151: CHDV 36#4.1: 334. Unpublished study prepared by Cyanamid Forschung GmbH and American Cyanamid Co. 54 p. {OPPTS 830.1550, 830.1600, 830.1620, 830.1670}	09-Dec-1997
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44448406	Esdaile, D. (1987) WL115110: A 90 Day Feeding Study in Rats: Lab Project Number: SBGR.86.256: 3412. Unpublished study prepared by Shell Research Ltd. 476 p. {OPPTS 870.3100}	09-Dec-1997
44448407	Esdaile, D. (1986) WL 115110: A 28 Day Feeding Study in Rats: Lab Project Number: SBGR.86.085: 3321. Unpublished study prepared by Shell Research Ltd. 316 p. {OPPTS 870.3100}	09-Dec-1997
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44448409	Greenough, R.; Duffen, J.; Goburdhun, K. (1987) WL 115110: 13 Week Oral Toxicity Study in Dogs: Lab Project Number: IRI 635469: 3394. Unpublished study prepared by Inveresk Research International Ltd. 184 p. {OPPTS 870.3150}	09-Dec-1997

MRID	Citation	Receipt Date
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44448416	Hazelden, K.; Wilson, J.; Barton, S. (1991) WL115110: Teratogenicity Study in Rabbits and WL115110 Dose Range Finding Study in Rabbits, Preliminary to Teratogenicity Study: Lab Project Number: IRI 3757: IRI 3942: 3371. Unpublished study prepared by Inveresk Research International. 141 p. {OPPTS 870.3700}	09-Dec-1997
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44448420	Clare, M.; McEnaney, S.; Meyer, A. (1992) Flufenoxuron: WL115110 Structural Chromosomal Aberration Studies: Lab Project Number: SBGR.86.047: SBGR.86.216: SBGR.87.117. Unpublished study prepared by Hazleton UK and Shell Research Ltd. 195 p. {OPPTS 870.5300}	09-Dec-1997

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44448427	Khunachak, A.; Furr, H.; Kennedy, E. (1997) Independent Laboratory Validations of Crop Analytical Method SAMS 432-3 for All Crop Commodities: Lab Project Number: RES 97-013: CS97PT01: 579/184-1012. Unpublished study prepared by Centre Analytical Laboratories, Inc., Restec Laboratories, Ltd. and Hazleton U.K. 207 p. {OPPTS 860.1340}	09-Dec-1997
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44448432	Gill, J.; Pack, S. (1993) Flufenoxuron: Residues in Milk, Milk Products and Tissues of Dairy Cows Arising From Consumption of Diet Containing Test Compound: Lab Project Number: SBTR.92.038: SLL 171/911459: 4252. Unpublished study prepared by Shell Research Ltd., Huntingdon Research Centre Ltd. and Hazleton UK. 181 p. {OPPTS 860.1480}	09-Dec-1997
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44448434	Furr, H.; Young, H. (1997) Flufenoxuron (CL 811678): Magnitude of the Residue in Oranges: Lab Project Number: 579/175: 4253: 4251. Unpublished study prepared by Hazelton (sic) Europe and PRDL, Cyanamid Ag., Ltd. 293 p. {OPPTS 860.1500}	09-Dec-1997
44448435	Bosio, P.; Carlon, R.; Furr, H. (1993) Flufenoxuron: Magnitude of the Residue in Grapes: Lab Project Number: BEGR.89.001: BETR.91.015: BETR.92.010. Unpublished study prepared by Shell Chimie and Hazelton (sic) Europe. 219 p. {OPPTS 860.1500}	09-Dec-1997
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46482200	BASF Corp. (2005) Submission of Product Chemistry and Residue Data in Support of the Petition for Tolerance of Flufenoxuron on Apples, Pears, Oranges and Grapes. Transmittal of 15 Studies.	28-Feb-2005
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46482202	Peterson-Thiery, M. (2004) Flufenoxuron TC: Composition of the Technical Grade Active Ingredient (TGAI): Final Report. Project Number: 2004/1004227. Unpublished study prepared by BASF Aktiengesellschaft. 9 p.	28-Feb-2005
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46482207	Young, H. (1999) Flufenoxuron (AC 811678) 100 g a.s./L DC (CF 800008): Decline Curve Residue Study on Flufenoxuron in Vines (Spain 1998): Final Report. Project Number: FX/SP/98/350, FX/713/012, 4494. Unpublished study prepared by Cyanamid Agriculture, Ltd. 39 p.	28-Feb-2005
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MRID	Citation	Receipt Date
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