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U. S. ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 11/20/97

SUBJECT: **PP#4F4367 & 5F4490. HUMAN HEALTH RISK ASSESSMENT FOR
BENSULFURON METHYL IN/ON CRAYFISH AND RICE STRAW.**

DP Barcode:	D238880	Caswell No.:	359H
PRAT Case No.:	285867	Chemical No.:	128820
Submission No.:	S516270		
Trade Name:	Londax 60DF	Class:	Herbicide
EPA Reg No.:	352-325	40 CFR §180.445	
Priority:	3		

TO: Jim Tompkins PM Team 25
Herbicide Branch/RD (7505C)

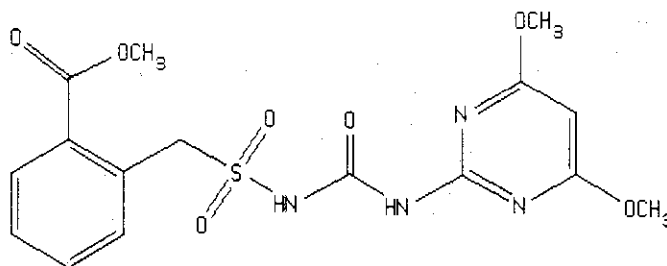
FROM: William D. Wassell, Chemist
John E. Whalan, Toxicologist
RAB2/HED (7509C)

THRU: Richard Loranger, Branch Senior Scientist
RAB2/HED (7509C)

INTRODUCTION

Tolerances are established (40 CFR §180.445) for residues of the herbicide bensulfuron methyl (methyl-2[[[[[(4,6-dimethoxy-pyrimidin-2-yl)amino]carbonyl]amino]sulfonyl]methyl]benzoate) in or on the raw agricultural commodities (RAC's) rice (grain) at 0.02 ppm and rice, straw at 0.05 ppm. The registrant, E.I. duPont de Nemours and Company, has proposed a revised tolerance for residues of bensulfuron methyl in or on rice straw at 0.3 ppm (PP#5F4490). The petitioner is proposing to modify the pre-harvest interval (PHI) for the use from 80 to 60 days. The tolerance level for rice grain is to remain unchanged. The registrant has also proposed the establishment of a tolerance for residues of bensulfuron methyl in or on crayfish at 0.05 ppm (PP#4F4367).

The chemical structure for bensulfuron methyl is as follows:



I. EXECUTIVE SUMMARY

Although bensulfuron methyl has not received a carcinogenicity classification, the HED RfD Committee found no evidence of carcinogenicity in the mouse or rat. Thus, a cancer risk assessment is not required.

Occupational and residential risk assessments were not required as no short-, intermediate-, or long-term dermal or inhalation toxicity endpoints were identified by the HAZ-ID SARC (September 11, 1997).

An acute dietary toxicological endpoint has not been identified for bensulfuron methyl. Therefore, this risk assessment is not required.

Aggregate chronic risk estimates do not exceed HED's level of concern. Based on available data, establishment of the proposed tolerance for bensulfuron methyl in/on crayfish and increasing the tolerance level for bensulfuron methyl in/on rice, straw should not pose an unacceptable aggregate risk to infants, children, or adults.

HED recommends in favor of the establishment of tolerances for residues of bensulfuron methyl in/on crayfish at 0.05 ppm and rice straw 0.3 ppm.

II. SCIENCE ASSESSMENT

A. Human Risk Assessment

1. Hazard Assessment

a. Acute Toxicity

Table 1. Summary of Acute Toxicity Data for Bensulfuron Methyl

Guideline No.	Study Type	MRIDs #	Results	Toxicity Category
81-1	Acute Oral	00148295	LD ₅₀ >5000 mg/kg	IV
81-2	Acute Dermal	40089312	LD ₅₀ >2000 mg/kg	IV
81-3	Acute Inhalation	40089313 40311905	LC ₅₀ >5 mg/L	IV
81-4	Primary Eye Irritation	00147385	Non irritant	IV
81-5	Primary Skin Irritation	unknown	Non-irritant	IV
81-6	Dermal Sensitization	4217630	Non-sensitizer	NA
81-8	Acute Neurotoxicity	--	Not required	--

b. Subchronic Toxicity

In a **90-day feeding study in rats**, groups of 16 male and 16 female CD rats were dosed with INF-5384 (95.7%, 98.5%, and 98.4% bensulfuron methyl) in their feed at doses of 0, 100, 1500, or 7500 ppm. These doses were equivalent to 0, 6.3, 93, or 474 mg/kg/day in males, and 0, 7.5, 111, or 567 mg/kg/day in females. Mild findings of neutropenia in both sexes and liver weight increases are not considered biologically significant. Biologically significant findings at the high-dose included mildly elevated cholesterol values (males only), mildly elevated kidney weights (males only) and heart weights (females only), and slight paleness of the hepatocellular cytoplasm (males only). The NOEL is 1500 ppm (93 and 111 mg/kg/day in males and females, respectively), and the LEL is 7500 ppm (474 and 567 mg/kg/day in males and females, respectively) based on the effects described above. (MRID No. 00148301)

In a **90-day feeding study in mice**, groups of 20 male and 20 female specific pathogen free ICR-JCL mice were dosed with DPX-F4384 (≥95% bensulfuron methyl) in their feed at doses of 0, 300, 1000, 3000, or 10,000 ppm. The only compound-related toxicities observed in this study were dose-related fatty deposition in the cortico-medullary junction of the adrenals in females, and an increase in liver size due to swelling of centrilobular hepatocytes in both sexes. The latter lesion was observed at all dose levels and was generally slight. The fact that there were few instances of hepatocyte degeneration or necrosis suggests that this lesion was probably a normal, reversible metabolic response to a toxic agent. The NOEL was 1000 ppm (132 and 133 mg/kg/day in males and females, respectively), and the LEL was 3000 ppm (387 and 407 mg/kg/day in males and females, respectively) based on the effects described above. (MRID No. 00147395)

In a **90-day feeding study in dogs**, groups of 4 male and 4 female beagle dogs were dosed with bensulfuron methyl in their feed at doses of 0 (vehicle control), 100, 1000, or 10,000 ppm for 90 days. There were no significant clinical signs, food consumption changes, or body weight changes at dietary doses as high as

10,000 ppm. The only clinical pathology anomalies were moderately elevated alkaline phosphatase and SGPT (ALT) levels in the high-dose males and females at the 1, 2, and 3-month sampling intervals, indicating hepatic damage. Organ weight changes included elevated weights for liver and testes, and decreased weights for heart, and ovary/fallopian tube. The only significant gross lesions were liver enlargement and discoloration, and gall bladder calculus. Microscopic lesions included gall bladder calculus, bile stasis, centrilobular hepatocyte swelling, and vacuolation of the seminiferous tubules. These lesions were seen at the 10,000 ppm dose. No microscopic lesions were found to account for the decreased ovary/fallopian tube weights; the weight changes may have been due to improper trimming prior to weighing, and are therefore not seen as a toxic effect. Also, there were no corresponding lesions to account for the mildly decreased heart weights in males. The NOEL was 1000 ppm (32.1 and 36.3 mg/kg/day for males and females, respectively), and the LEL was 10,000 ppm (340 and 360 mg/kg/day for males and females, respectively) based on the effects described above. (MRID No. 00147397)

The requirement for a **21-day dermal study** was waived. The absence of toxicity and skin irritation on abraded and intact skin in the acute dermal limit test and the primary dermal irritation studies suggests that dermal exposure poses no hazard.

c. Chronic Toxicity/Carcinogenicity

In a **chronic feeding/carcinogenicity study in rats**, groups of 80 male and 80 female CrI:CD (SD)BR rats were dosed with INF-5384 (95 and 95.9% bensulfuron methyl) in their feed at doses of 0, 50, 750, or 7500 ppm. These doses were equivalent to 0, 2.0, 30, or 309 mg/kg/day in males, and 0, 2.7, 40, or 405 mg/kg/day in females. Clinical anomalies were observed only at the 7500 ppm dose. The males had elevated blood urea nitrogen and creatinine at 24 months, and the females had decreased body weight gain in the latter part of the study as might be expected in senescent animals. Histopathologic lesions included diffuse fatty changes in male livers, and centrilobular hepatocellular hypertrophy and centrilobular hepatocyte cytoplasmic basophilia margination in both sexes. These lesions were seen at the 1-year and terminal sacrifices, but were less frequent at the terminal sacrifice. In the absence of collaborative elevated liver enzymes, these lesions are considered to be evidence of normal hepatic detoxification. There was no compound-related neoplasia found in the rats. The NOEL was 750 ppm (30 and 40 mg/kg/day in males and female, respectively), and the LEL was 7500 ppm (309 and 405 mg/kg/day in males and females, respectively) based on the effects described above. (MRID No. 40089316)

In a **chronic feeding/carcinogenicity study in mice**, groups of 92 male and 92 female specific pathogen free ICR mice (Crj:CD-1 from Charles River, Japan) were dosed with DPX-F5384 (95.9% bensulfuron methyl) in their feed at doses of 0, 10, 150, 2500, and 5000 ppm. These doses were equivalent to 0, 0.870, 13.35, 226, or 455 mg/kg/day in males, and 0, 0.928, 13.63, 227, or 460 mg/kg/day in females. Very little toxicity was observed in this study. There were no dose-related effects on mortality, clinical signs, body weights, food consumption, or food efficiency. The high-dose males and females had oligodipsia during most of the study. Elevated alkaline phosphatase, ALT, AST, and total cholesterol were indicative of hepatotoxicity. Most dose-related gross lesions were found in the high-dose mice which died or were sacrificed *in extremis*, and included enlarged livers, nodules and masses in the liver, and abdominal cavity ascites. Increased liver weights were found in the high-dose males and females. The incidence of compound-related histopathologic lesions was low, and primarily involved the liver. They included centrilobular hepatocyte swelling in males, and focal hepatocellular necrosis and increased brown pigment

deposition of stellate cells in the female livers. There was no dose-related effect on benign or malignant tumor formation. The primary target organ was the liver (based on clinical pathology, liver weights, gross pathology, and histopathology). The NOEL was 2500 ppm (226 and 227 mg/kg/day in males and female, respectively), and the LEL was 5000 ppm (455 and 460 mg/kg/day in males and females, respectively) based on the effects described above. (MRID No. 40089317)

In a **1-year toxicity study in dogs**, beagles (5/sex/dose) received diets containing bensulfuron methyl (95.9% pure) at 0, 50, 750 or 7500 ppm for 52 weeks. These doses were equivalent to 0, 1.4, 21.4 or 237.3 mg/kg/day in males and 0, 1.4, 19.9, or 222.6 mg/kg/day in females; respectively. No treatment related effects were observed on survival, clinical signs, body weight or food consumption. The target organ for bensulfuron methyl-induced toxicity was the liver as demonstrated by elevated levels of alkaline phosphatase and SGPT (ALT), increases in liver weights and brown pigment in the biliary canaliculi. Gross necropsy revealed discoloration of oral tissues, gums, and tonsils, along with corroborative histopathology (inflammation) suggest that bensulfuron methyl may have directly irritated the oral mucosa, especially both sexes of dogs at 7500 ppm. The NOEL was 750 ppm (21.4 and 19.9 mg/kg/day in males and females, respectively), and the LOEL was 7500 ppm (237.3 and 222.6 mg/kg/day in males and females, respectively) based on the effects described above. (MRID No. 40089319)

d. Developmental Toxicity

In a **developmental toxicity study in rats**, groups of 25 pregnant CrI:CD (SD) BR rats were given oral administration of bensulfuron methyl (95%) in corn oil at 0, 50, 500 or 2000 mg/kg/day during gestation days 7 through 16. Dams were sacrificed on gestation day 21. Due to sampling errors, the actual doses tested were not known, however, it appeared that the Limit-Dose of 1000 mg/kg/day was achieved at the high dose, which was analytically measured to be 1320 mg/kg/day. There was no evidence of maternal toxicity at any dose. For maternal toxicity, the NOEL was 1320 mg/kg/day (the highest dose tested). Developmental toxicity observed at the high dose manifested as statistically significant increases in skeletal variations that included extra ribs, reduced ossification of the sternbrae, and reduced ossification of the hyoid bones. For developmental toxicity, the NOEL was 500 mg/kg/day and the LOEL based on fetal skeletal alterations described above, was 1320 mg/kg/day. (MRID No. 40089318 and 40311902)

In a **developmental toxicity study in rabbits**, groups of 20 or 22 artificially inseminated New Zealand White rabbits received bensulfuron methyl (99% pure) in methyl cellulose at 0, 30, 300 or 1500 mg/kg/day via gavage during gestation days 7 through 19. Does were sacrificed on gestation day 29. Maternal toxicity at 1500 mg/kg/day was characterized as deaths (2 does), complete resorptions (2 does), abortions (1 doe), stained tail, red discharge, and reduced food consumption. Body weights were unaffected. For maternal toxicity, the NOEL was 300 mg/kg/day and the LOEL was 1500 mg/kg/day. No developmental toxicity was seen. For developmental toxicity, the NOEL was 1500 mg/kg/day, the highest dose tested. (MRID No. 40113801 and 40311906)

e. Reproductive Toxicity

In a **two-generation reproduction study**, male and female CrI:CD(SD)BR rats were fed diets containing bensulfuron methyl (95.9%) at 0, 50, 750 or 7500 ppm (approximately 0, 2, 30 or 309 mg/kg/day in males and 0, 2.7, 40 or 405 mg/kg/day in females, respectively). The parental systemic, reproductive, and

offspring NOEL was ≥ 7500 ppm (309/405 mg/kg/day in males and females, respectively). (MRID No. 40089316)

f. Mutagenicity

Table 2. Mutagenicity Studies of Bensulfuron Methyl

84-2a	Gene Mutation: Ames Assay MRID No. 40103704	Negative for <i>Salmonella</i> strains TA98, TA100, TA1535, and TA1537 with or without metabolic activation. No cytotoxicity data were presented.
84-2b	Structural Chromosome Aberration: In Vivo Bone Marrow Chromosome Study in Rats MRID No. 00147393	Negative
84-2c	Other Genotoxic Effects: Sister Chromatid Exchange in CHO Cells MRID No. 40089320	Negative

g. Metabolism

In a **rat metabolism study**, absorption of radiolabelled test article from the gut was nearly total. The major elimination routes were the urine (low-dose), and the feces (high-dose). No measurable quantities of test article or metabolites were found in respired air. Minute quantities of radioactivity ($\leq 2.1\%$) were distributed to the body tissues. Approximately half of the doses were eliminated within 24 hours (low-dose), or 48 hours (high-dose), and nearly 99% was eliminated within 96 hours. The parent compound and 6 metabolites were found in feces, and 8 metabolites were found in urine. (MRID No. 00147394)

h. Neurotoxicity

A neurotoxicity study of bensulfuron methyl is not necessary because the data base demonstrates no evidence of neurotoxicity.

i. Dermal Absorption

No dermal absorption studies are available. Based on the lack of dermal toxicity ($LD_{50} > 2000$ mg/kg) or irritation, the 21-day dermal toxicity study was waived.

j. Other Toxicological Considerations

Not applicable.

2. Dose Response Assessment

a. Special Sensitivity to Infants and Children

The prenatal developmental toxicity data demonstrated no indication of increased sensitivity of rabbits to *in utero* exposure to bensulfuron methyl. In addition, the multigeneration reproduction study data did not identify any increased sensitivity of rats to *in utero* or postnatal exposure. In both studies, the maternal LOEL was less than or equivalent to the NOEL for effects in the offspring. Minor ossification variations were observed in a developmental study in rats, but only at a dose of 1320 mg/kg/day which exceeds the limit dose of 1000 mg/kg/day as specified in Guideline §93-3a.

For chronic dietary risk assessment, the Committee determined that the 10x factor to account for enhanced sensitivity of infants and children (as required by FQPA) should be removed. The present UF of 100 (10X each for inter- and intra-species variability) is adequate to ensure protection of these population subgroups from exposure to bensulfuron methyl for reasons stated below:

- (i) There is no indication of increased sensitivity to young animals following pre- and/or post-natal exposure to bensulfuron methyl.
- (ii) There is no increased sensitivity to fetuses as compared to maternal animals following *in utero* exposures in rats and rabbits.
- (iii) There is no increased sensitivity to pups as compared to adults in a multi-generation reproduction toxicity study in rats.
- (iv) Considering the overall toxicity profile of bensulfuron methyl, it was noted that toxic effects were only observed at or near the Limit Dose with all short- and long-term studies.

b. Reference Dose (RfD)

Study Selected: Chronic Toxicity - Dog (§ 31- 1 b)

MRID No. 40089319

Executive Summary: In a 1-year toxicity study in dogs, beagles (5/sex/dose) received diets containing bensulfuron methyl at 0, 50, 750 or 7500 ppm for 52 weeks. These doses were equivalent to 0, 1.4, 21.4 or 237.3 mg/kg/day in males and 0, 1.4, 19.9, or 222.6 mg/kg/day in females, respectively. No treatment related effects were observed on survival, clinical signs, body weight or food consumption. The target organ for bensulfuron methyl-induced toxicity was the liver as demonstrated by elevated levels of alkaline phosphatase and SGPT (ALT), increases in liver weights and brown pigment in the biliary canaliculi. Gross necropsy revealed discoloration of oral tissues, gums, and tonsils, along with corroborative histopathology

(inflammation) suggest that bensulfuron methyl may have directly irritated the oral mucosa, especially both sexes of dogs at 7500 ppm.

Dose/Endpoint for establishing the RfD: NOEL = 750 ppm (21.4 and 19.9 mg/kg/day in males and females, respectively) based on the discoloration and inflammation of the oral mucosa, elevated alkaline phosphatase, SGPT (ALT), and liver weights, and brown pigment in biliary canaliculi in both sexes at 7500 ppm (LOEL; 237.3 and 222.6 mg/kg/day in males and females, respectively).

Uncertainty Factor (UF): UFs of 10 each were used to extrapolate from animals to humans, and to account for variation in sensitivity in humans. The 10x factor (required by FQPA) to account for enhanced sensitivity to infants and children has been removed.

Derivation of the RfD:

$$\frac{19.9 \text{ mg/kg/day (NOEL)}}{100 \text{ (UF)}} = 0.20 \text{ mg/kg/day}$$

Comments about Study/Endpoint/Uncertainty Factor(s): The RfD was verified by HED on April 7, 1988, and by the EPA on May 25, 1988.

c. Carcinogenic Classification and Risk Quantification

Although bensulfuron methyl has not received a carcinogenicity classification, the HED RfD Committee found no evidence of carcinogenicity in the mouse or rat. (HED RfD Committee, April 7, 1988)

d. Developmental Classification

Bensulfuron methyl is not a developmental toxicant. (Hazard ID Committee, September 11, 1997, position authored by Susan Makris)

e. Dermal Absorption

No dermal absorption studies are available. Based on the lack of dermal toxicity (LD50 >2000 mg/kg) or irritation, the 21-day dermal toxicity study was waived. Dermal absorption is not an issue since the dermal route of exposure is non-toxic. (Hazard ID Committee, September 11, 1997)

f. Other Toxicological Endpoints

i. Acute Dietary

No toxicological effects attributable to a single exposure (dose) were identified in any of the studies. Therefore, this risk assessment is not required. (Hazard ID Committee, September 11, 1997)

ii. Short and Intermediate Term Occupational and Residential (dermal and inhalation)

Short-Term Dermal: No toxicological endpoints were identified. The compound is non-toxic via the dermal route in rats with an LD₅₀ of >2000 mg/kg and is a non-irritant in rabbits. Consequently, the 21-day dermal toxicity study was waived. No toxicological effects attributable to this exposure scenario (i.e., 1-7 days) were identified in the other studies and the compound is not a developmental toxin by the oral route (i.e., the LOELs were 1320 mg/kg/day and 1500 mg/kg/day in rats and rabbits, respectively). Therefore, this risk assessment is not required. (Hazard ID Committee, September 11, 1997)

Short-Term Inhalation: Based on the LC₅₀ of >5 mg/L (limit-concentration), bensulfuron methyl is placed in Toxicity Category IV. Therefore, a separate risk assessment via this route of exposure is not required. (Hazard ID Committee, September 11, 1997)

Intermediate-Term Dermal: No appropriate endpoints were identified. The compound is non-toxic via the dermal route in rats with an LD₅₀ of >2000 mg/kg and is a non-irritant in rabbits. Consequently, the 21-day dermal toxicity study was waived. Therefore, this risk assessment is not required. (Hazard ID Committee, September 11, 1997)

Intermediate-Term Inhalation: Based on the LC₅₀ of >5 mg/L (limit-concentration), bensulfuron methyl is placed in Toxicity Category IV. Therefore, a separate risk assessment via this route of exposure is not required. (Hazard ID Committee, September 11, 1997)

iii. Chronic Occupational and Residential (Non-Cancer)

Chronic Dermal: No appropriate endpoints were identified. The compound is non-toxic via the dermal route in rats with an LD₅₀ of >2000 mg/kg and is a non-irritant in rabbits. Consequently, the 21-day dermal toxicity study was waived. Therefore, this risk assessment is not required. (Hazard ID Committee, September 11, 1997)

Chronic Inhalation: Based on the LC₅₀ of >5 mg/L (limit-concentration), bensulfuron methyl is placed in Toxicity Category IV. Therefore, a separate risk assessment via this route is not required. (Hazard ID Committee, September 11, 1997)

TABLE 2. Summary of Toxicological Endpoints for Bensulfuron Methyl

Exposure Duration	Exposure Route	Endpoint and Toxicological Effect
Acute	Dietary	Not applicable
Short-Term (1-7 days) Occupational/Residential	Dermal	Not applicable
Intermediate-Term (one week to several months) Occupational/Residential	Dermal	Not applicable
All time periods	Inhalation	Not applicable
Cancer	Dietary	No evidence of carcinogenicity
Chronic (non-cancer)	Dietary	RfD = 0.20 mg/kg/day

The Hazard I.D. SARC report (9/11/97) indicates that occupational/residential exposure risk assessments (namely, short-term dermal, intermediate-term dermal, long-term dermal, and inhalation) are not required as no appropriate endpoints were identified.

3. Dietary Exposure and Risk Assessment/Characterization

a. Dietary Exposure (Food Sources)

i. Directions for Use

Rice: Bensulfuron methyl is registered for control of pre-flood weeds, submerged weeds and weeds emerged above the water surface in rice. The petitioner has proposed a change in the pre-harvest interval (PHI) for rice (Memo, F.D. Griffith, 6/19/95, PP#7F3506, D213786) and has proposed the removal of a restriction against the farming of crayfish in flooded fields (Memo, G.F. Otakie, 3/25/96, PP#4F4367, D224418).

Bensulfuron methyl is formulated as Londax DF (EPA Reg. No. 352-325) containing 60% active ingredient. DuPont has proposed the application of Londax DF to rice, post flood, at a rate of 1 to 1.67 oz product per acre (0.6 to 1 oz ai/A) by ground or air. One application is proposed per year. The product should be applied at the 1 to 3 leaf stage. The registrant recommends for best weed control the flood should remain static for at least 7 days in 3 inches of water with 2 to 3 weeks being the preferred time.

Restrictions include do not apply through any type of irrigation system and do not rotate to crops other than rice for 120 days. The proposed PHI is 60 days. The change in PHI from 80 to 60 days is the significant change proposed in PP#7F3506.

Crayfish: PP#4F4367 proposes the removal of a restriction against the farming of crayfish in flooded rice fields. The proposed PHI for crayfish is 80 days which at the time of the proposal was equal to the PHI for rice. The petitioner has now proposed a 60 day PHI for rice. Thus, **the PHI for crayfish must be changed to 60 days. RD should ensure that this label change is made.**

ii. Nature of the Residue - Plants

The petitioner has previously presented two metabolism studies for bensulfuron methyl in/on rice (PP#5G3268 & PP#7F3506). In summary, there is some translocation of residues with the major pathway being oxidative o-dealkylation of the parent DPX-F5384 to the desmethyl metabolite ODM-DPX-F5384. The desmethyl metabolite is cleaved at the C-N bond to form sulfonamide which quickly undergoes ring closure to form homosaccharin; the end product. Hydroxylation of the 5 position of the pyrimidine ring occurs forming the metabolite HPY-DPX-F5384. This hydroxyl metabolite can also be cleaved to the sulfonamide. An alternative pathway is cleavage to the C-N bond in the parent to form the sulfonamide. One side reaction is the formation of the free acid metabolite, FA-DPX-F5384.

Due to the very low levels of total residue with the small percentage of FA-DPX-F5384 and HPY-DPX-F5384 present, these metabolites need not be regulated. TOX Branch has expressed no concerns over the low levels of residue in rice plants for the homosaccharin, sulfonamide, and desmethyl metabolites.

The nature of the residue in rice is adequately understood. The residue of concern in rice is as per 40 CFR §180.445, bensulfuron methyl.

iii. Nature of the Residue - Livestock

Ruminants: A ruminant metabolism study involving bensulfuron methyl were previously submitted (Memo, F.D. Griffith, 12/14/88, PP#7F3506, DEB# 4491). Bensulfuron methyl is quickly and almost completely metabolized either by o-dealkylation to the desmethyl metabolite DES-DPX-F5384, or hydroxylated at the 5 position on the pyrimidine ring to form HPY-DPX-F5384. The minor ruminant pathway is cleavage of the C-N bond from either metabolite to form sulfonamide with rapid ring closure to form the end product homosaccharin.

Due to the low levels and percentage of total residue, homosaccharin and sulfonamide metabolites are not residues of concern. The nature of the residue in ruminants is adequately understood. **The residues of concern in ruminants are the parent bensulfuron methyl plus its desmethyl and hydroxyl metabolites.**

Poultry: Bensulfuron methyl poultry metabolism data were submitted and reviewed with PP# 2G4102 and as part of the July 1992 6(a)(2) report. The nature of the residue in poultry is not adequately understood. However, CBTS has previously stated that this use falls under 40 CFR §180.6(a)(3) for poultry. **Thus, we conclude the nature and magnitude of the residue in poultry are not of concern for the current petitions.**

iv. Residue Analytical Methods

Rice Commodities: The petitioner has previously submitted a new residue analytical method (HPLC-UV) containing column and eluent switching to gather the magnitude of the residue crop field trial data. The method is entitled "Analytical Method for the Determination of Bensulfuron Methyl Residues in Rice Grain and Rice Straw by HPLC Using a Column and Eluent Switching System" by M. Zhou dated September 16, 1993 and coded DuPont project number AMR 2722-93 and MRID # 435809-03.

Fortification recovery data for this method have been submitted (Memo, F.D. Griffith, 6/19/95, PP#7F3506, D213786). The petitioner provided method validation data using rice grain spiked with bensulfuron methyl at 0.01 ppm (Limit of Quantification or LOQ), 0.05 ppm, and 0.25 ppm with recoveries ranging from 83 to 106% averaging $96 \pm 7\%$, $n = 12$. Validation data from rice straw spiked with bensulfuron methyl at 0.05 ppm (LOQ), 0.25 ppm, and 1 ppm had recoveries ranging from 92 to 112% averaging $100 \pm 7\%$, $n = 12$. The petitioner also provided concurrent recovery data for bensulfuron methyl fortified in rice grain at 0.02 ppm, 0.05 ppm, and 0.1 ppm with recoveries ranging from 70 to 100%, averaging $88 \pm 10\%$, $n = 8$; and in rice straw fortified at 0.05 ppm, 0.1 ppm, 0.2 ppm, and 1 ppm with recoveries ranging from 67 to 100% averaging $87 \pm 11\%$, $n = 9$. The petitioner has presented an adequately validated method to gather the magnitude of the residue data in rice grain and straw.

The petitioner has provided a new residue analytical HPLC-UV method containing column and eluent switching to gather the magnitude of the residue processed food/feed data. The method is entitled: "Analytical Method for the Determination of Bensulfuron Methyl Residues in Rice and Its Processed Fractions by HPLC Using a Column and Eluent Switching System" by M. Zhou, et. al., dated August 17, 1994 and coded DuPont project number AMR 2866-93 and MRID # 435809-04. The method for bensulfuron methyl residues in processed rice commodities is nearly identical to the rice grain and straw method.

Fortification recovery data for bensulfuron methyl from rice processed commodities by this method have been submitted (Memo, F.D. Griffith, 6/19/95, PP#7F3506, D213786). The petitioner provided method validation data using polished rice grain spiked with bensulfuron methyl at 0.008 ppm (LOQ) and 0.04 ppm, and rice bran, hulls, and dust spiked with bensulfuron methyl at 0.02 ppm (LOQ) and 0.1 ppm. Recoveries from polished rice ranged from 100 to 116% averaging $107 \pm 6\%$, $n = 8$. Validation data from rice hulls had recoveries ranging from 90 to 108% averaging $98 \pm 8\%$, $n = 8$. Recoveries from rice bran ranged from 82 to 112% averaging $101 \pm 9\%$, $n = 8$. The petitioner also provided concurrent recovery data for bensulfuron methyl fortified in rice hulls, bran, and polished rice at 0.02 and 0.1 ppm with recoveries in the same range as the validation data ranging from 80% in rice bran to 112% in polished rice, averaging $92 \pm 15\%$, $n = 10$. The petitioner has presented a new adequately validated residue analytical method to gather the magnitude of the residue data in processed rice commodities of bran, hulls, and polished rice.

Since both new methods are significant improvements over existing procedures, these methods were submitted for publication in the Pesticide Analytical Manual volume II (PAM II). The method for rice grain is Method I and the methods for rice straw, husks and the confirmatory method are designated as Methods A, B, and C, respectively. (see correspondence of F.D. Griffith, EPA to A. Marcotte, FDA, 12/22/88).

Crayfish: A method for the determination of bensulfuron methyl in crayfish has been submitted to the FDA for inclusion in PAM II (see correspondence of W.D., Wassell, EPA to M. Clower, FDA, 10/16/97).

This method is entitled: "Analytical Method for the Determination of Bensulfuron Methyl Residues in Crayfish By HPLC Using a Column and Eluent Switching System" (Dupont Study No. AMR 2981-94, MRID No. 432564-02). This method has been successfully validated by an independent laboratory as per PR Notice 88-5 (MRID No. 432622-01) and by the Agency (Memo, G.F. Otakie, 9/3/96, PP#4F4367, D228554).

v. Multiresidue Methods

Bensulfuron methyl is not recoverable via the FDA Multiresidue Methods of PAMI (Memo, F.D. Griffith, 12/14/88, PP#7F3506, DEB No 4491).

vi. Storage Stability Data

Rice: The petitioner has previously presented frozen storage stability data for bensulfuron methyl on rice. Frozen storage data at -24°C were presented for various time intervals up to 3 years showing recoveries of bensulfuron methyl at 0.1 ppm in rice ranging from 90 to 113% (Memo, F.D. Griffith, 12/14/88, PP#7F3506, DEB No 4491). The rice samples from the magnitude of residue studies were stored frozen from harvest to analysis for 10 ½ to 13 months.

RAB2 concludes storage stability of residues of bensulfuron methyl in/on rice are not an issue for this petition.

Crayfish: Data concerning the storage stability of residues of bensulfuron methyl in/on crayfish were previously submitted (MRID No. 432564-06). CBTS has concluded that bensulfuron methyl residues are stable in crayfish up to 32 months when stored frozen. Since the maximum time crayfish samples were held in frozen storage before analysis in the submitted studies was 31 months, adequate storage stability data are available.

RAB2 concludes storage stability of residues of bensulfuron methyl in/on crayfish are not an issue for this petition.

vii. Crop Field Trials

Rice: The petitioner has previously submitted data (MRID No. 435809-01) concerning the magnitude of residues of bensulfuron methyl in/on rice (Memo, F.D. Griffith, 6/19/95, PP#5F4490, D213786). These data consist of 11 residue field trials in Arkansas (4), Mississippi, Louisiana (3), Missouri, and Texas (2). These field trial data were conducted in 1993 and as such were not subject to the residue field trial guidance of 6/94. Based upon this field trial data, CBTS concluded that the registrant has presented an adequate number and geographically representative crop field trials for an amended registration of Londax on rice.

The residue field trials consisted of untreated plots and plots treated at 1x (1 oz ai/A) and 2x (2 oz ai/A) the proposed use rate. Samples of rice grain and straw were harvested at maturity with PHI's ranging from 57 to 61 days.

Bensulfuron methyl residues above the method limit of quantification (0.02 ppm) were not detected in the rice grain samples from both application rates. Residues of bensulfuron methyl on rice straw from the proposed use rate ranged from the LOQ of < 0.05 ppm (6 samples) to 0.22 ppm. From the exaggerated 2X application bensulfuron residues ranged from 0.084 ppm to 0.74 ppm (1 sample above 0.25 ppm).

CBTS previously concluded that the petitioner has presented sufficient crop field trial residue data from the 60 day PHI to show that the established 0.02 ppm bensulfuron methyl tolerance on rice grain will not be exceeded when Londax is used as directed. **Thus, the tolerance level for bensulfuron methyl in/on rice grain need not be adjusted.**

CBTS also previously concluded the submitted magnitude of residue data support a tolerances level of 0.3 ppm for bensulfuron methyl in/on rice straw. The current established tolerance level for bensulfuron methyl residues in rice straw is 0.05 ppm.

RAB2 concludes the tolerance for residues of bensulfuron methyl in rice straw should be increased to 0.3 ppm as a result of the subject petition.

viii. Processed Food/Feed

The registrant has previously submitted data (MRID No. 435809-02) pertaining to the magnitude of bensulfuron methyl residues in rice processed commodities (Memo, F.D. Griffith, 6/19/95, PP#5F4490, D213786). In this study, one field trial was conducted in Mississippi during the 1993 crop year using the Lemont rice variety. The site had 4 plots; one plot for the control rice and 3 test (treated) plots. The test plots were each treated once at rates of 1 oz ai/A (1x), at 3 oz ai/A (3x), and at 5 oz ai/A (5x) with a 57 day PHI.

At maturity, 50 pounds of the rough paddy rice were harvested for a processing study from the control, 1X, and 3X application plots. We note there was a significant reduction in yield in harvested rice from the 5X application plot. The 4 samples were shipped at ambient temperature to the Food Protein Research and Development Center at Texas A and M University for processing into polished rice, bran, and hulls. After processing, samples were retained in frozen storage up to 6 ½ months.

No bensulfuron methyl residues were detected to the limit of quantitation (LOQ) of <0.02 ppm in the commodities rough rice, rice hulls, and rice bran from the control plot and the 1X and 3X plots; and to the LOQ of < 0.008 ppm in polished rice. From the 5X application 0.007 ppm was in the rough rice. No bensulfuron methyl residues were found in the rice bran or polished rice from the 5X application. In duplicate analysis of the rice hulls, bensulfuron methyl residues were 0.031 ppm (4.4X conc) and 0.014 ppm (2X conc). CBTS notes there is a large variation in results of duplicate analysis of the rice hulls. Since we are dealing with low residue values below the LOQ and proven sample variation plus the analytical method's inability to accurately distinguish between values below the LOQ, we do not consider this to be a real concentration requiring an additional tolerance.

RAB2 concludes the petitioner has conducted an adequate bensulfuron methyl rice processing study using rice bearing detectable residues following an exaggerated application rate. Bensulfuron methyl

did not concentrate in rice bran, hulls, and polished rice. Thus, food/feed additive tolerances are not required.

ix. Meat, Milk, Poultry, Eggs

Meat, Milk: The petitioner has previously presented a combined ruminant bensulfuron methyl metabolism and feeding study (Memo, F.D. Griffith, 12/14/88, DEB No. 4491). In this study, a lactating goat was fed the equivalent of 27.5 ppm ¹⁴C- bensulfuron methyl in the feed. This represents a 500x exaggeration of the maximum theoretical dietary burden. No measurable bensulfuron methyl residues were detected in kidney, fat, and muscle samples. A liver sample contained 0.4 ppm total bensulfuron methyl residues of which the desmethyl metabolite was 0.256 ppm and the homosaccharin and sulfonamide metabolites were 0.014 ppm each.

Based on the 500X exaggeration in the feeding study and the low dietary burden, we conclude there is no reasonable expectation of finite measurable bensulfuron methyl residues being in meat and milk from the proposed use. Thus, there is no need for secondary bensulfuron methyl tolerances in meat and milk and we further conclude the use falls under 40 CFR §180.6(a)(3) for ruminants.

Poultry, Eggs: CBTS has previously stated that this use falls under 40 CFR §180.6(a)(3) for poultry. Thus, RAB2 concludes the nature and magnitude of the residue in poultry are not of concern for the current petitions.

x. Water, Fish, and Irrigated Crops

Crayfish: The petitioner has previously submitted studies (MRID No. 432564-05) concerning the magnitude of residue in crayfish after application of bensulfuron methyl (Memo, G.F. Otakie, 9/18/96, PP#4F4367, D205675). Based upon these studies, CBTS has concluded that detectable residues of bensulfuron methyl in crayfish are unlikely. CBTS has no objection to a bensulfuron methyl tolerance at twice the LOQ of the method or 0.05 ppm. This conclusion was based upon a PHI of 80 days. RAB2 concludes that a change in the PHI from 80 days to 60 days will not result in residues of bensulfuron methyl above 0.05 ppm.

RAB2 concludes a tolerance of 0.05 ppm for bensulfuron methyl in crayfish should be established as a result of the subject petition.

xi. Food Handling

Not applicable.

xii. Confined Accumulation in Rotational Crops

The petitioner has previously presented a confined rotational crop study (MRID No. 400893-36) using ¹⁴C-phenyl and ¹⁴C-pyrimidine bensulfuron methyl treated soil at a rate of 67 gram ai/acre (2.4 oz ai/A, 2.4x) then aged 120 days and planted with beets, wheat, green onions, garlic, Chinese and dwarf cabbages which were grown to maturity (Memo, P.R. Datta, 4/6/88). Total ¹⁴C-bensulfuron methyl residues in these crops harvested after 105 days were all < 0.01 ppm. Based upon this study, CBTS concluded that the nature of

the residue in rotational crops is thus the same as in rice. The study adequately supports a 120 day plant back interval.

RAB2 concludes the rotational crop restrictions contained on the Londax DF (EPA Reg. No. 352-325) label are adequate.

xiii. Field Accumulation in Rotational Crops

Not Required.

xiv. Harmonization of Tolerances

There are no established CODEX, Canadian or Mexican residue limits for bensulfuron methyl in/on rice (grain and straw) and crayfish. Thus, harmonization of the proposed tolerances with CODEX, Canada and Mexico are not an issue for these petitions.

b. Dietary Exposure (Drinking Water Source)

There is no Maximum Contaminant Level (MCL) established for residues of bensulfuron methyl in drinking water. Additionally, no Health Advisory (HA) levels have been established for residues of bensulfuron methyl in drinking water [EPA Safe Drinking Water Hotline, 1-800-426-4791, queried 10/8/97].

EFED provided Tier I estimates of environmental concentration (EEC) for bensulfuron methyl from the use on rice (B. Grim, 10/8/97, D239662). Tier I estimates are based on GENEEC and SCI-GROW model results. GENEEC is a screening model which estimates the residues potentially found in surface water for use in ecological risk assessment. As such, it provides high-end values on the concentrations of pesticides that might be found in ecologically sensitive environments due to the use of a pesticide. EFED used the SCI-GROW (Screening Concentration In GROund Water) model to estimate the EEC of bensulfuron methyl in ground water. SCI-GROW is a prototype model for estimating "worst case" ground water concentrations of pesticides. SCI-GROW is biased in that studies where the pesticide is not detected in ground water are not included in the data set. Thus, it is not expected that residues levels in ground water will exceed the SCI-GROW estimates.

With most ground water sources there are no known predictable seasonal or longer-term trends in concentration of pesticide contaminants. Therefore, only one concentration is estimated, which should be used for both acute and chronic scenarios.

EFED provided the following estimates:

Surface water EEC (GENEEC):	1.74 ppb (acute)
	1.10 ppb (chronic)
Groundwater EEC (SCI-GROW):	0.032 ppb (acute and chronic)

In addition, EFED reported the results of an aquatic monitoring study for California surface water near a rice growing area. Maximum residues were at 1.82 ppb.

c. Dietary Risk Assessment and Characterization

Tolerances are established (40 CFR 180.445) for residues of bensulfuron methyl in or on rice (grain) at 0.02 ppm and rice straw at 0.05 ppm. The petitioner has proposed to increase the tolerance for rice straw to 0.3 ppm. A tolerance of 0.05 ppm for bensulfuron methyl residues in crayfish is proposed.

i. Chronic Risk

The DRES system does not contain the commodity crayfish. DRES does contain the commodity fish, shellfish which includes crayfish as well as other shellfish. For human dietary exposure calculations, RAB2 has substituted the commodity fish, shellfish for crayfish. In conducting this chronic dietary risk assessment, HED has made very conservative assumptions: (1) 100% of all commodities having bensulfuron methyl tolerances will contain residues; (2) those residues will be at the level of the tolerance; and (3) bensulfuron methyl residues in fish, shellfish will be at the proposed tolerance level for crayfish. These assumptions will result in an overestimate of dietary exposure. Thus, in making a safety determination for this tolerance, HED is taking into account this conservative exposure assessment.

The existing tolerances (published and pending, and including the proposed tolerance for crayfish) result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the RfD:

<u>Population Subgroup:</u>	<u>TMRC</u> <u>(mg/kg/day)</u>	<u>%RfD:</u>
U.S. Population (48 States)	0.000005	<1%
Nursing Infants (<1 year old)	0.000012	<1%
Non-Nursing Infants (<1 year old)	0.000026	<1%
Children (1-6 years old)	0.000007	<1%
Children (7-12 years old)	0.000005	<1%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children. **There are no population subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. Population (48 states).**

ii. Carcinogenic Risk

A carcinogenic risk assessment is not required as there is no evidence of carcinogenicity for bensulfuron methyl in the mouse or rat or dog (Hazard I.D. SARC report, 9/11/97).

iii. Acute Dietary Risk

An acute dietary risk assessment is not required as an acute toxicological endpoint was not identified for bensulfuron methyl (Hazard I.D. SARC report, 9/11/97).

iv. Drinking Water Risk (Chronic)

Based on the chronic dietary (food) exposure and using default body weights and water consumption figures, chronic levels of concern (LOC) for bensulfuron methyl in drinking water were calculated. For chronic exposure, based on an adult body weight of 70 kg and 2 L consumption of water per day, RAB2's level of concern from chronic exposure in drinking water is 7000 ppb. For children (10 kg and consuming 1 L water/day) our level of concern for drinking water is 2000 ppb.

Because all GENECC and SCI-GROW estimates for bensulfuron methyl were less than 2 ppb, potential residues in drinking water are not greater than HED's level of concern.

d. Statement of the adequacy of the dietary exposure data base to assess infants' and children's exposure

The dietary (food and water) exposure data base for bensulfuron methyl is adequate to assess infants' and children's exposure.

4. Occupational and Residential Exposure and Risk Assessment/Characterization

The Hazard I.D. SARC report (9/11/97) indicates that occupational/residential exposure risk assessments (namely, short-term dermal, intermediate-term dermal, long-term dermal, and inhalation) are not required as no appropriate endpoints were identified.

5. Aggregate Exposure and Risk Assessment/Characterization

a. Acute Aggregate Exposure and Risk

An acute risk assessment is not required as an appropriate endpoint was not identified for bensulfuron methyl. (Hazard ID Committee, September 11, 1997)

b. Short-term Aggregate Exposure and Risk

The Hazard I.D. SARC report (9/11/97) indicates that a short-term risk assessment is not required as no appropriate endpoints were identified.

c. Intermediate-term Aggregate Exposure and Risk

The Hazard I.D. SARC report (9/11/97) indicates that an intermediate-term risk assessment is not required as no appropriate endpoints were identified.

d. Chronic Aggregate Exposure and Risk

For the US population, <1% of the RfD is occupied by dietary (food) exposure. As noted above, potential chronic exposure from drinking water is at a level well below HED's level of concern. Because bensulfuron methyl is currently registered for use on food/feed crops only, no chronic residential exposure is anticipated.

RAB2 concludes chronic aggregate exposure to bensulfuron methyl is below our level of concern.

6. Other Food Quality Protection Act Considerations

a. Cumulative Risk

Bensulfuron methyl is a member of the sulfonylurea class of herbicides. Other members of this class include ethametsulfuron methyl, chlorimuron ethyl, thifensulfuron methyl, sulfometuron methyl, halosulfuron, metsulfuron methyl, prosulfuron, primisulfuron methyl, triasulfuron, chlorsulfuron, rimsulfuron, nicosulfuron, CGA-277476, and triflusulfuron-methyl (personal knowledge).

Section 408(b)(2)(D)(v) of the Food Quality Protection Act of 1996 requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity". The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical-specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether bensulfuron methyl has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that bensulfuron methyl has a common mechanism of toxicity with other substances.

b. Endocrine disruption

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

c. Determination of Safety (U.S. Population, Infants, and Children)

The chronic risk assessment (food only) assumed 100% crop- treated and tolerance level residues on all treated crops consumed, resulting in a significant over-estimate of dietary exposure. HED has concluded that the percentage of the RfD that will be utilized by chronic dietary (food only) exposure to residues of bensulfuron methyl is <1% for the U.S. Population, infants (nursing and non-nursing) and children (1 - 6 and 7 - 12 years old). We note that based upon conservative modeling results (GENEEC and SCI-GROW), potential residue estimates for bensulfuron methyl in drinking water do not exceed HED's level of concern. Despite the potential for exposure to bensulfuron methyl in drinking water, HED does not expect the chronic aggregate exposure to exceed 100% of the RfD. Since there are no residential uses of bensulfuron methyl, no chronic residential exposure is anticipated. RAB2 concludes that there is a reasonable certainty that no harm will result to infants and children from chronic aggregate exposure to bensulfuron methyl regulable residues.

7. Data requirements - all disciplines

There are no outstanding data requirements that would preclude the establishment of a tolerance for residues of bensulfuron methyl in/on crayfish or a revised tolerance for residues of bensulfuron methyl in/on rice, straw.

Attachments (1): Chronic DRES Analyses (W.D. Cutchin, 9/17/97).

cc with Attachments: W.D. Wassell, J. Whalan, RAB2, PP#4F4367, PP#5F4490, DRES (B. Steinwand), B. Grim (EFED, 7507C).

cc without Attachments: Caswell File.

RDI: RAB2: 11/19/97.

Disk: WDW-9, File: Bensulfuron.4

Attachment 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 359H

DATE: 09/17/97

PAGE:

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SK 9/18/97

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Bensulfuron methyl (Londax) Caswell #359H CAS No. 83055-99-6 A.I. CODE: 128820 CFR No. 180.445	1yr feeding- dog NOEL= 19.9000 mg/kg 750.00 ppm LEL= 223.0000 mg/kg 7500.00 ppm ONCO: Negative- 2 species.	Discoloration & inflammation of oral mucosa; elev. alkaline phosphatase, SGPT, & liver wts.; brown pigment in biliary canaliculi.	ADI UF -->100 OPP RfD= 0.200000 EPA RfD= 0.200000	No data gaps. No evidence of carcinogenicity in rats or mice. [Syn. DPX-F5384]	HED reviewed 08/03/86 EPA verified 09/02/86 HED reassess 04/07/88 EPA verified 05/25/88 On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)		
			NEW	PENDING	PUBLISHED
24004AA	RICE-ROUGH	7F3506			0.020000
24004AB	RICE-MILLED	7F3506			0.020000
53013AA	FISH-SHELLFISH	4F4367	0.050000		

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 09/17/97

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CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
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POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES	
	CURRENT TMRC*	NEW TMRC**			ARC	%RFD
U.S. POPULATION - 48 STATES	0.000003	0.000005	0.002443	0.000860		
U.S. POPULATION - SPRING SEASON	0.000003	0.000005	0.002326	0.000834		
U.S. POPULATION - SUMMER SEASON	0.000003	0.000005	0.002593	0.000956		
U.S. POPULATION - FALL SEASON	0.000003	0.000005	0.002510	0.000858		
U.S. POPULATION - WINTER SEASON	0.000003	0.000005	0.002346	0.000794		
NORTHEAST REGION	0.000004	0.000007	0.003318	0.001301		
NORTH CENTRAL REGION	0.000002	0.000003	0.001550	0.000473		
SOUTHERN REGION	0.000003	0.000005	0.002392	0.000792		
WESTERN REGION	0.000003	0.000005	0.002663	0.000951		
HISPANICS	0.000008	0.000009	0.004386	0.000303		
NON-HISPANIC WHITES	0.000002	0.000004	0.002092	0.000942		
NON-HISPANIC BLACKS	0.000005	0.000006	0.003060	0.000572		
NON-HISPANIC OTHERS	0.000016	0.000018	0.008900	0.001066		
NURSING INFANTS (< 1 YEAR OLD)	0.000012	0.000012	0.006208	0.000084		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000026	0.000026	0.013227	0.000007		
FEMALES (13+ YEARS, PREGNANT)	0.000002	0.000004	0.002244	0.001112		
FEMALES 13+ YEARS, NURSING	0.000003	0.000005	0.002318	0.001020		
CHILDREN (1-6 YEARS OLD)	0.000006	0.000007	0.003708	0.000517		
CHILDREN (7-12 YEARS OLD)	0.000004	0.000005	0.002631	0.000598		
MALES (13-19 YEARS OLD)	0.000003	0.000004	0.001840	0.000530		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000002	0.000004	0.001881	0.000722		
MALES (20 YEARS AND OLDER)	0.000003	0.000005	0.002426	0.001029		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000002	0.000004	0.001941	0.001015		

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

TOLERANCE ASSESSMENT SUMMARY FOR Bensulfuron methyl (Londax) DATE: 09/17/97
 CASWELL #359H

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.000004	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	0.002	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000002	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.001	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.000005	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	0.002	% OF THE ADI.

NO OTHER PENDING TOLERANCES ARE IN THE FILE

ANALYSIS FOR POPULATION SUB-GROUP: NURSING INFANTS (< 1 YEAR OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.000013	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	0.006	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	<0.000001	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.000	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.000013	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	0.006	% OF THE ADI.

NO OTHER PENDING TOLERANCES ARE IN THE FILE

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.000027	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	0.013	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	<0.000001	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.000	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.000027	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	0.013	% OF THE ADI.

NO OTHER PENDING TOLERANCES ARE IN THE FILE



13544

R061270

Chemical: Bensulfuron

PC Code: 128820

HED File Code 14000 Risk Reviews

Memo Date: 11/20/97 12:00:00 AM

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Accession Number: 412-04-0143

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