

US EPA ARCHIVE DOCUMENT



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

APR 16 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: Tolerance Assessment Analysis on the Chemical
Bifenthrin. (New Chemical).

To: George LaRocca PM# 15
Registration Division

From: Charles Frick *e. Frick 4/15/87*
Tolerance Assessment Program
Hazard Evaluation Division *DSD 4/15/87*

Thru: Charles L. Trichilo, Ph.D.
Chief, Residue Chemistry Branch
Hazard Evaluation Division

Please find attached the Tolerance Assessment System (TAS) tolerance assessment for Bifenthrin, which was conducted on request from Dr. Reto Engler, Toxicology Branch, HED. This is in compliance with the recent policy established in HED that TAS will be used for all Registration Standards, Special Reviews, and tolerances on new chemicals.

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TOLERANCE ASSESSMENT

CHEMICAL: BIFENTHRIN

1. The reference dose for this chemical is 0.0075 mg/kg/day (PADI). This value has not been approved by the Toxicology Branch or Agency Reference Dose Committees.

2. The food uses evaluated by the Tolerance Assessment System (TAS) are proposed tolerances; no tolerances have been established for this chemical (A list of these proposed tolerances is appended). The TAS program notes that RCB has not completed its review of these tolerances, therefore, the acceptability of the proposed tolerance values has not been established.

3. A comparison of these proposed tolerances to the PADI was conducted using the TAS Routine Chronic Analysis. The TAS analysis estimated the potential dietary exposures for the U.S. population average and for 22 subgroups (A summary table is appended). The Theoretical Maximum Residue Contribution (TMRC) for the U.S. population is 0.003 mg/kg/day, which occupies 40% of the PADI.

The three highest calculated exposures were for non-nursing infants (0.0274 mg/kg/day, 366% of the PADI), nursing infants (0.0193 mg/kg/day, 258% of the PADI) and children 1-6 years of age (0.0091 mg/kg/day, 122% of the PADI).

4. The majority of the TMRC was contributed by fresh apples and juice.

5. An assessment of the oncogenic risk follows on the next page.

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QUANTITATIVE RISK ASSESSMENT (ONCOGENICITY)

1. The chemical Bifenthrin has been classified as a C (q) oncogen by a peer review committee. A potency estimate Q^* of Bifenthrin has been calculated as 5.4×10^{-2} (mg/kg/day)⁻¹. This calculation is based on male mouse urinary bladder tumors (Leiomyosarcomas).

2. The following risk assessment is based on the above Q^* value and the TMRCs generated by the TAS analysis of the proposed tolerances for Bifenthrin.

$$\begin{aligned} \text{RISK} &= \text{EXPOSURE} \times Q^* \\ \text{RISK} &= \text{TMRC} \times 5.4 \times 10^{-2} \end{aligned}$$

Population Group: U.S. POPULATION AVERAGE

$$\begin{aligned} \text{RISK} &= 0.0030 \times 5.4 \times 10^{-2} \\ &= 0.00016 \\ &= 1.6 \times 10^{-4} \end{aligned}$$

Population Group: NON-NURSING INFANTS

$$\begin{aligned} \text{RISK} &= 0.0274 \times 5.4 \times 10^{-2} \\ &= 0.00148 \\ &= 1.5 \times 10^{-3} \end{aligned}$$

Population Group: NURSING INFANTS

$$\begin{aligned} \text{RISK} &= 0.0193 \times 5.4 \times 10^{-2} \\ &= 0.00104 \\ &= 1.0 \times 10^{-3} \end{aligned}$$

Population Group CHILDREN 1-6 YEARS

$$\begin{aligned} \text{RISK} &= 0.0091 \times 5.4 \times 10^{-2} \\ &= 0.00049 \\ &= 4.9 \times 10^{-4} \end{aligned}$$

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cc. TAS File
Reading File
C. Frick (RCB)
R. Engler (TOX)
S. Rathman (TOX)
B. Backus (TOX)
Circ.
PMSD
Bifenthrin SF

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ROUTINE CHRONIC ANALYSIS: ALL STATISTICS BASED ON INDIVIDUALS' 3-DAY AVERAGE CONSUMPTION 13:11 TUESDAY, APRIL 14, 1987 1

 *NAME: BIFENTHRIN
 *CASWELL NO: 463F CFR NO: CFR NOEL SF STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO. *
 *CAS NO: B 0.0075 100 1 Year Dog *****
 *STATUS CODES: C
 *RDV INFO: The ADI value used in this analysis is 0.0075 MG/KG OF BODY WEIGHT/DAY (Study A - Provisional) *
 *FILE INFO: NEW ACTION: No User Modifications APPROVED>Data NOT Used PUBLISHED: Data Used *

SUMMARY BY POPULATION SUBGROUP

	TOTAL TMRC ADJUSTED FOR BODY WEIGHT			EFFECT OF NEW ACTION		
(MG/KG BODY WEIGHT/DAY)	PRIOR TMRC (EXCLUDES NEW ACTION)	NEW TMRC (INCLUDES NEW ACTION)	DIFFERENCE (NEW TMRC- PRIOR TMRC)	DIFFERENCE AS PERCENT OF RDV	DIFFERENCE AS PERCENT OF RDV	DIFFERENCE AS PERCENT OF PRIOR TMRC
U.S. POP.--48 STATES--ALL SEASONS	0.000000	0.003011	40.143	0.003011	40.143	
U.S. POPULATION--SPRING SEASON	0.000000	0.002626	35.018	0.002626	35.018	
U.S. POPULATION--SUMMER SEASON	0.000000	0.002884	38.455	0.002884	38.455	
U.S. POPULATION--FALL SEASON	0.000000	0.003286	43.808	0.003286	43.808	
U.S. POPULATION--WINTER SEASON	0.000000	0.003248	43.310	0.003248	43.310	
NORTHEAST REGION	0.000000	0.003586	47.807	0.003586	47.807	
NORTH CENTRAL REGION	0.000000	0.002863	38.176	0.002863	38.176	
SOUTHERN REGION	0.000000	0.002388	31.840	0.002388	31.840	
WESTERN REGION	0.000000	0.003532	47.098	0.003532	47.098	
HISPANICS	0.000000	0.003343	44.573	0.003343	44.573	
NON-HISPANIC WHITES	0.000000	0.003108	41.443	0.003108	41.443	
NON-HISPANIC BLACKS	0.000000	0.002202	29.365	0.002202	29.365	
NON HISPANICS OTHER THAN BLACKS & WHITES	0.000000	0.003207	42.759	0.003207	42.759	
NURSING INFANTS (<1 YEAR OLD)	0.000000	0.019344	257.919	0.019344	257.919	
NON-NURSING INFANTS (<1 YEAR OLD)	0.000000	0.027428	365.704	0.027428	365.704	
FEMALES(13+, PREGNANT, NOT NURSING)	0.000000	0.001917	25.560	0.001917	25.560	
FEMALES(13+, NURSING)	0.000000	0.002470	32.927	0.002470	32.927	
CHILDREN(1-6 YRS)	0.000000	0.009117	121.566	0.009117	121.566	
CHILDREN(7-12 YRS)	0.000000	0.004220	56.267	0.004220	56.267	
MALES(13-19 YRS)	0.000000	0.002107	28.090	0.002107	28.090	
FEMALES(13-19 YRS, NOT PREG. OR NURSING)	0.000000	0.002000	26.673	0.002000	26.673	
MALES(20+ YRS)	0.000000	0.001562	20.820	0.001562	20.820	
FEMALES(20+ YRS, NOT PREG. OR NURSING)	0.000000	0.001664	22.181	0.001664	22.181	

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CASWELL NO.: 463F NAME: BIFENTHRIN
CFR NO.: CFR180. CAS NO.:
SHAUGHNESSY NO.:
OTHER NAMES:

STATUS CODES: RPAR:
RS:
IBT:
STATUS1:
STATUS2:
COMMENTS:

PESTICIDE TYPES	USAGE PATTERNS	STUDY A	STUDY B	STUDY C
INSECTICIDE:	TERRESTRIAL-FOOD:	1 YEAR		
FUNGICIDE:	NON-FOOD:	DOG		
HERBICIDE:	AQUATIC-FOOD:			
RODENTICIDE:	NON-FOOD:			
BIOLOGICAL:	GREENHOUSE-FOOD:	0.750		
PHEROMONE:	NON-FOOD:			
GROWTH REG.:	FORESTRY:			
BACTERIOCIDE:	DOMESTIC-OUTDOOR:	SF OR MODEL NO.: 100		
FUMIGANT:	INDOOR:	RDV(MG/KG/DAY): 0.0075		
ACARICIDE:		EFFECT LEVEL:		
OTHER:		CORE GRADE:		
		DOCUMENT NO.:		

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 *NAME: BIFENTHRIN
 *CASSELL NO: 463F
 *CAS NO:
 *STATUS CODES:

 *CFR NO: CFR
 *SHAUGHNESSY NO:

 STUDY A 0.0075
 B
 C
 SF 100
 MOEL
 RDV
 0.0075
 STUDY TYPE
 1 Year
 SPECIES
 Dog
 EFF. LEV.
 CORE GRADE
 DOC. NO.

LISTING OF NEW ACTION FOODS

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TOXICOLOGY BRANCH DECISION

CODE: A=APPROVED
 D=DISAPPROVED
 P=PENDING

FOOD DESCRIPTION	FOOD CODE	NEW ACTION TOLERANCE DATA VALUE (PPM)	TYPE	EXP. DATE
BEEF (BONELESS)-LEAN (W/O REMOVEABLE FAT)	53001MA	0.1000		
GOAT-MEAT BYPRODUCTS	53002BA	0.1000		
GOAT (ORGAN MEATS)-OTHER	53002BB	0.1000		
GOAT (BONELESS)-FAT	53002FA	0.1000		
GOAT (ORGAN MEATS)-KIDNEY	53002KA	0.1000		
GOAT (ORGAN MEATS)-LIVER	53002LA	0.1000		
GOAT (BONELESS)-LEAN (W/O REMOVEABLE FAT)	53002MA	0.1000		
HORSE	53003AA	0.1000		
RABBIT	53004AA	0.1000		
SHEEP-MEAT BYPRODUCTS	53005BA	0.1000		
SHEEP (ORGAN MEATS)-OTHER	53005BB	0.1000		
SHEEP (BONELESS)-FAT	53005FA	0.1000		
SHEEP (ORGAN MEATS)-KIDNEY	53005KA	0.1000		
SHEEP (ORGAN MEATS)-LIVER	53005LA	0.1000		
SHEEP (BONELESS)-LEAN (W/O REMOVEABLE FAT)	53005MA	0.1000		
PORK-MEAT BYPRODUCTS	53006BA	0.1000		
PORK (ORGAN MEATS)-OTHER	53006BB	0.1000		
PORK (BONELESS)-FAT (INCLUDING LARD)	53006FA	0.1000		
PORK (ORGAN MEATS)-KIDNEY	53006KA	0.1000		
PORK (ORGAN MEATS)-LIVER	53006LA	0.1000		
PORK (BONELESS)-LEAN (W/O REMOVEABLE FAT)	53006MA	0.1000		

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 *NAME: BIFENTHRIN
 *CASWELL NO: 463F
 *CAS NO:
 *STATUS CODES:

STUDY NO: A 0.0075
 SF 100
 NOEL
 RDV
 SPECIES EFF. LEV. CORE GRADE DOC. NO.
 Dog

SHAUGHNESSY NO: B
 C

LISTING OF NEW ACTION FOODS
 =====
 TOXICOLOGY BRANCH DECISION
 CODE: A=APPROVED
 D=DISAPPROVED
 P=PENDING

FOOD DESCRIPTION	FOOD CODE	NEW ACTION TOLERANCE DATA VALUE (PPM)	STUDY TYPE	TYPE	EXP. DATE
STRAWBERRIES	01016AA	1.0000	1 Year	Dog	
PECANS	03008AA	0.0500			
WALNUTS	03009AA	0.0500			
APPLES-FRESH	04001AA	2.5000			
APPLES-DRIED	04001DA	2.5000			
APPLES-JUICE	04001JA	2.5000			
PEARS-FRESH	04003AA	1.0000			
PEARS-DRIED	04003DA	1.0000			
PEACHES-FRESH	05004AA	2.0000			
PEACHES-DRIED	05004DA	2.0000			
COTTONSEED-OIL	27003OA	0.5000			
COTTONSEED-MEAL	27003MA	0.5000			
MILK-NON-FAT SOLIDS	50000OB	0.0200			
MILK-FAT SOLIDS	50000FA	0.0200			
MILK SUGAR (LACTOSE)	50000SA	0.0200			
BEEF-MEAT BYPRODUCTS	53001BA	0.1000			
BEEF(ORGAN MEATS)-OTHER	53001BB	0.1000			
BEEF-DRIED	53001DA	0.1000			
BEEF(BONELESS)-FAT (BEEF TALLOW)	53001FA	0.1000			
BEEF(ORGAN MEATS)-KIDNEY	53001KA	0.1000			
BEEF(ORGAN MEATS)-LIVER	53001LA	0.1000			