



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 *DS 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

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

*NAME: BIFENTHRIN

*CASWELL NO: 463F

*CAS NO:

*STATUS CODES:

*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

STUDY A 0.0075 NOEL SF STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO. *

RDV B 100 1 Year Dog *

C *

SUMMARY BY POPULATION SUBGROUP

	TOTAL TMRC ADJUSTED FOR BODY WEIGHT			EFFECT OF NEW ACTION		
	PRIOR TMRC (EXCLUDES NEW ACTION)	NEW TMRC (INCLUDES NEW ACTION)	NEW TMRC AS PERCENT OF RDV	DIFFERENCE (NEW TMRC- PRIOR TMRC)	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:	STUDY TYPE:		
FUNGICIDE:	NON-FOOD:	SPECIES:	1 YEAR	
NEMATOCIDE:	AQUATIC-FOOD:	DATE(M/D/Y):	DOG	
HERBICIDE:	NON-FOOD:	MOEL OR Q*(PPM):		
RODENTICIDE:	GREENHOUSE-FOOD:	MOEL(MG/KG):	0.750	
BIOLOGICAL:	NON-FOOD:	LEL:		
PHEROMONE:	FORESTRY:	SF OR MODEL NO.:	100	
GROWTH REG.:	DOMESTIC-OUTDOOR:	RDV(MG/KG/DAY):	0.0075	
BACTERIOCIDE:	INDOOR:	PROVISIONAL RDV:YES		
FUMIGANT:		EFFECT LEVEL:		
ACARICIDE:		CORE GRADE:		
OTHER:		DOCUMENT NO.:		

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LISTING OF TOLERANCE INFORMATION FOR SELECTED CHEMICAL

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

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

FOOD CODE	DESCRIPTION	: TOLERANCE :			: TOLERANCE VALUE (PPM) & TYPE :		
		: TYPE CHECK :	: EXPIRATION DATES :	: PETITION :	: PUBLISHED APPROVED :	: NEW :	: DATE :
01016AA	STRAWBERRIES	:	:	:	:	1.0000	:
03008AA	PECANS	:	:	:	:	0.0500	:
03009AA	WALNUTS	:	:	:	:	0.0500	:
04001AA	APPLES-FRESH	:	:	:	:	2.5000	:
04001DA	APPLES-DRIED	:	:	:	:	2.5000	:
04001JA	APPLES-JUICE	:	:	:	:	2.5000	:
04003AA	PEARS-FRESH	:	:	:	:	1.0000	:
04003DA	PEARS-DRIED	:	:	:	:	1.0000	:
05004AA	PEACHES-FRESH	:	:	:	:	2.0000	:
05004DA	PEACHES-DRIED	:	:	:	:	2.0000	:
270030A	COTTONSEED-OIL	:	:	:	:	0.5000	:
27003WA	COTTONSEED-NEAL	:	:	:	:	0.5000	:
500000B	MILK-NON-FAT SOLIDS	:	:	:	:	0.0200	:
50000FA	MILK-FAT SOLIDS	:	:	:	:	0.0200	:
50000SA	MILK SUGAR (LACTOSE)	:	:	:	:	0.1000	:
53001BA	BEEF-MEAT BYPRODUCTS	:	:	:	:	0.1000	:
53001BB	BEEF(ORGAN MEATS)-OTHER	:	:	:	:	0.1000	:
53001DA	BEEF-DRIED	:	:	:	:	0.1000	:
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	:	:	:	:	0.1000	:
53001KA	BEEF(ORGAN MEATS)-KIDNEY	:	:	:	:	0.1000	:
53001LA	BEEF(ORGAN MEATS)-LIVER	:	:	:	:	0.1000	:
53001MA	BEEF(BONELESS)-LEAN (U/O REMOVEABLE FAT)	:	:	:	:	0.1000	:
53002BA	GOAT-MEAT BYPRODUCTS	:	:	:	:	0.1000	:
53002BB	GOAT(ORGAN MEATS)-OTHER	:	:	:	:	0.1000	:
53002FA	GOAT(BONELESS)-FAT	:	:	:	:	0.1000	:
53002KA	GOAT(ORGAN MEATS)-KIDNEY	:	:	:	:	0.1000	:
53002LA	GOAT(ORGAN MEATS)-LIVER	:	:	:	:	0.1000	:
53002MA	GOAT(BONELESS)-LEAN (U/O REMOVEABLE FAT)	:	:	:	:	0.1000	:
53003AA	HORSE	:	:	:	:	0.1000	:
53004AA	RABBIT	:	:	:	:	0.1000	:
53005BA	SHEEP-MEAT BYPRODUCTS	:	:	:	:	0.1000	:
53005BB	SHEEP(ORGAN MEATS)-OTHER	:	:	:	:	0.1000	:
53005FA	SHEEP(BONELESS)-FAT	:	:	:	:	0.1000	:
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	:	:	:	:	0.1000	:
53005LA	SHEEP(ORGAN MEATS)-LIVER	:	:	:	:	0.1000	:
53005MA	SHEEP(BONELESS)-LEAN (U/O REMOVEABLE FAT)	:	:	:	:	0.1000	:
53006BA	PORK-MEAT BYPRODUCTS	:	:	:	:	0.1000	:
53006BB	PORK(ORGAN MEATS)-OTHER	:	:	:	:	0.1000	:
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	:	:	:	:	0.1000	:
53006KA	PORK(ORGAN MEATS)-KIDNEY	:	:	:	:	0.1000	:
53006LA	PORK(ORGAN MEATS)-LIVER	:	:	:	:	0.1000	:
53006MA	PORK(BONELESS)-LEAN (U/O REMOVEABLE FAT)	:	:	:	:	0.1000	:

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*NAME: BIFENTHRIN
*CASSELL NO: 463F
*CAS NO: 59400-51-6
*STATUS CODES: C

CFR NO: 463F
SHAUGHNESSY NO: C

STUDY A 0.0075
RDV NOEL
SF 100
STUDY TYPE 1 Year
SPECIES Dog
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: CFR NO: CFR
 *STATUS CODES: SHAUGHNESSY NO: B

LISTING OF NEW ACTION FOODS

TOXICOLOGY BRANCH DECISION
 CODE: A=APPROVED
 D=DISAPPROVED
 P=PENDING

FOOD DESCRIPTION	FOOD CODE	NOEL	RDV	STUDY	SF	STUDY TYPE	SPECIES	EFF. LEV.	CORE GRADE	DOC. NO.
STRAWBERRIES	01016AA			A	100	1 Year	Dog			*
PECANS	03008AA									*
WALNUTS	03009AA									*
APPLES-FRESH	04001AA									*
APPLES-DRIED	04001DA									*
APPLES-JUICE	04001JA									*
PEARS-FRESH	04003AA									*
PEARS-DRIED	04003DA									*
PEACHES-FRESH	05004AA									*
PEACHES-DRIED	05004DA									*
COTTONSEED-OIL	27003OA									*
COTTONSEED-MEAL	27003MA									*
MILK-NON-FAT SOLIDS	50000OB									*
MILK-FAT SOLIDS	50000FA									*
MILK SUGAR (LACTOSE)	50000SA									*
BEEF-MEAT BYPRODUCTS	53001BA									*
BEEF(ORGAN MEATS)-OTHER	53001BB									*
BEEF-DRIED	53001DA									*
BEEF(BONELESS)-FAT (BEEF TALLOW)	53001FA									*
BEEF(ORGAN MEATS)-KIDNEY	53001KA									*
BEEF(ORGAN MEATS)-LIVER	53001LA									*

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