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

MAY - 1 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Chlorethoxyfos in/on
Corn. PP# 3F4174.

FROM: Brian Steinwand *BS*
Dietary Risk Evaluation Section
Science Analysis Branch/HED (7509C)

Through: Elizabeth Doyle, Section Head *Elizabeth A. Doyle*
Dietary Risk Evaluation Section
SAB/Health Effects Division *W. Brown*

TO: D. Edwards/R. Kumar, PM Team 12
Registration Division (7505C)

Action Requested

Provide a dietary exposure analysis for the use of chlorethoxyfos in/on corn. The petition requests that a tolerance of 0.01 ppm be established on corn. CBTS recommends against this proposed tolerance due to outstanding data deficiencies as listed in the memo of J. Stokes (1/10/94). CBTS however, recommends that a DRES run be conducted regardless.

Discussion

Chlorethoxyfos is a new chemical and this petition represents the first food use.

Toxicological Endpoint:

The Reference Dose (RfD) used in the analysis is 0.0006 mg/kg bwt/day, based on a NOEL of .0610 mg/kg bwt/day from one year, 90-day and 6-month dog feeding studies with an uncertainty factor of 100 that demonstrated brain ChE inhibition in females (See memo, G. Ghali, 3/9/95). The RfD has been approved by the HED RfD committee (11/3/94), but has not been reviewed by the joint Committee meeting of the WHO/FAO. Chlorethoxyfos is classified as a Group D carcinogen, not classifiable as to human carcinogenicity, because of the inadequacy of evidence (See memo, G; Ghali, 3/9/95).



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Residue Information

As a new chemical, tolerances for chlorethoxyfos have yet to be published in the CFR. Tolerance level residues and 100 percent crop treated assumptions were made for the proposed commodities. Anticipated residues and percent crop treated information were not available for this analysis.

Results

A summary of the residue information considered in this analysis is attached as Table 1. A DRES chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. Summaries of the TMRCs and their representations as percentages of the Reference Dose (RfD) are included as Table 2 and 3.

Chronic Exposure Analysis

Exposure from Existing Tolerances for chlorethoxyfos:

<u>Subgroup</u>	<u>Exposure (mg/kg/day)</u>	<u>%RfD</u>
U.S. Population	0.000000	0.0
Children (1-6 years old)	0.000000	0.0

Proposed new Tolerances on corn:

U.S. Population	0.000006	1.0
Children (1-6 years old)	0.000015	2.4

If the new tolerances on corn are approved:

U.S. Population	0.000006	1.0
Children (1-6 years old)	0.000015	2.4

Conclusions

The chronic analysis for chlorethoxyfos is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with chlorethoxyfos. Even without refinements, the chronic dietary risk exposure to chlorethoxyfos appears to be minimal for this petition on corn at 0.01 ppm and does not exceed the RfD for any of the DRES subgroups.

Attachments

cc: DRES; Caswell 663P; RCAB; CBTS (J. Stokes); Tox I

* List commodities

TABLE 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Chlorethoxyfos (Fortress) Caswell #663P CAS No. 54593-83-8 A.I. CODE: 129006 CFR No.	Feeding studies- dog NOEL= 0.0610 mg/kg 2.00 ppm LEL= 0.1860 mg/kg 5.00 ppm ONCO: Under review.	Female brain ChE inhibit- ion. NOEL/LEL derived from the 1-Year, 90-Day & 6-Month dog studies.	ADI UF -->100 OPP RfD= 0.000600 EPA RfD= 0.000600	No data gaps.	RfD/PR reviewed 11/03/94

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			NEW	PUBLISHED
15004AA	CORN, POP	3F4174	0.010000	
15005AA	CORN, SWEET	3F4174	0.010000	
24002EA	CORN, GRAIN-ENDOSPERM	3F4174	0.010000	
24002HA	CORN, GRAIN-BRAN	3F4174	0.010000	
24002SA	CORN SUGAR	3F4174	0.010000	
270020A	CORN, GRAIN-OIL	3F4174	0.010000	

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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	0.000000	0.000006	0.962333	0.962333		
U.S. POPULATION - SPRING SEASON	0.000000	0.000005	0.905667	0.905667		
U.S. POPULATION - SUMMER SEASON	0.000000	0.000006	1.036000	1.036000		
U.S. POPULATION - FALL SEASON	0.000000	0.000006	0.963833	0.963833		
U.S. POPULATION - WINTER SEASON	0.000000	0.000006	0.944667	0.944667		
NORTHEAST REGION	0.000000	0.000005	0.766667	0.766667		
NORTH CENTRAL REGION	0.000000	0.000006	0.948333	0.948333		
SOUTHERN REGION	0.000000	0.000007	1.090667	1.090667		
WESTERN REGION	0.000000	0.000006	1.024167	1.024167		
HISPANICS	0.000000	0.000009	1.433000	1.433000		
NON-HISPANIC WHITES	0.000000	0.000005	0.896000	0.896000		
NON-HISPANIC BLACKS	0.000000	0.000007	1.185833	1.185833		
NON-HISPANIC OTHERS	0.000000	0.000005	0.808000	0.808000		
NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.000004	0.724833	0.724833		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.000014	2.312833	2.312833		
FEMALES (13+ YEARS, PREGNANT)	0.000000	0.000004	0.670333	0.670333		
FEMALES 13+ YEARS, NURSING CHILDREN (1-6 YEARS OLD)	0.000000	0.000004	0.683000	0.683000		
CHILDREN (7-12 YEARS OLD)	0.000000	0.000011	2.382000	2.382000		
MALES (13-19 YEARS OLD)	0.000000	0.000007	1.768500	1.768500		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000000	0.000005	1.085833	1.085833		
MALES (20 YEARS AND OLDER)	0.000000	0.000004	0.882167	0.882167		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000000	0.000003	0.643833	0.643833		
			0.558500	0.558500		

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

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TABLE 3

TOLERANCE ASSESSMENT SUMMARY FOR Chlorethoxyfos (Fortress)
CASWELL #663P

DATE: 04/21/95

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

EXISTING TOLERANCES (PUBLISHED ONLY) RESULT IN A TMRC OF: THE EXISTING TMRC IS EQUIVALENT TO:	0.000000 0.000	MG/KG/DAY % OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY) RESULT IN A TMRC OF: THESE NEW TOLERANCES WILL OCCUPY:	0.000006 0.962	MG/KG/DAY % OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY) ARE APPROVED THE RESULTANT TMRC WILL BE: THE NEW TMRC WILL OCCUPY	0.000006 0.962	MG/KG/DAY % OF THE ADI.

NO OTHER PENDING TOLERANCES ARE IN THE FILE

ANALYSIS FOR POPULATION SUB-GROUP: CHILDREN (1-6 YEARS OLD)

EXISTING TOLERANCES (PUBLISHED ONLY) RESULT IN A TMRC OF: THE EXISTING TMRC IS EQUIVALENT TO:	0.000000 0.000	MG/KG/DAY % OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY) RESULT IN A TMRC OF: THESE NEW TOLERANCES WILL OCCUPY:	0.000015 2.382	MG/KG/DAY % OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY) ARE APPROVED THE RESULTANT TMRC WILL BE: THE NEW TMRC WILL OCCUPY	0.000015 2.382	MG/KG/DAY % OF THE ADI.

NO OTHER PENDING TOLERANCES ARE IN THE FILE