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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

August 7, 1997

MEMORANDUM

SUBJECT: **CARFENTRAZONE-ETHYL - 128712.** Addendum to the July 15, 1997 Health Effects Division Risk Characterization Document for Use of Carfentrazone-ethyl (128712) in/on Corn and Wheat (PP#6G4615).

PRAT Case#: 287136
DP Barcode: None

FROM: José J. Morales, Chemist
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

THROUGH: Barbara Madden, Senior Scientist
Risk Characterization Branch
Health Effects Division (7509C)

TO: Dianne Morgan
Herbicide Branch
Registration Division (7505C)

The Registration Division (RD) has requested a quantitative dietary risk assessment be conducted for the experimental use permit (EUP) for use of carfentrazone-ethyl (128712) in/on corn and wheat (PP#6G4615) as an addendum to the Health Effects Division (HED) Risk Characterization Document of July 15, 1997 (Morales, J.J., 1997).

In the July 15, 1997 memo, HED recommend time-limited tolerances of 0.15 ppm in/on field corn forage, fodder, and grain and of 0.20 ppm for wheat hay, straw, and grain be established for carfentrazone-ethyl residues. Using these tolerances, HED conducted a chronic dietary risk assessment using the provisional Reference Dose (RfD) of 0.06 mg/kg/day identified in the Toxicology Branch II memo of August 15, 1996 (Malish, S.L.,1996). The RfD is based on the no observable effect level (NOEL) of 60 mg/kg/day from a 90-day rat

study (MRID 43189220) with a 1000 fold uncertainty factor.

The chronic dietary analysis indicates that exposure from the proposed time-limited tolerances for use of carfentrazone-ethyl in/on corn and wheat for the U.S. population would account for less than 1% of the RfD. For children (1-6 years), the subgroup with the highest exposure, 1% of the RfD would be utilized. A copy of the chronic dietary analysis is attached.

This chronic analysis for carfentrazone-ethyl is an upper-bound estimate of dietary exposure with all residues at tolerance level and assuming 100 percent of the commodities to be treated. Since only 4,000 acres of wheat and 4,000 acres of corn will be treated under this EUP program, which represents less than 1% of the total wheat and corn harvested in the United States, this dietary analysis represents an over estimate of the percent RfD that will be utilized by the proposed time-limited tolerances. Therefore, the chronic dietary risk resulting from the proposed time-limited tolerances for carfentrazone-ethyl will not exceed HED's level of concern.

There is no concern for cancer risks identified by HED; data from available studies do not indicate a treatment-related tumor problem, and cancer risk endpoints have not been identified.

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
CARFENTRAZONE-ETHYL	90-DAY RAT		UF -->1000		
Caswell #122003	NOEL= 60.0000 mg/kg		OPP RfD= 0.060000		
CAS No.	0.00 ppm		EPA RfD= 0.000000		
A.I. CODE: 122003	LEL= 0.0000 mg/kg				
CFR No.	0.00 ppm				
	ONCO:				

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.000000	0.000332	0.553762	0.553762		
U.S. POPULATION - SPRING SEASON	0.000000	0.000323	0.537848	0.537848		
U.S. POPULATION - SUMMER SEASON	0.000000	0.000325	0.542427	0.542427		
U.S. POPULATION - FALL SEASON	0.000000	0.000343	0.570850	0.570850		
U.S. POPULATION - WINTER SEASON	0.000000	0.000338	0.563945	0.563945		
NORTHEAST REGION	0.000000	0.000330	0.549995	0.549995		
NORTH CENTRAL REGION	0.000000	0.000339	0.564663	0.564663		
SOUTHREN REGION	0.000000	0.000330	0.550102	0.550102		
WESTERN REGION	0.000000	0.000330	0.549220	0.549220		
HISPANICS	0.000000	0.000359	0.598858	0.598858		
NON-HISPANIC WHITES	0.000000	0.000332	0.554023	0.554023		
NON-HISPANIC BLACKS	0.000000	0.000321	0.534358	0.534358		
NON-HISPANIC OTHERS	0.000000	0.000313	0.522187	0.522187		
NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.000132	0.219598	0.219598		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000000	0.000353	0.588220	0.588220		
FEMALES (13+ YEARS, PREGNANT)	0.000000	0.000240	0.399273	0.399273		
FEMALES 13+ YEARS, NURSING	0.000000	0.000286	0.476137	0.476137		
CHILDREN (1-6 YEARS OLD)	0.000000	0.000761	1.267973	1.267973		
CHILDREN (7-12 YEARS OLD)	0.000000	0.000555	0.925670	0.925670		
MALES (13-19 YEARS OLD)	0.000000	0.000388	0.646415	0.646415		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000000	0.000299	0.497612	0.497612		
MALES (20 YEARS AND OLDER)	0.000000	0.000256	0.426627	0.426627		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000000	0.000213	0.354915	0.354915		

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

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
CARFENTRAZONE-ETHYL	90-DAY RAT		UF -->1000		
Caswell #122003	NOEL= 60.0000 mg/kg		OPP RfD= 0.060000		
CAS No.	0.00 ppm		EPA RfD= 0.000000		
A.I. CODE: 122003	LEL= 0.0000 mg/kg				
CFR No.	0.00 ppm				
	ONCO:				

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
24002EA	CORN,GRAIN-ENDOSPERM	6G4615	0.150000		
24002HA	CORN,GRAIN-BRAN	6G4615	0.150000		
24002SA	CORN SUGAR	6G4615	0.150000		
24007AA	WHEAT-ROUGH	6G4615	0.200000		
24007GA	WHEAT-GERM	6G4615	0.200000		
24007HA	WHEAT-BRAN	6G4615	0.200000		
24007WA	WHEAT-FLOUR	6G4615	0.200000		
27002OA	CORN,GRAIN-OIL	6G4615	0.150000		

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July 15, 1997

MEMORANDUM

SUBJECT: **CARFENTRAZONE-ETHYL - 128712.** Health Effects Division Risk Characterization Document for Use of Carfentrazon-ethyl (F8426 50 DF) in/on Corn and Wheat (PP#6G4615).

PRAT Case#: 287136
DP Barcode: D236431

FROM: José J. Morales, Chemist
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Health Effects Division (7509C)

José J. Morales 7/15/97

THROUGH: Barbara Madden, Senior Scientist
Risk Characterization Branch
Health Effects Division (7509C)

TO: Dianne Morgan
Herbicide Branch
Registration Division (7505C)

EXECUTIVE SUMMARY

The Health Effects Division (HED) has reviewed toxicology and residue chemistry data submitted by the registrant in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and 40 CFR §158 to support the experimental use permit (EUP) of Carfentrazone-ehtyl in/on corn and wheat. Toxicology and residue chemistry data requirements for a food-use registration have been fully satisfied for this EUP. Therefore, HED can recommend for a time-limited tolerance for carfentrazone-ethyl use in/on corn and wheat. HED recommends a time-limited tolerance of 0.15 ppm for carfentrazon-ethyl residues in/on field corn forage, fodder, and grain; and of 0.20 ppm for wheat hay, straw, and grain.

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Due to the non-quantifiable carfentrazone-ethyl residues in/on the treated RAC's (except wheat forage, but in this EUP there is a feeding restriction) fed to livestock and the limited number of acres involved, there is no expectation of secondary residues in livestock commodities of meat, meat by-products, fat, milk, and eggs.

RISK CHARACTERIZATION

Chronic Dietary Risk: A chronic dietary risk (food and water) estimate for the general U.S. population was not conducted for the following reasons: the short duration of this EUP (2 years); the small percentage of treated acres for corn and wheat as a result of the proposed use (<1% of the total US production for both commodities); and the fact that these commodities are mixed (blended) before consumption.

Acute Dietary Risk: As part of the hazard assessment process, the Agency reviews the available toxicological database to determine the endpoints of concern for acute dietary risk. For carfentrazon-ethyl, the Agency does not have a concern for an acute dietary assessment since the available data do not indicate any evidence of significant toxicity from a one day or single event exposure by the oral route. Therefore, an acute dietary (food and water) risk assessment was not required.

Occupational and Residential Risk: No short- and intermediate-term endpoints for occupational and residential exposure were identified for this EUP. Also, there are no residential uses associated with this EUP. Therefore, an occupational and residential risk assessment was not required.