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

AUG 25 1986

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ASANA Insecticide 1.9 EC (24.0% ai)
EPA File Symbol 201-URI, and
Technical ASANA Insecticide (75.0% ai)
EPA File Symbol 201-URO

Tox. Chem No. 77A

FROM: William B. Greear, M.P.H. William B. Greear 8/22/86
Section VII, Toxicology Branch
Hazard Evaluation Division (TS-769C)

TO: Adam Heyward, PM Team 15
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

THRU: Albin B. Kocialski, Ph.D., Supervisory Pharmacologist
Section VII, Toxicology Branch
Hazard Evaluation Division (TS-769C) ABK 8/22/86
8/24/86

Under a cover letter dated July 30, 1986, E.L. Hobson of the Shell Chemical Company has submitted ". . . Acceptable Daily Intake (ADI) calculations for ASANA based on tolerances for only those crops that were registered for PYDRIN® Insecticide as of July 1984." In addition, Shell has included ADI calculations using the Tolerance Assessment System (TAS). The purpose of this submission is to provide documentation that the ADI will not be exceeded for any population subgroup using the TAS, in order to secure registrations for ASANA Insecticide 1.9 EC and Technical ASANA Insecticide. It is indicated that the provisional maximum permitted intake (PMPI) for a 60 kg adult is 31.9 percent. When utilizing the TAS, the percent of the PMPI for a 60 kg adult is 15.0 percent, for a nonnursing infant it is 54.5 percent, and for a nursing infant it is 25.8 percent.

The PMPI was calculated to be 1.5 mg/day. This value was obtained from a projected no-observable-effect level (NOEL) of 100 ppm that would be expected to be observed in the ongoing 1-year dog study and the utilization of a hundredfold safety factor. Currently, the Toxicology Branch (TB) is basing the ADI on the results of a 13-week rat study in which the NOEL was demonstrated to be 50 ppm. Using this NOEL of 50 ppm (2.5 mg/kg/day) and a safety factor of 100 results in an ADI of 0.025 mg/kg/day and an MPI of 1.5 mg/day. These values are identical with Shell's PADI and PMPI.

An analysis was conducted of all published permanent tolerances for fenvalerate as of July 1984, as previously agreed (see memorandum of meeting dated July 23, 1986). This list of commodities and their respective tolerances were identical to Shell's list presented in Section G (TAB 1, see attachment) with one exception. TB has no record that the tolerance for eggs of 0.01 ppm is an approved published tolerance, therefore, this tolerance was deleted from our calculations (see TAS printout of August 20, 1986). Data on the percent of the ADI utilized are provided for population subgroups in the following table.

Population Subgroup	Percent Utilization of the ADI
U.S. Pop.--48 States--All Seasons	136.419
U.S. Population--Spring Season	128.962
U.S. Population--Summer Season	135.375
U.S. Population--Fall Season	141.183
U.S. Population--Winter Season	140.081
Northeast Region	146.706
North Central Region	136.957
Southern Region	120.344
Western Region	149.517
Hispanics	161.747
Nonhispanic Whites	136.723
Nonhispanic Blacks	119.278
Nonhispanics Other Than Blacks & Whites	163.055

Population Subgroup (cont'd)	Percent Utilization of the ADI (cont'd)
Nursing Infants (< 1 year old)	137.094
Nonnursing Infants (< 1 year old)	478.378
Females (13+, Pregnant, Not Nursing)	96.555
Females (13+, Nursing)	129.254
Children (1-6 years)	360.156
Children (7-12 years)	229.546
Males (13-19 years)	148.098
Females (13-19 years, Not Preg. or Nursing)	117.293
Males (20+ years)	88.478
Females (20+ years, Not Preg. or Nursing)	78.744

The analysis presented above is not in agreement with the analysis provided by Shell. In TB's analysis, the ADI may be exceeded by as much as 378.378 percent for nonnursing infants less than 1 year old. The reasons for the discrepancy is unknown, however, it is strongly recommended that Shell provide TB with a detailed copy of their analysis so that the discrepancy may be resolved in an expeditious manner.

It is noted in Residue Chemistry Branch's memorandum of August 19, 1986, that established tolerances for residues of fenvalerate from the use of PYDRIN are adequate to cover residues of fenvalerate from the use of ASANA.

Recommendations

1. The toxicological data requirements for the registration of Technical ASANA Insecticide (EPA File Symbol 201-URO) and ASANA Insecticide 1.9 EC (EPA File Symbol 201-URI) have been satisfied. TB has no objection to their registration provided the precautionary statements for the technical and formulation are changed as recommended in TB's memorandum of July 10, 1986.

2. TB expresses concern over the use of this new enriched A-alpha fenvalerate technical and corresponding formulation with respect to its impact on the ADI.

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3. Concerning recommendation 2, above, TB suggests that Shell forward a copy of their analysis of the percent of the PMPI utilized (using the TAS), so that their calculations may be examined in depth.

4. Shell should be informed that the 1-year dog feeding study with the A-alpha enriched fenvalerate technical is still outstanding.

Attachment

NOEL* (Dog) = 100 ppm
PADI* = 0.025 mg/kg
PMPI* = 1.5 mg/day

SECTION G

ASANA™ INSECTICIDE
INCREMENTAL TOLERANCE CALCULATIONS
PROPOSED TOLERANCES

Commodity	Tolerance (ppm)	Food Factor	Total Diet (kg)	TMRC (mg/day)	% of PMPI
Apples	2.0	0.0253	1.5	0.0759	5.0600
Artichokes	0.2	0.0003	1.5	0.00009	0.0060
Broccoli	2.0	0.001	1.5	0.003	0.2000
Cabbage	10.0	0.0074	1.5	0.111	7.400
Cauliflower	0.5	0.0007	1.5	0.000525	0.0350
Corn, grain	0.02	0.0100	1.5	0.0003	0.0002
Cottonseed	0.2	0.0015	1.5	0.00045	0.0300
Cucumbers	0.5	0.0073	1.5	0.005475	0.3650
Dry beans	0.25	0.0031	1.5	0.0011625	0.0775
Dry peas	0.25	0.0069	1.5	0.0025875	0.1725
Eggs	0.01	0.0277	1.5	0.00042	0.0280
Eggplant	1.0	0.0003	1.5	0.00045	0.0300
Filberts	0.2	0.0003	1.5	0.00009	0.006
Meat, red	1.5	0.1081	1.5	0.24323	3.243
Melons	1.0	0.02	1.5	0.03	2.0000
Milk, whole	0.3	0.2862	1.5	0.12879	8.586
Peanuts	0.2	0.0036	1.5	0.00108	0.072
Pears	2.0	0.0026	1.5	0.0078	0.5200
Peas (succulent)	1.0	0.0069	1.5	0.01035	0.6900
Pecans	0.2	0.0003	1.5	0.00009	0.0060
Peppers	1.0	0.0003	1.5	0.00045	0.0300
Popcorn grain	0.1	0.0008	1.5	0.00012	0.0080
Potatoes	0.02	0.0543	1.5	0.001629	0.1086
Pumpkins & squash	1.0	0.0011	1.5	0.00165	0.1100
Soybeans	0.05	0.0092	1.5	0.00069	0.0460
Summer squash	0.5	0.0003	1.5	0.000225	0.0150
Sweet corn grain	0.1	0.0143	1.5	0.002145	0.1430
Tomatoes	1.0	0.0287	1.5	0.04305	2.8700
Walnuts	0.2	0.0003	1.5	0.00006	0.0040
				0.673109	31.862

* Provisional

DKP
July 24, 1986

CE8619703