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

Atrazine / Review #39 / 6.4.81 / 4 pages Releasable

MEMORANDUM

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

DATE: JUN 4 1981

SUBJECT: PP#0E2398 - Atrazine (2-chloro-4-ethylamino-6-isopropylamino-s-triazine) in Guava, Minor Use tolerance of 0.25 ppm.
CASWELL # 63

FROM: David Ritter, Toxicologist DR 6/3/81
Review Section #1
Toxicology Branch/HED (TS-769)

TO: Edward Gross, Acting Minor Use Officer
Registration Division (TS-767)

THRU: Chris Chaisson, Acting Chief
Toxicology Branch/HED (TS-769) Ok for WZB

Petitioner: IR - 4 Regional Coordinator
New Brunswick, NJ

Conclusion:

Toxicology Branch has no objection to establishing the proposed tolerance of 0.25 ppm in guava subject to the condition noted below.

Bases for the Conclusion:

1. The increase in potential dietary exposure is less than 1% of the existing Theoretical Maximum Resiudes Concentration (TMRC) from established tolerances.

2. Existing toxicity data support this minor use tolerance.

Conditional Requirement for Future Tolerances:

1. In order to support future tolerances in additional racs it is necessary that the petitioner provide a teratology study in a suitable species.

Detailed Considerations:

Tolerances have been established for residues of atrazine in human dietary items at levels up to 0.25 ppm in milk, and up to 15 ppm in animal feed items pursuant to 40 CFR 180.220.

The OPP Policy on Minor Uses (9/30/80) provides that consideration will be given to tolerances in cases where there is relatively low acreage and a large volume of production of the Active Ingredient (AI). The present use would fall into that classification.

The Policy further directs that conditional registration considerations should be applied to Minor Use tolerances. The "Guidelines for Conditional Registration" (FR 44:93, 5/11/79) state, in part, that "...no additional tolerances will be granted when a significant data gap exists unless the incremental residue concentration is insignificant, generally less than one percent..."

Toxicity data available for support of this proposal are summarized in the J. Svirbely review of PP#4F1425, 9/28/73, and include:

- two year rat feeding NOEL = 100 ppm (systemic).
- two year dog feeding NOEL = 150 ppm (systemic).
- Multigeneration rat reproduction study NOEL = 100 ppm.

Since there are significant data gaps (2nd oncogenic study and no teratology study;), application of the "one percent solution" is appropriate. From the printout, we note that the Maximal Permissible Intake (MPI) is 2.25 mg/day (60 kg), based on a 100-fold safety factor applied to the two year rat feeding NOEL of 100 ppm. Existing tolerances "use up" 0.0769 mg/day/1.5 kg or 3.42% of the MPI. We note that the TMRC due to potential residues on guava is 0.00011 mg/kg/1.5 kg or 0.1% of the existing TMRC. This falls well within the Guideline value of one percent of the existing TMRC.

However, we are requesting that a teratology study be provided in support of future tolerances under provisions of the Conditional Registration notice cited above.

Accordingly, we conclude that the proposed tolerance for residues of the herbicide, atrazine in guavas at 0.25 ppm is without hazard.

FREE STANDING MEMORANDUM

PP #0E2398 - Atarazine in guavas at 0.25 ppm, Minor Use proposal

Pursuant to DAA Johnson's memo of Policy, Tolerance Regulations, of 2/9/77, we are providing the following summary of background elements in this Toxicological Review:

1. Data considered -

   See text of review.

2. Data considered desirable but lacking -

   - 2nd Oncogenicity study
   - Teratology study

3. Action being taken to obtain, if needed.

   Not needed; Minor Use policy in effect.

4. Other tolerances and ADI

   See attached computer printout.

5. ADI and basis for determining

   See attached computer printout.

6. Pending regulatory actions against -

   None

7. Other relevent considerations -

   None not noted in the review.

File last updated 4/10/81

ACCEPTABLE DAILY INTAKE DATA

Dog	NOEL	S.F.	ADI	MPI
mg/kg	ppm		mg/kg/day	mg/day(60kg)
3.750	150.00	100	0.0375	2.2500

Published Tolerances

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Corn,all types(38)	0.250	2.51	0.00941
Macadamia nuts(87)	0.250	0.03	0.00011
Pineapple(123)	0.250	0.30	0.00111
Sorghum(147)	0.250	0.03	0.00011
Sugar,cane&beet(154)	0.250	3.64	0.01364
Wheat(170)	0.250	10.36	0.03886
Eggs(54)	0.020	2.77	0.00083
Milk&Dairy Products(93)	0.020	28.62	0.00858
Meat,inc poultry(89)	0.020	13.85	0.00415
Millet(94)	0.250	0.03	0.00011

MPI	TMRC	% ADI
2.2500 mg/day(60kg)	0.0769 mg/day(1.5kg)	3.42

****

Current Action PP# 0E2398

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Guava(184)	0.250	0.03	0.00011

MPI	TMRC	% ADI
2.2500 mg/day(60kg)	0.0770 mg/day(1.5kg)	3.42

****