5-14-96

Attachment 3. Memorandum of S. Knizner, 5/14/96, PP#6E4652

MEMORANDUM

DATE: 5/14/96

SUBJECT: **Quizalofop-ethyl - PP#6E4652.** IR-4 Petition for Tolerance in/on Mint.

DP Code: D223397 Priority: 6
Reg #: 352-541 Trade Name: Assure II
Chem #: 128711 40 CFR: 180.441
Caswell: 215D MRID #: 43917301

TO: Hoyt Jamerson, PM Team 43
ERMUS/RSB
Registration Division (7505W)

FROM: Steven Knizner, SanYvette Williams-Foy, Tina Manville
Pilot Interdisciplinary Risk Assessment Team
RCAB/HED (7509C)

THRU: Michael Metzger, Acting Chief
RCAB/HED (7509C)

INTRODUCTION

IR-4, on behalf of the Oregon Agricultural Experiment Station, requests the establishment of a tolerance for the combined residues of the herbicide quizalofop-p ethyl ester (ethyl(R)-2-[4-((6-chloroquinoxalin-2-yl)oxy)phenoxy] propionate), and the S enantiomers of the ester and the acid, all expressed as quizalofop-p ethyl ester, in or on the raw agricultural commodity mint at 3 ppm. Three Section 18 Specific Exemptions (WA, OR and MT) were granted in 1993 for the use of quizalofop-ethyl on mint.

RECOMMENDATION

Provided the petitioner **revises Section F of the tolerance petition to request establishment of a 2 ppm tolerance** for the combined residues of the herbicide quizalofop-p ethyl ester, and the S enantiomers of the ester and the acid, all expressed as quizalofop-p ethyl ester, in or on the raw agricultural commodities **peppermint, tops** and **spearmint, tops**, HED has no objections to the establishment of this tolerance. Dietary exposure risk estimates do not exceed HED's level of concern.

CONCLUSIONS

Hazard Assessment

In conjunction with the review of PP#5F4545 (petition for quizalofop-ethyl tolerances in/on foliage of legume vegetables and canola seed and processed commodities), TOX concluded that the current database

for quizalofop-ethyl was adequate (W. Phang, 2/26/96, D220477, D220479, D220481, see Attachment 1). That review went on to state that the RfD is 0.009 mg/kg/day. The RfD was established based on the results of the chronic feeding/oncogenicity study in rats (with a NOEL of 0.9 mg/kg/day and an uncertainty factor of 100). The Cancer Peer Review Committee has evaluated the data on the incidence of liver tumors found in the mouse oncogenicity study, and the same data were considered by the Science Advisory Panel. It was concluded that quizalofop-ethyl would probably be best classified as a Category "D" carcinogen (not classifiable as to human carcinogenicity). No acute dietary endpoints have been identified.

Dietary Exposure

1. CBTS has previously concluded that the nature of the quizalofop-p ethyl ester residue in plants is adequately understood based on metabolism studies in cottonseed, potatoes, soybeans, tomatoes and sugarbeets. The residues of concern are quizalofop-p ethyl ester and its acid metabolite, quizalofop-p, and the S enantiomers of both the ester and the acid, all expressed as quizalofop-p ethyl ester (F.Griffith, 2/21/96, PP# 5F4545/FAP# 6H5737). We consider it appropriate to translate these data to mint.

2. Method I in PAM II (DuPont Method AMR-153-83, rev. 3) is an adequate enforcement method for determination of quizalofop-p-ethyl ester and related regulated residues in mint.

3. **Adequate residue data were provided to support a tolerance of 2.0 ppm.** Section F of the petition should be modified to reflect this tolerance level. Additionally, in order to conform to the racs listed in Subdivision O, Table II (September, 1995), Section F should be modified to request tolerances for **Peppermint, tops** and **Spearmint, tops.**

4. Processing data provided indicate no concentration of residues in mint oil. No food additive tolerances are required for mint oil. There are no Delaney considerations associated with this tolerance petition.

2

5. Secondary residues are not expected in animal commodities as no feed items are associated with the proposed use in/on mint.

6. A DRES analysis was recently conducted (B.Steinwand, 3/7/96, "Dietary Exposure Analysis for Quizalofop ethyl in/on Legumes, Sugarbeets, and Soybeans"). For purposes of the current analysis, the "new" tolerances listed in the previous analysis were changed to pending status. Corrections to the database used in the 3/7/96 analysis included: 1) removal of carob, peanuts (whole) and peanut oil, which were inadvertently listed as new uses under PP#3F4268; and 2) residue levels for soybean flour were set at 0.5 ppm (instead of 0.7 ppm) in accordance with directions given in the CBTS memo dated 10/6/95 (F.Griffith, CBTS #16261, D219638).

a. Acute Dietary Risk. Because no acute dietary risk endpoints were identified, this analysis was not conducted.

b. Chronic Dietary Risk. A DRES chronic dietary risk analysis was performed using a worst case estimate of tolerance level residues and the assumption of 100% crop treated to calculate the TMRC for the US general population and 22 subgroups. Summaries of the TMRCs and their representations as percentages of the RfD are included in Attachment 2.

- US Population - Existing and pending tolerances result in a TMRC of 4.63×10^{-4} mg/kg/day, which represents 5.14% of the RfD for the US general population (48 states). The proposed use will add a TMRC of 2×10^{-6} mg/kg/day, which represents 0.016% of the RfD. The TMRC for the combined total (existing and pending tolerances + proposed use) will be 4.64×10^{-4} mg/kg/day, which will occupy 5.15% of the RfD.

- Highest Exposed Population Subgroup - Existing and pending tolerances (see Appendix Table III) result in a TMRC of 1.7×10^{-3} mg/kg/day, which represents 18.5% of the RfD for the highest exposed population subgroup, Non-nursing infants (<1 year old). The proposed use will not contribute to the dietary burden of this population subgroup.

Based on the risk estimates calculated, dietary exposure does not exceed HED's level of concern.

c. Dietary Cancer Risk. Because quizalofop ethyl is classified as a Category "D" carcinogen (not classifiable as to human carcinogenicity) dietary cancer risk was not estimated.

d. Anticipated Residues. Because the existing and pending tolerances plus the proposed use do not result in TMRCs that exceed the RfD for the US general population or any of the 22 subgroups analyzed, there is no need for anticipated residue assessment refinement.

DETAILED CONSIDERATIONS

3

DIETARY EXPOSURE

Residue Data

Table 1. Residue Consideration Summary Table

PARAMETER	RESIDUE DATA
CHEMICAL	Quizalofop-ethyl
FORMULATION	EC - Assure II Herbicide (10.3% quizalofop-ethyl by weight as ai)
CROP	Peppermint and Spearmint
TYPE APPLICATION	Ground
# APPLICATIONS	Maximum of 2
TIMING	When weeds (quackgrass, green foxtail, volunteer cereals, and/or wild oats) are from 2 to 10 inches tall.
RATE/APPLICATION	0.10 to 0.20 lbs ai/A
RATE/SEASON	0.20 lbs ai/A/season
RESTRICTIONS	Do not apply this product within 30 days of harvest. Do not apply through any type of irrigation system. Do not graze animals on green forage or stubble. Do not utilize hay or straw for animal feed or bedding. Use a minimum of 15 gallons of water per acre. Do not exceed 40 gallons of water per acre. Apply with ground equipment. Always include a spray adjuvant (petroleum based at 1.0% v/v or nonionic surfactant at 0.25% v/v).
RESIDUE DATA SOURCE	IR-4 (MRID #43917301)
FIELD TRIAL LOCATIONS	IN (1) - peppermint; OR (1) - peppermint; WA (1) - spearmint (see Note to PM following this Table)
SAMPLE HANDLING/ PROCESSING	Fresh "hay" samples were harvested either by hand, or by using a Swift flail harvester, or a mint chopper. All "hay" samples were immediately frozen and maintained frozen (<-10 C) until analysis. PIRAT notes that the samples designated "hay" actually correspond to the rac listed for peppermint and spearmint in Subdivision O, Table II (September 1995), which is "tops (leaves and stems)". Samples used for processing into oil were distilled from fresh hay the same day as harvest in the OR and WA trials (using small mint stills). For the IN trial, hay was air dried on a greenhouse bench for 15 days then water distilled.
PERFORMING LAB	Enviro-Test Laboratories, Edmonton, Alberta, Canada
ANALYTICAL METHOD	Analytical Method for the Quantification of Quizalofop (IN-YE945) and Quizalofop-Ethyl (DPX-79379) in Raw and Processed Agricultural Commodities (HPLC/UV) (MRID #43917301).
METHOD VALIDATION RESULTS	The analytical method was adequately validated using rac and oil samples fortified at various levels (from 0.05 to 0.5 ppm) with quizalofop-p-ethyl ester and quizalofop acid. Recoveries were in the range considered acceptable by the Agency (69 to 121%, average recovery 99% + 17%). Adequate representative chromatograms were presented.

Table 1. Residue Consideration Summary Table	
PARAMETER	**RESIDUE DATA**
FIELD TRIALS	Trials were conducted in 1990 in IN (1), OR (1), and WA (1). Each location consisted of one or two untreated control plots, two plots treated at 0.2 lb ai/A and two plots at 0.4 lb ai/A. One application was made, using ground equipment and a surfactant. Samples were harvested with either a 30 or 45 day PHI. In the OR and WA trials, oil samples were distilled the day of harvest using small vapor stills. In the IN trial, samples for oil were air dried 15 days, distilled in boiling water and then frozen. All samples were stored frozen (<-10 C or lower) until analysis. Field trial samples were stored frozen for a maximum of 654 days from harvest to analysis.
RESIDUE DATA (RAC)	For the proposed maximal seasonal label rate of 0.2 lb ai/A and the proposed 30 day PHI, combined regulated residues ranged from 0.06 to 1.0 ppm in/on fresh mint hay. Residue data are summarized below in Table 2.
RESIDUE DATA (PROCESSING STUDY)	All residues in mint oil produced from mint treated at either 0.2 or 0.4 lb ai/A and 30 day PHI were nondetectable (<0.05 ppm).
STORAGE STABILITY	Adequate data were presented to demonstrate that quizalofop ethyl ester and quizalofop acid were stable in mint hay and mint oil after up to approximately 600 days of frozen storage. These data are adequate to support the sample storage intervals in this study.
CODEX	There are no CODEX, Canadian, or Mexican MRLs for quizalofop-ethyl residues in/on mint.

NOTE to PM: Although current Chemistry Guidelines (see Pesticide Reregistration Rejection Rate Analysis Residue Chemistry Follow-up Guidance for Number and Location of Domestic Crop Field Trials, June 1994, EPA 738-K-94-001) require 5 field trials (3 in region 11 [WA, OR, ID] and 2 in region 5 [north-central US]). We note that the field trials for this study were conducted in 1990, prior to publication of the guidance. Because data are available for each location reflecting both a 1x and 2x maximum seasonal application rate scenario, PIRAT concludes that the number of field trials conducted is adequate in this case. However, for future mint tolerance petition submissions, IR-4 should be made aware of data requirements set forth in the guidance document.

5

Table 2. Summary of Field Trial Results.

Matrix	Applic. Rate (lb ai/A)	PHI (days)	Total Regulated Residues (ppm)		
			IN	OR	WA
tops	0.2 (1x rate)	30 (±2) (minimum PHI)	0.22	0.46	0.92
			0.06	0.38	1.0
	0.4	30 (±2)	0.35	1.0	2.6
			0.14	1.2	1.9
	0.2	45 (±3)	<0.05	0.14	0.21
			<0.05	0.22	0.35
	0.4	45 (±3)	<0.05	0.40	0.81
			0.06	0.42	0.64
oil	0.2	30 (±2)	<0.05	<0.05	<0.05
	0.4	30 (±2)	<0.05	<0.05	<0.05
	0.2	45 (±3)	<0.05	<0.05	<0.05
	0.4	45 (±3)	<0.05	<0.05	<0.05