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

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: August 25, 2011

SUBJECT: Preliminary Human Health Assessment for the Registration Review of Methyl Anthranilate

Registration Review Case #: 6056
PC Code: 128725
CAS #: 134-20-3
Chemical Class: Biochemicals

FROM: Sadaf Shaukat, Biologist
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Biopesticides & Pollution Prevention Division (7511P)

TO: Chris Pfeifer, Regulatory Action Leader
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ACTION REQUESTED

The following is a preliminary human health assessment for methyl anthranilate in support of the development of the Registration Review Work Plan.

RECOMMENDATIONS AND CONCLUSIONS

Executive Summary

Based on the available data and information, the Agency does not foresee the need for new data or for a new human health risk assessment for this active ingredient. Hazard and exposure information as well as Agency risk assessments on methyl anthranilate were evaluated against current safety standards established by the Agency's scientific policies and regulations and it was determined that there is no need to conduct an additional human health risk assessment. Methyl anthranilate is a naturally-occurring substance found in many plant species such as corn, sunflowers, grapes, and cherries. It is extremely volatile and degrades rapidly into non-toxic components such as anthranilic acid. There is reasonable certainty that no harm will result to the general population from exposure to methyl anthranilate in the products containing this active ingredient when they are used according to label instructions.

I. Background

Uses for products containing methyl anthranilate as the active ingredient include goose and bird repellents. Currently, there are eight end-use products that are registered with BPPD containing methyl anthranilate as the active ingredient.

II. Tolerances

§ 180.1143 Methyl anthranilate; exemption from the requirement of a tolerance.

Residues of methyl anthranilate, a biochemical pesticide, are exempt from the requirement of a tolerance in or on all food commodities, when used in accordance with good agricultural practices.

[67 FR 51088, Aug. 7, 2002]

III. Incidents

Three incidents were reported from January 1, 1992 to October 29, 2010. Each of the three incidents were attributable to either misuse or the inerts in the product, not the active ingredient methyl anthranilate.

IV. Toxicity Profile

Methyl anthranilate is a naturally-occurring substance found in many plant species such as corn, sunflowers, grapes, and cherries. It has been determined that due to the nature of this ingredient, it is unlikely that products containing it will have adverse effects on human health. All toxicology data requirements have been satisfied and it is unlikely that any additional data will be required. Toxicology data and or rationale to fulfill or waive these requirements are available on

the currently registered EPs; all of which indicate that these products are of low toxicity.

Please see the tables below for detailed information regarding the toxicity data requirements. Available toxicity data as required by 40 CFR 158.2050 regarding flower oils are summarized below in Tables 1-7.

Table 1. Methyl Anthranilate: Acute Oral Toxicity/OPPTS 870.1100

Active Ingredient	LD_{50}	Toxicity Category	MRID
Methyl Anthranilate	3,633 mg/kg (males) 3,000mg/kg (females) 3,288 mg/kg (sexes combined)	III	42608802

Table 2. Methyl Anthranilate: Acute Dermal Toxicity/OPPTS 870.1200

Active Ingredient	LD_{50}	Toxicity Category	MRID
Methyl Anthranilate	> 2,000 mg/kg*	III*	42608803

* 2,000 mg/kg was the highest dose tested in the study

Table 3. Methyl Anthranilate: Acute Inhalation Toxicity/OPPTS 870.1300

Active Ingredient	LC_{50}	Toxicity Category	MRID
Methyl Anthranilate			Waived (See Attachment A)

Table 4. Methyl Anthranilate: Acute Eye Irritation/OPPTS 870.2400

Active Ingredient	Results	Toxicity Category	MRID
Methyl Anthranilate	Slight to moderate conjunctival irritation; all cleared by 72 hours after treatment	III	42608804

Table 5. Methyl Anthranilate: Acute Dermal Irritation/OPPTS 870.2500

Active Ingredient	Results at 72 hrs	Toxicity Category	MRID
Methyl Anthranilate	No irritation	IV	42608805

Table 6. Methyl Anthranilate: Skin Sensitization/OPPTS 870.2600

Active Ingredient	Results	MRID
Methyl Anthranilate	Not a sensitizer	42608806

870.3100	90-day Oral	Waived (See Attachment B)
870.3250	90-day Dermal	Waived (See Attachment B)
870.3465	90-day Inhalation	Waived (See Attachment B)
870.3700	Prenatal Dev.	Waived (See Attachment B)
870.5100	Bacterial rev. mut	Waived (See Attachment B)
870.5300 & 5375	In vitro mammalian cell assay	Waived (See Attachment B)

Based on the information presented above, the Agency does not foresee the need for new data or for a new human health risk assessment. There is reasonable certainty that no harm will result to the general population from exposure to methyl anthranilate in the products containing this active ingredient when they are used according to label instructions.

cc: *S. Shaukat, C. Pfeifer*, BPPD Science Review File
S. Shaukat, FT, PY-S: 8/25/11