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

MAY 1 1986

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EPA File Symbol 618-OL - Abamectin (Avermectin or AVM)
AFFIRM® Technical Product Chemistry
Accession No. 260785, RCB No. 388

FROM: Leung Cheng, Chemist L. Cheng
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TO: George LaRocca, PM 15
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THRU: Edward Zager, Section Head E Zager
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Merck, Sharp & Dohme has supplied additional data and information on AFFIRM® Technical for registration. AFFIRM® Technical (containing 70% Avermectin B_1 and 5% related compounds) is a manufacturing-use product intended for the formulation of fire ant bait products.

No tolerances have been established for residues of avermectin. Petitions are pending for residues of avermectin on pasture and range grasses (PP#4F3065), citrus products and cattle (PP#5G3287/5H5474 and 50658-EUP-1) and cottonseed (PP#5G3320). Merck's initial request for registration was denied because of deficiencies cited in our review of November 4, 1985 (L. Cheng).

See the Confidential Appendix for the information on the amounts and identities of components in "AFFIRM® Technical." The Residue Chemistry Branch and Toxicology Branch are not concerned with the impurities associated with the technical material (see L. Cheng December 19, 1985, review of PP#5G3287/5H5474 and 50658-EUP-1 and W. Dykstra March 12, 1986, review of PP#5G3287/5H5474).

The current manufacturing process and batch analysis are also discussed in the Confidential Appendix.

In the Preliminary Analysis (§62-1), the percentages of the components present add up to > 100 percent, apparently due to incorrect calculations and incomplete data. The correct analysis should be submitted. See Confidential Appendix for further discussion on the Analytical Method (§62-3).

Some of the physical and chemical characteristics of technical abamectin and "AFFIRM® Technical" have been submitted previously (L. Cheng November 4, 1985, Accession No. 258707) and are summarized in table 1. Additional product chemistry data were included in this submission and are included in table 1.

We consider "AFFIRM® Technical" to be a manufacturing-use product rather than a technical product since it contains intentionally added inert ingredients. Technical abamectin is the material containing 95 percent abamectin and no added inerts. [Note: Technical products are also manufacturing-use products. However, not all manufacturing-use products are technical products.]

Storage stability data of AFFIRM® Technical demonstrate its stability in glass for at least 8 months at room temperature and for 6 weeks at 50 °C. Data on explodability and stability to metal ions, metal, and sunlight have still not been received.

Table 1

Physical and Chemical Properties

		Abamectin Technical	AFFIRM (MUP)
63-2	Color	off white/ slightly yellow	off white/slightly yellow
63-3	Physical State	Solid	Solid - slightly moist
63-4	Odor	Odorless	Odorless/odor of volatile solvents
63-5	Melting Point	155-157	Same as Technical
63-7	Density/Specific gravity	1.16 @ 21 °	1.13
63-8	Solubility (mg/mL)		
	chloroform	> 2 mg/mL	N/A
	dimethylacetamide	> 2	
	dimethylformamide	> 2	

Table 1

Physical and Chemical Properties (cont'd)

		Abamectin Technical	AFFIRM (MUP)
63-8	Solubility (mg/mL) (cont'd)		
	ethanol	> 3	
	glycerol formal	> 2	
	isopropyl myristate	> 2	
	polysorbate 80	> 2	
	polyethylene dycol 400	> 2	
	distilled water	$\leq$ 0.01	
	tap water	< 0.001	
	buffers pH 6, 7.4, 9.0	< 0.001	
	0.9% NaCl	< 0.001	
63-9	Vapor Pressure	1.5×10^{-9}	N/A
63-11	K_{ow}	9.9×10^{3}	N/A
63-12	pH	no acidic or basic group	N/A
63-13	Stability (to reaction)	Data Gap	Data Gap
63-14	Oxidizing/Reducing	N/A	N/A
63-15	Flammability	N/A	Not flammable
63-16	Explodability	N/A	Data Gap
63-17	Storage Stability	Given for pure B_1a 30 days at room temperature and dry air 7% decomposition 52 days at 30 ° 30% decomposition 52 days at 50 °	Avermectin B_1 wet cake stable for 8 months RT slight (1%) decomposition for 315 days at 50%
63-20	Corrosion Characteristics	Not corrosive to water impermeable containers	Same as technical

Conclusions and Recommendations

1. We consider AFFIRM® Technical to be a manufacturing-use product since it contains intentionally added inerts (not a technical). The range of the certified limits is too large. Certified limits should be reasonable in terms of expected product composition variability. Separate limits should be given for each inert.

2. The manufacturing process submitted is acceptable. Toxicology Branch is not concerned with the impurities associated with AVM B_1 (technical material).

3. In the Preliminary Analysis (§62-1), the percentages of the components present add up to > 100 percent, apparently due to incorrect calculations and incomplete data. The correct analysis should be submitted. See Confidential Appendix for further discussion on the Analytical Method (§62-3).

4. The Company will need to provide data on explodability and stability to metal, metal ions, and sunlight for the manufacturing-use product.

We recommend against the registration of AFFIRM® Technical for the reasons cited in conclusions 1, 3, and 4.

Attachment: Confidential Appendix (2 pages)

cc (without Attachment): Circular
cc (with Attachment): RF, SF, Cheng, PM 15, Amended Use F, PMSD/ISB only
RDI:S.V.Hummel:4/28/86:R.D.Schmitt:4/28/86
TS-769:L.Cheng:CM#2:RM810:4/3/86:557-7323
88138:Cheng:C.Disk:KENCO:4/29/86:dsg
LCheng:5/1/86

Page _____ is not included in this copy.

Pages 5 through 6 are not included in this copy.

The material not included contains the following type of information:

✓ Identity of product inert ingredients.

_____ Identity of product impurities.

✓ Description of the product manufacturing process.

✓ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.