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To Frances Mann	From Sheryl Reilly
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NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

UNITED STATES ENV
WAS

JUL 27 1994 (as amended)

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Supplementary Information regarding Registration of Technical Methyl Anthranilate and Two End-Use Products (REJEX-IT AP-50, File Symbol 58035-A; REJEX-IT TP-40, File Symbol 58035-T). Product Chemistry and Mammalian Toxicology Data (Case # 015580; Chemical # 128725; Submission # S469030, DP Barcode D204987)

TO: Robert Forrest, Product Manager (PM-14)
Daniel Peacock, Reviewer (PM-14)
Insecticide-Rodenticide Branch
Registration Division (7505C)

FROM: Sheryl K. Reilly, Ph.D., Biological Section
Science Analysis Branch
Health Effects Division (7509C)

Sheryl K. Reilly 9/27/94

THROUGH: Roy D. Sjoblad, Ph.D., Section Head
Biological Section, Science Analysis Branch
Health Effects Division (7509C)

R. D. Sjoblad

ACTION REQUESTED: PMC Specialties Group, Inc. has submitted the supplementary information requested in memoranda from S. Reilly to R. Forrest and D. Peacock, dated 4/29/94 and 5/9/94, to complete the registration application for technical methyl anthranilate (REJEX-IT™ MA) and three end-use products (REJEX-IT™ AP-50, REJEX-IT™ TP-40, and REJEX-IT™ AG-36). In the original submissions, the registrant had not provided a list of impurities, their percentages, or reasons for occurrence; further, no data verifying the efficacy of the methodologies used to detect MA for identifying or quantitating impurities, and most of the studies submitted for acute mammalian toxicology were graded Supplementary.

CONCLUSIONS: Methyl anthranilate is a biochemical pesticide, and its end-use products are to be used as non-food use bird repellants. Methyl anthranilate is considered GRAS under 21 CFR 182.60, and is used as a flavoring agent in foods (alcoholic and nonalcoholic beverages, ice cream, candy, baked goods, gelatins and puddings, chewing gum, and is also a component of perfumes.

The registrant has indicated that the reason no information was provided on impurities is that the technical grade methyl anthranilate is produced to meet or exceed U.S. Food Chemical Codex and U.S. Pharmacopia specifications, and is thus is a food-grade

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material. The end-use products are made from this technical material, and the label precautionary statements so indicate. Therefore, the requirement for data on impurities is waived Guideline 151-12: Discussion of the Formation of Unintentional Ingredients).

The registrant also provided a certificate of analysis for the test compound used in the acute studies, which gave the lot/batch number and purity of the test material used in the acute studies:

Product	Lot/Batch # Used in Acute Studies	Purity
REJEX-IT™ MA	022592	99.85%
REJEX-IT™ AP-50	32292	51.0%
REJEX-IT™ TP-40	22932	43.1%
REJEX-IT™ AG-36	ES930106A	15.9%

In the acute dermal and primary dermal irritation studies for REJEX-IT™ AP-50, the lot number for the test compound was reported as "56-612-69-02". It is not clear why the lot # reported in those studies differs from the lot/batch number reported in the supplementary data. Although the two studies were coregraded "Guideline", they are downgraded to supplementary, pending clarification of the discrepancy in the two lot numbers. The other acute studies which were coregraded supplementary are now upgraded to acceptable.

ok — per data faxed 7/29/94 SKR

The registrants submitted revised data waiver requests for acute inhalation studies on REJEX-IT™ AG-36 and REJEX-IT™ MA, and immune response studies for REJEX-IT™ MA (Guideline Reference numbers 152-12, 152-18, respectively). The acute inhalation studies are requested to be waived because pulmonary exposure will not result at a toxic concentration, and the label precautionary statement recommends that the applicator wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C). The immune response study is requested to be waived because the use patterns and protective clothing is not likely to increase worker exposure to above-dietary levels. SAB supports these waivers for the reasons provided.

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To Dan Peacock	From Cathy Shea
Co. EPA-OPP	Co. ERM-PMC
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Memorandum

To: Dan Peacock

From: Cathy Shea CS

Date: 28 July 1994

Subject: ReJeX-iT™ AP-50 (EPA File Symbol: 58035-A)

ERM

In response to our conversation earlier today, the ReJeX-iT™ AP-50 batch number for the Acute Dermal Toxicity Study (MRID 42087-03 and 432565-07) and the Primary Dermal Irritation Study (MRID 42087-05 and 432565-09), is 32292.

The lot number, 56-612-60-02 (expiration September 1, 1993), is for the saline vehicle used in these tests. The saline was manufactured by Abbott.

Please call either me or Judy Hushon at 703-734-9327 if you have any questions.

5-470858
D-205999

This information is acceptable and upgrades the acute dermal and dermal irritation studies to acceptable.

Sheryl K. Reilly
7-29-94