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

DEC 14 1990

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: DEET Product Chemistry Reregistration Standard Updates.

FROM: E. Zager, Acting Chief
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

TO: Lois Rossi, Chief
Reregistration Branch
Special Review & Reregistration Division (H7508C)

and

Reto Engler, Ph.D., Chief
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

Attached is the update to the Product Chemistry Chapter of the DEET Reregistration Standard prepared by Dynamac Corporation under supervision of CBRS, HED. It has undergone secondary review in the branch and has been revised to reflect Agency policies.

Revised data requirement tables are included.

If you need additional input please advise.

Attachment 1: DEET Product Chemistry Reregistration Standard Update

cc (With Attachment 1): RBP, DEET Reregistration Standard file, DEET Subject File, C. Furlow (PIB/FOD), J. Burrell (FOD), Dynamac, Circulation (7).

cc (Without Attachments): RF, P. Fenner-Crisp (HED).

DYNAMAC
CORPORATION

Final Report

DEET
Task 4: Product Chemistry Registration Standard Update

November 30, 1989

Revised Final Report dated December 14, 1990

Contract No. 68-D8-0080

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
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The Dynamac Building
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N,N-DIETHYL-M-TOLUAMIDE (DEET)

REGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 4

INTRODUCTION

A Product Search Listing conducted on 3/16/90 identifies 23 registered manufacturing-use products (MPs) containing DEET as a single or multiple active ingredient. A list of the registrants, their respective products and registration numbers appears in Table 1.

An Amended Registration Standard for DEET was issued on 3/12/85 following the issuance of the original Registration Standard dated 12/22/80. The amended standard requires all generic and product-specific product chemistry data for all DEET MPs. In response to these requirements, the DEET Joint Venture, on behalf of Miles Laboratories, MGK, Morflex Chemicals, and Virginia Chemicals (whose product has since been transferred to Hoechst Celanese), has submitted generic product chemistry data (1987; MRID 40140501). In addition to this submission, the noted registrants have individually responded to the Amended Registration Standard by submitting data for certain products listed in Table 1. This document reviews and evaluates product chemistry data pertaining to all MPs containing DEET as an active ingredient, including those products containing multiple active ingredients. The Amended Registration Standard for DEET also requires product chemistry data for all end-use products (EPs) that are not eligible for the formulators exemption [FIFRA sec 3(c)(2)(D)]; data pertaining to end-use products are not considered in this update document.

Corresponding to each of the Topical Discussions listed below are the Guideline Reference Numbers from "Pesticide Assessment Guidelines - Subdivision D - Product Chemistry", referred to in Title 40 of the Code of Federal Regulations (40 CFR), Part 158, "Data Requirements for Registration", Subpart C, "Product Chemistry Data Requirements". These regulations and guidelines explain the minimum data that the Agency needs to adequately assess the product chemistry of DEET.

	Guidelines Reference No. from 40 CFR §158.155-190
Product Composition and Manufacture	61-(1-3)
Analysis and Certification of Product Ingredients .	62-(1-3)
Physical and Chemical Characteristics	63-(2-20)

Table 1. Current registrants of DEET MPs and the data submitted in response to the Amended DEET Registration Standard dated 3/12/85.

Registrant and Product(s)	EPA Reg. Nos.	Data Submission[a]
Miles Laboratories, Inc.		
99.9% T	121-17	00149979, 40140501[c], CSF
Hoechst Celanese Corp.		
99.9% T	8340-39[b]	00152588, 00155132, 40140501[c], CSF
Morflex Chemical Company, Inc.		
99.9% T	51147-1	40140501[c]
75.0% FI	51147-2	CSF
McLaughlin Gormley King Company (MGK)		
99.9% T	1021-891	40140501[c], 40146001, 40158601
94.6% FI	1021-1354	None
90.0% FI	1021-1355	None
86.0% FI	1021-1276	CSF
83.34% FI	1021-1201	None
83.33% FI	1021-1214	None
80.0% FI	1021-1312	CSF
76.93% FI	1021-1111	None
76.92% FI	1021-1290	CSF
70.0% FI	1021-567	00163059, 40750101, CSF
70.0% FI	1021-1144	None
66.67% FI	1021-737	CSF
60.0% FI	1021-971	None
50.0% FI	1021-1070	None
41.67% FI	1021-1200	None
40.0% FI	1021-512	None
40.0% FI	1021-886	None
17.5% FI	1021-535	CSF
5.0% FI	1021-511	None

[a] Eight digit numbers are MRID documents from the Pesticide Document Management System. "CSF" refers to a Confidential Statement of Formula obtained from the registration jacket.

[b] Transferred on 4/18/89 from Virginia Chemicals, Inc. under EPA Reg. No. 1187-105.

[c] Submitted by the DEET Joint Venture for the 99.9% technicals manufactured by Miles (EPA Reg. No. 121-17), Morflex (EPA Reg. No. 51147-1), MGK (EPA Reg. No. 1021-891), and Hoechst Celanese (EPA Reg. No. 8340-39).

SUMMARY

The following Product Chemistry data are required:

- **For the Miles Laboratories, Inc.** 99.9% T (EPA Reg. No. 121-17): product composition, manufacturing process, discussion of the formation of impurities, preliminary analysis, certified limits, enforcement analytical methods, and physical chemical characteristics (boiling point, vapor pressure, solubility, octanol/water partition coefficient, stability, oxidizing/reducing action, flammability, explodability, viscosity, and corrosion characteristics).

- For the **Hoechst Celanese Corp.** 99.9% T (EPA Reg. No. 8340-39): product composition, discussion of the formation of impurities, certified limits, enforcement analytical methods, and physical chemical characteristics (boiling point, solubility, vapor pressure, octanol/water partition coefficient, stability, and corrosion characteristics).

- For the **Morflex Chemical Company, Inc.** 99.9% T (EPA Reg. No. 51147-1): product composition, manufacturing process, discussion of the formation of impurities, certified limits, enforcement analytical methods, and all physical chemical characteristics.

- For the **Morflex Chemical Company, Inc.** 75% FI (EPA Reg. No. 51147-2): discussion of the formation of impurities, certified limits, enforcement analytical methods, and storage stability.

- For the **McLaughlin Gormley King Company** 99.9% T (EPA Reg. No. 1021-891): product composition, manufacturing process, discussion of the formation of impurities, certified limits, enforcement analytical methods, and physical chemical characteristics (color, physical state, odor, boiling point, density, solubility, vapor pressure, pH, stability, oxidizing or reducing action, flammability, explosiveness, storage stability, viscosity, and corrosion characteristics).

- **For the McLaughlin Gormley King Company** 86% FI (EPA Reg. No. 1021-1276), 80% FI (EPA Reg. No. 1021-1312), 76.92% FI (EPA Reg. No. 1021-1290), 70% FI (EPA Reg. No. 1021-567), and 66.67% FI (EPA Reg. No. 1021-737): certified limits and storage stability data.

- For the **MGK** 17.5% FI (EPA Reg. No. 1021-535): storage stability data.

- For the **McLaughlin Gormley King Company** 94.6% FI (EPA Reg. No. 1021-1354), 90% FI (EPA Reg. No. 1021-1355), 83.34% FI (EPA Reg. No. 1021-1201), 83.33% FI (EPA Reg. No. 1021-1214), 76.93% FI (EPA Reg. No. 1021-1111), 70% FI (EPA Reg. No. 1021-1144), 60% FI (EPA Reg. No. 1021-971), 50% FI (EPA Reg. No. 1021-1070), 41.67% FI (EPA Reg. No. 1021-1200), 40% FI (EPA Reg. No. 1021-512), 40% FI (EPA Reg. No. 1021-886), and 5% FI (EPA Reg. No. 1021-511): a complete set of product chemistry data requirements for each product.

Note to P.M.: The nominal concentrations (as reported on the either the CSF or the preliminary analysis report) for all DEET technical products, as well as for the MGK 66.67% FI (EPA Reg. No. 1021-737), are not in agreement with the percent active ingredient listed on the label. We additionally note that the nominal concentration and/or certified limits for all MGK and Morflex FIs are based on the label claims for the respective technicals from which they were formulated; therefore, the labels for these FIs do not reflect the same concentration of DEET that would be obtained by analysis.

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Composition

The Amended DEET Registration Standard dated 3/12/85 requires additional generic and product-specific data concerning product composition. Miles Laboratories, Inc., Hoechst Celanese Corp., and Morflex Chemical Company have responded to these requirements for all of their products listed in Table 1; McLaughlin Gormley King Company has responded only for certain products. The submitted data are presented in Confidential Appendix A, and our conclusions are detailed below.

Data (CSF dated 6/5/85) submitted by **Miles Laboratories, Inc.** for the 99.9% T (EPA Reg. No. 121-17) do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition because the identity and nominal concentration of the individual isomers were not provided. Preliminary analysis data indicate that additional components are present at ≥0.1%. The identity, purpose, and nominal concentration of each of these additional components must be included on the CSF. We note that neither the mean concentration (as determined by preliminary analysis) nor the lower certified limit of DEET is reflected on the label for this product.

Data (CSF dated 10/7/85; registration jacket) submitted by **Hoechst Celanese Corp.** for the 99.9% T (EPA Reg. No. 8340-39) do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition because

ingredients present at ≥0.1% were not listed along with their nominal concentrations; furthermore, the nominal concentration was not reported for the active ingredients. We note that preliminary analysis of five batch samples of the Hoechst Celanese T product (see Confidential Appendix D) indicate that additional components are present. In addition, we note that neither the mean concentration (as determined by preliminary analysis) nor the lower certified limit of DEET is reflected on the label for this product.

Data (CSF dated 3/30/87; registration jacket) submitted by **Morflex Chemical Company, Inc.** for the 99.9% T (EPA Reg. No. 51147-1) do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition because nominal concentrations were not provided for any ingredient and impurities were not identified as such. We note that neither the mean concentration (as determined by preliminary analysis) nor the lower certified limit of DEET is reflected on the label for this product.

Data (CSF dated 6/12/85; registration jacket) for the Morflex 75% FI (EPA Reg. No. 51147-2) satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition. We note that the nominal concentration reported for this product correctly reflects the label claim of 99.9% DEET in the technical product, which is used to formulate this FI. However, if the label of the technical product is amended to more accurately reflect the mean concentration of DEET in the technical product, a new CSF for this FI will be required to reflect this change.

Data (1987; MRID 40158601) submitted by **McLaughlin Gormley King Company** for the 99.9% T (EPA Reg. No. 1021-891) do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition because the nominal concentrations and purposes of the listed ingredients were not reported. We note that neither the mean concentration (as determined by preliminary analysis) nor the lower certified limit of DEET is reflected on the label for this product.

Data submitted for the MGK 86% FI (EPA Reg. No. 1021-1276; CSF dated 3/15/90), 80% FI (EPA Reg. No. 1021-1312; CSF dated 3/15/90), 76.92% FI (EPA Reg. No. 1021-1290; CSF dated 3/15/90), 70% FI (EPA Reg. No. 1021-567; CSF dated 3/15/90), 66.67% FI (EPA Reg. No. 1021-737; CSF dated 3/30/90), and 17.5% FI (EPA Reg. No. 1021-535; CSF dated 3/15/90) satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition. We note that the nominal concentration reported for all FIs correctly reflects the label claim of 99.9% DEET in the technical product, which is used to formulate these FIs. However, if the label of the technical product is amended to more accurately reflect the mean concentration of DEET in the

technical product, new CSFs will be required for all MGK FIs as well.

No information on product identity has been submitted by **McLaughlin Gormley King Company** for the following formulation intermediate products: 94.6% FI (EPA Reg. No. 1021-1354), 90% FI (EPA Reg. No. 1021-1355), 83.34% FI (EPA Reg. No. 1021-1201), 83.33% FI (EPA Reg. No. 1021-1214), 76.93% FI (EPA Reg. No. 1021-1111), 70% FI (EPA Reg. No. 1021-1144), 60% FI (EPA Reg. No. 1021-971), 50% FI (EPA Reg. No. 1021-1070), 41.67% FI (EPA Reg. No. 1021-1200), 40% FI (EPA Reg. No. 1021-512), 40% FI (EPA Reg. No. 1021-886), and 5% FI (EPA Reg. No. 1021-511). Data requirements regarding this topic remain outstanding for these products.

We note that the nominal concentration of DEET reported on the CSF of the MGK 66.67% FI (EPA Reg. No. 1021-737) is not in agreement with the percent active ingredient listed on the label.

61-2. Starting Materials and Manufacturing Process

The Amended DEET Registration Standard dated 3/12/85 specifies generic and product-specific data requirements regarding starting materials and manufacturing and formulation processes. In response, Hoechst Celanese, Morflex, and McLaughlin Gormley King have submitted descriptions of production and formulation processes for certain registered MPs; these data appear in Confidential Appendix B. Our conclusions are presented below.

Data (1985; MRID 00155132) submitted by **Virginia Chemicals, Inc.** for the **Hoechst Celanese** 99.9% T (EPA Reg. No. 8340-39) satisfy the requirements of 40 CFR §158.160-162 (Guideline Reference No. 61-2) regarding starting materials and the manufacturing process. However, Hoechst Celanese must verify that both the manufacturing process and location has not changed since the transfer of ownership on 4/89 from Virginia Chemicals. All information will be required if either has changed.

Data (Registration jacket; no MRID assigned) submitted by **Morflex Chemical Company, Inc.** for the 75% FI (EPA Reg. No. 51147-2) satisfy the requirements of 40 CFR §158.160-162 (Guideline Reference No. 61-2) regarding starting materials and the formulation process. No additional data concerning this topic are required for this product.

Data (product registration jackets; no MRIDs assigned) submitted by **McLaughlin Gormley King Company** for 86% FI (EPA Reg. No. 1021-1276), 80% FI (EPA Reg. No. 1021-1312), 76.92% FI (EPA Reg. No. 1021-1290), 70% FI (EPA Reg. No. 1021-567), 66.67% FI (EPA Reg. No. 1021-737), and 17.5% FI (EPA Reg. No. 1021-535) satisfy the requirements of 40 CFR §158.160-162 (Guideline Reference No. 61-2) regarding starting materials and the formulation process.

No additional data concerning this topic are required for these MGK products.

No information on beginning materials and manufacturing process has been submitted for Miles Laboratories 99.9% T (EPA Reg. No. 121-17), Morflex Chemical 99.9% T (EPA Reg. No. 51147-1), and the following MGK products: 99.9% T (EPA Reg. No. 1021-891), 94.6% FI (EPA Reg. No. 1021-1354), 90% FI (EPA Reg. No. 1021-1355), 83.34% FI (EPA Reg. No. 1021-1201), 83.33% FI (EPA Reg. No. 1021-1214), 76.93% FI (EPA Reg. No. 1021-1111), 70% FI (EPA Reg. No. 1021-1144), 60% FI (EPA Reg. No. 1021-971), 50% FI (EPA Reg. No. 1021-1070), 41.67% FI (EPA Reg. No. 1021-1200), 40% FI (EPA Reg. No. 1021-512), 40% FI (EPA Reg. No. 1021-886), and 5% FI (EPA Reg. No. 1021-511). Data requirements regarding this topic remain outstanding for these products.

61-3. Discussion of the Formation of Impurities

The Amended DEET Registration Standard dated 3/12/85 specifies generic and product-specific data requirements regarding discussion of formation of impurities. In response, the DEET Joint Venture (1987; MRID 40140501) submitted a discussion of the formation of impurities in the "DEET Blend." The blend is a 1:1:1:1 composite of the 99.9% technical products registered to Miles Laboratories, Hoechst Celanese, Morflex Chemical, and MGK. This discussion which is presented in Confidential Appendix C does not satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding formation of impurities in the 99.9% technical products registered to Miles Laboratories (EPA Reg. No. 121-17), Hoechst Celanese (EPA Reg. No. 8340-39), Morflex Chemical (EPA Reg. No. 51147-1), and MGK (EPA Reg. No. 1021-891) because the discussions did not cover post-production reactions between ingredients, migration of components of packaging materials, carry-over of contaminants from production equipment, and process quality control measures. Additional discussion is required for these technical products.

McLaughlin Gormley King Company (product registration jacket; no MRIDs assigned) submitted additional product-specific information regarding the formation of impurities in MGK FI products. This discussion is summarized in Confidential Appendix C. This discussion satisfies the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding formation of impurities in the following MGK products: 86% FI (EPA Reg. No. 1021-1276), 76.92% FI (EPA Reg. No. 1021-1290), 70% FI (EPA Reg. No. 1021-567), 66.67% FI (EPA Reg. No. 1021-737), and 17.5% FI (EPA Reg. No. 1021-535).

No discussion of the formation of impurities has been submitted for the Morflex 75% FI (EPA Reg. No. 51147-2) and the following MGK formulation intermediate products: 94.6% FI (EPA Reg. No. 1021-1354), 90% FI (EPA Reg. No. 1021-1355), 83.34% FI (EPA Reg.

No. 1021-1201), 83.33% FI (EPA Reg. No. 1021-1214), 76.93% FI (EPA Reg. No. 1021-1111), 70% FI (EPA Reg. No. 1021-1144), 60% FI (EPA Reg. No. 1021-971), 50% FI (EPA Reg. No. 1021-1070), 41.67% FI (EPA Reg. No. 1021-1200), 40% FI (EPA Reg. No. 1021-512), 40% FI (EPA Reg. No. 1021-886), and 5% FI (EPA Reg. No. 1021-511). Data requirements regarding this topic remain outstanding for these products.

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

62-1. Preliminary Analysis

The Amended DEET Registration Standard dated 3/12/85 requires all data regarding preliminary analysis. In response, the registrants listed in Table 1 have submitted preliminary analysis data for their registered technical products as well as an analysis data of a "DEET Blend" (a 1:1:1:1 blend of the four registered technical products). These data appear in Confidential Appendix D; our conclusions are presented below.

Data (1985; MRID 00155132) submitted by **Virginia Chemicals, Inc.** for the **Hoechst Celanese** 99.9% T (EPA Reg. No. 8340-39) do not satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis because a more recent analysis submitted by the DEET Joint Venture (see p. 4 of this section) indicates that additional impurities are present in this product. Additional data concerning this topic are required for this product.

Data (jacket for 51147-1; no MRID assigned) submitted by **Morflex Chemical Company, Inc.** for the 99.9% T (EPA Reg. No. 51147-1) do not satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis because the data do not reflect the concentrations of impurities of the Morflex product alone. A new analysis must be submitted reflecting the impurity profile of this product.

Data (1987; MRID 40158601) submitted by **McLaughlin Gormley King Company** for the 99.9% T (EPA Reg. No. 1021-891) satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis. No additional data concerning this topic are required for this product.

Data (1987; MRID 40140501) submitted by the DEET Joint Venture for the **Miles Laboratories, Inc.** 99.9% T (EPA Reg. No. 121-17) do not satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis because only one batch was analyzed (five batches are required). Additional data are required for this product.

62-2. Certified Limits

The Amended DEET Registration Standard dated 3/12/85 requires all generic and product-specific data regarding certification of ingredient limits. In response, the registrants listed in Table 1 have submitted certification of ingredient limits for certain of the registered MPs. The data are presented in Confidential Appendix A; our conclusions are presented below.

Data (CSF dated 6/5/85) submitted by **Miles Laboratories, Inc.** for the 99.9% T (EPA Reg. No. 121-17) do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certification of limits because a lower and upper certified limit was not submitted for each of the isomers present.

Data (CSF dated 10/7/85; registration jacket) submitted by **Hoechst Celanese Corp.** for the 99.9% T (EPA Reg. No. 8340-39) do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certification of limits because upper certified limits were not submitted for the active ingredients, including for each individual isomer and lower certified limits were not submitted for each individual related isomer. We note that the ortho- and para-isomers of DEET are considered to be active ingredients since they are grouped under the same Pesticide Chemical Code as the meta-isomer; therefore, upper and lower certified limits are required for each of these ingredients.

Data (CSF dated 3/30/87; registration jacket) submitted by **Morflex Chemical Company, Inc.** for the 99.9% T (EPA Reg. No. 51147-1) do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certification of limits for the following reasons: (i) an upper certified limit was not reported for the meta-isomer (active ingredient); (ii) an upper certified limit was not provided for an impurity; (iii) the data were not submitted on EPA Form 8570-4 (Rev 2/85); and (iv) an explanation on how the upper limits were established was not provided. We note that the ortho- and para-isomers of DEET are considered to be active ingredients since they are grouped under the same Pesticide Chemical Code as the meta-isomer; therefore, upper and lower certified limits are required for each of these ingredients.

Data (CSF dated 6/12/85; registration jacket) submitted for the **Morflex 75% FI** (EPA Reg. No. 51147-2) do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certification of limits because lower and upper certified limits were not reported for the active and inert ingredients and certified limits were not reported on EPA Form 8570-4 (Rev. 2/85).

Data submitted by **McLaughlin Gormley King Company** (1987; MRID 40158601) for the 99.9% T (EPA Reg. No. 1021-891) do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certification of limits because an upper certified limit must be provided for the active ingredient and the certifications must be submitted on EPA Form 8570-4 (Rev. 2/85). We note that the ortho- and para-isomers of DEET are considered to be active ingredients since they are grouped under the same Pesticide Chemical Code as the meta-isomer; therefore, lower certified limits are required for each of these ingredients.

Data submitted for the MGK 86% FI (EPA Reg. No. 1021-1276; CSF dated 3/15/90), 80% FI (EPA Reg. No. 1021-1312; CSF dated 3/15/90), 76.92% FI (EPA Reg. No. 1021-1290; CSF dated 3/15/90), 70% FI (EPA Reg. No. 1021-567; CSF dated 3/15/90), and 66.67% FI (EPA Reg. No. 1021-737; CSF dated 3/30/90), do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certification of limits because the range of certified limits for the ingredient DEET exceed the range of standard certified limits without explanation by the registrant. Data submitted for the MGK 17.5% FI (EPA Reg. No. 1021-535; CSF dated 3/15/90) satisfy requirements pertaining to certified limits. However, if the label of the technical product is amended to more accurately reflect the mean concentration of DEET in the technical product, a new CSF for these FIs will be required to reflect this change in the certified limits.

No information on certified limits has been submitted by **McLaughlin Gormley King Company** for the following formulation intermediate products: 94.6% FI (EPA Reg. No. 1021-1354), 90% FI (EPA Reg. No. 1021-1355), 83.34% FI (EPA Reg. No. 1021-1201), 83.33% FI (EPA Reg. No. 1021-1214), 76.93% FI (EPA Reg. No. 1021-1111), 70% FI (EPA Reg. No. 1021-1144), 60% FI (EPA Reg. No. 1021-971), 50% FI (EPA Reg. No. 1021-1070), 41.67% FI (EPA Reg. No. 1021-1200), 40% FI (EPA Reg. No. 1021-512), 40% FI (EPA Reg. No. 1021-886), and 5% FI (EPA Reg. No. 1021-511). Data requirements regarding this topic remain outstanding for these products.

62-3. Enforcement Analytical Methods

The **Amended DEET** Registration Standard dated 3/12/85 specifies data requirements regarding analytical methods to verify certified limits. In response, The **DEET Joint Venture** (1987; MRID 40140501) on behalf of the members (Miles, MGK, Morflex, and Virginia Chemicals thus Hoechst) , **McLaughlin Gormley King Company** (1987; MRID 40158601), and **Morflex Chemical Company, Inc.** (1987; jacket for 51147-1; no MRID assigned) have submitted analytical methods for determination of the active ingredient (discussed below) and impurities (discussed in Confidential Appendix E). The submitted information does not satisfy the

requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods because appropriate validation data for the methods was not submitted. Additional information is required.

A capillary GLC method is used for determination of the active ingredient (meta-isomer). Samples are diluted with petroleum ether and an aliquot of this solution is assayed by GLC on a 25 meter cross-linked methylsilicone column using a flame ionization detector. No validation data for the method were provided.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The Amended DEET Registration Standard dated 3/12/85 requires all generic and product-specific data requirements pertaining to physical and chemical characteristics. In response, several registrants have submitted physical and chemical characteristics of the DEET purified active ingredient (PAI), technical grade of the active ingredient (TGAI), and manufacturing-use products (MP). These data are summarized below in Table 1.

Data (1985; MRID 00149979) submitted by **Miles Laboratories, Inc.** for the 99.9% T (EPA Reg. No. 121-17) do not satisfy many of the requirements of 40 CFR 158.190 (Guidelines Reference Nos. 63-2 through 63-20) because the registrant did not submit raw data, methods, and conditions under which solubility, octanol/water partition coefficient, storage stability, and corrosion characteristics data were collected. Furthermore, no data were submitted pertaining to boiling point, vapor pressure, stability, oxidizing/reducing action, flammability, explodability, and viscosity.

Data (1985; MRIDs 00152588 and 00155132) submitted by **Virginia Chemicals, Inc.** for the **Hoechst Celanese** 99.9% T (EPA Reg. No. 8340-39) do not fully satisfy the requirements of 40 CFR 158.190 (Guidelines Reference Nos. 63-2 through 63-20) because no data were submitted pertaining to boiling point, solubility, vapor pressure, octanol/water partition coefficient, stability, and corrosion characteristics. In addition, the registrant did not submit the raw data and conditions under which storage stability data were obtained.

Data (located in the registration jacket; no MRID assigned) submitted by **Morflex Chemical Company, Inc.** for the 75% FI (EPA Reg. No. 55147-2) satisfy all product-specific requirements of 40 CFR 158.190 (Guidelines Reference Nos. 63-2 through 63-20) with the exception of storage stability, for which raw data and information regarding the storage container are required.

Data (1986; 00163059 and 1987; MRID 40146001) submitted by **McLaughlin Gormley King Company** for the 99.9% T (EPA Reg. No.

1021-891) do not fully satisfy the requirements of 40 CFR 158.190 (Guidelines Reference Nos. 63-2 through 63-20) because no data were submitted pertaining to color, physical state, odor, boiling point, density, vapor pressure, stability, oxidizing or reducing action, flammability, explosiveness, storage stability, viscosity, and corrosion characteristics. In addition, data for solubility did not include representative polar and non-polar solvents.

Data (located in the registration jacket of respective products; no MRIDs assigned) submitted by **McLaughlin Gormley King Company** for the 86% FI (EPA Reg. No. 1021-1276), 80% FI (EPA Reg. No. 1021-1312), 76.92% FI (EPA Reg. No. 1021-1290), 70% FI (EPA Reg. No. 1021-567), 66.67% FI (EPA Reg. No. 1021-737), and 17.5% FI (EPA Reg. No. 1021-535) satisfy all of the product-specific requirements of 40 CFR 158.190 (Guidelines Reference Nos. 63-2 through 63-20) with the exception of storage stability data, which were not submitted for any of the noted MGK FI products. The submitted storage stability data (MRID 40750101) for the 70% FI (EPA Reg. No. 1021-567) were deemed unacceptable by the Agency (letter by P. Hutton, PM 17 to S. Rogosheke of McLaughlin Gormley King and Company; dated 3/2/90; registration jacket) because tests were conducted at a temperature of 100 C rather than at room temperature. The registrant was requested to submit an additional storage stability study in which the formulated product is stored in a container similar to those that will be used in the trade for a period of one year under warehouse conditions of temperature and humidity. The analysis should include data from time zero.

No physical and chemical characteristics have been submitted by **Morflex Chemical Company, Inc.** for the 99.9% T (EPA Reg. No. 51147-1) and by **McLaughlin Gormley King Company** for the following products: 94.6% FI (EPA Reg. No. 1021-1354), 90% FI (EPA Reg. No. 1021-1355), 83.34% FI (EPA Reg. No. 1021-1201), 83.33% FI (EPA Reg. No. 1021-1214), 76.93% FI (EPA Reg. No. 1021-1111), 70% FI (EPA Reg. No. 1021-1144), 60% FI (EPA Reg. No. 1021-971), 50% FI (EPA Reg. No. 1021-1070), 41.67% FI (EPA Reg. No. 1021-1200), 40% FI (EPA Reg. No. 1021-512), 40% FI (EPA Reg. No. 1021-886), and 5% FI (EPA Reg. No. 1021-511). Data requirements regarding physical and chemical characteristics remain outstanding for these products.

Table 1. Physical and chemical properties of the DEET purified active ingredient (PAI), technical grade of the active ingredient (TGAI), and manufacturing-use products.

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; EPA Reg. No.; MRID or Jacket)[a]
63-2. Color	**light amber to colorless** (99.9% T; 121-17; 00149979) **clear to lightly colored** [ASTM D 1535-68] (99.9% T; 8340-39; 00152588) **water white** (86% FI; 1021-1276; jacket) (66.67% FI; 1021-737; jacket) **clear** (75% FI; 51147-2; jacket) **very pale yellow** (80% FI; 1021-1312; jacket) (76.92% FI; 1021-1290; jacket) (70% FI; 1021-567; jacket) (17.5% FI; 1021-535; jacket)
63-3. Physical state	**liquid** (99.9% T; 121-17; 00149979) (99.9% T; 8340-39; 00152588) (86% FI; 1021-1276; jacket) (80% FI; 1021-1312; jacket) (76.92% FI; 1021-1290; jacket) (70% FI; 1021-567; jacket) (66.67% FI; 1021-737; jacket) (17.5% FI; 1021-535; jacket) **oily liquid** (75% FI; 51147-2; jacket)
63-4. Odor	**near odorless to slightly musty** (99.9% T; 121-17; 00149979) **little odor; bland** (99.9% T; 8340-39; 00152588) (76.92% FI; 1021-1290; jacket) **characteristic ethanol odor** (75% FI; 51147-2; jacket)

(Continued.)

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; EPA Reg. No.; MRID or Jacket)[a]
63-2. Odor (cont.)	**DEET-odor** (86% FI; 1021-1276; jacket) (80% FI; 1021-1312; jacket) (70% FI; 1021-567; jacket) (66.67% FI; 1021-737; jacket) **characteristic isopropanol odor** (17.5% FI; 1021-535; jacket)
63-5. Melting point	**N/A since all registered technical DEET products are liquid**
63-6. Boiling point	**no data reported**
63-7. Density, bulk density, or specific gravity	**specific gravity 0.996** (99.9% T; 121-17; 00149979) **0.9946 specific gravity at 25 C** [VCI method 0112-09-2.3.7, hydrometer] (99.9% T; 8340-39; 00152588) **1.007 ± 0.012 specific gravity** (86% FI; 1021-1276; jacket) **1.011 ± 0.012 specific gravity at 20 C** (80% FI; 1021-1312; jacket) **1.013 ± 0.01 specific gravity at 20 C** (76.92% FI; 1021-1290; jacket) **0.940-0.946 specific gravity at 25C** (75% FI; 51147-2; jacket) **1.02 ± 0.01 specific gravity at 25C** (70% FI; 1021-567; jacket) **0.990 ± 0.012 specific gravity** (66.67% FI; 1021-737; jacket) **0.833 ± 0.012 specific gravity at 20 C** (17.5% FI; 1021-535; jacket)
63-8. Solubility	**Completely miscible at all ratios in: ethanol, isopropanol, acetone, chloroform, dichloroethane, methanol,**

(Continued.)

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; EPA Reg. No.; MRID or Jacket)[a]
63-8. Solubility (cont.)	**toluene, octanol, petroleum ether, and most other organic solvents. Slightly soluble in water and glycerin.** (99.9% T; 121-17; 00149979) **solubility in water at 0.2-0.3 wt %** (99.9% T; 1021-891; 40146001)
63-9. Vapor pressure	**no data reported**
63-10. Dissociation constant	**not required according to Amended DEET Registration Standard**
63-11. Octanol/water partition coefficient	**100% in the octanol phase** [CFR, 45, 77350, 11/1/80] (99.9% T; 121-17; 00149979) **log K_{ow}=2.00** [CFR, Vol 50, No. 188, 9/27/85] (99.9% T; 1021-891; 40146001)
63-12. pH	**9.5 ± 1** (99.9% T; 121-17; 00149979) **N/A since product is not dispersible in water** (99.9% T; 8340-39; 00152588) (86% FI; 1021-1276; jacket) (80% FI; 1021-1312; jacket) (76.92% FI; 1021-1290; jacket) (70% FI; 1021-567; jacket) (66.67% FI; 1021-737; jacket) (17.5% FI; 1021-535; jacket) **8.5-9.5** (75% FI; 51147-2; jacket)
63-13. Stability	**stable at ambient temperatures** (86% FI; 1021-1276; jacket) (80% FI; 1021-1312; jacket) (76.92% FI; 1021-1290; jacket) (70% FI; 1021-567; jacket) (66.67% FI; 1021-737; jacket) (17.5% FI; 1021-535; jacket)

(Continued.)

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; EPA Reg. No.; MRID or Jacket)[a]
63-14. Oxidizing or reducing action	**does not have reducing or oxidizing properties** [44 Fed. Reg. 16267 (3/16/79)] (99.9% T; 8340-39; 00155132) (86% FI; 1021-1276; jacket) (80% FI; 1021-1312; jacket) (70% FI; 1021-567; jacket) (66.67% FI; 1021-737; jacket) (17.5% FI; 1021-535; jacket)
63-15. Flammability	**flash point >200 F** [Tag closed cup, ASTM D 56-70] (99.9% T; 8340-39; 00152588) (70% FI; 1021-567; jacket) **flash point** = 200 F [TCC] (86% FI; 1021-1276; jacket) (80% FI; 1021-1312; jacket) (76.92% FI; 1021-1290; jacket) (70% FI; 1021-567; jacket) (66.67% FI; 1021-737; jacket) **flash point = 80 F** [Tag closed cup, ASTM D-56] (75% FI; 51147-2 ; jacket) **flash point = 60 F** (17.5% FI; 1021-535; jacket)
63-16. Explodability	**no thermal explodability** [ASTM E698-79 and ARC] (99.9% T; 8340-39; 00155132) **N/A since product is not considered to be potentially explosive** (86% FI; 1021-1276; jacket) (80% FI; 1021-1312; jacket) (76.92% FI; 1021-1290; jacket) (75% FI; 51147-2; jacket) (70% FI; EPA Reg. No. 1021-567; jacket) (66.67% FI; 1021-737; jacket) (17.5% FI; 1021-535; jacket)
63-17. Storage stability	**stable two years at 72 F and for one year at 100 F** (99.9% T; 121-17; 00149979)

(Continued.)

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; EPA Reg. No.; MRID or Jacket)[a]
63-17. Storage stability (cont.)	**stable for one year in glass containers** (99.9% T; 8340-39; 00152588)
	no raw data are available; however, registrant claims, product will pass product specifications after one year (75% FI; 51147-2; jacket)
	stable for one year at 100 F in glass, Conolene, PET, Barex, HDPE containers, and welded-seam lined cans with epon-coated valve cups (70% FI; 1021-567; 40750101, 00163059)
63-18. Viscosity	**16.92 centistokes at 25 C** [ASTM D445-71 and D446-74 at 25 C] (99.9% T; 8340-39; 00155132)
	32.5 centipoises at 22 C (86% FI; 1021-1276; jacket) (76.92% FI; 1021-1290; jacket)
	31.5 centipoises at 23 C (80% FI; 1021-1312; jacket)
	5 centipoises at 25 C [spindle #1 at 30 rpm] (75% FI; 51147-2; jacket)
	37.5 centipoises at 22 C (70% FI; 1021-567; jacket)
	32.0 centipoises at 22 C (66.67% FI; 1021-737; jacket)
	9.5 centipoises at 22 C (17.5% FI; 1021-535; jacket)
63-19. Miscibility	**N/A; not required by Amended DEET Registration Standard**
63-20. Corrosiveness	**will not corrode or dissolve nylon, teflon, polyethylene, polypropylene, polyester; dissolves or softens many**

(Continued.)

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; EPA Reg. No.; MRID or Jacket)[a]
63-20. Corrosiveness (cont.)	**other plastics including polyvinyl chloride and tygon** (99.9% T; 121-17; 00149979)
	N/A since products are not considered to be corrosive (86% FI; 1021-1276; jacket) (80% FI; 1021-1312; jacket) (76.92% FI; 1021-1290; jacket) (70% FI; 1021-567; jacket) (66.67% FI; 1021-737; jacket) (17.5% FI; 1021-535; jacket)
	no corrosion was observed in welded seam lined cans with epon coated valve cups for one year at 100 F (70% FI; 1021-567; 40750101, 00163059)
	no evidence of corrosion has occurred in metal drums, pails, or tank trucks that are used for shipping and storage (75% FI; 51147-2; jacket)

[a] PAI = purified active ingredient. TGAI = technical grade of the active ingredient. MP = manufacturing-use product. FI = formulation intermediate. Hyphenated numbers represent EPA Registration Numbers. Eight-digit numbers are MRID documents from the Pesticide Document Management System (PDMS). "Jacket" refers to the pesticide registration jacket maintained for the specified product by Registration Division, OPP, EPA.

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41559001 Spagnoli, J. (1990) Product Chemistry for Cutter Evergreen Insect Repellent Pump Spray Formula MMI. Unpublished study prepared by Miles Inc. 19 p.

41559200 Miles Inc. (1990) Submission of Data To Support the Application for Amended Registration of Cutter Insect Repellent Pump Spray: Product Chemistry Study. Transmittal of 1 study.

41559201 Spagnoli, J. (1990) Product Chemistry for Cutter Insect Repellent Pump Spray Formula MMI. Unpublished study prepared by Miles Inc. 19 p.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE DEET TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-2. Beginning Materials and Production Process	TGAI	Partially	00155132	Yes[4]
61-3. Formation of Impurities	TGAI	Partially	40140501	Yes[5]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis	TGAI	Partially	00155132 40140501 40158601	Yes[6]
Physical and Chemical Characteristics[7]				
63-2. Color	TGAI	Partially	00149979 00152588	Yes[8]
63-3. Physical State	TGAI	Partially	00149979 00152588	Yes[8]
63-4. Odor	TGAI	Partially	00149979 00152588	Yes[8]
63-5. Melting Point	TGAI	N/A	N/A	No[9]
63-6. Boiling Point	TGAI	No	N/A	Yes[10]
63-7. Density, Bulk Density, or Specific Gravity	TGAI	Partially	00149979 00152588	Yes[8]
63-8. Solubility	TGAI or PAI	Partially	00149979 40146001	Yes[11]
63-9. Vapor Pressure	TGAI or PAI	No	N/A	Yes[12]
63-10. Dissociation Constant	TGAI or PAI	N/A	N/A	No
63-11. Octanol/Water Partitioning Coefficient	PAI	Partially	00149979 40146001	Yes[13]
63-12. pH	TGAI	N/A	N/A	No[14]
63-13. Stability	TGAI	Partially	N/A	Yes[12]
Other Requirements:				
64-1. Submittal of Samples	N/A	N/A	N/A	No

1. Data pertain to the 99.9% technical products registered to the following companies: Miles Laboratories, Inc. (EPA Reg. No. 121-17), Hoechst Celanese Corp. (EPA Reg. No. 8340-39), Morflex Chemical Company, Inc.

TABLE A. (Continued).

(EPA Reg. No. 51147-1), and McLaughlin Gormley King Company (MGK) (EPA Reg. No. 1021-891). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for DEET Manufacturing-Use Products".

2. Test substance: PAI = purified active ingredient; TGAI = technical grade of the active ingredient; MP = manufacturing-use product.

3. Underlining indicates documents that have been reviewed in this Update document.

4. Miles, Morflex, and MGK have not responded to data requirements for their technical products listed in Footnote 1; all data are required for these products. Hoechst Celanese has responded for its 99.9% T; however, the registrant must verify that the manufacturing process and location has not changed since the transfer of ownership effective 4/18/89; otherwise all data would be required.

5. The Deet Joint Venture has responded to data requirements for the technical products listed in Footnote 1; however all of the registrants must address post-production reactions between ingredients, migration of components of packaging materials, carry-over of contaminants from production equipment, and process quality control measures for their product.

6. Miles, Hoechst, and Morflex have responded to data requirements for their technical products listed in Footnote 1; however five or more recent representative samples must be analyzed for the amount of active ingredient and each impurity present at 0.1% or greater for each of these products individually. MGK has adequately responded for its 99.9% T.

7. As required by 40 CFR §158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-13, data must be submitted on physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, octanol/water partition coefficient, pH, and stability). There are additional data requirements listed in Table B pertaining to physicochemical characteristics of those technical products which are also manufacturing use products.

8. MGK and Morflex have not responded to data requirements for their technical products listed in Footnote 1; all data are required. Miles and Hoechst have adequately responded for their 99.9% Ts.

9. Data on melting point are not required since the technicals are a liquid at room temperature.

TABLE A. (Continued).

10. Miles, Hoechst, Morflex and MGK have not responded to data requirements for their technical products listed in Footnote 1; data on boiling point are required for these products.

11. Hoechst and Morflex have not responded to data requirements for their technical products listed in Footnote 1; all data are required. Miles has responded for its 99.9% T, but must submit the raw data to support the reported solubility information. MGK has also responded for its 99.9% T, but in addition must submit data using representative polar and nonpolar solvents.

12. Miles, Hoechst, Morflex, and MGK have not responded to data requirements for their technical products listed in Footnote 1; data are required from all registrants.

13. Morflex and Hoechst have not responded to data requirements for their technical products listed in Footnote 1; all data are required. Miles has responded for its 99.9% T; however the raw data and methods used must be submitted. MGK has adequately responded for its 99.9% T.

14. Data on pH are not required since the technical chemical is not dispersible in water.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR DEET MANUFACTURING-USE PRODUCTS.[1]

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-1. Product Composition	MP	Partially	40158601	Yes[4]
61-2. Beginning Materials & Production/Formulation Process	MP	Partially	00155132	Yes[5]
61-3. Formation of Impurities	MP	Partially	40140501	Yes[6]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis	MP	Partially	00155132 40140501 40158601	Yes[7]
62-2. Certified Limits	MP	Partially	40158601	Yes[8]
62-3. Enforcement Analytical Methods	MP	Partially	40140501 40158601	Yes[9]
Physical and Chemical Characteristics[10]				
63-2. Color	MP	Partially	00149979 00152588	Yes[11]
63-3. Physical State	MP	Partially	00149979 00152588	Yes[11]
63-4. Odor	MP	Partially	00149979 00152588	Yes[11]
63-7. Density, Bulk Density, or Specific Gravity	MP	Partially	00149979 00152588	Yes[11]
63-12. pH	MP	Yes	00149979	No[12]
62-14. Oxidizing or Reducing Action	MP	Partially	00155132	Yes[13]
62-15. Flammability	MP	Partially	00152588	Yes[14,15]
63-16. Explodability	MP	Partially	N/A	Yes[14,16]
63-17. Storage Stability	MP	Partially	00149979 00152588 00163059 40750101	Yes[17]
63-18. Viscosity	MP	Partially	00155132	Yes[14,18]
63-19. Miscibility	MP	N/A	N/A	No[19]

(Continued, footnotes follow)

TABLE B. (Continued).

Data Requirement	Test Substance	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
63-20. Corrosion Characteristics	MP	Partially	00149979 00163059 40750101	Yes[14]
Other Requirements:				
64-1. Submittal of Samples	N/A	N/A	N/A	No

1. Data requirements pertain to the 99.9% technical products registered to the following companies: Miles Laboratories, Inc. (EPA Reg. No. 121-17), Hoechst Celanese Corp. (EPA Reg. No. 8340-39), Morflex Chemical Company, Inc. (EPA Reg. No. 51147-1), and McLaughlin Gormley King Company (MGK) (EPA Reg. No. 1021-891). Requirements also pertain to the following FIs (EPA Reg. Nos. follow): the Morflex 75% FI (51147-2) and the MGK 94.6% FI (1021-1354), 90.0% FI (1021-1355), 86.0% FI (1021-1276), 83.34% FI (1021-1201), 83.33% FI (1021-1214), 80.0% FI (1021-1312), 76.93% FI (1021-1111), 76.92% FI (1021-1290), 70.0% FI (1021-567), 70.0% FI (1021-1144), 66.67% FI (1021-737), 60.0% FI (1021-971), 50.0% FI (1021-1070), 41.67% FI (1021-1200), 40.0% FI (1021-512), 40.0% FI (1021-886), 17.5% FI (1021-535), and 5.0% FI (1021-511). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the DEET Technical Grade of the Active Ingredient".

2. Test substance: PAI = purified active ingredient; TGAI = technical grade of the active ingredient; MP = manufacturing-use product.

3. Underlining indicates documents that have been reviewed in this Update document.

4. MGK has not responded to data requirements for the following FIs: 94.6%, 90%, 83.34%, 83.33%, 76.93%, 70% (EPA Reg. No. 1021-1144), 60%, 50%, 41.67%, both 40%s, and 5%; all data are required for these products. Miles, Hoechst, Morflex, and MGK have responded to data requirements for their 99.9% technical products listed in Footnote 1; however, all of the registrants must submit a nominal concentration for DEET, as well as the identity, purpose, and nominal concentrations of all other ingredients present at ≥0.1% by weight in their products. Morflex and MGK have adequately responded for the Morflex 75% FI and the following MGK FIs: 86%, 80%, 76.92%, 70% (EPA Reg. No. 1021-567), 66.67%, and 17.5%. However, if the label of the technical

TABLE B. (Continued).

products are amended to more accurately reflect the mean concentration of DEET in the technical product, new CSFs will be required for the related FIs.

5. MGK has not responded to data requirements for the following FIs: 94.6%, 90%, 83.34%, 83.33%, 76.93%, 70% (EPA Reg. No. 1021-1144), 60%, 50%, 41.67%, both 40%s, and 5%; all data are required for these products. Miles, Morflex, and MGK have not responded to data requirements for their 99.9% technical products listed in Footnote 1; all data are required. Hoechst has responded for its 99.9% T; however, they must verify that neither the manufacturing process nor the location of manufacture has changed since the transfer of ownership on 4/89 from Virginia Chemicals; otherwise all data would be required. Morflex and MGK have adequately responded for the Morflex 75% FI and the following MGK FIs: 86%, 80%, 76.92%, 70% (EPA Reg. No. 1021-567), 66.67%, and 17.5%.

6. MGK has not responded to data requirements for the following FIs: 94.6%, 90%, 83.34%, 83.33%, 76.93%, 70% (EPA Reg. No. 1021-1144), 60%, 50%, 41.67%, both 40%s, and 5%; all data are required for these products. Morflex has not responded for its 75% FI; all data are required. The Deet Joint Venture has responded for the Miles, Hoechst, Morflex, and MGK 99.9% techical products; however the registrants must submit a discussion regarding post-production reactions between ingredients, migration of components of packaging materials, carry-over of contaminants from production equipment, and process quality control measures. MGK has adequately responded for the following MGK FIs: 86%, 80%, 76.92%, 70% (EPA Reg. No. 1021-567), 66.67%, and 17.5%.

7. Miles, Hoechst, and Morflex have responded to data requirements for their 99.9% technical products listed in Footnote 1; however five or more recent representative samples must be analyzed for the amount of active ingredient and each impurity present at 0.1% or greater for each of these products individually. MGK has adequately responded for its 99.9% T.

8. MGK has not responded to data requirements for the following FIs: 94.6%, 90%, 83.34%, 83.33%, 76.93%, 70% (EPA Reg. No. 1021-1144), 60%, 50%, 41.67%, both 40%s, and 5%; all data are required for these products. MGK has responded for the following FIs: 86% FI (CSF dated 3/15/90), 80% FI (CSF dated 3/15/90), 76.92% FI (CSF dated 3/15/90), 70% FI (EPA Reg. No. 1021-567; CSF dated 3/15/90), and 66.67% FI (CSF dated 3/30/90); however an explaination as to why the certified limits for DEET exceed the range of standard certified limits is required. Morflex has responded for its 75% FI; however upper and lower certified limits for the active and inert ingredients are required. Miles has responded for its 99.9% T; however a lower and upper certified limit for each isomer of the active ingredient must be submitted. Hoechst has responded for its 99.9% T; however the registrant must submit upper certified limits for the active ingredients, including for

TABLE B. (Continued).

each individual isomer and lower certified limits for each individual related isomer of the active ingredient. Morflex has responded for its 99.9% T; however the following information are required: (i) an upper certified limit for the meta-isomer (active ingredient); (ii) an upper certified limit for an impurity; (iii) an explanation on how the upper limits were established, and (iv) lower certified limits for the ortho- and para-isomers of the active ingredient. MGK has responded for its 99.9% T; however the registrant must submit lower and upper certified limits for all of the active ingredients, including the related isomers. We note that the ortho- and para-isomers of DEET are considered to be active ingredients since they are grouped under the same Pesticide Chemical Code as the meta-isomer; therefore, upper and lower certified limits are required for each of these ingredients. If the label of the technical product is amended to more accurately reflect the mean concentration of DEET in the technical product, a new CSF for the related FIs will be required to reflect this change in the certified limits. Certifications must be submitted on EPA Form 8570-4 (Rev. 2/85).

9. The DEET Joint Venture on behalf of the members (Miles, MGK, Morflex, and Virginia Chemical thus Hoechst) has responded to the data requirements for the products listed in Footnote 1; however information regarding accuracy and precision of the submitted methods is required.

10. As required in 40 CFR §158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-20, data must be submitted on physicochemical characteristics of each manufacturing-use product (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, viscosity, miscibility, and corrosion characteristics). Additional data requirements regarding physicochemical properties of manufacturing-use products which contain only the technical grade of the active ingredient are listed in Table A, "Generic Data Requirements for the DEET Technical Grade of the Active Ingredient."

11. Adequate data have been submitted in response to the data requirements for the Hoechst and Miles 99.9% Ts, the Morflex 75% FI, and the following MGK products: 86% FI; 80% FI; 70% FI (EPA Reg. No. 1021-567); 66.67% FI; and the 17.5% FI. The registrants of all other products listed in Footnote 1 have not responded to data requirements; all data are required for these products.

12. Data on pH are not required since the test substances are not dispersible in water.

13. Adequate data have been submitted in response to the data requirements for the Hoechst 99.9% T and the following MGK products: 86% FI; 80% FI; 70% FI (EPA Reg. No. 1021-567); 66.67% FI; and the 17.5% FI. The

TABLE B. (Continued).

registrants of all other products listed in Footnote 1 have not responded to data requirements; data are required on oxidizing/reducing potential if the product contains an oxidizing or reducing agent.

14. Adequate data have been submitted in response to data requirements for the Hoechst 99.9% T, the Morflex 75% FI, and the following MGK FIs: the 86% FI; 80% FI; 76.92% FI; 70% FI (EPA Reg. No. 1021-567); 66.67% FI; and the 17.5% FI. The registrants of all other products listed in Footnote 1 have not responded to data requirements; all data are required for these products.

15. Data are required on flammability if the product contains combustible liquids.

16. Data are required if the product is potentially explosive.

17. Miles and Hoechst have responded to data requirements for their 99.9% Ts; however the raw data and conditions used are required. MGK has responded for its 70% FI (EPA Reg. No. 1021-567); however the registrant must submit a storage stability study in which the formulated product is stored in a container similar to those that will be used in the trade for a period of one year at warehouse temperatures and humidity. The registrants of all other products listed in Footnote 1 have not responded to data requirements; all data are required for these products.

18. Data on viscosity are required if the product is a liquid.

19. Data on miscibility are required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents. These data were not required by the Amended DEET Registration Standard.

N,N-DIETHYL-M-TOLUAMIDE (DEET)

REGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 4

(Final Report)

CONFIDENTIAL APPENDICES

Appendix A: 11 Page(s)
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Appendix D: 5 Page(s)
Appendix E: 1 Page(s)

Confidential Appendices to the Scientific Review of the Registration Standard Update Report for the pesticide DEET by the Dietary Exposure Branch [Confidential FIFRA Trade Secret/CBI].