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

JUN 13 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Folpet Product Chemistry Registration Standard Update.

FROM: Richard D. Schmitt, Ph.D., Chief
Dietary Exposure Branch (DEB)
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 an update of the Product Chemistry Chapter of the Folpet Registration Standard prepared by Dynamac Corporation under supervision of the Dietary Exposure Branch, HED. This document has undergone secondary review in the Branch and has been revised to reflect Agency policies.

All registered food uses for Folpet have been cancelled since issuance of the Folpet Reregistration Guidance Document. Accordingly, residue chemistry data requirements no longer apply and the established tolerances for residues of folpet in or on several raw agricultural commodities (40 CFR 180.191) should be revoked.

Please note that Confidential Business Information is attached as Appendices A, B, C, D and E.

If you need additional input please advise.

Attachment 1: Folpet Product Chemistry Reg. Standard Update

Attachment 2: Confidential Appendices A, B, C, D and E.

cc (with attachments 1 & 2): W. Smith, Folpet Reg. Std. file, Folpet Subject File, C. Furlow (PIB/FOD), J. Burrell (FOD), Dynamac.

cc (without attachments): RF, Circ.(8)

DYNAMAC
CORPORATION

Final Report

FOLPET
Task 4: Product Chemistry. Registration Standard Update

Contract No. 68-D8-0080

June 5, 1990

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

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FOLPET

REGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 4

INTRODUCTION

A Product Search Listing conducted 3/16/90 identifies three registered manufacturing-use products (MPs) for folpet: an ICI Americas Inc. 88% technical (T; EPA Reg. No. 10182-294) which was transferred from Chevron (EPA Reg No. 239-1763), and a Makhteshim Chemical Works 90% T (EPA Reg. No. 11678-18) and a 50% formulation intermediate (FI) (EPA Reg. No. 11678-29).

The Folpet Guidance Document dated 6/87 identifies outstanding data requirements for several product chemistry topics. When the Guidance Document was issued, folpet was registered for a variety of uses, including food crop uses. Subsequently, all uses for folpet were cancelled with the exception of its use as a preservative in paints and wood coatings. Of the 18 manufacturing-use products identified in the Guidance Document, all but those listed above were cancelled. Chevron Chemical Co. and Makhteshim Chemical Works established a Folpet Task Force, and in response to the Guidance Document submitted MRIDs 40494202, 40750801, and 40790301 in support of the Chevron 88% T (EPA Reg. No. 239-1763) and the Makhteshim 90% T (EPA Reg. No. 11678-18). In addition, Chevron has submitted MRIDs 40494201 and 40494203 in support of their 88% T (EPA Reg. No. 239-1763); Makhteshim has submitted MRIDs 40493601 and 40493602 in support of their 90% T (EPA Reg. No. 11678-18), and MRID 40493604 in support of their 50% FI (EPA Reg. No. 11678-29). These data are reviewed below for their adequacy in fulfilling outstanding data requirements.

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 folpet.

	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)

SUMMARY

The following folpet Product Chemistry data are required:

- For the ICI 88% T (EPA Reg. No. 10182-294), the registrant must indicate whether or not the manufacturing process and location have changed since transfer of ownership from Chevron (EPA Reg. No. 239-1763). If the manufacturing process and location have not changed, then data must be submitted pertaining to certification of limits, oxidizing or reducing action, explodability, storage stability, and corrosion characteristics. If the manufacturing process or location has changed, the full complement of product chemistry data must be submitted for the ICI 88% T.

- For the Makhteshim 90% T (EPA Reg. No. 11678-18) data must be submitted pertaining to certification of limits, stability, oxidizing or reducing action, explodability, and storage stability.

- For the Makhteshim 50% FI (EPA Reg. No. 11678-29) data must be submitted pertaining to starting materials, discussion of formation of impurities, certification of limits, and all physical and chemical characteristics.

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Composition

The Folpet Guidance Document dated 6/87 requires no additional product-specific data concerning product composition.

61-2. Starting Materials and Manufacturing Process

The Folpet Guidance Document dated 6/87 specifies product-specific data requirements for folpet regarding starting materials and the manufacturing/formulation processes.

In response to the Guidance Document, Chevron submitted data (1987; MRID 40494201) pertaining to the starting materials and the manufacturing process for the 88% T (EPA Reg. No. 239-1763). These data are presented in Confidential Appendix B and may be used to satisfy the requirements of 40 CFR §158.160-162 (Guideline Reference No. 61-2) regarding starting materials and the production process for the reregistration of the ICI 88% T (EPA Reg. No. 10182-294) upon notification from ICI that either the manufacturing process or location has not changed since the transfer of ownership from Chevron. However, if either the manufacturing process or the location has changed, all data

pertaining to the starting materials and manufacturing process are required for the ICI 88% T.

In response to the Guidance Document, Makhteshim submitted data (1988; MRID 40493602) pertaining to the starting materials and the manufacturing process for the 90% T (EPA Reg. No. 11678-18). These data are presented in Confidential Appendix B and satisfy the requirements of 40 CFR §158.160-162 (Guideline Reference No. 61-2) regarding starting materials and the production process for the 90% T (EPA Reg. No. 11678-18). No additional data are required.

In response to the Guidance Document, Makhteshim submitted data (1988; MRID 40493604) pertaining to the starting materials and the formulation process for the 50% FI (EPA Reg. No. 11678-29). These data are presented in Confidential Appendix B and do not satisfy the requirements of 40 CFR §158.160-165 (Guideline Reference No. 61-2) regarding starting materials for the Makhteshim 50% FI (EPA Reg. No. 11678-29) because the registrant did not submit specifications for the starting materials. Additional data are required.

61-3. Discussion of the Formation of Impurities

The Folpet Guidance Document dated 6/87 specifies product-specific data requirements for folpet regarding discussion of formation of impurities.

In response to the Guidance Document, the Folpet Task Force submitted a discussion of the formation of impurities (1988; MRID 40494202) in the Chevron 88% T (EPA Reg. No. 239-1763). This information is presented in Confidential Appendix C and may be used to satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities for the reregistration of the ICI 88% T (EPA Reg. No. 10182-294) upon notification from ICI that the manufacturing process and location have not changed since the transfer of ownership from Chevron. However, if either the manufacturing process or location has changed, all data pertaining to the discussion of formation of impurities are required for the ICI 88% T.

In response to the Guidance Document, Makhteshim submitted a discussion of the formation of impurities (1988; MRID 40493602) in the 90% T (EPA Reg. No. 11678-18). This information is presented in Confidential Appendix C and satisfies the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities in the Makhteshim 90% T (EPA Reg. No. 11678-18). No additional information is required.

In response to the Guidance Document requirement for discussion of formation of impurities in the Makhteshim 50% FI (EPA Reg. No. 11678-29), the registrant (1988; MRID 40493604) refers to their discussion of the formation of impurities in the 90% T (EPA Reg. No. 11678-18; 1988; MRID 40493602). This information does not satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities in the Makhteshim 50% FI (EPA Reg. No. 11678-29) because potential impurities resulting from reactions occurring during formulation and post-production were not discussed. Additional information is required.

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

62-1. Preliminary Analysis

The Folpet Guidance Document dated 6/87, specifies product-specific data requirements for folpet regarding preliminary analysis.

In response to the Guidance Document, the Folpet Task Force submitted preliminary analysis data (1988; MRID 40750801) for the Chevron 88% T and the Makhteshim 90% T (EPA Reg. Nos. 239-1763 and 11678-18, respectively). These data are presented in Confidential Appendix D.

Data submitted for the Chevron 88% T (EPA Reg. No. 239-1763) may be used to satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis for the ICI 88% T (EPA Reg. No. 10182-294) upon notification from ICI that the manufacturing process and location have not changed since the transfer of ownership from Chevron. However, if either the manufacturing process or the site has changed, all data pertaining to preliminary analysis are required for the ICI 88% T. In addition, it is requested that information as to the location of production of these preliminary analysis samples be supplied.

Data submitted for the Makhteshim 90% T (EPA Reg. No. 11678-29) satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis. However, it is requested that information as to the site/location of production of these preliminary analysis samples be supplied.

62-2. Certified Limits

The Folpet Guidance Document dated 6/87 specifies product-specific data requirements for folpet regarding certification of ingredient limits.

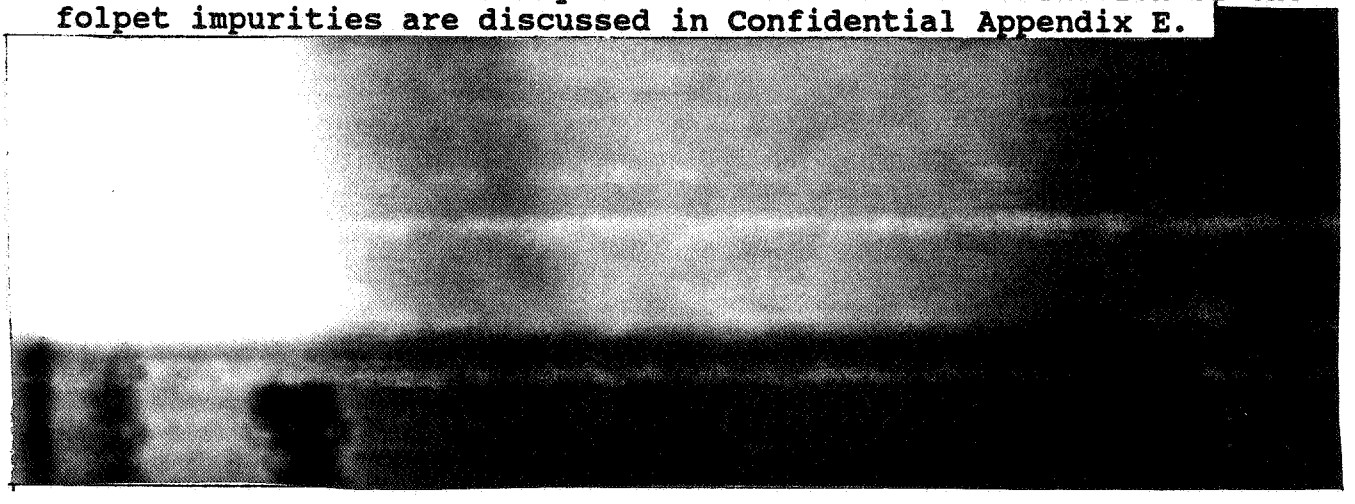
In response to the Guidance Document, the Folpet Task Force submitted a Confidential Statement of Formula dated 6/8/88 (CSF; MRID 40750801) for an Alternate Formulation (D) of the Chevron 88% T (EPA Reg. No. 239-1763). These data are presented in Confidential Appendix A. It is apparent from data presented in the MRID containing the CSF that nominal concentrations on the CSF represent the average of combined preliminary analysis data for the Chevron and Makhteshim technical products. In addition, four producers and two locations of formulation were listed for this CSF. We request clarification from the Folpet Task Force concerning the following details: (i) the relationship between the four producers listed and the data supplied in this CSF; (ii) the product(s) which this CSF represents; and (iii) the location of production for the product(s) which this CSF represents; and (v) how certified limits were determined. Data will not be evaluated until clarification is achieved.

No data pertaining to certification of ingredient limits have been submitted for the Makhteshim 90% T and 50% FI (EPA Reg. Nos. 11678-18 and 11678-29). Data requirements for certified limits are still outstanding for these products.

62-3. Enforcement Analytical Methods

The Folpet Guidance Document dated 6/87 identifies product-specific data requirements for folpet regarding analytical methods to verify certified limits.

In response to the Guidance Document, the Folpet Task Force submitted analytical methods (1988; MRID 40750801) for the analysis of folpet and its impurities in the Chevron 88% T and the Makhteshim 90% T (EPA Reg. Nos. 239-1763 and 11678-18, respectively). Included in the submission were chromatograms and validation data. The analytical methods for determination of the folpet impurities are discussed in Confidential Appendix E.



The data discussed above and in Confidential Appendix E satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the Makhteshim 90% T (EPA Reg. No. 11678-18). These methods may also be used to satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the reregistration of the ICI 88% T (EPA Reg. No. 10182-294) upon notification from ICI that the manufacturing process and location have not changed since the transfer of ownership from Chevron. However, if the manufacturing process or the location have been altered, additional data pertaining to enforcement analytical methods may be required for the ICI 88% T.

The method for the determination of the active ingredient and its impurities may be applied to the reregistration of the Makhteshim 50% FI (EPA Reg. No. 11678-29).

PHYSICAL AND CHEMICAL CHARACTERISTICS

The Folpet Guidance Document dated 6/87 identifies product-specific data requirements for physical and chemical characteristics pertinent to the technical grade of the active ingredient. However, to satisfy current requirements for this topic, physical and chemical characteristics are also required for the manufacturing-use products. The physical and chemical characteristics of the folpet purified active ingredient (PAI), technical grade of the active ingredient (TGAI), and manufacturing-use products (MP) are summarized in Table 1.

Data submitted by Chevron (1987; MRID 40494203) and the Folpet Task Force (1988; MRID 40790301) for the Chevron 88% T (EPA Reg. No. 239-1763) do not fully satisfy the requirements of 40 CFR §158.190 (Guideline Reference No. 63-2 through 63-20) regarding physical and chemical characteristics because no data were submitted concerning oxidizing or reducing action, explodability, storage stability, or corrosion characteristics (Guideline Reference Nos. 63-14 through 63-17 and 63-20). Data for these topics are required for the 88% T as an MP. Following notification from ICI that the manufacturing process and location have not changed since the transfer of ownership from Chevron, these data may be applied to the reregistration of the ICI 88% T (EPA Reg. No. 10182-294). If either the site or manufacturing process have changed, all data requirements pertaining to this topic remain outstanding with the exception of solubility, vapor pressure, dissociation constant, and octanol/water partition coefficient (Guideline Reference Nos. 63-8 through 63-11), which still apply to the transferred product.

Data submitted by Makhteshim (1988; MRID 40493601) for the 90% T (EPA Reg. No. 11678-18) do not fully satisfy the requirements of 40 CFR §158.190 (Guideline Reference No. 63-2 through 63-20)

because inappropriate data were submitted for stability. Stability data are to include the sensitivity of the active ingredient to metal ions and metals; the registrant submitted corrosion data for this topic. Furthermore, no data were submitted concerning oxidizing or reducing action, explodability, and storage stability (Guideline Reference Nos. 63-14 through 63-17). Additional data are required.

No physical/chemical data have been submitted for the Makhteshim 50% FI (EPA Reg. No. 11678-29). To satisfy current requirements physical and chemical characteristics pertinent to all manufacturing-use products are required.

Table 1. Physical and chemical properties of the folpet 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; Substrate; EPA Reg. No.; MRID or Jacket)[a]
63-2. Color	**off white** [Munsell Color System] (Chevron 88% T; TGAI; 239-1763; 40494203)
	tan (Makhteshim 90% T; TGAI; 11678-18; 40493601)
63-3. Physical state	**solid powder** (Chevron 88% T; TGAI; 239-1763; 40494203)
	amorphous powder (Makhteshim 90% T; TGAI; 11678-18; 40493601)
63-4. Odor	**slightly pungent and sulfurous** (Chevron 88% T; TGAI; 239-1763; 40494203)
	pungent (Makhteshim 90% T; TGAI; 11678-18; 40493601)
63-5. Melting point	**170.2-176.8 C** [Thomas Hoover Apparatus] (Chevron 88% T; TGAI; 239-1763; 40494203)
	169-176 C [Thomas Hoover Apparatus] (Makhteshim 90% T; TGAI; 11678-18; 40493601)
63-6. Boiling point	**not required** Folpet is a solid at room temperature.
63-7. Density, bulk density, or	**0.395 g/ml bulk density at 25 C** [modified ASTM E727-86]

(Continued.)

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; Substrate; EPA Reg. No.; MRID or Jacket)[a]
63-7. Specific gravity (cont.)	(Chevron 88% T; TGAI; 239-1763; 40494203) **0.4 g/ml with-out compaction** **0.6 g/ml with compaction** [graduated cylinder] (Makhteshim 90% T; TGAI; 11678-18; 40493601)
63-8. Solubility	**Solubility** **Solvent at 25 C (g/100 ml)** **water 0.000109** **acetone 2.71** **dichloromethane 8.19** **methanol 0.27** **hexane 0.03** **ethyl acetate 2.11** **toluene 2.00** **N-methyl pyrrolidone 15.94** (Chevron 88% T; PAI; 239-1763; 40494203) **Solubility** **Solvent at 25 C (g/100 ml)** **water 0.80 ppm** **acetone 3.40** **acetonitrile 1.90** **carbon tetrachloride 0.60** **heptane 0.045** **methanol 0.31** **n-octanol 0.14** **toluene 2.63** (Makhteshim 90% T; PAI; 11678-18; 40439601)
63-9. Vapor pressure	**not required** melting point of the PAI is >30 C
63-10. Dissociation constant	**not required** PAI is not an acid or base
63-11. Octanol/water partition coefficient	**log P = 1.64** [Federal Register, vol.45, No. 227, 722.122-4] (Chevron 88% T; PAI; 239-1763; 40494203) **K_{ow} = 1279** [EPA Test Method CG-1400]

(Continued.)

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; Substrate; EPA Reg. No.; MRID or Jacket)[a]
63-11. Octanol/water. . (cont.)	(Makhteshim 90% T; PAI; 11678-18; 40493601)
63-12. pH	**8.44 (1% dispersion)** **8.58 (10% dispersion)** [ASTM E70-77] (Chevron 88% T; TGAI; 239-1763; 40494203) **5.3 (1% solution in 1:1 water:acetone)** (Makhteshim 90% T; TGAI; 11678-18; 40493601)
63-13. Stability	**stable for 6 months at elevated and normal temperatures, in sunlight, and in metal cans** (Chevron 88% T; TGAI; 239-1763; 40790301) **stable when stored in dry conditions at ambient and elevated temperatures, and in sunlight; not stable under alkaline conditions** (Makhteshim 90% T; TGAI; 11678-18; 40493601)
63-14. Oxidizing or reducing action	**none submitted**
63-15. Flammability	not required for folpet T and FI products that are solids at room temperature
63-16. Explodability	**none submitted**
63-17. Storage stability	**none submitted**
63-18. Viscosity	not required for folpet T and FI products that are solids at room temperature
63-19. Miscibility	not required for folpet T and FI products that are solids at room temperature

(Continued.)

Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; Substrate; EPA Reg. No.; MRID or Jacket)[a]
63-20. Corrosiveness	**non-corrosive to stainless steel and aluminum, but is corrosive to carbon steel and copper** (Makhteshim 90% T; TGAI; 11678-18; 40493601)

[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.

Product Chemistry Citations (used):

40493601 Makhteshim Chemical Corks Ltd. (1988) Folpan (Folpet) Technical--Product Chemistry Data: Laboratory Project ID R-4784. Unpublished study prepared in cooperation with Analyst Ltd. 74 p.

40493602 Makhteshim Chemical Works Ltd. (1988) Folpan (Folpet) Technical--Product Chemistry Data: Laboratory Project ID R-4784. Unpublished study prepared by Makhteshim Chemical Works Ltd. 48 p.

40493604 Makhteshim Chemical Works Ltd. (1988) Folpan (Folpet) 50% MP--Product Chemistry Data: Laboratory Project ID R-4784. Unpublished study. 9 p.

40494201 Ashworth, D. (1987) Description of Beginning Materials and Manufacturing Process of Chevron Folpet Technical: 8729389. Unpublished study prepared by Chevron Chemical Co. 36 p.

40494202 Ashworth, D. (1988) Discussion of the Formation of Impurities of Chevron Folpet Technical: 8801619. Unpublished study prepared by Chevron Chemical Co. 10 p.

40494203 Thornberry, N. (1987) Physical and Chemical Characteristics of Chevron Folpet Technical: 8729390. Unpublished study prepared by Chevron Chemical Co. 27 p.

40750801 Updyke, J. (1988) Analysis and Certification of Product Ingredients: Folpet Technical: Laboratory Project ID 8812013. Unpublished study prepared by Chevron Chemical Co. 139 p.

40790301 Updyke, J. (1988) Stability of Folpet 88% Technical: Laboratory Project ID 8812012. Unpublished study prepared by Chevron Chemical Co. 5 p.

Product Chemistry Citations (not used):

These MRIDs pertain to end-use products or, in the case of MRID 40493603, a cancelled product.

40423601 Bushway, R. (1987) One Year Storage Stability Test on Super K-Gro Sevin Brand Carbaryl Insecticide Garden Dust: Alljack-1986-1. Unpublished study prepared by Univ. of Maine at Orono. 5 p.

40423701 Bushway, R. (1987) One Year Storage Stability Test on Supper K-Gro Rose & Floral Dust Controls Insects and diseases (Carbaryl, Malathion and Folpet): Alljack-1987-1. Unpublished study prepared by Univ. of Maine at Orono. 5 p.

40493603 Makhteshim Chemical Works Ltd. (1988) Folpan (Folpet) 80% MP--Product Chemistry Data: Laboratory Project ID R-4784. Unpublished study. 9 p.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE FOLPET 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	40493602 40493604 40494201	Yes[4]
61-3. Formation of Impurities	TGAI	Partially	40493602 40493604 40494202	Yes[5]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis	TGAI	Partially	40750801	Yes[6]
Physical and Chemical Characteristics[7]				
63-2. Color	TGAI	Yes	40493601 40494203	No
63-3. Physical State	TGAI	Yes	40493601 40494203	No
63-4. Odor	TGAI	Yes	40493601 40494203	No
63-5. Melting Point	TGAI	Yes	40493601 40494203	No[8]
63-6. Boiling Point	TGAI	N/A	N/A	No
63-7. Density, Bulk Density, or Specific Gravity	TGAI	Yes	40493601 40494203	No
63-8. Solubility	TGAI or PAI	Yes	40493601 40494203	No
63-9. Vapor Pressure	TGAI or PAI	N/A	N/A	No[9]
63-10. Dissociation Constant	TGAI or PAI	N/A	N/A	No[10]
63-11. Octanol/Water Partitioning Coefficient	PAI	Yes	40493601 40494203	No
63-12. pH	TGAI	Yes	40493601 40494203	No
63-13. Stability	TGAI	Partially	40790301 40493601	Yes[11]
Other Requirements:				
64-1. Submittal of Samples	N/A	N/A	N/A	No

1. Data requirements pertain to the Chevron 88% T (currently registered to ICI Americas, Inc. under EPA Reg. No. 10182-294) and Makhteshim Chemical Works 90% T and 50 % FI (EPA Reg. Nos. 11678-18 and 11678-29,

TABLE A. (Continued).

respectively). We note in order for the ICI 88% T to satisfy product chemistry data following the transfer of ownership from Chevron, the new registrant must submit, with the exception of certain physical/chemical properties (which may still be applied toward registration), a complete package encompassing all topics for the transferred product. In light of this situation, the requirements described in this table may be conditional. Upon notification from ICI that both the manufacturing process and location have not changed since the transfer of ownership, satisfaction of these requirements may be applied towards the registration of the ICI 88% T (EPA Reg. No. 10182-294). If either the site or manufacturing process have been modified, all product chemistry data requirements for this product remain outstanding. Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for Folpet 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. For the 50% FI (EPA Reg. No. 11678-29), Makhteshim must submit information regarding the specifications of starting materials.

5. The Folpet Task Force has responded for the Chevron 88% T and Makhteshim has responded for the 90% T and 50% FI; these data satisfy requirements for the TGAI for the technical products. For the Makhteshim 50% FI (EPA Reg No. 11678-29), data pertaining to the potential impurities resulting from reactions occurring during formulation and post-production reactions are required.

6. Makhteshim has not submitted data for the 50% FI. Five or more representative samples must be analyzed for the amount of active ingredient and each impurity present at 0.1% or greater. If these products are produced by a batch process, five separate batches should be represented in preliminary analyses. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. The preliminary analysis report should include the identity and quantity of each ingredient for which analysis is conducted along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided. The Folpet Task Force has responded for the Chevron 88% T and Makhteshim 90% T. These data will be evaluated following receipt of information regarding the location of production of the samples analyzed in preliminary analysis.

TABLE A. (Continued).

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. Data on melting point are required if the technical chemical is a solid at room temperature.

9. Data on vapor pressure are not required since the melting point of the PAI is >30 C.

10. Data on dissociation constant are not required since the PAI is not an acid or base.

11. Makhteshim has responded for the 90% T; however the registrant must submit data pertaining to the stability data of the active ingredient in the presence of metal ions and metals. This outstanding requirement also applies to the Makhteshim 50% FI TGAI. Chevron has responded for the 88% T; data are adequate.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR FOLPET 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	Yes	N/A	No
61-2. Beginning Materials & Production/Formulation Process	MP	Partially	40493602 40493604 40494201	Yes[4]
61-3. Formation of Impurities	MP	Partially	40493602 40493604 40494202	Yes[5]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis	MP	Partially	40750801	Yes[6]
62-2. Certified Limits	MP	Partially	40750801	Yes[7]
62-3. Enforcement Analytical Methods	MP	Yes	40750801	No
Physical and Chemical Characteristics[8]				
63-2. Color	MP	Partially	40493601 40494203	Yes[9]
63-3. Physical State	MP	Partially	40493601 40494203	Yes[9]
63-4. Odor	MP	Partially	40493601 40494203	Yes[9]
63-7. Density, Bulk Density, or Specific Gravity	MP	Partially	40493601 40494203	Yes[9]
63-12. pH	MP	Partially	40493601 40494203	Yes[9]
62-14. Oxidizing or Reducing Action	MP	No	N/A	Yes[10]
62-15. Flammability	MP	No	N/A	N/A[11]
63-16. Explodability	MP	No	N/A	Yes[12]
63-17. Storage Stability	MP	No	N/A	Yes[13]
63-18. Viscosity	MP	No	N/A	Yes[14]
63-19. Miscibility	MP	No	N/A	Yes[15]
63-20. Corrosion Characteristics	MP	Partially	40493601	Yes[16]
Other Requirements:				
64-1. Submittal of Samples	N/A	N/A	N/A	No

TABLE B. (Continued).

1. Data requirements pertain to the Chevron 88% T (currently registered to ICI Americas, Inc. under EPA Reg. No. 10182-294) and Makhteshim Chemical Works 90% T and 50 % FI (EPA Reg. Nos. 11678-18 and 11678-29, respectively). We note in order for the ICI 88% T to satisfy product chemistry data following the transfer of ownership from Chevron, the new registrant must submit , with the exception of certain physical/chemical properties (which may still be applied toward registration), a complete package encompassing all topics for the transferred product. In light of this situation, the requirements described in this table may be conditional. Upon notification from ICI that both the manufacturing process and location have not changed since the transfer of ownership, satisfaction of these requirements may be applied towards the registration of the ICI 88% T (EPA Reg. No. 10182-294). If either the site or manufacturing process have been modified, all product chemistry data requirements for this product remain outstanding. Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the Folpet 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. For the 50% FI (EPA Reg. No. 11678-29), Makhteshim must submit information regarding the specifications of starting materials.

5. Chevron and Makhteshim have responded for the 88% T and 90% T, respectively; these data satisfy the requirements for this topic. For the Makhteshim 50% FI (EPA Reg No. 11678-29), data pertaining to the potential impurities resulting from reactions occurring during formulation and post-production reactions are required.

6. Makhteshim has not submitted data for the 50% FI. Five or more representative samples must be analyzed for the amount of active ingredient and each impurity present at 0.1% or greater. If these products are produced by a batch process, five separate batches should be represented in preliminary analyses. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. The preliminary analysis report should include the identity and quantity of each ingredient for which analysis is conducted along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided. The Folpet Task Force has responded for the Chevron 88% T and

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TABLE B. (Continued).

Makhteshim 90% T. These data will be evaluated following receipt of information regarding the location of production of the samples analyzed in preliminary analysis.

7. Makhteshim has not submitted data for their products listed in footnote 1. The registrant must propose upper and lower limits for each active and inert ingredient, if such limits would differ from the standard certified limits determined by the Agency according to 40 CFR §158.175(b)(2). Also, if these manufacturing use products contain the technical grade of the active ingredient only or are produced by an integrated system, upper limits must be proposed for each toxicologically significant impurity associated with the active ingredients and found to be present in any sample of the product (standard certified limits cannot be used for impurities). Certified limits should be based on the sources and magnitude of variability in the manufacturing process and the stability of the ingredients following production. The registrant must certify the accuracy of the information presented, and that the certified limits will be maintained. An explanation of how each certified limit was established (e.g., sample analysis using a validated analytical procedure, quantitative estimate based on the amounts of ingredients used, etc.) must be provided, along with information on the accuracy and precision of any analytical procedures used. Certifications must be submitted on EPA Form 8570-4 (Rev. 2/85). The Folpet Task Force has responded for the Chevron 88% T; for this product, an explaination as to why the certified limits of the active ingredient exceed the range of standard certified limits described in 40 CFR §158.175(b)(2). The available data concerning certified limits will be evaluated following receipt of clarification from the Folpet Task Force concerning the information submitted in MRID 40750801: (i) the relationship between the four producers listed and the data supplied in this CSF; (ii) the product(s) which this CSF represents; and (iii) the location of production for the product(s) which this CSF represents.

8. 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 Folpet Technical Grade of the Active Ingredient."

9. Data concerning this topic are required for the Mahkteshim 50% FI (EPA Reg No. 11678-29).

10. Chevron and Makhteshim have not submitted data for their products listed in footnote 1. Data are required on oxidizing/reducing potential if the product contains an oxidizing or reducing agent.

TABLE B. (Continued).

11. Chevron and Makhteshim products listed in footnote 1 do not require flammmability data as they are solids at room temperature.

12. Chevron and Makhteshim have not submitted data for their products listed in footnote 1. Data are required on explodability if the product is potentially explosive.

13. Chevron and Makhteshim have not submitted data for their products listed in footnote 1; data requirements for this topic remain outstanding.

14. No data were submitted for the Makhteshim 50% FI; data are required if the product is a liquid. Chevron and Makhteshim products listed in footnote 1 do not require viscosity data as they are solids at room temperature.

15. No data were submitted for the Makhteshim 50% FI. Data on miscibility are required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents. Chevron and Makhteshim products listed in footnote 1 do not require miscibility data as they are solids at room temperature.

16. Chevron and Makhteshim have not responded for their 88% T and 50% FI, respectively, listed in footnote 1; data requirements remain outstanding for these products. Makhteshim has submitted corrosiveness data for the 90% T; these data are acceptable.

CONFIDENTIAL

FOLPET

REGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 4

(Final Report)

CONFIDENTIAL APPENDICES

Appendix A: 2 Page(s)
Appendix B: 3 Page(s)
Appendix C: 5 Page(s)
Appendix D: 3 Page(s)
Appendix E: 4 Page(s)

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

Folpet product chemistry RS update

Page _____ is not included in this copy.

Pages 25 through 41 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

X Description of the product manufacturing process

X Description of product 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.
