

US EPA ARCHIVE DOCUMENT

DATE OUT: 13/SEP/2001

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Technical Product [x], Manufacturer-Use Product [x]; End-Use Product []; **BARCODE No. : D277585; CASE No.: 008717; EPA RECEIVED DATE: 27/AUG/01; REG./File Symbol No.: 2724-313; PRODUCT NAME: Technical Propetamphos; COMPANY NAME: Wellmark International; MRID #: 423558-01, -02, -03, -04, 416074-02, -11, -22, and 419971-04; Action Code: 674**

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INTRODUCTION:

The registrant, Wellmark International, submitted the product chemistry data in MRID # 423558-01, -02, -03, -04, 416074-02, -11, -22, and 419971-04; the Confidential Statement of Formula (CSF), a basic formulation dated 16/OCT/96; and a draft label received by the Agency on 27/MAR/01; requesting for reregistration of Technical Propetamphos, Reg. No. 2724-313.

FINDINGS:

1. The Interim Reregistration Eligibility Decision (IREDD) for Case # 2550 was issued October 31, 2001 for the active ingredient, propetamphos. The Agency has completed its assessment of the human health and ecological risks associated with the use of pesticide containing the active ingredient propetamphos, as well as propetamphos-specific dietary risk assessment that does not consider the cumulative effects of Ops as a class. Based on a review of these data and public comments on the Agency's assessments for the active ingredient propetamphos, EPA has sufficient information on the human health and ecological effects of propetamphos to make interim decisions as part of the tolerance reassessment process under FFDCA and reregistration under FIFRA, as amended by FQPA. The Agency has determined that propetamphos is eligible for reregistration provided that: (i) current data gaps and additional data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures; and (iii) the cumulative risk assessment for the organophosphate compounds support a final reregistration eligibility decision. Label changes are described in Section IV. Based on its current evaluation of propetamphos alone, the Agency has determined that propetamphos products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from use of propetamphos.

2(a). Except for the data gaps noted in the Finding # 2(b), the submitted data in MRID # 423558-03 satisfy the data requirements for Guidelines 61-1 (830-1550, Product Identity and Composition). The submitted data in MRID # 423558-01 satisfy the data requirements for the Guidelines 61-2a (830-1600, Description of Materials Used to Produce the Product) and 61-2b (830-1620, Description of Manufacturing Process). The submitted data in MRID 423558-02 satisfy the data requirements for the guideline 61-3 (830-1670, Discussion of Formation of Impurities). The submitted data in MRID #

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423558-03 and -04 satisfy the data requirements for the Guidelines 62-1 (830-1700, Preliminary Analysis), 62-2 (830-1750, Certified Limits), and 62-3 (830-1800, Enforcement Analytical Method). The submitted data in MRID # 416074-01 satisfy the data requirements for Guidelines 63-2 (830-6302, Color), 63-3 (830-6303, Physical State), 63-4 (830-6304, Odor), 63-7 (830-7300, Density), 63-6 (830-7220, Boiling Point), and 63-7 (830-7300, Density/Bulk Density). The submitted data in MRID # 416971-04 and 416074-02 satisfy the data requirement for the guidelines 63-17 (830-6317, Storage Stability) and 63-20 (830-6320, Corrosion Characteristics). The submitted data in MRID # 416074-22 satisfy the data requirement for the Guideline 63-18 (830-7100, Viscosity). The flash point of the product in the CSF satisfy the data requirement for the Guideline 63-15 (830-6315, Flammability). The data requirements for the Guidelines 63-14 (830-6314, Oxidizing/Reducing Action), 63-16 (830-6316, Explodability), 63-19 (830-6319, Miscibility), and 63-21 (830-6321, Dielectric Breakdown Voltage), are not applicable to the product and are waived.

2(b). No data have been submitted for the Guidelines 63-8 (830-7840, Solubility), 63-9 (830-7950, Vapor Pressure), 63-10 (830-7370, Dissociation Constant in Water), 63-11 (830-7550, Partition Coefficient), 63-12 (830-7000, pH), and 63-13 (830-6313, Stability to Sunlight), and 830-7050 UV/Visible Light Absorption. The pH data are required for all liquid product. For measurement of pH, the registrant can try using 1% or 5% of the TGA1 to dissolve in water in accompany with stirring and ultra-sonication. The UV/VIS Absorption data can be used not only for environmental fate of the active ingredient; the data can be used by the Agency and other users to know whether it is subjected to decomposition under UV and Visible light wavelength in the warehouse conditions and to decide what containers can be used for packaging of the product; the UV/Visible light absorption data can provide the users or the Agency to know whether the active ingredient can be analyzed by HPLC using UV detector. The data requirement is listed in the Propetamphos RED page 29.

3. The submitted CSF, a basic formulation dated 16/OCT/96, has been filled out completely. All ingredients claimed in the CSF have been cleared for use in pesticide formulation. The CSF is acceptable.

4(a). Except for a minor revision required for draft label as noted in 4(b), the active ingredient statement complies with the requirements of PR Notices 91-2, 97-5, and 97-6. The Storage and Disposal statements are adequate.

4(b). (1) The flammability of the product at 82° F triggers a requirement for the statement "Combustible. Do not use or store near heat or open flame." must be placed under the Physical or Chemical Hazards heading. (2) For consistency, a statement "Do not contaminate water, food, and feed by storage and disposal." must be placed directly under the Storage and Disposal heading. (3) The storage and disposal statements must be placed in a box of solid line to increase its prominence. The revision of the draft label can be done after label review.

RECOMMENDATIONS:

Except the data gaps noted in Finding # 2(b), the registrant has satisfied all product chemistry data requirements for reregistration of this subject product. Once the outstanding data have been submitted and satisfied; and as mentioned in propetamphos IRED: (i) the current data gaps and additional data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures; and (iii) the cumulative risk assessment for the organophosphate compounds support a final reregistration eligibility decision; the Agency will have no objection to the reregistration of Technical Propetamphos, EPA Reg. No. 2724-313.

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Group B: Series 830- Physical and Chemical Properties (40 CFR 158.190)
 MRIDs #416074-11 and 416074-22.

(GRN)/TITLE 830-	Description.	Comments
-6302 Color.	Straw yellow.	A
-6303 Physical State.	Liquid.	A
-6304 Odor.	Odor of sulfur containing compounds.	A
-6314 Oxidizing/ Reducing Action	N/A, product contains no oxidizing or reducing agent.	N/A
-6315 Flammability	Flash Point: > 82 °F.	A
-6316 Explodability	N/A, the product contains no explosive agent.	N/A
-6319 Miscibility	N/A, product is not a emulsifiable liquid.	N/A
-6321 Dielectric Breakdown Voltage	N/A, product is not intended to use around electrical equipment.	N/A
-7000 pH	No data have been submitted.	Gap
-7100 Viscosity	37.5 mPa at 23°C; 11.6 mPa at 43°C.	A
- 7200 Boiling Point	Fraction 1: 44-48C; fraction 2: 136-143C; fraction 3: 143-144C.	A
-7300 Density	1.151 ± 0.002 g/ml or 9.6 lbs/gal.	A
- 7373 Dissociation Constant in Water	Data were not provided. (For TGAI)	Gap
-7570 Partition Coefficient (Octanol/Water)	Data were not provided. (For TGAI)	Gap
- 7840 Solubility (in water and organic solvents)	Data were not provided. (For TGAI)	Gap
-7950 Vapor Pressure	Data were not provided. (For TGAI)	Gap
-7050 UV/Visible Light Absorption	Data were not provided. (Fro TGAI)	Gap
-6313 Stability to Sunlight, Elevated and Normal Temperature, Metals and Metal Ions	Technical Propetamphos product were packaged in glass/PE Cone bottles and Steel Drum lined with phenolic coating and stored at ambient temperature for 0, 15, 25, 26, 29, 36, and 42 months. The concentrations of active	Additional data pertain to the stability to

	<p>ingredient in the product at initial and after the above periods of storage were found at nominal concentration >89.8 and >89.6%, respectively.</p> <p>Technical Product stored at 40C the nominal concentration at initial, after 3 and 6 weeks were found at 91.7, > 91.0, and 91.9%, respectively. Product stored at 50C for 3 and 6 weeks, the concentration of propetamphos were > 91.5 and 91.1%, respectively.</p> <p>No visible abnormalities of package were observed for the product and packaging stored at ambient temperature, 40C, and 50C for 3 and 6 weeks.</p>	<p>Sunlight or simulated sunlight (UV) are required.</p>
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A: acceptable; N/A: not applicable; Gap: data gap.

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Product Chem Review: 9-13-84 memo# 42358-01.02.03.04
416074-02, v. 22 + 499970

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Pages 5 through 8 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product impurities.
- Description of the product manufacturing process.
- Description of quality control procedures.
- Identity of the source of product ingredients.
- Sales or other commercial/financial information.
- A draft product label.
- The product confidential statement of formula.
- Information about a pending registration action.
- FIFRA registration data.
- The document is a duplicate of page(s) .
- The document is not responsive to the request.

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