

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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MEMORANDUM

SUBJECT: New Chemical-Consideration of Unconditional Registration for the Indoor Use of the New Synthetic Pyrethroid, Cyphenothrin (RS)-alpha-cyano-3-phenoxybenzyl (1RS) cis,trans-chrysanthemate (EPA File Symbols 39398-ET and 10308-RN)

..... **DECISION MEMORANDUM**

FROM: Anne E. Lindsay, Director
Office of Pesticide Programs

TO: Douglas D. Campt, Director
Office of Pesticide Programs

This memorandum recommends that you concur on the unconditional registration of **Red Earth G-8-F Aqua Fumigator** because this product meets the criteria for FIFRA section 3(c)5 and is thus eligible for unconditional registration. **Red Earth G-8-F Aqua Fumigator** represents the first use of the new synthetic pyrethroid Cyphenothrin. In conjunction with this end-use product registration, this memorandum also requests your concurrence on the registration of the technical product "Gokilaht" that is used in formulating the end-use product.

Background

On September 14, 1985 Sumitomo Chemical America, Inc. (Registrant) submitted an application for registration of a manufacturing use product (MUP) under the name Gokilaht Technical, a new synthetic pyrethroid. Since an application for registration on an end-use product was not submitted in conjunction with their application for registration of a technical product, the Agency required the registrant to identify what uses the manufacturing use product would support and to submit an application for an end-use product (EP). On May 26, 1987 the registrant submitted an application for registration of the end-use product **Red Earth G-8-F Aqua Fumigator** for general indoor use. FR-Notices announcing receipt of an application to register a product containing a new active were published in the Federal Register on December 26, 1985 (for MUP) and February 17, 1988 (for EP). No comments were received with respect to these notices.

CONCURRENCES

SYMBOL	1	2	3	4	5	6	7	8
	HK-52	HK-50C	HK-50E					
SURNAME	A. Heyrad	G. J. B...	J. K...					
DATE	9/30/91	9/3/91	9/3/91					

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Formulation, Use Pattern, and Product Limitations

Red Earth G-8-F Aqua Fumigator is formulated as a fumigating fogger containing 6.48% Gokilaht. It is for residential indoor use. The product consists of a two-part metal cartridge with the pesticide formulation in a "u" shaped cup surrounded by [REDACTED]

[REDACTED] and drives off the pesticide formulation. When activated, it fumigates the whole room with a white cloud of smoke. The smoke stays in the air during the three hour treatment, penetrating into cracks and crevices, under furniture and appliances to kill various insects. Red Earth G-8-F Aqua Fumigator can be used in areas of homes such as kitchens, living areas, garages, attics, basements and pet living areas. One unit (Net Contents 0.42 oz) will treat a room up to 19 ft. x 20 ft. Treated room must be kept closed for three hours. Before re-occupying area, room must be ventilated for 30 minutes. It is not for use in the food/feed areas of food/feed handling establishments, restaurants or other areas where food is commercially prepared or processed.

Summary and Status of Data Requirements

Based upon the proposed pattern of use, domestic indoor, the applicable data requirements and their status are as follows:

<u>Type of Data</u>	<u>Guideline Reference Number</u>	<u>Status</u>
Product Chemistry (MUP & EP)	61-1,2,3 62-1,2,3 63-1 thru 63-21	Acceptable
Toxicology (MUP & EP)		
Oral LD ₅₀	81-1	Core Guideline
Dermal LD ₅₀	81-2	" "
Inhalation LD ₅₀	81-3	Core Minimum
Primary Eye Irritation	81-4	" "
Primary Dermal Irritation	81-5	" "
Dermal Sensitization	81-6	" "
Subchronic Feeding (6 mos)	82-1(a)	" "
Subacute Inhalation	82-4	
Developmental Toxicity (rat & rabbit)	82-3	Core Guideline
Mutagenicity (Ames)	84-2(a)	Acceptable
Mutagenicity (Sister chromatic exchange)	84-2(b)	"
Mutagenicity (Micronucleus assay)	84-4	Acceptable

(continued)

<u>Type of Data</u>	<u>Guideline Reference Number</u>	<u>Status</u>
Ecological Effect Data (MUP)		
8-Day Dietary LC ₅₀ (Bobwhite Quail)	71-2	Core Guideline
Acute 96 hr LC ₅₀ (Rainbow Trout)	72-1	" "
Acute 48 hr LC ₅₀ (Daphnia Magna)	72-2	" "
Efficacy		
Field Testing against Houseflies, Mosquitoes and Cockroaches	95-11(b) (c)	Acceptable
Special Studies		
Air Monitoring	N/A	Acceptable
Child Resistant Packaging (CRP)	N/A	Does not meet criteria for CRP

Science Findings

Agency reviews of the product chemistry, toxicology, ecological effects, efficacy and exposure data have been completed and a summary assessment of these findings follows:

A. Product Chemistry

The various product chemistry requirements, including product composition, production process, discussion of formulation of impurities, certified limits, enforcement analytical method and physical/chemical characteristics for both the MUP and EP have been reviewed and found acceptable. Submission of samples of analytical grade and technical grade Gokilaht to the EPA Beltsville Labs has also been satisfied.

B. Toxicology

The Toxicology Branch (TB) has concluded that the results of the acute, subchronic, and chronic toxicology tests on Gokilaht Technical indicates that it is moderately acutely toxic through

the oral and acute inhalation routes of exposure, and is of low acute toxicity through the dermal and eye/skin routes of exposure. Based on these studies the appropriate signal word for this product is **WARNING**, Toxicity Category II.

The results of the acute toxicity tests on the **Red Earth G-8-F Aqua Fumigator** product indicates that it is of low toxicity through the oral, dermal, eye/skin irritation and inhalation routes of exposure, and has been classified as a moderate sensitizer. Based on these studies the appropriate signal word for this product is **CAUTION**, Toxicity Category IV.

According to the current Part 158 regulations, chronic feeding/oncogenicity and reproduction studies are listed as conditionally required for domestic indoor uses. The critical factors which determine whether these studies are required include; (1) if the chemical is structurally related to a known carcinogen, (2) if the chemical causes mutagenic effects, (3) if the proposed use requires a tolerance or an exemption for the requirement of tolerance and (4) if use of the pesticide results in human exposure over a portion of the human lifespan (significant in terms of the time of exposure or duration of exposure). The registrant submitted a 6 month subchronic rat feeding study, two sub-acute 28-day rat inhalation studies, mutagenicity, developmental toxicity studies to address the long term effects. TB concluded after reviewing these studies that chronic feeding/oncogenicity and reproduction studies were not required to support the proposed indoor use of cyphenothrin. Refer to the Pesticide Fact Sheet for summaries of the sub-acute, subchronic, mutagenic, and developmental toxicity studies that were determined to be acceptable.

C. Human Exposure

Due to the nature of this product, the Agency was concerned that use as directed may result in inhalation exposure by persons to the generated atmosphere and thus required air monitoring studies. Also review of the acute inhalation study showed a potential danger of carbon monoxide (CO) poisoning associated with the use of **Red Earth G-8-F Aqua Fumigator**. CO levels of 870 ppm (994 mg/m³) were achieved in the test chamber. This value would be in the range expected to cause coma and convulsions.

After review of the indoor monitoring study, the Occupational and Residential Exposure Branch (OREB) and TB concluded that the decomposition products after combustion (water, nitrogen, and CO) do not pose any greater hazard than the parent compound. With respect to the level of CO reported in the acute inhalation study, the registrant submitted additional

monitoring studies with the product in sealed 3000 ft³ Chambers (comparable to the 2560 ft³ room recommended on the label) to reflect actual use conditions. CO concentration measured after 3 hours ranged from 9.1-10.3 mg/m³ for one fumigator and from 24-28 mg/m³ for three fumigators (worst case). For perspective CO levels in American homes with smokers range from 1.6-26.2 mg/m³. The workplace Threshold Limit Value (TLV) is 57₃ mg/m³ and Short Term Workplace Exposure (STE) Limit is 458 mg/m³.

Based on this information HED concluded that the 870 ppm was present due to the design of the acute inhalation study and not typical of CO levels during real life exposure. The peak level predicted for the worst case exposure is 28 mg/m³ (25 ppm). Since this is below the workplace TLV and STE limits and this level falls off quickly to trivial values by 3 hours, the time for final reentry indicated on the label, the product should not pose a CO intoxication hazard to homeowners even if it is misused.

TB was concerned as to whether the product packaging would allow for the consumption of the formulation or [REDACTED] source by children. Also the formulations sweet smell and yellow-orange color could entice a child or animal to be accidentally poisoned. A review of the acute toxicity data for the end-use product indicated that the product (including [REDACTED]) did not meet toxicity criteria for child resistant packaging (CRP). Even though CRP was not required, the registrant did submit data to demonstrate inaccessibility of the [REDACTED] to children. Although this data was not classified as child-resistant effectiveness data, it nonetheless indicates that the [REDACTED] is minimally accessible to children. Thus, TB was no longer concerned with the need for CRP.

D. Ecological Effects (Environmental)

Ecological effects data characterize Gokilaht technical as highly toxic to aquatic organisms, moderately toxic to small mammals, and of low toxicity to birds. Thus the technical product must bear the following precautionary labeling "This product is extremely toxic to fish and other aquatic organisms." Since the end-use product is for indoor use only, no additional data is required and no Environmental Hazard warnings are necessary. Likewise, since the use pattern is indoor no environmental or groundwater data is required.

E. Efficacy

Although efficacy data in most cases is no longer required to be submitted for review, the registrant submitted minimal

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

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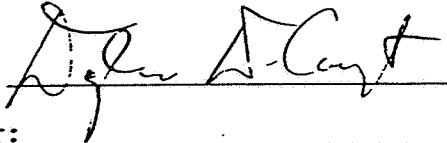
insecticidal efficacy data on houseflies, mosquitoes and cockroaches. The data presented was submitted in accordance with the criteria for the Product Performance Guidelines and was adequate to support the claim for control of insects listed on the label.

Regulatory Status

All data required in support of a Section 3 registration for indoor use have been submitted, evaluated, and found acceptable. There is no tolerance requirement, since this use pattern does not involve food/feed items. There are no data gaps for this use pattern. There are no pending regulatory actions against the registration of this pesticide for indoor use. A Pesticide Fact Sheet has been prepared and is attached for your review.

Recommendation

The Registration Division recommends that the Red Earth G-8-F Aqua Fumigator fogger product and Gokilaht Technical product containing the new synthetic pyrethroid Cyphenothrin be unconditionally registered under FIFRA Section 3(C)(5).

Concur: 

Nonconcur: _____

Date: 10/1/71