September 9, 1998

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical and it is presented here exactly as submitted.

OPP#34137

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CYANAMID

This Submission Does Not Contain 40 CFR Part 158 Data

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December 17, 1997

Mr. Jason Robertson
Office of Pesticide Programs
Special Review and Reregistration Division [7508W]
U.S. EPA; Crystal Mall, Bldg. #2, Rm. 266A
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: Phorate Reregistration; Case 0103;
Partial Response to the Draft Environmental Fate and Effects Science Chapter

Dear Mr. Robertson:

Phorate, the active ingredient in American Cyanamid Company's THIMET® brand soil and systemic insecticides, is undergoing reregistration at EPA. Part of the reregistration process includes an assessment of the risk to terrestrial and aquatic non-target species from exposure to the product. On August 11, 1997 Cyanamid received a copy of the draft environmental fate and ecotoxicology assessment (a.k.a., "science chapter") and recommendations composed in 1996 by the Agency's Environmental Fate and Effects Division (EFED) (P. Wagner memo to J. Housenger, July 18, 1996). The overall recommendation from EFED to the Special Review and Reregistration Branch was,

> "...consideration be given to the cancellation of the uses of phorate in all but the most extreme circumstances."

Considering the consequence of the recommendation, American Cyanamid Company commented in a letter to the Agency (J. Wrubel to J. Robertson, October 6, 1997) on the fact that the draft EFED science chapter did not accurately characterize the risk of phorate use to fish and birds, especially in light of the FIFRA Scientific Advisory Panel's May 1996 recommendation to employ probabilistic rather than the deterministic (i.e., LD_{50}/ft^2) approaches in assessing ecological risk.

At a June 23, 1997 public meeting meant to address the ecological risk assessment process, Mr. Stephen Johnson, Acting Deputy Office Director of OPP, presented an example of "1000 questions" that risk managers would typically ask risk assessors in order to formulate scientifically-sound risk management decisions. The attached document (Exhibit 1) is composed in the spirit of answering Mr. Johnson's "1000 questions" and is intended to assist the Agency's risk managers in placing phorate and its potential environmental risk into perspective.

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Use Pattern

Phorate was first registered in 1956. The American Cyanamid product, THIMET, is currently marketed as a clay-based granule containing 20% active ingredient. THIMET is also registered (but not sold) as a 10% a.i. and a 15% a.i. granule product. Phorate is "off-patent" and is generically available. The insecticide is labeled for use on field and sweet corn, cotton, potatoes, peanuts, sugar beets, sugarcane, grain sorghum, edible beans, soybeans, and wheat. THIMET applications are restricted to ground equipment and are made at planting (in-furrow or banded), at cultivation, or post-emergent over the crop row. As a risk mitigation measure, broadcast and aerial applications were previously removed from the label. The product is classified as "restricted use" due to concerns over acute oral and dermal toxicity and avian hazards. Currently 65% of THIMET is sold in the LOCK 'n LOAD® closed handling system. The LOCK 'n LOAD returnable container eliminates the bag disposal problem and reduces the possibility of accidental spills.

THIMET is a valuable crop protection tool used routinely in certain cropping systems. However, in relation to the total number (426 million) of arable acres in the United States, the actual amount of acres (2.6 million) treated with THIMET is small. Hence, the overall potential for non-target organism exposure to phorate is indeed limited.

Aquatic Risk

Since THIMET is applied using ground equipment only, the risk to aquatic organisms is limited to water bodies associated with fields treated with phorate where an exposure event occurs via surface run-off. The potential for an aquatic adverse effect is influenced by the size of the water body, the time after application, the size and slope of the field, the condition and type of soil, the proximity of the water body to the treated field, and the magnitude and intensity of the rainfall event.

American Cyanamid is aware of only eight aquatic incidents which have been associated with phorate in over 40 years of use. Thus, the high level of risk to aquatic organisms predicted in EFED's deterministic risk assessment is not validated by monitoring information. The small number and nature of the incidents in the field suggest that the risk of phorate to aquatic organisms is not widespread and repeated. A review of the incidents clearly indicate that a special series of events (e.g., massive rainfall occurring a short time after application) need to occur before phorate can possibly cause an adverse effect.

All eight aquatic incidents occurred in man-made farm ponds which, according to EPA's Office of Research and Development (ORD), are considered ecosystems of low ecological priority ("Priorities for Ecological Protection: An Initial List and Discussion Document for EPA", Ecological Concerns Workgroup, ORD, EPA, 1997). Thus EFED's entire deterministic risk assessment is based on systems that, by EPA's own definition, are of limited ecological importance and grossly overestimates the true risk of phorate to aquatic organisms and to aquatic ecosystems overall.

Terrestrial Risk

For terrestrial non-target species, the ecosystem at risk from phorate applications is limited to the cropped portion of the field, the field perimeter (i.e., turn rows), and vegetation and prey items containing residues. Except during unusual circumstances, the opportunity for birds to be exposed to phorate is limited to the cropped field and turn-row areas and is of limited duration due to the short environmental half-life of the molecule (T ½ = 2 to 15 days). The major route by which birds would be exposed to phorate is via ingestion of granules.

Based on deterministic risk assessment techniques derived from a 1966 paper by James DeWitt which examined the toxicity of persistent chlorinated hydrocarbons to birds, EFED has concluded that the use of the organophosphate, phorate, exceeds the level of concern for terrestrial species. Tremendous uncertainty surrounds EFED's use of deterministic methods (i.e., LD_{50}/ft^2) to accurately assess the risk to terrestrial species. This uncertainty led the FIFRA Scientific Advisory Panel to recommend the use of probabilistic assessment methodologies and to validate predictive models before they are used in a regulatory context. The few avian mortality incidents that have occurred does not validate the conclusion of the deterministic risk assessment when considering the extent of phorate use.

Few (if any) of the eighteen avian incidents associated with over 40 years of phorate use as an insecticide can be attributed to the proper utilization of the product as it is currently labeled and it is not readily apparent that further label mitigation is warranted.

Effect of Concern

It is well documented in results from laboratory studies that phorate is highly toxic to non-target terrestrial and aquatic species. Being based on organophosphate chemistry, the acute effect of concern for phorate is cholinesterase depression which can lead to

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mortality. Although some degree of theoretical risk exists for localized impacts on aquatic and terrestrial populations, there have been no documented cases where, following a proper application of THIMET, sufficient mortality occurred to potentially impact such a population. Accordingly, regional population effects are unexpected as well.

Alternative Products

Alternatives to phorate include compounds in the organophosphate, carbamate, and pyrethroid classes of chemistry in addition to a few products based on newer chemistry. A rudimentary comparison of the eco-toxicological profiles of the competitive products shows that most lead to trade-offs in toxicity to either birds, fish, or aquatic invertebrates (i.e., a product may be toxic to fish but not birds or *vice versa*). Because of this overall comparable toxicity and the broad pest control spectrum of phorate, it does not appear that potential replacements exist for phorate across many of its use areas.

In general, laboratory data are useful in comparing the relative toxicity among pesticides but are not necessarily useful in predicting effects in the field. The critical factor in determining risk to wildlife is the exposure to the pesticide. The lack of widespread and repeated mortality incidents attributed to phorate use supports the limited exposure of non-target organisms to the compound.

The points concerning the environmental risk of phorate conveyed in this letter are more thoroughly described in the attached document (see Exhibit 1). In addition, we are planning to submit under separate cover an environmental effects risk assessment for phorate written by a third party and a point-by-point response to EFED's draft science chapter. Please feel free to contact me directly at telephone number 609-716-2378, should you have any questions.

Sincerely,

John J Wrubel

John J. Wrubel
Product Registrations Manager
U.S. Plant Regulatory Affairs

encl.

cc: M. Mautz; OPP/RD/Team 14