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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT EPA ID No. 57875
Malathion, May 23, 1990 Letter of Understanding from
American Cyanamid Company Concerning the April 12, 1990
Meeting Between Company and OPP Representatives.

Project No.: 0-1612
Tox. Chem. No.: 535
Record No.: 267544

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Brian Dementi 8/10/90

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THRU: Roger Gardner, Acting Section Head
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Roger Gardner 8/13/90
LF 8/13/90

As a follow-up to the April 12, 1990 meeting between representatives from American Cyanamid and OPP personnel to discuss toxicology data requirements pursuant to the reregistration of malathion, American Cyanamid has filed with OPP the subject memorandum of understanding under the signature of William A. Steller, Manager, U. S. Regulatory Affairs.

Toxicology Branch acknowledges having received and read the cover letter and appended memo by Dr. Hess entitled "Malathion Reregistration Toxicology Requirements for USEPA".

The following comments appear appropriate.

Mr. Steller's letter in general appears adequate. However, Toxicology Branch must acknowledge lack of accord with the statement on page 2, "With respect to the initial EPA requirement to repeat the rat chronic oncogenicity study for maloxon, it was agreed by the Agency to hold this requirement in abeyance". Toxicology Branch considers this data requirement, as set forth in the February 1988 Registration Standard, to remain in place.

The appended memo of Dr. Hess contains a thorough discussion under item # 1 of American Cyanamid's views regarding the 1980 Food and Drug Research Lab's two-year study in Sprague-Dawley Rats. American Cyanamid appears to recognize the need for the histopathologic reanalysis of this study, a requirement which will be affirmed via letter to the company.

With respect to item 2 in Dr. Hess' memo, Toxicology Branch has reviewed the cited submittal on the 1978 NCI carcinogenicity study in the mouse and rendered its response under a separate memorandum dated July 12, 1990 (Project No.: 0-1329; EPA ID No.: 57875).

Item 3 of Dr. Hess' memo reiterates American Cyanamid's proposal for a subchronic rat study to assess cholinesterase inhibition. Toxicology Branch considers that the required chronic/oncogenicity study of malathion in the rat will be designed to obtain definitive cholinesterase data, thus obviating the need for this particular subchronic study in the rat.