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

FEB 29 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Irgasan; Toxicology Data Requirements

TO: Arturo Castillo PM-32
Registration Division (TS-767)

FROM: Robert P. Zendzian Ph. D. 1/30/84
Toxicology Branch
HED (TS-769)

THROUGH: William Butler, Head 2-27-84
Review Section III

William Burnam, Chief 2/29/84
Toxicology Branch

Compound Irgasan® (triclosan, DP-300, FAT 80)

Registration# 100-502

Accession #s 251771-74

Tox Chem# 186A

Registrant Ciba-Geigy

Irgasan is a disinfectant which is registered for a variety of uses. Due to a mixture of circumstances the toxicology data base of this compound is in disarray. The Registrant and the Agency are engaged in an effort to determine what toxocological studies are available and which of these can be used to satisfy the Agency's data requirements. The Registrant has submitted copies of all the reports of non-acute toxicity studies on Irgasan which they believe suitable for satisfying Agency requirements. These reports have been examined for their suitability in satisfying Agency data requirements and if not previously reviewed have been reviewed. Suitable studies have been compared against toxicology data needs for Irgasan, based on its registered uses, and a determination made of additional data requirements. The reported studies satisfy the Agency's requirements for subchronic oral studies, subchronic dermal studies and teratology studies. In addition data is on hand that satisfies

the Agency's requirements for mutagenicity studies. Agency requirements for a chronic oral study, two oncogenicity studies, a reproduction study and a metabolism study have not been satisfied.

The registrant, under a cover letter dated Nov 7, 1983, submitted reports of 13 studies and subsiquently submitted a 14th report. These studies are listed in Appendix A, Irgasan Data Requirements. Reviews of 9 of these studies were found in Toxicology Branch Files and the remaining 5 studies were reviewed (Appendex B, DERs). The five newly reviewed studies are;

1) 90 Days Oral Toxicity Study in Sprague Dawley Rats with CH 3565. F. Leuscher, A. Leuscher, W. Schwerdtfeger & W. Dontenwill, Laboratorium fur Pharmakologie und Toxikologie July 27, 1970

2) 90 Days Oral Toxicity Study in Beagle Dogs with CH 3565 F. Leuschner, A. Leuschner, W. Schwerdtfeger & W. Dontenwill Laboratorium fur Pharmakologie und Toxikologie, July 10,1970

3) 90 Days Oral Toxicity Study in New Zealand White Rabbits with CH 3565. F. Leuschner, A. Leuschner, W. Schwerdtfeger & W. Dontenwill. Laboratorium fur Pharmakologie und Toxikologie July 31,1970

4) 1 Year Oral Toxicity Study in Baboons with compound FAT 80 023/A. J.C. Drake & A. Buxtorf Geigy Pharmaceuticals, Toxicology Department, Stamford Lodge, Wilmslow, Cheshire. Jun 28, 1976

5) 90-day Oral Toxicity Study in Rats with FAT 80'023/H, Final Report. L.A. Goldsmith & D.K. Craig, Litton Bionetics LBI Project No 22188, Oct 11, 1983

Appendix A lists all of the types of nonacute studies required for Irgasan and and under each heading lists the studies which have been found to satisfy each particular requirement.

No usable chronic feeding (oral) or oncogenicity studies are available but the registrant has in progress a combined oral rat study which can satisfy the requirement for a combined chronic oral and oncogenicity study. A second oncogenicity study, in the mouse, is required.

No usable reproduction study is available and a reproduction study, in the rat, is required.

Three metabolism studies have been reviewed but these do not satisfy the requirement for a metabolism study. An oral metabolism study, in the rat, is required.

Numerous mutagenicity studies have been received and reviewed. They are uniformly negative. No further mutagenicity studies are required.