MEMORANDUM

SUBJECT: Irgasan; Toxicology Data Requirements

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

FROM: Robert P. Lezdzian Ph. D.
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HED (TS-769)

THROUGH: William Butler, Head
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William Burnam, Chief
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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 toxicological 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 terato
tology 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 subsequently 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 (Appendix B, DERs). The five newly reviewed studies are:


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


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.