IRB/TSS Precautionary Labeling Review July 11, 1984

TO: PM-17

SUBJECT: 1021-340
Pyrocide Intermediate 5192
McLaughlin Gormley King Co.
8810 Tenth Ave. North
Minneapolis, MN 55427

In TSS: 04-04-83
Record No.: 118545, 118546, 118547
Accession No.: 252717, 252716, 251314
Action: 305, 306, 306

FORMULATION: Reformulating Liquid

Active Ingredients	
Pyrethrins	9.0%
PBO, technical	18.0%
N-Octylbicycloheptene dicarboximide	30.0%
Petroleum Distillate	43.0%

6900, 6750, 5700

BACKGROUND: The registrant has resubmitted an acute inhalation LC_{50} study (Accession number 251314). This study was reviewed by Byron Backus on November 1, 1983 and was classified as core supplementary data. The registrant has also submitted two dermal sensitization studies for review.

SUBMITTED DATA: studies were done at:

Biosearch Incorporated
P. O. Box 8598
Philadelphia, PA 19101.

1A. Dermal Sensitization Study, date 08-11-75: Accession number 252716. Ten guinea pigs received an induction series of 10 24-hr exposures to 0.5 ml of undiluted test material. There was a gap of 24 hours between exposures. Following last exposure, animals were rested for 2 weeks and then challenged at a new site, with scoring at 24 and 48 hrs following this exposure. No reaction to challenge was reported.

1B. Dermal Sensitization Study, project number 83-3841A, date 01-13-84, Accession number 252717: Groups of 10M albino guinea pigs received an induction series of 10 six hour exposures to either 0.5 ml of 25% w/v suspension of pyrocide in mineral oil or 0.5 ml of 0.8% w/v suspension of 1-chloro-2.4-dinitrobenzene in an 83% ethanol in saline solution. Animals were allowed a 1-day rest period after each exposure. Following the last exposure, animals were rested for 2 weeks and then challenged at a new site, for 24 hours. Two weeks after the challenge application, the animals were re-challenged with the test material with scoring at 24 and 48 hours after each challenge.

5700, 6750, 6900,

All animals in the test group showed a mild reaction.

Core minimum data.
Mild sensitizer.

COMMENTS:

1. Product has been classified as a mild skin sensitizer on the basis of the more recent study (1B) which has a better protocol than the older study (1A). IRB/TSS suggests a label revision to include a statement like "This product is a mild skin sensitizer. Do not use in formulating end-use products that will result in repeated skin contact".

2. IRB/TSS stands by its earlier decision of classifying the acute inhalation LC_{50} study (accession number 251314) as core supplementary data. A copy of our November 1, 1983 review is attached. There is no mention of a 1:64 dilution in our review, and we do not know of any other review that the company might be referring to in their letter of November 28, 1983.

Rita Kumar
IRB/TSS

Rita Kumar

fo Products should have labelling to avoid prolonged or repeated contact with the skin as dermal sensitization may occur.