DATE: August 14, 1978

002370

SUBJECT: Explanation of acute inhalation toxicity study : label change of practical treatment of Ortho Triforine E.C. Caswell No. 890 AA

FROM: H.W. Spencer, Ph.D.
TOX/RD

TO: PM #21, E.M. Wilson

Registrant: Chevron Chemical Company
940 Hensley Street
Richmond, California 94304

Results: The agency questioned both the inhalation study and practical treatment statement in a memo to Chevron company dated 2/22/78.

Chevron Chemical Company indicated that:

(a) the material was CA 70203 used in the inhalation study reviewed.

(b) the formulation has been slightly changed from that tested (CA 70203).

The TOX Branch finds that the slightly altered formulation is insignificant for the acute studies and will not in all probability change the LD 50 or LC 50 values appreciably let alone the Toxicity Categories for labeling.

Data presented allows the TOX Branch to upgrade the inhalation study from INVALID to core minimum data.

TOX Branch notes in the previous review of the possible corrosive effects of the formulation. These corrosive effects would seem to be detrimental to the patient if emesis is induced, however, the leaving of a concentrated formulation in constant contact with the gastric mucosa also would seem to be as bad a condition.

TOX Branch does not feel that the question of dilution has been properly addressed as a practical treatment.

The TOX Branch requests a written statement of effects and recommended treatment from a recognized medical expert in the field of gastro-enterology who is fully familiar with the effects of these types of organic solvents on the gastro-intestinal tract for inclusion in the master file: showing that these questions have been adequately addressed.

8/15/78

EPA FORM 1320-6 (REV. 3-76)

181

1