



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

JAN 19 1995

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Triforine: Evaluation of supplemental data of a
developmental toxicity studies in rats

Caswell No. 890AA DP Code: D203580
EPA Chemical No. 107901 MRID No. 432221-01
Submission No. S465985

TO: R. Kendall/V. Dietrich PM Team 51
Special Review and Re-Registration Division (7508W)

FROM: Whang Phang, Ph.D. *Whang Phang 1/13/95*
Pharmacologist
Tox. Branch II/HED (7509C)

THROUGH: James Rowe, Ph.D. *James N. Rowe 1/18/95*
Section Head
and
Marcia van Gemert, Ph.D. *Marcia van Gemert 1/18/95*
Branch Chief
Tox. Branch II/HED (7509C)

Introduction

In 1993, Biologic Inc. submitted a developmental toxicity study in rats with triforine. This study was evaluated and classified as supplementary (Tox. Doc. No. 010687) because the report did not have any information on the purity of the test chemical.

Evaluation and Discussion

The supplemental data indicated that the test chemical was 99.8% pure. The study is upgraded to minimum and meets the data requirements for a developmental toxicity study in rats (Guideline No. 83-3a).

¹ Fuchs, A. (1993) Oral (gavage) teratogenicity study in rats. Unpublished study conducted by Hazleton Deutschland GmbH, Münster, Germany. Study No. 121-006. Feb., 1993. Submitted to EPA by Biologic Inc.; EPA MRID No. 428892-01.



Recycled/Recyclable
Printed with Soy/Genola Ink on paper that
contains at least 50% recycled fiber

011390

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



JAN 19 1995

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Triforine: Evaluation of supplemental data of a
developmental toxicity studies in rats

Caswell No. 890AA DP Code: D203580
EPA Chemical No. 107901 MRID No. 432221-01
Submission No. S465985

TO: R. Kendall/V. Dietrich, PM 1000 51
Special Review and Registration Division (7508W)

FROM: Whang Phang, Ph.D. *Whang Phang 1/13/95*
Pharmacologist
Tox. Branch II/HED (7509C)

THROUGH: James Rowe, Ph.D. *James N. Rowe 1/18/95*
Section Head
and
Marcia van Gemert, Ph.D. *Marcia van Gemert 1/18/95*
Branch Chief
Tox. Branch II/HED (7509C)

Introduction

In 1993, Biologic Inc. submitted a developmental toxicity study in rats with triforine. This study was evaluated and classified as supplementary (Tox. Doc. No. 010687) because the report did not have any information on the purity of the test chemical.

Evaluation and Discussion

The supplemental data indicated that the test chemical was 99.8% pure. The study is upgraded to minimum and meets the data requirements for a developmental toxicity study in rats (Guideline No. 83-3a).

¹ Fuchs, A. (1993) Oral (gavage) teratogenicity study in rats. Unpublished study conducted by Hazleton Deutschland GmbH, Münster, Germany. Study No. 121-006. Feb., 1993. Submitted to EPA by Biologic Inc.; EPA MRID No. 428892-01.

191



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber