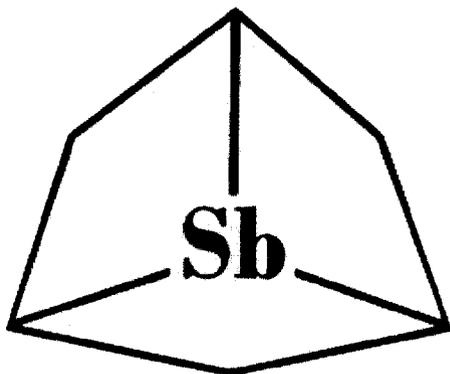


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MR 273330



International
**ANTIMONY
OXIDE**
Industry Association

VIA CERTIFIED MAIL

Document Processing Center
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Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

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Attention: TSCA Section 8(e) Coordinator



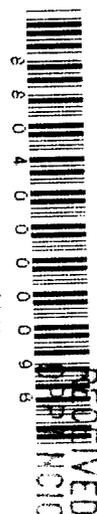
RE: TSCA Section 8(e) Notification on Antimony Trioxide
(CAS No.: 1309-64-4)

Dear Sir or Madam:

The International Antimony Oxide Industry Association (IAOIA)¹ submits this letter of substantial risk notification in accordance with Section 8(e) of the Toxic Substances Control Act, 15 USC 2607(e), and the Environmental Protection Agency's "Statement of Interpretation and Enforcement Policy" thereof 43 FR 1110, 35 seq., March 16, 1978. The notification is in regards to a report sponsored by IAOIA¹ entitled, "An inhalation developmental toxicity study in rats with antimony trioxide".

The test material, Antimony trioxide (CAS No.: 1309-64-4) was administered via nose-only inhalation to groups of 26 female rats at target concentrations of 0, 1.5, 3.0, or 6.0 mg/M³ for 6 hours per day from Days 0 through 19 of gestation. A concurrent control group of identical design received clean, filtered air on a comparable regimen.

¹ The International Antimony Oxide Industry Association consists of the following producers of antimony trioxide: Campine NV, Great Lakes Chemical Corp., Laurel Industries, Inc. (OxyChem), Penox SA, Produit Chimiques de Lucette, Sica, Nihon Seiko Co., LTD., Nissan Chemical Industries, LTD., Yamanaka and Co., Ltd., Sumitomo Metal Mining Co., LTD., and Tohko Industrial Corporation.



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All animals survived the study and no effect of treatment was evident from maternal clinical examinations, gestation body weight, or food consumption. Likewise, no effect of treatment was evident from maternal macroscopic findings, Day 20 gestation uterine implantation data, fetal sex ratios, fetal body weights, fetal crown rump-distance data or fetal examinations (external, visceral, or skeletal). While the study did not induce fetal toxicity at any of the concentrations employed, maternal effects were observed at every concentration level, 2.6, 4.4, or 6.3 mg/m³ (actual delivered concentrations). This was manifested as increases in lung weights, which were 24%, 31%, and 39% greater than controls for the 2.6, 4.4, and 6.3 mg/m³ groups, respectively. Further histopathological analysis, which was conducted specifically to delineate the reason for these increases revealed diffuse accumulation of pigmented alveolar macrophages which likely reflected phagocytosis and accumulation of the test article particulate matter. It was concluded that these findings are typical with exposures to particulate matter, especially when the route of exposure is nose-only.

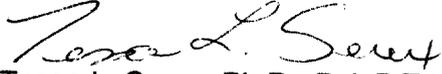
These types of findings were observed in 13-week and 1-year inhalation studies in Fischer 344 rats (Newton et al., 1994) sponsored by the Antimony Oxide Industry Association (AOIA). Rats in the 13-week study receiving 4.92 and 23.46 mg/m³ had significantly increased absolute and relative lung weights. While a similar increase in lung weights was not observed in the 1-year inhalation study (0.05, 0.5, and 5.0 mg/m³), a similar histopathological profile was observed coinciding with large tissue burdens of the particulate. In the 13-week and 1-year studies, a different strain of rat was used and the route of exposure was whole-body inhalation. Also, the particle size of the test material was 3.05 ± 0.21 and 3.76 ± 0.84 microns in the subchronic and chronic studies, respectively. In the current developmental study, particle size ranged from 1.59 to 1.82 microns. While the findings of the recently conducted developmental study do not provide evidence of a new or unexpected effect, changes in lung weights and histopathological findings were observed with a shorter duration of exposure.

The Lowest Observable Adverse Effect Level (LOAEL) for maternal effects was 2.6 mg/m³. This LOAEL was based on an increase in lung weights both absolute and relative to brain weights at all exposure levels evaluated. The changes were dose-responsive and differed statistically from controls. The No-Observed-Effect Level (NOEL) for developmental toxicity was 6.3 mg/m³, the highest exposure level evaluated.

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If you have any questions or other concerns please do not hesitate to phone me at 765-497-6637 or email tserex@glcc.com.

Sincerely yours,



Tessa L. Serex, Ph.D., D.A.B.T.
Toxicologist
Lead Technical Advisor to IAQIA

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