

8EHQ-0595-13455



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Chemical Information Division  
Office of Toxic Substances  
Room E-108  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, D.C. 20460

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Attention: Section 8(e) Coordinator

Re: Notice of Substantial Risk under TSCA 8(e) for Basic  
Chromium(III) Sulfate when Administered by Nose-only  
Inhalation to Rats for 90 Days  
EPA Docket No. ---- Unknown

Gentlemen:

The Industrial Health Foundation (IHF), acting as Agent for the IHF Chromium Chemicals Health and Environmental Committee, the membership of which consists of Harcos Chemical Group (American Chrome and Chemicals and British Chrome and Chemicals), AlliedSignal, Inc., Bayer AG, and Occidental Chemical Corporation, has been verbally informed of the preliminary, unaudited results of a 90-day nose-only inhalation study in rats (with recovery) on basic chrome(III) sulfate which was sponsored by that Committee.

A brief outline of the test procedures as extracted from the protocol is attached. Essentially, exposures were for 6 hrs/day, 5 days/week for 13 weeks to concentrations of 0, 17, 58, and 175 mg/m<sup>3</sup> of basic chrome(III) sulfate which corresponds to chromium(III) levels of 0, 3, 10, and 30 mg Cr/m<sup>3</sup>, respectively. The death of 1 animal from the high exposure group after 7 days of exposure has been tentatively ascribed to be exposure-related as severe body weight loss and respiratory signs preceded the death. Throughout the exposure duration, there were weight gain depressions in the mid- and high-level exposure groups which did not

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rebound to control values during the recovery period. Necropsy of a portion of the animals after 90 days of exposure showed gray lung discoloration in the mid- and high-level exposure groups and an increase in lung weights. Microscopic evaluation showed chronic inflammation of lung and larynx plus septal cell hyperplasia in the high exposure group. Necropsy of recovery animals which had been unexposed for 90 days still showed lung discoloration and increased lung weights in the mid- and high-level exposure groups. Some of the effects described above appear to have occurred in the low exposure group. However, pending statistical analysis, the significance of these effects is uncertain. A sub-group of animals exposed for 5 days showed changes in bronchioalveolar lavage fluid analysis for all exposure levels.

It seems likely to us that the noted effects were primarily due to the highly acidic nature of the test substance. However, in light of the fact that a NOEL does not seem to have been established in this test and that acceptable human exposures are likely to be based on the current TLV/PEL of 0.5 mg Cr/m<sup>3</sup> for chrome(III) compounds, it has been deemed desirable to call these study effects to your attention at the present time.

A copy of the final audited report will be provided to your office when available. In the interim, you may contact me at 412-363-6600 for further discussion on details of the findings.

Sincerely,

*William E. Rinehart*

William E. Rinehart, Sc.D.  
Consultant in Toxicology

Attachment

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## STUDY DESIGN

### Thirteen Week Subchronic Nose-Only Inhalation Study of Chromic Oxide and Basic Chrome Sulfate in Rats (With Recovery)

0, 4.4, 15, 44 mg/m<sup>3</sup> Chromium Sesquioxide  
(3, 10, 30 mg/m<sup>3</sup> as Cr)

0, 17, 58, 175 mg/m<sup>3</sup> Basic Chromium Sulfate  
(3, 10, 30 mg/m<sup>3</sup> as Cr)

F-344  
Rats

140 Males

140 Females

(20Sex/Group)

Exposure: 6 hr/day, 5 days/week

Recovery

5 days

13

26 weeks

5/sex/group  
Bronchoalveolar  
Lavage Fluid (BAL)  
Analysis

Sacrifice  
10/sex/group

Sacrifice  
5/sex/group

#### Observations:

Cage-side: 2x/day

Clin. Obs.: Weekly

Body weights: Weekly

Food Consumption: Observation weekly

Clinical: Hematology Blood Chemistry and Urinalysis, at 13 weeks  
Recovery optional. Blood and urine stored for Cr analysis

Ophthalmoscopic: Acclimation and final week of exposure

Sperm-evaluations: Count, morphology, motility at 13 weeks (5 males)

Necropsy: 13 and 26 weeks, samples stored for chromium analysis (lung, kidney femur)  
Histopathology: 13 weeks, recovery if effects observed 13 weeks