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DATA EVALUATION REPORT

CHEMICAL: Silver Copper Zeolite

CHEMICAL NO.: 129057

HED NO.: 9 - 2183A

STUDY TYPE: Acute Inhalation Study in Rats (81-3)

ACCESSION NUMBER: 416158-04

STUDY NO.: 63613-08

SPONSOR: Kanebo Zeolite USA, Inc.; 20th Fl., Empire State Bld.;
350 5th Ave. New York, NY 10118

TESTING FACILITY: Arthur D. Little, Inc.; Acorn Park; Cambridge
MA 02140

TITLE OF REPORT: Silver Copper Zeolite Acute Inhalation Toxicity
Study in Rats

AUTHOR: Bruce O. Stuart, Ph. D.

DATE ISSUED: September 27, 1989

GLP COMPLIANCE: Statement signed and dated on page 3.

QUALITY ASSURANCE: Statement signed and dated on page 6.

CONCLUSIONS: The results of this study indicate that the acute inhalation LC50 for Sprague Dawley rats exposed to the highest attainable concentration of Silver Copper Zeolite by whole body exposure is greater than 2.59 mg/liter. [Tox. Category III]

CLASSIFICATION: This study satisfies guideline requirements for an acute inhalation study according to Guideline #81-3 and is classified as Core - guideline.

A. MATERIALS:

Test compound: Silver Copper Zeolite in the form of a blue powder.
Purity - 99%.

Test animals: Species: rat, Strain: Sprague Dawley, Age: nine weeks, Weight: 297-343 g (Male) and 184-220 g (female), Source: Taconic Farms, Germantown, NY. They were quarantined for six days,

then examined for general health. Several animals had a slight porphyria around the nose that has been often observed in rats obtained from Taconic farms. This finding was judged not to affect results of this study.

B. STUDY DESIGN:

Test atmosphere generation:

The test article was generated into the inhalation chamber using an NBS Dust Generator. The nominal concentration of the test atmosphere was calculated by dividing the total amount of test material used (mg) by the total amount of air going to the chamber (l).

Gravimetric sample analysis was used to determine the average actual concentration of Silver Copper Zeolite. The average actual test atmosphere concentration was calculated based on the mean of four hourly samples.

Particle size analysis, using a Mercer-type cascade impactor, was performed during the second and fourth hour of exposure. The mean cumulative percentage of particles collected at each stage was calculated.

Dose administration:

During a four hour whole-body inhalation period, one group of 5 male and 5 female rats were exposed to the highest attainable concentration of Silver Copper Zeolite at a concentration of 2.59 mg/liter of air.

Methods of toxicological evaluation:

Clinical observations were performed after the 4-hour inhalation exposure. After that, clinical observations were performed once a day and in addition mortality checks were performed daily for 14 days. Any signs of abnormality including changes in skin, fur, eyes and mucous membranes, etc. were noted. Animals were weighed on day 1, 8 and 15 before sacrifice. Those animals surviving to the end of the study were sacrificed and necropsied.

Statistical analysis:

Mean and standard deviations of body weights were calculated at each time interval. Nominal and actual concentrations of Silver Copper Zeolite (mg/liter) were calculated. Particle size distribution, mass median aerodynamic diameter (MMAD) and the geometric standard deviation were also determined.

C. RESULTS:

Test atmosphere generation:

The nominal concentration of Silver Copper Zeolite was 11.5 mg/liter. The actual concentration was 2.59 mg/l and the mass median aerodynamic diameter (MMAD) of the generated particles was

2.2 microns with a geometric standard deviation of 2.8, and 1.7 microns with a geometric standard deviation of 3.0 during exposure hours two and four respectively. Based on graphical analysis, approximately 22% and 32% of the particles measured at 2 and 4 hours respectively were less than 1 um in diameter. From the Cascade Impactor data, the portion of particulates smaller than 1 um was slightly lower (16.7 and 27.6% at 2 and 4 hours, respectively).

Mortality and LC50:

No animals died during this study. The LC50 for male and female Sprague-Dawley rats is greater than the actual concentration of 2.59 mg/ml.

Body Weights:

There was no body weight loss in test animals during the test period up to day 15. The body weight change from Day 1 to Day 15 for male and female rats was 35 grams and 23 grams, respectively.

Clinical Observations:

There were no clinical observations that could be attributed to the administration of Silver Copper Zeolite.

Necropsy Findings:

There were no significant necropsy findings that could be attributed to test material administration.

The results of this study indicate that the acute inhalation LC50 for Sprague Dawley rats exposed to the highest attainable concentration of Silver Copper Zeolite by whole body inhalation is greater than 2.59 mg/liter. [Tox. Category III]

CLASSIFICATION: This study satisfies data requirements for an acute inhalation study according to Guideline #81-3 and is classified as Core-guideline.