

1/25/91

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DATA EVALUATION REPORT

CHEMICAL: Silver Copper Zeolite

CHEMICAL NO.: 129057

HED NO.: 9 - 2183A

STUDY TYPE: Guinea Pig sensitization (81-6)

ACCESSION NUMBER: 416158-06

STUDY NO.: 63613-13

TESTING FACILITY: Arthur D. Little, 30 Memorial Drive, Cambridge,
MA 02140

TITLE OF REPORT: Silver Copper Zeolite Guinea Pig Sensitization
Study - Buehler Method

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DATE ISSUED: October 3, 1989

GLP COMPLIANCE: Statement signed and dated on page 3.

QUALITY ASSURANCE: Statement signed and dated on page 5.

CONCLUSIONS: Based on results of this study, a 60% suspension (in 0.5% Carboxymethyl cellulose) of Silver Copper Zeolite would be regarded as a non-sensitizer on guinea pigs according to the Buehler method of testing.

This study satisfies guideline requirements for a guinea pig sensitization study (81-6).

CLASSIFICATION: Core - Guideline

A. MATERIALS:

Test compound: Silver Copper Zeolite in the form of a blue powder.
Purity - 99%.
Dinitrochlorobenzene (DNCB lot no. 44F-0565) at a 0.1% (w/v) concentration was used as a positive control.

Test animals: Species: guinea pig, Strain: female albino of the outbred strain that were Viral Antibody Free (VAF), Age: young

adult, Weight: 300 - 350 g, Source: Charles River Breeding Laboratories; Portage, PA.

B. STUDY DESIGN:

A range-finding study was conducted to determine dosage. A 60%(high dose) concentration of the chemical was chosen.

Induction Phase - Three groups of randomly chosen animals, each consisting of ten animals, were used. Those in Group 1 and 2 were weighed and shaved free of hair in the left flank area twenty-four hours before testing. A 2 x 2 cm patch of cotton, containing test or positive control material, was applied to the skin and secured there for six hours. After exposure, the bandage was removed and any excess test material was removed. The test and control article was applied to this area weekly, for a total of three exposures.

Challenge Phase - Animals in Group 1, 2 and 3 were challenged two weeks after the final induction exposure. Body weights were taken for Group 3 animals and a site on the right flank area of all three groups was shaved. After twenty-four hours, a non-irritating concentration of DNCB (Group 1) or test article (Group 2 and 3) was applied to the shaved areas for six hours. After this time, the bandage was removed and any excess material was wiped away. Body weights were taken at the end of the study. Evaluation for dermal reactions were done 24, 48 and 72 hours post patch application. The following scoring system was used:

- 0 = no reaction
- 1 = scattered mild redness
- 2 = moderate and diffuse redness
- 3 = intense redness with or without swelling

The test article is generally considered a sensitizer if the reactions on the test animals are greater than those observed on control. The degree of sensitization will then be classified according to the following criteria:

<u>Animals Sensitized</u>	<u>Classification</u>
0%	Non-sensitizer
1%-10%	Weak sensitizer
11%-30%	Mild Sensitizer
31%-60%	Moderate Sensitizer
61%-80%	Strong Sensitizer
81%-100%	Extreme Sensitizer

C. RESULTS:

The incidence and severity indices for the Challenge readings in Groups 1, 2 and 3 were recorded. Silver Copper Zeolite did not

elicit dermal reactions in Groups 2 or 3 indicating that Silver Copper Zeolite was not a sensitizer.

In Group 1, 6/10 of the test animals exposed to DNCB (positive control) exhibited positive reactions at the 24, 48 and 72 hour readings, thus indicating that it is a sensitizer.

Each group of animals had increased body weight throughout the study.

D. CONCLUSION:

Based on the results of this study, a 60% suspension (in 0.5% Carboxymethyl cellulose) of Silver Copper Zeolite would be regarded as a non-sensitizer on guinea pigs according to the Buehler method of testing.

This study satisfies guideline requirements for a guinea pig sensitization study (81-6) and is classified Core - Guideline.