DATA EVALUATION REPORT

ZEOMIC TYPE AJ10D SILVER ZEOLITE A

STUDY TYPES: Physical and Chemical Characteristics (OPPTS 830.6302-830.7300)

Prepared for

Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
2800 Crystal Drive
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37930
Task Order No. 271

Primary Reviewer: Robin Brothers, Ph.D..	Signature: Date:	Robin Brothers DEC 3 1 1998
Secondary Reviewers: Tim Borges, MT, ASCP, Ph.D., D.A.B.T.	Signature: Date:	T Borges DEC 3 1 1998
Robert H. Ross, M.S., Group Leader	Signature: Date:	Robert H. Ross DEC 3 1 1998
Quality Assurance: Lee Ann Wilson, M.A.	Signature: Date:	L. A. Wilson DEC 3 1 1998

Disclaimer

This Data Evaluation Report may have been altered by the Antimicrobials Division subsequent to signing by Oak Ridge National Laboratory personnel.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

EPA Reviewer: Nancy Whyte, Ph.D. _____, Date: _____
EPA Work Assignment Manager:
Peter Thompson, Ph.D. _____, Date: _____
Antimicrobials Division (7510W)

DATA EVALUATION REPORT

STUDY TYPE: Physical and Chemical Characteristics (OPPTS 830.6302-830.7300)

P.C. CODE: 072503

DP BARCODE: D250942

CASE: 064467

SUBMISSION: S549706

MRID NO.: 44652202

TEST MATERIAL: Zeomic Type AJ10D Silver Zeolite A (Active ingredient: silver 2.5%)

SYNONYMS: none given

SPONSOR: Sinanen Co. Ltd., 4-22, Kaigen 1-Chome, Minato-ku, Tokyo 105, Japan

TESTING FACILITY: none given

TITLE OF REPORT: Physical Chemical Properties

AUTHORS: Jerome H. Heckman, Mark L. Itzkoff, Andrew P. Jovanovich, and Takeshi Yoshinari

STUDY NUMBER: none given

STUDY COMPLETED ON: September, 1998

EXECUTIVE SUMMARY: The physical and chemical properties for Zeomic Type AJ10D Silver Zeolite A are given in MRID 44652201. The active ingredient in Zeomic Type AJ10 D is silver (2.5%). This is one in a series of Silver Zeolite products of similar composition with varying applications.

Classification of the Study: **Not Acceptable** but upgradeable if oxidation/reduction, chemical incompatibilities, storage stability test results and the correct density are provided. The range for the pH may require further explanation.

COMPLIANCE: These studies did not fall under the requirements of Good Laboratory Practices and no Quality Assurance reports were included. A signed and dated statement of no data confidentiality was provided.

A. PHYSICAL AND CHEMICAL CHARACTERISTICS (OPPTS 830.6302-830.7950)

830.6302 Color: white

830.6303 Physical State: dry powder (temperature not specified)

830.6304 Odor: none

830.6314 Oxidizing or Reducing action: not given

830.6315 Flammability: not flammable

830.6316 Explodability: not potentially explosive

830.6317 Storage stability: Product is chemically stable under normal and recommended storage conditions (dry, air-tight containers). No study is included. No reference is made to storage stability tests that may have been or are being conducted.

830.6320 Corrosion characteristics: Zeomic is designed to be imbedded in polymeric materials. No corrosion was noted in compounded products and it does not contain any components expected to be corrosive to polymers. A reference is made to a study in Volume 7 of the application. The reviewer did not have this volume.

830.6321 Dielectric breakdown voltage: Not applicable

830.7000 pH: 8-11 in 1% (wt/wt) or (vol/vol) solution. Temperature and equipment not specified.

830.7100 Viscosity: Not applicable

830.7300 Density : 2.15 ± 0.1 g/cm^3 (sample dried for 3 hours at 110°C). Method specified in MRID 44652201 is by pycnometer using dry samples (dried at 250°C for 3 hours). The density given on the Confidential Statement of Formula (CSF) does not agree with the information given in this volume. The CSF gives the density as [redacted] (not specified wet or dry). MRID 44652201 states the [redacted] content is approximately [redacted] by weight.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED.

B. DISCUSSION

The information on physical and chemical characteristics is presented in MRID 44652202. Additional information on the density and pH was found in MRID 44652201. Apart from the descriptions of methods used in MRID 44542201, there are no descriptions of equipment, methods, or studies supplied in this volume. A reference for corrosive characteristics study is given for Volume 7 of this submission which was not provided to the reviewer. The reviewer considers the range given for pH to be unusually large and may require further explanation.

C. STUDY DEFICIENCIES

No references were given for the oxidation/reduction and chemical incompatibility. There was no indication of a current or previous study for storage stability. No specific test or chemical reasoning is given for the discussion of explodability or flammability. The method was not specified for the pH or density determination in this volume but it is assumed from Volume 1 of this submission. The density given on the Confidential Statement of Formula does not agree with the information given in the text of either MRID 44652201 or 44652202.

Classification of the Study: **Not Acceptable** but upgradeable if oxidation/reduction, chemical incompatibilities, storage stability test results and the correct density are provided. The range for the pH may require further explanation.

DATA EVALUATION REPORT

Zeomic Type AJ10D Silver Zeolite A

STUDY TYPES: **Product Identity and Disclosure of Ingredients (OPPTS 830.1550)**
Description of Beginning Materials &
Manufacturing Process (OPPTS 830.1600, 830.1650)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)

Prepared for

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Antimicrobials Division (7510W)

DATA EVALUATION REPORT

STUDY TYPES: Product Identity and Disclosure of Ingredients (OPPTS 830.1550)
Description of Beginning Materials & Manufacturing Process (OPPTS 830.1600, 830.1650)
Discussion of Formation of Impurities (OPPTS 830.1670)
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Enforcement Analytical Method (OPPTS 830.1800)

CASE NO: 064467

PC CODE: 072503

DP BARCODE: D250942

SUBMISSION: S549706

MRID NO: 44652201

TEST MATERIAL: Zeomic Type AJ10D Silver Zeolite A (active ingredient: silver 2.5% (w/w))

SYNONYMS: none given

STUDY NUMBER: none

SPONSOR: SINANEN CO., Ltd., 4-22, Kaigan 1-Chome, Minato-ku, Tokyo 105, Japan

TESTING FACILITY: none given

TITLE OF REPORT: Volume 2 Product Identity, Composition and Analysis

AUTHORS: Jerome H. Heckman, Mark L. Itzkoff, Andrew P. Jovanovich, and Takeshi Yoshinari

REPORT ISSUED: September, 1998

Product Identity and Disclosure of Ingredients (OPPTS 830.1550)
Description of Beginning Materials & Manufacturing Process (OPPTS 830. 1600, 1650)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)

EXECUTIVE SUMMARY: The product identity, description of beginning materials, manufacturing process, formation of impurities, preliminary analysis, certified limits and enforcement analytical method for Zeomic Type AJ10D are discussed in MRID 44652201. The active ingredient is silver (2.5% w/w) with certified limits of 3.0 and 2.0% (upper and lower). [redacted]

Classification of the study -Product Identity and Disclosure of Ingredients (OPPTS 830.1550)- **Acceptable**

Description of Beginning Materials & Manufacturing Process (OPPTS 830.1600-1650)- **Acceptable**

Discussion of Formation of Impurities (OPPTS 830.1670)-**Acceptable**

Preliminary Analysis (OPPTS 830.1700)-**Not Acceptable**, but upgradeable if 5 samples are used and analyses are shown to be within production specifications and certified limits.

Certified Limits (OPPTS 830.1750)- **Not Acceptable**, but upgradeable if the text and CSF are harmonized and the ranges for silver and Zeolite A are adequately discussed.

Enforcement Analytical Method (OPPTS 830.1800)- **Acceptable**

COMPLIANCE: Signed and dated Data Confidentiality Statements were provided. No Quality Assurance Statements were provided. The document does not contain reports of any study and does not require the use of GLP.

A. PRODUCT IDENTITY AND DISCLOSURE OF INGREDIENTS (OPPTS 830.1550-1600)

Zeomic Silver Type AJ10D Zeolite A is a metal ion-exchange zeolite designed for use as an anti-microbial for use in formed plastics and polymeric products not for food use. Zeolite A is a synthetic aluminosilicate mineral that can form a framework structure that contains cavities at regular intervals. [redacted] The ions in the cavities are able to be exchanged with other ions in aqueous solutions. The active ingredient is silver 2.5%(w/w)

(introduced as silver nitrate). The inert ingredients include [redacted] No MSDSs or technical fact sheets were supplied for the technical grade ingredients, however adequate chemical descriptions were given of the ingredients. Once the product is finished, the authors state release of free silver from the zeolite is minimal. The chemical formula is

$[Na_{1.3}, Ag, Zn_{9.7}, (NH_4)_{5.8}] \cdot (AlO_2 \cdot SiO_2)_{23} \cdot 36\ H_2O$

and the structure of silver zeolite is represented Figure 1. There are no EPA registered sources for silver as an active ingredient. The [redacted] come from a variety of suppliers. The Zeolite A may be obtained from other sources or manufactured by the sponsor. Zeolites are listed as mixtures on TSCA inventory.

QUANTITATIVE INFORMATION ON INERT INGREDIENT INFORMATION IS NOT INCLUDED

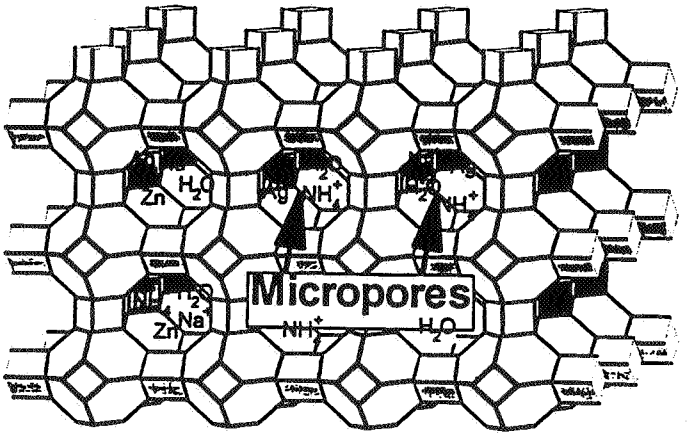

Figure 1. Structure of Silver Zeolite A

B. MANUFACTURING PROCESS (OPPTS 880.1200)

Zeomic Type AJ10 D Silver Zeolite A is [redacted]

8

[redacted]

The specific type of equipment used in the manufacture was not described.

C. DISCUSSION OF FORMATION OF IMPURITIES (OPPTS 880.1400)

No impurities are expected to form during the manufacturing process of Zeomic Type AJ10D. The manufacturing process occurs at [redacted]

D. PRELIMINARY ANALYSIS (OPPTS 830.1700)

Three lots of product were analyzed for a variety of parameters. The types of analyses performed include :

[redacted]

The samples for some of the tests were dried at [redacted] The analytical results from the dried material were used in determining the certified limits. The results of the analyses are given in Table 1 below. The specific gravity presented does not agree with the density presented in the CSF. The [redacted] concentrations reported in Table 1. are outside of the certified limits. The pH shows a wide range of variation.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

INGREDIENT INFORMATION IS NOT INCLUDED

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

[redacted]

Data from page 12 of 15, MRID 44652201

E. CERTIFIED LIMITS (OPPTS 830.1750)

The certified limits for ingredients in Zeomic Type AJ10D Silver Zeolite A are based on the dry manufacturing use product. All values are weight % and are taken from the Confidential Statement of Formula (CSF) in the Administrative Volume. The nominal concentration of silver is 2.5% [redacted] The certified limit ranges for the silver and Zeolite A are not within the specified ranges stated in OPPTS 830.1750. The certified limits given in the text on page 13 of 15 do not agree with the CSF. There is no explanation given for these discrepancies.

F. ENFORCEMENT ANALYTICAL METHOD (OPPTS 830.1800)

The methods for analysis of silver and [redacted] by standard addition are given. The actual [redacted]

G. DISCUSSION

The product identity and disclosure of ingredients were adequately described, and the manufacturing process was sufficiently explained except for the exact equipment used in the

formulation process. The preliminary analysis of samples was based on both dry and wet samples but only included samples from three batches. [redacted] analyses were outside the certified limits. The potential formation of unintentional ingredients was unlikely. The enforcement analytical methods are well explained. The certified limits presented in the CSF do not agree with the text. There is no discussion given as to why the certified limits may need to be outside of the standard ranges. The preliminary discussion of the nature in the product in the Administrative Volume indicates that control of the [redacted] and hence silver content by weight %, is one of the primary distinctions between the Zeomic products. The text also clearly states that the certified limits are based on the dry product. There is still confusion about the certified limits for this product.

H. STUDY DEFICIENCIES

The primary deficiencies are that only three batches/samples are presented in the preliminary analysis while the recommended number is 5. Also the Confidential Statement of Formula in the Administrative Volume does not agree with the text for certified limits. The upper and lower limits for the silver and Zeolite A are not within the recommended ranges and are not supported by discussion for the discrepancy. Minor deficiencies include the failure to adequately describe the specific type of manufacturing equipment (however the process itself is adequately described), and the failure to state how frequently the analysis of impurities is performed. The specific gravity presented in the Preliminary Analysis does not agree with the Confidential Statement of Formula. Samples analyzed in the preliminary analysis are outside the certified limits for [redacted]

Classification:
Product Identity and Disclosure of Ingredients (OPPTS 830.1550)- **Acceptable**
Description of Beginning Materials & Manufacturing Process (OPPTS 830.1600-1650)- **Acceptable**
Discussion of Formation of Impurities (OPPTS 830.1670)-**Acceptable**
Preliminary Analysis (OPPTS 830.1700)-**Not Acceptable**, but upgradeable if 5 samples are used and analyses are shown to be within production specifications and certified limits.
Certified Limits (OPPTS 830.1750)- **Not Acceptable**, but upgradeable if the text and CSF are harmonized and the ranges for silver and Zeolite A are adequately discussed.
Enforcement Analytical Method (OPPTS 830.1800)- **Acceptable**

[illegible] CONTAINS CONFIDENTIAL INFORMATION [illegible] INCLUDED
MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED
[illegible] INGREDIENT INFORMATION IS NOT INCLUDED