DATA EVALUATION REPORT

Zeomic Type AJ10N 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)
Physical and Chemical Characteristics (OPPTS 830.6302-7300)

Prepared for

Antimicrobials Division
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U.S. Environmental Protection Agency
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Arlington, VA 22202

Prepared by

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Toxicology and Risk Analysis Section
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Task Order No. 272

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Disclaimer

This Data Evaluation Report may have been altered by the Antimicrobial 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)

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CASE NO: 064337

PC CODE: 072501

DP BARCODE: D250944

SUBMISSION: S551445

MRID NO: 44677701

TEST MATERIAL: Zeomic Type AJ10N Silver Zeolite A (active ingredient: silver 2.2% (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, Physical/Chemical Properties

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

REPORT ISSUED: October, 1998

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 AJ10N are discussed in MRID 44677701. The active ingredient is silver (2.2% w/w) with certified limits of 2.4 and 2.0% (upper and lower).

[redacted]

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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 the specific gravity and pH for this product are specified.

Certified Limits (OPPTS 830.1750)- **Not Acceptable** but upgradeable if the ranges are discussed or the recommended ranges are used.

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

Physical and Chemical Characteristics (OPPTS 830.6302-7300)**Not Acceptable** but upgradeable if oxidation/reduction, chemical incompatibilities, storage stability test results and the correct density are provided.

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 AJ10N 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]

[redacted] The active ingredient is silver 2.2%(w/w) (introduced as silver nitrate). [redacted] No MSDSs or technical fact sheets were supplied for the technical grade ingredients, however adequate chemical descriptions were given of the ingredients in MRID 44652201. 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 in 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.

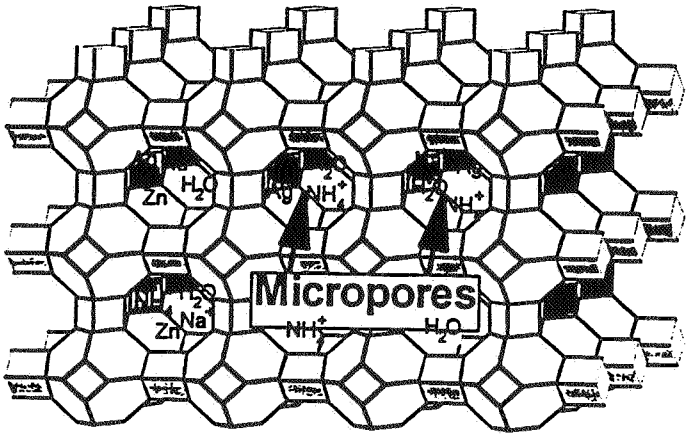

Figure 1. Structure of Silver Zeolite A

B. MANUFACTURING PROCESS (OPPTS 880.1200)

Information on the manufacturing process is taken from MRIDs 44652201 and 44677701. Zeomic Type AJ10 N Silver Zeolite A is produced in a [redacted]

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[redacted] The specific type of equipment used in the manufacture was not described. The references to figures in MRID 44652201 were incorrect.

C. DISCUSSION OF FORMATION OF IMPURITIES (OPPTS 880.1400)

Information on the formation of impurities is taken from MRID 44652201. No impurities are expected to form during the manufacturing process of Zeomic Type AJ10N. The [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 110°C for 3 hours, [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 reviewer finds it unusual that the specific gravity and pH would be identical between the formulations when the text in MRIDs 44652201 and 44677701 state different drying temperatures were employed.

INGREDIENT INFORMATION IS NOT INCLUDED

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

[redacted]

Data from page 6 of 8, MRID 44677701

E. CERTIFIED LIMITS (OPPTS 830.1750)

The certified limits for ingredients in Zeomic Type AJ10N 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 [redacted] The certified limit ranges for the silver and Zeolite A are not within the specified ranges stated in OPPTS 830.1750. 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 in MRID 44652201. [redacted]

G. 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 (no discussion given)

830.6316 Explodability: not potentially explosive (no discussion given)

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 the confidential attachment is by pycnometer using dry samples (dried at 110°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).

H. DISCUSSION

Many references were made to MRID 44652201. 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. The potential formation of unintentional ingredients was unlikely. The enforcement analytical methods are well explained. 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. A reference for corrosive characteristics study is given for MRID 44664404 of this submission which was not provided to the reviewer.

I. STUDY DEFICIENCIES

The primary deficiencies are that only three batches/samples are presented in the preliminary analysis while the recommended number is 5. 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 in another MRID), 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. The reviewer finds it unusual that the specific gravity and pH would be exactly the same for Type AJ10D and Type AJ10N considering different drying temperatures.

Classification:
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