

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
Zeomatic Type AJ10 H Silver Zeolite A

DP Barcode: 250950

Manufacturing-use [] OR

Reg. No. Or File Symbol: 71227-G

End-use Product [X]

TO: Tony Kish
PM team No. 33

FROM: Nancy Whyte, Chemist *NW 2/2/99*
Efficacy and Science Support Branch, Team 2
Antimicrobials Division (7510W)

THRU: Karen Hicks, Team 2 Leader
Efficacy and Science Support Branch
Antimicrobials Division (7510W)

THRU: Michele E. Wingfield, Chief
Efficacy and Science Support Branch
Antimicrobials Division (7510W)

Karen Hicks
Michele Wingfield

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

The registrant has submitted requests for registration of three very similar products which differ only in the amount of [REDACTED]. There are several deficiencies in the product chemistry data submitted. The initial review of the data was conducted by the contractor at Oak Ridge National Laboratories. The deficiencies are as follows: (OPPTS Guideline references noted)

1. The role of the [REDACTED] in the manufacturing process should be clarified.
2. The specific equipment used in the manufacturing process is not given.
3. The density, oxidation/reduction, chemical incompatibilities, and storage stability test results have not been provided. (830.6302-7300)
4. The range of the pH value should either be narrowed or the wide range explained. The temperature and the method used in the measurement were not given.
5. The certified upper and lower limits for the active ingredient silver are outside the Agency recommended range of +/- 5.0% for amounts between 1% and 20%. Variations from the accepted ranges are acceptable if an explanation of the necessity for such variation is supplied by the registrant. (830.1750)
6. The specific gravity listed on the Confidential Statement of Formula does not agree with that given in the narrative text, nor does the density.
7. Only three batches of the product were analyzed (830.1700) for content. The recommended number is five batches.

NEXT INGREDIENT INFORMATION IS NOT INCLUDED

DATA EVALUATION REPORT

Zeomic Type AJ10H 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
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. 270

Primary Reviewer:

Robin Brothers, Ph.D., D.A.B.T.

Signature:

Date:

Robin Brothers
DEC 31 1998

Secondary Reviewers:

Tim Borges, MT, ASCP, Ph.D., D.A.B.T.

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Date:

T.T. Borges
DEC 31 1998

Robert H. Ross, M.S., Group Leader

Signature:

Date:

Robert H. Ross
DEC 31 1998

Quality Assurance:

Lee Ann Wilson, M.A.

Signature:

Date:

L.A. Wilson
DEC 31 1998

Disclaimer

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

Zeomic Type AJ10H
MRID 44677801

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)
Physical and Chemical Characteristics (OPPTS 830.6302-7300)

EPA Reviewer: Nancy Whyte, Ph.D. _____, Date _____
EPA Work Assignment Manager, Peter Thompson, Ph.D. _____, Date _____
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)
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Physical and Chemical Characteristics (OPPTS 830.6302-7300)

CASE NO: 064336

PC CODE: 072501

DP BARCODE: D250950

SUBMISSION: S551454

MRID NO: 44677801

TEST MATERIAL: Zeomic Type AJ10H Silver Zeolite A (active ingredient: silver 2.7% (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

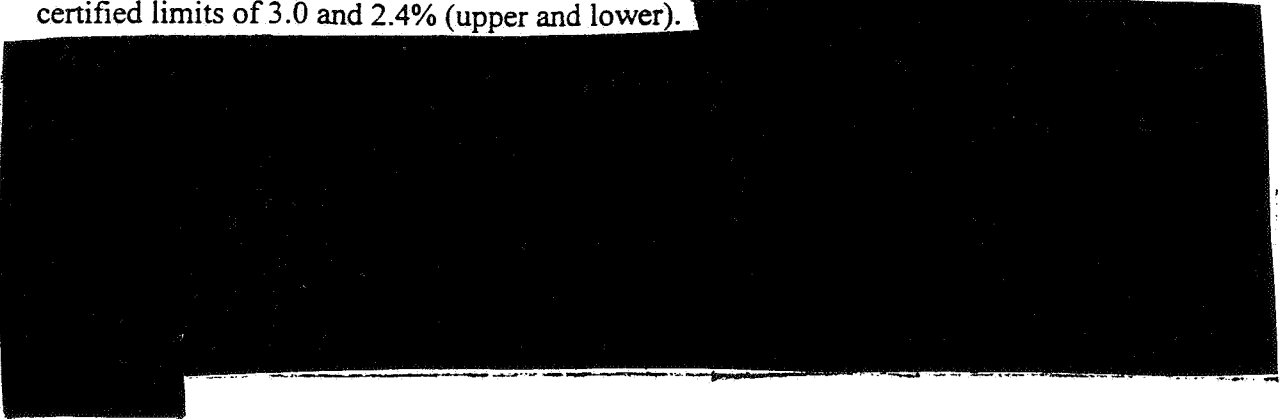
AUTHORS: Jerome H. Heckman, Andrew P. Jovanovich, and Takeshi Yoshinari

Zeomic Type AJ10H
MRID 44677801

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)
Physical and Chemical Characteristics (OPPTS 830.6302-7300)

REPORT ISSUED: October, 1998

EXECUTIVE SUMMARY: The product identity, description of beginning materials, manufacturing process, formation of impurities, preliminary analysis, certified limits, enforcement analytical method, and physical and chemical characteristics for Zeomic Type AJ10H are discussed in MRID 44677801. The active ingredient is silver (2.7% w/w) with certified limits of 3.0 and 2.4% (upper and lower).



Classification of the study -

Product Identity and Disclosure of Ingredients (OPPTS 830.1550)- **Acceptable**
Description of Beginning Materials & Manufacturing Process (OPPTS 830.1600-1650)-**Not Acceptable** but upgradeable if the addition of [REDACTED] is clarified.
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 pH and specific gravity for this formulation are supplied.
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 and the range for the pH is explained or narrowed.

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 do not require the use of GLP.

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

Zeomic Silver Type AJ10H Zeolite A is a metal ion-exchange zeolite designed for use as an anti-microbial 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.

The active ingredient is silver 2.7%(w/w) (introduced as silver nitrate). The inert ingredients include

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 that release of free silver from the zeolite is minimal. The chemical formula of this formulation was not provided as it contains no or and is obviously not the same generic formula presented in MRID 44652201 for all Silver Zeolites. The structure of a silver zeolite is represented in Figure 1. There are no EPA registered sources for silver as an active ingredient. The comes 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.

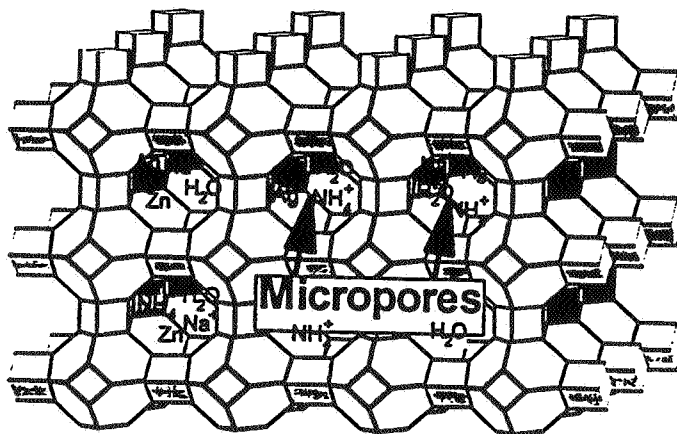


Figure 1. Structure of Silver Zeolite A

B. MANUFACTURING PROCESS (OPPTS 880.1200)

Information on the manufacturing process is taken from MRIDs 44652201 and 44677801. Zeomic Type AJ10H Silver Zeolite A is

Zeomic Type AJ10H
MRID 44677801

Product Identity and Disclosure of Ingredients (OPPTS 830.1550)
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Preliminary Analysis (OPPTS 830.1700)
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Physical and Chemical Characteristics (OPPTS 830.6302-7300)

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 AJ10H. The manufacturing process occurs at

D. PRELIMINARY ANALYSIS (OPPTS 830.1700)

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

The samples for some of the tests were dried at 550°C, The analytical results from the dried material was 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 44677801 state different drying temperatures were employed.

Data from page 6 of 8, MRID 44677801

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 2.7% with certified limits of 3.0 and 2.4% (upper, lower).

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. The actual measurement of the metal is by atomic absorption spectrophotometer.

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 MRID 44664404 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. The reviewer finds this range to be unusually large and nonspecific.
- 830.7100 Viscosity: Not applicable
- 830.7300 Density : $2.15 \pm 0.1 \text{ g/cm}^3$ (sample dried for 3 hours at 550°C). Method specified in the confidential attachment is by pycnometer using dry samples (dried at 550°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 not sufficiently explained and lacked detail on the addition of [REDACTED] and 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 another volume of this submission

which was not provided to the reviewer. The reviewer finds it unusual that the specific gravity and pH are given as exactly the same for the different formulations.

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. There is an inadequate description of the manufacturing process and the addition of [REDACTED] since the reference to MRID 44652201 contains [REDACTED]. Minor deficiencies include the failure to adequately describe the specific type of manufacturing equipment, 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 Preliminary Analysis fails to show the exact pH and specific gravity for this formulation and the range for the pH is unusually large and nonspecific.

Classification:

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

Description of Beginning Materials & Manufacturing Process (OPPTS 830.1600-1650)-**Not Acceptable** but upgradeable if the addition of [REDACTED] is clarified.

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 pH and specific gravity for this formulation are supplied.

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 and the range for the pH is explained or narrowed.