

US EPA ARCHIVE DOCUMENT

(10-18-99)

DATA EVALUATION REPORT

Sodium Chlorite (Chlorite Plus CD-2)

STUDY TYPES: Product Identity and Composition (OPPTS 830.1550)
 Description of the Materials Used to Produce the Product (OPPTS 830.1600)
 Description of Formulation Process (OPPTS 830.1650)
 Formation of Impurities (OPPTS 830.1670)
 Preliminary Analysis (OPPTS 830.1700/ 810.2100)
 Certified Limits (OPPTS 830.1750)
 Physical And Chemical Characteristics (OPPTS 830.6302-830.7300)

MRIDs: 44910701, 44910702, 44910703

Prepared for

Antimicrobials Division
 Office of Pesticide Programs
 U.S. Environmental Protection Agency
 1921 Jefferson Davis Highway
 Arlington, VA 22202

Prepared by

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 Action No. KO120

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 OCT 18 1999

Disclaimer

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

SODIUM CHLORITE (CHLORITE PLUS CD-2)
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EPA Reviewer: Nancy Whyte, Ph.D.
EPA Work Assignment Manager:
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Antimicrobials Division (7510W)

_____, Date: _____
_____, Date: _____

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P.C. CODE: 020502

DP BARCODE: D259334

CASE: 066250

SUBMISSION: S567976

MRID Nos.: 44910701, 44910702, 44910703

TEST MATERIAL: Chlorite Plus CD-2, EPA Reg. No. 5382-UA (Active ingredient: sodium chlorite 2.8%, equivalent to 2% aqueous stabilized chlorine dioxide)

SYNONYMS: stabilized chlorine/dioxide, sodium chlorite

SPONSOR: Vulcan Chemicals, P.O. Box 385015, Birmingham, AL 35238-5015

TESTING FACILITY: Vulcan Chemicals, 6200 South Ridge Road, Wichita, KS 67215

TITLES OF REPORTS:

MRID 44910701: Chlorite Plus CD-2: Product Chemistry
MRID 44910702: Physical and Chemical Characteristics
MRID 44910703: Chlorite Plus CD-2: Product Characterization for Lots used for Product Performance Studies

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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AUTHOR: Roger E. Etherington (all studies)

STUDY NUMBER: MRID 44910703: DBG-468-70

STUDY COMPLETED ON:

MRID 44910701: July 27, 1999

MRID 44910702: July 27, 1999

MRID 44910703: July 27, 1999

EXECUTIVE SUMMARY: The product identity and composition, description of materials used to produce the product, description of the formulation process, formation of impurities, preliminary analysis, certified limits, and physical and chemical properties for Chlorite Plus CD-2 are given in MRIDs 44910701, 44910702, and 44910703. Chlorite Plus CD-2 is an antimicrobial that is used as a source of chlorine dioxide for use in water systems, processing plants, and medical applications. The active ingredient in Chlorite Plus CD-2 is sodium chlorite. The product is a dilution of the Vulcan Chemicals product, Technical Sodium Chlorite Solution 50 (EPA Reg. No. 5382-41) with [REDACTED]. No unintentional impurities are likely to be formed in the batch formulation process. The nominal concentration of the pure active ingredient, sodium chlorite is 2.8% (w/w) with certified limits of 3.0 and 2.6% (upper, lower). The nominal concentration of the Technical Sodium Chlorite Solution (37% active ingredient) is 7.6% (w/w) with certified limits of 8.10 and 7.0% (upper and lower). Other intentionally added inert ingredients include (w/w) [REDACTED]

[REDACTED] The product may be used as is or mixed with citric acid or other organic acid as an activator of the chlorine dioxide. The analysis of three lots of product was included even though this is a simple formulation of a registered product. Physical and chemical properties were presented in an abbreviated tabular format.

Classification of the Study: /

Product Identity and Composition (OPPTS 830.1550): **Acceptable**

Description of the Materials Used to Produce (OPPTS 830.1600): **Acceptable**

Description of Formulation Process (OPPTS 830.1650): **Acceptable**

Formation of Impurities (OPPTS 830.1670): **Acceptable**

Preliminary Analysis (OPPTS 830.1700/ 810.2100): **Acceptable**

Certified Limits (OPPTS 830.1750): **Unacceptable** but upgradeable with use of ranges within guideline suggestions or explanation of certified limit ranges for sodium chlorite and [REDACTED]

Physical And Chemical Characteristics (OPPTS 830.6302-830.7300): **Unacceptable** but upgradeable with submission of appropriate documentation of results.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

SODIUM CHLORITE (CHLORITE PLUS CD-2)
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COMPLIANCE: These studies did not follow Good Laboratory Practices and GLP were not applicable to MRID 44910701. The company has not implemented the requirements of 40 CFR Part 160 at the laboratory. No Quality Assurance reports were included. A data confidentiality statement was provided for each study.

A. PRODUCT IDENTITY AND COMPOSITION (OPPTS 830.1550)

This information is taken from MRID 44910701, the CSF and the label. Chlorite Plus CD-2 is an end-use product that supplies chlorine dioxide for use as an antimicrobial agent in drinking water, water for food applications, medical uses and other industrial uses. The product will generally be diluted before any specific application and may be mixed with citric acid or other organic acid to activate chlorine dioxide. Technical Sodium Chlorite Solution 50 (EPA Reg. No. 5382-41) is the active ingredient and is 7.6% (w/w) of Chlorite Plus CD-2. Chlorite Plus CD-2 also contains

B. DESCRIPTION OF MATERIALS USED TO PRODUCE THE PRODUCTS AND FORMULATION PROCESS (OPPTS 830.1600 and 1650)

C. FORMATION OF IMPURITIES (OPPTS 830.1670)

There are no intentional reactions in the manufacture of the product. The product is the result of the formation of impurities is unlikely.

D. PRELIMINARY ANALYSIS (OPPTS 830.1700/ 810.2100)

Chlorite Plus CD-2 is a simple formulation of an EPA registered product (Technical Sodium Chlorite Solution 50, EPA Reg. No. 5382-41) and a preliminary analysis of samples is not required. MRID 44910703 contains the analysis of three lots of Chlorite Plus CD-2. The lots were used in antimicrobial efficacy tests. The results are presented in Table 1. Generally, the analysis of five lots of product is required for the preliminary analysis, however since this guideline is not a requirement for the product chemistry of simple

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formulations, these three lots are acceptable. The analysis for sodium chlorite was by an iodometric titration AWWA/ANSI B303-95), repeated three times over a three month period.

Lot No.	Manufacture Date	Wt. % Sodium Chlorite (by analysis date)		
		10/30/98	11/16/98	1/14/99
468-104-1	7/20/98	2.79	2.83	2.84
468-113-1	9/11/98	2.83	2.86	2.84
468-116-1	10/7/98	2.89	2.89	2.90

Data are from MRID 44910703, pg 4.

E. CERTIFIED LIMITS (OPPTS 830.1750)

The nominal concentration of the pure active ingredient, sodium chlorite, is 2.8% (w/w) with certified limits of 3.0 and 2.6% (upper, lower). The nominal concentration of the Technical Sodium Chlorite Solution (37% active ingredient) is 7.6% (w/w) with certified limits of 8.10 and 7.0% (upper and lower). Other intentionally added inert ingredients include (w/w)

[REDACTED] The certified limit ranges for the sodium chlorite and [REDACTED] are greater than the range given in OPPTS 830.1750 and there is no explanation given for the variance. The calculation given on the CSF showing the derivation of the pure A.I. (Box #10) uses a nominal concentration of 7.3% for the technical A.I. and shows a final value of 2.7% which is different from the value given in Box 13 of the CSF.

F. PHYSICAL AND CHEMICAL CHARACTERISTICS (OPPTS 830.6302-830.7300)

All data are from MRID 44910702 unless noted. The registrant has presented the physical and chemical characteristics in a form similar to that of PR Notice 98-1, however the official form in PR Notice 98-1 was not used. The registrant is not qualified to use PR Notice 98-1 because the registrant states that GLP are not in use at the test facilities and the storage stability tests were not performed under GLP. The registrant provides laboratory report numbers for documentation but did not supply the supporting information and methods with this submission. In presenting the information in this abbreviated manner the registrant fails to comply with both PR Notice 98-1 and the general requirements for presentation of physical chemical properties because neither are completed fully.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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- 830.6302 Color: clear, colorless
- 830.6303 Physical State: liquid, temperature not specified
- 830.6304 Odor: stated to be none
- 830.6314 Oxidizing or Reducing Action: No reaction was observed when mixed with zinc and iron powders for 24 hours. No temperature observations were noted. No other discussion of method was provided.
- 830.6315 Flammability: Product is an aqueous solution, waiver requested.
- 830.6316 Explosibility: The product does not contain potentially explosive ingredients, waiver requested.
- 830.6317 Storage Stability: The product is stable for one year without loss of activity or physical changes when stored at ambient or elevated temperatures. No data were provided. The preliminary analysis results presented in MRID 44910703 also support the storage stability since some of the samples were analyzed over a six month period of time.
- 830.6319 Miscibility: Not an emulsifiable or miscible liquid, waiver requested.
- 830.6320 Corrosion Characteristics: No evidence of corrosion of containers was noted in samples stored for 60 days. (ASTM G31)
- 830.7000 pH: 9.3 at 25 °C using a digital pH meter
- 830.7100 Viscosity: approximately 12 cps (25°C using a Brookfield Viscometer)
- 830.7300 Density : 1.002 g/cc at 25 °C using a digital density meter. The CSF lists density as 8.5 with no units provided.

G. DISCUSSION

This DER contains information from three MRIDs describing the product identity, beginning materials and formulation process, formation of impurities, certified limits, and physical and chemical characteristics of Chlorite Plus CD-2. The active ingredient in Chlorite Plus CD-2 is sodium chlorite. The product is a dilution of the Vulcan Chemicals product, Technical Sodium Chlorite Solution 50 (EPA Reg. No. 5382-41) with [REDACTED]

[REDACTED] No unintentional impurities are formed at quantities greater than 0.1% in the

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batch formulation process. The proposed label and CSF were also provided. The proposed label describes a wide range of applications from food and potable water uses, medical disinfection, to industrial uses. The comment made by the applicant in the label instructions is that any organic acid to be added as an activator of chlorine dioxide for food, water or medical uses should be of food grade quality. The registrant supplied the analysis of three lots of product but product analysis is not required for simple formulations of registered ingredients.

H. STUDY DEFICIENCIES

The registrant has presented the physical and chemical characteristics in a form similar to that of PR Notice 98-1, however the official form in PR Notice 98-1 was not used. The registrant is not qualified to use PR Notice 98-1 because the registrant states that GLP are not in use at the test facilities and the storage stability tests were not performed under GLP. The registrant provides laboratory report numbers for documentation but did not supply the supporting methods information with this submission. In presenting the information in this abbreviated manner the registrant fails to comply with both PR Notice 98-1 and the general requirements for presentation of physical chemical properties because neither are completed fully. The certified limit ranges for the sodium chlorite and [REDACTED] are greater than the range given in OPPTS 830.1750 and there is no explanation given for the variance. The calculation given on the CSF showing the derivation of the pure A.I.(Box #10) uses a nominal concentration of 7.3% for the technical A.I. and shows a final value of 2.7% which is different from the value given in Box 13 of the CSF.

Classification of the Studies:

Product Identity and Composition (OPPTS 830.1550): **Acceptable**
Description of the Materials Used to Produce (OPPTS 830.1600): **Acceptable**
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Preliminary Analysis (OPPTS 830.1700/ 810.2100): **Acceptable**
Certified Limits (OPPTS 830.1750): **Unacceptable** but upgradeable with use of ranges within [REDACTED] guideline suggestions or explanation of certified limit ranges for sodium chlorite and [REDACTED]
Physical And Chemical Characteristics (OPPTS 830.6302-830.7300): **Unacceptable** but upgradeable with submission of appropriate documentation of results.