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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 20 1999

Memorandum:

Subject: Secondary Review of the Data Evaluation Report (DER) for: SVP-Pure Sodium Chlorate Precursor, Purate Precursor.

To: Robert Brennis, Product Manager, Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)

From: A. Najm Shamim, Ph.D., Chemist
Risk Assessment & Science Support Branch
Antimicrobials Division (7510C)

A. Shamim 4/20/99

Thru: Laura Morris, Team Leader, Team 2
Risk Assessment & Science Support Branch
Antimicrobials Division (7510C)

Mark for 04/20/99

And

Norm Cook, Chief
Risk Assessment & Science Support Branch
Antimicrobials Division (7510C)

Norm Cook 04/20/99

DP Barcode: D254837
Case Type: Registration
MRID#: 44789101

Submission: S559800
PC Code: 073301
CAS#: 7775-09-9

Introduction:

The Chemical Hazard Evaluation Group of the Oak Ridge National Laboratory, a contractor to the Antimicrobials Division has completed a primary review on the Product Chemistry data titled: SVP-Pure Sodium Chlorate Precursor, Purate Precursor, submitted by EKA Chemicals Inc. The product is actually a Generator which contains the precursor (sodium chlorate) which in turn generates a pesticide: chlorine dioxide for use in water treatment.

Summary of Oak Ridge National Laboratory Review

1. The registrants submitted the Data Matrix, CSF for the basic and alternate formulations (dated March 25, 1999) on the Precursor and also the Draft Label (March, 1999) for the basic formulation.
2. The active ingredient in the basic formulation is sodium chlorate (40% w/w) and the CSF also identifies the certified limits of the active and was in compliance with PR-Notice 91-2.
3. The alternate formulation identifies the active to be sodium chlorate and hydrogen peroxide (10% w/w) as the diluent.
4. The submission does not include any QA statements as it did not require any GLP studies.
5. The submission includes the Product Identity, and Disclosure of Ingredients, Beginning Materials and Formulations, Discussion of Formation of Impurities, Certified Limits as required by OPPTS Guidelines Series 830 (Product Chemistry).
6. There is an apparent discrepancy in the nominal concentration values of the precursors ([REDACTED] and water/[REDACTED] as written in the CSF and as described in the action package (MRID#: 44789101, volume 2, pages. 9 and 10).

Conclusions & Recommendations by Risk Assessment & Science Support Branch

The Risk Assessment & Science Support Branch (RASSB) concurs with the Oak Ridge National Laboratory's observations and conclusions regarding the submission for product chemistry data and concludes that the package for registration for the SVP-Pure™ Sodium Chlorate Precursor by EKA Chemicals, Inc. is acceptable but notes the following discrepancies which raise some concerns which should be addressed by the registrants and resolved before the registration is granted:

- I. RASSB has noted that the registrants have not stated the identity of the impurities in the CSF and between the CSFs and the Draft Label [REDACTED] is unaccounted for.
- II. The CSFs for the basic and alternate formulations do not list [REDACTED] as an

MANUFACTURING PROCESS INFORMATION IS NOT RELEVANT

impurity in the reaction system; however, the registrants discuss the presence of [REDACTED] as an impurity [REDACTED] in the technical grade sodium chlorate. The exact percent of sodium chlorate should be mentioned in the end use formulations.

III. The submission includes two CSFs, one for the basic formulation and the second for alternate formulation. The basic formulation does not contain hydrogen peroxide (10% w/w) and lists sodium chlorate as the active. The alternate formulation lists both sodium chlorate (as active) and hydrogen peroxide as diluent. The chemical reaction that produces chlorine dioxide for municipal water treatment is as follows:

[REDACTED]

Without the presence of hydrogen peroxide the desired pesticide (chlorine dioxide) will not be formed. Because of these discrepancies, The Risk Assessment & Science Support Branch recommends:

A. The registrants should submit revised CSFs which should include the presence of [REDACTED] and its nominal concentration along with the identity and nominal concentrations of other impurities (if these are at least 0.1%)

B. Since without the presence of hydrogen peroxide, the stated reaction will not occur (production of chlorine dioxide), RASSB strongly recommends that the CSF containing hydrogen peroxide and sodium chlorate should be registered as the basic formulation and the one without hydrogen peroxide as the alternate.

C. The chemistry of chlorine dioxide is essentially that of its breakdown products. It has been recognized by the Agency (Office of Groundwater and Drinking Water: Occurrence Assessment For Disinfectants and Disinfection byproducts in Public Drinking Water Supplies, October, 1997) that chlorine dioxide breaks down in water into chlorite (ClO_2^-) and chlorate ion (ClO_3^-) in the ratio of 7:3. Hence if one starts with sodium chlorite or sodium chlorate to produce chlorine dioxide, the end products for both precursors are the same: chlorite and chlorate ions.

D. The proposed Label should clearly mention at the use level the exact amount of chlorine dioxide that will enter into the water at a treatment facility.

In addition, it should be pointed out that:

a. The Risk Assessment & Science Support Branch did not test the Chlorine Dioxide Generator to ensure that no sodium chlorate leaks out while the Generator is in use. The testing of devices is not required by FIFRA.

b. RASSB did not perform human exposure or risk assessment for the proposed use pattern. AD risk managers requested only a product chemistry review.

cc: File (073301)

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

DATA EVALUATION REPORT

SODIUM CHLORATE
(SVP-Pure Sodium Chlorate Precursor, Purate Precursor)

STUDY TYPES: Product Identity and Disclosure of Ingredients (OPPTS 830.1550)
Description of Beginning Materials &
Formulation Process (OPPTS 830.1600, 830.1650)
Discussion of Formation of Impurities (OPPTS 830.1670)
Certified Limits (OPPTS 830.1750)

Prepared for

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

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Action No. L0019

Primary Reviewer:
Robin Brothers, Ph.D., D.A.B.T.

Signature: *Robin Brothers*
Date: APR 13 1999

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Signature: *Sylvia Milanez*
Date: APR 13 1999

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

Signature: *Robert H. Ross*
Date: APR 13 1999

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: *J. A. Wilson*
Date: APR 13 1999

Disclaimer

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

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Sodium Chlorate
(SVP-Pure Sodium Chlorate Precursor, Purate Precursor)
MRID 44789101

Product Identity and Disclosure of Ingredients (OPPTS 830.1550)
Description of Beginning Materials & Formulation Process (OPPTS 830.1600, 1650)
Discussion of Formation of Impurities (OPPTS 830.1670)
Certified Limits (OPPTS 830.1750)

EPA Reviewer: A. Najm Shamin, 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, Description of Beginning Materials & Formulation Process, and Discussion of Formation of Impurities, Certified Limits (OPPTS 830.1550-830.1750).

CASE NO: 064866

PC CODE: 073301

DP BARCODE: D254837

SUBMISSION: S559800

MRID NO: 44789101

TEST MATERIAL: SVP-Pure Sodium Chlorate Precursor, Purate Precursor (EPA Reg. No. 49620-2) (active ingredient: sodium chlorate, 40% (w/w))

SYNONYMS: none given

STUDY NUMBER: none given

SPONSOR: EKA Chemicals Inc., 1775 West Oak Commons Court, Marietta, GA 30062-2254

TESTING FACILITY: none given

TITLE OF REPORT: Application for Pesticide Registration, SVP-Pure Sodium Chlorate Precursor (Purate Precursor), EPA File Symbol 49629-, Volume 2, Product Chemistry

AUTHORS: David Lovetro, Steven Beers, John B. Dubeck, Andrew P. Jovanovich, Martha E. Marrapese

REPORT ISSUED: March 25, 1999

EXECUTIVE SUMMARY: The product identity, beginning materials, formulation process, formation of impurities, and certified limits for SVP-Pure Sodium Chlorate Precursor and an alternative formulation Purate Precursor are discussed in MRID 44789101. MRID 44789102

was also provided but was not used in these reviews. The product is a formulation of sodium chlorate (EPA Reg. No. 49629-2), water and/or hydrogen peroxide. The product is used with other precursors to generate chlorine dioxide for water purification systems. The active ingredient is sodium chlorate (40% w/w) with certified limits of [REDACTED] (upper, lower, w/w). Intentionally added inert ingredients in SVP-Pure Chlorate Precursor include water as a solvent constituting [REDACTED] of the formulation with certified limits of [REDACTED] (upper, lower). Purate Precursor contains the same active ingredient as SVP-Pure and water [REDACTED] with certified limits of [REDACTED] (upper, lower) and hydrogen peroxide as a diluent (10% w/w) with certified limits of [REDACTED] (upper, lower). Impurities may be present in the active ingredient [REDACTED] with an upper certified limit of [REDACTED]. The formulation process for both Precursors involve batch processes and involves no intentional reactions.

Classification of the study - **Acceptable**

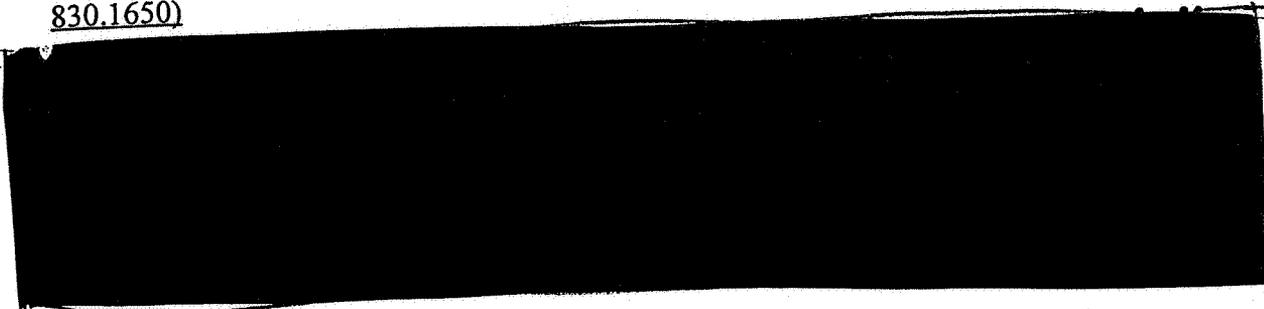
COMPLIANCE: Signed and dated Data Confidentiality Statements were provided. No Quality Assurance Statements were provided as no parts of this study required the use of GLP.

A. PRODUCT IDENTITY AND DISCLOSURE OF INGREDIENTS (830.1550)

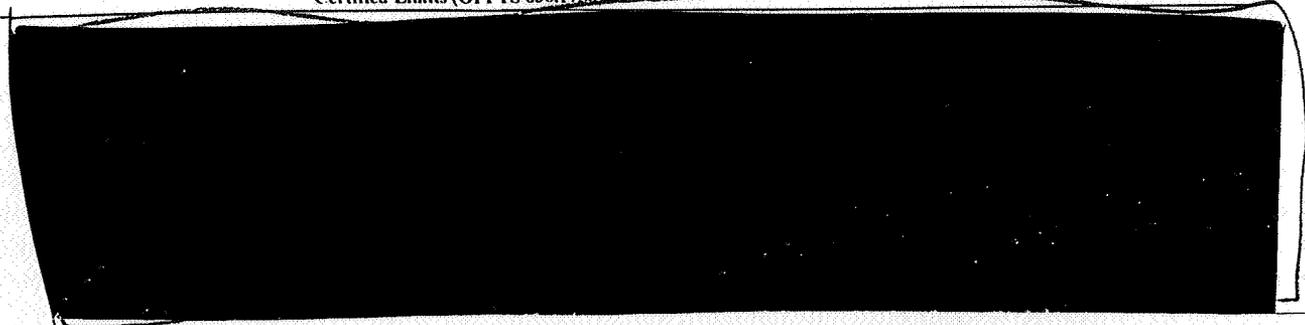
SVP-Pure Sodium Chlorate Precursor is a formulation of sodium chlorate and water used to generate chlorine dioxide. Purate Precursor is a formulation of sodium chlorate, water and hydrogen peroxide used to generate chlorine dioxide. The active ingredient in both Precursors is sodium chlorate (40% w/w, EPA Reg. No. 49620-2). In SVP-Pure Precursor water is added as a solvent at [REDACTED]. In Purate Precursor, water is present as [REDACTED] of the formulation with 10% of the formulation consisting of hydrogen peroxide. Impurities from the active ingredient may constitute [REDACTED] of the formulation.

The two Precursor products are used in the SVP-Pure Chlorine Dioxide Generator. The generator produces chlorine dioxide by combining three chemicals, sodium chlorate, hydrogen peroxide and sulfuric acid in exact proportion and conditions to produce chlorine dioxide on-site for water purification. The device does not generate perchlorate ion or residual unreacted chlorine

B. BEGINNING MATERIALS AND FORMULATION PROCESS (OPPTS 830.1600 and 830.1650)



MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED



C. DISCUSSION OF FORMATION OF IMPURITIES (OPPTS 830.1670)

No impurities are expected to form in the formulation of SVP-Pure Sodium Chlorate Precursor or Purate Precursor. Impurities are listed on the Confidential Statement of Formula (CSF) as [REDACTED] of the final formulation as being present in the EPA registered active ingredient. The MSDS for sodium chlorate lists the purity as 99.6% with [REDACTED] impurities. These impurities are listed on the MSDS as water and sodium chloride, however the text does not discuss the impurities. The discussion of the SVP-Pure Device Operation states that [REDACTED] may also be present in the sodium chlorate active ingredient at up to [REDACTED] but proper use of the product will reduce the [REDACTED] levels in the finished water to well below [REDACTED].

D. CERTIFIED LIMITS (OPPTS 830.1750)

The active ingredient is sodium chlorate (40% w/w) with certified limits of [REDACTED] (upper, lower, w/w). Intentionally added inert ingredients in SVP-Pure Chlorate Precursor include water as a solvent constituting [REDACTED] of the formulation with certified limits of [REDACTED] (upper, lower). Purate Precursor also contains water [REDACTED] with certified limits of [REDACTED] (upper, lower), and hydrogen peroxide as a diluent (10% w/w) with certified limits of [REDACTED] (upper, lower). Impurities (nonspecific) may be present in the active ingredient [REDACTED] with an upper certified limit of [REDACTED].

E. DISCUSSION

The product identity and disclosure of ingredients were adequately described, and the manufacturing process was sufficiently explained except for the description of temperature, tank material, and quality assurance tests. Technical fact sheets were supplied for the starting materials. A discussion of the use of the products in the chlorine dioxide generator was supplied. The discussion added that there would be low levels of [REDACTED] and [REDACTED] as the result of the use of this generator. Although the sponsor is requesting registration on this product, the sponsor is contesting the EPA's need to request such registration. MRID 44789102 was also provided but was not used in these reviews.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

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Sodium Chlorate
(SVP-Pure Sodium Chlorate Precursor, Purate Precursor)
MRID 44789101

Product Identity and Disclosure of Ingredients (OPPTS 830.1550)
Description of Beginning Materials & Formulation Process (OPPTS 830.1600, 1650)
Discussion of Formation of Impurities (OPPTS 830.1670)
Certified Limits (OPPTS 830.1750)

F. STUDY DEFICIENCIES

The MSDS for the active ingredient sodium chlorate lists the purity as 99.6% with [REDACTED] impurities. The overall amount of impurities stated as coming from the active ingredient on the CSF is also given as [REDACTED] for the total formulation (which is only 40% sodium chlorate) which is disagreement (overstatement) of the impurities in the final formulation. The nominal concentration of water in the text (page 9) for both Precursors does not agree with the CSF [REDACTED]. The CSF does not list the purity of the beginning materials. None of these deficiencies is serious enough to invalidate the study and the active ingredient is already EPA registered.

Classification: **Acceptable**

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED