

US EPA ARCHIVE DOCUMENT



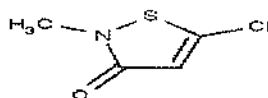
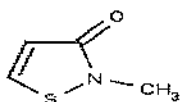
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 15, 2011.

DP BARCODE: D386125
MRID: 483415-00, 483415-01, 483415-02, 483415-03.
SUBJECT: **Proxel® CMC Industrial Preservative.**
REG. NO. OR FILE SYMBOL: 1258-RGGO
DOCUMENT TYPE: Product Chemistry Review
Manufacturing-use OR End - Use Product

INGREDIENTS (PC Codes)



2-Methyl-4-isothiazolin-3-one(107104) 5-Chloro-2-methyl-4-isothiazolin-3-one (107103)

CAS Number: (2682-20-4) (26172-55-4)

TEST LAB: Leesha Square, Arch Chemicals, Inc.

SUBMITTER: Arch Chemicals, Inc.

GUIDELINE: OPPTS 830 Series (Group A & B) guidelines

COMMODITIES: Formulation

REVIEWER: Salvador Rodríguez ORGANIZATION: AD

APPROVER : Karen P. Hicks APPROVED DATE: 03/17/11.



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OFFICE OF CHEMICAL
SAFETY
AND POLLUTION
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March 15, 2011.

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 1258-RGGO
From: Salvador Rodríguez, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Jacqueline CampbellMcFarlane / Jaclyn Carl
Team 34
Antimicrobials Division (7510P)

APPLICANT: Arch Chemicals, Inc.

Action code: A540

Due date: 05/20/11.

**Product Formulation
Active Ingredient(s)**

% by wt

5-Chloro-2-methyl-4-isothiazolin-3-one	1.11
2-Methyl-4-isothiazolin-3-one	0.39

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BACKGROUND:

Arch Chemicals, Inc. has submitted an application for registration of a new end-use product, Proxel CMC Industrial Preservative. This product is for use in the formulation of end-use industrial microbiocides. The following registered products are sources of the active ingredients: [REDACTED] and Arch CMIT/MIT (EPA Reg. No. 62190-32).

The data package included a letter from the applicant to EPA, dated December 30, 2010; EPA Form 8570-1 (Application for Pesticide), dated December 30, 2010; a Confidential Statement of Formula (CSF) for the basic formulation, dated December 30, 2010; a CSF for one alternate formulation, dated December 30, 2010; EPA Form 8570-27 (Formulator's Exemption Statement), dated December 30, 2010; EPA Form 8570-34 (Certification with Respect to Citation of Data), dated December 30, 2010; EPA Form 8570-35 (Data Matrix), dated December 30, 2010; a draft label (pin-punched 12-30-10); and three studies (MRID 483415-01 through 483415-03).

FINDINGS:

1. Group A product chemistry data requirements applicable to end-use products have been met. (MRID 483415-01)
2. Group B product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS 830.6317 (Storage Stability), and OPPTS 830.6320 (Corrosion Characteristics). See the "Recommendations" section of this report. (MRID #: 483415-02 and 483415-03)
3. The CSFs, dated 12/30/10, for the basic and for the alternate formulations are revised.
4. All certified limits meet the EPA Certified Standards Limits.
5. The CSF and the label have the same nominal.
6. The active ingredient (AI) meets the EPA standard certified limits.
7. Certain information on the product label could be improved, as noted in the "Recommendations" section of this report.
8. A statement of Good Laboratory Practice (GLP) compliance was provided for the study assigned MRID No. 483415-03. The study was conducted in compliance with current GLP standards as given in 40 CFR Part 160.
9. Certificate of Analysis, dated 06/08/09.

CONCLUSIONS:

The 830 Guidelines group "A" and "B" product chemistry requirements for the non-integrated end-use products are acceptable, with the exception of the OPPTS Guidelines: 830.6317 "Storage Stability" and 830.6320 "Corrosion Characteristics". The registrant must submit these two one year studies upon completion. The CSF dated 08/06/10, for the basic formulation is acceptable.

RECOMMENDATIONS:

- To satisfy OPPTS 830.6314 (Oxidation/Reduction: Chemical Incompatibility) requirements, a discussion of the product's potential incompatibility with common oxidizing and reducing agents, common fire extinguishing agents, and common solvents must be provided. An example set of test methods to quantify chemical incompatibility is presented in OPPTS 830.6314(b).
- To satisfy OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) requirements, results for a minimum of 1 year from a GLP-compliant storage stability and corrosion characteristics study must be provided
- The following revisions to the product label are recommended:
 - Place the "Storage and Disposal" section of the product label in a text box for prominence.
 - Under the "Pesticide Storage" section of the product label, add instructions that specify what to do if the product leaks or spills from the product container.

PRODUCT CHEMISTRY REVIEW

I. **CONFIDENTIAL STATEMENT OF FORMULA**

a. Type of formulation and source registration:

- Non-integrated formulation system [X]
- Are all TGAs used registered? Yes [] No []
- Integrated formulation system []
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [] No []

Note: This product is not intended for food use.

c. Physical state of product:

Liquid

d. The chemical IDs and analytical information (including that for the TGAs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No []

e. The NCs and CLs are acceptable.

Yes [X] No []

f. Active ingredients

	<u>NC</u>	<u>LCL</u>	<u>UCL</u>
	(%)	(%)	(%)
5-Chloro-2-methyl-4-isothiazolin-3-one	1.11	1.06	1.17
2-Methyl-4-isothiazolin-3-one	0.39	0.35	0.43

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [] No [] Not applicable [X]
- Have all impurities of $\geq 0.1\%$ in the product been identified?
Yes [] No [] Not applicable [X]

II PRODUCT LABEL

a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes No

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes No
- 1.0% or more of methyl alcohol: Yes No
- sodium nitrite at any level: Yes No
- a toxic List I inert at any level: Yes No
- arsenic in any form: Yes No

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes No Not applicable

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes No Not applicable

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes No

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes No

Note: Storage stability studies are ongoing and have not been completed.

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity ¹	A	483415-01
830.1600 Description of Materials	A	483415-01
830.1620 Production Process ²	NA	
830.1650 Formulation Process ³	A	483415-01
830.1670 Formation of Impurities ⁴	A	483415-01
830.1700 Preliminary Analysis ⁵	<i>[Not required for products produced by a non-integrated system.]</i>	
830.1750 Certified Limits ⁶	A	483415-01
830.1800 Enforcement Analytical Method ⁷	A	483415-03
830.1900 Submittal of Samples	<i>[Samples are to be provided on a case-by-case basis for end-use products.]</i>	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information.

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLs recommended in 40 CFR 158,175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	The color of the product is pale green at ambient laboratory temperature, based on visual inspection.	483415-03
830.6303 Physical State	A	The product is a clear mobile liquid, free of any extraneous matter, at ambient laboratory temperature.	483415-03
830.6304 Odor	A	The product has no discernable odor at ambient laboratory temperature.	483415-03
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	<i>[Not required for end-use products.]</i>	
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	The product contains acids, reducing agents and organic materials.	
830.6315 Flammability/Flame Extension	A	The product does not contain combustible liquids.	483415-02
830.6316 Explodability	A	The product is not potentially explosive.	483415-02
830.6317 Storage Stability	G	A 12-month storage stability study is currently underway.	
830.6319 Miscibility ¹	A	The product, when mixed with light mineral oil at 25°C, was not homogeneous and separated into layers after 30 minutes. Solutions of 0.3% and 0.5% were evaluated.	483415-03
830.6320 Corrosion Characteristics	G	A 12-month corrosion characteristics study is currently underway.	
830.6321 Dielectric Breakdown Voltage	NA	The product is not a liquid to be used around electrical equipment.	483415-02
830.7000 pH ²	A	Two determinations were made. The pH of the product (neat) was reported to be 3.2. Testing was conducted in compliance with GLP.	483415-03
830.7050 UV/Visible Absorption	NA	<i>[Not required for end-use products.]</i>	
830.7100 Viscosity	A	The mean viscosity of the product was reported to be 1.2 mPa·s at 20°C and 0.7 mPa·s at 40°C.	483415-03

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7200 Melting Point/Melting Range	NA	[Not required for end-use products.]	
830.7220 Boiling Point/Boiling Range	NA	[Not required for end-use products.]	
830.7300 Density/Relative Density/Bulk Density	A	The mean relative density of the product was reported to be 1.02 g/mL at 20°C (using a pycnometer).	483415-03
830.7370 Dissociation Constants in Water	NA	[Not required for end-use products.]	
830.7550/830.7560/830.7570 Partition Coefficient	NA	[Not required for end-use products.]	
830.7840/830.7860 Water Solubility	NA	[Not required for end-use products.]	
830.7950 Vapor Pressure	NA	[Not required for end-use products.]	

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¹If product is an emulsifiable liquid
²If product is dispersible with water