

US EPA ARCHIVE DOCUMENT

DATE OUT: 18/APR/2000

SUBJECT: PRODUCT CHEMISTRY REVIEW OF Manufacturing-Use Product[]; End-Use Product [x]; BARCODE No.: D264903 ; CASE No.: 035907 ; EPA RECEIVED DATE: 22/JUL/99 ; EPA REG./File Symbol No.: 1757-79; PRODUCT NAME: Amerstat 251; COMPANY NAME: Drew Industrial Division ; Action Code: 674 8-Month Response to Product Specific Data Call-In

FROM: Paul Horng, Ph.D., Chemist
Product Chemistry Team
PRB/SRRD (7508W)



TO: Frank Rubis, CRM
Product Reregistration Branch
PRB/SRRD (7508W)

INTRODUCTION:

The registrant, Drew Industrial Division, submitted product chemistry data in MRID # 448799-02; the Confidential Statement of Formula (CSF), a basic formulation dated 21/JUL/99; and the draft label received by the Agency on 22/JUL/99; requesting FIFRA Section 4 reregistration of end-use product, Amerstat 251, EPA Reg. No. 1757-79.

FINDINGS:

1. A Reregistration Eligibility Decision (RED), Case # 3092, was issued November 12, 1998 for the Technical Grade Active Ingredient (TGAi) methylisothiazolinone. The Agency has reviewed and determined that products containing active ingredient methylisothiazolinone for all uses are eligible for reregistration. The generic data base of product chemistry supporting the reregistration of methylisothiazolinone been reviewed and determined to be substantially complete. No data gap was cited.
- 2(a). Except for the data gap noted in # 2(b), the submitted data in MRID # 448799-02 satisfy the product chemistry data Guideline Series 61, and 63. Data for Guideline 62-1 (830-1700, Preliminary Analysis) are not required for the end-use product, if the starting materials are EPA registered products and the formulation process is not in an integrated system. Data for Guideline 62-2 (830-1750, Certified Limits) depend upon the approval of the CSF.
- 2(b). Data for Guideline 62-3 (830-1800, Enforcement Analytical Method) are not acceptable and are still outstanding.
3. The submitted CSF, a basic formulation dated 21/JUL/99, is not acceptable. Some revisions are required for the CSF. (1) The columns # 10, # 13a, and # 13b of the CSF must be filled out with Kathon 886 F [REDACTED] respectively. (2) The columns # 10, # 14a, # 14b, and # 15 in the second row of the CSF must be filled out with 5-chloro-2-methyl-4-isothiazolin-3-one, 1.15, 1.208 and 1.093%, and a.i., respectively. (3) The columns # 10, # 14a, # 14b, and # 15 in the third row of the CSF must be filled out with 2-methyl-4-isothiazolin-3-one, 0.41, 0.451, 0.369, and a.i., respectively. (4) The alternate starting material, [REDACTED] (5) [REDACTED] (6) The nominal [REDACTED]

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concentration of 2-methyl-4-isothiazolin-3-one in the basic and alternate CSF and the label must be changed from 0.35% to 0.41%. (7)

(9) The pH of the product in box # 8 of the CSF should be changed to 5.0-5.2 (1% in water).

4. The draft label is not acceptable. Some revisions are required for the draft label. (1) The concentration of the active ingredient 2-methyl-4-isothiazolin-3-one must be changed from 0.35 to 0.41%. In addition, the concentration of inert ingredient must be changed from 98.50 to 98.44% in the Ingredient Statement. (2) A statement "The product contains the active ingredients at 0.1326 pounds per gallon." must be placed directly under the ingredient statement. (3) A statement "Do not contaminate water, food, and feed by storage and disposal." must be placed directly under the Storage and Disposal statement. (4) The subheading Storage must be changed to Pesticide Storage. (5) The Storage and Disposal statement must be placed in a box of solid line to increase its prominence. The revisions of the draft label can be done after label review.

RECOMMENDATIONS:

Except for the data gap noted in Finding # 2 (b), and some revisions required for the CSF as noted in Finding # 3, the registrant has satisfied all product chemistry data requirements for reregistration of this subject product. Once the outstanding data have been submitted and satisfied; the revisions of the CSF have been made; the Agency will have no objection to reregistration of the end-use product, Amerstat 251, EPA Reg. No. 1757-79.

Group B: Series 830- Physical and Chemical Properties (40 CFR 158.190)

Cited from MRID # 448799-02.

GRN 830-	DATA OR QUALITATIVE	Comment
-6302 Color	Yellow to light green yellow.	A
-6303 Physical States	Clear Liquid.	A
-6304 Odor	Slight faint to no odor.	A
-6314 Oxidation/Reduction Action	The product does not exhibit any oxidizing or reducing action when exposed to metallurgy present in water treatment systems, such as stainless steel, copper and mild steel, at use concentrations. Concentrate can be adversely effected by oxidizing agents, reducing agents, amines, and mercaptans.	A
-6315 Flammability/	N/A, product contains no combustible liquid.	N/A
-6316 Explodability	N/A, product is in water base formulation and is not potentially explosive.	N/A
-6317 Storage Stability	No change in concentration on the active ingredients when stored for one year under ambient warehouse conditions in commercial packaging material composed of HDPE. Ambient warehouse temperature range from 20 to 40°C. If temperature exceed 50°C for over one month, shelf life is reduced to six month.	A
-6319 Miscibility	The aqueous solution of the product is not miscible with petroleum solvents. It is miscible with lower alcohols, acetic acid and 3.5 parts n-butanol. It is immiscible with acetone.	A

-6320 Corrosion Characteristics	The product was packaged in commercial packaging composed of HDPE under ambient warehouse conditions, no evidence of corrosion of the container was observed. Product does not have an adverse effect on PE, PP, 316L stainless steel, plastics, reinforced glass fiber, Teflon, Viton. Due to low pH of concentrate and the water content, the composition would be aggressive toward most stainless and mild steel if used for packaging or handling of the concentrate. Other incompatible materials are aluminum, copper, yellow brass, PVC, nitrile, neoprene, and EPDM.	A
-6321 Dielectric Breakdown Voltage	N/A, the product is not recommended for use in or around electrical equipment.	N/A
70(X) pH	5.0-5.2 (1% in water).	A
-7100 Viscosity	16 cps RVP Spindle # 1, at 100 RPM at 25.0°C.	A
-7300 Density/ Bulk Density	1.01 to 1.03 g/ml or 8.4 to 8.57 lbs/gal at 25°C.	A

N/A: not applicable. NR: not required. A: acceptable. Gap: data gap.

Confidential Appendix A

Inert ingredient information may be entitled to confidential treatment

830-1550 Product Identity and Composition.

This product contains the active ingredients 5-chloro-2-methyl-3(2H)-isothiazolone and 2-methyl-3(2H)-isothiazolone 1.15 and 0.41% by weight, respectively.

830-1600 Description of Materials Used to Produce the Product.

[REDACTED]

830-1650 Description of Formulation Process.

[REDACTED]

830-1670 Discussion of Formation of Impurities.

The registrant states that the formation of impurities as a result of the manufacture of Amerstat 251 is not evident. This is due to the fact that the formulation process is a simple blend. The components used in the formulation are not integrated to form alternate products.

830-1700 Preliminary Analysis.

Data are not required. The starting materials are EPA registered products and the formulation process is not in an integrated system.

830-1750 Certified Limits.

5-chloro-2-methyl-3(2H)-isothiazolone: nominal, 1.15 (gross 11.07) %; upper limit, 1.208; lower limit, 1.093%.

2-methyl-3(2H)-isothiazolone: nominal, 0.41 %; upper limit, 0.451; lower limit, 0.369%.

[REDACTED]

830-1800 Enforcement of Analytical Method

The active ingredients, 5-chloro-2-methyl-3(2H)-isothiazolone and 2-methyl-3(2H)-isothiazolone, in the product are determined by the specific gravity and pH.

The analytical methods are not acceptable. The data requirement for this guideline is still outstanding.

Specific gravity is a physical property of a product. It can be used as qualitative analysis, but it cannot be used as a quantitative analysis to determine the chemical compositions and quantity (percentage by weight) of 5-chloro-2-methyl-3(2H)-isothiazolone and 2-methyl-3(2H)-isothiazolone in the product. Two products have the same specific gravity are not necessary that they are the same product and have the same chemical composition.

Similarly, pH is the chemical property of a product. The determination of pH of a product is

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a qualitative analysis but it is not a quantitative analysis.

The registrant must develop a HPLC or GC analytical method which is proved to be with acceptable linearity, accuracy, and precision to analyze 5-chloro-2-methyl-3(2H)-isothiazolone and 2-methyl-3(2H)-isothiazolone in the product.

Paul Horng: Central File (Reg. No. 1757-79).
7508w:SRRD:PRB:CMZ: p.h.:18/APR/99:703-308-8053: <1757-79 >