

1100-84

12/2/1998

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DEC 02 1998

CRENOVA Inc.
P.O. Box 365
Turner Place
Piscataway, NJ 08855-0365

Subject: Nuosept 635-W Preservative
EPA Registration No. 1100-84
Your Amendment Dated: July 27, 1998

Attention: Mrs. Hope Stewart
Manager, Registrations

This letter is in response to your submission of acute inhalation data to bring NUOSEPT 635-W Preservative in full compliance with the Alkyl Amine Hydrochlorite Reregistration Eligibility Document (RED). On August 12, 1998, the Agency accepted an interim label pending the results of the acute inhalation data. After reviewing the submitted study, the interim draft label will be acceptable as the product label in compliance with the RED provided the following comments are addressed.

1. Acute Toxicity

The submitted acute inhalation toxicity study, MRID # 446139-01, is acceptable. The current acute toxicity profile for registration number 1100-84 is:

Acute Oral	IV
Acute Dermal	III
Acute Inhalation	III
Primary Eye Irritation	I
Primary Skin Irritation	I
Dermal Sensitization	sensitizer

The precautionary statements should be revised to reflect the following:

- a. Since acute inhalation is category III, the following precautionary statement should be added, "Avoid breathing spray mist."

CONCURRENCES

SYMBOL	NAME	DATE						

- b. The third sentence should be revised to "Wear chemical splash goggles or face shield, protective clothing, and rubber gloves."
- c. The statement, "This product is a sensitizer", should be deleted.

2. Statements of Practical Treatment

Since this product is category III for acute inhalation, the following statement needs to be added to the statements of practical treatment, preferably before the "If Swallowed" statement.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably by mouth-to-mouth. Get medical attention.

Also, the IF IN EYES statement should be revised to "Hold eyelids open and flush with a steady gentle stream of water for 15 minutes. Get medical attention."

A stamped copy of the label is enclosed for your records. Please submit one (1) copy of the final printed label.

If you have any questions regarding this letter, please contact Jacqueline Campbell at (703) 308-6416.

Sincerely,

Tracy Lantz
for Velma Noble
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510C)

NUOSEPT® 635-W PRESERVATIVE

D63 - 0011

SOLD FOR USE IN THE COATINGS INDUSTRY AS AN INDUSTRIAL PRESERVATIVE AGAINST BACTERIA.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

DANGER

CORROSIVE. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear chemical splash goggles and face shield, rubber gloves, pesticide respirator and protective clothing. Wash thoroughly with soap and water after handling. Harmful if absorbed through skin. Harmful if swallowed or inhaled. Use with adequate ventilation. Do not breathe vapor or spray mist. This product is a sensitizer. Prolonged or frequent skin contact may cause allergic reaction in some individuals. Remove and wash contaminated clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water. Get medical attention.

IF SWALLOWED: Call a doctor or Poison Control Center. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

ACTIVE INGREDIENT:

Alkyl (derived from fatty acids of coconut oil) amine hydrochloride.....

25.00 %

(#5.0% Caprylyl, 7.0% Capryl, 56.0% Lauryl, 18.0% Myristyl, 7.0% Palmityl, 5.0% Stearyl, 2.0% Linoleyl)

INERT INGREDIENTS:.....

75.00 %

TOTAL:.....

100.00 %

This product contains 1.98 lbs. alkyl amine hydrochloride per gallon.

KEEP OUT OF REACH OF CHILDREN

DANGER

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. A liquid organic biocide (also called an antimicrobial or in-can preservative), recommended for use as an industrial preservative for the protection of water based products such as resins, emulsion paints, adhesives, dispersed colors and printing inks against microbiological spoilage in the wet state. Typical use levels range from 0.15 to 0.3% by weight in the final formulations, but should not exceed 0.5% of the final product for any application.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC - 2 1998

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

HMIS RATINGS	
HEALTH	3
FLAMMABILITY	2
REACTIVITY	0



E2900CT00E9CT28299

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

PROHIBITIONS - Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE DISPOSAL - Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL - Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

STORAGE INSTRUCTIONS - Product should be stored in an area that is not subject to extreme temperatures. Proper protective equipment, as indicated above, should be worn when opening, transferring and using product. Close drum bungs tightly when not in use. Spill-leak procedures and additional handling information are contained in the Material Safety Data Sheet.

CRE
NOVA

A Hub Group Company



DRAFT

EPA Reg. No.: 1100-84

EPA Est. No.: 1100-CN-02

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