

6186-51

11-5-2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV - 5 2002

Brian T. Martin
Chemist
Damon Industries, Inc.
P.O. Box 2120
Alliance, Ohio 44601-0120

SUBJECT: Ster-O-Kem No. 15
EPA Registration Number: 6186-51
Application Date: July 30, 2002
Receipt Date: August 7, 2002

Dear Mr. Brian T. Martin:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

- Update Disposal Statements
- Update First Aid Statements
- Update Precautionary Statements

Conditions

Revise the label as follows:

1. Revise the "Precautionary Statements" to read: "Corrosive. Causes irreversible eye damage and skin burns. *Harmful if swallowed or absorbed through the skin.* Avoid breathing spray mist. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves and protective clothing when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

CONCURRENCES

SYMBOL	7510C						
SURNAME	S. J. [Signature]						
DATE	11/4/02						

2. Your current language in the sections headed "Important" does not meet today's standards. Revise your language to agree with other recently approved labels in the marketplace as follows: "Regular, effective cleaning and sanitizing...food preparation, storage or service *which could harbor hazardous microorganisms.*" and "Application of effective sanitizing procedures *reduces the number of those disease organisms which may be present on equipment and utensils after cleaning, and reduces the potential transfer* either directly through tableware such as glasses, cups and flatware or indirectly through food."

3. Revise the "Directions for Use" section of the label as follows:

A. Revise the heading to read "Sanitizing of Food Processing Equipment and Other Hard *Non-porous* Surfaces in Food Contact Locations:"

B. Delete the phrase "Wash and rinse all articles thoroughly" and replace with the following language as per DIS/TSS 17: "*Remove food particles and soil by a preflush, or pre-scrape and when necessary, pre-soak. Thoroughly wash surfaces with a good detergent or compatible cleaner and rinse with potable water, then apply by immersion, flooding, or spraying a solution of...*"

C. Replace the phrase: "Fresh solution should be prepared" with "*Prepare a fresh solution at least daily or when...*" as per PR Notice 2000-5 which describes the use of mandatory language.

D. Revise to state: *Sanitize* dishes, silverware, glasses, cooking utensils and other similar food processing equipment by immersion in a..." as per PR Notice 2000-5 deleting the language which is not mandatory: "can be sanitized."

E. Since your product your product is for use in food processing areas, add the following statement: "*When used in food processing areas, all food and packaging material must be removed or carefully protected.*"

F. Revise the directions for U.S. Public Health Service-Food Service Sanitation Recommendations" as follows:

1. Revise items #2 to read "...thoroughly with *potable* water."

2. Revise item #4 to include the following statement: "*Allow surfaces to remain wet for 1 minute.*"

General Comments

A stamped copy of the accepted labeling is enclosed. Submit (2) copies of the final printed labeling before distributing or selling this product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

Enclosure: Stamped Label
7510C:T.Lantz:11/1/02:6186-51

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER. Keep Out of Reach of Children. Corrosive. Causes irreversible eye damage and skin burns. May be harmful if absorbed through the skin. Harmful if swallowed. Harmful if inhaled. Avoid breathing spray mist. Do not get into eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves and protective clothing when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

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

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to small children. Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Wrap and discard in trash (or recycle).

IMPORTANT

Regular, effective cleaning and sanitizing of equipment, utensils, and work or dining surfaces minimizes the probability of contaminating food during preparation, storage or service, and the transmission of disease organisms to consumers and employees. Effective cleaning will remove soil and prevent the accumulation of food residues which may decompose or support the rapid development of food poisoning organisms or toxins. Application of effective sanitiz-



**STER-O-KEM® NO. 15
WITH
ORGANIC SOIL TOLERANCE**

SANITIZER-DEODORIZER WITH ORGANIC SOIL TOLERANCE • INSTITUTIONAL, INDUSTRIAL, SCHOOL, DAIRY & OTHER FARM USE • FOR FOOD HANDLING & PROCESSING AREAS, RESTAURANTS AND DAIRIES

Active Ingredients:
Alkyl (C12, 30%; C12, 40%; C12, 10%)
dimethyl benzyl ammonium chlorides
Octyl decyl dimethyl ammonium chloride
Didecyl dimethyl ammonium chloride
Dioctyl dimethyl ammonium chloride
Inert Ingredients:
TOTAL

E.P.A. Registration No. 6186-51 E.P.A. Establishment No. 6186-0H-1

**KEEP OUT OF REACH OF CHILDREN
DANGER PELIGRO**
SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
NET CONTENTS: 1 GALLON - 3.78 LITERS

**MANUFACTURED AND GUARANTEED BY
330 DAMON INDUSTRIES, INC. 1-362
621-5310 BOX 2120 ALLIANCE, OH 44601-0120**

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

NOV 5 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
and under EPA Reg. No. 6186-51

4/5

NO. 450

DAMON INDUSTRIES

JAN. 20. 2003 11:20AM



Ingredients:	
50% C ₁₂ , 40% C ₁₄ , 10%	
quaternary ammonium chlorides	1.024%
1 dimethyl ammonium chloride	0.768%
2 methyl ammonium chloride	0.384%
3 methyl ammonium chloride	0.384%
Ingredients:	97.440%
TOTAL	100.000%

CHILDREN
ELIGRO
 DIRECTIONS STATEMENTS
 - 3.78 LITERS

MANUFACTURED BY
ELIGRO, INC.
 44601-0120

1-800
 362-9850

ing procedures destroys those disease organisms which may be present on equipment and utensils after cleaning, and prevents the transfer of such organisms to consumers or employees, either directly through tableware such as glasses, cups and flatware or indirectly through the food.

To prevent cross-contamination, kitchenware and food-contact surfaces of equipment shall be washed, rinsed, and sanitized after each use and following any interruption of operation during which time contamination may have occurred.

Where equipment and utensils are used for the preparation of foods on a continuous or production-line basis, utensils and the food-contact surfaces of equipment shall be washed, rinsed, and sanitized at intervals throughout the day on a schedule based on food temperature, type of food, and amount of food particle accumulation.

DIRECTIONS FOR USE - SANITIZING

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Sanitizing of Food Processing Equipment and Other Hard Surfaces in Food Contact Locations: For sanitizing food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment and other hard non-porous surfaces. No potable water rinse is required. Wash and rinse all articles thoroughly, then apply a solution of 1/4 oz. Ster-O-Kem® #15 in 1 gallon of water (150 ppm active). Surfaces should remain wet for at least one minute followed by adequate draining and air drying. Fresh solution should be prepared daily or when the use-solution becomes visibly dirty. For mechanical application, used solution may not be reused for sanitizing applications.

Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard surfaces by cloth or brush or mechanical spray device. No potable water rinse is required.

Dishes, silverware, glasses, cooking utensils and other similar size

food processing equipment can be sanitized by immersion in a 1/4 oz. per 1 gallon solution of Ster-O-Kem #15. No rinse is allowed.

The udders, flanks and teats of dairy cows can be sanitized by washing with a solution of 1 oz. Ster-O-Kem #15 in 4 gallons of warm water. No potable water rinse is required. Use a fresh towel for each cow. Avoid contamination of sanitizing solution by dirt and soil. Do not dip used towel back into sanitizing solution. When solution becomes visibly dirty, discard and provide fresh solution.

At 1/4 oz. per gallon Ster-O-Kem #15 fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinance 1976 Recommendations of the U.S. Public Health Services in waters up to 800 ppm of hardness calculated as CaCO₃ when evaluated by the AOAC Germicidal and Detergent Sanitizer Method against Echerichia coli and Staphylococcus aureus.

U.S. PUBLIC HEALTH SERVICE - FOOD SERVICE SANITATION RECOMMENDATIONS

Cleaning and Sanitizing: Equipment and utensils shall be thoroughly pre-flushed or pre-scraped, and when necessary, pre-soaked to remove gross food particles and soil.

- 1) Thoroughly wash equipment and utensils in a hot detergent solution.
- 2) Rinse utensils and equipment thoroughly with clean water.
- 3) Sanitize equipment and utensils by immersion in a 1/4 oz. per gallon solution of Ster-O-Kem #15 (150 ppm active) for at least 60 seconds at a temperature of 75°F. This dilution is equivalent to a solution containing 50 ppm available chlorine.
- 4) For equipment and utensils too large to sanitize by immersion, apply a 9 oz. per 2 gallon solution of Ster-O-Kem #15 (300 ppm active) by rinsing, spraying or swabbing until thoroughly wetted.
- 5) Allow sanitized surfaces to drain and air dry. Do not rinse.

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JAN. 20, 2003 11:28PM
 DAMON INDUSTRIES
 NO. 490 P. 3/3