

5741-24

8/14/2002

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/8

AUG 14 2002

Mr. Ronald Cook
Spartan Chemical Company, Inc.
1110 Spartan Drive
Maumee, OH 43537

Subject: Consume Eco-Lyzer
EPA Registration No. 5741-24
Amendment Date: April 26, 2002
EPA Receipt Date: April 30, 2002

Dear Mr. Cook,

The following amendment is submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

- Addition of virucidal claim against HIV-1, Influenza A₂, and Herpes Simplex Type 1
- Additional container size and applicable marketing text
- Revision of acute inhalation precautionary statements

Conditions

Revise label as follows:

1. Revise the 2 liter bottle dispensing descriptor, "Bio-Transport 1" to read "Bio-Transport 1 Dispensing System."
2. On page 2 of 6, revise the first claim by removing the phrase, "the added power of," so that it reads "Consume Eco-lyzer is a dilutable neutral disinfectant cleaner with enzyme-producing bacteria for the extended control of malodors." The use of "added power" is considered a false and misleading claim of heighten efficacy.
3. On page 3 of 6, an asterisk must be placed after the term, virucidal in the disinfection directions and the virucidal disinfection heading.
4. On page 3 of 6, revise the fifth claim by deleting the phrase, "EPA recognized test methods, to state "AOAC Use Official test method."

SYMBOL							
SURNAME							
DATE							

- 5. On page 4 of 6, delete the statement, "Do not use this product on food contact surfaces in food preparation or storage areas. Do not use on utensils, dishes, or glasses, and place after the disinfection and virucidal directions on page 3 of 6.

Acceptable Data

The following efficacy data was reviewed and accepted. The data evaluation is attached for your review.

Data Requirement	Means of Support	Status
Virucidal effectiveness - Herpes Simplex Type 1	Submitted study, MRID 456175-01	Acceptable
Virucidal effectiveness - HIV-1	Submitted study, MRID 456175-02	Acceptable
Virucidal effectiveness - Influenza A2	Submitted study, MRID 456175-03	Acceptable

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

Enclosure: Efficacy Data Evaluation

Label for **Consume Eco-Lyzer**
EPA Reg. No. 5741-24
Spartan Chemical Company, Inc.
(Submitted to EPA 4/26/2002)



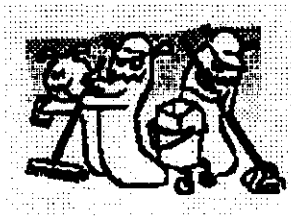
(Front Panel Copy:)

CONSUME ECO-LYZER

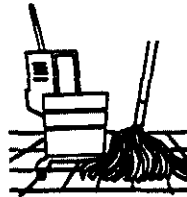
Neutral Disinfectant Cleaner with Residual Biological Odor Control

A revolutionary quaternary based disinfectant formulated to kill odor causing bacteria and viruses*, remove soils and leave non-pathogenic, enzyme-producing bacteria behind for residual control of nuisance odors.

(Note to EPA: The following text will be utilized on 2 liter bottles)
"BIO-TRANSPORT 1"



(Optional marketing graphic)



(Optional application graphic)

ACTIVE INGREDIENTS:

n-alkyl (C14-50%, C12-40%, C16-10%) dimethyl benzyl ammonium chloride.....	2.18%
n-octyl decyl dimethyl ammonium chloride.....	1.63%
dioctyl dimethyl ammonium chloride.....	0.82%
didecyl dimethyl ammonium chloride.....	0.82%
INERT INGREDIENTS:	<u>94.55%</u>
Total	100.00%

EPA Reg. No. 5741-24
EPA Est. No. 5741-OH-1

KEEP OUT OF REACH OF CHILDREN
DANGER
See side panel for additional precautionary statements
U.S. Patent Nos. 6,165,965 and 6,180,585
FOR INSTITUTIONAL AND INDUSTRIAL USE ONLY

SPARTAN CHEMICAL COMPANY, INC., 1110 Spartan Drive, Maumee, OH 43537
1-800-537-8990 / Medical Emergency: 888-314-6171 / www.spartanchemical.com

NET CONTENTS: 2 Liters/67.6 oz.
NET CONTENTS: 1 U.S. Gallon/3.79 Liters
NET CONTENTS: 5 U.S. Gallons/18.95 Liters

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 5741-24

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Label for **Consume Eco-Lyzer**
EPA Reg. No. 5741-24
Spartan Chemical Company, Inc.
(Submitted to EPA 4/26/2002)

(Back Panel Copy:)

CONSUME ECO-LYZER
Neutral Disinfectant Cleaner with Residual Biological Odor Control

Consume Eco-lyzer is a dilutable neutral disinfectant cleaner with the added power of enzyme-producing bacteria for the extended control of malodors.

Consume Eco-Lyzer is for use as a disinfectant, cleaner, and deodorizer on hard, non-porous, inanimate surfaces in office buildings, airports, hotels, motels, schools, colleges, veterinary clinics, zoos, animal life science laboratories, pet shops, kennels and grooming establishments. A one-step labor saver for restrooms, locker rooms, loading docks, dumpsters, kitchens, cafeterias, kennels and other areas where persistent malodors are a problem. Consume Eco-Lyzer is for use on hard, non-porous, inanimate surfaces such as floors and walls made of quarry tile, concrete, terrazzo, vinyl composition floor tile, metal (such as steel & stainless steel), glazed porcelain and plastic (such as polypropylene & polystyrene), etc.

NOTE: Consume Eco-Lyzer contains viable bacterial cultures. Do not use this product on food contact surfaces in preparation or storage areas to eliminate possible food contamination and spoilage. The bacteria in this product may cause infection if introduced into an open wound in sufficient quantity. Do not use in patient healthcare areas. To avoid cross contamination, this product should be diluted and/or applied only in equipment dedicated or restricted to products containing viable bacterial cultures.

At use-dilution, Consume Eco-Lyzer provides 850 ppms of quaternary germicide and is effective against the following pathogenic and odor-causing bacteria, according to EPA recognized test methods in the presence of 200 ppm synthetic hard water (calculated as CaCO₃) plus 5% blood serum: *Proteus vulgaris*, *Pseudomonas putrefaciens*, *Serratia odorifera*, *Staphylococcus aureus* and *Salmonella choleraesuis*. Consume Eco-Lyzer is also virucidal* and has been proven effective against HIV-1 (AIDS Virus), Herpes simplex Type 1 and Influenza A₂ on hard nonporous inanimate surfaces.

In addition to its disinfectant activity, Consume Eco-Lyzer offers biological odor control through enzymatic degradation of trapped organic soils. Each ounce of Consume Eco-Lyzer provides a multiple species blend of 4 billion bacteria chosen specifically for their ability to produce enzymes which attack and degrade common organic soils such as proteins, starches, carbohydrates, fats, greases and even urea (the principle component of urine) without the generation of nuisance odors.

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DIRECTIONS FOR USE:

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

General Purpose Cleaning and Deodorizing:

For pre-cleaning or degreasing of heavily soiled surfaces, dilute Consume Eco-Lyzer from 2 oz. per gallon to 6 oz. per gallon of water depending on the soil load. Apply the product with a cloth, mop, sponge, or by coarse foaming. Scrub surface. Rinse with water or allow to air dry.

General Purpose Disinfection:

Remove gross filth and heavy soil deposits before disinfection. Prepare use-solution of Consume Eco-Lyzer at 2 oz. per gallon of water. Thoroughly saturate surfaces for 10 minutes using a cloth, mop, sponge or coarse foamer. For virucidal activity, a 5 minute contact is adequate. Rinse with water or allow to air dry. Prepare fresh use-solution for each use, then discard.

Virucidal Disinfection of Hard Nonporous Inanimate Surfaces:

Remove gross filth and heavy soil deposits before disinfection. Prepare use-solution of Consume Eco-Lyzer at 2 oz. per gallon of water. Thoroughly saturate surfaces for 5 minutes using a cloth, mop, sponge or coarse foamer. Rinse with water or allow to air dry. Prepare fresh use-solution for each use, then discard. Use a 10 minute contact time for the bacteria claimed on this label.

***KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS**

PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES OR OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: Exposure to blood or body fluids should be avoided by use of barrier protection such as latex or other impervious gloves. Face shields and impervious gowns should also be worn if splashing of blood or body fluids may occur.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.

CONTACT TIME: Leave surfaces wet for 5 minutes. Use a 10 minute contact time for the bacteria claimed on this label.

DISPOSAL OF INFECTIOUS MATERIAL: Contaminated cleaning materials, blood and other body fluids should be autoclaved and/or disposed of according to local regulations for infectious waste disposal.

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Veterinary Practice / Animal Care / Zoos / Pet Shops / Kennels

Disinfection Directions:

Do not use on equipment or containers used for animal food or water.

For cleaning and disinfecting the following hard nonporous surfaces: floors, walls, cages, kennels, stables, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, cages, kennels, etc. Remove all liter, droppings and manure from floors, walls and surfaces of facilities occupied or transversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 2 oz. Consume Eco-Lyzer per gallon of water for a period of 10 minutes. Rinse with water or allow to air dry. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

Do not use this product on food contact surfaces in preparation or storage areas. Do not use on utensils, dishes, or glasses.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Harmful if absorbed through the skin. May be fatal if inhaled. Do not breath vapor or spray mist. Do not get in eyes, on skin, or on clothing. Wear protective eye wear (goggles/face shield/safety glasses), rubber gloves, and protective clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Use-Dilution Precautions: Harmful if inhaled. Avoid breathing vapor and spray mist. Remove contaminated clothing and wash clothing before reuse. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Avoid contact with skin. Wear protective eyewear (goggles /face shield / safety glasses). Wash thoroughly with soap and water after handling.

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(For use with five gallon pails and larger containers only)

ENVIRONMENTAL HAZARDS

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.

FIRST AID

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 on skin:	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 inhaled:	Move person to fresh air. If a 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.
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.

24 HOUR MEDICAL EMERGENCY NUMBER: 888-314-6171

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

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

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Spartan Chemical Company, Inc.
(Submitted to EPA 4/26/2002)

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(For use with one gallon jugs and smaller containers only)

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in original container in a cool, dry place.

Container Disposal: Securely wrap original container in several layers of newspaper and discard in trash.

(For use with five gallon pails and larger containers only)

STORAGE AND DISPOSAL

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 incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

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