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 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
 WASHINGTON, D.C. 20460

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OCT 30 1995

OFFICE OF  
 PREVENTION, PESTICIDES AND  
 TOXIC SUBSTANCES

Givaudan-Roure Corporation  
 100 Delawanna Avenue  
 Clifton, NJ 07014

Attention: Barbara Lewis  
 Manager, Product Safety

Subject: Giv-Gard DXN  
 EPA Registration No. 824-7  
 Your Amendment Dated July 26, 1995.

The amendment (use pattern clarification), referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Make the following labeling changes below before you release the product for shipment bearing the amended labeling. (master label)
  - a. Delete the word: "etc" (two locations-under the use directions section).
  - b. Revise the company address to read as above.
  - c. Revise the statement: "...for use only in industrial water-based products..." to read: "...for use only in industrial water-based products as outlined below..."
  - d. Since the product is a strong sensitizer, a statement to that effect must be declared on the label.
  - e. It is not necessary to declare the word: "dimethoxane" within the active ingredient section since the phrase "brand of dimethoxane" already appears directly under the product name. Eliminate the duplication.

CONCURRENCES

SYMBOL									
SURNAME									
DATE									

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 contains at least 50% recycled fiber

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3. Make the following labeling changes below before you release the product for shipment bearing the amended labeling. (Technical Literature).

a. The actual Material Safety Data Sheet was deleted from this bulletin. The Agency has no jurisdiction over the contents of the MSDS and therefore this MSDS will not be reviewed or stamped. This responsibility belongs to OSHA only. It has been noted that on page three, the MSDS is however referenced but it will not be part of the technical literature in EPA's label files. This MSDS will only be placed in our administrative files for reference only.

b. You are to assure yourself that the use concentrations as declared in the Activity section (in this bulletin) corresponds to the use levels as declared on the label.

c. Revise the word: biocide to read: microbiocide (applications and Directions for use section of the bulletin) second paragraph.

d. Delete the word: "etc" (two locations-under the "applications and Directions for Use" section).

4. A release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. A stamped copy of the labeling is enclosed for your records.

It has been noted for the record that additional label and/or data requirements may be necessary after the Agency completes the Reregistration review of this chemical.

If you have any questions concerning this letter, contact V. Goncarovs at 703-305-6663.

Sincerely,

Marion Johnson  
Product Manager (31)  
Antimicrobial Program Branch  
Registration Division (7505C)

Enclosures

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

GIVAUDAN - ROURE

ACCEPTED  
WITH COMMENTS  
In EPA Letter Dated  
OCT 30 1995

824-7

# GIV-GA

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing vapors. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

### ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. Keep out of lakes, ponds or streams. 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. Do not contaminate water by cleaning of equipment or disposal of wastes.

### PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

NET CONTENTS: GAL. LBS.

LOT NO.

GC-1537-B

## CAUTION

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

### STATEMENT OF PRACTICAL TREATMENT

**If swallowed:** Drink a large quantity of water. Do not induce vomiting. Immediately contact physician or Poison Control Center.

**If inhaled:** Remove to fresh air and call a physician immediately.

**If on skin:** Wash thoroughly with soap and water. Use large quantities of water.

**If in eyes:** Flush eyes immediately with plenty of water for at least 15 minutes. Immediately contact physician.

**If on clothing:** Remove contaminated clothing before reuse.

Manufactured by: GIVAUDAN-ROURE CORPORATION

125 Delawanna Avenue, Clifton, NJ 07011

**BEST COPY AVAILABLE**

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DRAFT

ROURE

# D DDXN®\*

ETHOXANE)

BACTERIOSTAT/FUNGISTAT

### ACTIVE INGREDIENT:

Dimethoxane;  
2, 6-Dimethyl-m-dioxan-4-ol acetate . . . . . 87%

INERT INGREDIENTS: . . . . . 13%  
100%

### DIRECTIONS FOR USE

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

Giv-Gard DDXN® (Brand of Dimethoxane) is a microbial growth inhibiting agent for use only in industrial water-based products. It is to be used as directed in Givaudan-Roure Corporation's Technical Bulletin.

For use in the following applications, Giv-Gard DDXN should be used at a level of 0.1% - 0.2% by weight of the system to be protected.

- Emulsions (such as latex, PVA, silicone, oil, acrylic, polyethylene, PVC)
- Paints (emulsions)
- Coatings
- Specialty industrial products (such as pigment slurries, dyestuffs, inks, thickeners / gums, lignosulfonates, etc.)
- Textile chemicals and finishes (such as dye levelers, textile auxiliaries, softeners, lubricants, antistats, sizings, print pastes, etc.)
- Industrial adhesives
- Leather processing liquors (such as dyes and wet processing leather finishes)
- Distillate fuels

**NOT FOR RESALE                      NOT FOR USE IN COSMETICS**

**THIS PRODUCT HAS NOT BEEN CLEARED UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT FOR USE IN THE MANUFACTURE OF ADHESIVES AND COATINGS THAT MAY COME IN CONTACT WITH FOOD.**

### STORAGE AND DISPOSAL

Keep container covered. Store in a dry, cool, well-ventilated area avoiding open flames or other sources of ignition.

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

### PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

Do not reuse empty container. Triple rinse (or equivalent) the container. Then offer to recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

**KEEP CONTAINER COVERED-STORE IN A DRY PLACE**

**NON-WARRANTY:** Our recommendations for use of this product are based upon test believed to be reliable. The use of this product being beyond the control of the manufacturer, no guarantee, expressed or implied, is made as to the effects of such or the results to be obtained if not used in accordance with directions and established safe practice. The buyer must assume all responsibility, including injury or damage, resulting from its mis-use as such, or in combination with other materials.

\*U.S. PAT. 3,167,477      EPA Reg. No. 824-7      EPA Est. No. 824-NJ-1

GIV

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# GIV-GARD DXN<sup>®</sup>

(BRAND OF DIMETHOXANE)

## BACTERIOSTAT-FUNGISTAT

TECHNICAL LITERATURE

ACCEPTED

LIBRARY

OCT 30 1995

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GIVAUDAN-ROURE

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# G I V - G A R D D X N<sup>®</sup>

(Brand of Dimethoxane)

(2,6-Dimethyl-m-Dioxan-4-ol Acetate)

Bacteriostat - Fungistat

## PRODUCT FEATURES

- Non-Formaldehyde
- Non-Formaldehyde Donor
- Liquid Product
- Water Soluble
- Broad-Spectrum Antimicrobial Activity
- Wide pH Range Usage
- Non-Chlorinated
- Non-Phenolic
- Non-Metallic
- Anionic, Cationic, Non-Ionic Compatible
- Cost-Effective
- CAS #000828-00-2
- Registered U.S. EPA #824-7
- U.S. Patent 3,167,477

ACCEPTED  
MAY 11 1995  
BY EPA

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# G I V - G A R D D X N®

## TABLE OF CONTENTS

- PHYSICAL AND CHEMICAL PROPERTIES
- METHOD OF ASSAY
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- APPLICATIONS AND DIRECTIONS FOR USE
- SUMMARY OF TOXICOLOGICAL DATA
- ADDITIONAL INFORMATION
- MATERIAL SAFETY DATA SHEET

ACCEPTED  
AND RECORDED  
OCT 30 1995

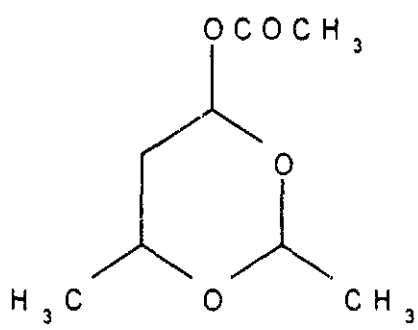
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# G I V - G A R D D X N<sup>®</sup>

(Brand of Dimethoxane)  
Bacteriostat - Fungistat

## PHYSICAL AND CHEMICAL PROPERTIES



APPROVED  
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Chemical Name:	2,6-Dimethyl-m-Dioxan-4-yl Acetate
Synonym:	6-Acetoxy-2,4-Dimethyl-m-Dioxane
Chemical Formula:	C <sub>8</sub> H <sub>14</sub> O <sub>4</sub>
Molecular Weight:	174.2
Color and Appearance:	Yellow to amber liquid
Specific Gravity @ 25°/25°C:	1.060 - 1.075
Refractive Index @ 20°C:	1.430 - 1.437
Boiling Point:	ca. 210°C
Freezing Point:	Below -25°C
Flash Point:	125°F (TCC)
Solubility:	Soluble in or miscible with water and organic solvents
CAS #:	000828-00-2
EPA Registration #:	824-7
U.S. Patent:	3,167,477



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METHOD OF ASSAY

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Assay: 85% - 95% (Sum of Two Major Peaks)

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Method: Using a gas chromatograph equipped with a Flame Ionization Detector (FID) and an electronic integrator, the analysis is performed on a 30-meter DB Wax fused silica capillary column (0.25 micron film thickness). Typical gas chromatographic operating conditions include:

Injection Split: 50:1  
Column Temperature: 50°C increased to 250°C  
Temperature Program: 10°C/minute

Inject a 0.2  $\mu$ L sample using the above operating conditions. Report the sum of the two major peaks.

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### ACTIVITY

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Giv-Gard DXN is a reliable preservative product developed by Givaudan-Roure scientists. It functions effectively against various spoilage microorganisms in water-based systems and emulsions.

Microbial growth inhibiting agents used in industry may or may not offer optimum preservative action depending on pH, type of emulsifier, and loss of material into the oil phase of emulsion systems.

Giv-Gard DXN remains in the water phase of aqueous systems and exerts its biological activity over a broad pH range. The product is effective against a wide spectrum of microorganisms and especially effective against Gram-negative bacteria. Gram-negative bacteria are the major organisms involved in bacterial spoilage problems.

Microbiological evaluation of Giv-Gard DXN in various products demonstrated antimicrobial activity against both Gram-negative and Gram-positive bacteria, as well as against various yeasts and fungi at concentrations in the range of 0.07% (700 ppm) to 0.25% (2,500 ppm). The minimum concentrations of Giv-Gard DXN effective in inhibiting various organisms in conventional microbiological tests are shown in Table I.

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TABLE I

ANTIMICROBIAL SPECTRUM OF GIV-GARD DXN

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<u>Organism</u>	<u>*MIC(ppm)</u>
<i>Staphylococcus aureus</i>	1250
<i>Bacillus subtilis</i>	625
<i>Pseudomonas aeruginosa</i>	625
<i>Pseudomonas fluorescens</i>	625
<i>Brevibacterium ammoniagenes</i>	625
<i>Escherichia coli</i>	625
<i>Aerobacter aerogenes</i>	625
<i>Salmonella typhosa</i>	625
<i>Salmonella choleraesuis</i>	312
<i>Shigella sonnei</i>	625
<i>Saccharomyces cerevisiae</i>	2500
<i>Pityrosporum ovale</i>	625
<i>Candida albicans</i>	1250
<i>Aspergillus niger</i>	1250
<i>Aspergillus flavus</i>	1250
<i>Aspergillus terreus</i>	1250
<i>Aspergillus oryzae</i>	1250
<i>Penicillium piscarium</i>	625
<i>Penicillium species (unknown)</i>	1250

\* Minimal inhibitory concentration (ppm) in agar by two-fold serial dilution technique. Bacteria on dextrose tryptone extract agar, 3 days at 34°C. Mold and yeasts on Sabouraud's dextrose agar, 5 days at 30°C.

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APPLICATIONS AND DIRECTIONS FOR USE

Giv-Gard DXN (Brand of Dimethoxane) exhibits excellent preservative performance in a wide array of applications. The product should be used only in the manufacture and/or processing of industrial water-based products to inhibit microbial growth.

We recommend an initial use concentration of 0.1% (1,000 ppm) Giv-Gard DXN based upon the total weight of the finished water-based product in which it is used\*. This concentration can be adjusted based upon the effectiveness of the biocide. You may experience a slight lowering of the pH of your product after the addition of Giv-Gard DXN. Should it be necessary to adjust the pH of the system, we suggest using 30 lbs. of sodium carbonate for every 100 lbs. of Giv-Gard DXN. Sodium and potassium hydroxide should be used with caution as some color formation may result. Ammonium hydroxide should not be used. A 10% neutralized solution can be prepared by following the instructions on the next page.

For the following industrial applications, Giv-Gard DXN should be used at a level of 0.1%-0.2% by weight of the system to be protected:

- Emulsions (such as latex, PVA, silicone, oil, acrylic, polyethylene, PVC)
- Paints (emulsions)
- Coatings
- Specialty industrial products (such as pigment slurries, dyestuffs, inks, thickeners/gums, lignosulfonates, etc.)
- Textile chemicals and finishes (such as dye levelers, textile auxiliaries, softeners, lubricants, antistats, sizings, print pastes, etc.)
- Industrial adhesives
- Leather processing liquors (such as dyes and wet processing leather finishes)
- Distillate fuels

\* 0.1 lbs. Giv-Gard DXN per 100 lbs. of product (For emulsions weighing the same as water, this will be 1.3 fluid ounces per 10 gallons.)

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PROCEDURE FOR THE PREPARATION OF A NEUTRALIZED SOLUTION

CONTAINING 10% w/w GIV-GARD DXN

Into a suitable mixing vessel (preferably one with rapid agitation) charge:

86.9 parts\*     Water (mw 18) and

3.1 parts\*     Sodium Carbonate (mw 106)

After all the sodium carbonate has dissolved, slowly add

10.0 parts\*     GIV-GARD DXN (mw 174.2)

Agitate for 24 hours. At this time the pH of the solution should be 7.0 - 7.1.

\*Parts = parts by weight

NOTES

- (1) The vessel should be vented to allow for the release of carbon dioxide which forms during the neutralization.
- (2) There was no temperature rise observed in preparing small batches of neutralized Giv-Gard DXN. However, caution should be observed when preparing larger quantities of solution.
- (3) Further adjustment of the pH can be made after the 24-hour neutralization by introduction of additional sodium carbonate.
- (4) Do not alter the order of addition of the reagents - e.g. do not dissolve the Giv-Gard DXN in water first and then add the sodium carbonate.
- (5) The Flash Point of the neutralized solution is 100°F (TCC).

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Irritation/Sensitization (humans)

Repeated insult patch test (Shelanski & Shelanski protocol) with a 1% solution on a panel of 52 subjects produced no irritation or sensitization reactions.

Acute inhalation toxicity (rats)

DXN was administered by inhalation as a vapor/aerosol to Sprague-Dawley CD® rats (5/sex/group) for four hours. Exposure level and particle size distribution were determined hourly by gas chromatography and Delron DCI-6 Cascade impactor, respectively. The mean analytical exposure concentrations were 4.0 and 3.1 mg/L, resulting in mortalities of 40% and 0%, respectively. The 4.0 mg/L was considered a maximum attainable exposure level based on pre-study trials. Therefore, the LC<sub>50</sub> for DXN was greater than this value. Signs of toxicity during the exposure included respiratory and secretory irritation. During the 14-day post-exposure observation period, similar responses persisted during the first week after exposure and then generally abated. A transient adverse effect upon body weight was produced by treatment. Gross postmortem observations were considered unremarkable.

FOR ADDITIONAL TOXICOLOGICAL INFORMATION, CONTACT  
YOUR GIV-GARD DXN SALES REPRESENTATIVE

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HANDLING, STORAGE AND DISPOSAL INFORMATION

Handling: Observe reasonable precautions to avoid ingestion, contact with skin and eyes, and inhalation of vapors. After handling Giv-Gard DXN, wash hands well before eating or drinking.

Storage: Giv-Gard DXN should be stored in a dry, cool, well ventilated area avoiding open flames or other sources of ignition. Keep container closed.

Disposal: Do not contaminate water, feed or food by storage or disposal of Giv-Gard DXN. Wastes resulting from the use of Giv-Gard DXN may be disposed of on site or at an approved waste disposal facility.

Disposal of any wastes must be in accordance with all current federal, state and local laws and regulations.

FOR ADDITIONAL HANDLING, STORAGE AND DISPOSAL INFORMATION  
CONSULT THE CURRENT MSDS FOR GIV-GARD DXN

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ADDITIONAL INFORMATION

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

This product has not been cleared under the Federal Food, Drug and Cosmetic Act for use in the manufacture of adhesives and coatings that may come in contact with food; not for use in cosmetics; not for resale.

Our recommendations for use of this product are based upon tests believed to be reliable. The use of this product being beyond the control of the manufacturer, no guarantee, expressed or implied, is made as to the effects of such or the results to be obtained if not used in accordance with directions and established safe practice. The buyer must assume all responsibility, including injury or damage, resulting from its misuse as such, or in combination with other materials.

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Date of Issue: July 1995

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