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|-------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|----------------------------------------|
| US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (75-767) WASHINGTON, DC 20460 | EPA REGISTRATION NO. 824-7 | DATE OF ISSUANCE FEB 20 1997 |
| | TERM OF ISSUANCE | |
| | NAME OF PESTICIDE PRODUCT Giv-Gard DXN | |

NOTICE OF PESTICIDE: REGISTRATION
 REREGISTRATION
 (Under the Federal Insecticide, Fungicide,
 and Rodenticide Act, as amended)

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Givaudan-Roure Corporation
 100 Delawanna Avenue
 Clifton, NJ 07014

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

Based on your response to the Reregistration Eligibility Document, EPA has reregistered the above named product subject to the comments recorded in the succeeding paragraphs. This action is taken under the authority of section 4(g)(2)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.

1. Make the following labeling changes before you release the product for shipment: (master label)

a. Refer to the enclosed Attachment (Label Review System) for the necessary revisions to the Precautionary Statements and the Statement of Practical Treatment.

b. Refer to the enclosed RED FACT sheet and include the sentence (highlighted): Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

2. Make the following labeling changes before you release the product for shipment: (Technical literature). NOTE: Since a revised bulletin was not submitted for our review, the previously stamped bulletin was restamped for reregistration. The previous label comments are relisted again below.

- a. 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.
- b. Revise the word: biocide to read: microbiocide (applications and Directions for use section of the bulletin) second paragraph.
- c. Delete the word: "etc" (two locations-under the "applications and Directions for Use" section).

A stamped copy of the label and bulletin is enclosed for your records.

Submit one copy of the final printed labeling before releasing the product in channels of trade with the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Sincerely,

Marion J. Johnson Jr.
Product Manager (31)
Antimicrobial Division (7505W)

Enclosures

BEST AVAILABLE COPY

GIVAUDAN-ROURE

GIVAUDAN-ROURE

GIV-GARD

(BRAND OF DIMETHOXANE)

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

CAUTION

Harmful if swallowed, inhaled or absorbed through the skin. This product may cause skin sensitization reactions in some people. 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. Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application. When handlers use closed metering systems, the handlers requirements may be reduced or modified to long-sleeve shirt, long pants, shoes and socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washing, use detergent and hot water. Keep and wash PPE separately from other laundry. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

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.

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. Flush with large quantities of water.

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

If on clothing: Remove contaminated clothing and wash before reuse.

Manufactured by: **GIVAUDAN-ROURE CORPORATION**
100 Delawanna Avenue, Clifton, N.J. 07014

NET CONTENTS: **1 GAL** LBS.

LOT NO.

ACCEPTED
with COMMENTS
to EPA Letter Detail
FEB 20 1997

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the purposes mentioned under FFA Sec. 262

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GIVAUDAN-ROURE

GARD DNX^(R)*

(BRAND OF DIMETHOXANE) BACTERIOSTAT/FUNGISTAT

CAUTION ADDITIONAL PRECAUTIONARY STATEMENTS

PRACTICAL TREATMENT

Use large quantity of water. Do not induce contact with physician or Poison Control.

Get fresh air and call a physician immediately.

Wash thoroughly with soap and water. Flush with plenty of water immediately. Contact physician immediately.

Remove contaminated clothing and wash immediately with plenty of clear water.

GIVAUDAN-ROURE CORPORATION
1000 Mountain Avenue, Clifton, N.J. 07014

1 GAL ACCEPTED COMMENTS EPA Letter District
EB 2 0 1997

ACTIVE INGREDIENT:
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 DNX^(R) (Brand of Dimethoxane) is a microbial growth inhibiting agent for use only in industrial water-based products as outlined below. It is to be used as directed in Givaudan-Roure Corporation's Technical Bulletin.

For use in the following applications, Giv-Gard DNX 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)
- Textile chemicals and finishes (such as dye levelers, textile auxiliaries, softeners, lubricants, antistats, sizings, print pastes)
- 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

CC-1537-C

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GIV-GARD DXN®

(BRAND OF DIMETHOXANE)

BACTERIOSTAT-FUNGISTAT

TECHNICAL LITERATURE

ACCEPTED
with COMMENTS
of EPA Label Dept

~~FEB 20 1997~~
Under the Federal Insecticide,
Fungicide and Disinfectant Act
no pesticide for the control of
insects under FFA Act No.
824-7

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GIVAUDAN-ROURE

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G I V - G A R D D X N[®]

(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
with COMMENTS
by EPA Office of Pesticides
FEB 20 1997
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended by the FIFRA
Amendments of 1972, EPA Reg. No.
824-7

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G I V - G A R D D X N[®]

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

~~CONFIDENTIAL~~

ACCEPTED
with COMMENTS
to EPA Letter Permit

FEB 20 1997

Under the Federal Insecticide, Fungicide, and Rodenticide Act
to amend for the purpose
of registration under EPA Act, etc.

824-7

~~CONFIDENTIAL~~

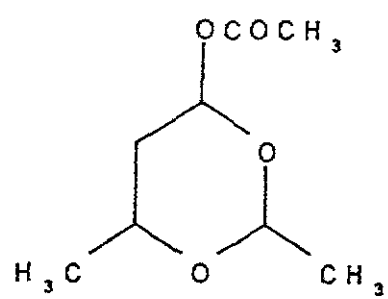
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G I V - G A R D D X N®

(Brand of Dimethoxane)
Bacteriostat - Fungistat

PHYSICAL AND CHEMICAL PROPERTIES



ACCEPTED
with COMMENTS
to EPA Letter Patent
FEB 20 1997
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended by the pesticide
regulation amendments EPA Reg. No.
824-7

| | |
|------------------------------|-----------------------------------------------------------|
| Chemical Name: | 2,6-Dimethyl-m-Dioxan-4-yl Acetate |
| Synonym: | 6-Acetoxy-2,4-Dimethyl-m-Dioxane |
| Chemical Formula: | C ₈ H ₁₄ O ₄ |
| 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

APPROVED
with COMMENTS
by EPA Letter #2084

FEB 20 1997

(Under the National Environmental
Protection Act and Executive Order
12812, the following methods are
approved for the purposes
specified under EPA Reg. No.
824.7

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

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 µL sample using the above operating conditions. Report the sum of the two major peaks.

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OFFICE OF THE SECRETARY
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FEB 20 1997
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
or amended for the purposes
regulated under EPA Reg. No.
824-7

ACTIVITY

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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ANNOUNCEMENT
of COMMENTS
to EPA Letter D-98-001

FEB 20 1997

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended by the pesticide reform law EPA Reg. No. 824-7

TABLE I
ANTIMICROBIAL SPECTRUM OF GIV-GARD DXN

| <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>Pityrosporium 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</i> species (unknown) | 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.

12-9-17

ACCEPTED
with COMMENTS
by EPA Letter dated

APPLICATIONS AND DIRECTIONS FOR USE

FEB 20 1997

Under the Federal Insecticide, Fungicide, and Rodenticide Act the pesticide registered with EPA Reg. No. 8247

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 additional of the reagents - e.g. do not dissolve the Giv-Gard DXN in water first and then added the sodium carbonate.
- (5) The Flash Point of the neutralized solution is 100°F (TCC).

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ACCEPTED
with COMMENTS
to EPA Letter Permit

FEB 20 1997

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the purposes
regulated under EPA Reg. No.
824-7

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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 LC₅₀ 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

BEST AVAILABLE COPY

ACCEPTED
with COMMENTS
in EPA Letter Docket

FEB 20 1997

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

824-7

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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

BEST AVAILABLE COPY

ACCEPTED
with COMMENTS
in EPA Letter Dated

FEB 20 1997

Under the Federal Insecticide, Fungicide, and Plant Growth Regulator Act
as amended, for the pesticide
registered under EPA Reg. No.
824-7

(13)

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.



ACCEPTED
w/ COMMENTS
in EPA Letter Dated

FEB 20 1997

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended by the FIFRA Act of 1974

824-7



Date of Issue: July 1995

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