

**SUNSTAR****Red Cote Liquid**

GUM BUTLER GUIDOR

Safety Data Sheet

*** DRAFT ***

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Revision Date: 03/24/2014 Date of issue: 03/24/2014

Version: 1.0

SECTION 1: IDENTIFICATION**1.1. Product Identifier****Product Name:** Red Cote Liquid**Description:** 2 oz bottle with dropper tip and white cap.**1.2. Intended Use of the Product****Use of the substance/mixture:** Dark red solution highlights harmful bacterial plaque on tooth surfaces and allows the patient to see areas where more brushing and flossing are needed.**1.3. Name, Address, and Telephone of the Responsible Party****Company**

Sunstar Americas, Inc.

4635 West Foster Avenue

Chicago, IL 60630

773-777-4000

www.gumbrand.com**1.4. Emergency Telephone Number****Emergency Number** : 1-800-752-7869 (within US) or 1-312-906-6194 (outside US)**SECTION 2: HAZARDS IDENTIFICATION****2.1. Classification of the Substance or Mixture****Classification (GHS-US)**

STOT RE 2 H373

2.2. Label Elements**GHS-US Labeling****Hazard Pictograms (GHS-US)** :

GHS08

Signal Word (GHS-US)

: Warning

Hazard Statements (GHS-US)

: H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary Statements (GHS-US)

: P260 - Do not breathe mist, spray.

P314 - Get medical advice and attention if you feel unwell.

P501 - Dispose of contents/container according to local, regional, national, and international regulations.

2.3. Other Hazards

A component of this product causes photosensitivity (chemical irritation) when exposed to light.

2.4. Unknown Acute Toxicity (GHS-US) No data available**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS****3.1. Substance**

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Spiro[isobenzofuran-1(3H),9'-[9H]xanthen]-3-one, 2',4',5',7'-tetrabromo-4,5,6,7-tetrachloro-3',6'-dihydroxy-, disodium salt	(CAS No) 18472-87-2	1.5	STOT RE 2, H373

Full text of H-phrases: see section 16

Additional Information: A synonym for the chemical listed above is D&C Red No. 28**SECTION 4: FIRST AID MEASURES****4.1. Description of First Aid Measures****First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.**First-aid Measures After Inhalation:** If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.**First-aid Measures After Skin Contact:** If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

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First-aid Measures After Eye Contact: If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do not induce vomiting. Seek medical attention if swallowed.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: Please refer to the package insert for more detailed information.

Symptoms/Injuries After Inhalation: None expected under normal conditions of use.

Symptoms/Injuries After Skin Contact: Absorbed through the skin. May cause mild skin irritation.

Symptoms/Injuries After Eye Contact: May cause eye irritation.

Symptoms/Injuries After Ingestion: Ingestion of large quantities is likely to be harmful or have adverse effects.

Chronic Symptoms: Prolonged exposure may cause effects in specific organs such as the liver, kidneys, blood, nervous system.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention (show the label if possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Not flammable. Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing.

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.2. Environmental Precautions

None known.

6.3. Methods and Material for Containment and Cleaning Up

Methods for Cleaning Up: For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

6.4. Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Storage Conditions: Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight.

7.3. Specific End Use(s) Dark red solution highlights harmful bacterial plaque on tooth surfaces and allows the patient to see areas where more brushing and flossing are needed.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

No Occupational Exposure Limits (OELs) have been established for this product or its chemical components.

8.2. Exposure Controls

Appropriate Engineering Controls

: Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels to a minimum.

Personal Protective Equipment

: Gloves. Safety glasses.



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- Hand Protection** : Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.
- Eye Protection** : In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.
- Skin and Body Protection** : In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with product is possible.
- Respiratory Protection** : Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

- Physical State** : Liquid
- Appearance** : Red liquid with characteristic cherry flavor.
- Odor** : Characteristic (cherry).
- Odor Threshold** : No data available
- pH** : 6.5 - 7
- Relative Evaporation Rate (butylacetate=1)** : No data available
- Melting/Freezing Point** : No data available
- Boiling Point** : No data available
- Flash Point** : No data available
- Auto-ignition Temperature** : No data available
- Decomposition Temperature** : No data available
- Flammability (solid, gas)** : No data available
- Vapor Pressure** : No data available
- Relative Vapor Density at 20 °C** : No data available
- Relative Density** : 1.01 - 1.03 at 25 °C (77 °F).
- Solubility** : Complete
- Partition coefficient: n-octanol/water** : No data available
- Viscosity** : No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1 Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2 Chemical Stability:** Stable under normal conditions.
- 10.3 Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4 Conditions to Avoid:** Direct sunlight. Extremely high or low temperatures.
- 10.5 Incompatible Materials:** Light.
- 10.6 Hazardous Decomposition Products:** Carbon oxides (CO, CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

- Acute Toxicity:** Not classified
- Skin Corrosion/Irritation:** Not classified (pH: 6.5 - 7)
- Serious Eye Damage/Irritation:** Not classified (pH: 6.5 - 7)
- Respiratory or Skin Sensitization:** Not classified
- Germ Cell Mutagenicity:** Not classified
- Carcinogenicity:** Not classified
- Reproductive Toxicity:** Not classified
- Specific Target Organ Toxicity (Single Exposure):** Not classified
- Specific Target Organ Toxicity (Repeated Exposure):** May cause damage to organs through prolonged or repeated exposure.
- Aspiration Hazard:** Not classified
- Symptoms/Injuries After Inhalation:** None expected under normal conditions of use.
- Symptoms/Injuries After Skin Contact:** Absorbed through the skin. May cause mild skin irritation.
- Symptoms/Injuries After Eye Contact:** May cause eye irritation.
- Symptoms/Injuries After Ingestion:** Ingestion is likely to be harmful or have adverse effects.
- Chronic Symptoms:** Prolonged exposure may cause effects in specific organs such as the liver, kidneys, blood, nervous system.

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SECTION 12: ECOLOGICAL INFORMATION

- 12.1. **Toxicity** No additional information available
- 12.2. **Persistence and Degradability** No additional information available
- 12.3. **Bioaccumulative Potential** No additional information available
- 12.4. **Mobility in Soil** No additional information available

SECTION 13: DISPOSAL CONSIDERATIONS

- 13.1. **Waste treatment methods**

Waste Disposal Recommendations: Dispose of waste according to all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

In Accordance With ICAO/IATA/IMDG/DOT

- 14.1. **UN Number** Not regulated for transport
- 14.2. **UN Proper Shipping Name** Not regulated for transport

SECTION 15: REGULATORY INFORMATION

- 15.1 **US Federal Regulations**

Spiro[isobenzofuran-1(3H),9'-[9H]xanthen]-3-one, 2',4',5',7'-tetrabromo-4,5,6,7-tetrachloro-3',6'-dihydroxy-, disodium salt (18472-87-2) (Synonym: D&C Red No. 28)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

- 15.2 **US State Regulations** Neither this product nor its chemical components appear on any US state lists.

SECTION 16: OTHER INFORMATION, INCLUDING DATA ON DATE OF PREPARATION OR LAST REVISION

Revision date : 03/24/2014

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
H373	May cause damage to organs through prolonged or repeated exposure

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)