

MATERIAL SAFETY DATA SHEET

(In accordance with EU Directive 67/548/EEC and 1999/45/EC, as amended respectively)

SECTION 1: COMPANY AND CHEMICAL INFORMATION

PRODUCT NAME HybenX® Oral Tissue Decontaminant (OTD Liquid) FOR PROFESSIONAL USE ONLY

MANUFACTURER NAME AND ADDRESS:

EPIEN Medical, Inc.
4225 White Bear Parkway
Suite 600
St. Paul, MN 55110
USA

EPIEN MEDICAL CUSTOMER SERVICE PHONE NUMBER:

001 651-653-3380 (8:00 a.m. – 4:30 p.m. Central Time)

Email: customerservice@epien.com

WEBSITES: www.epien.com

24 HOUR EMERGENCY PHONE NUMBER:

SafetyCall International **001 952-852-4659**

SECTION 2: HAZARDS IDENTIFICATION

POTENTIAL ADVERSE HEALTH EFFECTS: HybenX OTD is indicated as a topical rinse/solution that is delivered locally in the oral cavity by the dental professional using an irrigation syringe. For Professional Use Only.

HybenX is to be delivered topically with an irrigation syringe or other means chosen by the dental professional, to the gingival tissues or pockets surrounding the affected tooth/teeth. Treatment should start with the deepest portion and be irrigated thoroughly to the more superficial areas. The product should be applied for 10 to 20 seconds. **(Note: If the patient has not been given a local anesthetic the product may illicit a stinging sensation during application until it is rinsed off.)** Remove HybenX by thoroughly irrigating the oral cavity with water and evacuate with high speed suction. Removal of the product is important to stop the cleaning process. Incidental contact with the oral tissue will/may cause it to turn “white” until the tissue rehydrates itself. The dental professional can then complete the oral hygiene cleaning and dispose of the remaining product. Due to the viscosity of this product, it is recommended to always use a locked tip syringe. **Do not use if the patient is allergic to a material that contains sulfur in any form.**

DERMAL: Mild irritant.

INGESTION: Harmful if swallowed.

OCULAR: Irritant to eyes.

CHRONIC HEALTH EFFECTS: None known.

CARCINOGENICITY: None of the ingredients are considered to be carcinogenic by IARC, NTP, or OSHA.

TARGET ORGANS: Topical

PHYSICAL DESCRIPTION: Purple Liquid

ODOR: Faintly Acrid

NOTE: This is a medical product, packaged in small quantities, and intended for direct application to the inside of the mouth.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous ingredients*	Weight %	CAS #	EINECS #	Classification
Sulfonated phenolics	30-60%	1333-39-7 & 50855-43-1	215-587-0	C; R34
Sulfuric Acid	25-35%	7664-93-9	231-639-5	C; R35
Water (non hazardous)	Balance	7732-18-5		NA

*all ingredients in quantities > 0.1 % that are **potentially** hazardous per definitions found in Directive 67/548/EEC

NE = not established; **NA** = not applicable; **NDA** = no data available; **ACGIH** = American Conference of Governmental Industrial Hygienists;

TWA = Time-weighted average; **STEL** = Short-term exposure limit

SECTION 4: FIRST AID MEASURES

INTENDED SKIN CONTACT: If excess irritation occurs during use, a rinse with sodium bicarbonate (baking soda) solution will neutralize the reaction (use 0.5 teaspoon in 120 ml of water). If condition persists contact healthcare professional. **Do not use if the patient is allergic to a material that contains sulfur in any form.**

UNINTENDED SKIN CONTACT: Flush affected area with water. Seek medical attention if irritation develops and persists.

INGESTION: Rinse out mouth and dilute with fluids (no more than 8 ounces in adults and 4 ounces in children). **Do not induce vomiting.** Call a healthcare professional or Safety Call International.

EYE CONTACT: Flush thoroughly with water. If contact lenses present, remove and flush for additional 15 minutes with water, contact a healthcare professional.

INHALATION: Move to fresh air, seek medical attention if breathing difficulty develops.

SECTION 5: FIRE FIGHTING MEASURES

SUITABLE EXTINGUISHING MEDIA: Alcohol foam, dry chemical or CO₂.

UNSUITABLE EXTINGUISHING MEDIA: Water stream.

UNUSUAL FIRE AND EXPLOSION HAZARDS: Material may spatter when water is first applied.

PROTECTION OF FIREFIGHTERS

HAZARDOUS COMBUSTION PRODUCTS: Carbon monoxide and carbon dioxide, sulfur oxides

SPECIAL PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS: Use approved self-contained breathing apparatus (SCBA) and bunker or turn-out gear at warehouse/storage centers. *Note: Not relevant for dental offices.*

SECTION 6: ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE THE MATERIAL IS SPILLED:
 Industrial or transport spills - Do not attempt to clean up chemical spills without appropriate personal protective equipment (see section 8). Do not touch or walk through spilled material. Soak material up with inert sorbent (DO NOT use organic materials such as sawdust), and transfer to plastic containers for disposal. Keep waste out of sewers, watersheds, and waterways.

SECTION 7: HANDLING AND STORAGE

HANDLING: Avoid eye contact. Avoid skin contact. Avoid breathing mists, sprays or vapors. See comments regarding personal protective equipment (see Section 8).

STORAGE:
 Industrial or transport - Store upright in a cool, dry, well-ventilated area out of direct sunlight. Protect container from damage to avoid spills. Keep containers tightly closed at all times. Do not reuse container. Store away from incompatible materials (see Section 10). Keep out of reach of children.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Hazardous ingredients	ACGIH TLV TWA	ACGIH TLV STEL/C
Hydroxybenzenesulfonics	NE	NE
Sulfuric acid	0.2 mg/m ³	NE

Consult national exposure limits.

ENGINEERING CONTROLS: Transient use of small quantities, as directed, is unlikely to require the use of any engineering (ventilation) controls.

SKIN: Wear chemically resistant gloves (polyethylene) when handling large quantities (i.e., >1 gallon) if splash potential exists.

BODY PROTECTION: Prevent skin contact. If spilled on clothing, remove immediately, flush skin area and rinse garment thoroughly.

EYE PROTECTION: Wear goggles and face shield if potential exists for direct splash to eye tissue.

RESPIRATORY: Use approved respiratory protection as necessary if any of the occupational exposure limits in Section 8 are exceeded. Seek professional advice prior to respirator selection or use. Follow national respirator guidelines.

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SECTION 9: PHYSICAL CHEMICAL PARAMETERS

PHYSICAL STATE: Liquid	APPEARANCE: Purple
ODOR: Faintly Acrid	VAPOR PRESSURE: NA
FLASHPOINT: None	FLAMMABLE LIMITS: UEL NA LEL: NA
AUTOIGNITION TEMPERATURE: NE	VAPOR DENSITY (air=1): >1
% VOLATILE BY VOLUME: NA	EVAPORATION RATE (n-butyl acetate=1): <1
BOILING POINT: NE	FREEZING POINT: NE
SPECIFIC GRAVITY: NE	VISCOSITY: > 700 centipoise
SOLUBILITY IN WATER: Miscible	BULK DENSITY: 1.4g/ml
MELTING POINT: NE	pH: <2

SECTION 10: STABILITY AND REACTIVITY

STABILITY: Stable at standard temperature and pressure.
INCOMPATIBILITIES/MATERIALS AND CONDITIONS TO AVOID: Strong oxidizing and reducing agents, potassium chlorate/perchlorate/permanganate, sodium, lithium, bases, organic material, halogens, metal acetylides, oxides and hydrides, metals (evolves hydrogen gas). Large quantities of product should not be allowed to contact water.
POSSIBILITY OF HAZARDOUS REACTIONS: Hazardous polymerization will not occur.
HAZARDOUS DECOMPOSITION PRODUCTS: Sulphur oxides, carbon dioxide and carbon monoxide

SECTION 11: TOXICOLOGICAL INFORMATION

INGREDIENT BASED INFORMATION: Call 001-952-852-4659 for additional toxicity information on ingredients.
POSSIBLE TARGET ORGANS: Eyes and skin.
MEDICAL CONDITIONS THAT MAY BE AGGRAVATED BY EXPOSURE: Persons with pre-existing skin disorders may be more susceptible to the effects of this material. Do not use if the patient is allergic to a material that contains sulphur in any form.
CARCINOGENS: IARC – No [Significant exposure by inhalation to this product is unlikely – IARC has stated that “occupational exposure to strong-inorganic-acid mists is carcinogenic to humans (Group 1)”.]

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY: Expected to be toxic to aquatic organisms.	PERSISTENCE/DEGRADABILITY: Biodegradable
BIOACCUMULATION/ACCUMULATION: NDA	MOBILITY IN SOIL: NDA

SECTION 13: DISPOSAL INFORMATION

DISPOSAL COMMENTS: Chemicals must be disposed of in compliance with the respective national regulations.

SECTION 14: TRANSPORT INFORMATION

ADR SHIPPING NAME: Phenolsulphonic acid, liquid	UN NUMBER: UN 1803
HAZARD CLASS: 8	PACKING GROUP: II
SUBSIDIARY CLASS: None	MARINE POLLUTANT INFORMATION: NDA
CLASSIFICATION CODE: C3	LIMITED QUANTITIES: L22
TRANSPORT CATEGORY: 2	HAZARD IDENTIFICATION NO.: 80

SECTION 15: REGULATORY INFORMATION

CHEMICAL INVENTORIES: All components of this product listed in Section 3 are included on the European EINECS, U.S. TSCA, and the

Canadian DSL inventory lists.

CLASSIFICATION: C; R35

LABEL:



R35 - Causes severe burns (in larger quantities than contained in a single product dose)
 S1/2 – Keep locked up and out of reach of children.
 S26 – In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
 S45 – In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

SECTION 16: OTHER INFORMATION

TEXT OF ANY RISK PHRASES IN SECTION 3:

R34 – Causes burns. (in larger quantities than contained in a single product dose)
 R35 – Causes severe burns (in larger quantities than contained in a single product dose).

DATE OF PREPARATION: March 2009

REVISION: 1 (original)

INDICATION OF CHANGES: NA

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