

## Safety Data Sheet

### Section 1: Identification

**PRODUCT NAME: HYBENX® Advanced Dental Debridement** **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:**

1-651-653-3380 (8:00 a.m. – 4:30 p.m. Central Time)

**Email:** [customerservice@epien.com](mailto:customerservice@epien.com)

**WEBSITES:** [www.epien.com](http://www.epien.com), [www.HYBENXrootcanalcleanser.com](http://www.HYBENXrootcanalcleanser.com)

**24 HOUR EMERGENCY PHONE NUMBER:**

Safety Call International (866) 516-0243 / (952)-852-4659

HYBENX is indicated for use as an adjunctive rinse of tooth root surfaces during periodontal debridement procedures to help with the removal of contaminated debris from the sulcus;

HYBENX is indicated for use as an adjunctive rinse of exposed dentin surfaces in cavity preparations to assist in the removal of contaminated debris and smear layer;

HYBENX is indicated for use as an adjunctive rinse of the root canal systems and adjacent tooth surfaces during standard professional dental procedures to enhance the removal of post-instrumentation dentinal debris and smear-layer within the root canal systems.

HYBENX is contraindicated for use with calcium hydroxide paste and similar, related products. **Do not use if the patient is allergic to a material that contains sulfur in any form.**

### Section 2: Hazard(s) Identification

**HAZARD CLASS:** 8

**LABELS:** CORROSIVE



**NOTE:** *This is a medical product packaged in small quantities.*

### 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
<b>Non-Hazardous Ingredients</b>				
Water	Balance	7732-18-5	231-791-2	NA
FD&C Red #40 (Allura Red AC)	< 1 %	25956-17-6	247-368-0	NA
(Gel contains: Colloidal Silica)	1-5 %	112945-52-5	NA	NA

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

### Section 4: First-Aid Measures

**SYMPTOMS/EFFECTS**

**DERMAL:** Mild irritant

**INGESTION:** Harmful if swallowed

**OCULAR:** Irritant to eyes.

**CHRONIC HEALTH EFFECTS:** No

### **INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED**

**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 water (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 CO<sub>2</sub>.

**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, carbon dioxide, and 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. See section 8 for protective equipment.

### **Section 6: Accidental Release Measures**

#### **STEPS TO BE TAKEN IN CASE THE MATERIAL IS SPILLED:**

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 in a cool, dry, well-ventilated area out of direct sunlight at room temperature 15-30 °C or 59-86 F. Protect package from damage to avoid spills. Keep containers tightly closed at all times. Store away from incompatible materials (see Section 10). Keep out of reach of children.

### **Section 8: Exposure Controls/Personal Protection**

<b>Hazardous ingredients*</b>	<b>OSHA PEL** TWA</b>	<b>OSHA PEL STEL/C</b>	<b>ACGIH TLV TWA</b>	<b>ACGIH TLV STEL/C</b>
Sulphonated Phenolics	NE	NE	NE	NE
Sulfuric Acid	1.0 mg/m <sup>3</sup>	NE	0.2 mg/m <sup>3</sup>	NE

**NE** = not established **NA** = not applicable **NDA** = no data available

\*all ingredients in quantities > 1.0 % (0.1 % for carcinogens) that are **potentially** hazardous per OSHA definitions (skin) - indicates harmful amounts may be absorbed through the skin.

\*\* Some States enforce the PEL's that OSHA promulgated in 1989, which were subsequently vacated by the U.S. Supreme Court. Check with your State OSHA agency to determine which PEL is enforced in your jurisdiction.

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

**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 PROTECTION:** 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.

## Section 9: Physical and Chemical Properties

<b>PHYSICAL STATE:</b> Liquid or Gel	<b>COLOR:</b> Opaque Purple
<b>ODOR:</b> Faintly Acrid	<b>VAPOR PRESSURE:</b> NA
<b>FLASH POINT:</b> None	<b>FLAMMABLE LIMITS:</b> UEL NA LEL: NA
<b>AUTOIGNITION TEMPERATURE:</b> NE	<b>VAPOR DENSITY (air=1):</b> >1
<b>% VOLATILE BY VOLUME:</b> NA	<b>EVAPORATION RATE (n-butyl acetate=1):</b> <1
<b>BOILING POINT:</b> NE	<b>FREEZING POINT:</b> NE
<b>SPECIFIC GRAVITY:</b> NE	<b>VISCOSITY:</b> > 700 centipoise
<b>SOLUBILITY IN WATER:</b> Miscible	<b>BULK DENSITY:</b> 1.6 g/ml
<b>MELTING POINT:</b> NE	<b>pH:</b> <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:** Sulfur oxides, carbon dioxide and carbon monoxide.

## Section 11: Toxicological Information

**POSSIBLE TARGET ORGANS:** Eyes and skin.

**PRODUCT BASED INFORMATION:** Because of its nature, prolonged use on normal tissue should be avoided. HYBENX will eventually slough any tissue to which it is applied if excess volume is used and an application time is grossly extended. **Do not use if allergic to sulfur in any form.**

**INGREDIENT BASED INFORMATION:** Call Safety Call for additional toxicity information on ingredients.

**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 sulfur 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)”].

**SARA TITLE III (Superfund Amendments and Reauthorization Act)**

**Section 302 Extremely Hazardous Materials:** Sulfuric acid

**Section 304 Notification of Accidental Release:** None

**Sections 311/312 Hazard Categories:** Immediate (acute) Health Effects: Yes  
Delayed (Chronic) Health Effects: No  
Fire Hazard: No

**Sudden Release of Pressure Hazard:** No  
**Reactivity Hazard:** No

### Section 12: Ecological Information\* (non-mandatory)

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

### Section 13: Disposal Considerations\* (non-mandatory)

**DISPOSAL COMMENTS:** Chemicals must be disposed of in compliance with the respective national regulations. Chemicals must be disposed of in compliance with the respective national regulations. This material (as packaged) is most likely considered a RCRA hazardous waste (D002, Corrosive). Be aware that the waste owner has responsibility for final disposal. Regulations may also apply to empty containers, liners or rinsate. Laws may change or be reinterpreted; state and local regulations may be different from federal regulations. This information applies to materials as manufactured; contamination or processing may change waste characteristics and requirement.

### Section 14: Transport Information\* (non-mandatory)

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

### Section 15: Regulatory Information\* (non-mandatory)

**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

**United States**

**REPORTABLE QUANTITIES:** Sulfuric acid = 1000 lbs.

**California Proposition 65 Warning:** None

**Canada:** This product has been classified in accordance with the hazard criteria of the *Controlled Products Regulations* and the MSDS contains all the information required by the *Controlled Products Regulations*.

**WHMIS Classification:** D1A, E

### Section 16: Other Information

This SDS replaces all previous versions for this product. Please discard all previous versions as they may contain changed or obsolete information. The information in this SDS was obtained from sources we believe are reliable. However, the information is provided without any representation or warranty, expressed or implied, regarding its accuracy or completeness. Reviewed by Safety Call International, PLLC, Bloomington, MN, USA