EPIEN Medical

Safety Data Sheet

Section 1: Identification

PRODUCT NAME: DEBACTEROL® Canker Sore Pain Relief **FOR PROFESSIONAL USE ONLY**

MANUFACTURER NAME AND ADDRESS:

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

EPIEN MEDICAL CUSTOMER SERVICE PHONE NUMBER:
(888) 884-4675 (8:00 a.m. – 4:30 p.m. Central Time)
1-651-653-3380

Email: customerservice@epien.com
WEBSITE:
www.epien.com
www.debacterol.com

24 HOUR EMERGENCY PHONE NUMBER:
SafetyCall International (866) 516-0243 / (952)-852-4659

Debacterol® is indicated in the topical treatment of ulcerating lesions of the oral cavity such as Recurrent Aphthous Stomatitis (Canker Sores). Debacterol provides relief from the pain and discomfort of oral mucosal ulcers.

Debacterol is not intended for treatment of vesicular lesions, such as Cold Sores or Fever Blisters. **Do not use if 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, and intended for direct application to the inside of the mouth (for oral ulcers).***

Section 3: Composition/Information on Ingredients

Hazardous Ingredients	Weight %	CAS #
Sulfonated Phenolics	30-60 %	1333-39-7 & 50855-43-1
Sulfuric Acid	25-35 %	7664-93-9
Water (non hazardous)	Balance	7732-18-5

*all ingredients in quantities >1.0 % that are **potentially** hazardous per OSHA definitions **NE**=not established **NA**=not applicable **NDA**=no data available

Section 4: First-Aid Measures

SYMPTOMS/EFFECTS

DERMAL: Mild Irritant
INGESTION: Harmful if swallowed
OCULAR: Irritant to eyes
CHRONIC HEALTH EFFECTS: None known

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 120ml 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 SafetyCall 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, carbon dioxide, and sulfur oxides.

SPECIAL PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS: Use NIOSH/MSHA approved SCBA and bunker or turn-out gear. See section 8 for personal 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: Store in a cool, dry, well ventilated area out of direct sunlight at room temperature 15-30℃ or 59-86℉. 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

Hazardous ingredients*	OSHA PEL** TWA	OSHA PEL STEL/C	ACGIH TLV TWA	ACGIH TLV STEL/C
Sulfonated Phenolics	NE	NE	NE	NE
Sulfuric Acid	1.0 mg/m3	NE	0.2 mg/m3	NE

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

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

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

BODY PROTECTION: Prevent skin contact. Consumer: 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: NIOSH approved respiratory protection is necessary if any of the occupational exposure limits in Section 2 are exceeded. Seek professional advice prior to respirator selection or use. Follow OSHA respirator regulations (29 CFR 1910.134).

Section 9: Physical and Chemical Properties

PHYSICAL STATE: Liquid	**APPEARANCE:** Dark Brown
ODOR: Smoky creosote odor	**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:** NE
SOLUBILITY IN WATER: Miscible	**BULK DENSITY:** NE
MELTING POINT: NE	**PH:** <2

Section 10: Stability and Reactivity

STABILITY: Stable at STP (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

PRODUCT BASED INFORMATION: Because of its nature, prolonged use on normal tissue should be avoided. Debacterol 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 sulphur in any form.**

INGREDIENT BASED INFORMATION: Call SafetyCall International 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 sulfur in any form.

CARCINOGENS: IARC – No*; NTP – None; OSHA – None [* 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:** Yes

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

Section 12: Ecological Information* (non-mandatory)

ECOTOXICITY: Would be expected to be toxic to aquatic organisms but not with the small quantities contained in a single product dose.	**PERSISTENCE/DEGRADABILITY:** NDA
BIOACCUMULATION/ACCUMULATION: NDA	**MOBILITY IN SOIL:** NDA

Section 13: Disposal Considerations* (non-mandatory)

DISPOSAL COMMENTS: 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 requirements.

Section 14: Transport Information* (non-mandatory)

SHIPPING NAME: : Phenolsulfonic acid, liquid	**UN NUMBER:** 1803
HAZARD CLASS: 8	**PACKING GROUP:** II
SUBSIDIARY CLASS: None	**MARINE POLLUTANT INFORMATION:** NDA

Section 15: Regulatory Information* (non-mandatory)

CHEMICAL INVENTORIES: All components of this product listed in section 2 are listed on the TSCA inventory list, the DSL/NDSL and the EINECS.
REPORTABLE QUANTITIES: Sulfuric acid = 1000 lbs.
California Proposition 65 Warning: None

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 SafetyCall International, PLLC, Bloomington, MN, USA