

Document Detail

Type: 0090-MSDS
Document No.: 0090-SDS-010[00]
Title: Xylocaine 2% w/v with Adrenaline (Epinephrine) 1:80,000 DENTAL SDS - UK and Ireland
Comment
Status: CURRENT
Effective Date: 15-Jan-2018

Approvals

<u>Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
DPD Research and Development	Tom Simonton	12-Jan-2018 7:10 pm	GMT
Pharma Regulatory Affairs Approver	Lakeisha R Williams	12-Jan-2018 5:01 pm	GMT
Pharma Regulatory Affairs Approver	Deb Crouse	12-Jan-2018 4:50 pm	GMT
Pharma Marketing Approver	Richard Tootchen	12-Jan-2018 5:43 pm	GMT
Pharma Quality Assurance Approver	Candace Walker	12-Jan-2018 4:53 pm	GMT
Pharma Marketing Approver	Joe Santos	12-Jan-2018 7:11 pm	GMT
DPD Document Control	Lucy Brenneman	15-Jan-2018 3:09 pm	GMT
Pharma Document Control	Beth Bodnar	12-Jan-2018 7:14 pm	GMT



Safety Data Sheet

Safety Data Sheet conforms to Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 2015/830, US 29CFR1910.1200, and Canada Hazardous Products Regulation.

Date Issued: 02 January 2018
Document Number: SDS-010
Date Revised: New SDS
Revision Number: 00

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled): Xylocaine® 2% w/v with Adrenaline (Epinephrine)
1:80,000 DENTAL

Part/Item Number: 102, 502, 702

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use: Local anesthetic solution for dental use.
Restrictions on Use: For Professional Use Only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: DENTSPLY Pharmaceutical
Manufacturer/Supplier Address: 1301 Smile Way
York, PA 17404
Manufacturer/Supplier Telephone Number: 800-989-8826 or 717-767-8502 (Product Information)
Email address: DPDE-CustomerService@dentsplysirona.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number: 800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	Environmental	Physical
Not Hazardous	Not Hazardous	Not Hazardous

2.2 Label Elements:

None Required

Signal Word: None

Hazard Phrases	Precautionary Phrases
None Required	None Required

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS # / REACH Registration #	Classification	WT %
Non-hazardous ingredients	Mixture	Mixture	Not Hazardous	Balance
Lidocaine Hydrochloride Monohydrate	6108-05-0	200-803-8	Acute Tox. 4 (H302)	2.0
Epinephrine Bitartrate	51-42-3	200-097-1	Acute Tox. 2 (H300, H310, H330) Aquatic Chronic 3 (H412)	<0.1
Sodium Metabisulfite	7681-57-4	231-673-0	Acute Tox. 4 (H302) Eye Dam. 1 (H318) EUH031	<0.1

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS Classifications.

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

Eye	Flush victim's eyes with large quantities of water, while holding the eyelids apart. Get medical attention if irritation develops or persists.
Skin	Flush thoroughly with water. Remove and launder contaminated clothing before re-use.
Inhalation	None needed under normal use conditions. If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	Rinse mouth with water and give 1 glass of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if discomfort persists.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

May cause slight eye and skin irritation. Contact with skin, eyes or mucous membranes may cause numbness. May cause allergic reactions if inhaled or swallowed by some asthmatics and other 'sulfite sensitive' individuals.

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

Immediate medical attention should not be required. The safety and effectiveness of local anesthetics depend upon proper dosage, correct technique, adequate precautions and readiness for emergencies.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media: Use media appropriate for the surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture:

Product is not flammable. Thermal decomposition may yield chlorine, hydrogen chloride, or oxides of nitrogen.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures/Precautions for Fire Fighters:	Cool fire exposed containers and structures with water. Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.
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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid contact with eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8.

6.2 Environmental Precautions:

Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Contain and collect using an inert absorbent material and place in appropriate containers for disposal. Clean spill site with water.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling. Use in accordance with package instructions.

7.2 Conditions for Safe Storage, Including Any Incompatibilities: Store in accordance with label recommendations.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:**Occupational Exposure Limits:**

Non-hazardous Ingredients	None Established
Lidocaine Hydrochloride Monohydrate	None Established
Epinephrine Bitartrate	None Established
Sodium Metabisulfite	5 mg/m ³ TWA ACGIH TLV
	5 mg/m ³ TWA UK WEL
	5 mg/m ³ Belgium OEL

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: No special controls required.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Follow facility requirements. Wear safety glasses when the possibility exists for eye contact due to splashing or spraying material. In Europe follow EN 166.

Specific Skin Protection: Follow facility requirements. Wear impervious gloves to prevent skin contact. In Europe follow EN 374.

Specific Respiratory Protection: Follow facility requirements.

Specific Thermal Hazards: None required.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Clear, colorless liquid	Explosive limits:	LEL: Not applicable UEL: Not applicable
Odor:	Odorless	Vapor pressure (mmHg):	Not available
Odor threshold:	Not available	Vapor density:	Not available
pH:	Not available	Relative density:	Not available
Melting/freezing point:	Not available	Solubility(ies):	Aqueous solution
Initial boiling point and boiling range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	Not flammable	Auto-ignition temperature:	Not available
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability (solid, gas):	Not applicable	Viscosity:	Not available
Explosive Properties:	Not explosive	Oxidizing Properties:	Not an oxidizer

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Non-reactive.

10.2 Chemical Stability: Stable under normal storage and handling conditions.

10.3 Possibility of Hazardous Reactions: None known.

10.4 Conditions to Avoid: Avoid high temperatures. Protect from light. Do not freeze this product.

10.5 Incompatible materials: Avoid contact with water-reactive materials and strong reducing agents.

10.6 Hazardous Decomposition Products: Thermal decomposition may produce chlorine, hydrogen chloride, or oxides of nitrogen.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Liquid can cause slight irritation with tears and blurred vision. Numbness may occur.

Skin: Direct skin contact may cause slight skin irritation and numbness.

Ingestion: Swallowing may cause gastrointestinal irritation. Numbness may occur.

Inhalation: None expected from normal use. May cause slight respiratory tract irritation with coughing and anesthetic effects.

Chronic Health Effects: May cause hypersensitivity. Exposure to sodium metabisulfite may cause allergic reactions in some asthmatics and sulfite sensitive individuals.

Irritation: No data available. This product is not expected to cause eye irritation.

Corrosivity: No data available. This product is not expected to be corrosive.

Sensitization: Lidocaine: Allergic and anaphylactic reactions associated with lidocaine can occur in a small amount of the population. Sodium metabisulfite: In rare cases, may cause allergic reactions and asthma in some asthmatics and sulfite sensitive individuals. Reactions can include anaphylactic symptoms and life-threatening or less severe asthmatic episodes.

Carcinogenicity: None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: No data available. This product is not expected to cause mutagenic activity.

Aspiration Hazard: Not an aspiration hazard.

Acute Toxicity Data:

Lidocaine Hydrochloride Monohydrate: Oral rat LD50- 317 mg/kg

Epinephrine Bitartrate: Oral mouse LD50- 4 mg/kg

Sodium Metabisulfite: Oral rat LD50- 1131-3200 mg/kg

Reproductive Toxicity Data: No effects on male or female fertility were observed in rats for epinephrine 1:100,000 administered subcutaneously in doses up to 80 mg/kg/day (approximately 2 times the MRHD based on body surface area). For lidocaine, no teratogenic effects were noted in embryo-fetal development studies in which rats or rabbits were treated during the period of organogenesis. Embryotoxicity was seen in rabbits, at maternally toxic doses. In rats, decrease pup survival was seen for dams treated during late pregnancy and lactation, at a dose that was maternally toxic and affected the duration of gestation. This product is not expected to cause reproductive or developmental toxicity.

Specific Target Organ Toxicity Single Exposure (STOT-SE): No data available.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE): No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity: Sodium Metabisulfite: 96 hr LC50 Fish- 32 mg/L, 48hr EC50 Daphnia- 89 mg/L, 72 hr EC50 Algae- 48 mg/L
12.2 Persistence and Degradability: No data available.
12.3 Bio-accumulative Potential: No data available.
12.4 Mobility in Soil: No data available.
12.5 Results of PBT and vPvB Assessment: No data is currently available.
12.6 Other Adverse Effects: No data is currently available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Waste Treatment Recommendations: Treat in accordance with national and local regulations.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None	None	None
ADR/RID	None	Not Regulated	None	None	None
IMDG	None	Not Regulated	None	None	None
IATA/ICAO	None	Not Regulated	None	None	None

14.6 Special Precautions for User: Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product is not subject to reporting under CERCLA. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): This product is a pharmaceutical drug and not subject to chemical notification requirements.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories: See OSHA Hazard Classification in Section 2.

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None

State Regulations

California: This product does not contain substances known to the state of California to cause cancer and/or reproductive toxicity.

International Regulations

Canadian Environmental Protection Act: This product is a pharmaceutical drug and not subject to chemical notification requirements.

European Inventory of Existing Chemicals (EINECS): This product is a pharmaceutical drug and not subject to chemical notification requirements.

EU REACH: This product is a pharmaceutical drug and not subject to chemical notification requirements.

Australian Inventory of Chemical Substances: This product is a pharmaceutical drug and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a pharmaceutical drug and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a pharmaceutical drug and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a pharmaceutical drug and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a pharmaceutical drug and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health –1 Flammability – 0 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:

Acute Tox. 2 Acute Toxicity Category 2

Acute Tox. 4 Acute Toxicity Category 4

Aquatic Chronic 3 Aquatic Chronic Toxicity Category 3

Eye Dam. 1 Eye Damage Category 1

H300 Fatal if swallowed.

H302 Harmful if swallowed.

H310 Fatal in contact with skin.

H318 Causes serious eye damage.

H330 Fatal if inhaled.

H412 Harmful to aquatic life with long lasting effects.

EUH031 Contact with acids liberates toxic gas.

Supersedes: None

Date Updated: 2 January 2018

Revision Summary: New SDS

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.