



SAFETY DATA SHEET

2% Xylocaine™ Dental with epinephrine 1:50,000 (Lidocaine Hydrochloride 2% and epinephrine 1:50,000 injection)

2% Xylocaine™ Dental with epinephrine 1:100,000 (Lidocaine Hydrochloride 2% and epinephrine 1:100,000 injection)

SDS-002-XYLOCAINE W/EPI REV 01, April 2017

DENTSPLY International
DENTSPLY Pharmaceutical

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

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

1.1 Product Identifier:

Trade Name (as labeled): 2% Xylocaine™ Dental with epinephrine 1:50,000 (Lidocaine Hydrochloride 2% and epinephrine 1:50,000 injection)
2% Xylocaine™ Dental with epinephrine 1:100,000 (Lidocaine Hydrochloride 2% and epinephrine 1:100,000 injection)

Part/Item Number(s): 20016, 22216
80015, 82215

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

Recommended Use: Local anesthetic solution for use in peripheral nerve blocks

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: 1-800-989-8825

Email address: webmaster@dentsply.com



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1.4 Emergency Telephone Number: 1-800-989-8825

Please report all incidents to the company contacts listed above.

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification: This product is exempt from WHMIS 2015 as a drug product. Information provided is for worker education and training purposes.

Health	Environmental	Physical
Specific Target Organ Toxicity – Single Exposure: Narcotic effects, Category 3 (H336)	Not Hazardous	Not Hazardous

EU Classification: Not classified as dangerous

2.2 Label Elements:



Signal Word: Warning

Hazard Phrases	Precautionary Phrases
H336 – May cause drowsiness or dizziness May cause skin and/or eye irritation Causes central nervous system effects such as drowsiness, confusion, excitability and nervousness. Acts as a depressant on the cardiovascular system. Avoid use in individuals with hypersensitivities to amide-type anesthetics. Use with caution in individuals with diabetes and/or severe hypertension. CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOLOGICAL INFORMATION Signs and Symptoms of Overexposure: Drowsiness, confusion, excitability, nervousness, drop in blood pressure, fatigue, bluish discoloration of fingernails, lips, or skin, difficulties in breathing.	Prevention P261 – Do not breathe mist/vapours/spray P271 – Use in a well ventilated area Response P304 + P430 – If inhaled – remove victim to fresh air and keep at rest in a position comfortable for breathing P312 – Call a POISON CENTER or doctor/physician if you feel unwell Storage P405 – Store locked up Disposal P501 – Dispose of contents/container in accordance with local/provincial/federal regulations

2.3 Other Hazards: None known.



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3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Non-hazardous ingredients	Mixture	Mixture	Not Hazardous	<98
Lidocaine Hydrochloride	137-58-6	205-302-8	Xn, Xi R22, R36 Acute Tox. 3 H301 Eye Irrit. 2A H319	2.0
Epinephrine Bitartrate	51-42-3	200-097-1	T R24/25 Acute Tox 3 H301, 311	0.001-0.002

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

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

Eye	Flush victim's eyes with large quantities of water for at least 15 minutes, while holding the eyelids apart. Get medical attention if irritation develops or persists.
Skin	Wash skin thoroughly with soap and water. Get medical attention if irritation occurs and persists. Remove and launder clothing before re-use.
Inhalation	Remove victim to fresh air. Get medical attention if symptoms of exposure occur.
Ingestion	If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. Get medical attention if you feel unwell.
Personal Protective Equipment for First Aid Responders	Wear impermeable gloves to avoid skin contact (e.g. nitrile, natural rubber).

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

May cause slight eye and skin irritation. Skin contact may cause numbness.

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

Immediate medical attention should not be required.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.



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5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
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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:	Fight fire from safe distance or protected location. Water may be ineffective unless used as a fine spray or fog. Use water to cool fire-exposed containers. Contain water used in firefighting from entering sewers or natural waterways.
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Precautions for Fire Fighters:	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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Recommended Protective Equipment for Fire Fighters:



EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

6.2 Environmental Precautions:



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Prevent spills from entering sewers and watercourses. Cover drains.

6.3 Methods and Material for Containment and Cleaning up:

Clean up spills with normal procedures used for non-hazardous liquids. This can include: absorb spill with inert material, then place in a chemical waste container. Clean surface thoroughly with water to remove residual contamination.

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:

Caution should be used to prevent against ingestion and contact with eyes
Handle with care to avoid breakage.

7.2 Conditions for Safe Storage, Including Any Incompatibilities: Store in a cool, dry place. Avoid extremes in temperature.

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	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established



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Lidocaine	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Epinephrine	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Biological Exposure Limits: None Established		

8.2 Exposure Controls:
Appropriate Engineering Controls: Use with local exhaust ventilation to minimize exposure levels.
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. Specific Skin Protection: Follow facility requirements. Wear impervious gloves to prevent skin contact. Specific Respiratory Protection: Follow facility requirements. Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment			
EYES/FACE	HANDS	RESPIRATORY	SKIN

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Clear, colorless liquid	Explosive limits:	LEL: Not available UEL: Not available
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Odor:	Odorless	Vapor pressure (mmHg):	17 mmHg @ 20°C
Odor threshold:	Not available	Vapor density:	0.6 (Air = 1)
pH:	Not available	Relative density:	1.0
Melting/freezing point:	32°F (0°C)	Solubility(ies):	Complete
Initial boiling point and boiling range:	212°F (100°C)	Partition coefficient: n-octanol/water:	Not available
Flash point:	Not flammable	Auto-ignition temperature:	Not available
Evaporation rate:	1 (Butyl acetate = 1)	Decomposition temperature:	Not available
Flammability (solid, gas):	Not applicable	Viscosity:	Not available
Explosive Properties:	None	Oxidizing Properties:	None

9.2 Other Information: None available



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10. STABILITY AND REACTIVITY

10.1 Reactivity: Not reactive.

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: None known.

10.4 Conditions to Avoid: None known.

10.5 Incompatible materials: Incompatible with compounds which react violently with water.

10.6 Hazardous Decomposition Products: None

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Liquid can cause slight irritation with tears and blurred vision. May cause numbness of sensation.

Skin: May cause slight skin irritation and numbness.

Ingestion: May cause slight gastrointestinal irritation.

Inhalation: May cause slight respiratory tract irritation with coughing and anesthetic effects.

Chronic Health Effects: None known.

Irritation: May cause slight eye and skin irritation.

Corrosivity: No data available.

Sensitisation: Allergic and anaphylactic reactions associated with lidocaine in Xylocaine™ can occur in a small amount of the population.

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

Mutagenicity: No data available.

Medical Conditions Aggravated by Exposure: None known.

Acute Toxicity Data:

Not expected to be acutely toxic.

Acute measures of toxicity (i.e. LD50 and LC50) are not available for this mixture.



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LD50 for Lidocaine Hydrochloride: 317 mg/kg oral rat LD50 for Epinephrine Bitartrate: 4 mg/kg oral mouse
Reproductive Toxicity Data: No significant effects were observed on fetal development. However, animal studies have found that continuous exposure throughout pregnancy may decrease birth weight.
Specific Target Organ Toxicity (STOT): <u>Single Exposure:</u> Causes central nervous system effects such as drowsiness, confusion, excitability and nervousness. Acts as a depressant on the cardiovascular system. <u>Repeated Exposure:</u> Repeat or chronic exposure may cause hypersensitivity and the development of methemoglobinemia.

12. ECOLOGICAL INFORMATION

12.1 Toxicity: No data available.
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 available.
12.6 Other Adverse Effects: No data available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:
Regulations: Dispose in accordance with all national and local regulations.
Properties (Physical/Chemical) Affecting Disposal: None currently known.
Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION



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	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	Not applicable
ADR/RID	None	Not Regulated	None	None	Not applicable
IMDG	None	Not Regulated	None	None	Not applicable
IATA/ICAO	None	Not Regulated	None	None	Not applicable

14.6 Special Precautions for User: Avoid temperature extremes. Prevent from freezing.

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 medical device 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:

Immediate Hazard:	No	Pressure Hazard:	No
Delayed Hazard:	No	Reactivity Hazard:	No
Fire Hazard:	No		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		



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State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
None		

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): This product is exempt from WHMIS 2015 as a drug product.

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

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

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

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

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

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

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

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

Philippine Inventory of Chemicals and Chemical Substances: This product is a pharmaceutical formulation 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:

Xn Harmful



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Xi Irritant

T Toxic

R22 Harmful if swallowed.

R24/25 Toxic in contact with skin and if swallowed.

R36 Irritating to eyes.

Acute Tox. 3 Acute Toxicity Category 3

Acute Tox. 4 Acute Toxicity Category 4

Eye Irrit. 2 Eye Irritation Category 2

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H319 Causes serious eye irritation.

Supersedes: 06 March 2017

Date of Current Revision: 17 April 2017

Revision Summary: Added Canadian part numbers, changed the emergency contact number. Updated sections: 2, 3, 4, 6, 7, 11.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.