

SAFETY DATA SHEETS

This SDS packet was issued with item:

072806602

N/A

MATERIAL SAFETY DATA SHEET

PRODUCT ID: PRILOCAINE HYDROCHLORIDE INJECTION

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Prilocaine Hydrochloride USP, 4% Injection
Brand Name:	CITANEST® PLAIN DENTAL (prilocaine hydrochloride injection, USP)
Manufacturer / Supplier:	DENTSPLY Pharmaceutical 1301 Smile Way York, PA, USA 1-800-989-8825 http://www.dentsply.com
Prepared By:	Novocol Pharmaceutical in conjunction with a third party consultant
Emergency Phone Number:	1-416-522-3854
Product Use:	Local anesthetic solution for use in peripheral nerve blocks
Date of Preparation:	August 15, 2010

SECTION 2: HAZARDS IDENTIFICATION

Emergency Overview:	Clear, odourless liquid May cause severe eye irritation and permanent damage 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.
WHMIS Regulatory Status:	Not WHMIS-Controlled
Potential Health Effects:	Routes of Exposure: eye, skin, ingestion Eye: May cause severe irritation, permanent damage, allergic reaction Skin: May cause irritation, allergic reaction Ingestion: May cause irritation, allergic reaction Chronic Effects: May cause hypersensitivity. Associated with the development of methemoglobinemia. Signs and Symptoms of Overexposure: Drowsiness, confusion, excitability, nervousness, drop in blood pressure, fatigue, bluish discoloration of fingernails, lips, or skin, difficulties in breathing. CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOLOGICAL INFORMATION
Potential Environmental Effects:	Not available

MATERIAL SAFETY DATA SHEET

PRODUCT ID: PRILOCAINE HYDROCHLORIDE INJECTION

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Identity	Concentration (Percent weight/weight)	CAS Number	LD ₅₀	LC ₅₀
Prilocaine Hydrochloride	4	1786-81-8	550 mg/kg skin mouse	Not available

SECTION 4: FIRST AID MEASURES

Inhalation:	Remove patient from exposure.
Eye Contact:	Immediately flush eyes with plenty of water for at least 15 minutes while holding eyelids open. Rinse continuously while on way to get medical attention.
Skin Contact:	Remove contaminated clothing. Wash skin with soap and water
Ingestion:	Get immediate medical attention Do not induce vomiting unless instructed to do so by poison control or physician.

SECTION 5: FIRE FIGHTING MEASURES

Conditions of Flammability:	Not flammable
Means of Extinction:	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials
Sensitivity to Mechanical Impact:	No
Sensitivity to Static Discharge:	No
Hazardous Combustion Products:	Not available
Special Protective Actions for Firefighters:	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing

SECTION 6: ACCIDENTAL RELEASE MEASURES

Leak and Spill Procedure:	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.
Other Information:	Caution should be used to prevent against ingestion and contact with eyes. Wear safety glasses with sideshields.

MATERIAL SAFETY DATA SHEET

PRODUCT ID: PRILOCAINE HYDROCHLORIDE INJECTION

SECTION 7: HANDLING AND STORAGE

Handling Procedures and Equipment:	Caution should be used to prevent against ingestion and contact with eyes. Handle with care to avoid breakage.
Storage Requirements:	Store in a cool, dry place. Avoid extremes in temperature.
Packaging:	USP Type 1 glass cartridge with rubber stopper and cap

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:	Chemical Agent	Occupational Exposure Limits (OEL)			
		ACGIH ^a		Ontario	
		TWA ^b	STEL ^c	TWA ^b	STEL ^c
	Prilocaine Hydrochloride	Not available	Not available	Not available	Not available
a – American Conference of Governmental Industrial Hygienists b – Time Weighted Average c - Short-term Exposure Limit					
Personal Protective Equipment (PPE):					
Gloves (specify):	Not normally required				
Respiratory (specify):	Not normally required				
Eye (specify):	If potential for contact with eyes exists, wear safety glasses with side shields.				
Footwear (specify):	Not normally required				
Other Equipment (specify):	RESUSCITATIVE EQUIPMENT AND DRUGS SHOULD BE AVAILABLE DURING DENTAL PROCEDURES				
Engineering Controls (e.g. ventilation, enclosed process, specify):	Not normally required				

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid
Odour and Appearance:	Clear and odourless
Odour Threshold:	Not applicable
Specific Gravity (water=1):	1
Solubility in Water	Soluble
Co-efficient of Water/Oil Distribution:	Not available
Vapour Pressure:	17 mm Hg @ 20°C

MATERIAL SAFETY DATA SHEET

PRODUCT ID: PRILOCAINE HYDROCHLORIDE INJECTION

Boiling Point (°C):	100°C
Melting/Freezing Point (°C):	0°C
pH:	Not available
Vapour Density (Air=1):	0.6
Evaporation Rate (Butyl Acetate=1):	1
Flashpoint (°C) and Method:	Not flammable (water based)
Upper Flammable Limit (%):	Not available
Lower Flammable Limit (%):	Not available
Auto-ignition Temperature (°C):	Not available

SECTION 10: STABILITY AND REACTIVITY

Stability:	Stable
Incompatible Materials:	Incompatible with compounds which react violently with water
Conditions of Reactivity:	None
Hazardous Decomposition Products:	None

SECTION 11: TOXICOLOGICAL INFORMATION

Route of Entry:	<input checked="" type="checkbox"/> Skin Contact <input type="checkbox"/> Skin Absorption <input checked="" type="checkbox"/> Eye Contact <input type="checkbox"/> Inhalation <input checked="" type="checkbox"/> Ingestion
Irritancy to Product:	Not available
Synergistic Products:	Not available
Carcinogenicity:	This product has not been listed as a carcinogen or a potential carcinogen by the ACGIH, the International Agency for Research on Cancer (IARC), the US National Toxicology Program (NTP) or the US Occupational Safety and Health Administration (OSHA).
Reproductive Toxicity:	In limited testing, there is no evidence at this time of impaired fertility.
Teratogenicity:	In limited testing, there is no evidence at this time of harm to the fetus.
Mutagenicity:	Not available
Sensitivity to Product:	Not available

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity:	Not available
Persistence / Degradability:	Not available
Bioaccumulation / Accumulation:	Not available

MATERIAL SAFETY DATA SHEET

PRODUCT ID: PRILOCAINE HYDROCHLORIDE INJECTION

Mobility in Environmental Media: Not available

Other Adverse Effects: Not available

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal: Observe all Federal/Provincial/State and Local disposal regulations

SECTION 14: TRANSPORTATION INFORMATION

Basic Shipping Description: Not available

Additional Information: Not available

Special Precautions: Avoid temperature extremes. Prevent from freezing.

SECTION 15: REGULATORY INFORMATION

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*.

Regulatory Status: This product is exempt from WHMIS as a drug product

SECTION 16: OTHER INFORMATION

Name of person or group that prepared MSDS: Environmental Health & Safety

Phone #: 519-623-4800

MSDS Version#: # 3 (replaces V.2 of March 9, 2007)

Information and statements contained in this document have been obtained from manufacturers, suppliers and recognized reference sources as provided to or obtained by Novocol Pharmaceutical of Canada, Inc.

Novocol Pharmaceutical of Canada, Inc. believes the information to be reliable but expressly disclaims any liability for providing such information and toxicology to our customers.



MATERIAL SAFETY DATA SHEET
Citanest® Plain Dental (prilocaine hydrochloride injection, USP)

MSDS-015-CITANEST PLAIN-US REV.00, November 2014

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): Citanest® Plain Dental (prilocaine hydrochloride injection, USP)
Part/Item Number(s): 46616

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

1.4 Emergency Telephone Number:

Please report all incidents to the company contacts listed above.

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

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

EU Classification: Not classified as dangerous

2.2 Label Elements:

None Required



MATERIAL SAFETY DATA SHEET
Citanest® Plain Dental (prilocaine hydrochloride injection, USP)

MSDS-015-CITANEST PLAIN-US REV.00, November 2014

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 #	Classification	WT %
Non-hazardous ingredients	Mixture	Mixture	Not Hazardous	96
Prilocaine Hydrochloride	1786-81-8	217-244-0	Xn, Xi R22, R36 Acute Tox. 4 H302 Eye Irrit. 2A H319	4

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, 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.

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.

5. FIRE-FIGHTING MEASURES





5.1 Extinguishing Media: Use material appropriate for surrounding materials.



MATERIAL SAFETY DATA SHEET
Citanest® Plain Dental (prilocaine hydrochloride injection, USP)

MSDS-015-CITANEST PLAIN-US REV.00, November 2014

5.2 Special Hazards Arising from the Substance or Mixture:
Product is not flammable. Thermal decomposition may yield chlorine 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.		
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.		
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:
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.



MATERIAL SAFETY DATA SHEET
Citanest® Plain Dental (prilocaine hydrochloride injection, USP)

MSDS-015-CITANEST PLAIN-US REV.00, November 2014

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Avoid contact with skin, eyes or clothing. Wear protective clothing and equipment as described in Section 8. Avoid breathing mists or vapors. Wash thoroughly with soap and water after handling.

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	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Prilocaine Hydrochloride	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
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MATERIAL SAFETY DATA SHEET
Citanest® Plain Dental (prilocaine hydrochloride injection, USP)

MSDS-015-CITANEST PLAIN-US REV.00, November 2014

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Clear liquid	Explosive limits:	LEL: Not available UEL: Not available
Odor:	Odorless	Vapor pressure (mmHg):	Same as water
Odor threshold:	Not available	Vapor density:	Same as water
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:	Same as water	Decomposition temperature:	Not available
Flammability (solid, gas):	Not applicable	Viscosity:	Not available
Explosive Properties:	None	Oxidizing Properties:	None

9.2 Other Information: None available

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: Avoid contact with water-reactive materials.



MATERIAL SAFETY DATA SHEET
Citanest® Plain Dental (prilocaine hydrochloride injection, USP)

MSDS-015-CITANEST PLAIN-US REV.00, November 2014

10.6 Hazardous Decomposition Products: Chlorine and 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. 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: Prilocaine hydrochloride is metabolized into ortho-toluidine which is associated with chronic health effects.

Irritation: May cause slight eye and skin irritation.

Corrosivity: No data available.

Sensitisation: Product is not expected to cause sensitization.

Carcinogenicity: Prilocaine Hydrochloride: Chronic oral toxicity studies of ortho-toluidine, a metabolite of prilocaine, in mice and rats shows that ortho-toluidine is an animal carcinogen. The lowest dose at which effects are seen is approximately 50 times higher than the maximum dose of prilocaine hydrochloride to which a human would be exposed during normal use. Ortho-toluidine is classified by IARC as Category 1 (Carcinogenic to Humans) and by NTP as Reasonably Anticipated to be a Human Carcinogen. None of the components are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: Prilocaine Hydrochloride: Ortho-toluidine has been associated with mutagenicity in *Escherichia coli* DNA repair and phase-induction assays and *Salmonella typhimurium* with metabolic activation. Other tests in *Salmonella typhimurium* with or without metabolic activation and single strand breaks in DNA of V79 hamster cells were negative.

Medical Conditions Aggravated by Exposure: None known.

Acute Toxicity Data:

Prilocaine hydrochloride: Skin mouse LD50 550 mg/kg

Reproductive Toxicity Data: Studies in rats up to 30 times the normal human dose has shown evidence of impaired fertility and harm to the fetus. There is no clear indication of effects in humans.

Specific Target Organ Toxicity (STOT):

Single Exposure: None known.

Repeated Exposure: 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.



MATERIAL SAFETY DATA SHEET
Citanest® Plain Dental (prilocaine hydrochloride injection, USP)

MSDS-015-CITANEST PLAIN-US REV.00, November 2014

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 adverse effects are expected

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: This product will polymerize when exposed to sunlight. Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

Waste Treatment Recommendations: Dispose 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	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: 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 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.



MATERIAL SAFETY DATA SHEET
Citanest® Plain Dental (prilocaine hydrochloride injection, USP)

MSDS-015-CITANEST PLAIN-US REV.00, November 2014

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		

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): Medical devices are not subject to WHMIS.

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.



MATERIAL SAFETY DATA SHEET
Citanest® Plain Dental (prilocaine hydrochloride injection, USP)

MSDS-015-CITANEST PLAIN-US REV.00, November 2014

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

Xi Irritant

R22 Harmful if swallowed.

R36 Irritating to eyes.

Acute Tox. 4 Acute Toxicity Category 4

Eye Irrit. 2 Eye Irritation Category 2

H302 Harmful if swallowed.

H319 Causes serious eye irritation.

Supersedes: 19 July 2013

Date of Current Revision: 8 August 2014

Revision Summary: Converted MSDS to Reach SDS. Updated all sections.

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

Document Detail

1

Type: 0090-MSDS
Document No.: 0090-SDS-008[00]
Title: 4% Citanest Plain Dental - US and CA
Comment
Status: CURRENT
Effective Date: 12-Jan-2018

Approvals

<u>Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
Pharma Marketing Approver	Joe Santos	12-Jan-2018 2:40 pm	GMT
Pharma Regulatory Affairs Approver	Deb Crouse	10-Jan-2018 6:43 pm	GMT
Pharma Regulatory Affairs Approver	Lakeisha R Williams	10-Jan-2018 4:21 pm	GMT
Pharma Marketing Approver	Richard Tootchen	10-Jan-2018 6:57 pm	GMT
Pharma Quality Assurance Approver	Candace Walker	10-Jan-2018 4:05 pm	GMT
DPD Research and Development	Tom Simonton	10-Jan-2018 8:48 pm	GMT
DPD Document Control	Lucy Brenneman	12-Jan-2018 7:47 pm	GMT
Pharma Document Control	Beth Bodnar	12-Jan-2018 4:18 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, Canada Hazardous Products Regulation.

Date Issued: 01 November 2017
Document Number: SDS-008
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): 4% Citanest® Plain DENTAL (prilocaine HCl Injection, USP)
Part/Item Numbers: 46616
71115

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: 800-989-8826 or 717-767-8502 (Product Information)
Email address: DPDE-CustomerService@dentsplysirona.com

1.4 Emergency Telephone Number:

Transportation Emergency Contact 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

3.1 Mixture:

Hazardous Components	C.A.S. #	EINECS # REACH Registration #	Classification	WT %
Prilocaine Hydrochloride	1786-81-8	217-244-0	Acute Tox. 4 (H302) Eye Irrit 2 (H319)	4

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	If small quantities are swallowed, rinse out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if you feel unwell.

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.

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 material appropriate for surrounding materials.

5.2 Special Hazards Arising from the Substance or Mixture:

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

5.3 Advice for Fire-Fighters:

Fire Fighting Cool fire exposed containers and structures with water. Firefighters should wear full

Procedures/Precautions for Fire Fighters:	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:

Prilocaine Hydrochloride	None Established
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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):	17 mmHg @ 68°F (20°C)
Odor threshold:	Not available	Vapor density:	0.6
pH:	Not available	Relative density:	1.0
Melting/freezing point:	32°F (0°C)	Solubility(ies):	Soluble in water
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	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.

10.6 Hazardous Decomposition Products: Thermal decomposition may produce chlorine 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: Prilocaine hydrochloride is metabolized into ortho-toluidine which is associated with chronic health effects.

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: Product is not expected to cause sensitization.

Carcinogenicity: Prilocaine Hydrochloride: Chronic oral toxicity studies of ortho-toluidine, a metabolite of prilocaine, in mice and rats shows that ortho-toluidine is an animal carcinogen. The lowest dose at which effects are seen is approximately 50 times higher than the maximum dose of prilocaine hydrochloride to which a human would be exposed during normal use. Ortho-toluidine is classified by IARC as Category 1 (Carcinogenic to Humans) and by NTP as Reasonably Anticipated to be a Human Carcinogen. None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: Prilocaine Hydrochloride: Ortho-toluidine, a metabolite of prilocaine, has been associated with mutagenicity in Escherichia coli DNA repair and phase-induction assays and Salmonella typhimurium with metabolic activation. Other tests in Salmonella typhimurium with or without metabolic activation and single strand breaks in DNA of V79 hamster cells were negative. This product is not expected to cause mutagenic activity

Aspiration Hazard: Not an aspiration hazard.

Acute Toxicity Data:

Prilocaine Hydrochloride: Skin mouse LD50- 550 mg/kg, Intravenous mouse LD50- 55 mg/kg, Intravenous rat LD50- 56.6 mg/kg, Subcutaneous mouse LD50- 632 mg/kg, Subcutaneous rat LD50- 790 mg/kg

Reproductive Toxicity Data: In limited testing, there is no evidence at this time of impaired fertility or harm to the fetus. 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): 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 adverse effects are expected

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.

Philippines Inventory of Chemicals and 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.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health: 1 Flammability: 0 Physical Hazard: 0

Full Text of Hazard Statements and Abbreviations used In Section 3:

Acute Tox. 4 Acute Toxicity Category 4

Eye Irrit 2 Eye Irritant Category 2

H302 Harmful if swallowed.

H319 Causes serious eye irritation.

Supersedes: 8 August 2014, MSDS -015

Date Updated: 1 November 2017

Revision Summary: Updated all sections to current format. Add Canada part number, therefore create a new document number.

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