

Document Detail

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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
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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: 29 December 2017
Document Number: SDS-009
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Revision Number: 00

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

1.1 Product Identifier:

Trade Name (as labeled): Citanest® with Octapressin DENTAL

Part/Item Number: 185, 585, 785

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

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS # REACH Registration #	Classification	WT %
Non-hazardous ingredients	Mixture	Mixture	Not Hazardous	Balance
Prilocaine Hydrochloride	1786-81-8	217-244-0	Acute Tox. 4 (H302) Eye Irrit. 2 (H319)	3
Felypressin	56-59-7	200-282-7	Not Hazardous	<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	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. May cause allergic reactions if inhaled or swallowed by some asthmatics.

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 oxides of carbon and 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.

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
Prilocaine Hydrochloride	None Established
Felypressin	None Established

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:	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:	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 temperatures above 77°F (25°C). 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 oxides of carbon and 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 Prilocaine hydrochloride may cause allergic reactions in some asthmatics. 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: No data available.

Carcinogenicity: Prilocaine Hydrochloride: Chronic oral toxicity studies of ortho-toluidine, a metabolite of prilocaine, in mice and rats show 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

Felypressin: No toxicity data available

Reproductive Toxicity Data: This product is not expected to cause reproductive or developmental toxicity.

Specific Target Organ Toxicity Single Exposure (STOT-SE): Causes central nervous system effects such as drowsiness, confusion, excitability and nervousness. Acts as a depressant on the cardiovascular system.

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: None

Date Updated: 29 December 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.