

## Document Detail

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**Type:** 0090-MSDS  
**Document No.:** 0090-MSDS-008-CITANEST FORTE TEMPLATE[00]  
**Title:** Citanest Forte Dental Global Template  
**Comment**  
**Status:** CURRENT  
**Effective Date:** 05-Feb-2015

## Approvals

<u>Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
Pharma Regulatory Affairs Approver	Huston Howell	13-Nov-2014 8:40 pm	GMT
Pharma Quality Assurance Approver	Robert Moyer	05-Feb-2015 2:58 pm	GMT
Pharma Document Control	Ivi R. Shaw	05-Feb-2015 3:01 pm	GMT



# MATERIAL SAFETY DATA SHEET

Citanest® Forte Dental (prilocaine hydrochloride injection, USP and Epinephrine)

MSDS-008-CITANEST FORTE-TEMPLATE REV.00, November 2014

## DENTSPLY International

DENTSPLY <<marketing division>>

# 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® Forte Dental (prilocaine hydrochloride injection, USP and Epinephrine)

Part/Item Number(s):

<<enter all applicable SKU numbers>>

#### 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:

<<marketing division>>

Manufacturer/Supplier Address:

<<marketing division address>>

Manufacturer/Supplier Telephone Number:

<<marketing division contact telephone number>>

Email address:

<<marketing division contact email address>>

#### 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:

<b>GHS Classification:</b>		
<b>Health</b>	<b>Environmental</b>	<b>Physical</b>
Not Hazardous	Not Hazardous	Not Hazardous

EU Classification: Not classified as dangerous

#### 2.2 Label Elements:



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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 #	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
Sodium Metabisulfite	7681-57-4	231-673-0	Xn, Xi R22, R31, R41 Acute Tox. 4 H302 Eye Dam. 1 H318	0.005
Citric Acid	77-92-9	201-069-1	Not Hazardous	0.002
Epinephrine	51-43-4	200-098-7	T R24/25 Acute Tox 3 H301, 311	0.00005

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:

<b>Eye</b>	Flush victim's eyes with large quantities of water, while holding the eyelids apart. Get medical attention if irritation develops or persists.
<b>Skin</b>	Wash skin thoroughly with soap and water. Get medical attention if irritation occurs and persists. Remove and launder clothing before re-use.
<b>Inhalation</b>	Remove victim to fresh air. Get medical attention if symptoms of exposure occur.
<b>Ingestion</b>	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:



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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.

**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:**



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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 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	5 mg/m <sup>3</sup> COM REL TWA
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established



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Sodium Metabisulfite	United States	5 mg/m <sup>3</sup> TWA ACGIH TLV
	Germany	None Established
	United Kingdom	5 mg/m <sup>3</sup> TWA UK WEL
	European Union	None Established
Citric Acid	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established

Epinephrene	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:**



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<b>Appearance:</b>	Clear, colorless liquid	<b>Explosive limits:</b>	<b>LEL:</b> Not available <b>UEL:</b> Not available
<b>Odor:</b>	Odorless	<b>Vapor pressure (mmHg):</b>	Same as water
<b>Odor threshold:</b>	Not available	<b>Vapor density:</b>	Same as water
<b>pH:</b>	3.3-5.5	<b>Relative density:</b>	1.007
<b>Melting/freezing point:</b>	32°F (0°C)	<b>Solubility(ies):</b>	Complete
<b>Initial boiling point and boiling range:</b>	>212°F (>100°C)	<b>Partition coefficient: n-octanol/water:</b>	Not available
<b>Flash point:</b>	Not flammable	<b>Auto-ignition temperature:</b>	Not available
<b>Evaporation rate:</b>	Same as water	<b>Decomposition temperature:</b>	Not available
<b>Flammability (solid, gas):</b>	Not applicable	<b>Viscosity:</b>	Not available
<b>Explosive Properties:</b>	None	<b>Oxidizing Properties:</b>	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.

**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.



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<p><u>Skin:</u> May cause slight skin irritation and numbness.</p> <p><u>Ingestion:</u> May cause slight gastrointestinal irritation.</p> <p><u>Inhalation:</u> May cause slight respiratory tract irritation with coughing and anesthetic effects.</p>
<p><b>Chronic Health Effects:</b> Prilocaine hydrochloride is metabolized into ortho-toluidine which is associated with chronic health effects.</p>
<p><b>Irritation:</b> May cause slight eye and skin irritation.</p>
<p><b>Corrosivity:</b> No data available.</p>
<p><b>Sensitisation:</b> Product contains sodium metabisulfite, a sulfite that may cause allergic reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.</p>
<p><b>Carcinogenicity:</b> 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.</p>
<p><b>Mutagenicity:</b> Prilocaine Hydrochloride: Ortho-toluidine has been associated with mutagenicity in <i>Escherichia coli</i> DNA repair and phase-induction assays and <i>Salmonella typhimurium</i> with metabolic activation. Other tests in <i>Salmonella typhimurium</i> with or without metabolic activation and single strand breaks in DNA of V79 hamster cells were negative.</p>
<p><b>Medical Conditions Aggravated by Exposure:</b> None known.</p>
<p><b>Acute Toxicity Data:</b> Prilocaine hydrochloride: Skin mouse LD50 550 mg/kg Epinephrine: Dermal rat LD50 5 mg/kg</p>
<p><b>Reproductive Toxicity Data:</b> 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.</p>
<p><b>Specific Target Organ Toxicity (STOT):</b> <u>Single Exposure:</u> None known.  <u>Repeated Exposure:</u> Repeat or chronic exposure may cause hypersensitivity and the development of methemoglobinemia.</p>

## 12. ECOLOGICAL INFORMATION

<p><b>12.1 Toxicity:</b> No data available.</p>
<p><b>12.2 Persistence and Degradability:</b> No data available.</p>
<p><b>12.3 Bio-accumulative Potential:</b> No data available.</p>
<p><b>12.4 Mobility in Soil:</b> No data available.</p>





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**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
<b>DOT</b>	None	Not Regulated	None	None	Not applicable
<b>ADR/RID</b>	None	Not Regulated	None	None	Not applicable
<b>IMDG</b>	None	Not Regulated	None	None	Not applicable
<b>IATA/ICAO</b>	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.

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

**SARA Section 311/312 (40 CFR 370) Hazard Categories:**



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<b>Immediate Hazard:</b>	No	<b>Pressure Hazard:</b>	No
<b>Delayed Hazard:</b>	No	<b>Reactivity Hazard:</b>	No
<b>Fire Hazard:</b>	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.

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



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**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

T Toxic

R22 Harmful if swallowed.

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

R31 Contact with acids liberates toxic gas.

R36 Irritating to eyes.

R41 Risk of serious damage 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.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

Supersedes: 15 October 2010

Date of Current Revision: 9 October 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.