Created on: 15 October 2010
Replaces version dated: March 2000

13. DISPOSAL CONSIDERATIONS	
Disposal Methods:	Epinephrine is a good candidate for disposal by fluidized bed, rotary kiln, or liquid injection forms of incineration. Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified. Containers may still present a chemical hazard/ danger when empty. Return to supplier for reuse/ recycling if possible. Disposal Method : Epinephrine RCRA Code PO42

14. TRANSPORT INFORMATION	
UN Number:	Not available
UN Proper Shipping Name:	Not regulated for transport of dangerous goods
Transport Hazard Class(es):	Non-dangerous goods
Packing Group:	None
Environmental Hazards:	Non-Hazardous
Special Requirements:	None

15. REGULATORY INFORMATION	
Other Regulatory Information:	**TSCA (Toxic Substances Control Act) Regulations, 40CFR 710**: This product is a drug and is exempt from TSCA regulation. **CERCLA and SARA Regulations (40CFR 355,370 and 372)**: This product does not contain any chemical subject to the reporting requirements of SARA Section 313. **CERCLA/SUPERFUND**: Contains reportable Quantity Substances, epinephrine and bisulfate. **Other Determined Regulation**: California Proposition 65: No warnings are necessary.

16. OTHER INFORMATION	
Date of Preparation of this MSDS:	15 October 2010
References:	Toxicological information obtained from RTECS, Toxline and publicly available sources

STOT-repeated Exposure	Chronic effects are unlikely to occur. Repeated exposure to high levels of an amide anaesthetic in animals produced adverse effects on the liver and CNS. Prilocaine may cause methemoglobinemia in high doses and so may aggravate congenital or idiopathic methemoglobinemia.
Aspiration Hazard	Aspiration hazard is low. May cause tingling/numbness in exposed areas (paresthesia). Intratracheal (rabbit) LD50 for prilocaine is 65 mg/kg.

12. ECOLOGICAL INFORMATION

No information on this formulation. The product is soluble in water. The following information refers to active ingredient prilocaine:

Toxicity:	Harmful to aquatic organisms. LC50 (zebra fish) (96 hour) 188 mg/L. EC50 (Daphnia magna) (48 hour) 61 mg/L. EC50 (green algae) (72 hour) 154 mg/L.
Persistence and Degradability:	May cause long-term adverse effects in the aquatic environment. Not readily biodegradable. (ISO7827-1984(E))
Bioaccumulation Potential:	The substance has low potential for bioaccumulation. **Log Kow:** Prilocaine base: 2.11 Epinephrine base= -1.37 (experimental) **Log Koc:** Prilocaine base: 2.611 (MCI method) Epinephrine base: 1.868 (MCI method) **Log BCF:** Prilocaine base: 1.059 Epinephrine base: 0.500 **Atmospheric Half-Life:** Prilocaine base: 2.46 h Epinephrine base: 1.86 h as calculated via applicable algorithms encoded in EpiSuite 4.0 (USEPA 2010)
Mobility in Soil:	No information available

Reproductive Toxicity:	Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis). Reproduction studies have been performed in rats at doses up to 30 times the human dose of citanest without epinephrine and revealed no evidence of impaired fertility or harm to the fetus due to prilocaine. There are no adequate and well-controlled studies in pregnant women. Animal reproduction studies are not always predictive of human response. General consideration should be given to this fact before administering prilocaine to women of childbearing potential, especially during early pregnancy when maximum organogenesis takes place. Cataracts in rat fetus have been produced by giving near-lethal doses of epinephrine at a critical period in pregnancy, possibly affecting the developing lens by constricting the hyaloid arteries and causing anoxia. Epinephrine-induced limb defects were seen in rabbits after doses of 5-50 µg of adrenaline were injected directly into rabbit fetuses at 18 to 22 days of gestational age. Effects included hemorrhages, edema and necrosis of distal extremities. Intravenous infusion of epinephrine into pregnant rabbits elevated maternal blood pressure and caused extensive uterine vasoconstriction, placental cyanosis, and functional cardiovascular alterations in the fetus. The placental cyanosis coincided with, or slightly preceded, the fetal hemodynamic changes. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when prilocaine is administered to nursing women.
STOT-single Exposure	High blood levels can cause toxic effects on cardiovascular and central nervous systems. Drowsiness is usually an early sign of excessively high level.

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Replaces version dated: March 2000

Skin Corrosion / Irritation:	May cause mild skin irritation.
Serious Eye Damage / Irritation	May cause irritation, excessive watering (lacrimation) and eye damage, blurred vision and numbness.
Respiratory or Skin Sensitisation:	Repeated and/or prolonged contact may cause skin sensitization in a small proportion of the population. May cause numbness.
Germ Cell Mutagenicity:	An Ames test with epinephrine was negative. Studies on prilocaine either in vitro or in animals to evaluate the mutagenic potential have not been conducted. *O*-toluidine (0.5 mg/mL), a metabolite of prilocaine, showed positive results in Escherichia coli DNA repair and phage-induction assays. Urine concentrates from rats treated with *o*-toluidine (300 mg/kg, orally) were mutagenic for Salmonella typhimurium with metabolic activation. Several other tests, including reverse mutations in five different Salmonella typhimurium strains with or without metabolic activation and single strand breaks in DNA of V79 Chinese hamster cells, were negative.
Carcinogenicity:	Studies of prilocaine in animals to evaluate the carcinogenic potential have not been conducted. Chronic oral toxicity studies of *o*-toluidine, a metabolite of prilocaine, in mice (150–4800 mg/kg) and rats (150–800 mg/kg) have shown that *o*-toluidine is a carcinogen in both species. The lowest dose corresponds to approximately 50 times the maximum amount of *o*-toluidine to which a 50 kg subject would be expected to be exposed following a single injection (8 mg/kg) of prilocaine. In 2 yr inhalation studies, no carcinogenic effects were observed in male or female F344/N rats exposed to aerosols containing 1.5 or 5 mg/m^3 epinephrine hydrochloride or in B6C3F1 mice exposed to 1.5 or 3 mg/m^3 epinephrine hydrochloride. However, these studies were considered to be inadequate studies of carcinogenic activity because the concentrations used, which were chosen to represent multiples of therapeutic doses, were considered too low for the animals to have received an adequate systemic challenge from the compound when given by this route.

Partition Coefficient (n-octanol / water):	Not available
Auto-ignition Temperature:	Not available
Decomposition Temperature:	Not available
Viscosity:	Not available

10. STABILITY AND REACTIVITY	
Reactivity:	Non-reactive
Chemical Stability:	Product is considered stable under normal conditions
Possibility of Hazardous Reactions:	Epinephrine is unstable in alkaline solutions when exposed to air or light.
Conditions to Avoid:	Alkaline conditions and exposure to water reactive agents.
Incompatible Materials:	None known
Hazardous Decomposition Products:	None known.

11. TOXICOLOGICAL INFORMATION	
Acute Toxicity:	**LD50 / LC50 Mixture:** Unknown **Prilocaine hydrochloride** (Readily available toxicity data unavailable for base form)**:** Parenteral (man) LDLo: 12.43 mg/kg/1 h - I Nil Reported Intraperitoneal (rat) LD50: 148 mg/kg Subcutaneous (rat) LD50: 790 mg/kg Intravenous (rat) LD50: 56.6 mg/kg Intraperitoneal (mouse) LD50: 30 mg/kg Subcutaneous (mouse) LD50: 632 mg/kg Intravenous (mouse) LD50: 55 mg/kg Intravenous (guinea pig) LD50: 20 mg/kg Intravenous (rabbit) LD50: 18 mg/kg Intratracheal (rabbit) LD50: 65 mg/kg Altered sleep-time, convulsions recorded. **Values below for epinephrine bitartrate** (Readily available toxicity data unavailable for base form)**:** Oral (mouse) LD50: 4 mg/kg Intravenous (rat) LD50: 0.082 mg/kg Subcutaneous (rat) LD50: 8.3 mg/kg Only selected data are presented here. See actual entry in RTECS for complete information.

Special Protective Measures:	Wear suitable protective clothing **Eye:** Chemical goggles. **Hands/feet:** Wear chemical protective gloves, e.g. PVC. **Other:** Laboratory coat and P.V.C. apron. **Engineering controls:** Use in a well-ventilated area. General exhaust is adequate under normal operating conditions. Local exhaust ventilation may be required in specific circumstances. If needed, use a NIOSH approved respirator for vapors, dusts and mists with TLV greater than 0.05 mg/m^3. **Respiratory Protection:** Material does not require special ventilators, respirators, etc. **Work Hygienic Practices:** Avoid ingestion & contact with eyes. Remove / launder contaminated clothing & shoes before reuse. Wash hands after use. **Supplemental Health & Safety Information:** Irritating to the eye. Contact may also cause numbness and loss of sensation.

9. PHYSICAL AND CHEMICAL PROPERTIES	
Appearance:	Clear, colorless aqueous liquid
Odor (odor threshold):	Odorless
pH	3.3 - 5.5
Melting Point:	0ºC
Initial Boiling Point:	>100ºC
Boiling Range:	Not available
Flash Point:	Not available
Evaporation Rate:	Not available
Flammability:	Non combustible
Upper and Lower Flammability Limits	Not available
Vapor Pressure:	Not available
Vapor Density:	Not available
Relative Density:	1.007
Solubility(ies):	Miscible with water

Inhalation:	Unlikely route of exposure. Remove patient from exposure. Obtain medical attention if ill effects occur. May cause tingling/numbness in exposed areas (paresthesia). High atmospheric concentrations may lead to anesthetic effects.
Ingestion:	Do not induce vomiting. Rinse mouth with water and give 200-300 ml of water to drink (8-10 ounces). Never give anything by mouth if unconscious. Obtain medical attention.

5. FIRE FIGHTING MEASURES	
Suitable Extinguishing Media:	Use appropriate agent for involved fire (i.e., water spray, carbon dioxide, dry chemical powder or appropriate foam).
Specific Hazards Arising from the Chemical(s):	If involved in a fire, it may burn and emit noxious and toxic fumes.
Protection of Fire-fighters:	A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

6. ACCIDENTAL RELEASE MEASURES	
Personal Precautions:	Ensure suitable personal protection during removal of spillages. Take care to avoid needles and broken container.
Environmental Precautions:	Transfer spilled vials to a suitable container for disposal.
Containment and Clean up:	Clear up spillages. Wash the spillage area with water. Transfer spilled vials to a suitable container for disposal.

7. HANDLING AND STORAGE	
Handling:	No special precautions are necessary when handling packed product. In case of accident, avoid contact with skin and eyes. Do not breathe mist.
Storage:	Protect from light. Store in original containers and packaging as recommended by manufacturer. Keep containers securely sealed and cool. Store below 25ºC. Check that containers are clearly labelled.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
Exposure Control Limits:	Prilocaine hydrochloride - 5 mg/m^3 COM, REL TWA Sodium metabisulphite - 5 mg/m^3 TLV

MATERIAL SAFETY DATA SHEET
CITANEST® FORTE 4% INJECTION

Created on: 15 October 2010
Replaces version dated: March 2000

1. IDENTIFICATION (MATERIAL AND MANUFACTURER)		
Product Name:	Citanest® Forte 4% Injection	
Synonym(s):	Prilocaine and Epinephrine Injection, USP Citanest Forte 4% Injection with Epinephrine 1:200,000 Citanest with Epinephrine Citanest with Adrenaline	
Product Use:	Local anaesthetic for use in dental procedures	
Manufacturer / Supplier:	DENTSPLY Pharmaceutical 1301 Smile Way York, PA 17404 USA Telephone number: 1-800-225-2787 Fax number: 717-699-4148	
Emergency telephone number (US):	Primary:	717-767-8529 717-659-1926
	Secondary:	717-767-8523 717-887-9723
	Tertiary:	717-767-4120 717-495-5901

2. HAZARD IDENTIFICATION	
Hazard Classification:	Xn; R22, Carc3; R40 R43
GHS Hazard Labelling:	
Canadian Hazard Warning:	
Other Hazards:	None

3. COMPOSITION / INFORMATION ON INGREDIENTS		
Name	CAS Number	% conc
Prilocaine hydrochloride	1786-81-8	4.0
Epinephrine bitartrate	51-42-3	0.0005
Sodium metabisulphite	7681-57-4	0.05

4. FIRST AID MEASURES	
Eye Contact:	Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 15 minutes. Obtain medical attention.
Skin Contact:	Remove contaminated clothing. Wash skin with soap and water. If symptoms (irritation or blistering) occur obtain medical attention.