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Approvals

Role	Sign-off By	Sign-off Date
Pharma Regulatory Affairs Approver	Deb Crouse	12-Jul-2013 7:51 pm GMT
Pharma Quality Assurance Approver	Kevin Krebs	31-Jul-2013 9:02 pm GMT
Pharma Document Control	Ivi R. Shaw	01-Aug-2013 9:08 pm GMT

MATERIAL SAFETY DATA SHEET
ORAQIX®

Created on: 11 July 2013
Replaces version dated: 06 October 2010

1. IDENTIFICATION (MATERIAL AND MANUFACTURER)	
Product Name:	Oraqix®
Synonym(s):	Lidocaine and Prilocaine periodontal gel
Product Use:	Indicated for adults who require localized anesthesia in periodontal pockets during scaling and/or root planing.
Manufacturer / Supplier:	DENTSPLY Pharmaceutical 1301 Smile Way York, PA 17404 USA Telephone number: 1-800-225-2787 Fax number: 717-699-4148

Emergency telephone numbers:

Country	Call Order	Phone Number
USA	Primary	717-767-8523 717-887-9723
	Secondary:	717-767-4120 717-495-5901
Canada	Primary	1-800-263-1437

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
Lidocaine base	137-58-6	2.5
Prilocaine base	721-50-6	2.5

4. FIRST AID MEASURES	
Eye Contact:	Flush immediately with eye wash 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
Inhalation:	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 anaesthetic 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. May produce numbness of the tongue and anesthetic effects on the stomach. Ingestion of 5 to 25 mL of 2% viscous Xylocaine (lidocaine) has resulted in seizures in children.

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 containers. Clean spills with normal procedures used for non-hazardous liquids.
Environmental Precautions:	Transfer spilled vials to a suitable container for disposal. Sweep/soak up, place in a bag and hold for waste disposal.
Containment and Clean up:	Clear up spillages. Wash the spillage area with water. Transfer spilled vials to a suitable container for disposal. Ventilate area and wash spill site after material pickup is complete.

7. HANDLING AND STORAGE	
Handling:	No special precautions are necessary when handling packed product. In case of release, 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:	No exposure limits assigned for product. Prilocaine hydrochloride - 5 mg/m^3 COM, REL TWA
Special Protective Measures:	Wear suitable protective clothing **Eye:** Chemical goggles or face shield. **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.

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9. PHYSICAL AND CHEMICAL PROPERTIES	
Appearance:	Clear aqueous solution
Odour (odour threshold):	Odorless
pH	3.3 - 5.5
Melting Point:	Not available
Initial Boiling Point:	Not available
Boiling Range:	Not available
Flash Point:	Non Combustible
Evaporation Rate:	Not available
Flammability:	Not flammable
Upper and Lower Flammability Limits	Not Relevant
Vapour Pressure:	Not available
Vapour Density:	Not available
Relative Density:	1.0
Solubility(ies):	Not applicable
Partition Coefficient (n-octanol / water):	Not available
Auto-ignition Temperature:	Not applicable
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:	Unlikely unless in contact with alkaline conditions
Conditions to Avoid:	Open burning/incineration
Incompatible Materials:	Compounds that react violently with water. Strong reducing agents.
Hazardous Decomposition Products:	Fumes of Carbon Monoxide, Carbon Dioxide, Nitrogen Oxides Hydrogen Chloride gas

11. TOXICOLOGICAL INFORMATION	
Acute Toxicity:	**LD50 / LC50 Mixture:** Unknown **Lidocaine hydrochloride** (Readily available toxicity data unavailable for base form)**:** Intravenous / child Lowest published toxic dose: 60 mg/kg/1 hour Behavioral: Convulsions or effect on seizure threshold Vascular: BP lowering not characterized in autonomic section Intravenous / infant Lowest published toxic dose: 10 mg/kg Behavioral: Convulsions or effect on seizure threshold. Coma Lung, Thorax, or Respiration: Other changes Intravenous / man Lowest published toxic dose: 9 mg/kg/4 hour-continuous Cardiac: Cardiomyopathy including infarction Intravenous / man Lowest published toxic dose: 7.143 µg/kg Cardiac: Pulse rate increased without fall in BP Oral / infant Lowest published toxic dose: 1.632 mg/kg/1 week-intermittent Behavioral: Somnolence (general depressed activity). Convulsions or effect on seizure threshold **Prilocaine hydrochloride (**Readily available toxicity data unavailable for base form)**:** Parenteral (man) LDLo: 12.43 mg/kg/1h - 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. Only selected data are presented here. See actual entry in RTECS for complete information.
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 or prolonged contact may cause sensitization in a small proportion of the population. May cause numbness.
Germ Cell Mutagenicity:	Studies of prilocaine 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. Genotoxicity tests with lidocaine were negative. However, whilst Ames genotoxicity tests with 2,6-xylidine were negative a chromosome aberration test in CHO cells indicated an in vitro genotoxic potential of this metabolite of lidocaine.
Carcinogenicity:	Studies of prilocaine or lidocaine 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. Studies in rats with 2,6-xylidine indicated carcinogenic potential of this metabolite of lidocaine at high doses.
Reproductive Toxicity:	Prilocaine: Reproduction studies have been performed in rats at doses up to 30 times the human dose and revealed no evidence of impaired fertility or harm to the fetus. Lidocaine: No teratogenic effects were noted in embryo-fetal development studies in which rats or rabbits were treated during the period of organogenesis. Embryotoxicity was seen in rabbits, at maternally toxic doses. In rats, decreased pup survival was seen for dams treated during late pregnancy and lactation, at a dose that was maternally toxic and affected the duration of gestation. Lidocaine and prilocaine: No effects on embryo-fetal development were seen in a study in which lidocaine and prilocaine were given in combination, during organogenesis. There are, however, 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. Lidocaine, and in all probability, prilocaine are excreted in breast milk in small amounts. However it is unlikely that effects will be seen in the child following treatment with Oraqix. Thus breast-feeding can be continued following treatment, with

	caution exercised when administered to a nursing woman.
STOT-single Exposure	Systemic absorption of this product may result in toxic effects on the CNS and the cardiovascular system. Adverse effects could be more pronounced in those individuals with pre-existing diseases of central nervous system or cardiovascular system or those receiving medications that affect these systems (such as antihypertensive agents, antiarrhythmic agents or CNS depressant medications). Effects could also be more pronounced in individuals with a compromised ability to metabolize and clear active ingredients from the blood and body tissues (such as severe liver or kidney disease). Prilocaine may cause methemoglobinemia in high doses and so may aggravate congenital or idiopathic methemoglobinemia.
STOT-repeated Exposure	Chronic effects are unlikely to occur. Repeated exposure to high levels of an amide anesthetic 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:	**Log Kow:** Lidocaine base: 2.44 (experimental) Prilocaine base: 2.11 **Log Koc:** Lidocaine base: 2.623 (MCI method) Prilocaine base: 2.611 (MCI method) **Log BCF:** Lidocaine base: 1.277 Prilocaine base: 1.059 **Atmospheric Half-Life:** Lidocaine base: 2.35 h Prilocaine base: 2.46 h as calculated via applicable algorithms encoded in EpiSuite 4.0 (USEPA 2010)
Mobility in Soil:	No information available

13. DISPOSAL CONSIDERATIONS	
Disposal Methods:	Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state and local environmental regulations.

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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:	**EC Classification:** Exempt. **TSCA (Toxic Substances Control Act) Regulations, 40CFR 710**: This product is a drug and is exempt from TSCA regulation. **OSHA Status:** Hazardous as defined by OSHA 29 CFR 1910. 1200 (c) **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. **Federal Regulatory Information:** Regulated under OSHA and FDA **State Regulatory Information:** Consult with state environmental and/or public health agencies. **Health Canada:** Class D2 (Materials causing other toxic effects)

16. OTHER INFORMATION	
Date of Preparation of this MSDS:	10 July 2013
References:	Toxicological information obtained from RTECS, Toxline and publicly available sources