SDS-001-ORAQIX US & CAN REV.00, February 2017

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):	**Oraqix® (prilocaine hydrochloride and lidocaine hydrochloride periodontal gel)**
Part/Item Number(s):	**6631211020**
	66312020CA

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 US**
	1-800-263-1437 CAN
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

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	95
Prilocaine Base	721-50-6	211-957-0	Xn, Xi R22, R36 Acute Tox. 4 H302 Eye Irrit. 2A H319	2.5
Lidocaine Base	137-58-6	205-302-8	Xn, Xi R22, R36 Acute Tox. 4 H302 Eye Irrit. 2A H319	2.5

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.

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

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handing:
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	United States	5 mg/m^3 COM REL TWA
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established

Lidocaine	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:

Appearance:	Clear, colorless 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:	7.5-8.0	**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 and strong reducing agents.

10.6 Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, chlorine, hydrogen chloride, 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.
No data on repeated dose toxicity of lidocaine in laboratory animals were located. Lidocaine has been widely used in human and veterinary medicine for several decades. It is mainly used as a local anesthetic and therefore usually is administrated as a single dose.

Irritation: May cause slight eye and skin irritation.
Lidocaine: No skin irritation was observed (erythema or edema) in rabbits treated various topical formulations (poultice, gel or ointment) of 5% lidocaine.

Corrosivity: No data available.

Sensitisation: Allergic and anaphylactic reactions associated with lidocaine or prilocaine in Oraqix can occur in a small amount of the population.
No erythema or edema was observed in guinea pigs which were sensitized and challenged subsequently with lidocaine topical application.

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.
Lidocaine: Data on potential carcinogenic effects of lidocaine could not be located. However 2,6-xylidine is the critical metabolite of lidocaine with regard to human health safety, as this substance has been shown to be a nasal carcinogen in rats in NTP study. 2,6-xylidine is classified by IARC as Category 2B (Possibly carcinogenic to humans) and is classified as Carc 2 (suspected human carcinogen: H351 suspected of causing cancer) by EU CLP according to the Globally Harmonised System of Classification and Labelling of Chemicals.

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. Lidocaine: The Ames test (*Salmonella* strains TA100 and TA98) with or without metabolic activation did not reveal any mutagenic potential of lidocaine. Neither the Ames test (Salmonella strain TA1538 with 1, 10, 100 and 500 µg/plate) with or without metabolic activation (S9 fraction) with several metabolites of lidocaine, including 2,6-xylidine, revealed any mutagenic activity. Mutagenicity test were carried out with the metabolite 2,6 –xylidine. The Ames test, forward mutation in the mouse lymphoma TK locus assay, chromosomal aberration and sister chromatid exchange in Chinese Hamster Ovary cells, unscheduled DNA synthesis in rat hepatocytes in the *in vitro/in vivo* UDS assay, covalent binding to DNA in rat liver and ethmoid turbinates in vivo, micronuclei in mouse polychromated erythrocytes and the preferential killing of DNA repair deficient *E. coli* bacteria *in vivo*, using a host-mediated assay in the mouse. These tests indicated that 2,6-xylidine is a weak mutagenic agent *in vitro* and has weak genotoxic characteristics *in vivo*.

Medical Conditions Aggravated by Exposure: None known.

Acute Toxicity Data:

Prilocaine hydrochloride: Skin mouse LD_{50} 550 mg/kg

Lidocaine: Oral LD_{50} mouse: 220-292 mg/kg, Oral LD_{50} rats: 317 mg/kg, Subcutaneous LD_{50} mouse: 238 mg/kg, Subcutaneous LD_{50} rats: 335 mg/kg

ATE_{mix}: Oral rat LD50 10,000 mg/kg

Reproductive Toxicity Data: Studies in rats of prilocaine 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. For 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, decrease 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. Behavioural effects had been shown in the offspring of female rats administered lidocaine during the gestation period.

Specific Target Organ Toxicity (STOT):
Single Exposure: None known.

Repeated Exposure: Repeat or chronic exposure may cause hypersensitivity and the development of methemoglobanemia.

12. ECOLOGICAL INFORMATION

12.1 Toxicity: Prilocaine: Zebra fish LC50 188 mg/L/96 hr; Daphnia magna EC50 61 mg/L/48 hr; Green Algae EC50 154 mg/L/72 hr
12.2 Persistence and Degradability: Prilocaine: Not readily biodegradable.
12.3 Bio-accumulative Potential: Prilocaine: Log KOW: 2.44; Log BCF: 1.277 Lidocaine: Log KOW: 2.11; Log BCF: 1.059
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.

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.

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: 11 August 2016
Date of Current Revision: 03 February 2017
Revision Summary: Change pH specification range, change numbering of document

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