Safety Data Sheet

Safety Data Sheet conforms to Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010), US 29CFR1910.1200, and Canada Hazardous Products Regulation.

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Revision Number: 3

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: 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: 800-989-8826 or 717-767-8502 (Product Information)

Email address: DS-Pharma@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	95
Prilocaine Base	721-50-6	211-957-0	Acute Tox. 4, H302 Eye Irrit. 2A, H319 Skin Irrit. 2, H315 Aquatic Chronic 3, H412	2.5
Lidocaine Base	137-58-6	205-302-8	Acute Tox. 4, H302	2.5

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	Wash skin thoroughly with soap and water. Get medical attention if irritation occurs and persists. Remove and launder 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 be 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. Skin contact may cause numbness.

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 chlorine, hydrogen chloride, or oxides of 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. Avoid breathing mists or vapors. 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 Base	None Established
Lidocaine Base	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. 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):**	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):**	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:	Same as water	**Decomposition temperature:**	Not available
Flammability (solid, gas):	Not applicable	**Viscosity:**	Not available
Explosive Properties:	None	**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: This product will polymerize when exposed to sunlight.
10.4 Conditions to Avoid: Avoid extremely high or low temperatures. Protect from direct sunlight. Do not freeze this

product.

10.5 Incompatible materials: Avoid contact with water-reactive materials and strong reducing agents.

10.6 Hazardous Decomposition Products: Thermal decomposition may produce 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. 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: 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: 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. This product is not expected to be corrosive.

Sensitization: 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 Harmonized 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.

Aspiration Hazard: Not an aspiration hazard.

Acute Toxicity Data:

Product ATE: 10,000 mg/kg (oral)

Prilocaine hydrochloride: Skin mouse LD50 550 mg/kg

Lidocaine: Oral LD50 rats: 317 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. Behavioral effects had been shown in the offspring of female rats administered lidocaine during the gestation period.

Specific Target Organ Toxicity Single Exposure (STOT-SE): No data available.

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: Prilocaine: 96 hr LC50 Zebra fish- 188 mg/L, 48 hr EC50 Daphnia magna- 61 mg/L, 72 hr EC50 Green Algae 154 mg/L

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:

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.

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
Aquatic Chronic 3 Aquatic Chronic Toxicity Category 3
Eye Irrit. 2A Eye Irritant Category 2A
Skin Irrit. 2 Skin Irritant Category 2
H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H412 Harmful to aquatic life with long lasting effects.

Supersedes: 03 February 2017
Date Updated: 26 August 2020
Revision Summary: 3 yr review- updated SDS format and Sections 3, 11, and 12.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.