

MATERIAL SAFETY DATA SHEET

Created on 09.02.04

Replaces version dated: NEW MSDS

Section 1

Product and Company Identification

Product Identification: Oraqix[®]
(Lidocaine and Prilocaine periodontal gel)
2.5% / 2.5%

General Use: Indicated for adults who require localized anesthesia in periodontal pockets during scaling and/or root planning.

Product Identification: Clear, odorless aqueous solution

Manufacturer: AstraZeneca AB (for Dentsply International, Inc.)
AstraZeneca Liquid Production Sweden
Karlskoga Plant
Bjorkborn
S-691 27 Karlskoga
Sweden

Business Telephone: (717) 757-0200

Emergency Telephone: INFOTRACK (800) 535-5053

Section 2

Hazards Identification

Emergency Overview: As a result of the physical presentation of the product, the risk to health and the environment in the normal handling of the product is expected to be low.

Health Hazards (Acute & Chronic)

Target Organs: Skin, eye, Central Nervous System (CNS) and cardiovascular system. **As a result of the physical presentation of the product, the risk to health in the normal handling of the product is expected to be low.**

Acute Effects: Systemic absorption of this product may result in toxic effects on the CNS and the cardiovascular system. Allergic reactions may also occur in sensitive individuals. Significant adverse effects on intact skin are unlikely. Contact with mucous membranes may cause irritation and/or numbness (loss of sensation).

Chronic Effects: 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.

Signs & Symptoms of Overexposure

Inhalation (unlikely route of exposure) and Ingestion: Systemic effects may include nervousness, confusion, drowsiness, blurred vision, vomiting, tremors, convulsions, respiratory depression, slowing of the heart rate, blood pressure drop and unconsciousness. Local effects may include allergic reaction, irritation and numbness (loss of sensation).

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Skin / mucous membranes: May cause mild irritation. Repeated or prolonged contact may cause sensitization in a small proportion of the population. May cause numbness.

Eyes: May cause irritation, excessive watering (lacrimation) and eye damage, blurred vision and numbness.

Medical Conditions Aggravated by Exposure: Prilocaine may cause methemoglobinemia in high doses and so may aggravate congenital or idiopathic methemoglobinemia.

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).

LD50 / LC50 Mixture: Unknown

Route of Entry Indicators

Inhalation	Yes
Skin	Yes
Ingestion	Yes

Carcinogenicity Indicators

NTP	No
IARC	No
OSHA	No

Carcinogenicity Explanation: **Not applicable**

Section 3 Composition / Information on Ingredients

	<u>WT. %</u>	<u>CAS Registry #</u>
Lidocaine Base	2.50	137-58-6
Prilocaine Base	2.50	721-50-6

OSHA Hazardous Components (29 CFR 1910.1200):**EXPOSURE LIMITS 8 Hrs. TWA**

	<u>OSHA PEL</u>	<u>ACGIH TLV</u>
Lidocaine Base	Not Applicable	Not Applicable
Prilocaine Base	Not Applicable	Not Applicable

OSHA Regulatory Status: Hazardous as defined by OSHA 29 CFR 1910.1200(c).

Incompatibilities: Strong reducing agents

Hazardous Combustion or Decomposition Products: Fumes of Carbon Monoxide, Carbon Dioxide, Nitrogen oxides and Hydrogen Chloride gas.

Hazardous polymerization will not occur.

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Section 4 First Aid Measures

Seek Medical Attention For All Symptomatic Exposures

Inhalation: Remove to fresh air. Provide symptomatic and supportive treatment.

Oral: If conscious, rinse out mouth with water and observe for symptoms.

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.

Skin: Remove contaminated clothing and wash affected areas with soap and water.

Eyes: Flush immediately with plenty of water or sterile normal saline solution (if available) for at least 15 minutes.

Section 5 Fire Fighting Measures

Fire Fighting Procedures: No special fire fighting procedures. Fight as per requirements of involving fire.

Unusual Fire or Explosion Hazard: None

Extinguishing Media: Use appropriate agent for involved fire (i.e., water spray, carbon dioxide, dry chemical powder or appropriate foam).

Flash Point: Non Combustible

Autoignition Temperature: Not Applicable

Lower Limit(s): Not Relevant

Upper Limit(s): Not Relevant

Section 6 Accidental Release Measures

Spill Release Procedures: Clean spills with normal procedures used for non-hazardous liquids. Sweep/soak up, place in a bag and hold for waste disposal. Ventilate area and wash spill site after material pickup is complete.

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Section 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: Keep container tightly closed. Protect from light.

Section 8 Exposure Controls & Personal Protection

Respiratory Protection: Material does not require special ventilators, respirators, etc.

Ventilation: Local exhaust or good general ventilation.

Protective Gloves: Impervious.

Eye Protection: Safety glasses, goggles or face shield.

Other Protective Equipment: Clothing

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 & loss of sensation.

Section 9 Physical and Chemical Properties

Parameter – Oraqix

Physical State:	Liquid
Odor:	Odorless
pH:	3.3 - 5.5
Specific Gravity:	1.0 (water)

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Section 10 Stability & Reactivity Data

Stability Indicator: Yes**Materials to Avoid:** Compounds that react violently with water.**Stability Condition to Avoid:** Open burning/incineration**Hazardous Decomposition Products:** Fumes of Carbon Monoxide, Carbon Dioxide, Nitrogen Oxides Hydrogen Chloride gas**Hazardous Polymerization Indicator:** No**Conditions to Avoid Polymerization:** Not applicable

Section 11 Toxicological Information

RTECS #: Prilocaine Hydrochloride - TK6475000 ^A

ACUTE TOXICITY DATA AND REFERENCES:

ROUTE/ ORGANISM**DOSE****EFFECT****REFERENCE**

Implant / mouse

lethal dose (50 percent kill): 260 mg/kg

N/R

[29ZVAB](#) -,69,1969

implant / rabbit

lethal dose (50 percent kill): 110 mg/kg

N/R

[29ZVAB](#) -,69,1969

intraperitoneal / mouse

lethal dose (50 percent kill): 117 mg/kg

N/R

[JPPMAB](#) 40,592,1988

Intravenous / guinea pig

lethal dose (50 percent kill): 20 mg/kg

N/R

[TXAPA9](#) 2,295,1960

Intravenous / mouse

Lethal dose (50 percent kill): 32 mg/kg

N/R

[TXAPA9](#) 2,295,1960

^A - Readily available toxicity data unavailable for base form. Only selected Registry of Toxic Effects of Chemical Substances (RTECS) data are presented here. See actual entry in RTECS for complete information.

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Section 11 continued

Section 11 Toxicological Information

RTECS #: Lidocaine Hydrochloride – AN7600000 ^A

ACUTE TOXICITY DATA AND REFERENCES:

ROUTE/ ORGANISM**DOSE****EFFECT****REFERENCE**

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

[JTCTDW](#) 24,51,1986

Intravenous / infant

lowest published toxic dose: 10 mg/kg

Behavioral: Convulsions or effect on seizure threshold

Behavioral: Coma

Lung, Thorax, or Respiration: Other changes

[JTCTDW](#) 28,101,1990

Intravenous / man

lowest published toxic dose: 9 mg/kg/4 hour- continuous

Cardiac: Cardiomyopathy including infarction

[DICPBB](#) 19,669,1985

Intravenous / man

lowest published toxic dose: 7,143 µg/kg

Cardiac: Pulse rate increased without fall in BP

[CHETBF](#) 61,682,1972

Oral / infant

lowest published toxic dose: 1,632 mg/kg/1 week- intermittent

Behavioral: Somnolence (general depressed activity)

Behavioral: Convulsions or effect on seizure threshold

[CPEDAM](#) 22,190,1983^A - Readily available toxicity data unavailable for base form

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Section 12 Ecological Information^A

Parameter - Lidocaine Base^A
Prilocaine Base^A

Log Kow

-0.26

-0.38

Log Koc

3.131

3.071

Log BCF

0.500

0.500

Atmospheric Half-Life

2.7974 Hrs

3.099 Hrs

^A - as calculated via applicable algorithms encoded in EpiSuite (USEPA 2003)

Section 13 Disposal Considerations

Waste 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.

Section 14 MSDS Transport Information

Transport Information:

Contact manufacturer (Section 1)

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Section 15 Regulatory Information

SARA Title III Information: Contact local fire department regarding "Community Right-to-Know" requirements.

Federal Regulatory Information: Regulated under OSHA and FDA

State Regulatory Information: Consult with state environmental and/or public health agencies.

Section 16 Other Information

Other Information: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Dentsply, Inc. shall not be held liable for any damage resulting from handling or from contact with the above product.