PIERREL PHARMA S.R.L.

MATERIAL SAFETY DATA SHEET

articaine hydrochloride and epinephrine injection

v.6 dated January 3, 2018

Section 1: Identification

Product Identifier:	Articaine Hydrochloride 4% and Epinephrine 1:100,000 Injection Articaine Hydrochloride 4% and Epinephrine 1:200,000 Injection
Brand Name:	ORABLOC® (articaine hydrochloride 4% and epinephrine 1:100,000 and 1:200,000) Injection
Manufacturer Name:	Pierrel S.P.A.
Adrress	s.s. Appia 7Bis, 46/48 – 81043 Capua (Ce) – Italy
Phone number	+39 0823.626.111
Emergency phone number	Pierrel +1 610-989-4213 or 877-394-2465
Recommended use	Local anesthetic solution for infiltrative or conductive anesthesia in both simple and complex dental procedures.

Section 2: Hazard(s) Identification

Classification	Narcotic effects, Category 3
GHS Label Symbol	
Hazard Statements	**Warning** H336 - May cause drowsiness or dizziness May cause skin and/or eye irritation Causes central nervous system effects such as drowsiness, confusion, excitability and nervousness. Acts as a depressant on the cardiovascular system. Avoid use in individuals with hypersensitivities to amide-type anesthetics. Use with caution in individuals with diabetes and/or severe hypertension. CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOPIAL INFORMATION Signs and Symptoms of Overexposure: Drowsiness, confusion, excitability, nervousness, drop in blood pressure, fatigue, bluish discoloration of fingernails, lips, or skin, difficulties in breathing.
Precautionary Statements	**Prevention** P261 – Do not breathe mist/vapours/spray P271 – Use in a well-ventilated area **Response** P304+P430 – If inhaled – remove victim to fresh air and keep at rest in a position comfortable for breathing P312 – Call a POISON CENTER or doctor/physician if you feel unwell **Storage**

	P405 – Store locked up **Disposal** P501 – Dispose of contents/container in accordance with local/provincial/federal regulations
Potential Health Effects:	Routes of Exposure: eye, skin, ingestion. Eye: May cause irritation, allergic reaction. Skin: May cause irritation, allergic reaction Ingestion: May cause irritation, allergic reaction. Chronic Effects: May cause hypersensitivity. Associated with the development of methemoglobinemia. Signs and Symptoms of Overexposure: Drowsiness, confusion, excitability, nervousness, drop in blood pressure, fatigue, bluish discoloration of fingernails, lips, or skin, difficulties in breathing. CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOPIAL INFORMATION
Potential Environmental Effects:	Not available
Emergency Overview:	Clear, odourless liquid. May cause eye irritation. Causes central nervous system effects such as drowsiness, confusion, excitability and nervousness. Acts as a depressant on the cardiovascular system. Avoid use in individuals with hypersensitivities to amide-type anesthetics. Use with caution in individuals with diabetes and/or severe hypertension.

Section 3: Composition/Information on Ingredients

Chemical Identity	Concentration (% weight/weight)	Cas Number	LD50	LC50
Articaine Hydrochloride	4	23964-57-0	980 mg/kg oral rat	Not available
Epinephrine	0.0005 – 0.001	51-43-4	5 mg/kg dermal rat	Not available

Section 4: First-Aid Measures

Inhalation:	Remove patient from exposure
Eye Contact:	Flush eyes with plenty of water for at least 15 minutes while holding eyelids open. Get medical attention, if irritation persists.
Skin Conact:	Remove contaminated clothing. Wash skin with soap and water.
Ingestion:	Get immediate medical attention. Do not induce vomiting unless instructed to do so by poison control or physician.
Personal Protective Equipment for First Aid Responders:	Wear impermeable gloves to avoid skin contact (e.g. nitrile, natural rubber).

Section 5: Fire-Fighting Measures

Conditions of Flammability:	Not flammable
Suitable extinguishing madia:	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials
Sensitivity to Mechanical Impact:	No
Sensitivity to Static Discharge:	No
Hazardous Combustion Products:	Not available
Special Protective Actions for Firefighters:	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 6: Accidental Release Measures

Personal precautions and protective equipment:	Caution should be used to prevent against ingestion and contact with eyes. Wear safety glasses with side-shields.
Environmental precautions:	Prevent spills from entering sewers and watercourses. Cover drains.
Method and materials for containment and cleaning up, leak and spill procedure:	Clean up spills with normal procedures used for nonhazardous liquids. This can include: absorb spill with inert material, then place in a chemical waste container. Clean surface thoroughly with water to remove residual contamination.

Section 7: Handling and Storage

Handling Procedures and Equipment:	Caution should be used to prevent against ingestion and contact with eyes. Handle with care to avoid breakage.
Storage Requirements:	Store in a cool, dry place. Avoid extremes in temperature.
Packaging:	USP Type 1 glass with rubber stopper and cap
Sensitivity to mechanical impact:	No
Sensitivity to Static Discharge:	No

Section 8: Exposure Controls/Personal Protection

Exposure Limits:	Chemical Agent	Occupational Exposure limits (OEL)			
		ACGIH[a]		Ontario	
		TWA[b]	STEL[c]	TWA[b]	STEL[c]
	Articaine Hydrochloride	Not available	Not available	Not available	Not available
	Epinephrine	Not available	Not available	Not available	Not available

a – American Conference of Governmental Industrial Hygienists
b – Time Weighted Average
c – Short-Term Exposure Limit

Personal Protective Equipment (PPE)	
Gloves (specify):	Not normally required
Respiratory (specify):	Not normally required
Eye (specify):	Not normally required
Footwear (specify):	Not normally required

Other equipment (specify):	RESUSCITATIVE EQUIPMENT AND DRUGS SHOULD BE AVAILABLE DURING DENTAL PROCEDURES
Engineering Controls (e.g. ventilation, enclosed process, specify):	Not normally required

Section 9: Physical and Chemical Properties

Physical State:	Liquid
Odour and Appearance:	Clear and odourless
Odour Threshold:	Not applicable
Specific Gravity (Water=1):	1
Solubility in water:	Soluble
Co-efficient of Water/Oil Distribution:	Not available
Vapour Pressure:	17 mm Hg @ 20°C
Boiling Point (C):	100°C
Melting/Freezing Point (C):	0°C
pH:	Not available
Vapour Density (Air=1):	0.6
Evaporation Rate (Butyl Acetate=1):	1
Flashpoint (C) and Method:	Not flammable (water based)
Upper Flammable Limit (%):	Not available
Lower Flammable Limit (%):	Not available
Auto-ignition Temperature (C):	Not available

Section 10: Stability and Reactivity

Reactivity:	Stable
Chemical Stability:	Stable
Condition to avoid:	None
Incompatible Materials:	Incompatible with compounds which react violently with water
Hazardous Decomposition Products:	None

Section 11: Toxicological Information

Route of Entry:	■Skin Contact ■Skin Absorption ■Eye Contact ■Inhalation ■ Ingestion
Irritancy to Product:	Not available
Synergistic Products:	Not available
Carcinogenicity:	This product has not been listed as a carcinogen or a potential carcinogen by the ACGIH, the International Agency for Research on Cancer (IARC), the US National Toxicology Program (NTP) or the US Occupational Safety and Health Administration (OSHA).
Reproductive Toxicity:	Not available
Teratogenicity:	Animal studies have reported the increased incidence of stillbirths,

	skeletal abnormalities and delayed neurological development, but only at levels that were toxic to the mother.
Mutagenicity:	Not available
Sensitivity to Product:	Not available

Section 12: Ecological Information* (non-mandatory)

Not applicable

Section 13: Disposal Considerations* (non-mandatory)

Disposal:	Observe all Federal/Provincial/State and Local disposal regulations.

Section 14: Transport Information* (non-mandatory)

Basic Shipping Description:	Not available
Additional Information:	Not available
Special Precautions:	Avoid temperature extremes. Prevent from freezing. Keep at 77F (25°C) or below.

Section 15: Regulatory Information* (non-mandatory)

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all the information required by the Controlled Products Regulations.	
OSHA Regulatory Status:	Epinephrine is listed as a hazardous product in the RCRA (EPA) and CERCLA (EPA) regulations.
Regulatory Status:	This product is exempt from WHMIS as a drug product

Section 16: Other Information

Name of person or group that prepared SDS:	Pierrel S.P.A. orabloc@pierrelgroup.com
SDS Version #:	# 6 (replaces V.5 of October 10, 2016)

Information and statements contained in this document have been obtained from manufacturers, suppliers, and recognized reference sources as provided to or obtained by Pierrel SpA. Pierrel SpA believes the information to be reliable but expressly disclaims any liability for providing such information and toxicological data to our customers. For medical information regarding the product and its use, consult the Product Insert included in each box.