



PIERREL PHARMA S.R.L.

Safety Data Sheet

v.3 dated 08/03/2016

Section 1: Identification

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| Product Identifier: | Articaine Hydrochloride 4% and Epinephrine 100,000 Injection Articaine Hydrochloride 4% and Epinephrine 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. |
| Address | s.s. Appia 7Bis, 46/48 – 81043 Capua (Ce) – Italy |
| Phone number | +39 0823.626.211 |
| Emergency phone number | +39 0823.626.211 |
| Recommended use | Local anesthetic solution for infiltrative or conductive anesthesia in both simple and complex dental procedures. |
| Restrictions on use | |

Section 2: Hazard(s) Identification

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| 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. |
| 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 |

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

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| 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 Contact: | 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. |

Section 5: Fire-Fighting Measures

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| Conditions of Flammability: | Not flammable |
| Means of Extinction: | 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

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| 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. |
| Other Information: | Caution should be used to prevent against ingestion and contact with eyes. Wear safety glasses with side-shields. |

Section 7: Handling and Storage

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| 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 |

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)

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| 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

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| 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

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| Stability: | Stable |
| Incompatible Materials: | Incompatible with compounds which react violently with water |
| Conditions of reactivity: | None |
| Hazardous Decomposition Products: | None |

Section 11: Toxicological Information

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| Route of Entry: | <input checked="" type="checkbox"/> Skin Contact <input type="checkbox"/> Skin Absorption <input checked="" type="checkbox"/> Eye Contact <input type="checkbox"/> Inhalation <input checked="" type="checkbox"/> 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)

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| Disposal: | Observe all Federal/Provincial/State and Local disposal regulations. |
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Section 14: Transport Information* (non-mandatory)

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| 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)

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| 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

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| Name of person or group that prepared SDS: | Pierrel S.P.A. orabloc@pierrelgroup.com |
| SDS Version #: | 3 (replaces V.2 of March 19, 2013) |

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