




PIERREL PHARMA S.R.L.  
**MATERIAL SAFETY DATA SHEET**  
 articaïne hydrochloride and epinephrine injection  
 v.5 dated 10/18/2016

### Section 1: Identification

|                        |  |
|------------------------|--|
| Product Identifier:    | Articaïne Hydrochloride 4% and Epinephrine 1:100,000 Injection<br>Articaïne Hydrochloride 4% and Epinephrine 1:200,000 Injection |
| Brand Name:            | ORABLOC® (articaïne 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 0823.626.111   |
| Emergency phone number | Pierrel 610-989-4213   |
| 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        | <p><b>Warning</b></p> <p>H336 - May cause drowsiness or dizziness</p> <p>May cause skin and/or eye irritation</p> <p>Causes central nervous system effects such as drowsiness, confusion, excitability and nervousness. Acts as a depressant on the cardiovascular system.</p> <p>Avoid use in individuals with hypersensitivities to amide-type anesthetics. Use with caution in individuals with diabetes and/or severe hypertension.</p> <p><b>CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOLOGICAL INFORMATION</b></p> <p>Signs and Symptoms of Overexposure: Drowsiness, confusion, excitability, nervousness, drop in blood pressure, fatigue, bluish discoloration of fingernails, lips, or skin, difficulties in breathing.</p> |
| Precautionary Statements | <p><b>Prevention</b></p> <p>P261 – Do not breathe mist/vapours/spray</p> <p>P271 – Use in a well-ventilated area</p> <p><b>Response</b></p> <p>P304+P430 – If inhaled – remove victim to fresh air and keep at rest in a position comfortable for breathing</p> <p>P312 – Call a POISON CENTER or doctor/physician if you feel unwell</p> <p><b>Storage</b></p>  |

|                                  |   |
|----------------------------------|---|
|                                  | <p>P405 – Store locked up</p> <p><b>Disposal</b></p> <p>P501 – Dispose of contents/container in accordance with local/provincial/federal regulations</p>  |
| Potential Health Effects:        | <p>Routes of Exposure: eye, skin, ingestion. Eye: May cause irritation, allergic reaction. Skin: May cause irritation, allergic reaction</p> <p>Ingestion: May cause irritation, allergic reaction.</p> <p>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.</p> <p><b>CONSULT PRODUCT INSERT FOR CLINICAL AND PHARMACOPOL INFORMATION</b></p> |
| Potential Environmental Effects: | Not available   |
| Emergency Overview:              | <p>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.</p> <p>Avoid use in individuals with hypersensitivities to amide-type anesthetics. Use with caution in individuals with diabetes and/or severe hypertension.</p>  |

### Section 3: Composition/Information on Ingredients

| Chemical Identity       | Concentration<br>(% weight/weight) | Cas Number | LD50                  | LC50          |
|-------------------------|------------------------------------|------------|-----------------------|---------------|
| Articaine Hydrochloride | 4                                  | 23964-57-0 | 980 mg/kg<br>oral rat | Not available |
| Epinephrine             | 0.0005 – 0.001                     | 51-43-4    | 5 mg/kg<br>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 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.                 |
| 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 media:                | 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 <sup>a</sup>                 |                   | Ontario          |                   |
|   |                         | TWA <sup>b</sup>                   | STEL <sup>c</sup> | TWA <sup>b</sup> | STEL <sup>c</sup> |
|   | 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<br>b – Time Weighted Average<br>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              |                   |                  |                   |

|   |  |
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| 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<br>■ 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)

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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.<br>orabloc@pierrelgroup.com |
| SDS Version #:                             | # 5 (replaces V.4 of June 28, 2016)        |

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