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| Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010) | Date Issued: 22 June 2009  Document Number: 2731001Q  Date Revised: 21 May 2012  Revision Number: 1 |
| 1. **PRODUCT IDENTIFICATION** | |

**Trade Name (as labeled): Quala Topical Anesthetic Gel**

**Chemical Name/Classification:** Mixture

**Product Identifier (Part/Item Number):** 2731001, 2731002, 2731004, 2731005, 2731006, 2731007

**U.N. Number:** None

**U.N. Dangerous Goods Classification:** None

**Recommended Use:** Topical anesthetic

**Restrictions on Use:** Use only as directed

**Manufacturer/Supplier Name:** NDC, Inc.

**Manufacturer/Supplier Address:** 402 BNA Drive, Suite 500

Nashville, TN 37217

**Manufacturer/Supplier Telephone Number:** 800-929-4232 (Product Information)

**Emergency Contact Telephone Number:** 800-535-5053 (INFOTRAC)

1-352-323-3500 (Outside the United States – Call Collect)

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| 1. **HAZARD(s) IDENTIFICATION** |

**EU Classification (1999/45/EC as amended)::** Irritant (Xi) R43

**EU Labeling:**

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| Irritant  Irritant | Contains benzocaine  R43 May cause sensitization by skin contact.  S24/25 Avoid contact with skin and eyes.  S37 Wear suitable gloves |

**US Hazard Classification:** Hazardous

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| 1. **COMPOSITION AND INFORMATION ON INGREDIENTS** | | | | |
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| **Hazardous Components** | **C.A.S. #**  **EC#** | **IUPAC Name** | **Substance Classification** | **WT %** |
| Polyethylene Glycol | 25322-68-3 / Not available | poly(ethylene oxide) | Not applicable | 30-50 |
| Benzocaine | 94-09-7 /  202-303-5 | ethyl p-aminobenzoate | Xi, R43 | 20 |

**Refer to Section 16 for the full text of the EU Classifications and R Phrases.**

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| 1. **FIRST-AID MEASURES** |

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| **Routes of Exposure** | **First Aid Instructions** |
| **Eye** | Flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation or other symptoms persist. |
| **Skin** | Wash skin thoroughly with soap and water. Get medical attention if symptoms develop and persist. |
| **Inhalation** | None needed under normal use conditions. If irritation develops, remove to fresh air. Get medical attention if symptoms persist. |
| **Ingestion** | If swallowed, call a poison control center. Only induce vomiting if directed by medical personnel. Never give anything by mouth to an unconscious person. |
| **Most important symptoms of exposure** | Contact with skin, eyes or mucous membranes may cause numbness. Repeated skin contact may cause burning and itching of the skin with dermatitis or rash. |
| **Other** | None known. |
| **Note to Physicians (Treatment, Testing, and Monitoring):** Treatment of overexposure should be directed at the control of symptoms and clinical conditions. | |

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| 1. **FIRE-FIGHTING MEASURES** |

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| **Suitable Extinguishing Media:** | | Use media appropriate for surrounding fire. | | |
| **Fire Fighting Procedures:** | | Cool fire exposed containers and structures with water. | | |
| **Specific Hazards Arising from the Chemical:** | | None known. | | |
| **Precautions for Fire Fighters:** | | Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. | | |
| **Recommended Protective Equipment for Fire Fighters:** | | | | |
| EYES/FACE | SKIN | | RESPIRATORY | THERMAL |
| fullfaceprotect_subsectimg | handprotect_subsectimg | | lungprotect_subsectimg | bunnysuits_subsectimg |
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| 1. **ACCIDENTAL RELEASE MEASURES** | | | |
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| **Personal Precautions, PPE and Emergency Procedures:** For large spills, wear gloves and eye protection. Small spills do not require special precautions. | | | |
| **Environmental Precautions:** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities. | | | |
| **Methods and Materials for Containment and Clean-up:** Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal. | | | |
| **Recommended Personal Protective Equipment for Containment and Clean-up:** | | | |
| **EYES/FACE** | **SKIN** | **RESPIRATORY** | **THERMAL** |
| eyeprotect | handprotect_subsectimg |  |  |
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| 1. **HANDLING AND STORAGE** | | | | | | | | | |
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| **Precautions for Safe Handing:** Avoid contact with the eyes and skin. Wash thoroughly after handling. Use in accordance with package instructions. | | | | | | | | | |
| **Conditions for Safe Storage:** Avoid prolonged storage at elevated temperatures as product degradation may occur. | | | | | | | | | |
| 1. **EXPOSURE CONTROLS/PERSONAL PROTECTION** | | | | | | | | | |
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| **Occupational Exposure Limits:** | | | | | | | | | |
| Polyethylene Glycol | | United States | | 10 mg/m3 TWA AIHA WEEL (aerosol) | | | | | |
|  | | Germany | | 1000 mg/m3 (inhalable) DFG MAK | | | | | |
|  | | United Kingdom | | None Established | | | | | |
|  | | France | | None Established | | | | | |
|  | | Spain | | None Established | | | | | |
|  | | Italy | | None Established | | | | | |
|  | | European Union | | None Established | | | | | |
| Benzocaine | | United States | | None Established | | | | | |
|  | | Germany | | None Established | | | | | |
|  | | United Kingdom | | None Established | | | | | |
|  | | France | | None Established | | | | | |
|  | | Spain | | None Established | | | | | |
|  | | Italy | | None Established | | | | | |
|  | | European Union | | None Established | | | | | |
| **Biological Exposure Limits:** None Established | | | | | | | | | |
| **Appropriate Engineering Controls:** No special controls required. | | | | | | | | | |
| **Individual Protection Measures (PPE)**  **Specific Eye/face Protection:** Avoid eye contact. Safety glasses should be worn if contact is likely.  **Specific Skin Protection:** Avoid skin contact. Wear plastic or rubber gloves to avoid contact. Recommended glove: Plastic or rubber. Consult glove supplier for thickness and breakthrough times  **Specific Respiratory Protection:** None required under normal use conditions.  **Specific Thermal Hazards:** Not applicable | | | | | | | | | |
| **Recommended Personal Protective Equipment:** | | | | | | | | | |
| EYES/FACE | | | SKIN | | | RESPIRATORY | | THERMAL | |
| eyeprotect | | | handprotect_subsectimg | | |  | |  | |
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| **Environmental Exposure Controls:** None required for normal use. | | | | | | | | | |
| **General Hygiene Considerations and Work Practices:** Wash thoroughly after handling. Remove and launder contaminated clothing before reuse. | | | | | | | | | |
| **Protective Measures During Repair and Maintenance of Contaminated Equipment:** Not applicable for product. | | | | | | | | | |
| 1. **PHYSICAL AND CHEMICAL PROPERTIES** | | | | | | | | | |
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| **Appearance:** | | Gel | | | | **Explosive limits:** | | Not applicable | |
| **Odor:** | | Characteristic of flavor | | | | **Vapor pressure:** | | Negligible | |
| **Odor threshold:** | | Not available | | | | **Vapor density:** | | Not available | |
| **pH:** | | 6.05 | | | | **Relative density:** | | 1.091 @ 25°C | |
| **Melting/freezing point:** | | Not available | | | | **Solubility:** | | Disperses | |
| **Initial boiling point and range:** | | >482°F / >250°C | | | | **Partition coefficient: n-octanol/water:** | | Not available | |
| **Flash point:** | | >300°F / >149°C | | | | **Auto-ignition temperature:** | | Not available | |
| **Evaporation rate:** | | Not available | | | | **Decomposition temperature:** | | Not available | |
| **Flammability:** | | Not flammable | | | | **Viscosity:** | | 164,000 centipose | |
| **Explosive Properties:** | | None | | | | **Oxidizing Properties:** | | None | |

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| 1. **STABILITY AND REACTIVITY** |

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| **Reactivity:** Will not polymerize. |
| **Chemical Stability:** Stable. |
| **Possibility of Hazardous Reactions:** Hazardous reactions are unlikely. |
| **Conditions to Avoid:** None known. |
| **Incompatible materials:** Avoid oxidizing agents. |
| **Hazardous Decomposition Products**: Thermal decomposition may produce carbon and nitrogen oxides. |

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| 1. **TOXICOLOGICAL INFORMATION** |

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| **Potential Health Effects:**  Eyes: Direct contact may cause irritation with redness and tearing. Numbness may occur.  Skin: Direct contact may cause numbness. Prolonged or repeated skin contact may cause contact dermatitis or hypersensitivity to benzocaine with burning, stinging, tenderness and edema.  Ingestion: Swallowing may cause nausea, vomiting and diarrhea. In rare cases, bezocaine has been shown to cause methemoglobemia.  Inhalation: None expected from normal use. Inhalation of mists may cause respiratory irritation. |
| **Chronic Health Effects:** None expected. |
| **Carcinogenicity:** None of the components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives. |
| **Mutagenicity:** **No data available** |
| **Medical Conditions Aggravated by Exposure:** Employees with pre-existing skin disorders may be at increased risk from exposure. |
| **Acute Toxicity Data:**  Polyethylene Glycol: Oral mouse LD50 28,900 mg/kg  Benzocaine: LD50 oral rat 3,042 mg/kg |
| **Reproductive Toxicity Data:** No data available. |
| **Specific Target Organ Toxicity (STOT):**  Single Exposure: Benzocaine: When applied topically as recommended, benzocaine has been shown to be relatively nontoxic, however, sensitization may occur.  Repeated Exposure:Propylene glycol: In 2 week inhalation study, rats were administered whole body exposure for 6 hr/day for 9 days. No exposure related clinical signs or ophthalmic changes were noted and no mortality was recorded during the study. |

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| 1. **Ecological Information** |

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| **Toxicity:**  Propylene glycol: Salmo salar (Atlantic salmon) >1000 mg/L |
| **Persistence and Degradability:** Benzocaine: Readily biodegradable |
| **Bio-accumulative Potential:** Benzocaine: Estimated BCF is 5. Potential for bioaccumulation is low. |
| **Mobility in Soil:** Benzocaine**:** Moderate mobility based upon an estimated Koc of 250. |
| **Other Adverse Effects:** None known. |
| **Results of PBT/vPvB Assessment:** Not required. |

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| 1. **DISPOSAL CONSIDERATIONS** |

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| **Regulations:** Dispose in accordance with local and national environmental regulations |
| **Properties (Physical/Chemical) Affecting Disposal:** None known. |
| **Waste Treatment Recommendations:** None needed for normal anticipated use. |

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| 1. **TRANSPORT INFORMATION** |

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| **UN Number:** | ADR/RID: None | IMDG: None | | IATA: None | DOT: None | |
| **UN proper shipping name:** | ADR/RID: Not Regulated  IMDG: Not Regulated  IATA: Not Regulated  DOT: Not Regulated | | | | | |
| **Transport hazard class(es):** | ADR/RID: None | IMDG: None | IATA: None | | | DOT: None |
| **Packaging group:** | ADR/RID: None | IMDG: None | | IATA: None | DOT: None | |
| **Environmental hazards:** | ADR/RID: No | IMDG Marine pollutant: No | | IATA: No | DOT: No | |
| **Special precautions for user:** Not applicable | | | | | | |

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| 1. **REGULATORY INFORMATION** |

**U.S. Federal Regulations**

**Comprehensive Environmental Response and Liability Act of 1980 (CERCLA):**This product is not subject to CERCLA reporting requirements. 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 drug and not subject to chemical notification requirements.

**OSHA Hazard Classification:** Sensitizer

**Clean Water Act (CWA):** Not Listed

**Clean Air Act (CAA):** Not Listed

**Superfund Amendments and Reauthorization Act (SARA) Title III Information:**

**SARA Section 311/312 (40 CFR 370) Hazard Categories:**

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| **Immediate Hazard:** | **Yes** | **Pressure Hazard:** | **No** |
| **Delayed Hazard:** | **No** | **Reactivity Hazard:** | **No** |
| **Fire Hazard:** | **No** |  | |

**This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):**

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| **Components** | **C.A.S. #** | **WT %** |
| None |  |  |

**State Regulations**

**California:** This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

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| **Components** | **C.A.S. #** | **WT %** |
| None |  |  |

**International Regulations**

**EU REACH:** This product is a medicinal product and not subject to registration requirements.

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| 1. **OTHER INFORMATION** |
| Full text of Classification abbreviations used in Section 2 and 3:  Xi Irritant  R43 May cause sensitization by skin contact.  Date of SDS Preparation/Revision: 21 May 2012  Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits. |