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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 2009Document Number: 2731001QDate Revised: 21 May 2012Revision Number: 1 |
| 1. **PRODUCT IDENTIFICATION**
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**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**
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**EU Classification (1999/45/EC as amended)::** Irritant (Xi) R43

**EU Labeling:**

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| IrritantIrritant | Contains benzocaineR43 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/kgBenzocaine: 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 RegulatedIMDG: Not RegulatedIATA: Not RegulatedDOT: 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**
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**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**
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| Full text of Classification abbreviations used in Section 2 and 3: Xi IrritantR43 May cause sensitization by skin contact.Date of SDS Preparation/Revision: 21 May 2012Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits. |