Date of Issue:

15 September 2015

**SAFETY DATA SHEET**

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| **1. Substance and Source Identification** |

**Product Identifier**

**SRM Number:** 3260

**SRM Name:** Bitter Orange-Containing Solid Oral Dosage Form

**Other Means of Identification:** Not applicable.

**Recommended Use of This Material and Restrictions of Use**

This Standard Reference Material (SRM) is intended primarily for use in validating analytical methods for the determination of alkaloids in bitter orange-containing solid oral dosage forms and similar matrices. This SRM can also be used for quality assurance when assigning values to in-house control materials. A unit of SRM 3260 consists of five packets, each containing approximately 2.5 g of powdered material.

**Company Information**

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| National Institute of Standards and Technology |  |
| Standard Reference Materials Program |  |
| 100 Bureau Drive, Stop 2300 |  |
| Gaithersburg, Maryland 20899-2300 |  |
|  |  |
| Telephone: 301-975-2200 | Emergency Telephone ChemTrec: |
| FAX: 301-948-3730 | 1-800-424-9300 (North America) |
| E-mail: [SRMMSDS@nist.gov](mailto:SRMMSDS@nist.gov) | +1-703-527-3887 (International) |
| Website: <http://www.nist.gov/srm> |  |

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| **2. HAZARDS IDENTIFICATION** |

**Classification**

**Physical Hazard:** Not classified.

**Health Hazard:** Not classified.

**Label Elements**

**Symbol:** No symbol.

**Signal Word:** No signal word.

**Hazard Statement(s):** No applicable hazard statements.

**Precautionary Statement(s):** No applicable precautionary statements.

**Hazards Not Otherwise Classified:** None.

**Ingredients(s) with Unknown Acute Toxicity:** None.

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| **3. COMPOSITION AND INFORMATION ON HAZARDOUS INGREDIENTS** |

**Substance:** Bitter orange powder

**Other Designations:** Not available.

Components are listed in compliance with OSHA’s 29 CFR 1910.1200. For actual values, see the Certificate of Analysis.

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| **Hazardous Component(s)** | **CAS Number** | **EC Number** **(EINECS)** | **Nominal Mass Concentration (%)** |
| none | – | – | – |
| **Non-Hazardous Component(s)** |  |  |  |
| Bitter orange powder | not available | not available | 100 |

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| **4. FIRST AID MEASURES** |

**Description of First Aid Measures**

**Inhalation:** If adverse effects occur, remove to well‑ventilated (uncontaminated) area. If breathing is difficult, qualified personnel may administer oxygen. If not breathing, qualified personnel should give artificial respiration. Seek immediate medical attention.

**Skin Contact:** Rinse affected skin thoroughly with soap or mild detergent and water for at least 15 minutes. If skin irritation persists, seek medical aid and bring the container or label.

**Eye Contact:** Immediately flush eyes, including under the eyelids, with copious amounts of water for at least 15 minutes. Seek immediate medical attention.

**Ingestion:** If a large amount is swallowed, seek medical attention.

**Most Important Symptoms/Effects, Acute and Delayed:** No information available.

**Indication of any immediate medical attention and special treatment needed, if necessary:** If any of the above symptoms are present, seek immediate medical attention.

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| **5. FIRE FIGHTING MEASURES** |

**Fire and Explosion Hazards:** Negligible fire hazard. See Section 9, “Physical and Chemical Properties” for flammability properties.

**Extinguishing Media**

Suitable: Use extinguishing media based on surrounding fire.

Unsuitable: None listed.

**Specific Hazards Arising from the Chemical:** Not applicable.

**Special Protective Equipment and Precautions for Fire-Fighters:** Move container from fire area if it can be done without personal risk. Avoid inhalation of material or combustion by‑products. Wear full protective clothing and NIOSH‑approved self‑contained breathing apparatus (SCBA).

**NFPA Ratings** (0 = Minimal; 1 = Slight; 2 = Moderate; 3 = Serious; 4 = Severe)

Health = 0 Fire = 0 Reactivity = 0

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| **6. ACCIDENTAL RELEASE MEASURES** |

**Personal Precautions, Protective Equipment and Emergency Procedures:** Use suitable protective equipment; see Section 8, “Exposure Controls and Personal Protection”.

**Methods and Materials for Containment and Clean up:** Avoid generating and accumulating dust. Collect in appropriate container for disposal.

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| **7. HANDLING AND STORAGE** |

**Safe Handling Precautions:** See Section 8, “Exposure Controls and Personal Protection”.

**Storage and Incompatible Materials:** Keep separated from incompatible substances and ignition sources.

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| **8. EXPOSURE CONTROLS AND PERSONAL PROTECTION** |

**Exposure Limits:** No occupational exposure limits established for bitter orange powder. OSHA lists the following exposure limits for Particulates Not Otherwise Regulated.

OSHA (PEL): 15 mg/m3 TWA (total particulates)

5 mg/m3 TWA (respirable particulates)

**Engineering Controls:** Provide local exhaust or process enclosure ventilation system. Ensure compliance with applicable exposure limits.

**Personal Protection Measures:** In accordance with OSHA 29 CFR 1910.132, subpart I, wear appropriate Personal Protective Equipment (PPE) to minimize exposure to this material.

**Respiratory Protection:** If workplace conditions warrant a respirator, a respiratory protection program that meets OSHA 29CFR 1910.134 must be followed. Refer to NIOSH 42 CFR 84 for applicable certified respirators.

**Eye Protection:** Splash resistant safety goggles and emergency eyewash are recommended.

**Skin and Body Protection:** Chemical resistant clothing and gloves are recommended.

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| **9. PHYSICAL AND CHEMICAL PROPERTIES** |

| **Descriptive Properties** | Bitter orange powder |
| --- | --- |
| **Molar Mass (g/mol)** | not applicable |
| **Molecular Formula** | not applicable |
| **Appearance (physical state, color, etc.)** | powder |
| **Odor** | not available |
| **Odor threshold** | not available |
| **pH** | not available |
| **Evaporation rate** | not available |
| **Melting point/freezing point** | not available |
| **Relative Density** | not available |
| **Density** | not available |
| **Vapor Pressure** | not available |
| **Vapor Density (air = 1)** | not available |
| **Viscosity** | not available |
| **Solubilities** | not available |
| **Partition Coefficient (n‑octanol/water)** | not available |
| **Particle Size** | not available |
| **Thermal Stability Properties** |  |
| **Autoignition Temperature** | not available |
| **Thermal Decomposition** | not available |
| **Initial boiling point and boiling range** | not available |
| **Explosive Limits, LEL (Volume %)** | not available |
| **Explosive Limits, UEL (Volume %)** | not available |
| **Flash Point** | not available |
| **Flammability (solid, gas)** | not available |

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| **10. STABILITY AND REACTIVITY** |

**Reactivity:** Stable at normal temperatures and pressure.

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| **Stability:** | X | Stable |  | Unstable |

**Possible Hazardous Reactions:** Not applicable.

**Conditions to Avoid:** Avoid generating dust.

**Incompatible Materials:** None listed.

**Hazardous Decomposition:** None listed.

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| **Hazardous Polymerization:** |  | Will Occur | X | Will Not Occur |

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| **11. TOXICOLOGICAL INFORMATION** |

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| **Route of Exposure:** | X | Inhalation | X | Skin | X | Ingestion |

**Symptoms Related to the Physical, Chemical and Toxicological Characteristics:** Eye or skin mechanical irritation.

**Potential Health Effects (Acute, Chronic, and Delayed)**

**Inhalation:** May cause irritation.

**Skin Contact:** May cause irritation.

**Eye Contact:** May cause irritation.

**Ingestion:** Large quantities may cause gastrointestinal distress; no other adverse effects identified.

**Numerical Measures of Toxicity**

**Acute Toxicity:** No data available.

**Skin Corrosion/Irritation:** No data available.

**Serious Eye Damage/Irritation:** No data available.

**Respiratory Sensitization:** No data available.

**Skin Sensitization:** No data available.

**Germ Cell Mutagenicity:** No data available.

**Carcinogenicity:** Not classified.

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| **Listed as a Carcinogen/Potential Carcinogen** |  | **Yes** | X | **No** |

Bitter orange powder is not listed by IARC, NTP or OSHA as a carcinogen/potential carcinogen.

**Reproductive Toxicity:** No data available.

**Specific Target Organ Toxicity, Single Exposure:** No data available.

**Specific Target Organ Toxicity, Repeated Exposure:** No data available.

**Aspiration Hazard:** Not applicable.

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| **12. ECOLOGICAL INFORMATION** |

**Ecotoxicity Data:** No data available.

**Persistence and Degradability:** No data available.

**Bioaccumulative Potential:** No data available.

**Mobility in Soil:** No data available.

**Other Adverse effects:** No data available.

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| **13. DISPOSAL CONSIDERATIONS** |

**Waste Disposal:** Dispose in accordance with all applicable federal, state, and local regulations.

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| **14. TRANSPORTATION INFORMATION** |

**U.S. DOT and IATA:** This material is not regulated by DOT or IATA.

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| **15. REGULATORY INFORMATION** |

**U.S. Regulations**

CERCLA Sections 102a/103 (40 CFR 302.4): Not regulated.

SARA Title III Section 302 (40 CFR 355.30): Not regulated.

SARA Title III Section 304 (40 CFR 355.40): Not regulated.

SARA Title III Section 313 (40 CFR 372.65): Not regulated.

OSHA Process Safety (29 CFR 1910.119): Not regulated.

SARA Title III Sections 311/312 Hazardous Categories (40 CFR 370.21)

ACUTE HEALTH: No

CHRONIC HEALTH: No

FIRE: No

REACTIVE: No

PRESSURE: No

**State Regulations:** Not listed.

**U.S. TSCA Inventory:** Not listed.

**TSCA 12(b), Export Notification:** Not listed.

**Canadian Regulations:** WHMIS Information: Not provided for this material.

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| **16. OTHER INFORMATION** |

**Issue Date:** 15 September 2015

**Sources:** CDC; NIOSH;*NIOSH Pocket Guide to Chemical Hazards*; Department of Health and Human Services (DHHS), Centers for Disease Control and Prevention (CDC), National Institute for Safety and Health; *Particulates not otherwise regulated*, 13 February 2015; available at <http://www.cdc.gov/niosh/npg/npgd0480.html> (accessed Sep 2015).

**Key of Acronyms:**

|  |  |  |  |
| --- | --- | --- | --- |
| ACGIH | American Conference of Governmental Industrial Hygienists | NTP | National Toxicology Program |
| CAS | Chemical Abstracts Service | OSHA | Occupational Safety and Health Administration |
| CERCLA | Comprehensive Environmental Response, Compensation, and Liability Act | PEL | Permissible Exposure Limit |
| CFR | Code of Federal Regulations | RCRA | Resource Conservation and Recovery Act |
| DOT | Department of Transportation | REL | Recommended Exposure Limit |
| EINECS | European Inventory of Existing Commercial Chemical Substances | RQ | Reportable Quantity |
| EPCRA | Emergency Planning and Community Right-to-Know Act | RTECS | Registry of Toxic Effects of Chemical Substances |
| IARC | International Agency for Research on Cancer | SARA | Superfund Amendments and Reauthorization Act |
| IATA | International Air Transportation Agency | SCBA | Self‑Contained Breathing Apparatus |
| IDLH | Immediately Dangerous to Life and Health | SRM | Standard Reference Material |
| LC50 | Lethal Concentration | STEL | Short Term Exposure Limit |
| LD50 | Median Lethal Dose or Lethal Dose, 50 % | TLV | Threshold Limit Value |
| LEL | Lower Explosive Limit | TPQ | Threshold Planning Quantity |
| MSDS | Material Safety Data Sheet | TSCA | Toxic Substances Control Act |
| NFPA | National Fire Protection Association | TWA | Time Weighted Average |
| NIOSH | National Institute for Occupational Safety and Health | UEL | Upper Explosive Limit |
| NIST | National Institute of Standards and Technology | WHMIS | Workplace Hazardous Materials Information System |
| n.o.s. | Not Otherwise Specified |  |  |

**Disclaimer:** Physical and chemical data contained in this SDS are provided only for use in assessing the hazardous nature of the material. The SDS was prepared carefully, using current references; however, NIST does not certify the data in the SDS. The values for this material are given in the NIST Certificate of Analysis.

Users of this SRM should ensure that the SDS in their possession is current. This can be accomplished by contacting the SRM Program: telephone (301) 975-2200; fax (301) 948-3730; e-mail srmmsds@nist.gov; or via the Internet at <http://www.nist.gov/srm>.