Date of Issue:
02 November 2018

SAFETY DATA SHEET

1. SUBSTANCE AND SOURCE IDENTIFICATION

Product Identifier

SRM Number: 3238
SRM Name: Soy-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 validation of methods for determining isoflavones in solid oral dosage forms containing soy and in similar matrices. This SRM can also be used for quality assurance when assigning values to in-house reference materials. A unit of SRM 3238 consists of 5 packets, each containing approximately 2.6 g of material.

Company Information

National Institute of Standards and Technology
Standard Reference Materials Program
100 Bureau Drive, Stop 2300
Gaithersburg, Maryland 20899-2300

Telephone: 301-975-2200
FAX: 301-948-3730
E-mail: SRMMSDS@nist.gov
Website: https://www.nist.gov/srm

Emergency Telephone ChemTrec:
1-800-424-9300 (North America)
+1-703-527-3887 (International)

2. HAZARDS IDENTIFICATION

Note: This processed material is intended for laboratory use only; not for human consumption. SRM 3238 is supplied in a small quantity and under normal laboratory conditions it does not constitute a combustible dust hazard. The physical properties of this material indicate that accumulated dust on surfaces generated where operations produce fine particulates, may lead to combustible dust concentrations in air.

Classification

Physical Hazard: Not classified.
Health Hazard: Not classified.

Label Elements
Symbol
No Symbol

Signal Word
No Signal Word

Hazard Statement(s): Not applicable.

Precautionary Statement(s): Not applicable.

Hazards Not Otherwise Classified: Not applicable.

Ingredients(s) with Unknown Acute Toxicity: Not applicable.

3. COMPOSITION AND INFORMATION ON HAZARDOUS INGREDIENTS

Substance: Ground soy tablets

Other Designations: Soy powder

Components are listed in compliance with OSHA's 29 CFR 1910.1200.

Hazardous Component(s)	CAS Number	EC Number (EINECS)	Nominal Mass Concentration (%)
Ground soy tablets	not applicable	not applicable	100

4. First Aid Measures

Description of First Aid Measures:

Inhalation: If adverse effects occur, remove to uncontaminated area. If not breathing, give artificial respiration or oxygen by qualified personnel. Seek immediate medical attention.

Skin Contact: Wash skin with soap and water for at least 15 minutes. Thoroughly clean and dry contaminated clothing before reuse.

Eye Contact: Flush eyes with water for at least 15 minutes. If necessary, seek medical attention.

Ingestion: If adverse effects occur after ingestion, seek medical treatment.

Most Important Symptoms/Effects, Acute and Delayed: No data available; generated dust may cause soy flour related allergic reactions, and irritation.

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

5. Fire Fighting Measures

Fire and Explosion Hazards: Avoid generating dust; sufficient concentrations of fine dust dispersed in air, and in the presence of an ignition source is a potential hazard. See Section 9, "Physical and Chemical Properties" for flammability properties.

Extinguishing Media:

Suitable: Use extinguishing media appropriate for surrounding fire.
Unsuitable: None listed.

Specific Hazards Arising from the Chemical: None listed.

Special Protective Equipment and Precautions for Fire-Fighters: Avoid inhalation of material or combustion byproducts. 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

6. Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures: Any accumulated material on surfaces should be removed and properly disposed of. Use suitable protective equipment; see Section 8, "Exposure Controls and Personal Protection".

Methods and Materials for Containment and Clean up: Do not touch spilled material. Notify safety personnel of spills. Collect spilled material in appropriate container for disposal. Isolate hazard area and deny entry.

7. Handling and Storage

Safe Handling Precautions: Minimize dust generation and accumulation on surfaces. See Section 8, "Exposure Controls and Personal Protection".

Storage: Store and handling in accordance with all current regulations and standards. Keep separated from incompatible substances.

8. Exposure Controls and Personal Protection

Exposure Limits: This material is a particulate matter and adequate inhalation/respiratory protection should be used to minimize exposure. No occupational exposure limits have been established for soy powder. The exposure limits for Particulates Not Otherwise Regulated are applicable.

OSHA (PEL): 15 mg/m^3 (TWA, total particulates not otherwise regulated)
5 mg/m^3 (TWA, respirable particulates not otherwise regulated)

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

Personal Protection: 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/Face Protection: Wear splash resistant safety goggles with a face shield. An eye wash station should be readily available near areas of use.

Skin and Body Protection: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Chemical-resistant gloves should be worn at all times when handling chemicals.

9. PHYSICAL AND CHEMICAL PROPERTIES

Descriptive Properties:

Appearance (physical state, color, etc.):	powder
Molecular Formula:	not applicable
Molar Mass (g/mol):	not applicable
Odor:	not available
Odor threshold:	not available
pH:	not available
Evaporation rate:	not applicable
Melting point/freezing point (ºC):	not available
Relative Density (g/L):	not available
Vapor Pressure (mmHg):	not applicable
Vapor Density (air = 1):	not applicable
Viscosity (cP):	not applicable
Solubility(ies):	not available
Partition coefficient (n-octanol/water):	not available
Particle Size	≤180 µm (80 mesh)

Thermal Stability Properties:

Autoignition Temperature (ºC):	not available
Thermal Decomposition (ºC):	not available
Initial boiling point and boiling range (ºC):	not available
Explosive Limits, LEL (Volume %):	not available
Explosive Limits, UEL (Volume %):	not available
Flash Point (ºC)	not available
Flammability (solid, gas):	not available

10. STABILITY AND REACTIVITY

Reactivity: Stable at normal temperatures and pressure.

Stability: X Stable _____ Unstable

Possible Hazardous Reactions: None listed.

Conditions to Avoid: Avoid generating dust. Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

Incompatible Materials: None listed.

Fire/Explosion Information: See Section 5, "Fire Fighting Measures".

Hazardous Decomposition: None listed.

Hazardous Polymerization: _____ Will Occur X Will Not Occur

11. TOXICOLOGICAL INFORMATION

Route of Exposure: X Inhalation X Skin X Ingestion

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: No data available; generated dust may cause soy related allergic reactions, and irritation.

Potential Health Effects (Acute, Chronic and Delayed):

Inhalation: No data available; exposure may result in respiratory tract irritation.

Skin Contact: No data available; skin exposure may result in mechanical irritation.

Eye Contact: No data available; dust may cause mechanical irritation.

Ingestion: No data available; if ingested, irritation or food allergy related symptoms may occur.

Numerical Measures of Toxicity:

Acute Toxicity: Not classified; no data available.

Skin Corrosion/Irritation: Not classified; no data available.

Serious Eye Damage/ Eye Irritation: Not classified; no data available.

Respiratory Sensitization: Not classified; no data available.

Skin Sensitization: Not classified; no data available.

Germ Cell Mutagenicity: Not classified; no data available.

Carcinogenicity: Not classified.

Listed as a Carcinogen/Potential Carcinogen ____ Yes X No

Soy is not listed by NTP, IARC or OSHA as a carcinogen.

Reproductive Toxicity: Not classified; no data available.

Specific Target Organ Toxicity, Single Exposure: Not classified; no data available.

Specific Target Organ Toxicity, Repeated Exposure: Not classified; no data available.

Aspiration Hazard: Not classified; no data available.

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.

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORTATION INFORMATION

U.S. DOT and IATA: Not regulated by DOT or IATA.

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:

California Proposition 65: Not listed.

U.S. TSCA Inventory: Not listed.

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

Canadian Regulations:

WHMIS Information: Not provided for this material.

16. OTHER INFORMATION

Issue Date: 02 November 2018

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*, 04 April 2011; available at https://www.cdc.gov/niosh/npg/npgd0480.html (accessed Nov 2018).

Key of Acronyms:

ACGIH	American Conference of Governmental Industrial Hygienists	NRC	Nuclear Regulatory Commission
ALI	Annual Limit on Intake	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
EC50	Effective Concentration, 50 %	RM	Reference Material
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 Transport Association	SCBA	Self-Contained Breathing Apparatus
IDLH	Immediately Dangerous to Life and Health	SRM	Standard Reference Material
LC50	Lethal Concentration, 50 %	STEL	Short Term Exposure Limit
LD50	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

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 certified 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 https://www.nist.gov/srm.