MATERIAL SAFETY DATA SHEET (MSDS)



Date: 11/17/15

FASTRATE™ UNIT DOSE TITRATION STANDARDS

This document has been prepared in accordance with the requirements of the United States (US) Occupational Safety and Health Administration (OSHA) Hazard Communication Standard 29 Code of Federal Regulations (CFR) 1910.1200, the European Union (EU) Directive 91/155/EEC, and other regulatory requirements.

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: FASTRATE™ Unit Dose Titration Standard

Alternate Product Name(s): FASTRATE™ 1 mg Calibration Standard for Titration

FASTRATE™ 2 mg Calibration Standard for Titration FASTRATE™ 5 mg Calibration Standard for Titration FASTRATE™ 10 mg Calibration Standard for Titration FASTRATE™ 25 mg Calibration Standard for Titration

Product Code(s): Item Number 151001 − FASTRATETM 1 mg

Item Number 120213 – FASTRATE[™] 2 mg Item Number 120222 – FASTRATE[™] 5 mg Item Number 110809 – FASTRATE[™] 10 mg Item Number 111017 – FASTRATE[™] 25 mg

Chemical Name: Not applicable Molecular Formula: Not applicable

Chemical Family: Reference standard for analytical testing only. Not for use in humans or animals.

MSDS FID: 108249 Date Prepared: 11/17/15

Revision: 7

Classification: Non-hazardous

MANUFACTURER EMERGENCY CONTACT INFORMATION (U.S.)

FACET® Analytical Services and Technology, LLC

8261 Burnt Store Road Punta Gorda, FL 33950 T 941-505-7814 (FACET® Mfg Plant – P.G. Florida)

F 941-505-7815 www.facetllc.com

info@facetllc.com (email – general information)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Description: Mixture of compounds typical and common in the art of tablet making

A composition of fine or free-flowing powders (solids)

Ingredients: Chemical identity is being withheld as a trade secret but ingredients are classified

as non-hazardous

Individual ingredients are not classified as carcinogens

FASTRATE™ UNIT DOSE TITRATION STANDARDS (108249)

3. HAZARDS IDENTIFICATION

Emergency Overview: May form combustible dust concentrations in air when disturbed and dispersed.

May cause eye, skin, and respiratory tract irritation. Injestion may cause gastric disturbances. Avoid contact with eyes, skin, and clothing. Avoid inhalation of

dusts. Use local exhaust ventilation

Hazard Class: Not regulated; non-hazardous

Health Hazard: No significant health hazard expected

May be harmful if injested in great quantity

May be irritating to eyes and respiratory system if inhaled as dust

4. FIRST AID MEASURES

Eyes: Irrigate thoroughly with water (at least 15 minutes). If irritation persists, seek

medical attention

Skin: Wash thoroughly with soap and water. Seek medical attention if irritation

persists

Ingestion: No hazard anticipated from ingestion incidental to industrial exposure. Drink

plenty of water and seek medical attention if discomfort persists

Inhalation: Non-hazardous, nuisance dust. Remove to fresh air. If breathing difficulty or

discomfort persists, seek medical attention

Other: Low oral, dermal and inhalation toxicity that is non-irritating to skin and eyes and

non-sensitizing to the skin

5. FIRE FIGHTING MEASURES

Extinguishing Media: Water, dry powder, CO2

Fire and Explosion Hazards: Combustible. Dust explosion hazard. Avoid conditions of dust concentration,

especially overhead

Fire Fighting Procedures: Normal precautions against smoke inhalation; do not enter any enclosed or

confined space without wearing full protective clothing and Self-Contained

Date: 11/17/15

Breathing Apparatus (SCBA) approved for firefighting

Hazardous Decomposition: CO2, H2O, and typical combustion by-products

Flash Point and Method: Not applicable

Flammable Limits: Not applicable

Autoignition Temperature: Not available

6. ACCIDENTAL RELEASE MEASURES

General: Maintain good housekeeping procedures to minimize accumulation of settled

dust, especially on overhead surfaces

Personal Precautions: Typical Personal Protective Equipment (PPE) - dust mask, gloves, gown, and

goggles are recommended

Environmental Precautions: Non-hazardous. Spills of this material are not subject to any special reporting

requirements under the current environmental legislation in either the USA or

European Union

Recovery: Dispose of product in accordance with all applicable local, state, and federal

regulations

7. HANDLING AND STORAGE

General: Use local exhaust to control exposure to dust

Storage: Store in a well-closed tight container, at room temperature (15°C-30°C)

conditions. Keep away from moisture

Handling: Typical Personal Protective Equipment (PPE) - dust mask, gloves, gown, and

goggles are recommended. Cleaning and housekeeping procedures should

minimize dust creation

8. EXPOSURE CONTROLS/PERSONAL PROTECTION (NORMAL USE)

Occupational Exposure Limits: Non-hazardous nuisance dust. OSHA Permissible Exposure Limit (PEL) 15

mg/m3 total dust and 5 mg/m3 respirable fraction; 10 mg/m3 TWA (ACGIH)

Date: 11/17/15

Engineering Measures: Use local exhaust

PPE: Respiratory – dust mask or respirators recommended

Hand – gloves not required but recommended

Eye – goggles recommended

Clothing – gowns not required but recommended

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance: Round tablet with flat, beveled edges

Odor:

pH:

Viscosity:

Boiling Point:

Vapor Pressure:

Vapor Density:

Odorless

Not Applicable

Not Applicable

Not Applicable

Not Applicable

Not Applicable

Not Applicable

Solubility: Generally insoluble in water

10. STABILITY AND REACTIVITY

Stability: Stable if stored at recommended conditions

Conditions To Avoid: Dust formation; electro-static charge; all sources of ignition; moisture; high

temperature; high humidity

Hazardous Decomposition

Products: None known

Materials to Avoid: Oxidizing substances; processing equipment not suited for food and/or

pharmaceutical industries; strong alkalies; strong acids; strong bases

11. TOXICOLOGICAL INFORMATION

Eye Effects: None known; non-irritating

Skin: None known; non-irritating

Ingestion: No hazard anticipated incidental to industrial exposure

Inhalation: No hazard anticipated incidental to industrial exposure

Acute: Low oral, dermal and inhalation toxicity that is non-irritating to skin and eyes and

non-sensitizing to the skin

Chronic: No adverse human affects are known

No evidence of carcinogenic, mutagenic, or teratogenic effects

Carcinogenicity: IARC – Not listed

NTP – Not listed OSHA – Not listed ACGIH – Not listed

12. ECOLOGICAL INFORMATION

Environmental: Inherently biodegradable

Ecotoxicological: Rainbow Trout – 96 hour LC50 > 100%, saturated solution; NOEC = 100%;

Daphnia – 48 hour LC50 > 100%, saturated solution; NOEC = 100%; Algae - 96 hour EC50 > 100%, saturated solution; NOEC = 12.5%

Other: None known

13. DISPOSAL CONSIDERATIONS

No special methods suggested Dispose of product in accordance with all applicable local, state, and federal regulations

14. TRANSPORTATION INFORMATION

Not regulated: Reference standard for analytical testing only. Not for use in humans or animals

Transport Classification: Not regulated

Identification Number: Not applicable

Proper Shipping Name: Not applicable

ICAO/IAT/IMDG Class: Not applicable

Subsidiary Risk: Not applicable

Packing Group: Not applicable

ADR Class: Not applicable

Transport Hazard Symbol: Not applicable

Hazard Identification Number: Not regulated

Emergency Action Code: Not applicable

U.S. DOT: Not listed in Title 49 of the U.S. CFR as a hazardous material

MARPOL Designation: None

Canada (TDG): Not applicable

15. REGULATORY INFORMATION

United States: SARA Title III (Superfund Ammendments and Reauthorization Act)

Section 311 Hazard Categories (40 CFR 370) - None

Section 312 Threshold Planning Quantities (40 CFR 370): The threshold

Planning Quantity (TPQ) of this product if treated as a mixture is 10,000 lbs. This product contains the following ingredients with a TPQ of less than 10,000 lbs. -

None

Section 313 Reportable Ingredients (40 CFR 372) - This product does not

contain any toxic chemicals subject to the reporting requirements of Section 313,

Date: 11/17/15

Title III of SARA of 1986

15. REGULATORY INFORMATION (cont.)

TSCA (Toxic Substance Control Act): TSCA Inventory (40 CFR 710, Subpart b) – Yes

Canada: WHMIS (Workplace Hazardous Materials Information system) - Not a controlled

product under WHMIS

General: Symbols - Not classified as hazardous

Risk Phrases - Not classified as hazardous Safety Phrases - Not classified as hazardous

Supply Classification - Not regulated

16. OTHER INFORMATION

NFPA RATING: HEALTH = 1

FLAMMABILITY = 1 REACTIVITY = 0 SPECIAL = NONE

NFPA Degree of Hazard Code: 4 = Extreme

3 = High 2 = Moderate 1 = Slight 0 = Insignificant

NFPA = National Fire Protection Association

The above information is believed to be correct but is not purported to be all-inclusive and shall be used as a guide. FACET® Analytical Services and Technology, LLC shall not be held liable for any damage resulting from handling or from contact with the above product.

