SAFETY DATA SHEETS

This SDS packet was issued with item:

078929876

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078929878 078929880

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SAFETY DATA SHEET

Version 1.0

Revision Date: 18-Dec-2015

entyce
(capromorelin oral solution)

058966; 058967; 058968
as of 7/20/17

SECTION 1: IDENTIFICATION

1. Product identifiers

Product Code	FP-197 / AT002
Trade name	Entyce®
CAS-No.	NA
Molecular weight	NA
Type of preparation	Solution

2. Recommended uses of substances and uses advised against

Use	For Appetite stimulation in dogs.

3. Details of the supplier of the safety data sheet

Company	Aratana Therapeutics, Inc. 11400 Tomahawk Creek Parkway, Suite 340 Leawood, Kansas 66211 USA
Telephone	844-744-7389
Contact person	Dr. Andy Fox

4. Emergency telephone number

Emergency telephone number	844-640-5500

SECTION 2: HAZARDS IDENTIFICATION

1. Classification in accordance with paragraph (d) of OSHA Hazard Communication Standard 29CFR 1910.1200

Classification	Hazardous

2. Label elements (OSHA/GHS)

General Warnings	P101	If medical advice is needed, have product container or label at hand
	P102	Keep out of reach of children
	P103	Read label before use
	P403	Store in a well-ventilated place
	P233	Keep container tightly closed
Signal Word		WARNING
Hazard Statements	H317	May cause an allergic skin reaction, sensitizer
	H305	May be harmful if swallowed and enters airways
	H373	May cause damage to organs through prolonged or repeated exposure
	H360	May damage fertility or the unborn child Category 2B
Precautionary Statements		
	P264	Wash hands thoroughly after handling
	P280	Wear protective gloves/protective clothing
	P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
	P302 + P352	IF ON SKIN: Wash with plenty of soap and water

Hazard pictograms	

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Hazardous components

Common Name	FP-197 (Capromoreline Tartrate)
Chemical Name	N-{(1R)-2-[(3aR)-2-methyl-3-oxo-3a-benzyl(2H-4,5,6,7,3a-Pentahydro-5-azaindazol-5-yl)]-2-oxo-1-[(phenylmethoxy)methyl]ethyl}-2-amino-2-methylpropanamide, L-tartaric acid salt
Percent by Weight	2-3 %
CAS Number	193273-69-7

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	Move to fresh air and keep at rest. If not breathing, give artificial respiration. Seek medical attention immediately
Skin contact	Wash exposed area with soap and water. Remove contaminated clothing and launder before reuse. Seek medical attention if discomfort persists
Eye contact	Rinse eyes with flowing water for 15 minutes. Seek medical attention immediately

Ingestion	Wash out mouth with water provided person is conscious. Seek medical attention immediately

4.2 Most important symptoms/effects, acute and delayed

Poisoning Symptoms	None known

4.3 Indication of any immediate medical attention and special treatment needed

Antidote	NA

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media	Carbon Dioxide, Dry Chemical or water spray

5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products	Emits toxic fumes of carbon monoxide and oxides of nitrogen, and sulfur

5.3 Advice for firefights

Special protective equipment for fire fighters	Wear appropriate protective equipment including self contained breathing apparatus. Prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	Evacuate area. Shut off all sources of ignition. Use non-sparking tools. Personnel involved in clean-up should wear appropriate personal protective equipment and minimize exposure. Adequate skin and respiratory protection should be worn when cleaning up spills (e.g. respirator, safety goggles, rubber boots and rubber gloves).

6.2 Environmental precautions

Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up	Use HEPA filtered vacuum, or gently sweep up dry solids, and place spill residue in closed containers. Clean spill area thoroughly. Dispose of all waste in accordance with applicable pharmaceutical waste disposal regulations.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe handling advice	Do not breathe vapor. Substance should be handled in a laboratory fume hood and individuals should use eye protection, gloves, and proper gowning. Dust generation or volatile vapors should be minimized.
Storage	Store in properly labeled HDPE or glass containers. Keep away from heat, sparks and flames
Advice on common storage	Ambient
Storage temperature	Store at 20-25 °C (68-77°F)

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

1. Control parameters

Components with workplace control parameters			
Identification	CAS-No.	Notes	Exposure limit(s)
NA			

2. Exposure controls

Personal protective equipment - Open handling

Respiratory protection	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for weighing, charging, grinding, or crushing. If respiratory protection is needed, use only protection authorized in the U.S. Federal OSHA Standard (29 CFR 1910.134), applicable U.S. State regulations, or the applicable local standards. For nuisance exposures use type P95 (US) particle respirator. For higher level protection use type OV/AG/P100 (US) respirator cartridges. Oxygen levels below 19.5% are considered IDLH by OSHA. In such atmospheres, use of a full-face piece

	pressure/demand SCBA or a full-face piece, supplied air respirator with auxiliary self-contained air supply is required under OSHA's Respiratory Protection Standard (1910.134).
Hand protection	Wear chemical impervious gloves (e.g., Solvex™, Neoprene). Thin mil nitrile gloves are appropriate in a laboratory or clinical setting. Inspect gloves prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this substance. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
Eye protection	Ensure eyewash/safety shower stations are available near areas where this substance is used. Use approved safety goggles or safety glasses, as described in OSHA 29 CFR 1910.133. Splash goggles with a face shield may be needed if significant splash hazards exist.
Skin and body protection	Lab coat or normal body protection is adequate. If needed, use body protection appropriate for task (e.g., Tyvek suit, rubber apron) to protect from splashes and sprays.
Hygiene measures	Wash hands thoroughly following use

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Clear, colorless to light yellow or orange solution
Odor	Vanillin odor
Odor threshold	Not determined
pH	3.0 – 4.0
Melting point/freezing point	Not determined

Initial boiling point and boiling range	Not determined
Flash point	Not determined
Evaporation rate	Not determined
Flammability	Not determined
Vapor pressure	Not determined
Vapor density	Not determined
Relative density	Not determined
Solubility	Marginally soluble ine water, and soluble in methanol
Partition coefficient	Not determined
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
Viscosity	50 – 90 centipoises

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Reactivity	As a precaution, keep away from strong oxidizers

10.2 Chemical stability

Thermal Decomposition Hazard	N/A

10.3 Possibility of hazardous reactions

Hazardous reactions	N/A

10.4 Conditions to avoid

Conditions to avoid	Not determined

10.5 Incompatible materials

Materials to avoid	As a precautionary measure, keep away from strong oxidizers.

10.6 Hazardous decomposition products

Hazardous decomposition products	Carbon monoxide, nitrogen oxide

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute oral toxicity	Not determined
Acute inhalation toxicity	Not determined
Acute dermal toxicity	Not determined
Skin/eye irritation	Not determined
Sensitization	Not known, however prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals
Mutagenicity (in vitro/in vivo)	Not determined
Carcinogencity	Unknown – None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA
Reproductive toxicity	Unknown
Specific Target Organ Toxicity	Irritant to skin and may produce allergic reaction. Potentially toxic to bone marrow, blood, CNS, gastric system, reproductive system, kidney, and liver.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish	Unknown – Not determined
Toxicity to daphnia	Unknown – Not determined
Toxicity to algae	Unknown – Not determined
Toxicity to soil organisms	Unknown – Not determined

12.2 Persistence and degradability

Biodegradability	Unknown – Not determined
Bioaccumulation	Unknown - Not determined

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product	Dispose in accordance with applicable federal, state, and local regulations
Contaminated packaging	Dispose of container and unused contents in accordance with federal, state and local regulations

SECTION 14: TRANSPORT INFORMATION

14.1 Land transport (ADR/RID)

UN number	Not regulated

14.2 Sea transport (IMDG)

UN number	Not regulated

14.3 Air transport (ICAO/IATA)

UN number	Not regulated

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

SARA 311/312 Acute	Not listed
California Proposition 65	Not listed

15.2 Chemical Safety Assessment

Assessment	Not required

SECTION 16: OTHER INFORMATION

This version replaces all previous versions

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a quality specification or a warranty of any kind, expressed or implied. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text. This information shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.