



SAFETY DATA SHEET

Revision Date 02-Oct-2018

Version 10

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Chemical Name Eluxadoline

Other means of identification

Product Code 864825-13-8

Synonyms Viberzi

Recommended use of the chemical and restrictions on use

Recommended Use Product used to treat adults who have Irritable Bowel Syndrome with Diarrhea

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet

Manufacturer

Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525

E-mail address SDS@Allergan.com

Emergency telephone number

Emergency Telephone Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Label elements

Emergency Overview

The product contains no substances which at their given concentration, are considered to be hazardous to health

Appearance powder

Physical state Solid

Odor No information available

Chemical Name
Eluxadoline

Symptoms
The most common adverse effects include nausea, abdominal pain and constipation

Chemical Name
Eluxadoline

Medical Conditions Aggravated by Exposure
Viberzi is contraindicated in patients with known or suspected biliary duct obstruction; or sphincter of Oddi disease or dysfunction. Also alcoholism, alcohol abuse or alcohol addiction, or in patients who drink more than 3 alcoholic beverages per day.

Contraindicated in patients with a history of pancreatitis; or structural diseases of the pancreas, including known or suspected pancreatic duct obstruction. Contraindicated in patients with severe hepatic impairment. Contraindicated in patients with a history of chronic or severe constipation or sequelae from constipation, or known or suspected mechanical gastrointestinal obstruction

Other Information

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	EINECS	Weight-%
Eluxadoline	864825-13-8	N/A	100

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures

Eye contact	Rinse immediately with plenty of water and seek medical advice.
Skin Contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
Inhalation	Remove to fresh air.
Ingestion	Consult a physician if necessary.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

Fire may produce irritating, corrosive and/or toxic gases.

Explosion data

Sensitivity to Mechanical Impact	Not impact sensitive.
Sensitivity to Static Discharge	Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Environmental precautions	See Section 12 for additional ecological information.
Methods for containment	Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Advice on safe handling Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

Incompatible materials None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL (ug/m ³)
Eluxadoline 864825-13-8	N/A	N/A	N/A	1.5

Appropriate engineering controls

Engineering Controls The following requirements list high level controls designed to control exposure below the OEL. More specific requirements may apply.

Powder Handling Isolator or direct connection with appropriate contained transfer device, and WIP for cleaning

Solutions/Suspensions and coated tablet handling (no powders or aerosols) Not Applicable

Packaging (uncoated tablets, hot side work) Appropriate contained transfer device WIP/CIP for the hopper (if possible), and contained ventilated filler

Laboratory Powder Handling or aerosol generation VBSE, BSC or Glove Box

Personal Decontamination Procedure/Controls Required
Unless, In controlled containment: Recommended.

Individual protection measures, such as personal protective equipment

PPE The following high level PPE requirements assume Engineering Controls that reduce exposure below the limit are not in place. More specific requirements may apply

Powder Handling PAPR with full hooded top with max APF and HEPA filter or supplied air, gloves (Taped cuffs), disposable or launderable coveralls (Category III equivalent), and booties

Solutions/Suspensions and coated tablet handling (no powders or aerosols) Gloves, long sleeved GMP clothing and safety equipment for the area

Packaging (uncoated tablets, hot side work) During cleaning and hopper filler operator - PAPR with full hooded head top with max APF and HEPA filter or supplied air, double gloves (Taped cuffs), disposable or launderable coveralls (Category III equivalent), and booties 1/2 mask, gloves, long sleeved GMP clothing and safety equipment for the area

Laboratory Powder Handling or aerosol generation	Minimum lab PPE gloves No controls-controlled area, min lab PPE, gloves and appropriately fitted 1/2 mask for powders
Eye/face protection	No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.
Skin and body protection	During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).
Respiratory protection	Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Solid	Appearance	powder
Color	No information available	Odor	No information available
Odor threshold	No information available		

Property

pH
 Melting point/freezing point
 Boiling point / boiling range
 Flash point
 Evaporation rate
 Flammability (solid, gas)
 Flammability Limit in Air
 Upper flammability limit:
 Lower flammability limit:
 Vapor pressure
 Vapor density
 Specific Gravity
 Water solubility
 Solubility in other solvents
 Partition coefficient
 Autoignition temperature
 Decomposition temperature
 Explosive properties
 Oxidizing properties

Values

No information available
 No information available
 No information available
 No information available
 No information available
 No information available
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 No information available

Other Information

Molecular weight	569.65
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

10. STABILITY AND REACTIVITY

Reactivity

Not defined As Reactive substance

Chemical stability

Stable under normal conditions.

Possibility of Hazardous Reactions

None under normal processing.

Conditions to avoid

Aerosol formation.

Incompatible materials

None known based on information supplied.

Hazardous Decomposition Products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure****Acute toxicity**

Chemical Name	Inhalation	Eye contact	Skin Contact	Ingestion
Eluxadoline	See Symptoms for more information.	Non irritant - Bovine Corneal Opacity and Permeability (BCOP) test.	See Symptoms for more information.	See Symptoms for more information.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Eluxadoline	2000 mg/kg oral rat - NON Lethal	N/A	N/A

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Eluxadoline	Not mutagenic in the standard battery of tests.	Not suspected of being a human carcinogen.	This product does not contain any known or suspected reproductive hazards.	No information available

Chemical Name	STOT - single exposure	STOT - repeated exposure
Eluxadoline	No information available.	No information available.

Target Organ Effects Gastrointestinal tract (GI).

Numerical measures of toxicity - Product Information**12. ECOLOGICAL INFORMATION****Ecotoxicity**

Other adverse effects No information available

13. DISPOSAL CONSIDERATIONS**Waste treatment methods**

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging Do not reuse container. Dispose of contents/containers in accordance with local regulations.

14. TRANSPORT INFORMATION

DOT Not regulated

<u>TDG</u>	Not regulated
<u>ICAO (air)</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG</u>	Not regulated
<u>ADR</u>	Not regulated
<u>ADN</u>	Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Not Listed
DSL/NDSL	Not Listed
EINECS/ELINCS	Not Listed

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute health hazard	Yes
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations

16. OTHER INFORMATION

Revision Date	02-Oct-2018
Revision Note	No information available

Disclaimer

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 warranty or quality specification. 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.

End of Safety Data Sheet