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

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EINECS</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eluxadoline</td>
<td>864825-13-8</td>
<td>N/A</td>
<td>100</td>
</tr>
</tbody>
</table>

*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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
<th>Allergan OEL (ug/m^3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eluxadoline</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>1.5</td>
</tr>
<tr>
<td>864825-13-8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Unlimited, 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>No information available</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
</tr>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Odor</td>
<td>No information available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>No information available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No information available</td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>No information available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No information available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability Limit in Air</td>
<td>No information available</td>
</tr>
<tr>
<td>Upper flammability limit:</td>
<td>No information available</td>
</tr>
<tr>
<td>Lower flammability limit:</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor density</td>
<td>No information available</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>No information available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No information available</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No information available</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>No information available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No information available</td>
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<tr>
<td>Explosive properties</td>
<td>No information available</td>
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<tr>
<td>Oxidizing properties</td>
<td>No information available</td>
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<tr>
<td>Molecular weight</td>
<td>569.65</td>
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<tr>
<td>VOC Content (%)</td>
<td>No information available</td>
</tr>
<tr>
<td>Density</td>
<td>No information available</td>
</tr>
<tr>
<td>Bulk density</td>
<td>No information available</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Inhalation</th>
<th>Eye contact</th>
<th>Skin Contact</th>
<th>Ingestion</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eluxadoline</td>
<td>2000 mg/kg oral rat - NON Lethal</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>STOT - single exposure</th>
<th>STOT - repeated exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eluxadoline</td>
<td>No information available.</td>
<td>No information available.</td>
</tr>
</tbody>
</table>

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
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