

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Date of Issue: 05/18/2023

Version: 2.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier Product Form: Tablet

Product Name: VEOZAH Tablets (45mg)

Chemical Name: Proprietary Generic Name: Fezolinetant Formula: Proprietary

1.2. Intended Use of the Product

Use of the Substance/Mixture: Pharmaceutical research, manufacturing

and clinical use. For professional use only

1.3. Name, Address, and Telephone of the Responsible Party Company

Astellas US LLC 2375 Waterview Drive Northbrook, IL 60062 Tel.: 800-888-7704 www.us.astellas.com

1.4. Emergency Telephone Number

Emergency Number : 800-727-7003

Medical Communications

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Acute Tox. 4 (Oral) H302 Repr. 1B H360 STOT RE 2 H373

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)





Signal Word (GHS-US) : Danger

Hazard Statements (GHS-US) : H302 - Harmful if swallowed.

H360 - May damage fertility or the unborn child.

H373 - May cause damage to organs (blood) through prolonged or repeated

exposure (oral).

Precautionary Statements (GHS-US) : P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P260 - Do not breathe vapors, mist, or spray.

P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P280 - Wear protective gloves, protective clothing, and eye protection. P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.

P308+P313 - If exposed or concerned: Get medical advice/attention.

P314 - Get medical advice/attention if you feel unwell.

P330 - Rinse mouth. P405 - Store locked up.

P501 - Dispose of contents/container in accordance with local, regional, national,

and international regulations.

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2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions. Product is in tablet form, but contains substances that are combustible dusts. If these substances in their powder form are allowed to accumulate, dispersed in sufficient quantities in air, and in the presence of an ignition source, it may cause a dust explosion.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	%	GHS US classification
D-Mannitol	1,2,3,4,5,6-Hexanehexol / Mannitol, D- / Hexanehexol / Mannite / MANNITOL / Mannitol	(CAS-No.) 69-65-8	< 38	Comb. Dust
Fezolinetant	ESN364/ESN-364	(CAS-No.) 1629229-37- 3	> 32	Acute Tox. 3 (Oral), H301 Repr. 1B, H360 STOT RE 2, H373
Hydroxypropyl ether of cellulose	Cellulose, 2-hydroxypropyl ether / Hydroxypropyl cellulose / Hydroxypropylcellulose / HYDROXYPROPYLCELLULOSE / 2- Hydroxypropyl cellulose / Hyprolose	(CAS-No.) 9004-64-2	> 12	Comb. Dust
Cellulose	Microcrystalline cellulose / CELLULOSE / Cellulose, microcrystalline / MICROCRYSTALLINE CELLULOSE	(CAS-No.) 9004-34-6	> 12	Comb. Dust
Cellulose hydroxypropyl methyl ether	Cellulose, 2-hydroxypropyl methyl ether / Hydroxypropyl methyl cellulose / Hydroxypropyl methyl cellulose, ether / Hydroxy propyl methyl cellulose / Hydroxypropyl methyl cellulose / Hydroxypropyl methyl cellulose / Hydroxypropyl methyl cellulose / Hydroxypropyl methylcellulose / Hydroxypropylmethylcellulose / Hydroxypropyl Methylcellulose / Hydroxypropyl methylcellulose / Hydroxypropyl methyl cellulose / Hydroxymethyl propyl cellulose / 2-Hydroxypropyl cellulose / 2-Hydroxypropyl cellulose / 2-Hydroxypropyl cellulose / 2-Hydroxypropyl cellulose / Hydroxypropylmethyl cellulose / Hydroxypropylmethyl cellulose / Hydroxypropylmethyl cellulose / Hydroxypropylmethyl cellulose / Hypromellose 2910	(CAS-No.) 9004-65-3	< 2	Comb. Dust
Magnesium stearate	Octadecanoic acid, magnesium salt / Stearate, magnesium / Stearic acid, magnesium salt / Octadecanoic acid, magnesium salt (2:1) / Magnesium distearate / MAGNESIUM STEARATE / Salts of stearic acids with magnesium bases / Dioctadecanoate magnesium / Magnesium octadecanoate / Bis(octadecanoic acid)magnesium salt / Salt of stearic acid with magnesium base / magnesium stearate	(CAS-No.) 557-04-0	>1	Comb. Dust

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Talc (Mg3H2(SiO3)4)	Talc / Magnesium silicate / Talc (containing no asbestos fibers) / Talc (containing no asbestos) / Talc (containing no asbestos) / Talc not containing asbestiform fibres / Talc, not containing asbestos / Talc, containing no asbestos fibres / Talc (nonasbestos form) / Talc (nonasbestos form) / Talc (nonasbestos form) / Talc, nonfibrous type / Talc, non fibrous / Talc (containing no asbestos fibres) / Non-asbestiform talc / Talc (not containing asbestos) / C.I. 77718 / TALC / Trimagnesium tetrasilicon undecaoxide hydrate / Talc, nonasbestiform / Talc, non-fibrous / Pigment White 26 / Magnesium silicate, hydrous / Talc, not	(CAS-No.) 14807-96-6	<1	Not classified
	containing mineral fibers		1	
	(including asbestos) /			
	Asbestiform talc / Talc powder			
Polyethylene glycol	Poly(oxy-1,2-ethanediyl), .alpha.hydroomegahydroxy-/ Polyethylene glycol 6000 / Polyethylene glycol ether / Polyethylene glycol ether / Polyethylene glycol other / Polyethylene glycol other / Polyethylene glycol 400 / Ethylene oxide polymer / 1,2- Ethanediol, homopolymer / Polyethylene glycol 8000 / PEG / Macrogols / Macrogol / PEG-9 / .alphaHydroomega hydroxypoly(oxyethylene) / PEG- 14 / .alphaHydroomega hydroxypoly(oxy-1,2-ethanediyl) / Ethoxylated 1,2-ethanediol / Polyethylene glycol 35 / Polyethylene glycol 35 / Polyethylene glycol 115 / Poly(ethylene glycol 115 / Poly(ethylene plycol) 400 / PEG-115 M / PEG-135 / PEG-14 M / PEG-150 / PEG-160 / PEG-160 M / PEG-18 / PEG-180 / PEG-180 M / PEG-1M / PEG-20 / PEG-200 / PEG-20 M / PEG-20 / PEG-23 / PEG-32 / PEG-33 / PEG-350 / PEG-40 / PEG-450 / PEG-45 / PEG-450 / PEG-450 / PEG-50 / PEG-55 / PEG-5M / PEG-50 / PEG-65 M / PEG-50 / PEG-65 M / PEG-75 / PEG-70 / PEG-90 M / PEG-90 /	(CAS-No.) 25322-68-3	<1	Comb. Dust
Titanium dioxide	Ethylene glycol homopolymer C.I. 77891 / C.I. Pigment White 6 / Titanium oxide (TiO2) / CI 77891 / Titanium(IV) oxide / C.I. Pigment White 7 / Pigment White 6 / Titanium dioxide nanoparticles / Titanium oxide / Titanium dioxide(2)	(CAS-No.) 13463-67-7	<1	Not classified

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Iron oxide (Fe2O3)	C.I. 77491 / C.I. Pigment Red 101 / Diiron trioxide / Ferric oxide / Iron sesquioxide / Iron(III) oxide / Red Iron Oxide / Rouge / CI 77491 / Iron trioxide / Sienna / Pigment Red 101 / Red iron oxide / Red iron oxide pigment / Iron Oxide Red / Diiron(III)	(CAS-No.) 1309-37-1	<1	Comb. Dust
	, , ,			
	trioxide / Iron oxide / Ferric			
	oxide red / Iron oxide, red			

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 5 minutes. If exposed or concerned: Get medical advice/attention.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

First-aid Measures After Ingestion: Product is a pharmaceutical preparation intended for oral usage. In cases of overdosage, rinse mouth if person is conscious and alert to surroundings and place them on their side. Contact a Poison Control Center or physician immediately. DO NOT INDUCE VOMITING!.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: May damage fertility. May damage the unborn child. Harmful if swallowed. May cause damage to organs (blood) through prolonged or repeated exposure (oral).

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects or death in significant amounts.

Chronic Symptoms: May damage fertility or the unborn child. May cause damage to organs (blood) through prolonged or repeated exposure (oral). Titanium dioxide is pressed into a tablet and is not able to become airborne. Thus, the hazards usually associated with titanium dioxide are not applicable to this product.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: For particulates and dust: Combustible dust. Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection. **Hazardous Combustion Products:** Under fire conditions this material may produce hazardous carbon dioxide (CO2), carbon monoxide (CO), Metal oxides, Sulfur oxides, Fluorine compounds, Nitrous fumes, Nitrogen oxides, various low molecular weight hydrocarbons, and smoke.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Do not breathe dust.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

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Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. **Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Recover the product by vacuuming, shoveling or sweeping. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Product is in tablet form, but contains substances that are combustible dusts. If these substances in their powder form are allowed to accumulate, dispersed in sufficient quantities in air, and in the presence of an ignition source, it may cause a dust explosion.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust. Handle empty containers with care because they may still present a hazard. Do not get in eyes, on skin, or on clothing.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Pharmaceutical. See insert for more information.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

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Cellulose (90	004-34-6)	
USA ACGIH	ACGIH OEL TWA	10 mg/m³
USA NIOSH	NIOSH REL (TWA)	10 mg/m³ (total dust)
		5 mg/m³ (respirable dust)
USA OSHA	OSHA PEL (TWA) [1]	15 mg/m³ (total dust)
		5 mg/m³ (respirable fraction)
Magnesium	stearate (557-04-0)	
USA ACGIH	ACGIH OEL TWA	10 mg/m³ (inhalable particulate matter (Stearates)
		3 mg/m³ (respirable particulate matter (Stearates)
Talc (Mg3H2	(SiO3)4) (14807-96-6)	
USA ACGIH	ACGIH OEL TWA	2 mg/m³ (particulate matter containing no asbestos and <1%
		crystalline silica, respirable particulate matter)
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen containing no asbestos
		fibers
USA NIOSH	NIOSH REL (TWA)	2 mg/m³ (containing no Asbestos and <1% Quartz-respirable dust)
USA IDLH	IDLH	1000 mg/m³ (containing no asbestos and <1% quartz)
USA OSHA	OSHA PEL (TWA) [2]	20 mppcf ((not containing asbestos) containing <1% quartz, if 1%
		quartz or more; use quartz limit)
		(See 29 CFR 1910.1000 TABLE Z-3)

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Polyethylene	glycol (25322-68-3)		
USA AIHA	WEEL TWA	10 mg/m³ (molecular weight>200-aerosol)	
Titanium dio	Titanium dioxide (13463-67-7)		
USA ACGIH	ACGIH OEL TWA	10 mg/m³	
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen	
USA NIOSH	NIOSH REL (TWA)	2.4 mg/m³ (CIB 63-fine)	
		0.3 mg/m³ (CIB 63-ultrafine, including engineered nanoscale)	
USA IDLH	IDLH	5000 mg/m ³	
USA OSHA	OSHA PEL (TWA) [1]	15 mg/m³ (total dust)	
Iron oxide (F	e2O3) (1309-37-1)		
USA ACGIH	ACGIH OEL TWA	5 mg/m³ (respirable particulate matter)	
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen	
USA NIOSH	NIOSH REL (TWA)	5 mg/m³ (dust and fume)	
USA IDLH	IDLH	2500 mg/m³ (dust and fume)	
USA OSHA	OSHA PEL (TWA) [1]	10 mg/m³ (fume)	
		15 mg/m³ (total dust (Rouge)	
		5 mg/m³ (respirable fraction (Rouge)	

8.2. **Exposure Controls**

Appropriate Engineering Controls

: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.









Materials for Protective Clothing

Hand Protection Eye and Face Protection Skin and Body Protection Respiratory Protection

Solubility

Partition Coefficient: N-Octanol/Water

: Chemically resistant materials and fabrics.

: Wear protective gloves. : Chemical safety goggles.

: Wear suitable protective clothing.

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information : When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties 9.1.

Physical State : Solid **Appearance** : No data available Odor : No data available **Odor Threshold** : No data available : No data available **Evaporation Rate** : No data available **Melting Point** : No data available **Freezing Point** : No data available **Boiling Point** : No data available **Flash Point** : No data available **Auto-ignition Temperature** : No data available **Decomposition Temperature** : No data available Flammability (solid, gas) : No data available Vapor Pressure : No data available Relative Vapor Density at 20°C : No data available **Relative Density** : No data available

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: No data available

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Viscosity

: No data available

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions

Hazardous polymerization will not occur.

10.4. Conditions to Avoid

Avoid creating or spreading dust. Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products

Under fire conditions this material may produce hazardous carbon dioxide (CO2), carbon monoxide (CO), Metal oxides, Sulfur oxides, Fluorine compounds, Nitrous fumes, Nitrogen oxides, various low molecular weight hydrocarbons, and smoke.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity (Oral): Harmful if swallowed.
Acute Toxicity (Dermal): Not classified
Acute Toxicity (Inhalation): Not classified

VEOZALI Toblete (AFma)		
VEOZAH Tablets (45mg)	007.50 // 1 / 1 / 1	
ATE (Oral)	937.50 mg/kg body weight	
D-Mannitol (69-65-8)		
LD50 Oral Rat	13500 mg/kg	
Hydroxypropyl ether of cellulose (9004-64-2)		
LD50 Oral Rat	10200 mg/kg	
Cellulose (9004-34-6)		
LD50 Oral Rat	> 5000 mg/kg	
LD50 Dermal Rabbit	> 2000 mg/kg	
LC50 Inhalation Rat	> 5800 mg/m³ (Exposure time: 4 h)	
Magnesium stearate (557-04-0)		
LD50 Oral Rat	> 2000 mg/kg	
Cellulose hydroxypropyl methyl ether (9004-65-3)		
LD50 Oral Rat	≥ 4000 mg/kg	
Polyethylene glycol (25322-68-3)		
LD50 Oral Rat	47000 mg/kg	
LD50 Dermal Rabbit	> 20 g/kg	
Titanium dioxide (13463-67-7)		
LD50 Oral Rat	> 10000 mg/kg	
LC50 Inhalation Rat	5.09 mg/l/4h	
Iron oxide (Fe2O3) (1309-37-1)		
LD50 Oral Rat	> 10000 mg/kg	
Fezolinetant (1629229-37-3)		
LD50 Oral Rat	> 300 mg/kg	
Chin Correction / Irritation - Not classified		

Skin Corrosion/Irritation: Not classified
Serious Eye Damage/Irritation: Not classified
Respiratory or Skin Sensitization: Not classified
Germ Cell Mutagenicity: Not classified
Carcinogenicity: Not classified

Talc (Mg3H2(SiO3)4) (14807-96-6)	
IARC group	3

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National Toxicology Program (NTP) Status	Evidence of Carcinogenicity.	
Titanium dioxide (13463-67-7)		
IARC group	2B	
OSHA Hazard Communication Carcinogen List In OSHA Hazard Communication Carcinogen list.		
Iron oxide (Fe2O3) (1309-37-1)		
IARC group	3	

Reproductive Toxicity: May damage fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): May cause damage to organs through prolonged or repeated exposure.

Fezolinetant (1629229-37-3)	
NOAEL (oral,rat,90 days) 200 mg/kg/day (female rats)	
NOAEL (subacute,oral, rat, 28 days)	100 mg/kg/day
NOAEL (subacute, oral, cynomolgus monkey, 35 days)	25 mg/kg/day

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects or death in significant amounts.

Chronic Symptoms: May damage fertility or the unborn child. May cause damage to organs (blood) through prolonged or repeated exposure (oral). Titanium dioxide is pressed into a tablet and is not able to become airborne. Thus, the hazards usually associated with titanium dioxide are not applicable to this product.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

- •	
Talc (Mg3H2(SiO3)4) (14807-96-6)	
LC50 Fish 1	> 100 g/l (Exposure time: 96 h - Species: Brachydanio rerio [semi-static])
Iron oxide (Fe2O3) (1309-37-1)	
LC50 Fish 1	100000 mg/l (Exposure time: 96 h - Species: Danio rerio [static])

12.2. Persistence and Degradability

VEOZAH Tablets (45mg)	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

VEOZAH Tablets (45mg)	
Bioaccumulative Potential Not established.	
Talc (Mg3H2(SiO3)4) (14807-96-6)	
BCF Fish 1	(no known bioaccumulation)

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

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14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

VEOZAH Tablets (45mg)	
SARA Section 311/312 Hazard Classes	Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Reproductive toxicity Health hazard - Acute toxicity (any route of exposure)
D-Mannitol (69-65-8)	
Listed on the United States TSCA (Toxic Substan	ices Control Act) inventory - Status: Active
Hydroxypropyl ether of cellulose (9004-64-2)	
Listed on the United States TSCA (Toxic Substan	ices Control Act) inventory - Status: Active
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the
	Chemical Data Reporting Rule, (40 CFR 711).
Cellulose (9004-34-6)	
Listed on the United States TSCA (Toxic Substan	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the
	Chemical Data Reporting Rule, (40 CFR 711).
Magnesium stearate (557-04-0)	
Listed on the United States TSCA (Toxic Substan	ices Control Act) inventory - Status: Active
Cellulose hydroxypropyl methyl ether (9004-65	·
Listed on the United States TSCA (Toxic Substan	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the
	Chemical Data Reporting Rule, (40 CFR 711).
Talc (Mg3H2(SiO3)4) (14807-96-6)	
Listed on the United States TSCA (Toxic Substan	ices Control Act) inventory - Status: Active
Polyethylene glycol (25322-68-3)	
Listed on the United States TSCA (Toxic Substan	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the
	Chemical Data Reporting Rule, (40 CFR 711).
Titanium dioxide (13463-67-7)	
Listed on the United States TSCA (Toxic Substan	ices Control Act) inventory - Status: Active
Iron oxide (Fe2O3) (1309-37-1)	
Listed on the United States TSCA (Toxic Substan	ices Control Act) inventory - Status: Active

15.2. US State Regulations

Cellulose (9004-34-6)

- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) List
- U.S. Massachusetts Right To Know List

Talc (Mg3H2(SiO3)4) (14807-96-6)

- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) List
- U.S. Massachusetts Right To Know List

Titanium dioxide (13463-67-7)

- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) List
- U.S. Massachusetts Right To Know List

Iron oxide (Fe2O3) (1309-37-1)

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- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) List
- U.S. Massachusetts Right To Know List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 04/13/2022

Other Information : This document has been prepared in accordance with the SDS

requirements of the OSHA Hazard Communication Standard 29 CFR

1910.1200

GHS Full Text Phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Comb. Dust	Combustible Dust
Repr. 1B	Reproductive toxicity Category 1B
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
H301	Toxic if swallowed
H302	Harmful if swallowed
H360	May damage fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as quaranteeing any specific property of the product.

SDS US (GHS HazCom)

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