

#### **Safety Data Sheet**

SDS Title:	SDS Number:	Page Number:
Liraglutide Injection Safety Data Sheet	SDS-000098	Page 1 of 17
Function:	Effective Date:	Version number:
Regulatory Affairs	September 20, 2024	1.0

### **Section 1. Identification**

**GHS** product identifier : Liraglutide Injection Other means of identification: Not available. **Product type** : Liquid.

#### Relevant identified uses of the substance or mixture and uses advised against

**Product use** : Pharmaceuticals. (For intended use only.)

Observe technical data sheet/instructions for use.

Specific Treatments: Anti-Diabetic Agent

Area of application : Professional applications.

Supplier's details : Meitheal Pharmaceuticals, Inc.

8700 W. Bryn Mawr, Suite 600S

Chicago, IL 60631

Telephone: 224-443-4617 www.meithealpharma.com

e-mail address of person responsible for this SDS

: info@meithealpharma.com

**Emergency telephone** number (with hours of

operation)

: 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

### Section 2. Hazards identification

**OSHA/HCS** status : This material is considered hazardous by the OSHA Hazard Communication Standard

(29 CFR 1910.1200).

Classification of the : H351 CARCINOGENICITY - Category 2

substance or mixture H361 TOXIC TO REPRODUCTION - Category 2

**GHS** label elements

**Hazard pictograms** 



Signal word : Warning

: H351 - Suspected of causing cancer. **Hazard statements** 

H361 - Suspected of damaging fertility or the unborn child.

**Precautionary statements** 



#### Meitheal Pharmaceuticals, Inc. Safety Data Sheet

		Page Number: Page 2 of 17
	Effective Date: September 20, 2024	Version number: 1.0

### Section 2. Hazards identification

**Prevention** : P201 - Obtain special instructions before use.

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

P280 - Wear protective gloves, protective clothing and eye or face protection.

: P308 + P313 - IF exposed or concerned: Get medical advice or attention. Response

**Storage** : P405 - Store locked up.

**Disposal** : P501 - Dispose of contents and container in accordance with all local, regional, national

and international regulations.

Hazards not otherwise

classified

identification

: None known.

# Section 3. Composition/information on ingredients

Substance/mixture : Mixture Other means of

: Not available.

Ingredient name	Other names	%	Identifiers
Water	-	≥90	CAS: 7732-18-5
propane-1,2-diol	Propylene Glycol	≤3	CAS: 57-55-6
liraglutide		≤1	CAS: 204656-20-2
phenol		<1	CAS: 108-95-2
Phosphoric acid, disodium salt, dihydrate	-	≤0.3	CAS: 10028-24-7
sodium hydroxide	<u>-</u> .	≤0.1	CAS: 1310-73-2
Hydrochloric acid		≤0.1	CAS: 7647-01-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

### Section 4. First aid measures

#### **Description of necessary first aid measures**

**Eye contact** 

: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10

minutes. Get medical attention.

: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not Inhalation

> breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in

recovery position and get medical attention immediately. Maintain an open airway.

Loosen tight clothing such as a collar, tie, belt or waistband.

Skin contact : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before

reuse. Clean shoes thoroughly before reuse.



#### Meitheal Pharmaceuticals, Inc. Safety Data Sheet

SDS Title: Liraglutide Injection Safety Data Sheet		Page Number: Page 3 of 17
Function:	Effective Date:	Version number:
Regulatory Affairs	September 20, 2024	1.0

### Section 4. First aid measures

Ingestion

: Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

#### Most important symptoms/effects, acute and delayed

#### Potential acute health effects

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 No known significant effects or critical hazards.
 Ingestion
 No known significant effects or critical hazards.

#### Over-exposure signs/symptoms

Eye contact : No specific data.

**Inhalation** : Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

**Skin contact**: Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

Ingestion : Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

### Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large

quantities have been ingested or inhaled.

**Specific treatments**: No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. It may be

dangerous to the person providing aid to give mouth-to-mouth resuscitation.

#### See toxicological information (Section 11)



#### Meitheal Pharmaceuticals, Inc. Safety Data Sheet

SDS Title:	SDS Number:	Page Number:
Liraglutide Injection Safety Data Sheet	SDS-000098	Page 4 of 17
Function:	Effective Date:	Version number:
Regulatory Affairs	September 20, 2024	1.0

# Section 5. Fire-fighting measures

#### **Extinguishing media**

Suitable extinguishing media

: Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media

: Do not use water jet.

Specific hazards arising from the chemical

: In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous thermal decomposition products

: Decomposition products may include the following materials: carbon dioxide

carbon monoxide

Special protective actions for fire-fighters

Special protective equipment for fire-fighters

: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

### Section 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders

If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

**Environmental precautions** 

: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

#### Methods and materials for containment and cleaning up

Small spill

: Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.



Safety Data Sheet

SDS Number: SDS-000098	Page Number: Page 5 of 17
Effective Date: September 20, 2024	Version number: 1.0

### Section 6. Accidental release measures

#### Large spill

: Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Contain and collect spillage with non-combustible, absorbent material e. g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

# Section 7. Handling and storage

#### **Precautions for safe handling**

**Protective measures** 

Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

## Section 8. Exposure controls/personal protection

#### **Control parameters**

#### Occupational exposure limits

Ingredient name	Exposure limits
Water	None.
propane-1,2-diol	OARS WEEL (United States, 4/2022)
•	TWA 8 hours: 10 mg/m³.
liraglutide	None.
phenol	ACGIH TLV (United States, 1/2024) A4. Absorbed
•	through skin.
	TWA 8 hours: 5 ppm.
	TWA 8 hours: 19 mg/m³.
	NIOSH REL (United States, 10/2020) Absorbed
	through skin.



Phosphoric acid, disodium salt, dihydrate

sodium hydroxide

Hydrochloric acid

Safety Data Sheet

SDS Title:	SDS Number:	Page Number:
Liraglutide Injection Safety Data Sheet	SDS-000098	Page 6 of 17
Function:	Effective Date:	Version number:
runction.	Ellective Date.	version number:

## Section 8. Exposure controls/personal protection

TWA 10 hours: 5 ppm. TWA 10 hours: 19 mg/m³. CEIL 15 minutes: 15.6 ppm. CEIL 15 minutes: 60 mg/m³.

OSHA PEL (United States, 5/2018) Absorbed through

skin.

TWA 8 hours: 5 ppm. TWA 8 hours: 19 mg/m³.

CAL OSHA PEL (United States, 5/2018) Absorbed

through skin.

TWA 8 hours: 19 mg/m³. TWA 8 hours: 5 ppm.

None.

ACGIH TLV (United States, 1/2024)

C: 2 mg/m<sup>3</sup>.

NIOSH REL (United States, 10/2020)

CEIL: 2 mg/m<sup>3</sup>.

**OSHA PEL (United States, 5/2018)** 

TWA 8 hours: 2 mg/m3.

CAL OSHA PEL (United States, 5/2018)

C: 2 mg/m<sup>3</sup>.

ACGIH TLV (United States, 1/2024) A4.

C: 2 ppm.

NIOSH REL (United States, 10/2020)

CEIL: 5 ppm. CEIL: 7 mg/m<sup>3</sup>.

OSHA PEL (United States, 5/2018)

CEIL: 5 ppm. CEIL: 7 mg/m<sup>3</sup>.

CAL OSHA PEL (United States, 5/2018)

C: 2 ppm.

TWA 8 hours: 0.45 mg/m<sup>3</sup>. TWA 8 hours: 0.3 ppm.

Appropriate engineering controls

: If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

**Environmental exposure controls** 

: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

**Individual protection measures** 



#### Meitheal Pharmaceuticals, Inc. Safety Data Sheet

SDS Title: Liraglutide Injection Safety Data Sheet		Page Number: Page 7 of 17
Function:	Effective Date:	Version number:
Regulatory Affairs	September 20, 2024	1.0

### Section 8. Exposure controls/personal protection

Hygiene measures

: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

**Eye/face protection** 

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

**Skin protection** 

**Hand protection** 

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

**Body protection** 

: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection

Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

# Section 9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

#### **Appearance**

Physical state : Liquid. [Clear.]
Color : Colorless.
Odor : Not available.
Odor threshold : Not available.
pH : 7.9 to 8.4
Melting point : Not available.
Boiling point or initial : Not available.

boiling point and boiling

range

Flash point : Not available.
Evaporation rate : Not available.
Flammability : Not available.



#### Meitheal Pharmaceuticals, Inc. Safety Data Sheet

SDS Title: Liraglutide Injection Safety Data Sheet		Page 8 of 17
Function: Regulatory Affairs	Effective Date: September 20, 2024	Version number: 1.0

# Section 9. Physical and chemical properties

Lower and upper explosion limit/flammability limit

: Not available.

Vapor pressure

	Vapor Pressure at 20°C			Vapor pressure at 50°C		
Ingredient name	mm Hg	kPa	Method	mm Hg	kPa	Method
Water	17.5	2.3		92.258	12.3	

Relative vapor density

: Not available. : 1.0013 [Water = 1]

**Relative density** 

1.0013 g/cm3 [25°C (77°F)]

Solubility(ies)

**Density** 

Media Result

Easily soluble water

Miscible with water

Yes.

Partition coefficient: n-

: Not applicable.

octanol/water **Auto-ignition temperature** 

: Not available.

**Decomposition temperature** 

: Not available.

**SADT** 

: Not available.

**Viscosity** 

: Dynamic (room temperature): Not applicable. Kinematic (room temperature): Not applicable.

Kinematic (40°C (104°F)): Not applicable.

Flow time (ISO 2431)

: Not available.

**Particle characteristics** 

Median particle size

: Not applicable.

**Other information** 

Physical/chemical properties comments : No additional information.

## Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

**Chemical stability** : The product is stable.

**Possibility of hazardous** 

reactions

: Under normal conditions of storage and use, hazardous reactions will not occur.

Under normal conditions of storage and use, hazardous polymerization will not occur.

**Conditions to avoid** : No specific data.



**Safety Data Sheet** 

SDS Title: Liraglutide Injection Safety Data Sheet		Page Number: Page 9 of 17
Function:	Effective Date:	Version number:
Regulatory Affairs	September 20, 2024	1.0

### Section 10. Stability and reactivity

**Incompatible materials** 

: Reactive or incompatible with the following materials: oxidizing materials.

Hazardous decomposition products

: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

# **Section 11. Toxicological information**

#### Information on toxicological effects

### **Acute toxicity**

Product/ingredient name	Result	Species	Dose	Exposure
propane-1,2-diol	LD50 Dermal	Rabbit	20800 mg/kg	-
	LD50 Oral	Rat	20 g/kg	-
phenol	LC50 Inhalation Dusts and mists	Rat	316 mg/m <sup>3</sup>	4 hours
	LD50 Dermal	Rabbit	630 mg/kg	-
	LD50 Dermal	Rat	669 mg/kg	-
	LD50 Oral	Rat	317 mg/kg	-
sodium hydroxide	LD50 Oral	Rat	325 mg/kg	-

### **Irritation/Corrosion**

Product/ingredient name	Result	Species	Score	Exposure	Observation
propane-1,2-diol	Eyes - Mild irritant	Rabbit	-	100 mg	-
	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
phenol	Eyes - Mild irritant	Rabbit	-	0.5 minutes 5 mg	-
	Eyes - Severe irritant	Rabbit	_	5 mg	_
	Skin - Mild irritant	Rabbit	-	100 mg	-
	Skin - Severe irritant	Rabbit	-	535 mg	-
sodium hydroxide	Eyes - Mild irritant	Rabbit	-	400 ug	-
•	Eyes - Severe irritant	Rabbit	-	1 %	-
	Eyes - Severe irritant	Rabbit	-	0.5 minutes 1 mg	-
	Eyes - Severe irritant	Rabbit	-	24 hours 50	-
	Skin - Severe irritant	Rabbit	-	24 hours 500 mg	-
Hydrochloric acid	Eyes - Mild irritant	Rabbit	-	0.5 minutes 5	-

### **Sensitization**

Not available.

#### **Mutagenicity**

**Conclusion/Summary** 

: Not available.

**Carcinogenicity** 



### Safety Data Sheet

SDS Title: Liraglutide Injection Safety Data Sheet		Page Number: Page 10 of 17
Function: Regulatory Affairs	Effective Date: September 20, 2024	Version number: 1.0

# **Section 11. Toxicological information**

Conclusion/Summary :

: Not available.

**Classification** 

Product/ingredient name	OSHA	IARC	NTP
phenol	-	3	-
Hydrochloric acid	-	3	-

#### Reproductive toxicity

Conclusion/Summary : Not available.

**Teratogenicity** 

Conclusion/Summary: Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
phenol	Category 1	-	-
sodium hydroxide	Category 3	-	Respiratory tract irritation
Hydrochloric acid	Category 3	-	Respiratory tract irritation

### Specific target organ toxicity (repeated exposure)

Name	•	Route of exposure	Target organs
phenol	Category 2		kidneys, liver, nervous system

#### **Aspiration hazard**

Not available.

Information on the likely routes of exposure

: Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

#### Potential acute health effects

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 No known significant effects or critical hazards.
 Ingestion
 No known significant effects or critical hazards.

### Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.

**Inhalation** : Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations



**Safety Data Sheet** 

SDS Title:	SDS Number:	Page Number:
Liraglutide Injection Safety Data Sheet	SDS-000098	Page 11 of 17
Function:	Effective Date:	Version number:
Regulatory Affairs	September 20, 2024	1.0

# **Section 11. Toxicological information**

**Skin contact**: Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

**Ingestion**: Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

#### Delayed and immediate effects and also chronic effects from short and long term exposure

**Short term exposure** 

Potential immediate : Not available.

effects

Potential delayed effects : Not available.

Long term exposure

Potential immediate : Not available.

effects

Potential delayed effects : Not available.

Potential chronic health effects

General: No known significant effects or critical hazards.

Carcinogenicity : Suspected of causing cancer. Risk of cancer depends on duration and level of exposure.

Mutagenicity : No known significant effects or critical hazards.Reproductive toxicity : Suspected of damaging fertility or the unborn child.

#### **Numerical measures of toxicity**

#### **Acute toxicity estimates**

Product/ingredient name	Oral (mg/ kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/ I)
propane-1,2-diol	20000	20800	N/A	N/A	N/A
phenol sodium hydroxide	317 325	630 N/A	N/A N/A	N/A N/A	0.316 N/A



**Safety Data Sheet** 

SDS Title:	SDS Number:	Page Number:
Liraglutide Injection Safety Data Sheet	SDS-000098	Page 12 of 17
Function:	Effective Date:	Version number:
Regulatory Affairs	September 20, 2024	1.0

# **Section 12. Ecological information**

### **Toxicity**

Product/ingredient name	Result	Species	Exposure
propane-1,2-diol	Acute EC50 24200 mg/l Fresh water	Algae	72 hours
	Acute EC50 >110 ppm Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 1020000 µg/l Fresh water	Crustaceans - Ceriodaphnia dubia	48 hours
	Acute LC50 710000 µg/l Fresh water	Fish - Pimephales promelas	96 hours
phenol	Acute EC50 36 mg/l Marine water	Algae - Hormosira banksii - Gamete	72 hours
	Acute EC50 61.1 µg/l Fresh water	Algae - Raphidocelis subcapitata	96 hours
	Acute EC50 94 mg/l Fresh water	Aquatic plants - Lemna aequinoctialis	96 hours
	Acute EC50 4200 µg/l Fresh water	Daphnia - <i>Daphnia magna</i>	48 hours
	Acute LC50 800 µg/l Marine water	Crustaceans - Archaeomysis	48 hours
		kokuboi - Juvenile (Fledgling, Hatchling, Weanling)	
	Acute LC50 1555 µg/l Fresh water	Fish - Cirrhinus mrigala - Larvae	96 hours
	Chronic NOEC 16 µg/l Marine water	Algae - <i>Hormosira banksii</i> - Gamete	72 hours
	Chronic NOEC 1.5 mg/l Fresh water	Daphnia - <i>Daphnia magna</i>	21 days
	Chronic NOEC 118 µg/l Fresh water	Fish - Oncorhynchus mykiss	90 days
sodium hydroxide	Acute EC50 40.38 mg/l Fresh water	Crustaceans - Ceriodaphnia dubia - Neonate	48 hours
	Acute LC50 125 ppm Fresh water	Fish - <i>Gambusia affinis</i> - Adult	96 hours
Hydrochloric acid	Acute LC50 240000 µg/l Marine water	Crustaceans - Carcinus maenas - Adult	48 hours
	Acute LC50 282 ppm Fresh water	Fish - <i>Gambusia affinis</i> - Adult	96 hours

**Conclusion/Summary** 

: Not available.

#### Persistence and degradability

Product/ingredient name	Test	Result		Dose		Inoculum
propane-1,2-diol phenol	OECD 301F Ready Biodegradability - Manometric Respirometry Test OECD 301C Ready Biodegradability - Modified MITI Test (I)		eadily - 28 days dily - 4.16667 days	100 mg/l	DOC	-
Product/ingredient name	Aquatic half-life		Photolysis		Biodeg	radability
propane-1,2-diol phenol	-		-		Readily Readily	



**Safety Data Sheet** 

SDS Title: Liraglutide Injection Safety Data Sheet	SDS Number: SDS-000098	Page 13 of 17
Function:	Effective Date:	Version number:
Regulatory Affairs	September 20, 2024	1.0

# Section 12. Ecological information

#### **Bioaccumulative potential**

Product/ingredient name	LogPow	BCF	Potential
Water	-1.38	-	Low
propane-1,2-diol	-1.07	-	Low
phenol	1.47	647	High

#### **Mobility in soil**

Soil/water partition coefficient (Koc)

: Not available.

Other adverse effects

: No known significant effects or critical hazards.

## Section 13. Disposal considerations

#### **Disposal methods**

: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and

# Section 14. Transport information

	DOT Classification	IMDG	IATA	
UN number	Not regulated.	Not regulated.	Not regulated.	
UN proper shipping name	-	-	-	
Transport hazard class(es)	-	-	-	
Packing group	-	-	-	
Environmental hazards	No.	No.	No.	

#### **Additional information**



Safety Data Sheet

SDS Title:	SDS Number:	Page Number:
Liraglutide Injection Safety Data Sheet	SDS-000098	Page 14 of 17
Function:	Effective Date:	Version number:
Regulatory Affairs	September 20, 2024	1.0

### **Section 14. Transport information**

Special precautions for user : Transport within user's premises: always transport in closed containers that are

upright and secure. Ensure that persons transporting the product know what to do in the

event of an accident or spillage.

Transport in bulk according

to IMO instruments

: Not available.

### Section 15. Regulatory information

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined

United States inventory (TSCA 8b): Not determined.

Clean Water Act (CWA) 307: phenol

Clean Water Act (CWA) 311: phenol, Phosphoric acid, disodium salt, dihydrate; sodium

hydroxide; Hydrochloric acid

Clean Air Act Section 112

(b) Hazardous Air Pollutants (HAPs) Listed

**Clean Air Act Section 602** 

Class I Substances

: Not listed

**Clean Air Act Section 602** 

Class II Substances

: Not listed

**DEA List I Chemicals** 

(Precursor Chemicals)

: Not listed

**DEA List II Chemicals** 

: Not listed

(Essential Chemicals)

#### **SARA 302/304**

#### Composition/information on ingredients

			SARA 302 TPQ		SARA 304 RQ	
Name	%	EHS	(lbs)	(gallons)	(lbs)	(gallons)
phenol	<1	Yes.	500 / 10000	-	1000	-
Hydrochloric acid	≤0.1	Yes.	500	•	5000	-

SARA 304 RQ : 181818.2 lbs / 82545.5 kg [21777.9 gal / 82438.3 L]

**SARA 311/312** 

Classification : CARCINOGENICITY - Category 2

**TOXIC TO REPRODUCTION - Category 2** 

**Composition/information on ingredients** 



**Safety Data Sheet** 

SDS Title:	SDS Number:	Page Number:
Liraglutide Injection Safety Data Sheet	SDS-000098	Page 15 of 17
Function:	Effective Date:	Version number:
Regulatory Affairs	September 20, 2024	1.0

# Section 15. Regulatory information

Name	%	Classification
propane-1,2-diol	≤3	EYE IRRITATION - Category 2B
liraglutide	≤1	CARCINOGENICITY - Category 2
		TOXIC TO REPRODUCTION - Category 2
phenol	<1	ACUTE TOXICITY (oral) - Category 4
		ACUTE TOXICITY (dermal) - Category 3
		ACUTE TOXICITY (inhalation) - Category 2
		SKIN CORROSION - Category 1B
		SERIOUS EYE DAMAGE - Category 1
		GERM CELL MUTAGENICITY - Category 2
		SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) -
		Category 1
		SPECIFIC TARGET ORGAN TOXICITY (REPEATED
		EXPOSURE) - Category 2
		HNOC - Corrosive to digestive tract
Dhoonhorio acid dicadium calt	≤0.3	HNOC - Corrosive to respiratory tract EYE IRRITATION - Category 2A
Phosphoric acid, disodium salt, dihydrate	≥0.5	ETETICITATION - Category 2A
sodium hydroxide	≤0.1	CORROSIVE TO METALS - Category 1
30didiii iiyaroxide	_0.1	ACUTE TOXICITY (oral) - Category 4
		SKIN CORROSION - Category 1A
		SERIOUS EYE DAMAGE - Category 1
	, X	SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)
		(Respiratory tract irritation) - Category 3
		HNOC - Corrosive to digestive tract [severe]
Hydrochloric acid	≤0.1	CORROSIVE TO METALS - Category 1
		SKIN CORROSION - Category 1B
		SERIOUS EYE DAMAGE - Category 1
		SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)
		(Respiratory tract irritation) - Category 3
		HNOC - Corrosive to digestive tract

#### **SARA 313**

Not applicable.

#### **State regulations**

Massachusetts: None of the components are listed.New York: None of the components are listed.

New Jersey : The following components are listed: PROPYLENE GLYCOL; PHENOL

Pennsylvania : The following components are listed: 1,2-PROPANEDIOL

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

### **International regulations**

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.



Safety Data Sheet

SDS Number: SDS-000098	Page Number: Page 16 of 17
Effective Date: September 20, 2024	Version number: 1.0

## Section 15. Regulatory information

### **Montreal Protocol**

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

**Rotterdam Convention on Prior Informed Consent (PIC)** 

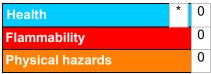
Not listed.

**UNECE Aarhus Protocol on POPs and Heavy Metals** 

Not listed.

### Section 16. Other information

### **Hazardous Material Information System (U.S.A.)**



Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

#### **National Fire Protection Association (U.S.A.)**



: 09/20/2024

#### Procedure used to derive the classification

Classification	Justification
<b> </b>	Calculation method Calculation method

#### **History**

Date of issue/Date of

revision

Date of previous issue : No previous validation

Version : 1.0

Prepared by : Sphera Solutions



SDS Title:	SDS Number:	Page Number:
Liraglutide Injection Safety Data Sheet	SDS-000098	Page 17 of 17
	Effective Date: September 20, 2024	Version number: 1.0

### **Section 16. Other information**

Key to abbreviations

: ATE = Acute Toxicity Estimate

AMP = Acceptable maximum peak above the acceptable ceiling concentration for an

Safety Data Sheet

8-hr shift

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as

modified by the Protocol of 1978. ("Marpol" = marine pollution)

N/A = Not available UN = United Nations

References

: HCS (U.S.A.)- Hazard Communication Standard

International transport regulations

Indicates information that has changed from previously issued version.

#### **Notice to reader**

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.