Lilly

SAFETY DATA SHEET

1. Identification

Product identifier REYVOW™

Other means of identification

Item Code 702581, 701681, 701682, ZD4491, ZD4312, 701312, 701295, 701313, ZD2103, TA4736, ZD2102,

TA4491, ZD2101, TA4312, 701282, 701172, 701181, 701180, 701062, 701063, 701095, 701096

LY Number LY573144

Recommended use Pharmaceutical

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name Eli Lilly and Company
Address Lilly Corporate Center
Indianapolis, IN 46285

United States

Telephone Phone: +1-317-276-2000

E-mail lilly sds@lilly.com

Emergency phone number CHEMTREC: +1-800-424-9300

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Acute toxicity, oral Category 4

Serious eye damage/eye irritation Category 1
Reproductive toxicity Category 2

Specific target organ toxicity, single exposure Category 3 narcotic effects

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement

H302 Harmful if swallowed.

H318 Causes serious eye damage.

H361 Suspected of damaging the unborn child.
H336 May cause drowsiness or dizziness.

Precautionary statement

Prevention

P201 Obtain special instructions before use.

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

P261 Avoid breathing dust.

P271 Use only outdoors or in a well-ventilated area.

P264 Wash thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response

P305 + P351 +

P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

P330 Rinse mouth.

P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

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Storage

Store in a well-ventilated place. Keep container tightly closed. P403 + P233

Store locked up. P405

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations. P501

Hazard(s) not otherwise classified (HNOC)

None known.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Lasmiditan Hemisuccinate	LY573144 Hemisuccinate 573144 1/2 Succinate Butanedioic acid, compd. with 2,4,6-trifluoro-N-[6-[(1-methyl-4-piperidiny I)carbonyl]-2-pyridinyl]benzamide (1:2) 2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl)benzamide Lasmiditan Hemisuccinate Milled IUPAC: 2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl)benzamide LY573144 Hemisuccinate	439239-92-6	51.4
Composition comments	Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.		
4. First-aid measures			
Inhalation	Remove to fresh air. If breathing stops, provide	artificial respiration. Get me	dical attention

Inhalation	Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention
	immediately.

immediately.

Skin contact Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. Immediately

take off all contaminated clothing. Get medical attention if irritation develops and persists.

In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under Eye contact

the eyelids, for at least 15 minutes. Get medical attention.

Immediately give large quantities of water to drink. Never give anything by mouth to a victim who is Ingestion

unconscious or is having convulsions. Call a physician immediately.

Most important symptoms/effects, acute and

delayed

Harmful if swallowed. Causes serious eye damage. May cause developmental effects based on animal data. May cause drowsiness or dizziness.

Indication of immediate medical attention and special treatment needed

None known.

5. Fire-fighting measures

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). Unsuitable extinguishing Do not use water jet as an extinguisher, as this will spread the fire. media

Specific hazards arising from the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Use water spray to cool unopened containers.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment. protective equipment and emergency procedures

Methods and materials for Do not sweep. Collect spill using a vacuum cleaner with a HEPA filter. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist/wet containment and cleaning up material and remove by mopping or wet wiping.

Material name: REYVOW™ SDS US 2/7 **Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Minimize dust generation and accumulation. Keep away from heat and sources of ignition. Avoid contact with eyes, skin, and clothing. See Section 8 of the SDS for Personal Protective Equipment.

Conditions for safe storage, including any incompatibilities Keep container tightly closed in a dry and well-ventilated place.

8. Exposure controls/personal protection

Occupational exposure limits

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Components	Туре	Value
Lasmiditan Hemisuccinate (CAS 439239-92-6)	TWA (12hrs)	25 ug/m3
	TWA (8hrs)	40 ug/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

The recommendations in this section are intended for manufacturing or other situations where

exposure to contents may occur.

Open handling is not recommended. Use appropriate control measures such as fume hood,

ventilated enclosure, local exhaust ventilation, or down-draft booth.

Individual protection measures, such as personal protective equipment

Eye/face protection Safety glasses with side shields recommended. If splash potential or dusty operations, wear

goggles/faceshield.

Skin protection

Hand protection Chemical resistant gloves.

Other Chemical-resistant gloves and impermeable body covering to minimize skin contact.

Use a properly fitted, air purifying or air fed respirator complying with an approved standard if a risk Respiratory protection

assessment indicated that is necessary. If the applicable occupational exposure level (OEL) is anticipated to be exceeded, wear an approved respirator with sufficient protection factor to control

exposure below the OEL.

General hygiene considerations

Engineering controls should be used as the primary means to control workplace exposures. Follow good workplace hygiene practices such as washing hands after handling this material.

9. Physical and chemical properties

Appearance

Solid. Physical state **Form** Tablet.

Color White or Grey White or Purple Grey or Grey

Odor Not available. Odor threshold Not available. Not available. Not available. Melting point/freezing point Initial boiling point and boiling Not available.

range

Not available. Flash point Not available. **Evaporation rate** Flammability (solid, gas) Not available. Upper/lower flammability or explosive limits

Explosive limit - lower (%) Not available. Explosive limit - upper (%) Not available. Not available. Vapor pressure Not available. Vapor density Relative density Not available.

Solubility(ies)

Solubility (water) Not available. Partition coefficient Not available.

(n-octanol/water)

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Not available. Auto-ignition temperature **Decomposition temperature** Not available. Viscosity Not available.

Other information

Not explosive. **Explosive properties** Oxidizing properties Not oxidizing.

10. Stability and reactivity

Reactivity Not water reactive.

Chemical stability Material is stable under normal conditions. Possibility of hazardous Hazardous polymerization does not occur.

reactions

Contact with incompatible materials. Conditions to avoid Incompatible materials Strong oxidizing substances.

Hazardous decomposition

products

None known.

11. Toxicological information

Information on toxicological effects

Acute toxicity Harmful if swallowed.

Components **Test Results Species**

Lasmiditan Hemisuccinate (CAS 439239-92-6)

Acute Oral

LD50 Rat > 300 mg/kg (estimated, 4-5 day study)

(Convulsions and/or mortality)

Skin corrosion/irritation Epiderm (TM) Skin Irritation: Non-irritant (Lasmiditan Hydrochloride)

> Epiderm (TM) Corrosivity: Non-corrosive (Lasmiditan Hydrochloride) Based on available data, the classification criteria are not met.

Serious eve damage/eve

irritation

Bovine Corneal Opacity and Permeability assay: Severe eye irritation. (Lasmiditan Hemisuccinate)

Respiratory or skin sensitization

Due to lack of data the classification is not possible. Respiratory sensitization Skin sensitization Due to lack of data the classification is not possible.

Germ cell mutagenicity In vitro and in vivo tests did not show mutagenic effects. (Lasmiditan Hemisuccinate)

Based on available data, the classification criteria are not met.

Not carcinogenic in a two-year rat carcinogenicity study or a 6-month transgenic mouse study. Not Carcinogenicity

listed by IARC, NTP, ACGIH or OSHA. (Lasmiditan Hemisuccinate) Based on available data, the classification criteria are not met.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

There were no effects on male or female fertility in studies with rats. In embryofetal development Reproductive toxicity

studies (rats, rabbits), fetal development was delayed (decreased fetal body weights and skeletal variations) at maternally toxic doses. In rabbits, a slight increase in embryofetal mortality and a low incidence of fetal malformations occurred in a single study at a maternally toxic dose. Oral administration of lasmiditan to rats throughout pregnancy and lactation resulted in increases in stillbirth and neonatal mortality at the highest dose tested, which was associated with maternal

toxicity and delayed parturition. (Lasmiditan Hemisuccinate)

Specific target organ toxicity -

single exposure

Drowsiness and dizziness have been reported during therapeutic administration of Lasmiditan

Hemisuccinate

Specific target organ toxicity -

repeated exposure

Nervous system effects were reported in animal studies after repeated exposure to high doses. Kidney and heart effects were reported in rats after repeated exposure to high doses. These

effects were considered to be specific to rats only. (Lasmiditan Hemisuccinate)

Based on available data, the classification criteria are not met.

Aspiration hazard Not applicable.

Material name: REYVOW™ SDS US

12. Ecological information

Ecotoxicity

Toxic to aquatic life.

Components		Species	Test Results
Lasmiditan Hemisuccina	ite (CAS 439239-	92-6)	
Other	EC50	Pseudokirchnerella subcapitata	7.4 mg/l, 72 h (OECD 201)
			4.3 mg/l, 72 h (OECD 201)
	LOEC	Pseudokirchnerella subcapitata	3.9 mg/l, 72 h (OECD 201) (yield and growth rate)
	NOEC	Pseudokirchnerella subcapitata	1.5 mg/l, 72 h (OECD 201) (yield and growth rate)
Aquatic			
Crustacea	EC50	Daphnia magna	17 mg/l, 48 h (OECD 202)
	LOEC	Daphnia magna	5.4 mg/l, 21 d (OECD 211)
			4.3 mg/l, 48 h (OECD 202)
	NOEC	Daphnia magna	2.7 mg/l, 21 d (OECD 211)
Fish	EC50	Fathead minnow (Pimephales promelas)	72 mg/l, 96 h (OECD 203)
	LOEC	Fathead minnow (Pimephales promelas)	27 mg/l, 96 h (OECD 203)
			10 mg/l, 28 d (OECD 210)
	NOEC	Fathead minnow (Pimephales promelas)	5.2 mg/l, 28 d (OECD 210)
Other	EC50	Sewage Microorganisms	279 mg/l, 3 h (OECD 209)
			15.6 mg/l, 3 h (OECD 209)
	LOEC	Sewage Microorganisms	100 mg/l, 3 h (OECD 209)(heterotrophic)
			1 mg/l, 3 h (OECD 209)(nitrification)
	NOEC	Sewage Microorganisms	10 mg/l, 3 h (OECD 209) (nitrification)
			0.1 mg/l, 3 h (OECD 209) (heterotrophic)

A LAEG is the maximum allowable concentration at the point of application that is expected to result in no appreciable risk to populations of aquatic and terrestrial organisms, or to human health.

LILLY AQUATIC EXPOSURE GUIDELINES:

Lasmiditan Hemisuccinate

Acute LAEG (at the edge of the acute mixing zone): 654 µg/l Chronic LAEG (at the edge of the chronic mixing zone): 27 µg/l Drinking water LAEG (at the point where surface water is taken for drinking water): 13 µg/l

Persistence and degradability

Hydrolysis half-life: (in days) pH 4,7,9 stable

Biodegradation: 56% in 28 days. (OECD 302A)

DT50: 13.25 Days (OECD 302A)

Biodegradation: 57% in 28 days. (OECD 314B)

DT50: 14.11 Days (OECD 314B)

Degradation in aquatic sediment: 100 Days DT50: 3.78 to 6.22 Days (water layer) DT50: 148 to 222 Days (total system)

Dissociation constant (pKa): 9.0, 10.7

Bioaccumulative potential

log Kow: < 4.

Partition coefficient n-octanol / water (log Kow)

Lasmiditan Hemisuccinate < 0, (-0.561, pH4)

0.978, (pH 7) 2.77, (pH 9)

Adsorption (sludge) Koc: 81 to 234 l/kg Mobility in soil

Adsorption (soil) Koc: 14280 to 28595 I/kg

Not available. Other adverse effects

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations.

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14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Not available.

Annex II of MARPOL 73/78 and

the IBC Code

15. Regulatory information

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication US federal regulations

Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Acute toxicity (any route of exposure) Classified hazard Serious eye damage or eye irritation categories

Reproductive toxicity

Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

(SDWA)

International Inventories

Country(s) or region On inventory (yes/no)* Inventory name

Canada Domestic Substances List (DSL) No Canada Non-Domestic Substances List (NDSL) Nο

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 10-11-2019 **Revision date** 02-07-2023

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Material name: REYVOW™ SDS US

List of abbreviations ACGIH: American Conference of Governmental Industrial Hygienists.

DOT: Department of Transportation (49 CFR 172.101)

EC50: Effective Concentration 50%.

EINECS: European Inventory of Existing Commercial Chemical Substances. GHS: Globally Harmonized System of Classification and Labeling of Chemicals.

IATA: International Air Transport Association.

IMDG Code: International Maritime Dangerous Goods Code.

LC50: Lethal Concentration 50%.

LD50: Lethal Dose 50%. LEG: Lilly Exposure Guideline.

MARPOL: International Convention for the Prevention of Pollution from Ships.

NOEC: No observed effect concentration. NTP: National Toxicology Program.

OSHA: Occupational Safety & Health Administration.

TWA: Time Weighted Average Value.

DisclaimerAs of the date of issuance, we are providing available information relevant to the handling of this

material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature

which may accompany the finished product.

For additional information contact:

Eli Lilly and Company Hazard Communication +1-317-651-9533

Revision information

Product and Company Identification: Alternate Trade Names

Other information, including date of preparation or last revision: List of abbreviations

Material name: REYVOW™ sps us

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