

Material Safety Data Sheet	
SECTION 1: Identification of the substance/mixture and of the company/undertaking	
Product identifier: Sincalide for Injection	CAS No.: 25126-32-3
Substance name: Sincalide	EC No.: NA
Route of administration: For Intravenous use	
REACH Registration No.: NA	
Use: The following SDS applies only to formulated Sincalide product in vials and standard shipments of these vials. If handling Sincalide for Injection, in manufacturing situations, consult the MSDS for the active ingredient and take appropriate precautions.	
Manufacturer Name and Address:	GLAND PHARMA LTD. DUNDIGAL(R&D) Sy.No.143 to 148,150 & 151, D.P. Pally Near Gandimaisamma X Roads, Dundigal (M) Medchal-Malkajgiri District Hyderabad - 500043 TELANGANA, INDIA
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Supplier Name	Gland Pharma Limited
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e-Mail address: purchase@glandpharma.com	
Effective Date: 18 April, 2023	Revision No.: 00
SECTION 2: Hazards identification	
Classification according to Regulation (EC) No 1272/2008 (CLP): NA	
Classification According to EU-directive 67/548/EEC or 1999/45/EC: NA	
<u>Classification of the substance or mixture:</u>	
The substance is not classified, according to the Globally Harmonized System (GHS).	
<u>Label elements</u>	
· GHS label elements: None · Hazard pictograms: None · Signal word: None	
Hazard statements:	
H315: Causes skin irritation.	
H319: Causes serious eye irritation.	
H335: May cause respiratory irritation.	
· Classification system: · NFPA ratings (scale 0 - 4) • Health = 0 • Fire = 0 • Reactivity = 0	

HMIS-ratings (scale 0 - 4)

- Health = 0
- Fire = 0
- Reactivity = 0

Other hazards**• Results of PBT and vPvB assessment**

- PBT: Not applicable.
- vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

Identification name	CAS No.	Weight % content	Manufacturer
Sincalide	25126-32-3	<100%	Gland
Mannitol	69-65-8	**	Gland
L-Arginine Hydrochloride	1119-34-2	**	Gland
L-Lysine Hydrochloride	657-27-2	**	Gland
L-Methionine	63-68-3	**	Gland
Pentetic acid	67-43-6	**	Gland
Sodium Metabisulfate	7681-57-4	**	Gland
Sodium Hydroxide	1310-73-2	**	Gland
Hydrochloric acid	7647-01-0	**	Gland

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

SECTION 4: First aid measures**First Aid Measures:**

- **Inhalation:** If breathed in, move person into fresh air. If not breathing, give artificial respiration. Move the victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and consult a doctor immediately. Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.
- **Skin:** Immediately wash skin copiously with soap and water. Take victim immediately to hospital. Consult a physician. Remove all contaminated clothes and footwear immediately unless stuck to skin. Drench the affected skin with running water for 10 minutes or longer if substance is still on skin. Consult a doctor.
- **Eye:** Immediately rinse out with water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Consult a physician. Bathe the eye with running water for 15 minutes. Consult a doctor.
- **Ingestion:** Wash out mouth with water. Drink plenty of water. Consult a physician. Never give anything by mouth to an unconscious person. Do not induce vomiting. If conscious, give half a litre of water to drink immediately. Consult a doctor
- **Notes to physician:** Treat symptomatically and supportively.

Indication of any immediate medical attention and special treatment needed: Not applicable.

SECTION 5: Firefighting measures

- **Extinguishing Media:** Carbon dioxide, dry chemical powder, foam. Suitable extinguishing media for the surrounding fire should be used.
- **Suitable extinguishing agents:**
Use firefighting measures that suit the environment.
A solid water stream may be inefficient.
- **Special hazards arising from the substance or mixture** Not applicable.
- **Protective equipment:** Firefighters should wear adequate personal protective equipment with protection of respiratory tract (self-contained breathing apparatus) (SCBA). In addition, firefighters should wear flame and chemicals resistant clothing, boots and gloves.
- **Exposure hazards:** In combustion emits toxic fumes. Nitrogen oxides (NO_x).
- **Advice for firefighters**
Protective equipment: No special measures required. Wear self-contained breathing apparatus.
Wear protective clothing to prevent contact with skin and eyes.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Wear protective equipment. Keep unprotected persons away. Avoid inhaling dust and fumes.

Environmental precautions:

Do not let product enter drains. Do not allow product to reach sewage system or any water course.

Methods and materials for containment and cleaning up:

Soak up with absorbent material, discard. Methods and material for containment and cleaning up: Retrieve product by mechanical means. Sweep material onto paper and place into a fiber drum for reclamation or disposal. The spill area should be ventilated and decontaminated after material has been picked up.

Protective Action Criteria for Chemicals

- **PAC-1:** Substance is not listed.
- **PAC-2:** Substance is not listed.
- **PAC-3:** Substance is not listed.

SECTION 7: Handling and storage

Handling

Precautions for safe handling: Avoid direct contact with the substance. Ensure there is sufficient ventilation of the area. Do not handle in a confined space. Avoid the formation or spread of dust in the air. Only use in fume hood.

Advice on protection against fire and explosion

Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene measures

General industrial hygiene practice.

Conditions for safe storage, including any incompatibilities**Storage conditions**

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Storage stability

Recommended storage temperature -20 °C

Storage class

Storage class (TRGS 510): 13: Non-Combustible Solids

SECTION 8: Exposure controls/personal protection**Control parameters****Ingredients with workplace control parameters****Exposure controls****Personal protective equipment****Eye/face protection:**

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

- **Skin protection:**

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

- **Body Protection:**

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

- **Respiratory protection:**

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

- **Control of environmental exposure**

Do not let product enter drains.

SECTION 9: Physical and chemical properties

Appearance/Physical State: Powder

Color: White

Odour: NA
Odor Threshold: Not determined
Molecular Weight: 1,143.3 g/mol
pH: 6.5-7.5
Melting point/Freezing point: NA
Structural Formula: C₄₉H₆₂N₁₀O₁₆S₃
Initial Boiling Point/Boiling Point Range: NA
Evaporation Rate: NA
Flammability (solid, gas): NA
Upper/Lower Flammability or Explosive Limits: NA
Vapor Pressure: NA
Vapor Density: NA
Specific Gravity: NA
Solubility: soluble in water
Partition coefficient: n-octanol/water: NA
Auto-ignition temperature: NA
Decomposition temperature: NA

SECTION 10: Stability and Reactivity

Reactivity:

Not applicable

Chemical Stability:

Stable under recommended storage conditions

Possibility of hazardous reactions:

Not applicable.

Conditions to avoid:

Incompatible materials.

Incompatible materials:

Strong oxidizing agents.

Hazardous decomposition products:

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NO_x), Sulfur oxides

SECTION 11: Toxicological information

Toxicological effects

Acute toxicity:

Skin corrosion/irritation: Not applicable.

Skin sensitization: Not applicable.

Germ cell mutagenicity: Not applicable.

Carcinogenicity:

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity: Not applicable.

STOT-single exposure: Not applicable.

STOT-repeated exposure: Not applicable.

Aspiration hazard: Not applicable.

Likely routes of exposure: Respiratory organs, mouth, skin, and eyes.

Primary irritant effect:

on the skin:

No irritant effect.

Material contains low concentration of components that are mild irritants or possible irritants. It may have potential to cause mild irritation, however, moderate or severe irritation is not expected.

on the eye: No irritating effect.

Sensitization:

No sensitizing effects known.

This material may act as a sensitizer (allergen) for those persons who are allergic to the formulation or components in the formulation.

Other information (about experimental toxicology):

By Inhalation: Inhaling trace amounts of airborne dust would not be expected to produce symptoms. However, some peptides are active following inhalation.

By Ingestion: Inadvertent ingestion of trace amounts of this material would not be expected to result in symptoms.

Reproductive Toxicity: Stage II teratology studies showed no effects in rabbits and hamsters injected with sincalide in doses up to 750 ng/kg. Studies in rats administered sincalide subcutaneously at doses 12.5 times the maximum recommended human dose showed no evidence of harm to the fetus. Sincalide should not be administered to pregnant women near term due to its smooth muscle stimulation effect, which could result in premature labor.

Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

Contact with small quantities of material for short periods is not expected to result in pharmacologic or toxic effects. At therapeutic doses, sincalide causes reversible pharmacological effects on the gallbladder, pancreas and intestinal smooth muscle. Exposure to therapeutic doses may cause small

gallbladder stones to be evacuated, leading to blockage of the bile duct. It may also cause aggravation of pre-existing pancreatitis or of the symptoms of pre-existing bowel inflammation or obstruction. Sincalide should not be administered to pregnant women near term; due to its effects on smooth muscle, it may induce labor.

Symptoms of exposure: Stomach-Irregularities-Based on Human Evidence.

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological information

· **Toxicity**

· **Aquatic toxicity:** Not applicable.

· **Persistence and degradability:** Not applicable.

· **Behavior in environmental systems:**

· **Bioaccumulative potential:** Not applicable.

· **Mobility in soil:** Not applicable.

Additional ecological information:

· **General notes:**

Water hazard class 1 (Self-assessment): slightly hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects:** Not applicable.

SECTION 13: Disposal considerations

Waste treatment methods

Disposal methods

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems. MATERIAL SHOULD BE DISPOSED OF IN ACCORDANCE WITH LOCAL, STATE AND FEDERAL REGULATIONS.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials. Dispose of as special waste in compliance with local and national regulations Observe all federal, state and local environmental regulations.

Recommendation: Smaller quantities can be disposed of with household waste.

Uncleaned packagings:

Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport Information

- **UN-Number**
 - DOT, IMDG, IATA not regulated
- **UN proper shipping name**
 - DOT, IMDG, IATA not regulated
- **Transport hazard class(es)**
 - DOT, ADN, IMDG, IATA
 - Class not regulated
- **Packing group**
 - DOT, IMDG, IATA not regulated
- **Environmental hazards:** Not applicable.
- **Special precautions for user:** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:**
Not applicable.
- **UN "Model Regulation":** not regulated

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture:
Not applicable.

Sara

Section 355 (extremely hazardous substances): Substance is not listed.

Section 313 (Specific toxic chemical listings): Substance is not listed.

TSCA (Toxic Substances Control Act): Substance is not listed.

Hazardous Air Pollutants: Substance is not listed.

Proposition 65

Chemicals known to cause cancer: Substance is not listed.

Chemicals known to cause reproductive toxicity for females: Substance is not listed.

Chemicals known to cause reproductive toxicity for males: Substance is not listed.

Chemicals known to cause developmental toxicity: Substance is not listed.

Carcinogenic categories

EPA (Environmental Protection Agency): Substance is not listed.

TLV (Threshold Limit Value): Substance is not listed.

NIOSH-Ca (National Institute for Occupational Safety and Health): Substance is not listed.

Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

Code letter and hazard designation of product:

Hazard-determining components of labeling:

EU Risk And Safety phrases:

S24/25: avoid contact with skin and eyes

S26: in case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S28: after contact with skin, wash immediately with plenty of water

S36/37/39: wear protective clothing, gloves and eye/face protection

R28: very toxic if swallowed

R38: irritating to skin

R41: risk of serious damages to eyes

R48: toxic; danger of serious damage to health by prolonged exposure

R62: possible risk of impaired fertility

R63: possible risk of harm to unborn child

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Department issuing SDS: Environment protection department.

Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

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Further information Not applicable

This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer specific information about this product when used according to manufacturer's directions. 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 completeness of the information 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.

Disclaimer: The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a potent pharmaceutical product.