



## SAFETY DATA SHEET

### Sodium oxybate, 0.5 g/mL Oral solution

#### 1. IDENTIFICATION

**Manufacturer:**

Ascent Pharmaceuticals Inc  
400 S. Technology Drive  
Central Islip, NY 11722  
USA

**Emergency Phone:**

1-855-221-1622

**Product Name:** Sodium oxybate, 0.5 g/mL **Oral solution**

**Synonym(s):** sodium oxybate, sodium gamma-hydroxybutyrate; butanoic acid, 4-hydroxybutyrate monosodium salt.

**Trade Name(s):** Sodium oxybate, 0.5 g/mL oral solution

#### 2. HAZARDS IDENTIFICATION

Not considered hazardous when handled under normal conditions. Accidental ingestion of large amounts may be harmful.

**Classification of the Substance or Mixture- Not Classified**

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions

**Emergency Overview:**

**Warning:** May cause eye and skin irritation. May cause drowsiness if ingested.

**Medical Conditions**

**Aggravated by Exposure:** None known

**Target Organs:** Neurological

**Primary Entry Routes:** Absorption through eyes, ingestion.

**Acute Effects:**

**Eyes** Causes painful stinging or burning of eyes and lids, watering of eyes, conjunctivitis, opaqueness of cornea, possibly leading to loss of sight.



**Skin:** May cause irritation. If significant amount absorbed dermally may cause anesthetic or narcotic effects.

**Inhalation:** May cause irritation. If misted, or a high concentrations, may cause pallor, nausea, anesthetic or narcotic effects.

**Ingestion:** Sedative and hypnotic effect in humans at >50mg/kg. Can cause profound sedative-hypnotic effects in animals in doses of 60 mg/kg. Can affect monosynaptic reflexes at 10 mg/kg.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

<b><u>Ingredient</u></b>	<b><u>CAS</u></b>	<b><u>Concentration %</u></b>
Sodium Oxybate	502-85-2	43 % (approx.)
Excipients	NA	57 % (approx.)

### 4. FIRST AID MEASURES

**Inhalation:** May cause irritation if inhaled. In case of accidental inhalation, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms appear.

**Eye Contact:**

Do not allow victim to rub or keep eyes tightly shut. Watering of eyes, conjunctivitis, opaqueness of cornea, possibly leading to loss of sight. Get medical attention if irritation occurs.

**Skin Contact:** May cause irritation. If significant amount absorbed dermally may cause anesthetic or narcotic effects. Get medical attention if irritation develops. Take off contaminated clothing and wash before reuse.

**Ingestion:** Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.



## 5. FIRE-FIGHTING MEASURES

**Extinguisher Media:** Use an extinguishing agent suitable for the surrounding fire.

**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Fire and Explosion Hazards:** None known under normal conditions of product handling.

**Hazardous Decomposition Products:** gases hazardous to health may be formed.

## 6. ACCIDENTAL RELEASE MEASURES

The following are recommended for manufacturing or other situations where exposure may occur.

**Personal Precautions:** Not necessary for small spills. For large spills, immediately contact emergency personnel. Keep unnecessary personnel away. Use suitable protective equipment.

**Methods for cleaning up:** Contain the source of spill if it is safe to do so. Collect spilled material. A damp cloth or a filtered vacuum should be used to clean spills. Clean spill area thoroughly.

## 7. HANDLING AND STORAGE

**Handling:** Restrict access to working area. No special control measures required for the normal handling of this product. Keep away from heat, sparks and open flame. Store in original tightly closed container. Store away from incompatible materials if bottles are crushed and/or broken, avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases.

**Storage Conditions:** Controlled Room Temperature: 20° to 25° C (68° to 77° F).

Store the medicine in a tight, light resistant container at room temperature, away from heat, moisture, and direct light.



## 8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Solution bottles are not considered hazardous under normal handling procedures and the following are recommended for manufacturing or other situations where exposure may occur.

**Engineering Controls:** Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls.

### **Personal Protective Equipment:**

**Eye/Face Protection:** Wear safety glasses with side shields wherever the potential exists for direct exposure.

**Skin Protection:** Use disposable chemical resistant gloves

**Respiratory Protection:** None required with normal handling of finished product.

Use a NIOSH approved respirator or an alternate approved dust mask should be used.

**Additional Exposure Precautions:** None required with normal handling of finished product. Use disposable outer garments or chemical resistant garments of equal or greater protection, when there is potential for direct contact with Solution. Protect exposed skin.

## 9.PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Aqueous liquid

**Boiling Point:** Not available

**pH:** 7.3 to 7.8

**Melting range:** Not available

**Evaporation Rate:** Not available

**Vapor Density:** 0.02 (as water).

**Vapor Pressure:** 16 m/Hg

## 10. STABILITY AND REACTIVITY

**Stability:** The product is stable under recommended storage conditions.

**Conditions to avoid:** Keep away from heat, sparks and open flame. Contact with incompatible materials.



**Incompatibilities:** Strong oxidizing agents

**Hazardous Decomposition Products:** No data available

## 11. TOXICOLOGICAL INFORMATION

**General:** Handling of formulated product is not expected to cause any adverse effects.

Oxybate :IP rat LD<sub>50</sub> 3700 mg/kg

## 12. ECOLOGICAL INFORMATION

**Eco-toxicity:** No information is available about the potential of this product to produce adverse environmental effects.

Avoid release in to the environment

Runoff from fire control or dilution water may cause pollution.

## 13. DISPOSAL CONSIDERATIONS

**Waste Disposal:** Dispose of waste in accordance with all applicable DEA, Federal, State, or local regulations.

## 14. TRANSPORT INFORMATION

**Regulatory Organizations:**

**DOT:** Not Regulated

**IATA:** Not Regulated

**IMDG:** Not Regulated

## 15. REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible Ascent and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

**Safety, health and environmental regulations:** This safety data sheet was prepared according to GHS. Being pharmaceutical product, this product is not subject to GHS-related regulations (labelling, SDS, and others).



## 16. OTHER INFORMATION

### **SDS Sections Revised:** New SDS

As 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 MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY 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 or product literature which may accompany the finished product.

### **GLOSSARY:**

**CAS Number** = Chemical Abstract Service Registry Number

**CERCLA** = Comprehensive Environmental Response Compensation and Liability Act (of 1980)

**DOT** = Department of Transportation

**ECG** = Electrocardiography

**IARC** = International Agency for Research on Cancer

**ICAO/IATA** = International Civil Aviation Organization/ International Air Transport Association

**IMO** = International Maritime Organization

**MSDS** = Material Safety Data Sheet

**NA** = Not Applicable

**NIOSH** = National Institute for Occupational Safety and Health

**NTP** = National Toxicology Program

**OSHA** = Occupational Safety and Health Administration

**SARA** = Superfund Amendments and Reauthorization Act

**SSRI's** = Selective serotonin reuptake inhibitor

**TSCA** = Toxic Substances Control Act

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