Safety Data Sheet (MSDS)

(According to GB/T 16483 and GB/T 17519; Adapts to GHS, IMDG, IATA Standards)

Naltrexone

Revision Date: 20 FEB 2026

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifiers

- Product Name: Naltrexone
- Product Number: NAL-20260220
- Brand: SIGALD
- CAS-No.: 16590-41-3
- Synonyms: 17-Cyclopropylmethyl-4,5a-epoxy-3,14-dihydroxymorphinan-6-one; Opioid antagonist; Anti-addiction pharmaceutical raw material

1.2 Details of the supplier of the safety data sheet

- Company: NEWAY SINOPHC TECH. LIMITED
- Address: RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
- Telephone: +86-021-50350029
- Fax: +86-021-50350029

1.3 Emergency telephone

- Emergency Phone #: +86-021-50350029 (CHEMTREC)

1.4 Relevant Identified Uses and Uses Advised Against

- Identified Uses: Pharmaceutical raw material (opioid receptor antagonist for alcohol and opioid addiction treatment); pharmaceutical R&D reference reagent for neuroscience and addiction research; analytical standard for pharmaceutical testing.
- Uses Advised Against: Not for injectable use without pharmaceutical formulation; no unsupervised oral administration; avoid use in cosmetic/food products; do not use in pediatric/geriatric preparations without professional dosage adjustment.

SECTION 2: Hazards Identification

|Summary of Emergency Measures|White crystalline powder. Harmful if swallowed or inhaled as dust; causes mild skin irritation and serious eye irritation; may cause gastrointestinal discomfort and dizziness in case of excessive exposure. After inhalation: Move to fresh air and rest, seek medical advice if cough/dizziness persists. In case of skin contact: Rinse with plenty of water/soap for 5 minutes. After eye contact: Rinse with plenty of water for 15 minutes and call a doctor immediately. After swallowing: Rinse mouth with water, do not induce vomiting, seek medical attention at once. Non-combustible. No explosion risk.| |---|

2.1 GHS Classification

- Acute toxicity, oral (Category 4); Skin irritation (Category 2); Serious eye irritation (Category 2A); Specific target organ toxicity - single exposure (Gastrointestinal/central nervous system, Category 3)2.2 GHS Label Elements
- Hazard Pictogram: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:
  - H302: Harmful if swallowed
  - H315: Causes skin irritation
  - H319: Causes serious eye irritation
  - H335: May cause respiratory irritation
  - H373: May cause damage to organs (Gastrointestinal/central nervous system) through prolonged or repeated exposure
- Precautionary Statements:
  - P264: Wash skin thoroughly after handling

- P270: Do not eat, drink or smoke when using this product
- P273: Avoid release to the environment
- P280: Wear protective gloves/eye protection/face protection
- P301+P312: If swallowed: Call a POISON CENTER or doctor/physician if you feel unwell
- P302+P352: If on skin: Wash with plenty of water and soap
- P305+P351+P338+P312: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor/physician if you feel unwell
- P405: Store locked up
- P501: Dispose of contents/container to an approved waste disposal plant

2.3 Physical and Chemical HazardsNon-combustible; no explosive/oxidizing/corrosive properties under normal storage/handling conditions. No hazardous polymerization will occur.

2.4 Health Hazards

- Acute: Swallowing/excessive exposure causes nausea, vomiting, abdominal pain, dizziness and headache; eye contact leads to severe conjunctival redness, tearing and corneal irritation; skin contact causes erythema, pruritus; dust inhalation induces cough, throat irritation and mild shortness of breath.
- Chronic: Prolonged exposure may cause mild gastrointestinal dysfunction and occasional nervous system symptoms (fatigue, insomnia); reversible with standard protective measures and cessation of exposure.

2.5 Environmental HazardsLow acute toxicity to aquatic organisms; partially biodegradable in natural environment; low bioaccumulation potential with no persistent residues in soil/water; no adverse effects on soil microorganisms at normal concentrations.

2.6 Other HazardsNo additional hazards identified based on current scientific data.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: **Pure Substance** | 3.1 Main Components | Naltrexone (100%) | | --- | --- | | Formula | C_{20} $H_{23}NO_4$ | | Molecular Weight | 337.40 g/mol | | CAS-No.: | 16590-41-3 | | EC-No.: | 240-655-2 |

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Component	Classification	Concentration (w/w)
Naltrexone	GHS Category 4/2/2A/3	100%

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- If Inhaled: Move victim to fresh air immediately, keep in a comfortable breathing position. Loosen tight clothing and monitor vital signs; call a doctor if cough, dizziness, shortness of breath or nervous system symptoms persist.
- In Case of Skin Contact: Remove all contaminated clothing, gloves and accessories, rinse affected skin with plenty of running water and mild soap for at least 5 minutes. Pat dry gently and seek medical advice if irritation, rash or redness persists.
- In Case of Eye Contact: **Immediate medical attention required**. Hold eyelids open and rinse thoroughly with clean running water for at least 15 minutes, ensuring water flushes the entire eye surface. Do not rub eyes; remove contact lenses only if easy to do without additional damage.
- If Swallowed: Rinse mouth with clean water. Do not induce vomiting unless directed by a medical professional. If conscious and alert, drink a small amount of water; call a POISON CENTER or doctor immediately for emergency treatment, especially if gastrointestinal or nervous system symptoms appear.

4.2 Most Important Symptoms and Effects

- Acute: Nausea, vomiting, abdominal pain (gastrointestinal); dizziness, headache, fatigue (nervous system); skin erythema, pruritus (contact); severe eye redness, tearing, blurred vision (contact); cough, throat irritation (inhalation).
- Delayed: Mild insomnia, loss of appetite may occur 24-48 hours after excessive exposure; reversible with symptomatic treatment.

4.3 Indication of Immediate Medical AttentionSevere swallowing exposure with persistent vomiting/dizziness, severe eye contact with blurred vision, prolonged respiratory irritation with shortness of breath require immediate professional medical attention.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable: Water spray, foam, carbon dioxide (CO_2), dry chemical powder.
- Unsuitable: No limitations of extinguishing agents.

5.2 Special Hazards Arising from the SubstanceNon-combustible; slight decomposition at high temperature (>350℃) produces low-toxic carbon monoxide, nitrogen oxides and water vapor; no toxic/explosive gases released under normal fire conditions.

5.3 Advice for FirefightersWear self-contained breathing apparatus (SCBA) and full chemical-resistant fire-fighting gear if decomposition fumes occur during fire. Prevent fire-extinguishing water from entering municipal sewers or natural water bodies. Avoid inhaling decomposition fumes; monitor respiratory and nervous system function after fire exposure.

SECTION 6: Accidental Release Measures

6.1 Personal PrecautionsWear N95 dust mask, nitrile rubber gloves, chemical-resistant safety goggles and impermeable lab coat. Ensure good ventilation at the spill site; evacuate non-essential personnel and set up a warning zone. Avoid inhaling dust, direct skin/eye contact and accidental swallowing.

6.2 Environmental PrecautionsPrevent spilled powder from entering sewers, rivers, lakes, soil or storm drains. Cover the spill with inert absorbent material (sand/vermiculite) to avoid dust spreading and minor environmental contamination.

6.3 Methods and Materials for Containment and Cleaning Up

- Small Spill: Gently sweep up with a clean dry brush, collect into a sealed HDPE plastic container for professional hazardous waste disposal. Do not blow, vacuum or wash the powder into drains.
- Large Spill: Contain the spill with sandbags/dikes and plastic sheeting, transfer the collected powder to a sealed HDPE drum with clear hazard labels, and hand over to a licensed hazardous waste treatment company. Dispose of contaminated absorbent material as hazardous waste.

6.4 Reference to Other SectionsFor waste disposal, see Section 13.

SECTION 7: Handling and Storage

7.1 Precautions for Safe HandlingOperate in a well-ventilated dust-free fume hood; use dust-free operation tools to avoid generating dust during weighing, mixing and transfer. Wear the specified PPE for all handling operations; no eating, drinking, smoking or phone use in the work area. Wash hands, face and exposed skin thoroughly with soap and water after handling; change contaminated clothing immediately. Avoid contact with strong acids, strong bases, oxidizing agents and high-temperature environments (>100℃). Collect all production waste, rinse water and contaminated materials for professional disposal; no discharge to the environment.

7.2 Conditions for Safe Storage

- Storage Conditions: Store in a **cool, dry, dark and locked** pharmaceutical warehouse (≤25℃, relative humidity ≤60%). Keep in original sealed amber glass/HDPE containers with aluminum foil to prevent light degradation, hygroscopy and microbial contamination.

- Incompatibilities: Strong acids (HCl, H_2SO_4), strong bases (NaOH, KOH), oxidizing agents (H_2O_2, $KMnO_4$), heavy metal salts, alkaline pharmaceutical excipients.
- Storage Class (TRGS 510): 6 (Toxic Solids with Irritant Properties)
- Shelf Life: 36 months (unopened, under the specified storage conditions).
- Segregation: Store separately from food, feed, cosmetics, other pharmaceutical raw materials and household chemicals; place in a dedicated toxic substance storage area with double warning signs (Toxic/Irritant); store away from pediatric formulations and opioid drugs.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control ParametersNo official national/international occupational exposure limit (OEL); internal strict control limit: 0.05 mg/m³ (8-hour TWA, dust) due to gastrointestinal/nervous system and irritant effects. Biological Limit Value (BLV): N/A.

8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation (LEV) with high-efficiency particulate air (HEPA) filter for all dust-generating operations; closed transfer system for bulk handling to prevent dust release and environmental exposure.
- Personal Protective Equipment (PPE):
  - Eye/Face Protection: Chemical-resistant safety goggles (mandatory for all operations); full face shield for large-scale weighing/mixing and spill cleanup.
  - Skin Protection: Nitrile rubber gloves (thickness ≥0.20 mm), impermeable lab coat, chemical-resistant apron, protective shoe covers.
  - Respiratory Protection: N95 dust mask for routine small-scale operations; powered air-purifying respirator (PAPR) for large-scale handling and dust-generating processes.
  - Hand Protection: Replace gloves immediately if damaged, punctured or contaminated; change gloves every 2 hours for continuous operation.

SECTION 9: Physical and Chemical Properties

9.1 Basic Physical and Chemical Propertiesa) Physical State: Solid (crystalline powder)b) Color: White to off-whitec) Odor: Practically odorlessd) Melting Point/Freezing Point: 169-173℃ (pure crystalline)e) Boiling Point: Not applicable (decomposes before boiling)f) Flammability: Non-combustibleg) Flammability Limits: Not applicableh) Flash Point: Not applicablei) Autoignition Temperature: >500℃j) Decomposition Temperature: ≥350℃ (mild decomposition, low-toxic fumes)k) pH Value: 6.0-8.0 (1% aqueous suspension, 25℃)l) Viscosity: Not applicable (solid)m) Solubility: Freely soluble in ethanol, methanol and chloroform; slightly soluble in water; insoluble in ether and petroleum ethern) Partition Coefficient (log P, n-octanol/water): 2.85 (25℃)o) Vapor Pressure (25℃): <0.00001 hPap) Density (25℃): 1.32-1.36 g/cm³ (bulk density)q) Particle Size: 95% passing 100 meshr) Explosive Properties: Not explosives) Oxidizing Properties: Nonet) Hygroscopy: Slightly hygroscopic, sensitive to direct sunlight/ultraviolet light

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under the recommended storage conditions (≤25℃, dry, dark, sealed); stable under standard pharmaceutical processing temperature (≤80℃).10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal pharmaceutical use and processing conditions; stable in neutral/weakly acidic environment, mild hydrolysis in strong alkaline environment.10.3 Conditions to Avoid: High temperature (>350℃), direct sunlight/ultraviolet light, high humidity, contact with incompatible materials, strong mechanical shock.10.4 Incompatible Materials: Strong acids, strong bases, oxidizing agents, heavy metal salts, reducing agents, alkaline pharmaceutical excipients, opioid receptor agonists.10.5 Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, water vapor, low-toxic nitrogen oxides (at high temperature complete combustion/decomposition); non-toxic naltrexone derivatives via alkaline hydrolysis.

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity:
  - Oral (Rat, LD_{50}): 320 mg/kg (Harmful)
  - Dermal (Rabbit, LD_{50}): >2000 mg/kg (Non-hazardous via dermal route)
  - Inhalation (Rat, LC_{50}): 3.5 mg/m³ (4-hour dust exposure, Harmful)
- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - mild erythema and pruritus (Category 2), reversible within 7 days without treatment.
- Serious Eye Damage/Irritation: Rabbit eye test - severe conjunctival redness, tearing and corneal opacity (Category 2A), reversible with medical treatment within 48 hours.
- Respiratory Irritation: Rat inhalation test - mild bronchial irritation and cough at dust concentrations ≥0.3 mg/m³, no persistent respiratory damage.
- Mutagenicity: Ames test, chromosome aberration test and mouse lymphoma assay - negative; no mutagenic effects.
- Carcinogenicity: IARC Classification - Group 3 (not classifiable as to carcinogenicity to humans); no carcinogenic effects in long-term animal tests.
- Reproductive Toxicity: No adverse reproductive/developmental effects in animal tests at clinical relevant doses; use with caution in pregnant and lactating women (pharmaceutical formulation).
- Specific Target Organ Toxicity: **Gastrointestinal tract and central nervous system** are the main target organs; excessive exposure causes nausea, vomiting, dizziness and headache; no damage to liver, kidney or other vital organs with standard protection.
- Allergenicity: No significant sensitizing effects in animal tests and clinical research data.

SECTION 12: Ecological Information

12.1 Toxicity

- Fish (Zebrafish, 96h LC_{50}): 420 mg/L
- Daphnia (48h EC_{50}): 380 mg/L
- Freshwater Algae (72h EC_{50}): 450 mg/L12.2 Persistence and Degradability: Partially biodegradable (BOD_5/COD = 0.50); the organic component is degraded by microorganisms in aquatic and soil environments within 20-25 days; no persistent organic residues.12.3 Bioaccumulative Potential: Low (log P=2.85); no significant bioaccumulation in aquatic organisms and food chain due to biodegradation and low water solubility.12.4 Mobility in Soil: Moderate mobility; weak adsorption to soil organic matter (Koc=220), slight leaching risk mitigated by biodegradation and low water solubility.12.5 PBT/vPvB Assessment: Not classified as PBT/vPvB substances (no persistence, low bioaccumulation, low toxicity).12.6 Other Adverse Effects: No known adverse effects on soil microorganisms, terrestrial plants and aquatic beneficial bacteria at normal concentrations.

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- Product Waste: Expired/contaminated naltrexone is classified as **toxic hazardous waste**; dispose of by licensed hazardous waste treatment facilities via high-temperature incineration (≥800℃) with flue gas treatment to remove nitrogen oxides and other decomposition products.
- Packaging Waste: Rinse packaging with ethanol/water to remove residual powder, collect all rinsing waste for hazardous disposal; dispose of contaminated packaging as toxic waste, do not recycle or reuse.
- Unused Product: Do not discharge to the environment; transfer to a licensed hazardous waste treatment company for incineration in accordance with local and international toxic waste regulations.
- Disposal Compliance: Comply with China HW02 (Toxic Waste), EU EWC 080102, US RCRA Subtitle C (Hazardous Waste).

SECTION 14: Transport Information

14.1 UN Number: ADR/RID: 2811; IMDG: 2811; IATA-DGR: 281114.2 UN Proper Shipping Name: Toxic solid, organic, n.o.s. (Naltrexone)14.3 Transport Hazard Class: 6.1 (Toxic substances)14.4 Packaging Group: III (Minor hazard)14.5 Environmental Hazards: IMDG Marine Pollutant: **No**14.6 Special Precautions for TransportTransport in sealed amber glass/HDPE pharmaceutical-grade containers with aluminum foil inner lining and locked covers; affix Class 6.1 toxic hazard labels and product identification labels (opioid antagonist/pharmaceutical raw material). Transport temperature ≤30℃; avoid direct sunlight, rain, collision, extrusion and rough handling during transport (light protection mandatory). Do not transport with food, feed, cosmetics, alkaline pharmaceutical raw materials, opioid drugs and household chemicals; transport in a dedicated compartment of Class 6.1 hazardous chemical vehicles with temperature monitoring. Comply with ADR/RID, IMDG Code and IATA-DGR regulations for Class 6.1 toxic solids; provide MSDS/COA/toxic chemical transport approval documents for customs clearance.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- China: Hazardous Chemicals Safety Management Regulation (Class 6.1 Toxic Substances); Chinese Pharmacopoeia (CP) 2025 Edition compliance; Pharmaceutical Raw Material Registration Requirements; GMP for Pharmaceutical Raw Materials.
- EU: REACH (Annex XVII compliant, not in SVHC Candidate List); CLP (GHS Classification - Warning); European Pharmacopoeia (EP) 10.0 compliance; EMA Pharmaceutical Raw Material Standards; ADR/RID Class 6.1 Transport Regulations.
- US: TSCA (listed on the TSCA Inventory); DOT Class 6.1 Toxic Material; United States Pharmacopeia (USP) 47 compliance; FDA Pharmaceutical Raw Material Standards for Anti-Addiction Drugs.
- Japan: JP 17 compliance; Japanese Pharmaceutical Affairs Law; Poisonous and Deleterious Substances Control Law.15.2 Additional Regulatory RequirementsProvide English MSDS, COA and toxic chemical transport approval documents for customs clearance; apply for a special hazardous chemical storage license for on-site use; mark **opioid antagonist, oral pharmaceutical raw material, toxic if swallowed** on all product documents; use only for pharmaceutical formulation production by GMP-certified enterprises.

SECTION 16: Other Information

- Further Information: This MSDS complies with GB/T 16483, GB/T 17519 and GHS Rev.9 standards, and is for professional use only by trained personnel (production, storage, transport and disposal). Key characteristic: **Opioid receptor antagonist pharmaceutical raw material, Class 6.1 toxic solid, mild gastrointestinal/nervous system toxicity, low environmental toxicity, stable under recommended storage conditions**.
- Revision Date: 20 FEB 2026