Safety Data Sheet

Material Name: (1S,15S,16R,17R,18S,19E,21E,25E,27E,29E,31E)-33-[(2S,3S,4S,5S,6R)-4-amino-3,5-dihydroxy-6-methyloxan-2-yl]oxy-1,3,4,7,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxabicyclo[33.3.1]nonatriaconta-19,21,25,27,29,31-hexaene-36-carboxylic acid

Catalog Number: 8130032

CAS Number: 1400-61-9

Company Information

Name: SLP Pharma co.

Address: www.slppharma.com

Email: info@slppharma.com

1. Hazards Identification

GHS Classification

Note: This chemical does not meet GHS hazard criteria for 75% (6 of 8) of all reports. Pictograms displayed are for 25% (2 of 8) of reports that indicate hazard statements.

Signal: Danger

GHS Hazard Statements: H300 (12.5%): Fatal if swallowed [Danger Acute toxicity, oral]

GHS Hazard Statements: H335 (12.5%): May cause respiratory irritation [Warning Specific target organ toxicity, single exposure; Respiratory tract irritation]

GHS Hazard Statements: H372 (12.5%): Causes damage to organs through prolonged or repeated exposure [Danger Specific target organ toxicity, repeated exposure]

Precautionary Statement Codes: P260, P261, P264, P270, P271, P301+P316, P304+P340, P319, P321, P330, P403+P233, P405, and P501

Precautionary Statement Codes: (The corresponding statement to each P-code can be found at the GHS Classification page.)

ECHA C&L Notifications Summary: Aggregated GHS information provided per 8 reports by companies from 3 notifications to the ECHA C&L Inventory. Each notification may be associated with multiple companies.

ECHA C&L Notifications Summary: Reported as not meeting GHS hazard criteria per 6 of 8 reports by companies.

ECHA C&L Notifications Summary: There are 2 notifications provided by 2 of 8 reports by companies with hazard statement code(s).

ECHA C&L Notifications Summary: Information may vary between notifications depending on impurities, additives, and other factors. The percentage value in parenthesis indicates the notified classification ratio from companies that provide hazard codes. Only hazard codes with percentage values above 10% are shown. For more detailed information, please visit ECHA C&L website.

Hazard Classes and Categories

N/A: Acute Tox. 1 (12.5%)

N/A: STOT SE 3 (12.5%)

N/A: STOT RE 1 (12.5%)

---

2. Accidental Release Measures

Disposal Methods

N/A: SRP: At the time of review, criteria for land treatment or burial (sanitary landfill) disposal practices are subject to significant revision. Prior to implementing land disposal of waste residue (including waste sludge), consult with environmental regulatory agencies for guidance on acceptable disposal practices.

---

3. Handling and Storage

Storage Conditions

N/A: Nystatin oral suspension and tablets should be stored in tight, light-resistant containers at room temperature (eg, 15-30 °C); exposure of the tablets to temperatures exceeding 40 °C and freezing of the oral suspension should be avoided. Nystatin powder should be stored in tight, light-resistant containers and refrigerated at 2-8 °C.

N/A: Most nystatin preparations for topical application to the skin should be stored at 15-30 °C and protected from freezing. Mycostatin® vaginal tablets should be stored at 2-15 °C. Nystatin lozenges for oral topical administration should be stored in tight, light-resistant containers and refrigerated at 2-8 °C.

---

4. Exposure Control and Personal Protection

Allowable Tolerances

N/A: A tolerance of zero is established for residues of nystatin in or on eggs and the uncooked edible tissues of swine and poultry.

---

5. Regulatory Information

New Zealand EPA Inventory of Chemical Status: Nystatin: Does not have an individual approval but may be used under an appropriate group standard

FDA Requirements

N/A: The Approved Drug Products with Therapeutic Equivalence Evaluations List identifies currently marketed prescription drug products, incl nystatin, approved on the basis of safety and effectiveness by FDA under sections 505 of the Federal Food, Drug, and Cosmetic Act.

N/A: Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses. A number of active ingredients have been present in OTC drug products for various uses, as described below. However, based on evidence currently available, there are inadequate data to establish general recognition of the safety and effectiveness of these ingredients for the specified uses: nystatin is included in topical antifungal drug products.

N/A: A tolerance of zero is established for residues of nystatin in or on eggs and the uncooked edible tissues of swine and poultry.

N/A: New animal drugs for use in animal feeds. Requirement of a medicated feed mill license. Nystatin is included on this list.

N/A: For more FDA Requirements (Complete) data for NYSTATIN (7 total), please visit the HSDB record page.

---

6. Other Safety Information

Chemical Assessment: IMAP assessments - Nystatin: Human health tier I assessment

Chemical Assessment: IMAP assessments - Nystatin: Environment tier I assessment

---