Safety Data Sheet

Material Name: (2R,3S,4R,5R,6R)-5-amino-2-(aminomethyl)-6-[(1R,2R,3S,4R,6S)-4,6-diamino-2-[(2S,3R,4S,5R)-4-[(2R,3R,4R,5S,6S)-3-amino-6-(aminomethyl)-4,5-dihydroxyoxan-2-yl]oxy-3-hydroxy-5-(hydroxymethyl)oxolan-2-yl]oxy-3-hydroxycyclohexyl]oxyoxane-3,4-diol;sulfuric acid

Catalog Number: 8120037

CAS Number: 4146-30-9

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 96.3% (52 of 54) of all reports. Pictograms displayed are for 3.7% (2 of 54) of reports that indicate hazard statements.

GHS Hazard Statements: Not Classified

GHS Hazard Statements: Reported as not meeting GHS hazard criteria by 52 of 54 companies (only 3.7% companies provided GHS information). For more detailed information, please visit ECHA C&L website.

ECHA C&L Notifications Summary: Aggregated GHS information provided per 54 reports by companies from 3 notifications to the ECHA C&L Inventory.

ECHA C&L Notifications Summary: Reported as not meeting GHS hazard criteria per 52 of 54 reports by companies.

ECHA C&L Notifications Summary: There are 2 notifications provided by 2 of 54 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.

Signal: Warning

GHS Hazard Statements: H361 (100%): Suspected of damaging fertility or the unborn child [Warning Reproductive toxicity]

GHS Hazard Statements: H373 (100%): May causes damage to organs through prolonged or repeated exposure [Warning Specific target organ toxicity, repeated exposure]

Precautionary Statement Codes: P203, P260, P280, P318, P319, 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: The GHS information provided by 1 company from 1 notification to the ECHA C&L Inventory.

Signal: Danger

GHS Hazard Statements: H317 (95.7%): May cause an allergic skin reaction [Warning Sensitization, Skin]

GHS Hazard Statements: H334 (40.1%): May cause allergy or asthma symptoms or breathing difficulties if inhaled [Danger Sensitization, respiratory]

GHS Hazard Statements: H335 (46.2%): May cause respiratory irritation [Warning Specific target organ toxicity, single exposure; Respiratory tract irritation]

GHS Hazard Statements: H361 (21.8%): Suspected of damaging fertility or the unborn child [Warning Reproductive toxicity]

GHS Hazard Statements: H412 (10.5%): Harmful to aquatic life with long lasting effects [Hazardous to the aquatic environment, long-term hazard]

Precautionary Statement Codes: P203, P233, P260, P261, P271, P272, P273, P280, P284, P302+P352, P304+P340, P318, P319, P321, P333+P317, P342+P316, P362+P364, P403, 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 372 reports by companies from 27 notifications to the ECHA C&L Inventory. Each notification may be associated with multiple companies.

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.

Signal: Warning

GHS Hazard Statements: H302 (15.4%): Harmful if swallowed [Warning Acute toxicity, oral]

GHS Hazard Statements: H332 (15.4%): Harmful if inhaled [Warning Acute toxicity, inhalation]

GHS Hazard Statements: H361 (84.6%): Suspected of damaging fertility or the unborn child [Warning Reproductive toxicity]

GHS Hazard Statements: H373 (76.9%): May causes damage to organs through prolonged or repeated exposure [Warning Specific target organ toxicity, repeated exposure]

Precautionary Statement Codes: P203, P260, P261, P264, P270, P271, P280, P301+P317, P304+P340, P317, P318, P319, P330, 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 13 reports by companies from 5 notifications to the ECHA C&L Inventory. Each notification may be associated with multiple companies.

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: Not Classified

N/A: Repr. 2 (100%)

N/A: STOT RE 2 (100%)

N/A: Skin Sens. 1 (95.7%)

N/A: Resp. Sens. 1 (40.1%)

N/A: STOT SE 3 (46.2%)

N/A: Repr. 2 (21.8%)

N/A: Aquatic Chronic 3 (10.5%)

N/A: Acute Tox. 4 (15.4%)

N/A: Acute Tox. 4 (15.4%)

N/A: Repr. 2 (84.6%)

N/A: STOT RE 2 (76.9%)

Hazards Summary

N/A: Allergic contact dermatitis reported in healthcare, veterinarian, and feed-mill workers; [Kanerva, p. 1819]

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2. Accidental Release Measures

Disposal Methods

N/A: SRP: Expired or waste pharmaceuticals shall carefully take into consideration applicable DEA, EPA, and FDA regulations. It is not appropriate to dispose by flushing the pharmaceutical down the toilet or discarding to trash. If possible return the pharmaceutical to the manufacturer for proper disposal being careful to properly label and securely package the material. Alternatively, the waste pharmaceutical shall be labeled, securely packaged and transported by a state licensed medical was...

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3. Handling and Storage

Storage Conditions

N/A: Store at 20 deg to 25 °C (68 deg to 77 °F)

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4. Exposure Control and Personal Protection

Acceptable Daily Intakes

N/A: The ADI for total residues of neomycin is 6 micrograms per kilogram of body weight per day.

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5. Regulatory Information

California Safe Cosmetics Program (CSCP) Reportable Ingredient: Hazard Traits - Developmental Toxicity

California Safe Cosmetics Program (CSCP) Reportable Ingredient: Authoritative List - Prop 65

California Safe Cosmetics Program (CSCP) Reportable Ingredient: Report - regardless of intended function of ingredient in the product

New Zealand EPA Inventory of Chemical Status: Neomycin: Does not have an individual approval but may be used as a component in a product covered by a group standard. It is not approved for use as a chemical in its own right.

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

New Zealand EPA Inventory of Chemical Status: Framycetin sulfate: Does not have an individual approval but may be used as a component in a product covered by a group standard. It is not approved for use as a chemical in its own right.

FDA Requirements

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

N/A: The Generic Animal Drug and Patent Restoration act requires that each sponsor of an approved animal drug must submit to the FDA certain information regarding patents held for the animal drug or its method of use. The Act requires that this information, as well as a list of all animal drug products approved for safety and effectiveness, be made available to the public. Neomycin is included on this list.

N/A: The Generic Animal Drug and Patent Restoration act requires that each sponsor of an approved animal drug must submit to the FDA certain information regarding patents held for the animal drug or its method of use. The Act requires that this information, as well as a list of all animal drug products approved for safety and effectiveness, be made available to the public. Neomycin palmitate is included on this list. /Neomycin palmitate/

N/A: The Generic Animal Drug and Patent Restoration act requires that each sponsor of an approved animal drug must submit to the FDA certain information regarding patents held for the animal drug or its method of use. The Act requires that this information, as well as a list of all animal drug products approved for safety and effectiveness, be made available to the public. Neomycin sulfate is included on this list. /Neomycin sulfate/

N/A: For more FDA Requirements (Complete) data for Neomycin (8 total), please visit the HSDB record page.

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6. Other Safety Information

Chemical Assessment: IMAP assessments - Neomycin, sulfate (salt): Human health tier I assessment

Chemical Assessment: IMAP assessments - Neomycin, sulfate (salt): Environment tier I assessment

Special Reports

N/A: WHO; Environmental Health Criteria 119: Principles and Methods for the Assessment of Nephrotoxicity Associated with Exposure to Chemicals (1991)
