

NEOMYCIN SULPHATE

Version No:2.0
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GHS SAFETY DATA SHEET

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

NEOMYCIN SULFATE

OTHER NAMES

C23-H46-N6-O13.xH2SO4, "Biosol Veterinary", Myacine, "Fradiomycin sulfate", Neosulf, "Lidamycin Creme", Neobrethin, Mycifradin-N, Tuttomycin

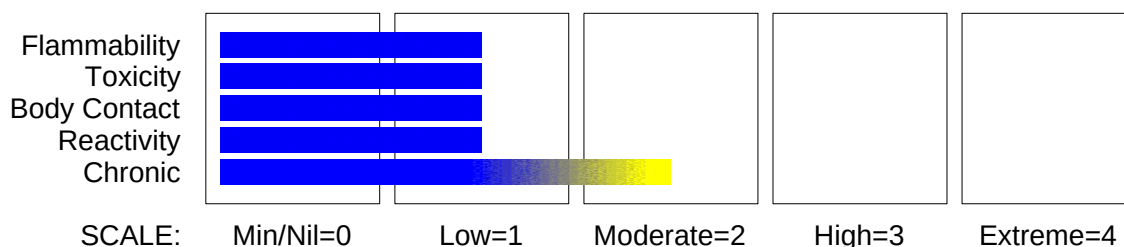
PRODUCT USE

An antibiotic of bacterial origin used in medicine as an antibacterial against many strains of Gram-positive and Gram-negative bacteria.

SUPPLIER

Company: S D FINE- CHEM LIMITED
Address:
315- 317, T.V. INDUSTRIAL ESTATE,
248, WORLI,
MUMBAI- 400030.INDIA.
technical@sdfine.com
Telephone: 91- 22- 24959898
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HAZARD RATINGS



Section 2 - HAZARDS IDENTIFICATION

GHS Classification

Skin Corrosion/Irritation Category 3
Skin Sensitizer Category 1

continued...

NEOMYCIN SULPHATE



EMERGENCY OVERVIEW

HAZARD

WARNING

Determined by using GHS criteria:
H316 H317
Causes mild skin irritation
May cause allergic skin reaction

PRECAUTIONARY STATEMENTS

Prevention

Avoid breathing dust/fume/gas/mist/vapours/spray.
Contaminated clothing should not be allowed out of the workplace.

Response

If skin irritation occurs, seek medical advice/attention.
If skin irritation or rash occurs, seek medical advice/attention.
Wash contaminated clothing before reuse.
IF ON SKIN: Gently wash with plenty of soap and water.
Specific treatment: refer to Label or MSDS.

Disposal

Dispose of contents and container in accordance with relevant legislation.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
neomycin sulfate	1405-10-3	>95

Section 4 - FIRST AID MEASURES

SWALLOWED

For advice, contact a Poisons Information Centre or a doctor.
Poison Information Centres in each State capital city can provide additional assistance.

EYE

If this product comes in contact with the eyes:

- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- If pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

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SKIN

If skin contact occurs:

- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

INHALED

- If dust is inhaled, remove from contaminated area.
- Encourage patient to blow nose to ensure clear passage of breathing.
- If irritation or discomfort persists seek medical attention.

NOTES TO PHYSICIAN

Aminoglycoside antibiotics may be removed by haemodialysis or to a lesser extent by peritoneal dialysis. Calcium salts given intravenously have been used to counter neuromuscular blockade; the effectiveness of neostigmine has been variable.

MARTINDALE: The Extra Pharmacopoeia, 29th Edition.

Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves for fire only.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use fire fighting procedures suitable for surrounding area.
- DO NOT approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

FIRE/EXPLOSION HAZARD

- Solid which exhibits difficult combustion or is difficult to ignite.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.
- Dry dust can also be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
- Build-up of electrostatic charge may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.
- All movable parts coming in contact with this material should have a speed of less than 1-metre/sec.

Combustion products include: carbon monoxide (CO), nitrogen oxides (NO_x) and sulfur oxides (SO_x).

FIRE INCOMPATIBILITY

Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.

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Personal Protective Equipment

Gas tight chemical resistant suit.
Limit exposure duration to 1 BA set 30 mins.

Section 6 - ACCIDENTAL RELEASE MEASURES

EMERGENCY PROCEDURES

MINOR SPILLS

- Remove all ignition sources.
- Clean up all spills immediately.
- Avoid contact with skin and eyes.
- Control personal contact by using protective equipment.
- Use dry clean up procedures and avoid generating dust.
- Place in a suitable labelled container for waste disposal.

MAJOR SPILLS

- Clean up all spills immediately.
- Wear protective clothing, safety glasses, dust mask, gloves.
- Secure load if safe to do so. Bundle/collect recoverable product.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up (consider explosion-proof machines designed to be grounded during storage and use).
- Water may be used to prevent dusting.
- Collect remaining material in containers with covers for disposal.
- Flush spill area with water.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



+: May be stored together
O: May be stored together with specific preventions
X: Must not be stored together

Personal Protective Equipment advice is contained in Section 8 of the MSDS.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid generating and breathing dust
- Avoid contact with skin and eyes.
- Wear nominated personal protective equipment when handling.
- Use in a well-ventilated area.
- Use good occupational work practices.
- Observe manufacturer's storing and handling recommendations.

SUITABLE CONTAINER

Packaging as recommended by manufacturer.
· Check that containers are clearly labelled.

NEOMYCIN SULPHATE

STORAGE INCOMPATIBILITY

Avoid reaction with oxidising agents.
Avoid strong acids, bases.

STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storing and handling recommendations.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- neomycin sulfate: CAS:1405- 10- 3 CAS:124847- 89- 8 CAS:8057- 38- 3 CAS:12710- 33- 7 CAS:37318- 28- 8 CAS:56571- 68- 7 CAS:57866- 39- 4 CAS:63626- 34- 6 CAS:125863- 87- 8 CAS:126663- 40- 9 CAS:126683- 25- 8 CAS:127085- 47- 6 CAS:1339- 25- 9 CAS:8013- 33- 0 CAS:60799- 77- 1

MATERIAL DATA

No exposure limits set by NOHSC or ACGIH.

PERSONAL PROTECTION



EYE

No special equipment needed when handling small quantities of substance.

For bulk handling wear:

Chemical goggles or

Face shield.

HANDS/FEET

Rubber gloves

PVC gloves

Protective shoe covers

Head covering.

OTHER

No special equipment when handling small quantities of substance otherwise:

Coveralls

For Emergencies:

Vinyl suit

Safety shower

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RESPIRATOR

High Efficiency Dust Respirator (P2, P3)

For non-routine emergencies wear full face mask self-contained breathing apparatus.

RESPIRATOR

Protection Factor	Half- Face Respirator	Full- Face Respirator	Powered Air Respirator
10 x ES	P1 Air- line*	- -	PAPR- P1 -
50 x ES	Air- line**	P2	PAPR- P2
100 x ES	-	P3	-
		Air- line*	-
100+ x ES	-	Air- line**	PAPR- P3

* - Negative pressure demand ** - Continuous flow.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required.

For further information consult your Occupational Health and Safety Advisor.

ENGINEERING CONTROLS

Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.

HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.

Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.

When handling quantities up to 500 kilogram, work in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/containment technology.

Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.

Barrier/ containment technology and direct coupling (totally enclosed processes that create a barrier between the equipment and the room) typically use double or split butterfly valves and hybrid unidirectional airflow/ local exhaust ventilation solutions (e.g. powder containment booths). Glove bags, isolator glove box systems are optional. HEPA filtration of exhaust from dry product handling areas is required.

Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:
solvent, vapours, etc. evaporating from tank (in still air)
aerosols, fumes from pouring operations,
intermittent container filling, low speed
conveyer transfers (released at low velocity
into zone of active generation)
direct spray, drum filling, conveyer loading,
crusher dusts, gas discharge (active generation
into zone of rapid air motion)

Air Speed:
0.25- 0.5 m/s (50- 100 f/min.)

0.5- 1 m/s (100- 200 f/min.)

1- 2.5 m/s (200- 500 f/min.)

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Within each range the appropriate value depends on:

Lower end of the range

- 1: Room air currents minimal or favourable to capture
- 2: Contaminants of low toxicity or of nuisance value only.
- 3: Intermittent, low production.
- 4: Large hood or large air mass in motion

Upper end of the range

- 1: Disturbing room air currents
- 2: Contaminants of high toxicity
- 3: High production, heavy use
- 4: Small hood- local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated.

The following protective devices are recommended where exposures exceed the recommended exposure control guidelines by factors of:

- 10; high efficiency particulate (HEPA) filters or cartridges
- 10-25; loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator.
- 25-50; a full face-piece negative pressure respirator with HEPA filters
- 50-100; tight-fitting, full face-piece HEPA PAPR
- 100-1000; a hood-shroud HEPA PAPR or full face-piece supplied air respirator operated in pressure demand or other positive pressure mode.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

White to slightly yellow powder, soluble in water.
Faint earthy odour. Soluble in water 1 in 3; very slightly soluble in alcohol; insoluble in acetone, chloroform and ether. Hygroscopic.
Stable at room temperature. Protect from light.

PHYSICAL PROPERTIES

Solid.
Mixes with water.

Molecular Weight: 614 (neomycin)
Melting Range (°C): Heat labile
Solubility in water (g/L): Miscible
pH (1% solution): 5- 7.5 (3%)
Volatile Component (%vol): 7 approx.
Relative Vapour Density (air=1): Not applicable
Lower Explosive Limit (%): Not available.
Autoignition Temp (°C): Not available.
State: Divided solid

Boiling Range (°C): Not available.
Specific Gravity (water=1): Not available.
pH (as supplied): Not applicable
Vapour Pressure (kPa): Not applicable.
Evaporation Rate: Not applicable
Flash Point (°C): Not applicable
Upper Explosive Limit (%): Not available.
Decomposition Temp (°C): Not available.

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Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
 - Product is considered stable.
 - Hazardous polymerisation will not occur.
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Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

Although ingestion is not thought to produce harmful effects (as classified under EC Directives), the material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.

EYE

Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn). The dust may produce eye discomfort causing transient smarting, blinking.

SKIN

Limited evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis. Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions.

Sensitisation may result in allergic dermatitis responses including rash, itching, hives or swelling of extremities.

The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.

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INHALED

The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

There exists limited evidence that shows that skin contact with the material is capable either of inducing a sensitisation reaction in a significant number of individuals, and/or of producing positive response in experimental animals.

Principal routes of exposure are by accidental skin and eye contact and inhalation of generated dusts.

Prolonged exposure to aminoglycoside antibacterial agents may result in allergic reactions and significant nephrotoxicity. Prolonged oral doses may cause a malabsorption syndrome with steatorrhoea (fatty faeces) and severe diarrhoea.

Hearing loss (especially in the high-tone range) may occur in some patients; vestibular damage may also occur. Ototoxicity of this type has been reported following topical application of the antibiotic to severe burns. Reversible kidney damage may also occur and acute kidney failure has been described. Aminoglycosides accumulate in the renal cortex and produce morphological changes in the proximal tubular cells. Impairment of renal function is usually mild and non-oliguric but acute tubular necrosis and interstitial nephritis have occurred. Aminoglycoside-induced nephrotoxicity and ototoxicity appear to be independent events. Aminoglycosides produce a curare-like neuromuscular blocking action and respiratory depression and muscular paralysis may occur usually after intrapleural and intraperitoneal instillation. The exact mechanism of this blockade appears to be due to both pre- and post- synaptic action of acetylcholine release and uptake. Visual hallucinations, polyneuropathy and encephalopathy have been reported in patients undergoing aminoglycoside therapy. Hypersensitivity reactions are common, especially after local use and anaphylactic reactions may occur. Prolonged use may produce hypo-magnesaemia, hypocalcaemia and hypokalaemia especially in patients with malignant disease receiving antineoplastics. Infrequent effects of therapy include anaemia, purpura (small haemorrhages of the skin and mucous membranes), convulsions, increased serum-aminotransferase levels and increased serum-bilirubin levels.

TOXICITY AND IRRITATION

TOXICITY

Oral (woman) TDLo: 12600 mg/kg/7d

IRRITATION

Skin (human): 6 mg/3d - I - Mild

Section 12 - ECOLOGICAL INFORMATION

No data for neomycin sulfate.

Section 13 - DISPOSAL CONSIDERATIONS

- Recycle wherever possible. Special hazard may exist - specialist advice may be required.
- Consult manufacturer for recycling options.
- Consult State Land Waste Management Authority for disposal.
- Bury or incinerate residue at an approved site.
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.
- Puncture containers to prevent re-use and bury at an authorised landfill.

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Section 14 - TRANSPORTATION INFORMATION

HAZCHEM: None

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS:UN, IATA,
IMDG

Section 15 - REGULATORY INFORMATION

REGULATIONS

No regulations applicable

No data available for neomycin sulfate as CAS: 1405-10-3, CAS: 124847-89-8, CAS: 8057-38-3, CAS: 12710-33-7, CAS: 37318-28-8, CAS: 56571-68-7, CAS: 57866-39-4, CAS: 63626-34-6, CAS: 125863-87-8, CAS: 126663-40-9, CAS: 126683-25-8, CAS: 127085-47-6, CAS: 1339-25-9, CAS: 8013-33-0, CAS: 60799-77-1.

Section 16 - OTHER INFORMATION

INGREDIENTS WITH MULTIPLE CAS NUMBERS

Ingredient Name	CAS
neomycin sulfate	1405- 10- 3, 124847- 89- 8, 8057- 38- 3, 12710- 33- 7, 37318- 28- 8, 56571- 68- 7, 57866- 39- 4, 63626- 34- 6, 125863- 87- 8, 126663- 40- 9, 126683- 25- 8, 127085- 47- 6, 1339- 25- 9, 8013- 33- 0, 60799- 77- 1

The above information is believed to be accurate and represent the best information currently available to us, but does not represent any warranty expressed or implied of the properties of the product. User should make their own investigation to determine the suitability of the information for their particular purpose.

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