

# Tadim, Colistimethate Sodium Powder For Nebuliser Solution

Phebra Pty Ltd

Chemwatch Hazard Alert Code: 2

Chemwatch: 23-3154

Version No: 7.1.1.1

Safety Data Sheet according to WHS and ADG requirements

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S.GHS.AUS.EN

## SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

### Product Identifier

Product name	Tadim, Colistimethate Sodium Powder For Nebuliser Solution
Synonyms	Tadim, Colistimethate Sodium Powder For Nebuliser Solution, 1 Million IU of Powder.
Other means of identification	Not Available

### Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Water for Injection. Used for the treatment of colonization and infections of the lung due to susceptible Pseudomonas aeruginosa in patients with cystic fibrosis. Requires reconstitution with Water for Injections before use.
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### Details of the supplier of the safety data sheet

Registered company name	Phebra
Address	19 Orion Road Lane Cove West NSW 2066 Australia
Telephone	+61 2 9420 9199 1800 720 020
Fax	+61 2 9420 9177
Website	www.phebra.com
Email	info@phebra.com

### Emergency telephone number


Association / Organisation	Not Available
Emergency telephone numbers	+61 401 264 004
Other emergency telephone numbers	N/A

## SECTION 2 HAZARDS IDENTIFICATION

### Classification of the substance or mixture

Poisons Schedule	S4
Classification <sup>[1]</sup>	Acute Toxicity (Oral) Category 4
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HSIS ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI

### Label elements

Hazard pictogram(s)	
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SIGNAL WORD	<b>WARNING</b>
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### Hazard statement(s)

H302	Harmful if swallowed.
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### Precautionary statement(s) Prevention

P264	Wash all exposed external body areas thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.

### Precautionary statement(s) Response

P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P330	Rinse mouth.

### Precautionary statement(s) Storage

## Tadim, Colistimethate Sodium Powder For Nebuliser Solution

Not Applicable

### Precautionary statement(s) Disposal

<b>P501</b>	Dispose of contents/container in accordance with local regulations.
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## SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

### Substances

See section below for composition of Mixtures

### Mixtures

CAS No	%[weight]	Name
8068-28-8	100	<u>colistimethate sodium</u>

## SECTION 4 FIRST AID MEASURES

### Description of first aid measures

<b>Eye Contact</b>	<p>If this product comes in contact with eyes:</p> <ul style="list-style-type: none"> <li>▶ Wash out immediately with water.</li> <li>▶ If irritation continues, seek medical attention.</li> <li>▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
<b>Skin Contact</b>	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> <li>▶ Flush skin and hair with running water (and soap if available).</li> <li>▶ Seek medical attention in event of irritation.</li> </ul>
<b>Inhalation</b>	<ul style="list-style-type: none"> <li>▶ If dust is inhaled, remove from contaminated area.</li> <li>▶ Encourage patient to blow nose to ensure clear passage of breathing.</li> <li>▶ If irritation or discomfort persists seek medical attention.</li> </ul>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>▶ <b>IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.</b></li> <li>▶ For advice, contact a Poisons Information Centre or a doctor.</li> <li>▶ Urgent hospital treatment is likely to be needed.</li> <li>▶ In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.</li> <li>▶ If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. Further action will be the responsibility of the medical specialist.</li> <li>▶ If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS.</li> </ul> <p><b>Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:</b></p> <ul style="list-style-type: none"> <li>▶ <b>INDUCE</b> vomiting with fingers down the back of the throat, <b>ONLY IF CONSCIOUS</b>. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</li> </ul> <p><b>NOTE:</b> Wear a protective glove when inducing vomiting by mechanical means.</p>

### Indication of any immediate medical attention and special treatment needed

As in all cases of suspected poisoning, follow the ABCDEs of emergency medicine (airway, breathing, circulation, disability, exposure), then the ABCDEs of toxicology (antidotes, basics, change absorption, change distribution, change elimination).

For poisons (where specific treatment regime is absent):

#### BASIC TREATMENT

- ▶ Establish a patent airway with suction where necessary.
- ▶ Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- ▶ Administer oxygen by non-rebreather mask at 10 to 15 L/min.
- ▶ Monitor and treat, where necessary, for pulmonary oedema.
- ▶ Monitor and treat, where necessary, for shock.
- ▶ Anticipate seizures.
- ▶ **DO NOT** use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.

#### ADVANCED TREATMENT

- ▶ Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.
- ▶ Positive-pressure ventilation using a bag-valve mask might be of use.
- ▶ Monitor and treat, where necessary, for arrhythmias.
- ▶ Start an IV D5W TKO. If signs of hypovolaemia are present use lactated Ringers solution. Fluid overload might create complications.
- ▶ Drug therapy should be considered for pulmonary oedema.
- ▶ Hypotension with signs of hypovolaemia requires the cautious administration of fluids. Fluid overload might create complications.
- ▶ Treat seizures with diazepam.
- ▶ Proparacaine hydrochloride should be used to assist eye irrigation.

BRONSTEIN, A.C. and CURRANCE, P.L.

EMERGENCY CARE FOR HAZARDOUS MATERIALS EXPOSURE: 2nd Ed. 1994

Treat symptomatically.

## SECTION 5 FIREFIGHTING MEASURES

### Extinguishing media

- ▶ Water spray or fog.
- ▶ Foam.

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## Tadim, Colistimethate Sodium Powder For Nebuliser Solution

- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).
- ▶ Carbon dioxide.

### Special hazards arising from the substrate or mixture

<b>Fire Incompatibility</b>	▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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### Advice for firefighters

<b>Fire Fighting</b>	<ul style="list-style-type: none"> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Use water delivered as a fine spray to control fire and cool adjacent area.</li> <li>▶ <b>DO NOT</b> approach containers suspected to be hot.</li> <li>▶ Cool fire exposed containers with water spray from a protected location.</li> <li>▶ If safe to do so, remove containers from path of fire.</li> <li>▶ Equipment should be thoroughly decontaminated after use.</li> </ul>
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▶ Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.</li> <li>▶ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions).</li> <li>▶ 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 (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.</li> <li>▶ In the same way as gases and vapours, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL) are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC).</li> <li>▶ When processed with flammable liquids/vapors/mists, ignitable (hybrid) mixtures may be formed with combustible dusts. Ignitable mixtures will increase the rate of explosion pressure rise and the Minimum Ignition Energy (the minimum amount of energy required to ignite dust clouds - MIE) will be lower than the pure dust in air mixture. The Lower Explosive Limit (LEL) of the vapour/dust mixture will be lower than the individual LELs for the vapors/mists or dusts.</li> </ul> <p>Combustion products include:</p> <ul style="list-style-type: none"> <li>▶ carbon monoxide (CO)</li> <li>▶ carbon dioxide (CO<sub>2</sub>)</li> <li>▶ nitrogen oxides (NO<sub>x</sub>)</li> <li>▶ sulfur oxides (SO<sub>x</sub>)</li> <li>▶ other pyrolysis products typical of burning organic material.</li> </ul>
<b>HAZCHEM</b>	Not Applicable

## SECTION 6 ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

See section 8

### Environmental precautions

See section 12

### Methods and material for containment and cleaning up

<b>Minor Spills</b>	<ul style="list-style-type: none"> <li>▶ Clean up waste regularly and abnormal spills immediately.</li> <li>▶ Avoid breathing dust and contact with skin and eyes.</li> <li>▶ Wear protective clothing, gloves, safety glasses and dust respirator.</li> <li>▶ Use dry clean up procedures and avoid generating dust.</li> <li>▶ Vacuum up or sweep up. <b>NOTE:</b> Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).</li> <li>▶ Dampen with water to prevent dusting before sweeping.</li> <li>▶ Place in suitable containers for disposal.</li> </ul>
<b>Major Spills</b>	<p>Moderate hazard.</p> <ul style="list-style-type: none"> <li>▶ <b>CAUTION:</b> Advise personnel in area.</li> <li>▶ Alert Emergency Services and tell them location and nature of hazard.</li> <li>▶ Control personal contact by wearing protective clothing.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Recover product wherever possible.</li> <li>▶ <b>IF DRY:</b> Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal.</li> </ul>

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

## SECTION 7 HANDLING AND STORAGE

### Precautions for safe handling

<b>Safe handling</b>	<ul style="list-style-type: none"> <li>▶ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions)</li> <li>▶ Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame.</li> <li>▶ Establish good housekeeping practices.</li> <li>▶ Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.</li> </ul>
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## Tadim, Colistimethate Sodium Powder For Nebuliser Solution

	<ul style="list-style-type: none"> <li>▶ Use continuous suction at points of dust generation to capture and minimise the accumulation of dusts. Particular attention should be given to overhead and hidden horizontal surfaces to minimise the probability of a "secondary" explosion. According to NFPA Standard 654, dust layers 1/32 in.(0.8 mm) thick can be sufficient to warrant immediate cleaning of the area.</li> <li>▶ Do not use air hoses for cleaning.</li> <li>▶ Limit all unnecessary personal contact.</li> <li>▶ Wear protective clothing when risk of exposure occurs.</li> <li>▶ Use in a well-ventilated area.</li> <li>▶ Avoid contact with incompatible materials.</li> <li>▶ When handling, <b>DO NOT eat, drink or smoke.</b></li> <li>▶ Keep containers securely sealed when not in use.</li> <li>▶ Avoid physical damage to containers.</li> <li>▶ Always wash hands with soap and water after handling.</li> </ul>
<b>Other information</b>	<ul style="list-style-type: none"> <li>▶ Store in original containers.</li> <li>▶ Keep containers securely sealed.</li> <li>▶ Store in a cool, dry, well-ventilated area.</li> <li>▶ Store away from incompatible materials and foodstuff containers.</li> <li>▶ Protect containers against physical damage and check regularly for leaks.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> </ul>

### Conditions for safe storage, including any incompatibilities

<b>Suitable container</b>	<ul style="list-style-type: none"> <li>▶ Glass container is suitable for laboratory quantities</li> <li>▶ Polyethylene or polypropylene container.</li> <li>▶ Packing as recommended by manufacturer.</li> <li>▶ Check all containers are clearly labelled and free from leaks.</li> </ul>
<b>Storage incompatibility</b>	<ul style="list-style-type: none"> <li>▶ Avoid strong acids, bases.</li> <li>▶ Avoid reaction with oxidising agents</li> </ul>

## SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control parameters

#### OCCUPATIONAL EXPOSURE LIMITS (OEL)

#### INGREDIENT DATA


Not Available

#### EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
Tadim, Colistimethate Sodium Powder For Nebuliser Solution	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
colistimethate sodium	Not Available	Not Available

### Exposure controls

<b>Appropriate engineering controls</b>	<p>Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.</p> <p>HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.</p> <p>Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.</p> <p>A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg.</p> <p>When handling quantities up to 500 gram 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.</p> <p>Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.</p>
<b>Personal protection</b>	
<b>Eye and face protection</b>	<p>When handling very small quantities of the material eye protection may not be required.</p> <p>For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:</p> <ul style="list-style-type: none"> <li>▶ Chemical goggles.</li> <li>▶ Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.</li> <li>▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available.</li> </ul>
<b>Skin protection</b>	See Hand protection below
<b>Hands/feet protection</b>	<p>The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.</p> <p>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.</p> <p>Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturizer is recommended.</p>

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## Tadim, Colistimethate Sodium Powder For Nebuliser Solution

	<p>Suitability and durability of glove type is dependent on usage.</p> <ul style="list-style-type: none"> <li>▶ Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference.</li> <li>▶ Double gloving should be considered.</li> <li>▶ PVC gloves.</li> <li>▶ Change gloves frequently and when contaminated, punctured or torn.</li> <li>▶ Wash hands immediately after removing gloves.</li> <li>▶ Protective shoe covers. [AS/NZS 2210]</li> <li>▶ Head covering.</li> </ul> <p>Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.</p> <ul style="list-style-type: none"> <li>▶ polychloroprene.</li> <li>▶ nitrile rubber.</li> <li>▶ butyl rubber.</li> <li>▶ fluorocautchouc.</li> <li>▶ polyvinyl chloride.</li> </ul> <p>Gloves should be examined for wear and/ or degradation constantly.</p>
<b>Body protection</b>	See Other protection below
<b>Other protection</b>	<ul style="list-style-type: none"> <li>▶ For quantities up to 500 grams a laboratory coat may be suitable.</li> <li>▶ For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.</li> <li>▶ For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.</li> <li>▶ For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.</li> <li>▶ Eye wash unit.</li> <li>▶ Ensure there is ready access to an emergency shower.</li> <li>▶ For Emergencies: Vinyl suit</li> </ul>
<b>Thermal hazards</b>	Not Available

**Respiratory protection**

Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:001, ANSI Z88 or national equivalent)

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

\* - Negative pressure demand \*\* - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO<sub>2</sub>), G = Agricultural chemicals, K = Ammonia(NH<sub>3</sub>), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- ▶ Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- ▶ The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- ▶ Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- ▶ Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- ▶ Use approved positive flow mask if significant quantities of dust becomes airborne.
- ▶ Try to avoid creating dust conditions.

**SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES****Information on basic physical and chemical properties**

<b>Appearance</b>	White or almost white crystalline powder; soluble in water. The pH of a solution diluted to 125,000IU/ml is 6.5-8.5.		
<b>Physical state</b>	Divided Solid	<b>Relative density (Water = 1)</b>	Not Available
<b>Odour</b>	Not Available	<b>Partition coefficient n-octanol / water</b>	Not Available
<b>Odour threshold</b>	Not Available	<b>Auto-ignition temperature (°C)</b>	Not Available
<b>pH (as supplied)</b>	Not Available	<b>Decomposition temperature</b>	Not Available
<b>Melting point / freezing point (°C)</b>	Not Available	<b>Viscosity (cSt)</b>	Not Applicable
<b>Initial boiling point and boiling range (°C)</b>	Not Applicable	<b>Molecular weight (g/mol)</b>	Not Available
<b>Flash point (°C)</b>	Not Available	<b>Taste</b>	Not Available
<b>Evaporation rate</b>	Not Applicable	<b>Explosive properties</b>	Not Available
<b>Flammability</b>	Not Available	<b>Oxidising properties</b>	Not Available
<b>Upper Explosive Limit (%)</b>	Not Available	<b>Surface Tension (dyn/cm or mN/m)</b>	Not Applicable
<b>Lower Explosive Limit (%)</b>	Not Available	<b>Volatile Component (%vol)</b>	Not Applicable
<b>Vapour pressure (kPa)</b>	Not Applicable	<b>Gas group</b>	Not Available

## Tadim, Colistimethate Sodium Powder For Nebuliser Solution

<b>Solubility in water (g/L)</b>	Miscible	<b>pH as a solution (1%)</b>	Not Available
<b>Vapour density (Air = 1)</b>	Not Applicable	<b>VOC g/L</b>	Not Available

### SECTION 10 STABILITY AND REACTIVITY

<b>Reactivity</b>	See section 7
<b>Chemical stability</b>	<ul style="list-style-type: none"> <li>▶ Unstable in the presence of incompatible materials.</li> <li>▶ Product is considered stable.</li> <li>▶ Hazardous polymerisation will not occur.</li> </ul>
<b>Possibility of hazardous reactions</b>	See section 7
<b>Conditions to avoid</b>	See section 7
<b>Incompatible materials</b>	See section 7
<b>Hazardous decomposition products</b>	See section 5

### SECTION 11 TOXICOLOGICAL INFORMATION

#### Information on toxicological effects

<b>Inhaled</b>	<p>The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models). Nevertheless inhalation of dusts, or fumes, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.</p> <p>Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual. 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.</p> <p>If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.</p>	
<b>Ingestion</b>	<p>Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.</p>	
<b>Skin Contact</b>	<p>Skin contact is not thought to produce harmful health effects (as classified under EC Directives using animal models). Systemic harm, however, has been identified following exposure of animals by at least one other route and the material may still produce health damage following entry through wounds, lesions or abrasions.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.</p>	
<b>Eye</b>	<p>Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.</p>	
<b>Chronic</b>	<p>Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis, caused by particles less than 0.5 micron penetrating and remaining in the lung.</p> <p>Prolonged or repeated use of antibiotics, at therapeutic doses, may produce bacterial resistance for some types of bacteria. Prolonged use may result in the overgrowth of non-susceptible organisms (i.e.</p> <p>Exposure to small quantities may induce hypersensitivity reactions characterised by acute bronchospasm, hives (urticaria), deep dermal wheals (angioneurotic oedema), running nose (rhinitis) and blurred vision. Anaphylactic shock and skin rash (non-thrombocytopenic purpura) may occur.</p>	
<b>Tadim, Colistimethate Sodium Powder For Nebuliser Solution</b>	<b>TOXICITY</b> Not Available	<b>IRRITATION</b> Not Available
<b>colistimethate sodium</b>	<b>TOXICITY</b> Oral (rat) LD50: 5450 mg/kg <sup>[2]</sup>	<b>IRRITATION</b> Not Available

**Legend:** 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. \* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

<b>COLISTIMETHATE SODIUM</b>	<p>The following adverse reactions have been reported with colistimethate sodium (syn: colistin sulfomethate sodium):</p> <p>Gastrointestinal: gastrointestinal upset</p> <p>Nervous System: tingling of extremities and tongue, slurred speech, dizziness, vertigo and paresthesia</p> <p>Integumentary: generalized itching, urticaria and rash</p> <p>Body as a Whole: fever</p> <p>Laboratory Deviations: increased blood urea nitrogen (BUN), elevated creatinine and decreased creatinine clearance</p> <p>Respiratory System: respiratory distress and apnea</p> <p>Renal System: nephrotoxicity and decreased urine output</p> <p>Transient neurological disturbances may occur. These include circumoral paraesthesia or numbness, tingling or formication of the extremities, generalized pruritus, vertigo, dizziness, and slurring of speech. Reduction of dosage may alleviate symptoms. Therapy need not be discontinued, but such patients should be observed with particular care.</p> <p>Respiratory arrest has been reported following intramuscular administration of colistimethate sodium. Impaired renal function increases the possibility of apnea and neuromuscular blockade following administration of colistimethate sodium</p> <p>The main toxicities described with intravenous treatment are nephrotoxicity (damage to the kidneys) and neurotoxicity (damage to the nerves) but this may reflect the very high doses given, which are much higher than the doses currently recommended by any manufacturer and for which no adjustment was made for renal disease. Neuro- and nephrotoxic effects appear to be transient and subside on discontinuation of therapy or reduction in dose .</p> <p>At a dose of 160 mg colistimethate IV every eight hours, very little nephrotoxicity is seen.</p> <p>Intramuscular (child) LDLo: 90 mg/kg/18h-I</p>
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## Tadim, Colistimethate Sodium Powder For Nebuliser Solution

Acute Toxicity	✓	Carcinogenicity	⊘
Skin Irritation/Corrosion	⊘	Reproductivity	⊘
Serious Eye Damage/Irritation	⊘	STOT - Single Exposure	⊘
Respiratory or Skin sensitisation	⊘	STOT - Repeated Exposure	⊘
Mutagenicity	⊘	Aspiration Hazard	⊘

Legend: ✗ – Data available but does not fill the criteria for classification

✓ – Data available to make classification

⊘ – Data Not Available to make classification

## SECTION 12 ECOLOGICAL INFORMATION

## Toxicity

Tadim, Colistimethate Sodium Powder For Nebuliser Solution	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available

colistimethate sodium	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available

## Legend:

Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

**DO NOT** discharge into sewer or waterways.

## Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

## Bioaccumulative potential

Ingredient	Bioaccumulation
	No Data available for all ingredients

## Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

## SECTION 13 DISPOSAL CONSIDERATIONS

## Waste treatment methods

Product / Packaging disposal	<ul style="list-style-type: none"> <li>▶ Containers may still present a chemical hazard/ danger when empty.</li> <li>▶ Return to supplier for reuse/ recycling if possible.</li> </ul> <p>Otherwise:</p> <ul style="list-style-type: none"> <li>▶ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.</li> <li>▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product.</li> </ul> <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> <li>▶ Reduction</li> <li>▶ Reuse</li> <li>▶ Recycling</li> <li>▶ Disposal (if all else fails)</li> </ul> <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. In most instances the supplier of the material should be consulted.</p> <ul style="list-style-type: none"> <li>▶ <b>DO NOT</b> allow wash water from cleaning or process equipment to enter drains.</li> <li>▶ It may be necessary to collect all wash water for treatment before disposal.</li> <li>▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.</li> <li>▶ Where in doubt contact the responsible authority.</li> <li>▶ Recycle wherever possible.</li> <li>▶ Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.</li> <li>▶ Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or Incineration in a licensed apparatus (after admixture with suitable combustible material)</li> <li>▶ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.</li> </ul>
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## SECTION 14 TRANSPORT INFORMATION

**Labels Required**

Marine Pollutant	NO
HAZCHEM	Not Applicable

**Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

**Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

**Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

**Transport in bulk according to Annex II of MARPOL and the IBC code**

Not Applicable

**SECTION 15 REGULATORY INFORMATION****Safety, health and environmental regulations / legislation specific for the substance or mixture****COLISTIMETHATE SODIUM(8068-28-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS**

Australia Inventory of Chemical Substances (AICS)

National Inventory	Status
Australia - AICS	Y
Canada - DSL	N (colistimethate sodium)
Canada - NDSL	Y
China - IECSC	N (colistimethate sodium)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	Y
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	N (colistimethate sodium)
USA - TSCA	Y
<b>Legend:</b>	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

**SECTION 16 OTHER INFORMATION****Other information****Ingredients with multiple cas numbers**

Name	CAS No
colistimethate sodium	8068-28-8, 82497-00-5

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

**Definitions and abbreviations**

PC – TWA: Permissible Concentration-Time Weighted Average  
 PC – STEL: Permissible Concentration-Short Term Exposure Limit  
 IARC: International Agency for Research on Cancer  
 ACGIH: American Conference of Governmental Industrial Hygienists  
 STEL: Short Term Exposure Limit  
 TEEL: Temporary Emergency Exposure Limit,  
 IDLH: Immediately Dangerous to Life or Health Concentrations  
 OSF: Odour Safety Factor  
 NOAEL: No Observed Adverse Effect Level  
 LOAEL: Lowest Observed Adverse Effect Level  
 TLV: Threshold Limit Value  
 LOD: Limit Of Detection  
 OTV: Odour Threshold Value  
 BCF: BioConcentration Factors  
 BEI: Biological Exposure Index

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