



# NORTH CHINA PHARMACEUTICAL HUASHENG CO., LTD.

No.8 Yangzi Rd., Shijiazhuang Economic & Technical Development Zone, Hebei, China  
Fax: 0086-311- 83090280

Homepage: <http://www.ncpchs.com>  
E-mail: [qa@ncpchs.com](mailto:qa@ncpchs.com)  
Tel: 0086-311-83090294

## SAFETY DATA SHEET

According to Regulation (EC) No. 1272/2008

Version 1.1

Print Date January 18, 2019

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

#### 1.1 Product identifiers

Product name: Cyclosporine  
Brand: NCPC  
CAS-No. : 59865-13-3

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

Identified uses: Manufacture of substances


#### 1.3 Details of the supplier of the safety data sheet

Company: North China Pharmaceutical Huasheng Co., Ltd.  
No. 8 Yangzi Road, Shijiazhuang Economic & Technical Development Zone, Hebei, China  
Telephone: 0086-311-83090294  
Fax: 0086-311-83090280  
E-mail address: [qa@ncpchs.com](mailto:qa@ncpchs.com)

#### 1.4 Emergency telephone number

Emergency Phone #: 0086-311-83090284

### 2. HAZARDS IDENTIFICATION

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 4
	Carcinogenicity	Category 1A
	Specific target organ toxicity, repeated exposure	Category 1 (immune system, kidney)
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		

<b>Signal word</b>	Danger
<b>Hazard statement</b>	Harmful if swallowed. May cause cancer. Causes damage to organs (immune system, kidney) through prolonged or repeated exposure.
<b>Precautionary statement</b>	
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety



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<b>Response</b>	precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If exposed or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell.
<b>Storage</b>	Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known
<b>Supplemental information</b>	Potent pharmacologically active material.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance			
Chemical name	Common name and synonyms	CAS number	%
Cyclosporine	Ciclosporin	59865-13-3	100

### 4. FIRST AID MEASURES

<b>Inhalation</b>	Move to fresh air. If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists. Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell.
<b>Ingestion</b>	
<b>Most important symptoms/effects, acute and delayed</b>	Immunosuppression. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically. Overdose treatment should be symptomatic and supportive and may include the following: Support respiratory and cardiovascular function. Induced vomiting is not recommended. Consider activated charcoal or gastric lavage after a potentially toxic ingestion. Control seizures with a benzodiazepine; if seizures persist or recur, administer phenobarbital. Correct magnesium deficits.



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## General information

Calcium channel blockers may be the preferred agent for treatment of cyclosporine-induced hypertension, as they may prevent nephrotoxicity. Low-dose dopamine is effective for treatment of nephrotoxicity. Azithromycin or metronidazole has been used to treat gingival hyperplasia. Monitor cyclosporine plasma levels, kidney and liver function, and serum electrolytes. Hemodialysis does not appear to be effective in increasing clearance of cyclosporine. [Poisindex 2005; Poisoning & Toxicity 2005]

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

## 5. FIRE-FIGHTING MEASURES

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO <sub>2</sub> . Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire fighting equipment/instructions</b>	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. ACCIDENTAL RELEASE MEASURES

<b>Personal precautions, protective equipment and emergency procedures</b>	For personal protection, see section 8 of the SDS. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear
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<b>Methods and materials for containment and cleaning up</b>	appropriate personal protective equipment. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. HANDLING AND STORAGE

<b>Precautions for safe handling</b>	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
<b>Skin protection</b>	
<b>Hand protection</b>	Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an



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<b>Other</b>	organic solvent, wear gloves that provide protection against the solvent. Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.
<b>Respiratory protection</b>	Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Chose respiratory protection appropriate to the task and the level of existing engineering controls.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	Appearance descriptions are general information and not specific to any USP lot.
<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Color</b>	White.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	298.4 - 303.8 °F (148 - 151 °C)
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit – lower (%)</b>	Not available.
<b>Flammability limit – upper (%)</b>	Not available.



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<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	< 0.0000001 kPa at 25 °C
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Practically insoluble.
<b>Solubility (other)</b>	Acetone: Soluble. Alcohol: Soluble. Chloroform: Soluble. Ether: Soluble.
<b>Partition coefficient (n-octanol/water)</b>	2.92
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Cyclic polypeptide.
<b>Molecular formula</b>	C <sub>62</sub> H <sub>111</sub> N <sub>11</sub> O <sub>12</sub>
<b>Molecular weight</b>	1202.6

## 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Oxidizing agents.
<b>Hazardous decomposition products</b>	NO <sub>x</sub> . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure



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<b>Inhalation</b>	Knowledge about health hazard is incomplete.
<b>Skin contact</b>	Knowledge about health hazard is incomplete.
<b>Eye contact</b>	Knowledge about health hazard is incomplete.
<b>Ingestion</b>	Harmful if swallowed. Based on information from therapeutic use, this material may cause: Immunosuppression. Kidney damage.
<b>Symptoms related to the physical, chemical, and toxicological characteristics</b>	Bleeding, tender, or swollen gums. Increased hair growth. Trembling. Seizures. Tremor. Sweating. Headache. Fever. Chills. Lethargy. Leg cramps. Gastrointestinal disturbances. Frequent, painful, or difficult urination.
<b>Information on toxicological effects</b>	
<b>Acute toxicity</b>	Harmful if swallowed.
<b>Skin corrosion/irritation</b>	Knowledge about health hazard is incomplete.
<b>Serious eye damage/eye irritation</b>	Knowledge about health hazard is incomplete.
<b>Respiratory or skin sensitization</b>	
<b>Respiratory sensitization</b>	Knowledge about health hazard is incomplete.
<b>Skin sensitization</b>	Knowledge about health hazard is incomplete.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.

## Mutagenicity

Ames test (Salmonella typhimurium)

Result: Negative.

Dominant lethal test

Result: Negative.

Species: Mouse

In vitro sister chromatid exchange (human lymphocytes)

Result: Positive.

Mutagenicity, Chromosomal aberrations in bone marrow of Chinese hamsters

Result: Negative.

Mutagenicity, Gene mutations in Chinese hamster cells

Result: Negative.

**Carcinogenicity** May cause cancer. The risk of these malignancies is related to the intensity and duration of immunosuppression.

## IARC Monographs. Overall Evaluation of Carcinogenicity

Cyclosporine (CAS 59865-13-3)

1 Carcinogenic to humans.

## OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.



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## US. National Toxicology Program (NTP) Report on Carcinogens

	Cyclosporine (CAS 59865-13-3)	Known To Be Human Carcinogen.
<b>Reproductive toxicity</b>	Knowledge about health hazard is incomplete.	
<b>Reproductivity</b>	100 mg/kg/day Reproductivity, Increased prenatal and postnatal mortality and reduced fetal weight. Result: Positive. Species: Rabbit 30 mg/kg Reproductivity, No increase in malformations was found at maternally toxic doses, but fetal death and growth retardation occurred. Result: Negative. Species: Rat < 17 mg/kg/day Reproductivity, No embryolethal or teratogenic effects. Result: Positive. Species: Rat	
<b>Specific target organ toxicity-single exposure</b>	Knowledge about health hazard is incomplete.	
<b>Specific target organ toxicity-repeated exposure</b>	Causes damages to organs (immune system kidney) through prolonged or repeated exposure.	
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.	
<b>Further information</b>	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.	

## 12. ECOLOGICAL INFORMATION

<b>Ecotoxicity</b>	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	
<b>Octanol/water partition coefficient log Kow</b>	2.92
<b>Mobility in soil</b>	No data available.
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. DISPOSAL CONSIDERATIONS





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<b>Disposal instructions</b>	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. TRANSPORT INFORMATION

### DOT

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

### General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment

## 15. REGULATORY INFORMATION

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### SARA 304 Emergency release notification

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.



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## Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories**  
Immediate Hazard - Yes  
Delayed Hazard - Yes  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

### SARA 302 Extremely hazardous substance

Not listed

**SARA 311/312** Yes

### Hazardous chemical

**SARA 313 (TRI reporting)**

Not regulated.

### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

#### Safe Drinking Water Act (SDWA)

Not regulated.

### US state regulations

#### US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

Cyclosporine (CAS 59865-13-3) Listed: January 1, 1992

### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes



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Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s)

### **16. OTHER INFORMATION**

#### **Further information**

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.