

Creation Date 18-Sep-2012

Revision Date 20-Nov-2012

Revision Number 2

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

### Product Identifier

Product Description:

Prednisolone

Cat No.

449470000; 449470010; 449470050; 449470250

Synonyms

1-Dehydrohydrocortisone

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

Recommended Use

Laboratory chemicals

Uses advised against

No Information available

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

#### Company

Acros Organics BVBA  
Janssen Pharmaceuticaaan 3a  
2440 Geel, Belgium

E-mail address

begel.sdsdesk@thermofisher.com

### Emergency Telephone Number

For information in the US, call: 001-800-ACROS-01

For information in Europe, call: +32 14 57 52 11

Emergency Number, Europe: +32 14 57 52 99

Emergency Number, US: 001-201-796-7100

CHEMTREC Phone Number, US: 001-800-424-9300

CHEMTREC Phone Number, Europe: 001-703-527-3887

## SECTION 2. HAZARDS IDENTIFICATION

### Classification of the substance or mixture

REGULATION (EC) No 1272/2008

Reproductive Toxicity

Category 1B

### Classification according to EU Directives 67/548/EEC or 1999/45/EC

For the full text of the R-phrases and H-Statements mentioned in this Section, see Section 16

Symbol(s)

T - Toxic

R-phrases(s)

R61 - May cause harm to the unborn child

### Label Elements

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## SECTION 2. HAZARDS IDENTIFICATION



**Signal Word**

**Danger**

**Hazard Statements**

H360D - May damage the unborn child

**Precautionary Statements - EU (§28, 1272/2008)**

P281 - Use personal protective equipment as required

P202 - Do not handle until all safety precautions have been read and understood

**Other Hazards**

No information available.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	EC-No.	Weight %	CAS-No	67/548/EEC Classification	CLP Classification - Regulation (EC) No 1272/2008	REACH No.
Prednisolone 50-24-8	EEC No. 200-021-7	>95	50-24-8	Repr. Cat. 2; R61	Repr. 1B (H360D)	-

**For the full text of the R-phrases and H-Statements mentioned in this Section, see Section 16**

## SECTION 4. FIRST AID MEASURES

**Description of first aid measures**

**Eye Contact**

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.

**Skin Contact**

Wash off immediately with plenty of water for at least 15 minutes. Get medical attention immediately if symptoms occur.

**Ingestion**

Do not induce vomiting. Call a physician or Poison Control Center immediately.

**Inhalation**

Move to fresh air. If breathing is difficult, give oxygen. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with a respiratory medical device. Get medical attention immediately if symptoms occur.

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**Notes to Physician**

Treat symptomatically

**SECTION 5. FIRE-FIGHTING MEASURES****Extinguishing media****Suitable Extinguishing Media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**Extinguishing media which must not be used for safety reasons**

No information available.

**Special hazards arising from the substance or mixture**

Thermal decomposition can lead to release of irritating gases and vapors

**Advice for fire-fighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Thermal decomposition can lead to release of irritating gases and vapors.

**SECTION 6. ACCIDENTAL RELEASE MEASURES****Personal precautions, protective equipment and emergency procedures**

Ensure adequate ventilation. Use personal protective equipment. Avoid dust formation.

**Environmental precautions**

Should not be released into the environment.

**Methods and material for containment and cleaning up**

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation.

**SECTION 7. HANDLING AND STORAGE****Precautions for Safe Handling**

Wear personal protective equipment. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not breathe dust.

**Conditions for safe storage, including any incompatibilities**

Keep containers tightly closed in a dry, cool and well-ventilated place.

**Specific End Uses**

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## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### Exposure limits

##### Component

Prednisolone

Russia - TWA	Slovak Republic	Slovenia	Sweden	Turkey
Skin notation MAC: 0.01 mg/m <sup>3</sup>				

#### Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

#### Derived No Effect Level (DNEL)

No information available.

#### Predicted No Effect Concentration (PNEC)

No information available.

### Exposure controls

#### Engineering Measures

Ensure adequate ventilation, especially in confined areas Ensure that eyewash stations and safety showers are close to the workstation location

#### Personal protective equipment

##### Eye Protection

Safety glasses with side-shields

##### Hand Protection

Protective gloves

##### Skin and body protection

Wear appropriate protective gloves and clothing to prevent skin exposure

##### Respiratory Protection

Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced

#### Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice

#### Environmental exposure controls

No information available.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Physical State

Solid

#### Appearance

White

#### odor

odorless

#### pH

No information available.

#### Boiling Point/Range

No information available.

#### Melting Point/Range

240°C / 464°F

#### Flash Point

No information available.

#### Autoignition Temperature

No information available.

#### Water Solubility

Slightly soluble

## SECTION 10. STABILITY AND REACTIVITY

### Reactivity

### Chemical Stability



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Stable under normal conditions.

**Possibility of Hazardous Reactions****Hazardous Polymerization  
Hazardous Reactions .**

Hazardous polymerization does not occur.  
None under normal processing..

**Conditions to Avoid**

Avoid dust formation, Incompatible products, Excess heat.

**Incompatible Materials**

Acids, Bases, Strong oxidizing agents.

**Hazardous Decomposition Products**

Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>).

**SECTION 11. TOXICOLOGICAL INFORMATION****Information on Toxicological Effects****Acute Toxicity****Component Information****Component  
Prednisolone**

LD50 Oral	LD50 Dermal	LC50 Inhalation (Dust)
1680 mg/kg (Mouse) 2848 mg/kg (Mouse) 3857 mg/kg (Rat)		

**Chronic Toxicity****Carcinogenicity**

There are no known carcinogenic chemicals in this product

**Sensitization**

No information available.

**Mutagenic Effects**

No information available

**Reproductive Effects**

May cause harm to the unborn child

**Developmental Effects**

No information available.

**Target Organs**

None known.

**Other Adverse Effects**

The toxicological properties have not been fully investigated. See actual entry in RTECS for complete information

**Endocrine Disruptor Information**

None known

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## SECTION 12. ECOLOGICAL INFORMATION

### Toxicity

#### Ecotoxicity effects

Do not empty into drains

### Persistence and degradability

No information available

### Bioaccumulative potential

No information available.

### Mobility in soil

No information available.

### Results of PBT and vPvB assessment

### Other adverse effects

No information available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Waste treatment methods

#### Waste from Residues / Unused Products

Dispose of in accordance with local regulations

#### Contaminated Packaging

Empty containers should be taken to local recyclers for disposal

## SECTION 14. TRANSPORT INFORMATION

### IMDG/IMO

Not regulated

### ADR

Not regulated

### IATA

Not regulated

## SECTION 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

### International Inventories

Component	EINECS	ELINCS	NLP	TSCA	DSL	NDSL	PICCS	ENCS	CHINA	AICS	KECL
Prednisolone	200-021-7	-		X	X	-	X	-	X	X	X

**Prednisolone****Revision Date 20-Nov-2012****Legend****TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List**PICCS** - Philippines Inventory of Chemicals and Chemical Substances**ENCS** - Japan Existing and New Chemical Substances**CHINA** - China Inventory of Existing Chemical Substances**AICS** - Inventory of Chemical Substances**KECL** - Existing and Evaluated Chemical Substances**Chemical Safety Assessment****SECTION 16. OTHER INFORMATION****Full text of R-phrases referred to under sections 2 and 3**

R61 - May cause harm to the unborn child

**Revision Date** 20-Nov-2012**Revision Summary****Reason for revision** (M)SDS sections updated, 2, 3, 11, 16.**This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006****Disclaimer**

The information provided on this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

**End of Safety Data Sheet**