

16 α -HYDROXPREDNISOLONE

MATERIAL SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006
Revision: 00 – Revision date: 26.08.2011

SECTION 1

IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

1.1 Product identifier

Product name: 16 α -hydroxyprednisolone
CAS Number: 13951-70-7
EC Number: 237-731-1
INDEX Number: No data available
Registration Number: No data available
Molecular Weight: 376.44
Molecular Formula: C₂₁H₂₈O₆

1.2 Relevant identified uses of the substance

Common use: Chemical intermediate for the preparation of pharmaceutical products

1.3 Details of the supplier of the safety data sheet

Company name: STERLING S.r.l
Address: Via della Carboneria, 30
06073 Solomeo di Corciano (PG) – Italy

E-mail address: spatriarca@sterling.it
Telephone: 075/5294001
Fax: 075/5294000

1.4 Emergency telephone number

Italy: +39 02 66101029 (Poison Information Centre Niguarda Ca' Granda – Milano)
Foreign countries: Contact the closest Poisons Information Centre.

SECTION 2

HAZARDS IDENTIFICATION

2.1 Classification of the substance

2.1.1 Classification according to Regulation (EC) N. 1272/2008 (CLP/GHS)

Not hazardous substance according to Regulation (EC) N. 1272/2008 (CLP/GHS)

2.1.2 Classification of the substance according to Directive 67/548/EEC

Not hazardous substance according to Directive 67/548/EEC

Full text of R and H-phrases: see section 16

2.2 Label elements

Not applicable

2.3 Other hazards

No data available

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance

Product name :	16 α -hydroxyprednisolone
Chemical name :	11 β ,16 α ,17,21-tetrahydroxypregna-1,4 diene-3,20-dione
Molecular Weight :	376.44
Molecular formula :	C ₂₁ H ₂₈ O ₆
CAS No. :	13951-70-7
EC No. :	237-731-1
Concentration :	>98 %

3.2 Mixture

Not applicable

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

General advice:	In case of contact with the substances immediately change contaminated clothing.
Ingestion:	In case of ingestion, if conscious, rinse mouth with water. If the casualty is unconscious, place in the recovery position.
Inhalation:	Remove casualty to fresh air as quickly as possible. Keep warm and at rest. If breathing is difficult, give oxygen if possible, or assisted ventilation.
Skin contact:	In case of skin contact with powders or solutions immediately rinse affected area with copious amount of water and then wash with soap and water. Remove contaminated clothing and shoes.
Eye contact:	Irrigate eyes with copious amounts of water for at least 10-15 min, holding eyelids apart to ensure thorough rinsing.

4.2 Most important symptoms and effects, both acute and delayed

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

4.3 Indication of any immediate medical attention and special treatment needed

Immediately call a POISON CENTER or doctor/physician for all cases of contact. Induce vomiting only if indicated by your doctor.

SECTION 5 FIRE-FIGHTING MEASURES

5.1 *Extinguishing media*

Suitable extinguishing media: Carbon Dioxide (CO₂), foam, dry chemical powder, water spray, and water jet, unless otherwise stated.

Unsuitable extinguishing media: None

5.2 *Special hazards arising from the substance*

Specific hazard(s): The product is combustible and, like the dust in general, can make an explosive mixture with air. When heated or in the event of a fire, vapors may be harmful to health: carbon oxides (COx).

5.3 *Advice for firefighters*

Special fire fighting procedures: Protective Equipment: Wear full fire resistant self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 *Personal precautions, protective equipment and emergency procedures*

Procedure(s) of personal precaution(s): Keep non-involved personnel away from the area of spillage.
Avoid the generation and spreading of dust.
Ventilate area.
Eliminate sources of ignition.
Avoid contact with skin, eyes and inhalation of dust.
Avoid contact with eyes and skin.
See also sections 8 (protective equipment)

6.2 *Environmental precautions*

Prevent product from entering sewers, rivers or other bodies of water.
If required, notify relevant authorities according to all applicable regulations.

6.3 *Methods and material for containment and cleaning up*

Collect free product with suitable mechanical means. Avoid creating dust by spraying the product with water, if there is no contraindication. Ventilate area and wash spill site after material pickup is complete. Transfer the gathered product and the washings to suitable tanks or containers and store/dispose according to relevant regulations.

6.4 *Reference to other sections*

See also sections 8 (protective equipment) and 13 (disposal).

SECTION 7

HANDLING AND STORAGE

7.1 *Precautions for safe handling*

Use of personal protective equipment must be consistent with good occupational hygiene practices.

Avoid contact with skin, eyes and clothing.

Avoid prolonged or repeated exposure.

Do not breathe dust, mist, and/or vapors associated with the material.

Do not reuse contaminated clothing.

Do not eat, drink or smoke when using this product.

Wash hands thoroughly with soap and water before meals and after work shift.

7.2 *Conditions for safe storage*

Store away from all heat sources, including direct sunlight. Open flame. Sources of ignition. Sparks. Incompatible materials.

SECTION 8

EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 *Control Parameter*

Exposure limit values (ACGIH 2010):

- TLV TWA: No data available

- TLV STEL: No data available

Monitoring procedures: Refer to Dir. 96/82/EC.

8.2 *Exposure Controls*

8.2.1 *Appropriate engineering controls*

When feasible, use closed loop systems or with local exhaust. When inside buildings or confined spaces, ensure adequate ventilation.

The lyophilized powder should be used in biological safety cabinets or in systems with equivalent content.

Provide eyewash fountains at the workplace.

8.2.2 *Personal protection measures, such as personal protective equipment*

Personal Protective Equipment: The personal protective equipment should be chosen in the configuration according to the concentration and quantity of hazardous substances specifically for the workplace.

- a) *Eye / Face Protection:* Wear safety goggles (EN 166).

- b) *Skin and body Protection:* Protective clothing global. Use rubber or synthetic gloves (EN 374). For handling solutions, ensure that the glove material is protective against the solvent being used.

- c) *Respiratory Protection:* Avoid inhalation of dust, respiratory protection: dust mask with filter type P3 (EN 143).
Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

- d) *Heat Dangers:* The product is not handled hot.

8.2.3 Environmental Exposure Controls

Use according to good manufacturing practices avoiding litter.

Take all the technical precautions necessary to prevent the spread of the product into the surrounding.



SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance	White to Off-White Solid
b) Odor	-
c) Odor threshold	No data available
d) pH	No data available
e) Melting point/freezing point	235 - 238 °C
f) Initial boiling point and boiling range	591.514 °C @ 760 mmHg (estimated)
g) Flash point	Not applicable
h) Evaporation rate	No data available
i) Flammability (solid, gas)	No data available
j) Upper/lower flammability or explosive limits	No data available
k) Vapor pressure	No data available
l) Vapor density	No data available
m) Relative density	No data available
n) Solubility(ies)	Freely soluble in dimethylsulfoxide.
o) Partition coefficient: n-octanol/water	Log Kow = 1.06 (estimated)
p) Auto-ignition temperature	No data available
q) Decomposition temperature	No data available
r) Viscosity	Not applicable
s) Explosive properties	No data available
t) Oxidising properties	No data available

9.2 Other information

No data available

SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

The substance does not present additional dangers of reactivity than those reported in the next subtitles.

10.2 Chemical stability

Store away from all heat sources, including direct sunlight, open flame, sources of ignition and sparks.

10.3 Possibility of hazardous reactions

Product does not polymerise.

10.4 Conditions to avoid

Heat. Static Electricity.

10.5 Incompatible materials

Store separately from oxidizing agents.

10.6 Hazardous decomposition products

Carbon oxides (CO_x).

SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Signs and Symptoms of Exposure: To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

CLASS OF RELEVANT RISK FOR SUBSTANCE:

a) Acute toxicity:	Not reported evidence concerning this effect
b) Skin corrosion / irritation:	Not reported evidence concerning this effect
c) Serious eye damage / serious eye irritation:	Not reported evidence concerning this effect
d) Respiratory / skin sensitization:	Not reported evidence concerning this effect
e) Germ cell mutagenicity:	Not reported evidence concerning this effect
f) Carcinogenicity:	Not reported evidence concerning this effect
g) Reproductive toxicity:	Not reported evidence concerning this effect
h) Specific target organ toxicity (STOT)-Single exposure-	Not reported evidence concerning this effect
h) Specific target organ toxicity (STOT)-Repeated exposure-	Not reported evidence concerning this effect
j) Aspiration hazard	Not applicable
Other information	

SECTION 12 ECOLOGICAL INFORMATION

Ecological Information: Use according to good manufacturing practices, avoid dispersion into the environment. Notify relevant authorities according to all applicable regulations if the product can reach waterways or sewers or contaminate soil or vegetation.

12.1 Toxicity

Not reported evidence concerning this effect

12.2 Persistence and degradability

Not reported evidence concerning this outcome

12.3 Bioaccumulative potential

Not reported evidence concerning this outcome

12.4 Mobility in soil

Not reported evidence concerning this outcome

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Prevent environmental discharge.
Dispose of waste or used sacks/containers according to local regulations.

SECTION 14 TRANSPORT INFORMATION

The substance is not considered dangerous within the meaning of the regulations governing the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and by air (IATA/ICAO).

SECTION 15 REGULATORY INFORMATION

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

Authorizations according to REACH Regulation:	the substance is not subjected
Restrictions according to REACH Regulation:	the substance is not subjected
Other UE:	The substance is not dangerous under the Seveso Regulation (Dir. 96/82/CE and f.a.)

15.2 Chemical Safety Assessment

A chemical safety assessment has not been carried out for this product.

SECTION 16**OTHER INFORMATION**

<i>List of relevant phrases</i>	Classification according to Regulation (EC) No 1272/2008 (CLP/GHS) as amended - Classification according to European Directive 67/548/CEE as amended -
<i>Guidelines for the formation</i>	Workers potentially exposed to this substance must be trained adequately on the basis of the contents of this MSDS.
<i>More information</i>	No data available
<i>Bibliography</i>	NCBI – PUBCHEM Compound Database BANCA DATI SOSTANZE CHIMICHE - ICARO S.R.L. - CORTONA (AR)
<i>Update Reason</i>	Update according to Annex I of Regulation UE453/2010 which amended Annex II of EC Regulation 1907/2006 (REACH).

Revision: 00 – Revision date: 26.08.2011

The contained information is based upon our current understanding. It is applicable only to the indicated product and does not constitute any guarantee of the properties of the product. The user is responsible to ensure his or her own fitness and completeness of such information in relation to the specific use. The contained information is intended for the use of the product exclusively by appropriately qualified personnel. STERLING S.r.l. shall not be held liable for any damages caused from handling or from contact with the substance.

STERLING S.r.l.