

SAFETY DATA SHEETS

This SDS packet was issued with item:

078940489

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078946074

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Prednisolone acetate
CAS No. 52-21-1

Other means of identification

Synonyms RU357, Detahydrocortisone acetate, Prednisolone 21-acetate, Active ingredient of HYDROCORTANCYL

Other Information

- Substance pharmacologically active.
- Anti-inflammatory glucocorticoid.

Recommended use of the chemical and restrictions on use

Recommended Use Active ingredient for medical use.
Active ingredient for veterinary use.

Uses advised against Not available.

Details of the supplier of the safety data sheet

Supplier Address
Sanofi-Aventis U.S. LLC,
A SANOFI COMPANY,
55 Corporate Drive,
Bridgewater, NJ 08807

Emergency telephone number

Company Phone Number US Customer Service: (800) 207-8049

24 Hour Emergency Phone Number Chemtrec (US): 1-800-424-9300
Chemtrec (Outside US): +1 (703) 527-3887
Sanofi-Aventis US: 908-981-5550

2. HAZARDS IDENTIFICATION

Classification

Health Hazards
Classified.

Reproductive toxicity	Category 2
Specific target organ toxicity (repeated exposure)	Category 2

Physical hazards
Not classified.

OSHA Regulatory Status

This product is considered hazardous by the 2012 OSHA Hazard Communication Standard/Globally Harmonized System of Classification and Labelling of Chemicals (GHS); (29 CFR 1910.1200; Revision 3).

Label elements**Emergency Overview****Warning****Hazard statements**

Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure.
May form combustible dust concentrations in the air.

**Appearance** Not available**Physical state** Solid**Odor** Odorless**Precautionary Statements - Prevention**

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves, protective clothing and eye protection.
Do not breathe dust.

Precautionary Statements - Response

If exposed or concerned or if you feel unwell: Get medical attention.

Precautionary Statements - Storage

Store locked up.

Precautionary Statements - Disposal

Dispose of contents and container in accordance with applicable regional, national and local laws and regulations.

Hazards not otherwise classified (HNOC)

Combustible dust.

3. COMPOSITION/INFORMATION ON INGREDIENTS**Formula** $C_{23}H_{30}O_6$

Chemical Name	CAS No.	Weight-%
Prednisolone acetate	52-21-1	100

4. FIRST AID MEASURES**First aid measures****General advice**

Take the victim out of the contaminated area. Remove contaminated clothing immediately and dispose of safely.

Eye contact

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

Skin Contact

Rinse immediately with plenty of water for at least 15 minutes. Seek medical advice.

Inhalation	Move to fresh air. Make the victim blow his nose. Seek medical advice.
Ingestion	Do not induce vomiting. Make the victim rinse his mouth with water. Seek medical advice immediately.
Self-protection of the first aider	Do not use mouth-to-mouth methods if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms	No acute effects.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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5. FIRE-FIGHTING MEASURES**Suitable extinguishing media**

All means. (E.g. water, carbon dioxide, dry chemical extinguisher). Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media	Strong water jet.
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Specific hazards arising from the chemical

In case of fire, the product may emit toxic and/or irritating fumes. Thermal decomposition/oxidation hazards may include:

- Carbon monoxide (CO)
- Carbon dioxide (CO₂)

Hazardous combustion products	Not available.
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Explosion data

Sensitivity to Mechanical Impact	Not available.
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Sensitivity to Static Discharge	Combustible dust. (See Section 9).
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Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

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

Personal precautions	Particle full-face respirator or powered-air purifying respirator. Suitable gloves. Dedicated work clothes.
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Environmental precautions

Environmental precautions	Avoid any spreading of the product.
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Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
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Methods for cleaning up	Pick up and transfer to properly labeled containers.
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7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling

Industrial Scale: Local ventilation and emission point dust extraction. Enclosed transfer recommended. Take precautionary measures against electrostatic loading. Ground vessels and equipment well. Handle milled or in bulk only after a detailed safety study.

Laboratory Scale: Handling in a hood.

Conditions for safe storage, including any incompatibilities

Storage Conditions

Keep away from chemicals as it is a pharmaceutical substance. Keep in closed container, away from moisture and light. Keep protected from air. Take precautionary measures against static discharges. Keep at ambient temperature.

Packaging materials

Glass, polyethylene.

Incompatible materials

Strong oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Based on a review of animal and clinical literature, an Occupational Exposure Limit (OEL) of 50 µg/m³ is recommended as an 8-hour TWA for Prednisolone acetate.

Appropriate engineering controls

Engineering Controls

See Section 7: Precautions for safe handling.

Individual protection measures, such as personal protective equipment

Eye/face protection

Industrial Workplace: See respiratory protection
Laboratory: Safety glasses.

Skin and body protection

Industrial Workplace: Work clothes. Suitable gloves. Glove material: Nitrile rubber; Layer thickness: 0.11 mm. Break through time: > 480 min.
Laboratory: Working clothes. Suitable gloves recommended.

Respiratory protection

Industrial Workplace: Particle full-face mask or powered-air purifying respirator.
Laboratory: Handling in a hood.

General Hygiene Considerations

Industrial Workplace: Wash hands.
Laboratory: Wash hands.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state
Appearance
Color

Solid
Not available
White

Odor
Odor threshold

Odorless
Not available.

Property
pH

Values
Not available.

Remarks

Melting point/freezing point

227 °C

Boiling point / boiling range	Not available.
Flash point	Not applicable.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Flammability Limit in Air	
Upper flammability limit:	Not available.
Lower flammability limit:	Not available.
Vapor pressure	Not data available.
Vapor density	Not available.
Specific Gravity	Not available.
Water solubility	Insoluble in water.
Solubility in other solvents	Soluble in ethanol. Soluble in acetone.
Partition coefficient	log(Pow): 3.81
Auto-ignition temperature	Not available.
Decomposition temperature	240°C Under nitrogen 170°C Under oxygen
Kinematic viscosity	Not available.
Dynamic viscosity	Not available.
Minimum ignition energy	Extremely sensitive to ignition (1 mJ < MIE < 3 mJ)
Oxidizing properties	Not available.
<u>Other Information</u>	
Softening point	Not available.
Molecular weight	Not available.
VOC Content (%)	Not available.
Density	No data available.
Bulk density	approx. 400 kg/m ³

10. STABILITY AND REACTIVITY

Reactivity

Not available.

Chemical stability

No data available.

Possibility of Hazardous Reactions

Not available.

Conditions to avoid

Not available.

Incompatible materials

Strong oxidizing agents.

Hazardous Decomposition Products

- Carbon monoxide (CO)
- Carbon dioxide (CO₂)

11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Acute toxicity	Acute dermal toxicity (LD ₅₀):	3,500 mg/kg (Mouse)
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Information on toxicological effects

Symptoms	Not available.
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Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	No experimental data available. No cases reported at workplace.
Serious eye damage/eye irritation	No experimental data available. No cases reported at workplace.
Sensitization	No experimental data available. No cases reported at workplace.
Germ cell mutagenicity	Not available.
Carcinogenicity	Not available.
Reproductive toxicity	In animals, experiments have shown teratogenic effects, varying with species. In humans, retrospective studies haven't shown abnormal effects due to administration of corticoids during the first trimester.
STOT - single exposure	No data available.
STOT - repeated exposure	Not available.
Subchronic toxicity	Not available.
Target Organ Effects	Not available.
Neurological effects	Not available.
Other adverse effects	Bodyweight gain. Acne. Purpura and stretch marks. Excitation and sleep disorders. Metabolic and endocrine disorders.
Aspiration hazard	Not available.

12. ECOLOGICAL INFORMATION**Ecotoxicity**

No data available.

Persistence and degradability

No data available.

Bioaccumulation

Unlikely to be bioaccumulative in living organisms (Log Pow<4).

Mobility

Not available.

Other adverse effects

No ecological data available.

13. DISPOSAL CONSIDERATIONS**Waste treatment methods**

Disposal of wastes	Disposal should be in accordance with applicable regional, national and local laws and regulations.
Contaminated packaging	Do not reuse container.
US EPA Waste Number	Not available.

14. TRANSPORT INFORMATION

<u>DOT</u>	Not classified as dangerous in the meaning of transport regulations.
<u>IATA</u>	Not classified as dangerous in the meaning of transport regulations.
<u>IMDG</u>	Not classified as dangerous in the meaning of transport regulations.
<u>ADR</u>	Not classified as dangerous in the meaning of transport regulations.

15. REGULATORY INFORMATION**US Federal Regulations****SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

16. OTHER INFORMATION

Issue Date 19-Apr-2013
Revision Date 29-Nov-2016
Revision Note Formatted to the new 2012 GHS Standard.

Disclaimer

The information contained herein is based upon data considered true and accurate. Sanofi-Aventis U.S. LLC. makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

End of Safety Data Sheet