

SAFETY DATA SHEETS

This SDS packet was issued with item:

078014381

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

078943846



March 1, 2011

Material Safety Data Sheet (MSDS) is a written or printed material concerning a hazardous chemical which is prepared in accordance with the Occupational Safety and Health Administration (OSHA) 29 CFR 1910.1200 (Hazard Communication Standard).

The purpose of the MSDS is to communicate information concerning hazards and appropriate protective measures to *employees who produce the hazardous chemical*.

OSHA's Hazard Communication Standard **does not require** that an MSDS be provided for finished pharmaceutical products intended for sale to consumers in a retail establishment or for personal consumption. Therefore, an MSDS is not required for Fludrocortisone Acetate Tablets, USP. If additional assistance is required with this product or you have received this letter in error please contact me.

Regards,

Rob McCafferty, CIH
Teva Americas Manager, IH



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Issuing Date 02-Jul-2009

Revision date 15-Jan-2020

Revision Number 13

1. Identification

1.1. Product identifier

Product Name FLUDROCORTISONE ACETATE
CAS No. 514-36-3
EINECS 208-180-4
Chemical name Pregn-4-ene-3,20-dione, 9- fluoro-11,17-dihydroxy-21-(acetyloxy)-,(11b)
Synonyms Cortineff; Florinef acetate; Scherofluron
Pure substance/mixture Substance
Contains Pregn-4-ene-3,20-dione, 9- fluoro-11,17-dihydroxy-21-(acetyloxy)-, (11b)
Formula $C_{23}H_{31}FO_6$
Molecular weight 422.5

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

Uses/ Identified uses Active Pharmaceutical Ingredient
Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

Sicor Società Italiana Corticosteroidi S.r.l. Teva Corporate Headquarters
Milano (MI) Piazzale Luigi Cadorna 4 5 Basel Street PO Box 3190
CAP 20123 Petach Tikva, Israel
Italy

For further information, please contact

E-mail address SDS.TevalL@teva.co.il

1.4. Emergency telephone number

Emergency Telephone United States/Canada/Puerto Rico: 1-800-424-9300 (Chemtrec) [24-hrs]
International: +1-703-741-5970 (Chemtrec) [24-hours]

2. Hazard(s) identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Reproductive toxicity	Category 1B - (H360FD)
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Specific target organ toxicity (repeated exposure)	Category 1 - (H372)
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2.2. Label elements

Contains Pregn-4-ene-3,20-dione, 9- fluoro-11,17-dihydroxy-21-(acetyloxy)-, (11b)

**Signal word**

Danger

Hazard statements

H360FD - May damage fertility. May damage the unborn child

H372 - Causes damage to organs through prolonged or repeated exposure

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

P201 - Obtain special instructions before use

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

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P501 - Dispose of contents/ container to an approved waste disposal plant

Additional information

This product requires tactile warnings if supplied to the general public. This product requires child resistant fastenings if supplied to the general public.

2.3. Other hazards

No information available

3. Composition/information on ingredients

3.1 Substances

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH registration number
Pregn-4-ene-3,20-dione, 9-fluoro-11,17-dihydroxy-21-(acetyloxy)-, (11b)	EEC No. 208-180-4	514-36-3	100	Repr. 1B (H360FD) STOT RE 1 (H372)	No data available

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

4. First-aid measures

4.1. Description of first aid measures**General advice**

Show this safety data sheet to the doctor in attendance.

Inhalation

Remove to fresh air.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Skin contact

Wash skin with soap and water. In the case of skin irritation or allergic reactions see a

physician.

Ingestion Clean mouth with water and drink afterwards plenty of water.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. Fire-fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media No information available.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.

Other information Refer to protective measures listed in Sections 7 and 8.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

7. Handling and storage

7.1. Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Ensure adequate ventilation.
General hygiene considerations	Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions	Store locked up.
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7.3. Specific end use(s)

Risk Management Methods (RMM)	The information required is contained in this Material Safety Data Sheet.
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8. Exposure controls/personal protection**8.1. Control parameters****Exposure Limits**

TEVA OEL	Teva OEL (8hr-TWA): 0.2 µg/m ³
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Derived No Effect Level (DNEL)	No information available.
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Predicted No Effect Concentration (PNEC)	No information available.
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8.2. Exposure controls**Personal protective equipment**

Eye/face protection	No special protective equipment required.
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Hand protection	Wear suitable gloves.
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Skin and body protection	Wear suitable protective clothing.
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Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
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General hygiene considerations	Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.
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Environmental exposure controls	No information available.
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9. Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	Solid
Appearance	No information available
Color	white

Odor	No information available.	
Odor threshold	No information available	
<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	No data available	None known
Melting point / freezing point	233 - 234 °C	
Boiling point / boiling range	575 °C	
Flash point	302 °C	
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	Partially soluble	
Solubility(ies)	Sparingly soluble in Ethano Slightly soluble in Ether	
Partition coefficient	2.71 (calc)	
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No information available	
Oxidizing properties	No information available	
Partition coefficient n-octanol /water (log KOW)	No information available	
<u>9.2. Other information</u>		
Softening point	No information available	
Molecular weight	422.5	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

10. Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions Hazardous polymerization does not occur.

10.4. Conditions to avoid

Conditions to avoid Extremes of temperature and direct sunlight. Exposure to air or moisture over prolonged periods. Heat, flames and sparks.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

11. Toxicological information**11.1. Information on toxicological effects****Information on likely routes of exposure****Product Information**

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity**Acute toxicity****Component Information**

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Pregn-4-ene-3,20-dione, 9-fluoro-11,17-dihydroxy-21-(acetyloxy)-, (11b)	>1000 mg/kg (Rat)		

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	Classification based on data available for ingredients.
STOT - single exposure	No information available.
STOT - repeated exposure	Causes damage to organs through prolonged or repeated exposure.
Aspiration hazard	No information available.

12. Ecological information

12.1. Toxicity

Ecotoxicity The environmental impact of this product has not been fully investigated.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Other adverse effects

Other adverse effects No information available.

13. Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

IMDG

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Marine pollutant	Not applicable
14.6	
14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code	No information available

RID

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated

14.4 Packing group	Not regulated
Description	
14.5 Environmental hazards	Not applicable
14.6	

ADR

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Hazard class	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6	

IATA

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6	

15. Regulatory information

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

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

TSCA	Contact supplier for inventory compliance status
DSL/NDL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AICS	Contact supplier for inventory compliance status

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

16. Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H360FD - May damage fertility. May damage the unborn child
H372 - Causes damage to organs through prolonged or repeated exposure

Legend

SVHC: Substances of Very High Concern for Authorization:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AELG(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
RTECS (Registry of Toxic Effects of Chemical Substances)
World Health Organization

Issuing Date 02-Jul-2009

Revision date 15-Jan-2020

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

The information provided in 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 guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered 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 materials or in any process, unless specified in the text.

End of Safety Data Sheet