

Safety Data Sheet (SDS) According to the REACH Regulation (EC) No. 1907/2006

Issuing Date: 2015-01-16

Revision Date: 2017-09-12

Version: 2

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product No 14776
Product name Dexamethasone
Reach registration number This substance/mixture contains only ingredients which have been registered, or are exempt from registration, according to Regulation (EC) No. 1907/2006.

Contains

Formula C₂₂H₂₉FO₅
Molecular Weight 392.5 g/mol

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

Identified uses For research use only

1.3. Details of the supplier of the safety data sheet

Importer (Applicable in EU only) Cell Signaling Technology Europe B.V. Schuttersveld 2 2316 ZA Leiden The Netherlands TEL: +31 (0)71 7200 200 FAX: +31 (0)71 891 0098	Manufacturer Cell Signaling Technology, Inc. 3 Trask Lane Danvers, MA 01923 United States TEL: +1 978 867 2300 FAX: +1 978 867 2400
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Website www.cellsignal.com
E-mail Address info@cellsignal.eu

1.4. Emergency telephone number

CHEMTREC 24 hours a day, 7 days a week, 365 days a year
+1 703 527 3887 (INTERNATIONAL) +1 800 424 9300 (NORTH AMERICA)

Europe 112

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Reproductive toxicity	Category 1B - (H360Df)
Specific target organ toxicity - repeated exposure (STOT RE)	Category 2 - (H373)

For the full text of the H-phrases & EUH-phrases mentioned in this Section, see Section 16

2.2. Label elements**Signal word**

Danger

Hazard statement(s)

H360Df - May damage the unborn child. Suspected of damaging fertility

H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statement(s)

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

P281 - Use personal protective equipment as required

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

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

2.3. Other hazards

None under normal use conditions.

SECTION 3: Composition/information on ingredients

3.1 Substances**Synonyms**

Dexamethasone;
 Fluormethylprednisolone;
 Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17,21-trihydroxy-16-methyl-, (11β,16α)-

FormulaC₂₂H₂₉FO₅**Chemical nature**

Monoconstituent substance.

Chemical Name	CAS No	Weight %	EC No	Classification (1272/2008)	REACH Registration Number
dexamethasone	50-02-2	100	200-003-9	Repr. 1B (H361Df) STOT RE 2 (H373)	no data available

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

SECTION 4: First aid measures

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

Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.

Inhalation

Immediate medical attention is required. Move to fresh air. If not breathing, give artificial respiration.

Skin contact

Immediate medical attention is required. Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.

Eye contact

Rinse thoroughly with plenty of water, also under the eyelids. Keep eye wide open while

Ingestion rinsing.
Do NOT induce vomiting. Immediate medical attention is required. Never give anything by mouth to an unconscious person. Drink plenty of water.

Protection of first-aiders Use personal protective equipment. Avoid contact with skin, eyes and clothing.

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

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

Notes to physician Treat symptomatically.

SECTION 5: Firefighting 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

Thermal decomposition can lead to release of irritating gases and vapors.

5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective suit. Use personal protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Evacuate personnel to safe areas. Ensure adequate ventilation.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Do not flush into surface water or sanitary sewer system.

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 Use personal protective equipment. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid dust formation. Clean contaminated surface thoroughly.

6.4. Reference to other sections

See Sections 8 & 13 for additional information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

When using, do not eat, drink or smoke. Provide regular cleaning of equipment, work area and clothing. Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. Keep away from food, drink and animal feeding stuffs.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

7.3. Specific end use(s)

Use as a laboratory reagent.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters**8.2. Exposure controls****Appropriate engineering controls**

Showers, eyewash stations, and ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection	Tightly fitting safety goggles.
Skin protection	
Hand protection	Impervious gloves.
Other	Impervious gloves. Impervious clothing.
Respiratory protection	In case of inadequate ventilation wear respiratory protection.

Environmental Exposure Controls

No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid
Appearance	Crystalline Powder
Color	White, light cream
Odor	Slight
Odor Threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH		No information available
Melting point/freezing point	262-264 °C	
Initial boiling point and boiling range		No information available
Flash point		No information available.
Evaporation rate		No information available
Flammability (solid, gas)		No information available
Upper flammability limit		No information available
Lower flammability limit		No information available
Vapor pressure		No information available
Vapor density		No information available
Relative density		No information available
Solubility	Soluble in water @ 89.0 mg/mL	@ 25 °C soluble
Partition coefficient: n-octanol/water		
Autoignition temperature		No information available
Decomposition temperature		No information available.
Viscosity		No information available
Explosive properties		No information available
Oxidizing properties		No information available

9.2. Other information

Softening point	No information available
Molecular Weight	392.5 g/mol
Solubility in other solvents	Acetone, Ethanol, Chloroform, Soluble in dimethyl sulfoxide (DMSO) @ 40 mg/mL
VOC content	No information available

Density No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization Hazardous polymerization does not occur.

Hazardous reactions None under normal processing.

10.4. Conditions to avoid

None known based on information supplied.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

May emit toxic fumes under fire conditions. Hydrogen fluoride.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

This material should only be handled by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals. It should be borne in mind that the toxicological and physiological properties of this compound is not well defined.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
dexamethasone	3 g/kg (Rat)	-	-

Information on likely routes of exposure

Inhalation May cause irritation of respiratory tract.
Eye contact May cause irritation.
Skin contact May be absorbed through the skin in harmful amounts.
Ingestion Target Organ Effects. Reproductive Toxicity.

Symptoms No information available.
Skin corrosion/irritation No information available.
Serious eye damage/eye irritation No information available.
Sensitization No information available.
Mutagenic effects Not mutagenic in AMES Test. Negative in the mouse micronucleus test.
Carcinogenic effects No information available.
Reproductive toxicity Glucocorticoids may cause fetal damage when administered to pregnant women. One retrospective study of 260 women who received pharmacologic dosages of glucocorticoids during pregnancy revealed 2 instances of cleft palate, 8 stillbirths, 1 spontaneous abortion, and 15 premature births. Another study reported 2 cases of cleft palate in 86 births. Occurrence of cleft palate in these studies is higher than in the general population but could have resulted from the underlying diseases as well as from the steroids. Other fetal abnormalities that have been reported following glucocorticoid administration in pregnant women include hydrocephalus and gastroschisis.

Topical ocular administration of 0.15% dexamethasone (0.375 mg/kg/day) on gestational days 10 to 13 produced embryofetal lethality and a high incidence of cleft palate in mice. In rabbits, topical ocular administration of 0.1% dexamethasone throughout organogenesis (0.13 mg/kg/day, on gestational day 6 followed by 0.20 mg/kg/day on gestational days 7-18) produced intestinal anomalies, intestinal aplasia, gastroschisis and hypoplastic kidneys. In oral teratogenicity studies with rats using dose levels ranging from 10 to 1250/kg bw/day, maternal toxicity was found at 50 µg/kg bw/day and above. At doses at and above 1000 µg/kg bw/day, dexamethasone caused structural malformations (hydrops fetalis, cleft palate). Thymus involution and a decrease in body weight were observed in fetuses, resulting in an overall NOEL for embryotoxicity in rats of 10 µg/kg bw/day.

STOT - single exposure
STOT - repeated exposure

No information available.

Following repeated oral administration of dexamethasone to rats and dogs in short-term toxicity studies the main target organs were the thymus and the adrenal gland. Corticosteroid concentrations in plasma and hepatic glycogen were reduced, whereas serum lipid levels were increased. In rats dosed orally with 0.3, 1, 3, 10, 30, or 100 µg dexamethasone/kg bw/day for 90 days, thymus involution and morphological changes in the adrenal gland and a decrease in corticosterone and white blood cell counts were observed in male and female rats at doses above 10 µg/kg bw/day.

Target Organ Effects
Aspiration Hazard
Other information

Liver, Thymus, Reproductive system, Endocrine system.

No information available.

No information available.

SECTION 12: Ecological information

12.1. Toxicity

No information available.

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

Bioaccumulation Not likely to bioaccumulate.
Bioconcentration factor (BCF) 14

Chemical Name	Octanol-Water Partition Coefficient
dexamethasone	1.83

12.4. Mobility in soil

Is predicted to have low mobility in the environment.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

No information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues / unused products Dispose of in accordance with local regulations.
Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.
Other information According to the European Waste Catalogue, Waste Codes are not product specific, but

application specific. Waste codes should be assigned by the user based on the application for which the product was used.

SECTION 14: Transport information

IMDG/IMO

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	None
14.6 Special precautions for user	None
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not regulated

ADR/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
14.5 Environmental hazards	None
14.6 Special precautions for user	None

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	None
14.6 Special precautions for user	None

SECTION 15: Regulatory information

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

Candidate List of Substances of Very High Concern for Authorization Information

This product does not contain Substances of Very High Concern (SVHC).

SEVESO Directive Information

This product does not contain substances identified in the SEVESO Directive.

International inventories

TSCA 8(b)	Complies
DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	-
IECSC	Complies
KECL	Complies
PICCS	Complies
AICS	Complies

International inventories legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
 DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
 EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU 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

For this substance a chemical safety assessment has not been carried out

SECTION 16: Other information

Full text of H-Statements referred to under Sections 2 and 3

H360Df - May damage the unborn child. Suspected of damaging fertility

H373 - May cause damage to organs through prolonged or repeated exposure

Classification procedure: Expert judgment and weight of evidence determination.

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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.