

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

Revision Date 15-Aug-2023 Revision Number 2.1

### 72092 - Dexamethasone

# Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Document Number DX21080

Product Name Dexamethasone

**Synonym** MK 125; NSC 34521;

9-fluoro-11b,17a,21-trihydroxy-16-methyl-pregna-1,4-diene-3,20-dione

Pure substance/mixture Substance

Contains 9-fluoro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione

Molecular weight 392.5

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

Recommended Use Laboratory chemicals

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

### Manufacturer

STEMCELL Technologies SARL

40 Rue des Berges, Miniparc Polytec, Bâtiment Sirocco, 38000 Grenoble, France

+33 (0) 4 76 04 75 30

STEMCELL Technologies Germany GmbH

Stolberger Str. 200, 50933, Köln, Germany

+33 (0) 4 76 04 75 30

STEMCELL Technologies UK Ltd.

Building 7100, Cambridge Research Park, Beach Drive, Waterbeach, Cambridge, UK, CB25 9TL

+33 (0) 4 76 04 75 30

For further information, please contact

#### 1.4. Emergency telephone number

Emergency Telephone No information available

Emergency Telephone - §45 - (EC)1272/2008

Europe 112

# **Section 2: HAZARDS IDENTIFICATION**



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#### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Reproductive toxicity	Category 2 - (H361)
Specific target organ toxicity (repeated exposure)	Category 2 - (H373)

### 2.2. Label elements

Contains 9-fluoro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione



Signal word Warning

### **Hazard statements**

#### **Hazard statements**

H361 - Suspected of damaging fertility or the unborn child

H373 - May cause 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

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

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

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

P314 - Get medical advice/attention if you feel unwell

P501 - Dispose of contents/container to industrial incineration plant

### **Additional information**

This product requires tactile warnings if supplied to the general public

### 2.3. Other hazards

No information available

# Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Synonym

Not applicable

	Chemical name	EC No.	CAS No.	Weight-%	Classification according to	REACH
1					Regulation (EC) No.	Registration



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				1272/2008 [CLP]	Number
9-fluoro-11,17,21-trihydroxy-16-meth	200-003-9	50-02-2	100	STOT RE 2 (H373)	No data available
ylpregna-1,4-diene-3,20-dione				Repr. 2 (H361)	

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

# **Section 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

# **Section 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

No information available.



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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.

### Section 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.

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.

### **Section 7: HANDLING AND STORAGE**

7.1. Precautions for safe handling

Advice on safe handling Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this

product. Remove contaminated clothing and shoes. Handle in accordance with good

industrial hygiene and safety practice. 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. Store in accordance with information listed on the Product Information



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Sheet (PIS).

7.3. Specific end use(s)

**Identified Uses** 

Risk Management Methods (RMM) The information required is contained in this Material Safety Data Sheet.

# Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

**Derived No Effect Level (DNEL)**No information available.

Predicted No Effect Concentration

(PNEC)

No information available.

8.2. Exposure controls

Personal protective equipment

**Eye/face protection** No special protective equipment required.

**Hand protection** Wear suitable gloves.

**Skin and body protection** Wear suitable protective clothing.

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.

General hygiene considerations Do not eat, drink or smoke when using this product. Wash hands before breaks and

immediately after handling the product.

**Environmental exposure controls** No information available.



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# **Section 9: PHYSICAL AND CHEMICAL PROPERTIES**

9.1. Information on basic physical and chemical properties

Physical state Solid

**Appearance** Crystalline

ColorNo information availableOdorNo data available.Odor thresholdNo data available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

No data available None known pН No data available None known Melting point / freezing point None known Boiling point / boiling range No data available Flash point No data available None known No data available **Evaporation rate** None known Flammability (solid, gas) No data available. None known Flammability Limit in Air None known

Upper flammability limit:
Lower flammability limit:
Appr pressure

No data available
No data available

Vapor pressureNo data availableNone knownVapor densityNo data availableNone knownRelative densityNo data availableNone knownWater solubilityNo data availableNone knownSolubility(ies)~0.1 mg/mL in a 1:10 solution ofNone known

DMSO:PBS (pH 7.2); ~3 mg/mL in EtOH; ~30 mg/mL inDMSO, ~25

mg/mL in DMF;

Partition coefficientNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperatureNo data availableNone knownKinematic viscosityNo data availableNone knownDynamic viscosityNo data availableNone known

**Explosive properties**No information available

Oxidizing properties No information available

9.2. Other information

Softening point No information available

Molecular weight 392.5

Molecular formula C22H29FO5

VOC Content (%)

Liquid Density

Bulk density

No information available
No information available

### **Section 10: STABILITY AND REACTIVITY**

10.1. Reactivity



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**Reactivity** No information available.

10.2. Chemical stability

Stability Stable under recommended transport or storage conditions.

**Explosion data** 

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

**Hazardous polymerization** Hazardous polymerization does not occur.

10.4. Conditions to avoid

Conditions to avoid Protect from light.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products Carbon dioxide (CO2). Carbon monoxide. Hydrogen fluoride.

# Section 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



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**Symptoms** No information available.

Numerical measures of toxicity

**Acute toxicity** 

The following values are calculated based on chapter 3.1 of the GHS document

**ATEmix (oral)** 3,003.00 mg/kg

**Unknown acute toxicity** 100 % of the mixture consists of ingredient(s) of unknown toxicity.

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.

100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Product Information

**Oral LD50** >3,000 mg/kg (Rat)

**Component Information** 

our portone in ormation					
Chemical name	Oral LD50	Dermal LD50	Inhalation LC50		
9-fluoro-11,17,21-trihydroxy-16-	> 3 g/kg (Rat)				
methylpregna-1,4-diene-3,20-di					
one					

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

Skin corrosion/irritation	No information available.
Product Information	
Serious eye damage/eye irritation Product Information	No information available.
Respiratory or skin sensitization Product Information	No information available.
Germ cell mutagenicity Product Information	No information available.
Carcinogenicity Product Information	No information available.
Reproductive toxicity	Classification based on data available for ingredients.

**Product Information** 



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No information available. STOT - single exposure

Product Information

STOT - repeated exposure May cause damage to organs.

Product Information

**Aspiration hazard** No information available.

**Section 12: ECOLOGICAL INFORMATION** 

12.1. Toxicity

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

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

**Product Information** 

12.2. Persistence and degradability

No information available. Persistence and degradability

12.3. Bioaccumulative potential

No information available. **Bioaccumulation** 

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.

**Section 13: DISPOSAL CONSIDERATIONS** 

13.1. Waste treatment methods

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



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**products** environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

# **Section 14: TRANSPORT INFORMATION**

Note: Transport in accordance with local, state, and federal regulations.

#### **IMDG**

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Marine pollutantNot applicable

14.6 Special Provisions None

14.7. Transport in bulk according to No information available

Annex II of MARPOL and the IBC

Code

#### RID

14.1UN NumberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing GroupNot regulated14.5Environmental hazardNot applicable

14.6 Special Provisions None

### ADR

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Environmental hazardNot applicable

**14.6 Special Provisions** None

IATA Not regulated

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Environmental hazardNot applicable

14.6 Special Provisions None

# **Section 15: REGULATORY INFORMATION**



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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 Complies
DSL/NDSL Complies
EINECS/ELINCS Complies

**ENCS** Does not comply

IECSCCompliesKECLCompliesPICCSCompliesAICSComplies

### 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 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

# **Section 16: OTHER INFORMATION**



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

Full text of H-Statements referred to under section 3

H361 - Suspected of damaging fertility or the unborn child

H373 - May cause 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

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

#### **Disclaimer**

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