

Betamethasone valerate

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Date of issue: 02/04/2012 Revision date: 27/02/2017

Supersedes 04/04/2012

615854

Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Betamethasone valerate
IUPAC name : 9-Fluoro-11 β ,21-dihydroxy-16 β -methyl-3,20-dioxopregna-1,4-dien-17-yl pentanoate
EC No : 218-439-3
CAS No : 2152-44-5
Product code : 615854
Formula : C₂₇H₃₇FO₆
Synonyms : Betamethasone 17-valerate
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Reproductive toxicity, Category 2	H361
Specific target organ toxicity — Repeated exposure, Category 2	H373
Hazardous to the aquatic environment — Chronic Hazard, Category 2	H411

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS08

GHS09

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H361 - Suspected of damaging fertility or the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure
H411 - Toxic to aquatic life with long lasting effects

Precautionary statements (CLP)

: P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P273 - Avoid release to the environment
P308+P313 - IF exposed or concerned: Get medical advice/attention

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Betamethasone valerate	(CAS No) 2152-44-5 (EC No) 218-439-3	97 - 103	Repr. 2, H361 STOT RE 2, H373 Aquatic Chronic 2, H411

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures**4.1. Description of first aid measures**

- First-aid measures after inhalation : Assure fresh air breathing. Get medical advice and attention if you feel unwell.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : Rinse immediately with plenty of water. If eye irritation persists, take medical advice.
- First-aid measures after ingestion : Rinse mouth. Never give anything by mouth to an unconscious person. Seek medical advice.

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

- Symptoms/injuries : Exposure may produce an allergic reaction. May produce irregular heart beat and nervous symptoms. Gastrointestinal complaints. Weakening of the immune system.
- Chronic symptoms : May affect: . endocrine system. Based on animal experimentation, it is proved that product has shown teratogenic effects.

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

No additional information available

SECTION 5: Fire-fighting measures**5.1. Extinguishing media**

- Suitable extinguishing media : Carbon dioxide. Dry powder. Foam. Water spray.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide. Hydrogen fluoride.
- Explosion hazard : Product is not explosive.

5.3. Advice for firefighters

- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****6.1.1. For non-emergency personnel**

- Emergency procedures : Ensure adequate air ventilation. Avoid raising dust.

6.1.2. For emergency responders

- Protective equipment : Wear proper protective equipment. Wear respiratory protection.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up dry powder and dispose properly. To clean the floor or objects contaminated by this product, use : Sodium hypochlorite solution.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed. Protect from sunlight.

Maximum storage period : 5 year

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Hand protection:**

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck). Chemical resistant apron

Respiratory protection:

Dust production: dust mask with filter type P3

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 476.6 g/mol
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: ca. 192 °C
Freezing point	: No data available

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Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Insoluble in water. Soluble in : Acetone. Slightly soluble in: Ethanol.

Log Pow	: 3.909
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available

Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

Light (daylight). heat.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide. Hydrogen fluoride.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity	: Not classified
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Betamethasone valerate (2152-44-5)	
LD50 oral rat	> 3000 mg/kg

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified

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Carcinogenicity	: Not classified
Reproductive toxicity	: Suspected of damaging fertility or the unborn child.
STOT-single exposure	: Not classified
STOT-repeated exposure	: May cause damage to organs through prolonged or repeated exposure.
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Betamethasone valerate (2152-44-5)	
EC50 Daphnia 1	1.9 mg/l 48 h

12.2. Persistence and degradability

Betamethasone valerate (2152-44-5)	
Persistence and degradability	Minimally biodegradable.

12.3. Bioaccumulative potential

Betamethasone valerate (2152-44-5)	
Log Pow	3.909

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available



SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Avoid release to the environment.
Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
3077	3077
14.2. UN proper shipping name	
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Not applicable
14.3. Transport hazard class(es)	
9	9
	
14.4. Packing group	
III	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : Yes	Dangerous for the environment : Yes

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ADR	IATA
No supplementary information available	

14.6. Special precautions for user**- Overland transport**

Classification code (ADR) : M7

Excepted quantities (ADR) : E1

Hazard identification number (Kemler No.) : 90

Orange plates :

90
3077

Tunnel restriction code (ADR) : E

EAC code : 2Z

- Air transport

No data available

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Betamethasone valerate is not on the REACH Candidate List

Betamethasone valerate is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association

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ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : Supplier. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of H- and EUH-statements:

Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Repr. 2	Reproductive toxicity, Category 2
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H361	Suspected of damaging fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure
H411	Toxic to aquatic life with long lasting effects

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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product