

Betamethasone dipropionate

Safety Data Sheet

615846

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

2015/830

Date of issue: 04/04/2012

Revision date 07/06/2020

Supersedes 27/02/2017

Version: 3.0

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

1.1. Product identifier

Product form	: Substance
Substance name	: Betamethasone dipropionate
IUPAC name	: 9-Fluoro-11 β -hydroxy-16 β -methyl-3,20-dioxopregna-1,4-diene-17,21-diyl dipropionate
EC-No.	: 227-005-2
CAS-No.	: 5593-20-4
Product code	: 615846
Formula	: C ₂₈ H ₃₇ FO ₇
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
Use of the substance/mixture	: Active ingredient for the preparation of pharmaceuticals
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@ducheffa.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)
------------------	------------------------------------------------------------------------------------------------------------------

Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Reproductive toxicity, Category 2 H361
Specific target organ toxicity — Repeated exposure, Category 1 H372
Hazardous to the aquatic environment — Chronic Hazard, Category 2 H411

Full text of 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] Extra labelling to display/Extra classification(s) to display

Hazard pictograms (CLP)



Signal word (CLP) : Danger

Hazard statements (CLP) : H361 - Suspected of damaging fertility or the unborn child.
H372 - Causes 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

Substance type : Pharmaceuticals

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Betamethasone dipropionate	(CAS-No.) 5593-20-4 (EC-No.) 227-005-2	97 - 102	Repr. 2, H361 STOT RE 1, H372 Aquatic Chronic 2, H411

Safety Data Sheet

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

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 general	: If medical advice is needed, have product container or label at hand.
First-aid measures after inhalation	: Allow affected person to breathe fresh air 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/effects	: 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: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: All extinguishing agents can be used.
------------------------------	-----------------------------------------

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

No additional information available

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.

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

Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Personal protective equipment:

Safety glasses. Dust/aerosol mask with filter type P3. Gloves.

Hand protection:

Safety Data Sheet

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

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

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

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	: 504.6 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	: 176 - 180 °C
Freezing point	: No data available
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	: 4.07
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

Safety Data Sheet

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

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

Betamethasone dipropionate (5593-20-4)

LD50 oral rat > 4000 mg/kg

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Suspected of damaging fertility or the unborn child.

STOT-single exposure : Not classified

STOT-repeated exposure : Causes damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified

SECTION 12: Ecological information**12.1. Toxicity**

Betamethasone dipropionate (5593-20-4)	
EC50 Daphnia 1	1.9 mg/l 48 h

12.2. Persistence and degradability

Betamethasone dipropionate (5593-20-4)	
Biodegradation	28 %

12.3. Bioaccumulative potential

Betamethasone dipropionate (5593-20-4)	
Log Pow	4.07

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

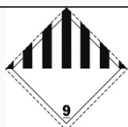

No additional information available

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Regional legislation (waste)	: Disposal must be done according to official regulations.
Waste treatment methods	: Avoid release to the environment.
Product/Packaging 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.	Environmentally hazardous substance, solid, n.o.s.
14.3. Transport hazard class(es)	
9	9
	
14.4. Packing group	
III	III
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No

Betamethasone dipropionate

615846


Safety Data Sheet

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

ADR	IATA
No supplementary information available	

14.6. Special precautions for user

. Overland transport

Classification code (ADR)	: M7
Special provisions (ADR)	: 274, 335, 375, 601
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Special packing provisions (ADR)	: PP12, B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1, BK1, BK2, BK3
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAV, LGBV
Vehicle for tank carriage	: AT
Transport category (ADR)	: 3
Special provisions for carriage - Packages (ADR)	: V13
Special provisions for carriage - Bulk (ADR)	: VC1, VC2
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13
Hazard identification number (Kemler No.)	: 90
Orange plates	: 
Tunnel restriction code (ADR)	: -
EAC code	: 2Z

- Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y956
PCA limited quantity max net quantity (IATA)	: 30kgG
PCA packing instructions (IATA)	: 956
PCA max net quantity (IATA)	: 400kg
CAO packing instructions (IATA)	: 956
CAO max net quantity (IATA)	: 400kg
Special provisions (IATA)	: A97, A158, A179, A197
ERG code (IATA)	: 9L

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 dipropionate is not on the REACH Candidate List

Betamethasone dipropionate 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		Modified	change of logo
8.2	Personal protective equipment	Added	

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
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 : 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. Supplier.

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 1	Specific target organ toxicity — Repeated exposure, Category 1
H361	Suspected of damaging fertility or the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
H411	Toxic to aquatic life with long lasting effects.

SDS EU (REACH Annex II) duchefa nieuwe logo

Betamethasone dipropionate

615846

Safety Data Sheet

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

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.