

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## Betamethasone Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.0	06.04.2024	9373195-00008	Date of first issue: 27.08.2021

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

#### 1.1 Product identifier

Trade name : Betamethasone Lotion Formulation

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

Use of the Sub-stance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.  
Shotton Lane  
NE23 3JU Cramlington NU - Great Britain

Telephone : +44 1 670 59 32 05

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

#### 1.4 Emergency telephone number

+1-215-631-6999

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Flammable liquids, Category 2  
Eye irritation, Category 2  
Reproductive toxicity, Category 1B  
Specific target organ toxicity - single exposure, Category 3  
Specific target organ toxicity - repeated exposure, Category 1  
Long-term (chronic) aquatic hazard, Category 1

H225: Highly flammable liquid and vapour.  
H319: Causes serious eye irritation.  
H360D: May damage the unborn child.  
H336: May cause drowsiness or dizziness.  
H372: Causes damage to organs through prolonged or repeated exposure.  
H410: Very toxic to aquatic life with long lasting effects.

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### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H225      Highly flammable liquid and vapour. H319      Causes serious eye irritation. H336      May cause drowsiness or dizziness. H360D      May damage the unborn child. H372      Causes damage to organs through prolonged or repeated exposure. H410      Very toxic to aquatic life with long lasting effects.
Precautionary statements	:	<b>Prevention:</b> P201      Obtain special instructions before use. P210      Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P273      Avoid release to the environment. P280      Wear protective gloves/ protective clothing/ eye protection/ face protection. <b>Response:</b> P308 + P313      IF exposed or concerned: Get medical advice/ attention. P391      Collect spillage.

Hazardous components which must be listed on the label:

Propan-2-ol  
betamethasone

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Vapours may form explosive mixture with air.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)

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Propan-2-ol	67-63-0 200-661-7 603-117-00-0	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	>= 30 - < 50
betamethasone	378-44-9 206-825-4	Acute Tox. 2; H330 Repr. 1B; H360D STOT RE 1; H372 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Ad- renal gland) Aquatic Chronic 1; H410  M-Factor (Chronic aquatic toxicity): 1,000  specific concentra- tion limit STOT RE 1; H372 >= 0.01 % Repr. 1B; H360D >= 0.01 % STOT RE 1; H372 >= 0.01 % Repr. 1B; H360D >= 0.01 %	>= 0.025 - < 0.1
Substances with a workplace exposure limit :			
Propylene glycol	57-55-6 200-338-0		>= 30 - < 50

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

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- In case of skin contact : In case of contact, immediately flush skin with plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water  
for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

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

- Risks : Causes serious eye irritation.  
May cause drowsiness or dizziness.  
May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.

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

- Treatment : Treat symptomatically and supportively.
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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

- Unsuitable extinguishing media : High volume water jet

### 5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Do not use a solid water stream as it may scatter and spread fire.  
Flash back possible over considerable distance.  
Vapours may form explosive mixtures with air.  
Exposure to combustion products may be a hazard to health.

- Hazardous combustion products : Carbon oxides

### 5.3 Advice for firefighters

- Special protective equipment : In the event of fire, wear self-contained breathing apparatus.

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for firefighters

Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Remove all sources of ignition.  
Ventilate the area.  
Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Non-sparking tools should be used.  
Soak up with inert absorbent material.  
Suppress (knock down) gases/vapours/mists with a water spray jet.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

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- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.  
Use explosion-proof electrical, ventilating and lighting equipment.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapours.  
Do not swallow.  
Do not get in eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Non-sparking tools should be used.  
Keep container tightly closed.  
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
Take precautionary measures against static discharges.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition.
- Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Flammable solids  
Pyrophoric liquids  
Pyrophoric solids  
Self-heating substances and mixtures  
Substances and mixtures, which in contact with water, emit flammable gases  
Explosives  
Gases  
Very acutely toxic substances and mixtures

### 7.3 Specific end use(s)

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Specific use(s) : No data available

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Propan-2-ol	67-63-0	STEL	500 ppm 1,250 mg/m <sup>3</sup>	GB EH40
		TWA	400 ppm 999 mg/m <sup>3</sup>	GB EH40
Propylene glycol	57-55-6	TWA (Total vapour and particles)	150 ppm 474 mg/m <sup>3</sup>	GB EH40
		TWA (particles)	10 mg/m <sup>3</sup>	GB EH40
betamethasone	378-44-9	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm <sup>2</sup>	Internal

##### Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
Propan-2-ol	Workers	Inhalation	Long-term systemic effects	500 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	888 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	89 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	319 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	26 mg/kg bw/day
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Workers	Inhalation	Long-term systemic effects	168 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term systemic effects	50 mg/m <sup>3</sup>

##### Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Propan-2-ol	Fresh water	140.9 mg/l
	Marine water	140.9 mg/l
	Intermittent use/release	140.9 mg/l
	Sewage treatment plant	2251 mg/l
	Fresh water sediment	552 mg/kg dry

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		weight (d.w.)
	Marine sediment	552 mg/kg dry weight (d.w.)
	Soil	28 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	160 mg/kg food
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57.2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)

### 8.2 Exposure controls

#### Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies.

If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Use explosion-proof electrical, ventilating and lighting equipment.

#### Personal protective equipment

- Eye/face protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.
- Skin and body protection : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Equipment should conform to BS EN 14387
- Filter type : Combined particulates and organic vapour type (A-P)



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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Appearance	:	lotion
Colour	:	colourless
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	4.5
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	21.4 °C Method: closed cup
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

#### 9.2 Other information

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Flammability (liquids) : Not applicable

Particle size : Not applicable

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : Highly flammable liquid and vapour.  
Vapours may form explosive mixture with air.  
Can react with strong oxidizing agents.

#### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

#### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Propan-2-ol:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 25 mg/l  
Exposure time: 6 h  
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

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Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
LD50 (Mouse): > 4,500 mg/kg  
Acute inhalation toxicity : LC50 (Rat): 0.4 mg/l  
Exposure time: 4 h

### Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Propan-2-ol:

Species : Rabbit  
Result : No skin irritation

#### betamethasone:

Species : Rabbit  
Result : Mild skin irritation

#### Propylene glycol:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

### Serious eye damage/eye irritation

Causes serious eye irritation.

### Components:

#### Propan-2-ol:

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days

#### betamethasone:

Species : Rabbit  
Result : No eye irritation

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### Propylene glycol:

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : No eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

### Components:

#### Propan-2-ol:

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

#### betamethasone:

Exposure routes : Dermal  
Species : Guinea pig  
Result : Weak sensitizer

#### Propylene glycol:

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Propan-2-ol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
  
Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
  
Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

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### betamethasone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: positive

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)  
Species: Mouse  
Application Route: Oral  
Result: equivocal

Germ cell mutagenicity- Assessment : Weight of evidence does not support classification as a germ  
cell mutagen.

### Propylene glycol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

### Carcinogenicity

Not classified based on available information.

### Components:

#### Propan-2-ol:

Species : Rat  
Application Route : inhalation (vapour)  
Exposure time : 104 weeks  
Method : OECD Test Guideline 451  
Result : negative

#### Propylene glycol:

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative

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### Reproductive toxicity

May damage the unborn child.

### Components:

#### Propan-2-ol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

#### betamethasone:

Effects on foetal development : Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL: 0.05 mg/kg body weight  
Result: Fetotoxicity, Malformations were observed.

Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 0.42 mg/kg body weight  
Result: Malformations were observed.

Species: Mouse  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL: 1 mg/kg body weight  
Result: Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

#### Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Mouse  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### STOT - single exposure

May cause drowsiness or dizziness.

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### Components:

#### **Propan-2-ol:**

|| Assessment : May cause drowsiness or dizziness.

#### **STOT - repeated exposure**

Causes damage to organs through prolonged or repeated exposure.

### Components:

#### **betamethasone:**

|| Target Organs : Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland  
|| Assessment : Causes damage to organs through prolonged or repeated exposure.

#### **Repeated dose toxicity**

### Components:

#### **Propan-2-ol:**

|| Species : Rat  
|| NOAEL : 12.5 mg/l  
|| Application Route : inhalation (vapour)  
|| Exposure time : 104 Weeks

#### **betamethasone:**

|| Species : Rabbit  
|| LOAEL : 0.05 %  
|| Application Route : Skin contact  
|| Exposure time : 10 - 30 d  
|| Target Organs : Pituitary gland, Immune system, muscle

|| Species : Rat  
|| LOAEL : 0.05 %  
|| Application Route : Skin contact  
|| Exposure time : 8 Weeks  
|| Target Organs : thymus gland

|| Species : Mouse  
|| LOAEL : 0.1 %  
|| Application Route : Skin contact  
|| Exposure time : 8 Weeks  
|| Target Organs : thymus gland

|| Species : Dog  
|| LOAEL : 0.05 mg/kg  
|| Application Route : Oral  
|| Exposure time : 28 d  
|| Target Organs : Blood, thymus gland, Adrenal gland

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### Propylene glycol:

Species : Rat, male  
NOAEL :  $\geq 1,700$  mg/kg  
Application Route : Ingestion  
Exposure time : 2 yr

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

### Components:

#### betamethasone:

Inhalation : Target Organs: Adrenal gland  
Skin contact : Symptoms: Redness, pruritis, Irritation

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### Propan-2-ol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l  
Exposure time: 96 h  
Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)):  $> 10,000$  mg/l  
Exposure time: 24 h  
Toxicity to microorganisms : EC50 (Pseudomonas putida):  $> 1,050$  mg/l  
Exposure time: 16 h

##### betamethasone:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Americamysis):  $> 50$  mg/l  
Exposure time: 96 h  
Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)):  $> 34$  mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility  
NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility  
Toxicity to fish (Chronic toxicity) : NOEC: 0.052 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)



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Method: OECD Test Guideline 210  
NOEC: 0.07 µg/l  
Exposure time: 219 d  
Species: *Oryzias latipes* (Japanese medaka)  
Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 8 mg/l  
Exposure time: 21 d  
Species: *Daphnia magna* (Water flea)  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1,000

### Propylene glycol:

Toxicity to fish : LC50 (*Oncorhynchus mykiss* (rainbow trout)): 40,613 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Ceriodaphnia dubia* (water flea)): 18,340 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (*Skeletonema costatum* (marine diatom)): 19,300 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to microorganisms : NOEC (*Pseudomonas putida*): > 20,000 mg/l  
Exposure time: 18 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 13,020 mg/l  
Exposure time: 7 d  
Species: *Ceriodaphnia dubia* (water flea)

## 12.2 Persistence and degradability

### Components:

#### Propan-2-ol:

Biodegradability : Result: rapidly degradable

BOD/COD : BOD: 1,19 (BOD5)  
COD: 2,23  
BOD/COD: 53 %

#### Propylene glycol:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 98.3 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

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### 12.3 Bioaccumulative potential

#### Components:

##### **Propan-2-ol:**

|| Partition coefficient: n-octanol/water : log Pow: 0.05

##### **betamethasone:**

|| Partition coefficient: n-octanol/water : log Pow: 2.11

##### **Propylene glycol:**

|| Partition coefficient: n-octanol/water : log Pow: -1.07  
Method: Regulation (EC) No. 440/2008, Annex, A.8

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Other adverse effects

#### Product:

|| Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.  
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.  
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.  
Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Empty containers retain residue and can be dangerous.  
Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.  
If not otherwise specified: Dispose of as unused product.

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### SECTION 14: Transport information

#### 14.1 UN number

**ADN** : UN 1219  
**ADR** : UN 1219  
**RID** : UN 1219  
**IMDG** : UN 1219  
**IATA** : UN 1219

#### 14.2 UN proper shipping name

**ADN** : ISOPROPANOL, SOLUTION  
**ADR** : ISOPROPANOL, SOLUTION  
**RID** : ISOPROPANOL, SOLUTION  
**IMDG** : ISOPROPANOL, SOLUTION  
**II** (betamethasone)  
**IATA** : Isopropanol, solution

#### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
<b>ADN</b>	: 3	
<b>ADR</b>	: 3	
<b>RID</b>	: 3	
<b>IMDG</b>	: 3	
<b>IATA</b>	: 3	

#### 14.4 Packing group

**ADN**  
Packing group : II  
Classification Code : F1  
Hazard Identification Number : 33  
Labels : 3

**ADR**  
Packing group : II  
Classification Code : F1  
Hazard Identification Number : 33  
Labels : 3  
Tunnel restriction code : (D/E)

**RID**  
Packing group : II  
Classification Code : F1  
Hazard Identification Number : 33  
Labels : 3

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### IMDG

Packing group : II  
Labels : 3  
EmS Code : F-E, S-D

### IATA (Cargo)

Packing instruction (cargo aircraft) : 364  
Packing instruction (LQ) : Y341  
Packing group : II  
Labels : Flammable Liquids

### IATA (Passenger)

Packing instruction (passenger aircraft) : 353  
Packing instruction (LQ) : Y341  
Packing group : II  
Labels : Flammable Liquids

## 14.5 Environmental hazards

### ADN

Environmentally hazardous : yes

### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

## 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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

Remarks : Not applicable for product as supplied.

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## SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

|| UK REACH List of restrictions (Annex 17)

: Conditions of restriction for the following entries should be considered:  
Number on list 3  
Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the

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restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : Not applicable  
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) : Not applicable  
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable  
UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable  
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : Not applicable

### Control of Major Accident Hazards Regulations 2015 (COMAH)

		Quantity 1	Quantity 2
P5c	FLAMMABLE LIQUIDS	5,000 t	50,000 t
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

### The components of this product are reported in the following inventories:

AICS : not determined  
DSL : not determined  
IECSC : not determined

## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

### Full text of H-Statements

H225 : Highly flammable liquid and vapour.

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H319 : Causes serious eye irritation.  
H330 : Fatal if inhaled.  
H336 : May cause drowsiness or dizziness.  
H360D : May damage the unborn child.  
H372 : Causes damage to organs through prolonged or repeated exposure.  
H410 : Very toxic to aquatic life with long lasting effects.

### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Aquatic Chronic : Long-term (chronic) aquatic hazard  
Eye Irrit. : Eye irritation  
Flam. Liq. : Flammable liquids  
Repr. : Reproductive toxicity  
STOT RE : Specific target organ toxicity - repeated exposure  
STOT SE : Specific target organ toxicity - single exposure  
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits  
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)  
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Flam. Liq. 2	H225
Eye Irrit. 2	H319
Repr. 1B	H360D
STOT SE 3	H336
STOT RE 1	H372
Aquatic Chronic 1	H410

### Classification procedure:

Based on product data or assessment
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

GB / EN