

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Betamethasone valerate ROTICHROM® HPLC

article number: **1KN2**
Version: **1.0 en**

date of compilation: 2021-06-07

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

1.1 Product identifier

| | |
|---------------------------------|---|
| Identification of the substance | Betamethasone valerate ROTICHROM® HPLC |
| Article number | 1KN2 |
| Registration number (REACH) | It is not required to list the identified uses because the substance is not subject to registration according to REACH (< 1 t/a). |
| EC number | 218-439-3 |
| CAS number | 2152-44-5 |

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

| | |
|---------------------------|---|
| Relevant identified uses: | Laboratory and analytical use Laboratory chemical |
| Uses advised against: | Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household). |

1.3 Details of the supplier of the safety data sheet

Carl Roth GmbH + Co KG
Schoemperlenstr. 3-5
D-76185 Karlsruhe
Germany

Telephone: +49 (0) 721 - 56 06 0

Telefax: +49 (0) 721 - 56 06 149

e-mail: sicherheit@carloth.de

Website: www.carloth.de

Competent person responsible for the safety data sheet: Department Health, Safety and Environment

e-mail (competent person): sicherheit@carloth.de

1.4 Emergency telephone number

| Name | Street | Postal code/city | Telephone | Website |
|---|-----------|----------------------|--------------|---------|
| National Poisons Information Service City Hospital | Dudley Rd | B187QH Birmingham | 844 892 0111 | |

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

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| Section | Hazard class | Cat-egory | Hazard class and category | Hazard statement |
|---------|---|-----------|---------------------------|------------------|
| 3.7 | Reproductive toxicity | 1B | Repr. 1B | H360D |
| 3.9 | Specific target organ toxicity - repeated exposure | 2 | STOT RE 2 | H373 |
| 4.1C | Hazardous to the aquatic environment - chronic hazard | 2 | Aquatic Chronic 2 | H411 |

For full text of abbreviations: see SECTION 16

The most important adverse physicochemical, human health and environmental effects

Delayed or immediate effects can be expected after short or long-term exposure. Spillage and fire wa-
ter can cause pollution of watercourses.

2.2 Label elements

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

Signal word

Danger

Pictograms

GHS08, GHS09



Hazard statements

H360D May damage the unborn child (if exposed)
H373 May cause damage to organs through prolonged or repeated exposure
H411 Toxic to aquatic life with long lasting effects

Precautionary statements

Precautionary statements - prevention

P273 Avoid release to the environment
P280 Wear protective gloves/eye protection/face protection

Precautionary statements - response

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

For professional users only

Labelling of packages where the contents do not exceed 125 ml

Signal word: **Danger**

Symbol(s)



H360D May damage the unborn child (if exposed).
P280 Wear protective gloves/eye protection/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.

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2.3 Other hazards

Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substances

| | |
|-------------------|------------------------|
| Name of substance | Betamethasone valerate |
| Molecular formula | $C_{27}H_{37}FO_6$ |
| Molar mass | 476,6 g/mol |
| CAS No | 2152-44-5 |
| EC No | 218-439-3 |

SECTION 4: First aid measures

4.1 Description of first aid measures



General notes

Take off contaminated clothing.

Following inhalation

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

Following skin contact

Rinse skin with water/shower.

Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

Following ingestion

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

none

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SECTION 5: Firefighting measures

5.1 Extinguishing media



Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings
water, foam, dry extinguishing powder, ABC-powder

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Combustible.

Hazardous combustion products

In case of fire may be liberated: Carbon monoxide (CO), Carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Do not allow firefighting water to enter drains or water courses. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

Use personal protective equipment as required. Avoid contact with skin, eyes and clothes. Do not breathe dust.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains. Take up mechanically.

Advice on how to clean up a spill

Take up mechanically. Control of dust.

Other information relating to spills and releases

Place in appropriate containers for disposal.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid exposure. Avoid dust formation.

Measures to prevent fire as well as aerosol and dust generation

Removal of dust deposits.

Measures to protect the environment

Avoid release to the environment.

Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place. Keep in a cool place.

Incompatible substances or mixtures

Observe hints for combined storage.

Consideration of other advice:

Ventilation requirements

Use local and general ventilation.

Specific designs for storage rooms or vessels

Recommended storage temperature: 2 – 8 °C

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

| Country | Name of agent | CAS No | Identifier | TWA [mg/m ³] | STEL [mg/m ³] | Ceiling-C [mg/m ³] | Notation | Source |
|---------|---------------|--------|------------|--------------------------|---------------------------|--------------------------------|----------|-----------|
| GB | dust | | WEL | 10 | | | i | EH40/2005 |
| GB | dust | | WEL | 4 | | | r | EH40/2005 |

Notation

Ceiling-C Ceiling value is a limit value above which exposure should not occur

i Inhalable fraction

r Respirable fraction

STEL Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

TWA Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

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8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection.

Skin protection



• hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 ° C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

• type of material

NBR (Nitrile rubber)

• material thickness

>0,11 mm

• breakthrough times of the glove material

>480 minutes (permeation: level 6)

• other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

Respiratory protection



Respiratory protection necessary at: Dust formation. Particulate filter device (EN 143). P2 (filters at least 94 % of airborne particles, colour code: White).

Environmental exposure controls

Keep away from drains, surface and ground water.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | |
|--|---|
| Physical state | solid |
| Form | powder |
| Colour | white |
| Odour | odourless |
| Melting point/freezing point | 192 - 196 °C |
| Boiling point or initial boiling point and boiling range | not determined |
| Flammability | this material is combustible, but will not ignite readily |
| Lower and upper explosion limit | not determined |
| Flash point | not applicable |
| Auto-ignition temperature | not determined |
| Decomposition temperature | not relevant |
| pH (value) | not applicable |
| Kinematic viscosity | not relevant |
| <u>Solubility(ies)</u> | |
| Water solubility | (poorly soluble (1 till < 10 mg/l)) |
| <u>Partition coefficient</u> | |
| Partition coefficient n-octanol/water (log value): | 3,6 (TOXNET) (Experimental data) |
| Vapour pressure | not determined |
| Density | not determined |
| Relative vapour density | information on this property is not available |
| Particle characteristics | No data available. |

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard classes: hazard classes acc. to GHS (physical hazards): not relevant

Other safety characteristics: There is no additional information.

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SECTION 10: Stability and reactivity

10.1 Reactivity

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

Violent reaction with: strong oxidiser

10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

10.5 Incompatible materials

There is no additional information.

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity

Shall not be classified as acutely toxic.

| Acute toxicity | | | | | |
|----------------|----------|--------------|---------|--------|--------|
| Exposure route | Endpoint | Value | Species | Method | Source |
| oral | LD50 | >3.000 mg/kg | rat | | TOXNET |

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

May damage the unborn child (if exposed).

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

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Specific target organ toxicity - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

| Hazard category | Target organ | Exposure route |
|-----------------|----------------|----------------|
| 2 | several organs | if exposed |

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

• If swallowed

Data are not available.

• If in eyes

Data are not available.

• If inhaled

Data are not available.

• If on skin

Data are not available.

• Other information

This information is based upon the present state of our knowledge. Substance not yet fully tested

11.2 Endocrine disrupting properties

Not listed.

11.3 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Toxic to aquatic life with long lasting effects.

Biodegradation

Data are not available.

12.2 Process of degradability

Theoretical Oxygen Demand: 2,216 mg/mg
Theoretical Carbon Dioxide: 2,493 mg/mg

12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

| | |
|---------------------------|----------------------------------|
| n-octanol/water (log KOW) | 3,6 (TOXNET) (Experimental data) |
|---------------------------|----------------------------------|

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

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12.6 Endocrine disrupting properties

Not listed.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used.

13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. Waste catalogue ordinance (Germany).

13.3 Remarks

Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities. Please consider the relevant national or regional provisions.

SECTION 14: Transport information

14.1 UN number or ID number

| | |
|-------------|---------|
| ADR/RID/ADN | UN 3077 |
| IMDG-Code | UN 3077 |
| ICAO-TI | UN 3077 |

14.2 UN proper shipping name

| | |
|----------------|--|
| ADR/RID/ADN | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
| IMDG-Code | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
| ICAO-TI | Environmentally hazardous substance, solid, n.o.s. |
| Technical name | Betamethasone valerate |

14.3 Transport hazard class(es)

| | |
|-------------|---|
| ADR/RID/ADN | 9 |
| IMDG-Code | 9 |
| ICAO-TI | 9 |

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14.4 Packing group

| | |
|-------------|-----|
| ADR/RID/ADN | III |
| IMDG-Code | III |
| ICAO-TI | III |

14.5 Environmental hazards

hazardous to the aquatic environment

14.6 Special precautions for user



Provisions for dangerous goods (ADR) should be complied within the premises.

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

14.8 Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information

| | |
|---|---|
| Proper shipping name | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
| Particulars in the transport document | UN3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., (Betamethasone valerate), 9, III, (-) |
| Classification code | M7 |
| Danger label(s) | 9, "Fish and tree" |
|   | |
| Environmental hazards | yes (hazardous to the aquatic environment) |
| Special provisions (SP) | 274, 335, 375, 601 |
| Excepted quantities (EQ) | E1 |
| Limited quantities (LQ) | 5 kg |
| Transport category (TC) | 3 |
| Tunnel restriction code (TRC) | - |
| Hazard identification No | 90 |
| Emergency Action Code | 2Z |

International Maritime Dangerous Goods Code (IMDG) - Additional information

| | |
|--|--|
| Proper shipping name | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
| Particulars in the shipper's declaration | UN3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., (Betamethasone valerate), 9, III |
| Marine pollutant | yes (hazardous to the aquatic environment), (Betamethasone valerate) |
| Danger label(s) | 9, "Fish and tree" |



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| | |
|--------------------------|-------------------------|
| Special provisions (SP) | 274, 335, 966, 967, 969 |
| Excepted quantities (EQ) | E1 |
| Limited quantities (LQ) | 5 kg |
| EmS | F-A, S-F |
| Stowage category | A |

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

| | |
|---|--|
| Proper shipping name | Environmentally hazardous substance, solid, n.o.s. |
| Particulars in the shipper's declaration | UN3077, Environmentally hazardous substance, solid, n.o.s., (Betamethasone valerate), 9, III |
| Environmental hazards | yes (hazardous to the aquatic environment) |
| Danger label(s) | 9, "Fish and tree" |
|  | |
| Special provisions (SP) | A97, A158, A179, A197, A215 |
| Excepted quantities (EQ) | E1 |
| Limited quantities (LQ) | 30 kg |

SECTION 15: Regulatory information

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

| Dangerous substances with restrictions (REACH, Annex XVII) | | | | |
|--|---|--------|-------------|----|
| Name of substance | Name acc. to inventory | CAS No | Restriction | No |
| Betamethasone valerate | substances in tattoo inks and permanent make-up | | R75 | 75 |

Legend

- R75 1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:
- (a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
 - (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
 - (c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
 - (d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:
 - (i) 0,1 % by weight, if the substance is used solely as a pH regulator;
 - (ii) 0,01 % by weight, in all other cases;
 - (e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
 - (f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:
 - (i) "Rinse-off products";
 - (ii) "Not to be used in products applied on mucous membranes";
 - (iii) "Not to be used in eye products";
 - (g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use

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Legend

preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column; (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.

2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.

3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:

(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);

(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

(a) the statement "Mixture for use in tattoos or permanent make-up";

(b) a reference number to uniquely identify the batch;

(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;

(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;

(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;

(g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.

8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list

Not listed.

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Seveso Directive

| 2012/18/EU (Seveso III) | | | |
|-------------------------|--|---|-------|
| No | Dangerous substance/hazard categories | Qualifying quantity (tonnes) for the application of lower and upper-tier requirements | Notes |
| E2 | environmental hazards (hazardous to the aquatic environment, cat. 2) | 200 500 | 57) |

Notation

57) Hazardous to the Aquatic Environment in category Chronic 2

Deco-Paint Directive

| | |
|-------------|-----|
| VOC content | 0 % |
|-------------|-----|

Industrial Emissions Directive (IED)

| | |
|-------------|-----|
| VOC content | 0 % |
|-------------|-----|

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

not listed

Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

not listed

Water Framework Directive (WFD)

| List of pollutants (WFD) | | | | |
|--------------------------|---|--------|-----------|---------|
| Name of substance | Name acc. to inventory | CAS No | Listed in | Remarks |
| Betamethasone valerate | Organohalogen compounds and substances which may form such compounds in the aquatic environment | | A) | |
| Betamethasone valerate | Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment | | A) | |

Legend

A) Indicative list of the main pollutants

Regulation on the marketing and use of explosives precursors

not listed

Regulation on drug precursors

not listed

Regulation on substances that deplete the ozone layer (ODS)

not listed

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article number: 1KN2

Regulation concerning the export and import of hazardous chemicals (PIC)

not listed

Regulation on persistent organic pollutants (POP)

not listed

National inventories

| Country | Inventory | Status |
|---------|-----------|---------------------|
| AU | AICS | substance is listed |
| CA | DSL | substance is listed |
| EU | ECSI | substance is listed |
| JP | CSCL-ENCS | substance is listed |
| NZ | NZIoC | substance is listed |
| PH | PICCS | substance is listed |
| TW | TCSI | substance is listed |

Legend

| | |
|-----------|---|
| AICS | Australian Inventory of Chemical Substances |
| CSCL-ENCS | List of Existing and New Chemical Substances (CSCL-ENCS) |
| DSL | Domestic Substances List (DSL) |
| ECSI | EC Substance Inventory (EINECS, ELINCS, NLP) |
| NZIoC | New Zealand Inventory of Chemicals |
| PICCS | Philippine Inventory of Chemicals and Chemical Substances (PICCS) |
| TCSI | Taiwan Chemical Substance Inventory |

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance.

SECTION 16: Other information

Abbreviations and acronyms

| Abbr. | Descriptions of used abbreviations |
|-------------|---|
| ADN | Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways) |
| ADR | Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road) |
| ADR/RID/ADN | European Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN) |
| CAS | Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances) |
| Ceiling-C | Ceiling value |
| CLP | Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures |
| DGR | Dangerous Goods Regulations (see IATA/DGR) |
| EC No | The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union) |
| EH40/2005 | EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-licence/) |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINCS | European List of Notified Chemical Substances |

Safety data sheet

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| Abbr. | Descriptions of used abbreviations |
|-----------|---|
| EmS | Emergency Schedule |
| GHS | "Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations |
| IATA | International Air Transport Association |
| IATA/DGR | Dangerous Goods Regulations (DGR) for the air transport (IATA) |
| ICAO | International Civil Aviation Organization |
| ICAO-TI | Technical instructions for the safe transport of dangerous goods by air |
| IMDG | International Maritime Dangerous Goods Code |
| IMDG-Code | International Maritime Dangerous Goods Code |
| LD50 | Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval |
| NLP | No-Longer Polymer |
| PBT | Persistent, Bioaccumulative and Toxic |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| RID | Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail) |
| STEL | Short-term exposure limit |
| SVHC | Substance of Very High Concern |
| TWA | Time-weighted average |
| VOC | Volatile Organic Compounds |
| vPvB | Very Persistent and very Bioaccumulative |
| WEL | Workplace exposure limit |

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

List of relevant phrases (code and full text as stated in chapter 2 and 3)

| Code | Text |
|-------|--|
| H360D | May damage the unborn child (if exposed). |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H411 | Toxic to aquatic life with long lasting effects. |

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.