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Safety data sheet according to 1907/2006/EC, Article 31

Printing date 22.10.2021 Version number 2.00 Revision: 22.10.2021

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

- · Product identifier
- · Trade name: Triamcinolone acetonide 2% with white petrolatum
- · Article number: 7296
- · Registration number The substance is exempt from REACH-registration.
- Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the mixture Ingredient for pharmaceutical drugs
- · Uses advised against No relevant information available.
- · Details of the supplier of the safety data sheet
- Manufacturer/Supplier:

CAELO

Caesar & Loretz GmbH

Herderstr. 31

D-40721 Hilden

GERMANY

· Further information obtainable from:

E-mail: info@caelo.de

Tel.: +49210349940 (during regular opening hours)

Emergency telephone number:

Poison Information Center Bonn Venusberg-Campus 1, 53127 Bonn

Tel: +49 (0) 228-192400

2 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Repr. 1A H360 May damage fertility or the unborn child.

- · Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms



GHS08

- · Signal word Danger
- · Hazard statements

H360 May damage fertility or the unborn child.

Precautionary statements

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

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P103	Read carefully and follow all instructions.	
P201	Obtain special instructions before use.	
P202	Do not handle until all safety precautions have been read and understood.	
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing	protection.
P308+P313	For the street is a second of the street is	
P405	Store locked up.	
P501	Dispose of contents/container in accordance with local/regional/national/internat	ional

· Other hazards

· Results of PBT and vPvB assessment

regulations.

PBT: Not applicable.vPvB: Not applicable.

3 Composition/information on ingredients

· Chemical characterisation: Mixtures

· **Description:** Mixture: consisting of the following components.

· Dangerous components:

CAS: 76-25-5 Triamcinolonacetonid EINECS: 200-948-7 Repr. 1A, H360

· Non-hazardous components CAS: 8009-03-8 Vaseline

4 First aid measures

- · Description of first aid measures
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: Generally the product does not irritate the skin.
- After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.
- Information for doctor:
- · Most important symptoms and effects, both acute and delayed

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- Extinguishing media
- · Suitable extinguishing agents:

All regular extinguishing media can be used.

Use fire extinguishing methods suitable to surrounding conditions.

Special hazards arising from the substance or mixture

Combustible but not oxidising. In case of fire dangerous vapours/gases can be generated: Smoke gases.

- Advice for firefighters
- · Protective equipment: In case of fire wear suitable protective clothes and respiratory protection.

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· Additional information

Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid contact with the substance.

- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- Methods and material for containment and cleaning up:

Take up dry. Clean up with water.

Dispose contaminated material as waste according to item 13.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

- · Handling:
- · Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Provide eye rinsing kit.

- · Information about fire and explosion protection: Keep ignition sources away Do not smoke.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:

Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).

- · Information about storage in one common storage facility: Store away from oxidising agents.
- · Further information about storage conditions: Protect from exposure to the light.
- · Storage class: TRHS 510: 6.1 C Combustible acutely toxic or chronic substances
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- Control parameters
- Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- Exposure controls
- Personal protective equipment:
- General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Store protective clothing separately.

- · Respiratory protection: Dust protection mask.
- Protection of hands: Protective gloves

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· Material of gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Safety glasses

· Body protection: Protective work clothing

9 Physical and chemical properties

Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Solid Colour: White

Odour: Nearly odourlessOdour threshold: Not determined.pH-value: Not applicable.

· Change in condition

Melting point/freezing point: 35-40 °C Initial boiling point and boiling range: Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gas): Product is not flammable.

Decomposition temperature: Not determined.Auto-ignition temperature: Not determined.

• **Explosive properties:** Product does not present an explosion hazard.

· Explosion limits:

Lower:
Upper:
Not determined.
Not determined.

Vapour pressure:
Not applicable.

Density:
Relative density
Vapour density
Vapour density
Evaporation rate
Not determined.
Not applicable.
Not applicable.

· Solubility in / Miscibility with

water: Soluble.

· Partition coefficient: n-octanol/water: Not determined.

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· Viscosity:

Dynamic: Not applicable. **Kinematic:** Not applicable.

Other information
 No further relevant information available.

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- Incompatible materials: Strong oxidizing agents
- Hazardous decomposition products:

Hydrohalogens

Halogenated hydrocarbons

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity

May damage fertility or the unborn child.

- · STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- $\cdot \ \textbf{Bioaccumulative potential} \ \ \text{No further relevant information available}.$
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

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Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to local regulations.

14 Transport information

· **UN-Number** Not subject to transport regulations.

ADR, IMDG, IATA not regulated

· UN proper shipping name

· ADR, IMDG, IATA not regulated

· Transport hazard class(es)

· ADR, ADN, IMDG, IATA

· Class not regulated

· Packing group

ADR, IMDG, IATA not regulated
 Environmental hazards: Not applicable.
 Special precautions for user Not applicable.

Transport in bulk according to Annex II of

Marpol and the IBC Code Not applicable.

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV) Not listed
- · REGULATION (EC) No 1907/2006 ANNEX XVII Not listed
- · National regulations:
- · Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)

TRHS 510: 6.1 C Combustible acutely toxic or chronic substances

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended.

- · Reasons for alterations This version replaces all old versions.
- Relevant phrases

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· Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Repr. 1A: Reproductive toxicity – Category 1A

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