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

Printing date 20.03.2023 Version number 1.00 Revision: 20.03.2023

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

· Product identifier

· Trade name: Triamcinolone acetonide, micronized, API

· Article number: 2705

· CAS Number:

76-25-5

· EC number:

200-948-7

- · 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 or active pharmaceutical ingredient.

- · 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 substance is classified and labelled according to the CLP regulation.

· Hazard pictograms



Signal word Danger



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· Hazard statements

H360 May damage fertility or the unborn child.

Precautionary statements

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 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Determination of endocrine-disrupting properties Not applicable.

3 Composition/information on ingredients

- · Substances
- · CAS No. Description

CAS: 76-25-5 Triamcinolonacetonid

- · Identification number(s)
- · EC number: 200-948-7

4 First aid measures

- · Description of first aid measures
- After inhalation:

Bring the person out of the contaminated area to fresh air.

Call a doctor immediately.

Show product-label or this MSDS.

· After skin contact:

Take off contaminated clothes and shoes, wash immediately with plenty of water and soap.

- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing:

Rinse mouth with plenty of water.

Do not induce vomiting; call for medical help immediately.

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.

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· 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.
- · 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

· Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Provide eye rinsing kit.

Information about fire - and explosion protection:

Dust can combine with air to form an explosive mixture.

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

- · Control parameters
- Ingredients with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists valid during the making were used as basis.
- Exposure controls
- · Appropriate engineering controls No further data; see item 7.
- · Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

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Wash hands before breaks and at the end of work.

- · Respiratory protection: Dust protection mask.
- Hand protection Protective gloves
- · 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

Rubber gloves

PVC gloves

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/face protection Tightly sealed goggles
- · Body protection: Protective work clothing

9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information

· Physical state Solid · Colour: White

Odour:
 Odour threshold:
 Melting point/freezing point:
 Nearly odourless
 Not determined.
 292–294 °C

· Boiling point or initial boiling point and boiling

range Undetermined.

· **Flammability** Product is not flammable.

· Lower and upper explosion limit

Lower: Not determined.
 Upper: Not determined.
 Flash point: Not applicable.
 Decomposition temperature: Not determined.
 pH Not applicable.

· Viscosity:

Kinematic viscosityDynamic:Not applicable.Not applicable.

· Solubility

water: Not determined.
 Partition coefficient n-octanol/water (log value)
 Vapour pressure: Not applicable.

· Density and/or relative density

Density: Not determined.
 Relative density Not determined.
 Vapour density Not applicable.
 Particle characteristics Not determined

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· Other information

Appearance:

· Form: Solid

Important information on protection of health and environment, and on safety.

· Auto-ignition temperature: Not determined.

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

· Change in condition

• Evaporation rate Not applicable.

Information with regard to physical hazard

classes

· Explosives Void Void

· Flammable gases Void

Void · Aerosols Void

Void

· Oxidising gases Void Void

· Gases under pressure Void Void

· Flammable liquids Void

Void · Flammable solids Void

Void Self-reactive substances and mixtures Void

Void · Pyrophoric liquids Void

· **Pyrophoric solids** Void

Void • Self-heating substances and mixtures Void

Void

· Substances and mixtures, which emit flammable

gases in contact with water Void Void

· Oxidising liquids Void Void

· Oxidising solids Void Void

· Organic peroxides Void

· Corrosive to metals Void

Void
Desensitised explosives
Void
Void

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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 Reacts with oxidising agents.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: Hydrohalogens

11 Toxicological information

- Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.
- LD/LC50 values relevant for classification:

Oral LD50 5,000 mg/kg (mouse)

LD50 (i.p.) 105 mg/kg (mouse)

Skin corrosion/irritation

May cause skin irritation.

Based on available data, the classification criteria are not met.

· Serious eye damage/irritation

Slight irritation.

Based on available data, the classification criteria are not met.

· Respiratory or skin sensitisation

Can have a sensitizing effect.

Based on available data, the classification criteria are not met.

- · 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.
- · Information on other hazards
- · Endocrine disrupting properties

On the basis of the available data, the substance does not meet the criteria for the identification of substances having properties of interference with the endocrine system, in accordance with Article 59, paragraph 1 of the REACH Regulation and the criteria established in the Delegated Regulation (EU) 2017 / 2100 of the Commission or in Commission Regulation (EU) 2018/605.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.

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- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · Endocrine disrupting properties

Based on the available data, the substance does not meet the criteria for the identification of substances with properties affecting the endocrine system according to Article 59(1) of the REACH Regulation and the criteria of the Commission Delegated Regulation (EU) 2017/2100 or in the Commission Regulation (EU) 2018/605.

- · Other adverse effects
- Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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 or ID 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.

Maritime transport in bulk according to IMO

instruments Not applicable.

'UN "Model Regulation": not regulated

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

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DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

Substance is 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.
- · Date of previous version: 20.03.2023
- 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

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

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Repr. 1A: Reproductive toxicity - Category 1A

* Data compared to the previous version altered.

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