

OTTO CHEMIE PVT LTD

An ISO 9001 : 2015 & GMP Certified Company
101, Aarkay Ruby Industrial Estate (1B), Opp Shree Narayan Industrial Estate,
Chinchpada, Vasai East, Waliv, Maharashtra 401208. Tel : + 91 98200 41841
Email : info@ottokemi.com Web : www.ottokemi.com

MATERIAL SAFETY DATA SHEET (MSDS)

SECTION 1. Product identifiers

Product name: Hydrocortisone acetate, puriss, 99%
Product Code: H 1528
CAS No : 50-03-3

1.2. Relevant identified uses of the substance or mixture and uses advised against
Use : Industrial. For professional use only.

1.3. Details of the supplier of the safety data sheet

Company identification
OTTO CHEMIE PVT LTD
101, Aarkay Ruby Industrial Estate(1B), Opp Shree Narayan Industrial Estate,
Chinchpada, Vasai East, Waliv, Maharashtra 401208.
Email info@ottokemi.com

1.4. Emergency telephone number

Phone no. : + 91 22 2207 0099 (9:00am - 6:00 pm)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Reproductive toxicity, (Category 1B)

Specific target organ toxicity - repeated exposure, (Category 2)

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram

Signal Word

Hazard Statements

H360Df

H373

Precautionary Statements

P202

P260

P280

P308 + P313

P405

P501

Supplemental Hazard Statements

Reduced Labeling (<= 125 ml)

Pictogram

Signal Word

Hazard Statements

H360Df

Precautionary Statements

P202

P280

P308 + P313

P405

P501

H360Df: May damage the unborn child.

Suspected of damaging fertility.

H373: May cause damage to organs through prolonged or repeated exposure.

Danger

May damage the unborn child. Suspected of damaging fertility. May cause damage to organs through prolonged or repeated exposure.

Do not handle until all safety precautions have been read and understood.

Do not breathe dust.

Wear protective gloves/ protective clothing/ eye protection/ face protection.

IF exposed or concerned: Get medical advice/ attention.

Store locked up.

Dispose of contents/ container to an approved waste disposal plant.

none

Danger

May damage the unborn child. Suspected of damaging fertility.

Do not handle until all safety precautions have been read and understood.

Wear protective gloves/ protective clothing/ eye protection/ face protection.

IF exposed or concerned: Get medical advice/ attention.

Store locked up.

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Supplemental Hazard Statements none

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.

Ecological information:

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information:

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Caution: Physiologically highly active, therapeutically usable substance. The substance must be handled with the care required for hazardous materials.

SECTION 3: Composition/information on ingredients

3.1 Substances

Synonyms : 4-Pregnene-11 β ,17 α ,21-triol-3,20-dione 21-acetate
11 β ,17 α ,21-Trihydroxy-4-pregnene-3,20-dione 21-acetate
17-Hydroxycorticosterone 21-acetate
21-Acetoxy-4-pregnene-11 β ,17 α -diol-3,20-dione
17- α -Hydroxycorticosterone acetate

Formula : C₂₃H₃₂O₆
Molecular weight : 404,50 g/mol
CAS-No. : 50-03-3
EC-No. : 200-004-4

| Component | Classification | Concentration |
|-------------------------------------|-----------------------------------|---------------|
| Hydrocortisone 21-acetate | | |
| CAS-No. 50-03-3 EC-No. 200-004-4 | Repr. 1B; STOT RE 2; H360Df, H373 | <= 100 % |

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of first-aid measures

General advice

Show this material safety data sheet to the doctor in attendance.

If inhaled

After inhalation: fresh air. Call in physician.

In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower. Consult a physician.

In case of eye contact

After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

If swallowed

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water Foam Carbon dioxide (CO₂) Dry powder

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Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Carbon oxides

Combustible.

Development of hazardous combustion gases or vapours possible in the event of fire.

5.3 Advice for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

5.4 Further information

Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up carefully. Dispose of properly. Clean up affected area. Avoid generation of dusts.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Work under hood. Do not inhale substance/mixture.

Hygiene measures

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed. Dry. Keep in a well-ventilated place. Keep locked up or in an area accessible only to qualified or authorized persons.

Storage class

Storage class (TRGS 510): 6.1C: Combustible, acute toxic Cat.3 / toxic compounds or compounds which causing chronic effects

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

8.2 Exposure controls

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

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Full contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail

sales@kcl.de, test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the EC approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

protective clothing

Respiratory protection

required when dusts are generated.

Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.

Recommended Filter type: Filter type P3

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer.

These measures have to be properly documented.

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | |
|---|--|
| a) Physical state | powder |
| b) Color | white |
| c) Odor | No data available |
| d) Melting point/freezing point | Melting point/range: 223 °C - dec. |
| e) Initial boiling point and boiling range | No data available |
| f) Flammability (solid, gas) | No data available |
| g) Upper/lower flammability or explosive limits | No data available |
| h) Flash point | Not applicable |
| i) Autoignition temperature | No data available |
| j) Decomposition temperature | No data available |
| k) pH | No data available |
| l) Viscosity | Viscosity, kinematic: No data available Viscosity, dynamic: No data available |
| m) Water solubility | No data available |
| n) Partition coefficient: n-octanol/water | No data available |
| o) Vapor pressure | No data available |
| p) Density | No data available |
| Relative density | No data available |
| q) Relative vapor | No data available |

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density
r) Particle characteristics No data available
s) Explosive properties No data available
t) Oxidizing properties none
9.2 Other safety information
No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

Avoid moisture.

no information available

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Routes of Entry: Absorbed through skin. Dermal contact. Eye contact. Toxicity to Animals:

Oral LD50 Rat: 1500 mg/kg; Dermal LD50 Rabbit: 2000mg/kg

Inhalation LC50 Rat: > 50mg/L.

Chronic Effects on Humans: CARCINOGENIC EFFECTS: Classified None. by NTP, None. by OSHA, None. by NIOSH.

Other Toxic Effects on Humans: Hazardous in case of skin contact (irritant), of inhalation (lung irritant).

Special Remarks on Toxicity

to Animals: Not available.

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans: Not available.

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to bacteria

12.2 Persistence and degradability

Biodegradability aerobic - Exposure time 28 d

Result: > 70 % - Readily biodegradable.

(OECD Test Guideline 301B)

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB 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 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

No data available

SECTION 14: Transport information

14.1 UN number

ADR/RID: -

IMDG: -

IATA: -

14.2 UN proper shipping name

ADR/RID : Not dangerous goods

IMDG : Not dangerous goods

IATA : Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: -

IMDG: -

IATA: -

14.4 Packaging group

ADR/RID: -

IMDG: -

IATA: -

14.5 Environmental hazards

ADR/RID: no

IMDG Marine pollutant: no

IATA: no

14.6 Special precautions for user

No data available

Further information

Not classified as dangerous in the meaning of transport regulations.

SECTION 15: Regulatory information

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Authorisations and/or restrictions on use

Other regulations

Observe work restrictions regarding maternity protection in accordance to Dir 92/85/EEC or stricter national regulations where applicable.

Take note of Dir 94/33/EC on the protection of young people at work.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other Information

This safety data sheet should be used in conjunction with technical sheets. It does not replace them. The information given is based on our knowledge of this product, at the time of publication. It is given in good faith. The attention of the user is drawn to the possible risks incurred by using the product for any other purpose other than that for which it was intended. This does not in any way excuse the user from knowing and applying all the regulations governing his activity. It is the sole responsibility of the user to take all precautions required in handling the product. The aim of the mandatory regulations mentioned is to help the user to fulfill his obligations regarding the use of hazardous products.

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