

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

#### 1.1. Product identifier

|                |   |
|----------------|---|
| Product form   | : Substance   |
| Substance name | : Fludrocortisone acetate   |
| Chemical name  | : 9-Fluoro-11beta,17-dihydroxy-3,20-dioxopregn-4-en-21-yl acetate |
| Product code   | : 201600392   |

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

##### 1.2.1. Relevant identified uses

|                              |  |
|------------------------------|--|
| Main use category            | : The product is intended for research, analysis and scientific education. |
| Use of the substance/mixture | : For professional use only  |
| Function or use category     | : Laboratory chemicals   |

##### 1.2.2. Uses advised against

|                     |  |
|---------------------|--|
| Restrictions on use | : Do not use : Ingestion, Inhalation, Dermal |
|---------------------|--|

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

European Directorate for the Quality of Medicines & Healthcare  
EDQM, Council of Europe 7, Allée Kastner, CS30026  
F- 67081 Strasbourg  
France  
T +33(0)388412035 - F +33(0)388412771  
[sds@edqm.eu](mailto:sds@edqm.eu) - [www.edqm.eu](http://www.edqm.eu)

#### 1.4. Emergency telephone number

|                  |                   |
|------------------|-------------------|
| Emergency number | : +33(0)390215608 |
|------------------|-------------------|

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

|  |      |
|--|------|
| Reproductive toxicity, Category 1B                             | H360 |
| Specific target organ toxicity – Repeated exposure, Category 1 | H372 |
| Full text of H- and EUH-statements: see section 16             |      |

##### Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS08

|                                |  |
|--------------------------------|--|
| Signal word (CLP)              | : Danger   |
| Hazard statements (CLP)        | : H360 - May damage fertility or the unborn child.<br>H372 - Causes damage to organs (endocrine system) through prolonged or repeated exposure.  |
| Precautionary statements (CLP) | : P201 - Obtain special instructions before use.<br>P202 - Do not handle until all safety precautions have been read and understood.<br>P260 - Do not breathe dust.<br>P264 - Wash hands, forearms and face thoroughly after handling.<br>P270 - Do not eat, drink or smoke when using this product. |

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P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
P314 - Get medical advice/attention if you feel unwell.  
P405 - Store locked up.  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

Hazard pictograms (CLP) :



GHS08

### 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

| Name  | Product identifier | %     | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---|--------------------|-------|---|
| 9-Fluoro-11beta,17-dihydroxy-3,20-dioxopregn-4-en-21-yl acetate | -                  | ≤ 100 | Repr. 1B, H360<br>STOT RE 1, H372                               |

Full text of H- and EUH-statements: see section 16

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation : Move to fresh air. Allow affected person to breathe fresh air.  
First-aid measures after skin contact : Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of water and detergent.  
First-aid measures after eye contact : Rinse with water while holding the eyes wide open.  
First-aid measures after ingestion : Rinse mouth. Specific medical surveillance. Prolonged medical observation may be indicated.

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

Symptoms/effects : Delayed adverse effects possible.  
Symptoms/effects after inhalation : Insufficient data available.  
Symptoms/effects after skin contact : Insufficient data available.  
Symptoms/effects after eye contact : Insufficient data available.  
Symptoms/effects after ingestion : Symptoms may include dizziness, headache, nausea and loss of coordination.

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

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active substance. Pharmaceutical.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Extinguishing blanket.

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

Fire hazard : See Heading 2.2.

### 5.3. Advice for firefighters

Firefighting instructions : Use extinguishing media appropriate for surrounding fire.

## SECTION 6: Accidental release measures

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

General measures : Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.

#### 6.1.1. For non-emergency personnel

Emergency procedures : Wear suitable protective clothing, gloves and eye or face protection.

#### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

No additional information available

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

Methods for cleaning up : Ensure waste is collected and contained. Clean thoroughly. Wash the non-recoverable remainder with : Sodium hypochlorite solution.

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Additional hazards when processed : The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended.

Precautions for safe handling : Material should be handled with caution. Avoid any direct contact with the product. Material should be handled in a laboratory hood whenever possible.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures.

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

Technical measures : Comply with applicable regulations.

Storage conditions : Store locked up.

### 7.3. Specific end use(s)

See Heading 1.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

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### 8.1.4. DNEL and PNEC

No additional information available

### 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

##### Eye protection:

Safety glasses. DIN EN 166

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Use chemically protective clothing. DIN EN 13034

##### Hand protection:

Chemically resistant protective gloves. ISO 374-1

#### 8.2.2.3. Respiratory protection

##### Respiratory protection:

Dust production: dust mask with filter type P3. DIN EN 140 & 149. Liquid product : Aerosol mask. Wear breathing apparatus if exposed to vapours/dusts/aerosols

#### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

No additional information available

## SECTION 9: Physical and chemical properties

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

|   |                    |
|---|--------------------|
| Physical state                                  | : Solid            |
| Colour  | : Not available    |
| Appearance                                      | : Powder.          |
| Odour   | : Not applicable.  |
| Odour threshold                                 | : Not available    |
| Melting point                                   | : Not available    |
| Freezing point                                  | : Not available    |
| Boiling point                                   | : Not available    |
| Flammability                                    | : Not available    |
| Explosive limits                                | : Not applicable   |
| Lower explosion limit                           | : Not applicable   |
| Upper explosion limit                           | : Not applicable   |
| Flash point                                     | : Not applicable   |
| Auto-ignition temperature                       | : Not applicable   |
| Decomposition temperature                       | : Not available    |
| pH  | : Not available    |
| pH solution                                     | : Not available    |
| Viscosity, kinematic                            | : Not applicable   |
| Solubility                                      | : Water: < 0,1 g/l |
| Partition coefficient n-octanol/water (Log Kow) | : Not available    |
| Vapour pressure                                 | : Not available    |
| Vapour pressure at 50°C                         | : Not available    |
| Density   | : Not available    |

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|                                 |                  |
|---------------------------------|------------------|
| Relative density                | : Not available  |
| Relative vapour density at 20°C | : Not applicable |
| Particle size                   | : Not available  |

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Stable under normal conditions.

### 10.2. Chemical stability

No additional information available

### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

None under normal use. See Section 7.

### 10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

## SECTION 11: Toxicological information

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

|                             |                                      |
|-----------------------------|--------------------------------------|
| Acute toxicity (oral)       | : Not classified (Inconclusive data) |
| Acute toxicity (dermal)     | : Not classified (Lack of data)      |
| Acute toxicity (inhalation) | : Not classified (Lack of data)      |

#### 9-Fluoro-11beta,17-dihydroxy-3,20-dioxopregn-4-en-21-yl acetate

|               |              |
|---------------|--------------|
| LD50 oral rat | > 1000 mg/kg |
|---------------|--------------|

|                                   |  |
|-----------------------------------|--|
| Skin corrosion/irritation         | : Not classified (Lack of data)  |
| Serious eye damage/irritation     | : Not classified (Lack of data)  |
| Respiratory or skin sensitisation | : Not classified (Lack of data)  |
| Germ cell mutagenicity            | : Not classified (Lack of data)  |
| Carcinogenicity                   | : Not classified (Lack of data)  |
| Reproductive toxicity             | : May damage fertility or the unborn child.  |
| STOT-single exposure              | : Not classified (Lack of data)  |
| STOT-repeated exposure            | : Causes damage to organs (endocrine system) through prolonged or repeated exposure. |
| Aspiration hazard                 | : Not classified (Technical impossibility to obtain the data)                        |

### 11.2. Information on other hazards

No additional information available

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### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general : Hazardous waste. Use suitable disposal containers.  
Hazardous to the aquatic environment, short-term (acute) : Not classified (Lack of data)  
Hazardous to the aquatic environment, long-term (chronic) : Not classified (Lack of data)

#### 12.2. Persistence and degradability

No additional information available

#### 12.3. Bioaccumulative potential

No additional information available

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Results of PBT and vPvB assessment

No additional information available

#### 12.6. Endocrine disrupting properties

No additional information available

#### 12.7. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

### SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

| ADR                                     | IMDG           | IATA           |
|---|----------------|----------------|
| <b>14.1. UN number or ID number</b>     |                |                |
| Not applicable                          | Not applicable | Not applicable |
| <b>14.2. UN proper shipping name</b>    |                |                |
| Not applicable                          | Not applicable | Not applicable |
| <b>14.3. Transport hazard class(es)</b> |                |                |
| Not applicable                          | Not applicable | Not applicable |
| <b>14.4. Packing group</b>              |                |                |
| Not applicable                          | Not applicable | Not applicable |
| <b>14.5. Environmental hazards</b>      |                |                |
| Not applicable                          | Not applicable | Not applicable |
| No supplementary information available  |                |                |

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### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not applicable

#### Air transport

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

##### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

##### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

##### PIC Regulation (Prior Informed Consent)

Not applicable.

##### POP Regulation (Persistent Organic Pollutants)

Not applicable.

##### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

##### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

##### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

### Indication of changes

| Section | Changed item          | Change | Comments |
|---------|-----------------------|--------|----------|
|         | Supersedes version of | Added  |          |
|         | Revision date         | Added  |          |

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| Indication of changes |   |          |          |
|-----------------------|---|----------|----------|
| Section               | Changed item  | Change   | Comments |
| 2.1                   | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Modified |          |
| 2.2                   | Hazard statements (CLP)   | Modified |          |
| 4.2                   | Symptoms/effects after ingestion                                | Added    |          |
| 11.1                  | Reason for no classification                                    | Added    |          |
| 11.1                  | LD50 oral rat   | Modified |          |
| 12.1                  | Reason for no classification                                    | Added    |          |

| Full text of H- and EUH-statements: |   |
|-------------------------------------|---|
| H360                                | May damage fertility or the unborn child.                       |
| H372                                | Causes damage to organs through prolonged or repeated exposure. |
| Repr. 1B                            | Reproductive toxicity, Category 1B                              |
| STOT RE 1                           | Specific target organ toxicity – Repeated exposure, Category 1  |

Safety Data Sheet (SDS), EU

**DISCLAIMER OF LIABILITY** The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.