

Fusidic acid

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: :

Version: 1.0

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

1.1. Product identifier

Product form : Substance
Substance name : Fusidic acid
Chemical name : Acid (ent)-16a acetoxy-3b,11b-dihydroxy-4b,8b,14a-trimethyl-18-nor-5b,10a-cholesta-(17Z)-17(20),24-dien-21-oic acid hemihydrate
CAS No : 6990-06-3
Product code : 1428144
Formula : C₃₁H₄₈O₆, ½ H₂O
Product group : Raw material

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : Industrial
For professional use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Duchefa FARMA BV
A. Hofmanweg 71
2031BH Haarlem - Netherlands
T +31(0)23-5319093 - F +31(0)23-5318027
info@duchefa.com - www.duchefa.com

1.4. Emergency telephone number

| Country | Organisation/Company | Address | Emergency number |
|----------------|---|---------------------------------|------------------|
| UNITED KINGDOM | Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust | Avonley Road SE14 5ER London | 0870 243 2241 |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

Fusidic acid

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substance

Name : Fusidic acid

CAS No : 6990-06-3

| Name | Product identifier | % | Classification according to Directive 67/548/EEC |
|------------------------------------|--------------------|-----|--|
| Fusidic acid (Main constituent) | (CAS No) 6990-06-3 | 100 | Not classified |

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|------------------------------------|--------------------|-----|---|
| Fusidic acid (Main constituent) | (CAS No) 6990-06-3 | 100 | Not classified |

Full text of R- and H-phrases: see section 16

3.2. Mixture

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|---|
| First-aid measures general | : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). |
| First-aid measures after inhalation | : Assure fresh air breathing. Allow the victim to rest. |
| First-aid measures after skin contact | : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. |
| First-aid measures after eye contact | : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist. |
| First-aid measures after ingestion | : Rinse mouth. Ingestion. to be avoided. Swallowing small amounts is not likely to cause any damage. |

Fusidic acid

Safety Data Sheet

according to Regulation (EC) No. 453/2010

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

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Explosion hazard : Explosive.

Hazardous decomposition products in case of fire : Toxic and irritating gases are released.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with substance.

6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection. See Heading 13. Disposal considerations.

Fusidic acid

Safety Data Sheet

according to Regulation (EC) No. 453/2010

SECTION 7: Handling and storage

7.1. Precautions for safe handling

| | |
|-------------------------------|--|
| Precautions for safe handling | : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. |
| Handling temperature | : 2 - 8 °C |
| Hygiene measures | : Wash contaminated clothing before reuse. |

7.2. Conditions for safe storage, including any incompatibilities

| | |
|------------------------|---|
| Technical measures | : Proper grounding procedures to avoid static electricity should be followed. |
| Storage conditions | : Keep only in the original container in a cool, well ventilated place away from : Heat sources. Keep container closed when not in use. |
| Incompatible products | : Strong bases. Strong acids. |
| Incompatible materials | : Sources of ignition. Direct sunlight. |
| Storage temperature | : 2 - 8 °C |

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

| | |
|-------------------------------|--|
| Personal protective equipment | : Avoid all unnecessary exposure. |
| Hand protection | : Wear protective gloves. |
| Eye protection | : Chemical goggles or safety glasses. |
| Respiratory protection | : Wear appropriate mask. |
| Other information | : Do not eat, drink or smoke during use. |

Fusidic acid

Safety Data Sheet

according to Regulation (EC) No. 453/2010

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|---|
| Physical state | : Solid |
| Appearance | : Crystalline powder. |
| Molecular mass | : 525,7 g/mol |
| Colour | : White to off-white. |
| Odour | : characteristic. |
| Odour threshold | : No data available |
| pH | : 4,77 - 4,82 in water |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point | : No data available |
| Freezing point | : No data available |
| Boiling point | : No data available |
| Flash point | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Flammability (solid, gas) | : Non flammable |
| Vapour pressure | : No data available |
| Relative vapour density at 20 °C | : No data available |
| Relative density | : No data available |
| Solubility | : Insoluble in water. Soluble in ethanol. |
| Log Pow | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosive properties | : No data available |
| Oxidising properties | : No data available |
| Explosive limits | : No data available |

9.2. Other information

No additional information available

Fusidic acid

Safety Data Sheet

according to Regulation (EC) No. 453/2010

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Moisture. Heat. Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

At high temperatures : release of (highly) toxic gases/vapours. fume. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

| Fusidic acid(6990-06-3) | | |
|-------------------------|--|----------------|
| LD50 oral | | 1,5 g/kg mouse |

| | |
|--|--|
| Skin corrosion/irritation | : Not classified Based on available data, the classification criteria are not met pH: 4,77 - 4,82 in water |
| Serious eye damage/irritation | : Not classified Based on available data, the classification criteria are not met pH: 4,77 - 4,82 in water |
| Respiratory or skin sensitisation | : Not classified Based on available data, the classification criteria are not met |
| Germ cell mutagenicity | : Not classified Based on available data, the classification criteria are not met |
| Carcinogenicity | : Not classified Based on available data, the classification criteria are not met |
| Reproductive toxicity | : Not classified Based on available data, the classification criteria are not met |
| Specific target organ toxicity (single exposure) | : Not classified Based on available data, the classification criteria are not met |
| Specific target organ toxicity (repeated exposure) | : Not classified Based on available data, the classification criteria are not met |

Fusidic acid

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Aspiration hazard : Not classified
Based on available data, the classification criteria are not met

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

| Fusidic acid(6990-06-3) | |
|-------------------------------|------------------|
| Persistence and degradability | Not established. |

12.3. Bioaccumulative potential

| Fusidic acid(6990-06-3) | |
|---------------------------|------------------|
| Bioaccumulative potential | Not established. |

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

| Fusidic acid(6990-06-3) | |
|--|--|
| This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII | |
| This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII | |

12.6. Other adverse effects

: Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

Fusidic acid

Safety Data Sheet

according to Regulation (EC) No. 453/2010

14.2. UN proper shipping name

| | |
|-----------------------------|------------------|
| Proper Shipping Name (ADR) | : Not applicable |
| Proper Shipping Name (IMDG) | : Not applicable |
| Proper Shipping Name (IATA) | : Not applicable |
| Proper Shipping Name (ADN) | : Not applicable |
| Proper Shipping Name (RID) | : Not applicable |

14.3. Transport hazard class(es)

ADR

| | |
|----------------------------------|------------------|
| Transport hazard class(es) (ADR) | : Not applicable |
|----------------------------------|------------------|

IMDG

| | |
|-----------------------------------|------------------|
| Transport hazard class(es) (IMDG) | : Not applicable |
|-----------------------------------|------------------|

IATA

| | |
|-----------------------------------|------------------|
| Transport hazard class(es) (IATA) | : Not applicable |
|-----------------------------------|------------------|

ADN

| | |
|----------------------------------|------------------|
| Transport hazard class(es) (ADN) | : Not applicable |
|----------------------------------|------------------|

RID

| | |
|----------------------------------|------------------|
| Transport hazard class(es) (RID) | : Not applicable |
|----------------------------------|------------------|

14.4. Packing group

| | |
|----------------------|------------------|
| Packing group (ADR) | : Not applicable |
| Packing group (IMDG) | : Not applicable |
| Packing group (IATA) | : Not applicable |
| Packing group (ADN) | : Not applicable |
| Packing group (RID) | : Not applicable |

14.5. Environmental hazards

| | |
|-------------------------------|--|
| Dangerous for the environment | : No |
| Marine pollutant | : No |
| Other information | : No supplementary information available |

14.6. Special precautions for user

14.6.1. Overland transport

14.6.2. Transport by sea

14.6.3. Air transport

14.6.4. Inland waterway transport

| | |
|---------------------------|------|
| Carriage prohibited (ADN) | : No |
| Not subject to ADN | : No |

14.6.5. Rail transport

| | |
|---------------------------|------|
| Carriage prohibited (RID) | : No |
|---------------------------|------|

Fusidic acid

Safety Data Sheet

according to Regulation (EC) No. 453/2010

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

No REACH Annex XVII restrictions

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

| | |
|-------------------|--|
| Data sources | : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. |
| Other information | : DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. REACH Disclaimer: This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number). None. |

SDS EU (REACH Annex II) Duchefa

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product