

SAFETY DATA SHEET

Version 4.10
Revision Date 09/23/2016
Print Date 11/07/2018

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product name : Misoprostol

Product Number : M6807

Brand : Sigma

CAS-No. : 59122-46-2

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

Identified uses : Laboratory chemicals, Synthesis of substances

1.3 Details of the supplier of the safety data sheet

Company : Sigma-Aldrich
3050 Spruce Street
SAINT LOUIS MO 63103
USA

Telephone : +1 800-325-5832

Fax : +1 800-325-5052

1.4 Emergency telephone number

Emergency Phone # : +1-703-527-3887 (CHEMTREC)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Acute toxicity, Oral (Category 3), H301

Reproductive toxicity (Category 1B), H360

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

2.2 GHS Label elements, including precautionary statements

Pictogram



Signal word : Danger

Hazard statement(s)

H301

Toxic if swallowed.

H360

May damage fertility or the unborn child.

Precautionary statement(s)

P201

Obtain special instructions before use.

P202

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

P264

Wash skin thoroughly after handling.

P270

Do not eat, drink or smoke when using this product.

P280

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

P301 + P310 + P330

IF SWALLOWED: Immediately call a POISON CENTER/doctor. Rinse mouth.

P308 + P313
P405
P501

IF exposed or concerned: Get medical advice/ attention.
Store locked up.
Dispose of contents/ container to an approved waste disposal plant.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Synonyms : (±)-15-Deoxy-(16RS)-16-hydroxy-16-methylprostaglandin E₁ methyl ester

Formula : C₂₂H₃₈O₅

Molecular weight : 382.53 g/mol

CAS-No. : 59122-46-2

Hazardous components

Component	Classification	Concentration
Misoprostol		
	Acute Tox. 3; Repr. 1B; H301, H360	<= 100 %
Ethyl acetate		
	Flam. Liq. 2; Eye Irrit. 2A; STOT SE 3; H225, H319, H336	>= 1 - < 5 %

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

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. 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

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

No data available

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear respiratory protection. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Recommended storage temperature -20 °C

7.3 Specific end use(s)

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

Component	CAS-No.	Value	Control parameters	Basis
Ethyl acetate	141-78-6	TWA	400.000000 ppm	USA. ACGIH Threshold Limit Values (TLV)
	Remarks	Upper Respiratory Tract irritation Eye irritation		
		TWA	400.000000 ppm 1,400.000000 mg/m3	USA. NIOSH Recommended Exposure Limits
		TWA	400.000000 ppm 1,400.000000 mg/m3	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		The value in mg/m3 is approximate.		
		TWA	400 ppm	USA. ACGIH Threshold Limit Values (TLV)
		Upper Respiratory Tract irritation Eye irritation		

		TWA	400 ppm 1,400 mg/m ³	USA. NIOSH Recommended Exposure Limits
		TWA	400 ppm 1,400 mg/m ³	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
		The value in mg/m ³ is approximate.		
		PEL	400 ppm 1,400 mg/m ³	California permissible exposure limits for chemical contaminants (Title 8, Article 107)

Hazardous components without workplace control parameters

8.2 Exposure controls

Appropriate engineering controls

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Personal protective equipment

Eye/face protection

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

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.

Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- | | |
|---|--|
| a) Appearance | Form: viscous liquid
Colour: yellow |
| b) Odour | No data available |
| c) Odour Threshold | No data available |
| d) pH | No data available |
| e) Melting point/freezing point | No data available |
| f) Initial boiling point and boiling range | No data available |
| g) Flash point | No data available |
| h) Evaporation rate | No data available |
| i) Flammability (solid, gas) | No data available |
| j) Upper/lower flammability or explosive limits | No data available |
| k) Vapour pressure | No data available |

l) Vapour density	No data available
m) Relative density	No data available
n) Water solubility	No data available
o) Partition coefficient: n-octanol/water	No data available
p) Auto-ignition temperature	No data available
q) Decomposition temperature	No data available
r) Viscosity	No data available
s) Explosive properties	No data available
t) Oxidizing properties	No data available

9.2 Other safety information

No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

Other decomposition products - No data available

Hazardous decomposition products formed under fire conditions. - Nature of decomposition products not known.

In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - 81 mg/kg

LD50 Oral - Mouse - 27 mg/kg

LD50 Oral - Rat - 81 mg/kg (Misoprostol)

LD50 Oral - Mouse - 27 mg/kg (Misoprostol)

Inhalation: No data available

Inhalation: No data available (Misoprostol)

Dermal: No data available

Dermal: No data available

Dermal: No data available (Misoprostol)

No data available

LD50 Intraperitoneal - Rat - 40 mg/kg

LD50 Intramuscular - Rat - 19 mg/kg

LD50 Intraperitoneal - Rat - 40 mg/kg (Misoprostol)

LD50 Intramuscular - Rat - 19 mg/kg (Misoprostol)

Skin corrosion/irritation

No data available

No data available

No data available (Misoprostol)

Serious eye damage/eye irritation

No data available

No data available

No data available (Misoprostol)

Respiratory or skin sensitisation

No data available

No data available

No data available (Misoprostol)

Germ cell mutagenicity

No data available

No data available

No data available (Misoprostol)

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

No data available

Presumed human reproductive toxicant May cause congenital malformation in the fetus.

No data available

Presumed human reproductive toxicant May cause congenital malformation in the fetus. (Misoprostol)

No data available (Misoprostol)

Reproductive toxicity - Rat - Oral

Effects on Fertility: Pre-implantation mortality (e.g., reduction in number of implants per female; total number of implants per corpora lutea). Effects on Fertility: Litter size (e.g.; # fetuses per litter; measured before birth).

Reproductive toxicity - Rat - Oral

Effects on Newborn: Growth statistics (e.g., reduced weight gain).

Reproductive toxicity - Mouse - Oral

Effects on Fertility: Female fertility index (e.g., # females pregnant per # sperm positive females; # females pregnant per # females mated).

Reproductive toxicity - Mouse - Subcutaneous

Effects on Fertility: Female fertility index (e.g., # females pregnant per # sperm positive females; # females pregnant per # females mated).

Reproductive toxicity - Rabbit - Oral

Maternal Effects: Uterus, cervix, vagina.

Reproductive toxicity - Rat - Oral

Effects on Fertility: Pre-implantation mortality (e.g., reduction in number of implants per female; total number of implants per corpora lutea). Effects on Fertility: Litter size (e.g., # fetuses per litter; measured before birth). (Misoprostol)

Reproductive toxicity - Rat - Oral

Effects on Newborn: Growth statistics (e.g., reduced weight gain). (Misoprostol)

Reproductive toxicity - Mouse - Oral

Effects on Fertility: Female fertility index (e.g., # females pregnant per # sperm positive females; # females pregnant per # females mated). (Misoprostol)

Reproductive toxicity - Mouse - Subcutaneous

Effects on Fertility: Female fertility index (e.g., # females pregnant per # sperm positive females; # females pregnant per # females mated). (Misoprostol)

Reproductive toxicity - Rabbit - Oral

Maternal Effects: Uterus, cervix, vagina. (Misoprostol)

No data available

May cause reproductive disorders. Exposure during pregnancy can provoke uterine contractions which can result in fetal asphyxia.

No data available

May cause reproductive disorders. Exposure during pregnancy can provoke uterine contractions which can result in fetal asphyxia. (Misoprostol)

No data available (Misoprostol)

Developmental Toxicity - Human - female - Oral

Specific Developmental Abnormalities: Central nervous system. Specific Developmental Abnormalities: Craniofacial (including nose and tongue). Specific Developmental Abnormalities: Other developmental abnormalities.

Developmental Toxicity - Human - female - Oral

Specific Developmental Abnormalities: Craniofacial (including nose and tongue).

Developmental Toxicity - Human - female - Multiple

Specific Developmental Abnormalities: Central nervous system. Specific Developmental Abnormalities: Craniofacial (including nose and tongue).

Developmental Toxicity - Rabbit - female

Effects on Embryo or Fetus: Fetal death. Specific Developmental Abnormalities: Musculoskeletal system.

Developmental Toxicity - Human - female - Oral

Specific Developmental Abnormalities: Central nervous system. Specific Developmental Abnormalities: Craniofacial (including nose and tongue). Specific Developmental Abnormalities: Other developmental abnormalities. (Misoprostol)

Developmental Toxicity - Human - female - Oral

Specific Developmental Abnormalities: Craniofacial (including nose and tongue). (Misoprostol)

Developmental Toxicity - Human - female - Multiple

Specific Developmental Abnormalities: Central nervous system. Specific Developmental Abnormalities: Craniofacial (including nose and tongue). (Misoprostol)

Developmental Toxicity - Rabbit - female

Effects on Embryo or Fetus: Fetal death. Specific Developmental Abnormalities: Musculoskeletal system. (Misoprostol)

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

RTECS: Not available

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Effects due to ingestion may include:, Gastrointestinal disturbance, Nausea, Vomiting, To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Effects due to ingestion may include:, Gastrointestinal disturbance, Nausea, Vomiting, To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. (Misoprostol)

Stomach - Irregularities - Based on Human Evidence

Kidney - Irregularities - Based on Human Evidence

Stomach - Irregularities - Based on Human Evidence

Kidney - Irregularities - Based on Human Evidence (Ethyl acetate)

Stomach - Irregularities - Based on Human Evidence (Misoprostol)

Kidney - Irregularities - Based on Human Evidence (Ethyl acetate)

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

No data available

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects

No data available

No data available

No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)

UN number: 2810 Class: 6.1 Packing group: III

Proper shipping name: Toxic, liquids, organic, n.o.s. (Misoprostol)

Reportable Quantity (RQ):

Poison Inhalation Hazard: No

IMDG

UN number: 2810 Class: 6.1 Packing group: III EMS-No: F-A, S-A

Proper shipping name: TOXIC LIQUID, ORGANIC, N.O.S. (Misoprostol)

IATA

UN number: 2810 Class: 6.1 Packing group: III

Proper shipping name: Toxic liquid, organic, n.o.s. (Misoprostol)

15. REGULATORY INFORMATION

SARA 302 Components

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards

Acute Health Hazard, Chronic Health Hazard

Massachusetts Right To Know Components

	CAS-No.	Revision Date
Ethyl acetate	141-78-6	1993-04-24

Pennsylvania Right To Know Components

	CAS-No.	Revision Date
Misoprostol	59122-46-2	
Ethyl acetate	141-78-6	1993-04-24

New Jersey Right To Know Components

	CAS-No.	Revision Date
Misoprostol	59122-46-2	
Ethyl acetate	141-78-6	1993-04-24

California Prop. 65 Components

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

	CAS-No.	Revision Date
Misoprostol	59122-46-2	2007-09-28

16. OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

Acute Tox.	Acute toxicity
Eye Irrit.	Eye irritation
Flam. Liq.	Flammable liquids
H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
H360	May damage fertility or the unborn child.
Repr.	Reproductive toxicity
STOT SE	Specific target organ toxicity - single exposure

HMIS Rating

Health hazard:	2
Chronic Health Hazard:	*
Flammability:	0
Physical Hazard	0

NFPA Rating

Health hazard:	3
Fire Hazard:	0
Reactivity Hazard:	0

Further information

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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the

product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

Preparation Information

Sigma-Aldrich Corporation
Product Safety – Americas Region
1-800-521-8956

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