Mesalazine impurity C

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/04/2023 Version: 1.0

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

1.1. Product identifier

Product form	:	Substance
Substance name	:	Mesalazine impurity C
Chemical name	:	2-aminophenol
EC Index-No.	:	612-033-00-3
EC-No.	:	202-431-1
CAS-No.	:	95-55-6
Product code	:	201601066

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 - 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]

Germ cell mutagenicity, Category 2	H341
Acute toxicity (inhal.), Category 4	H332
Acute toxicity (oral), Category 4	H302

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 GHS07

Signal word (CLP)	:	Warning
Hazard statements (CLP)	:	H341 - Suspected of causing genetic defects. H332 - Harmful if inhaled. H302 - Harmful if swallowed.

Precautionary statements (CLP) : P202 - Do not handle until all safety precautions have been read and understood.
P308+P313 - IF exposed or concerned: Get medical advice/attention.

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]
2-aminophenol	CAS-No.: 95-55-6 EC-No.: 202-431-1 EC Index-No.: 612-033-00-3	≤ 100	Muta. 2, H341 Acute Tox. 4 (Inhalation), H332 (ATE=1,5 mg/l/4h) Acute Tox. 4 (Oral), H302 (ATE=1300 mg/kg bodyweight)

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 skin contact : Wipe off as much as possible (using a clean, soft, absorbent material).

First-aid measures after eye contact : Rinse eyes with water as a precaution.

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

No additional information available

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 : Extinguishing blanket.

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

6.1.1. For non-emergency personnel

Emergency procedures : Avoid all unnecessary exposure.

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

No additional information available

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

No additional information available

7.2. Conditions for safe storage, including any incompatibilities

No additional information available

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

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. Both local exhaust and general room ventilation are usually required.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

No additional information available

8.2.2.2. Skin protection

Skin and body protection:
Lab coat

Hand protection:
Protective gloves

8.2.2.3. Respiratory protection

No additional information available

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 available
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	:	Not available
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
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

None known.

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)	:	Harmful if swallowed.
Acute toxicity (dermal)	:	Not classified
Acute toxicity (inhalation)	:	Harmful if inhaled.
Skin corrosion/irritation	:	Not classified
Serious eye damage/irritation	:	Not classified
Respiratory or skin sensitisation	:	Not classified
Germ cell mutagenicity	:	Suspected of causing genetic defects.
Carcinogenicity	:	Not classified
Reproductive toxicity	:	Not classified
STOT-single exposure	:	Not classified
STOT-repeated exposure	:	Not classified
Aspiration hazard	:	Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	:	Presents no specific risk for the environment.
Hazardous to the aquatic environment, short–term (acute)	:	Not classified
Hazardous to the aquatic environment, long–term (chronic)	:	Not classified

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

No additional information available

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

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

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

Full text of H- and EUH-statements:	
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
H302	Harmful if swallowed.
H332	Harmful if inhaled.
H341	Suspected of causing genetic defects.
Muta. 2	Germ cell mutagenicity, Category 2

Safety Data Sheet (SDS), EU

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