

Sulpiride impurity A

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 23/06/2023 Revision date: 23/03/2026 Supersedes version of: 23/06/2023 Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Sulpiride impurity A
Chemical name : [(2RS)-1-Ethylpyrrolidin-2-yl]methanamine
EC-No. : 247-466-3
CAS-No. : 26116-12-1
Product code : 202300243
Synonyms : 2-(Aminomethyl)-1-ethylpyrrolidine

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

Relevant identified uses

Use of the substance/mixture : Scientific research and development
Technical testing and analysis
For professional use only
Function or use category : Laboratory chemicals

Uses advised against

Restrictions on use : Not for food, drug or home use

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]

Flammable liquids, Category 3 H226
Skin corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category 2 H319
Specific target organ toxicity – Single exposure, Category 3, H335
Respiratory tract irritation

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

Adverse physicochemical, human health and environmental effects

Causes serious eye irritation. Causes skin irritation. May cause respiratory irritation. Flammable liquid and vapour.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS02

GHS07

Signal word (CLP) : Warning

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Hazard statements (CLP)	: H226 - Flammable liquid and vapour. H315 - Causes skin irritation. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation.
Precautionary statements (CLP)	: P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 - Keep container tightly closed. P240 - Ground and bond container and receiving equipment. P241 - Use explosion-proof electrical/ventilating/lighting equipment. P261 - Avoid breathing dust/fume/gas/mist/vapours/spray. P264 - Wash hands, forearms and face thoroughly after handling. P271 - Use only outdoors or in a well-ventilated area. P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P302+P352 - IF ON SKIN: Wash with plenty of water. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 - Call a POISON CENTRE or doctor if you feel unwell. P321 - Specific treatment (see supplemental first aid instruction on this label). P332+P313 - If skin irritation occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse. P370+P378 - In case of fire: Use media other than water to extinguish. P403+P233 - Store in a well-ventilated place. Keep container tightly closed. P403+P235 - Store in a well-ventilated place. Keep cool. 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.

No labelling required

2.3. Other hazards

Other information : Warning - substance not yet tested completely.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
[(2RS)-1-Ethylpyrrolidin-2-yl]methanamine	CAS-No.: 26116-12-1 EC-No.: 247-466-3	≤ 100	Flam. Liq. 3, H226 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.

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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. Get medical advice if skin irritation persists.
First-aid measures after eye contact	: Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

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

Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye irritation. Redness, pain.

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	: Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.
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5.3. Advice for firefighters

Firefighting instructions	: Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid contact with skin, eyes and clothing.
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For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
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6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment	: Absorb with an inert material and place in an appropriate waste disposal container.
Methods for cleaning up	: Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

6.4. Reference to other sections

See Section 13 for disposal information.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.
Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
Packaging materials : Keep in original containers.

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

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of mist, spray or aerosol exposure: Breathing apparatus with filter (P3). Where excessive vapour may result, wear approved mask .

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Colour : Not available
Molecular mass : 128,2 g/mol
Odour : Not available
Odour threshold : Not available
Melting point : Not available
Freezing point : Not available
Boiling point : ≈ 60 °C
Flammability : Flammable liquid and vapour.
Lower explosion limit : Not available
Upper explosion limit : Not available
Flash point : 56 °C

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Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
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 available
Particle characteristics	: Not applicable

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Flammable liquid and vapour.

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

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified (Lack of data)
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)
Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
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	: Not classified (Lack of data)
STOT-single exposure	: May cause respiratory irritation.
STOT-repeated exposure	: Not classified (Lack of data)
Aspiration hazard	: Not classified (Lack of data)

11.2. Information on other hazards

No additional information available

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SECTION 12: Ecological information

12.1. Toxicity

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

[(2RS)-1-Ethylpyrrolidin-2-yl]methanamine (26116-12-1)

Persistence and degradability	Not rapidly degradable
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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		
UN 1993	UN 1993	UN 1993
14.2. UN proper shipping name		
FLAMMABLE LIQUID, N.O.S.	FLAMMABLE LIQUID, N.O.S.	Flammable liquid, n.o.s.
Transport document description		
UN 1993 FLAMMABLE LIQUID, N.O.S., 3, III, (D/E)	UN 1993 FLAMMABLE LIQUID, N.O.S., 3, III	UN 1993 Flammable liquid, n.o.s., 3, III
14.3. Transport hazard class(es)		
3	3	3
		

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ADR	IMDG	IATA
14.4. Packing group		
III	III	III
14.5. Environmental hazards		
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No EmS-No. (Fire): F-E EmS-No. (Spillage): S-E	Dangerous for the environment: No
No supplementary information available		

14.6. Special precautions for user

Overland transport

Classification code (ADR)	: F1
Special provisions (ADR)	: 274, 601
Limited quantities (ADR)	: 5I
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P001, IBC03, LP01, R001
Mixed packing provisions (ADR)	: MP19
Portable tank and bulk container instructions (ADR)	: T4
Portable tank and bulk container special provisions (ADR)	: TP1, TP29
Tank code (ADR)	: LGBF
Vehicle for tank carriage	: FL
Transport category (ADR)	: 3
Special provisions for carriage - Packages (ADR)	: V12
Special provisions for carriage - Operation (ADR)	: S2
Hazard identification number (Kemler No.)	: 30
Orange plates	: 
Tunnel restriction code (ADR)	: D/E

Transport by sea

Special provisions (IMDG)	: 223, 274, 955
Limited quantities (IMDG)	: 5 L
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: LP01, P001
IBC packing instructions (IMDG)	: IBC03
Tank instructions (IMDG)	: T4
Tank special provisions (IMDG)	: TP1, TP29
Stowage category (IMDG)	: A

Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y344
PCA limited quantity max net quantity (IATA)	: 10L
PCA packing instructions (IATA)	: 355
PCA max net quantity (IATA)	: 60L
CAO packing instructions (IATA)	: 366
CAO max net quantity (IATA)	: 220L
Special provisions (IATA)	: A3
ERG code (IATA)	: 3L

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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SECTION 15: Regulatory information

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

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

Ozone Regulation (2024/590)

Not listed on the Ozone Depletion list (Regulation EU 2024/590)

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (EU 2019/1148)

Not listed on the Explosives Precursors list (EU)

Drug Precursors Regulation (EC 273/2004)

Not listed on the Drug Precursors list (EU)

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	Supersedes version of	Added
	Revision date	Added
1.1	Synonyms	Added
1.1	EC-No.	Added
1.1	CAS-No.	Added
1.2	Restrictions on use	Modified
1.2	Use of the substance/mixture	Modified
1.2	Main use category	Removed
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.3	Other information	Added
4.1	First-aid measures after ingestion	Added
4.1	First-aid measures after inhalation	Added
4.1	First-aid measures general	Added
4.1	First-aid measures after skin contact	Modified
4.1	First-aid measures after eye contact	Modified
4.2	Symptoms/effects after inhalation	Added
4.2	Symptoms/effects after skin contact	Added

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Indication of changes		
Section	Changed item	Comments
4.2	Symptoms/effects after eye contact	Added
5.1	Unsuitable extinguishing media	Added
5.1	Suitable extinguishing media	Modified
5.2	Hazardous decomposition products in case of fire	Added
5.2	Fire hazard	Removed
5.3	Protection during firefighting	Added
5.3	Firefighting instructions	Modified
6.1	Protective equipment	Added
6.1	General measures	Added
6.1	Emergency procedures	Modified
6.2	Environmental precautions	Added
6.3	For containment	Added
6.3	Methods for cleaning up	Added
6.4	Reference to other sections (8, 13)	Added
7.1	Precautions for safe handling	Added
7.1	Hygiene measures	Added
7.2	Packaging materials	Added
7.2	Storage conditions	Added
7.3	Specific end uses	Removed
8.2	Eye protection	Added
8.2	Respiratory protection	Added
8.2	Hand protection	Modified
8.2	Appropriate engineering controls	Modified
8.2	Skin and body protection	Modified
9	Flammability	Added
9	Molecular mass	Added
9	Boiling point	Added
10.1	Reactivity	Modified
10.3	Possibility of hazardous reactions	Removed
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
12.1	Ecology - general	Removed

Full text of H- and EUH-statements:	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 3	Flammable liquids, Category 3
Skin Irrit. 2	Skin corrosion/irritation, Category 2

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Full text of H- and EUH-statements:

STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation
H226	Flammable liquid and vapour.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Safety Data Sheet (SDS), EU

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