



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 su	bstance/mixture and of the company/undertaking
1.1. Product identifier	
Product form Substance name	 Substance (1RS,1'RS)-2,2'-azanediylbis[1-[(2SR)-6-fluoro-3,4-dihydro-2H-1-benzopyran-2-yl]ethan-1-ol]
Product code	: 202100174
1.2. Relevant identified uses of the sub	stance or mixture and uses advised against
1.2.1. Relevant identified uses	
Main use category Use of the substance/mixture Function or use category	 The product is intended for research, analysis and scientific education. For professional use only 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 Medicin EDQM, Council of Europe 7, Allée Kastner, CS 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 I	mixture
Classification according to Regulation (EC)	
Acute toxicity (oral), Category 4 Acute toxicity (dermal), Category 4 Acute toxicity (inhal.), Category 4 Hazardous to the aquatic environment – Chroni Full text of H- and EUH-statements: see sectior	H302 H312 H332 c Hazard, Category 1 H410
Adverse physicochemical, human health an	d environmental effects
Expert judgement and weight of evidence deter	mination.
2.2. Label elements	
Labelling according to Regulation (EC) No. 1 Hazard pictograms (CLP)	
Signal word (CLP)	GHS07 GHS09 : Warning
Hazard statements (CLP)	 H302+H312+H332 - Harmful if swallowed, in contact with skin or if inhaled. H410 - Very toxic to aquatic life with long lasting effects.
Precautionary statements (CLP)	 P261 - Avoid breathing dust/fume/gas/mist/vapours/spray. P264 - Wash hands, forearms and face thoroughly after handling.

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- P270 Do not eat, drink or smoke when using this product.
- P271 Use only outdoors or in a well-ventilated area.
- P273 Avoid release to the environment.

P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

- P301+P312 IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.
- P302+P352 IF ON SKIN: Wash with plenty of water.
- P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P312 Call a POISON CENTRE or doctor if you feel unwell.
- P321 Specific treatment (see supplemental first aid instruction on this label).
- P330 Rinse mouth.
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P391 Collect spillage.
- 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

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]
(1RS,1'RS)-2,2'-azanediylbis[1-[(2SR)-6-fluoro-3,4- dihydro-2H-1-benzopyran-2-yl]ethan-1-ol]	-	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Acute Tox. 4 (Dermal), H312 (ATE=1100 mg/kg bodyweight) Acute Tox. 4 (Inhalation), H332 (ATE=1.5 mg/l/4h) Aquatic Chronic 1, H410

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 First-aid measures after eye contact	Wipe off as much as possible (using a clean, soft, absorbent material).Rinse eyes with water as a precaution.
4.2. Most important symptoms and ef	fects, both acute and delayed

No additional information available

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

No additional information available

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SECTION 5: Firefighting measur	'es	
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

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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. 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
Odour	:	Not available
Odour threshold	:	Not available
	:	Not available
Melting point	•	
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
рН	:	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
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9.2. Other information

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Particle size

: Not available

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
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Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Harmful in contact with skin.
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	: Not classified
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.

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Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic) Not rapidly degradable	: Very toxic to aquatic life with long lasting effects.
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

n accordance with ADR / IMDG / IATA		
ADR	IMDG	ΙΑΤΑ
14.1. UN number or ID number		
UN 3077	UN 3077	UN 3077
14.2. UN proper shipping name		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.
Transport document description		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III
14.3. Transport hazard class(es)		
9	9	9

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	IMDO	
ADR	IMDG	ΙΑΤΑ
14.4. Packing group		
III	III	111
I4.5. Environmental hazards		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes	Dangerous for the environment: Yes
No supplementary information available		
4.6. Special precautions for user		
verland transport		
lassification code (ADR)	: M7	
pecial provisions (ADR)	: 274, 335, 375, 601	
mited quantities (ADR)	: 5kg	
xcepted quantities (ADR)	: E1	
acking instructions (ADR)	: P002, IBC08, LP02, R001	
pecial packing provisions (ADR)	: PP12, B3	
lixed packing provisions (ADR)	: MP10	
ortable tank and bulk container instructions (ADR)		
ortable tank and bulk container instructions (ADIC)		
ADR)	. 11 55	
ank code (ADR)	: SGAV, LGBV	
ehicle for tank carriage	: AT	
ransport category (ADR)	: 3	
pecial provisions for carriage - Packages (ADR)	: V13	
pecial provisions for carriage - Bulk (ADR)	: VC1, VC2	
pecial provisions for carriage - Loading, unloading		
nd handling (ADR)	. 6016	
	. 00	
azard identification number (Kemler No.)	: 90	
range plates	90	
	70	
	3077	
	3077	
unnel restriction code (ADR)	: -	
ransport by sea		
pecial provisions (IMDG)	: 274, 335, 966, 967, 969	
imited quantities (IMDG)	: 5 kg	
xcepted quantities (IMDG)	: E1	
acking instructions (IMDG)	: LP02, P002	
pecial packing provisions (IMDG)	: PP12	
3C packing instructions (IMDG)	: IBC08	
3C special provisions (IMDG)	: B3	
ank instructions (IMDG)	: BK1, BK2, BK3, T1	
ank special provisions (IMDG)	: TP33	
mS-No. (Fire)	: F-A	
mS-No. (Spillage)	: S-F	
towage category (IMDG)	: A	
towage and handling (IMDG)	: SW23	
ir transport		
CA Excepted quantities (IATA)	: E1	
CA Limited quantities (IATA)	: Y956	
	: 30kgG	
CA limited quantity max net quantity (IATA)	-	
CA packing instructions (IATA)	: 956	
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CAO max net quantity (IATA)	: 400kg
Special provisions (IATA)	: A97, A158, A179, A197
ERG code (IATA)	: 9L

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 (Dermal)	Acute toxicity (dermal), Category 4	
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4	
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1	
H302	Harmful if swallowed.	
H312	Harmful in contact with skin.	
H332	Harmful if inhaled.	
H410	Very toxic to aquatic life with long lasting effects.	

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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.