



CONSEIL DE L'EUROPE

# (1R,2S)-2-(3,4-difluorophenyl)cyclopropan-1amine;(2S)-2-hydroxy-2-phenylacetic acid

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

1.1. Product identifier	
Product form Substance name Product code	<ul> <li>Substance</li> <li>(1R,2S)-2-(3,4-difluorophenyl)cyclopropan-1-amine;(2S)-2-hydroxy-2-phenylacetic acid</li> <li>202000100</li> </ul>
1.2. Relevant identified uses of the subst	ance or mixture and uses advised against
1.2.1. Relevant identified uses	
Main use category Use of the substance/mixture Function or use category	<ul> <li>The product is intended for research, analysis and scientific education.</li> <li>For professional use only</li> <li>Laboratory chemicals</li> </ul>
1.2.2. Uses advised against	
Restrictions on use	: Do not use : Ingestion, Inhalation, Dermal
1.3. Details of the supplier of the safety d	lata sheet
European Directorate for the Quality of Medicines EDQM, Council of Europe 7, Allée Kastner, CS30 F– 67081 Strasbourg France T + 33(0)388412035 E + 33(0)388413771	

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

Acute toxicity (oral), Category 3	H301
Skin sensitisation, Category 1	H317
Specific target organ toxicity – Repeated exposure, Category 2	H373
Hazardous to the aquatic environment – Chronic Hazard, Category 2	H411
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	o. 1272/2008 [CLP]		
Hazard pictograms (CLP)			
	GHS06	GHS08	GHS09

Signal word (CLP) Hazard statements (CLP) : Danger

: H301 - Toxic if swallowed.

H317 - May cause an allergic skin reaction.

H373 - May cause damage to organs through prolonged or repeated exposure.

H411 - Toxic to aquatic life with long lasting effects.

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Precautionary statements (CLP)	: P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
	P264 - Wash hands, forearms and face thoroughly after handling.
	P270 - Do not eat, drink or smoke when using this product.
	P272 - Contaminated work clothing should not be allowed out of the workplace.
	P273 - Avoid release to the environment.
	P280 - Wear protective gloves/protective clothing/eye protection/face protection.
	P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor.
	P302+P352 - IF ON SKIN: Wash with plenty of water.
	P314 - Get medical advice/attention if you feel unwell.
	P321 - Specific treatment (see supplemental first aid instruction on this label).
	P330 - Rinse mouth.
	P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364 - Take off contaminated clothing and wash it before reuse.
	P391 - Collect spillage.
	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 pack	
Hazard pictograms (CLP)	
	GHS06 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]
(1R,2S)-2-(3,4-difluorophenyl)cyclopropan-1- amine;(2S)-2-hydroxy-2-phenylacetic acid	-	≤ 100	Acute Tox. 3 (Oral), H301 (ATE=100 mg/kg bodyweight) Skin Sens. 1, H317 STOT RE 2, H373 Aquatic Chronic 2, H411

### 3.2. Mixtures

Not applicable

SECTION 4: First aid measures	
4.1. Description of first aid measures	
First-aid measures after inhalation	: Move to fresh air. Allow affected person to breathe fresh air.
First-aid measures after skin contact	: Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of water and detergent.
First-aid measures after eye contact	: Rinse with water while holding the eyes wide open.
First-aid measures after ingestion	: Rinse mouth. Immediately call a POISON CENTER/doctor. Prolonged medical observation may be indicated.

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Symptoms/effects	: Delayed adverse effects possible.
Symptoms/effects after inhalation	: Insufficient data available.
Symptoms/effects after skin contact	: Insufficient data available.
Symptoms/effects after eye contact	: Insufficient data available.

SECTION 5: Firefighting measures	5	
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 e	quipment and emergency procedures	
General measures	: Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.	
6.1.1. For non-emergency personnel		
Emergency procedures	: Wear suitable protective clothing, gloves and eye or face protection.	
6.1.2. For emergency responders		
No additional information available		
6.2. Environmental precautions		
No additional information available		
6.3. Methods and material for containing	nent and cleaning up	
Methods for cleaning up	: Ensure waste is collected and contained. Clean thoroughly. Wash the non-recoverable remainder with : Sodium hypochlorite solution.	
6.4. Reference to other sections		

No additional information available

SECTION 7: Handling and storage		
7.1. Precautions for safe handling		
Additional hazards when processed	: The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended.	
Precautions for safe handling	: Material should be handled with caution. Avoid any direct contact with the product. Material should be handled in a laboratory hood whenever possible.	
Hygiene measures	: Handle in accordance with good industrial hygiene and safety procedures.	
7.2. Conditions for safe storage, inclu	ding any incompatibilities	
Technical measures	: Comply with applicable regulations.	

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Storage conditions

: Store locked up.

### 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. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

### 8.2.2. Personal protection equipment

### 8.2.2.1. Eye and face protection

Eye protection: Safety glasses. DIN EN 166

### 8.2.2.2. Skin protection

Skin and body protection: Use chemically protective clothing. DIN EN 13034

### Hand protection:

Chemically resistant protective gloves. ISO 374-1

### 8.2.2.3. Respiratory protection

### **Respiratory protection:**

Dust production: dust mask with filter type P3. DIN EN 140 & 149. Liquid product : Aerosol mask. Wear breathing apparatus if exposed to vapours/dusts/aerosols

### 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 Colour : Solid : Not available

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Odour Odour threshold Melting point Freezing point Boiling point Flammability Explosive limits Lower explosion limit Upper explosion limit Flash point Auto-ignition temperature Decomposition temperature	<ul> <li>Not applicable.</li> <li>Not available</li> <li>Not available</li> <li>Not available</li> <li>Not available</li> <li>Not available</li> <li>Not available</li> <li>Not applicable</li> </ul>
pH solution Viscosity, kinematic Solubility Partition coefficient n-octanol/water (Log Kow) Vapour pressure Vapour pressure at 50°C Density Relative density Relative vapour density at 20°C Particle size	<ul> <li>Not available</li> <li>Not applicable</li> <li>Not available</li> </ul>

### 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

No additional information available

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)

: Toxic if swallowed.

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Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: May cause damage to organs through prolonged or repeated exposure.
Aspiration hazard	: Not classified

### 11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information	
12.1. Toxicity	
Ecology - general Hazardous to the aquatic environment, short–term (acute) Hazardous to the aquatic environment, long–term (chronic)	<ul> <li>Hazardous waste. Use suitable disposal containers.</li> <li>Not classified</li> <li>Toxic to aquatic life with long lasting effects.</li> </ul>
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	
Regional legislation (waste) Product/Packaging disposal recommendations	<ul> <li>Dispose in a safe manner in accordance with local/national regulations.</li> <li>Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.</li> </ul>

### SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

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ADR	IMDG	ΙΑΤΑ
14.1. UN number or ID number		
UN 2811	UN 2811	UN 2811
14.2. UN proper shipping name		
TOXIC SOLID, ORGANIC, N.O.S.	TOXIC SOLID, ORGANIC, N.O.S.	Toxic solid, organic, n.o.s.
Transport document description		
UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III, (E), ENVIRONMENTALLY HAZARDOUS	UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III, MARINE POLLUTANT/ENVIRONMENTALLY HAZARDOUS	UN 2811 Toxic solid, organic, n.o.s., 6.1, III ENVIRONMENTALLY HAZARDOUS
14.3. Transport hazard class(es)		
6.1	6.1	6.1
6	6	6
14.4. Packing group		
III	111	Ш
14.5. Environmental hazards		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes	Dangerous for the environment: Yes
No supplementary information available		
14.6. Special precautions for user		
Overland transport		
Classification code (ADR)	: T2	
Special provisions (ADR)	: 274, 614	
Limited quantities (ADR)	: 5kg	
,		
Excepted quantities (ADR)	: E1	
Packing instructions (ADR)	: P002, IBC08, LP02, R001	
Special packing provisions (ADR)	: B3	
Mixed packing provisions (ADR)	: MP10	
Portable tank and bulk container instructions (ADR)	) : T1	
Portable tank and bulk container special provisions (ADR)	: TP33	
Tank code (ADR)	: SGAH, L4BH	
Fank special provisions (ADR)	: TU15, TE19	
	: AT	
/ehicle for tank carriage		
Fransport category (ADR)	: 2	
Special provisions for carriage - Bulk (ADR) Special provisions for carriage - Loading, unloading	: VC1, VC2, AP7 ; : CV13, CV28	
and handling (ADR)		
Special provisions for carriage - Operation (ADR)	: S9	
Hazard identification number (Kemler No.) Orange plates	: 60	
	<u>60</u> 2811	
Tunnel restriction code (ADR)	: E	
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Transport by sea	
Special provisions (IMDG)	: 223, 274
Packing instructions (IMDG)	: P002
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: T1
Tank special provisions (IMDG)	: TP33
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-A
Stowage category (IMDG)	: A
Properties and observations (IMDG)	: Toxic if swallowed, by skin contact or by inhalation.
Air transport	

PCA Excepted quantities (IATA)	:	E1
PCA Limited quantities (IATA)	:	Y645
PCA limited quantity max net quantity (IATA)	:	10kg
PCA packing instructions (IATA)	:	670
PCA max net quantity (IATA)	:	100kg
CAO packing instructions (IATA)	:	677
CAO max net quantity (IATA)	:	200kg
Special provisions (IATA)	:	A3, A5
ERG code (IATA)	:	6L

### 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

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### 15.2. Chemical safety assessment

No additional information available

### **SECTION 16: Other information**

Full text of H- and EUH-statements:	
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
H301	Toxic if swallowed.
H317	May cause an allergic skin reaction.
H373	May cause damage to organs through prolonged or repeated exposure.
H411	Toxic to aquatic life with long lasting effects.
Skin Sens. 1	Skin sensitisation, Category 1
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2

Safety Data Sheet (SDS), EU

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