

Safety Data Sheet

FCB-Parent API

according to Regulation (EU) nr. 1907/2006

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

1.1. Product identifier

Product name FCB-Parent API
Product code RO4995855-000

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

Use - intermediate in the synthesis of an active pharmaceutical compound

1.3. Details of the supplier of the safety data sheet

Company information	Enquiries: F. Hoffmann-La Roche AG Postfach CH-4070 Basel Switzerland	Local representation:
	Phone +41-61/688 54 80	
	Fax +41-61/681 72 76	
	E-Mail info.sds@roche.com	

1.4. Emergency telephone number

Emergency telephone number Phone +41-61/688 54 80

SECTION 2: Hazards identification

2.1. / 2.2. Classification of the substance or mixture / Label elements

GHS Classification no classification and labelling according to CLP (EC Regulation 1272/2008)

2.3. Other hazards

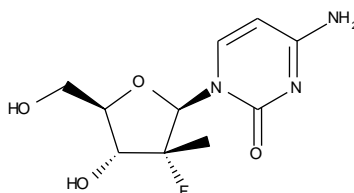
Note - may form explosible dust-air mixture if dispersed

SECTION 3: Composition/information on ingredients

Characterization cytosine nucleoside analog
Chemical name - 2'- α -Fluoro-2'- β -C-methyl-deoxycytidine

FCB-Parent API

Synonyms	<ul style="list-style-type: none">- PSI-6130- FCB Step 10- HCV Polymerase Inhibitor (parent)
CAS number	817204-33-4
Roche number	RO4995855-000
Empirical formula	$C_{10}H_{14}FN_3O_4$
Molecular mass	259.24 g/mol



SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	<ul style="list-style-type: none">- rinse immediately with tap water for at least 20 minutes - open eyelids forcibly- consult a physician if irritation persists
Skin contact	<ul style="list-style-type: none">- remove contaminated clothes, wash affected skin with water and soap - do not use any solvents
Inhalation	<ul style="list-style-type: none">- remove the casualty to fresh air and keep him/her calm- in the event of symptoms get medical treatment

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

Note	<ul style="list-style-type: none">- no information available
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physician	<ul style="list-style-type: none">- treat symptomatically
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	<ul style="list-style-type: none">- water spray jet, dry powder, foam, carbon dioxide
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5.2. Special hazards arising from the substance or mixture

Specific hazards	<ul style="list-style-type: none">- high probability of ignition of dust whirled up- consider dust explosion hazard- substance is hazardous for water: contain fire-fighting wastewater
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5.3. Advice for firefighters

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| Protection of fire-fighters | - use self-contained breathing apparatus |
| Special method of fire-fighting | - if possible precipitate fire gases with a water jet |

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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| Personal precautions | - no special precautions required |
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6.2. Environmental precautions

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| Environmental protection | - do not allow to enter drains or waterways
- if the substance reaches waters or the sewer system, inform the competent authority |
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6.3. Methods and material for containment and cleaning up

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| Methods for cleaning up | - collect solids (avoid dust formation) and hand over to waste removal |
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

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| Technical measures | - processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)
- avoid dust formation; high dust explosion hazard
- connect the equipment to earth, avoid effective sources of ignition
- avoid electric charging of dust clouds |
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7.2. Conditions for safe storage, including any incompatibilities

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| Storage conditions | - keep container tightly closed
- room temperature
- store in a dry place |
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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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| Threshold value (Roche) air | - IOEL (Internal Occupational Exposure Limit): 1.5 mg/m ³ |
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8.2. Exposure controls

Respiratory protection	- in case of open handling of larger quantities or accidental release: particle mask or respirator with independent air supply
Hand protection	- protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection	- safety glasses
Body protection	- wear conductive shoes

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Colour	white to off-white
Form	powder
Solubility	95'100 mg/l, water (20 °C, OECD No. 105)
Partition coefficient	log P _{ow} 0.99 (octanol/water) pH 7.0 (HPLC Method, OECD No. 117)
Melting temperature	215 to 219 °C

9.2. Other information

Note	- no information available
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SECTION 10: Stability and reactivity**10.1. Reactivity**

Note	- no information available
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10.2. Chemical stability

Note	- no information available
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10.3. Possibility of hazardous reactions

Note	- no information available
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10.4. Conditions to avoid

Conditions to avoid	- light - air - humidity - temperatures above 110 °C
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10.5. Incompatible materials

Materials to avoid - strong oxidizing agents

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- LD ₀ 5'000 mg/kg (oral, rat)
Subacute toxicity	- NOAEL 900 mg/kg/d (oral, rat, 14 d)
Local effects	- skin: non-irritant (rabbit; OECD No. 404)
Sensitization	- no information available
Mutagenicity	- does not induce chromosomal aberrations in vitro (OECD No. 473 (Mammalian Cytogenic Test)) - not mutagenic (OECD No. 474 (Micronucleus Test)) - not mutagenic (Ames test; OECD No. 471 (Salmonella typhimurium, Escherichia coli))
Carcinogenicity	- no information available
Reproductive toxicity	- no information available
STOT-single exposure	- no information available
STOT-repeated exposure	- no information available
Aspiration hazard	- no information available

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- barely toxic for algae (Desmodesmus (=Scenedesmus) subspicatus) ErC ₅₀ (72 h) > 100 mg/l (nominal concentration) EyC ₅₀ (72 h) > 100 mg/l (nominal concentration) NOEC (72 h) 2.46 mg/l (average measured concentration) (OECD No. 201) - barely toxic for planktonic crustaceans (Daphnia magna) EC ₅₀ (48 h) > 100 mg/l (nominal concentration) NOEC (48 h) 100 mg/l (nominal concentration) (OECD No. 202)
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- no adverse influence on substrate biodegradation (activated sludge)
concentration (28 d) 55.5 mg/l (nominal concentration)
(Manometric Respirometry Test, OECD No. 301 F)

12.2. Persistence and degradability

- Ready biodegradability
- not readily biodegradable
< 10 % BOD/ThOD, 28 d
(Manometric Respirometry Test, OECD No. 301 F)

12.3. Bioaccumulative potential

- Note
- no information available

12.4. Mobility in soil

- Note
- no information available

12.5. Results of PBT and vPvB assessment

- Note
- no information available

12.6. Other adverse effects

- Note
- no information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

- Waste from residues
- incinerate in qualified installation with flue gas scrubbing
 - observe local/national regulations regarding waste disposal

SECTION 14: Transport information

- Note
- not classified as Dangerous Good according to the Dangerous Goods Regulations

SECTION 15: Regulatory information

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

- Water hazard class (Germany)
- 1: weakly hazardous for water (own classification according to directive VwVwS of 27.07.2005)

SECTION 16: Other information

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| Safety-lab number | - BS-9839 |
| Edition documentation | - changes from previous version in sections 2, 6 |

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.