

Safety Data Sheet

COPEGUS(R) F.C. Tablets (200 mg)

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

1.1. Product identifier

Product name	COPEGUS(R) F.C. Tablets (200 mg)
Product code	SAP-10058353
Synonyms	<ul style="list-style-type: none"> - Virazole substance *1 - Viramide substance *1 - Virazide substance *1 - COPEGUS F.C. Tablets 200 mg - COPEGUS Film Coated Tablets 200 mg

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

Use	- pharmaceutical active substance (nucleoside analog) with antiviral effect *1
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1.3. Details of the supplier of the safety data sheet

Company information	<p>Enquiries: Local representation:</p> <p>Genentech, Inc.</p> <p>1 DNA Way</p> <p>South San Francisco</p> <p>USA-CA 94080</p> <p>United States of America</p> <p>Phone 001-(650) 225-1000</p> <p>E-Mail info.sds@roche.com</p> <p>US Chemtrec phone:</p> <p>(800)-424-9300</p>
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1.4. Emergency telephone number

Emergency telephone number	US Chemtrec phone: (800)-424-9300
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*1 referring to:	Ribavirin
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COPEGUS(R) F.C. Tablets (200 mg)

SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification

Health Hazards:

3.7 Reproductive toxicity (Category 1B)

H360Df May damage the unborn child. Suspected of damaging fertility.

3.8 Specific target organ toxicity - Single exposure (Category 3)

H335 May cause respiratory irritation.

Signalword: Danger

Label:



Precautionary statements:

- P201 Obtain special instructions before use.
- P281 Use personal protective equipment as required.
- P309 + P311 IF exposed or you feel unwell: Call a POISON CENTER or doctor/physician.

Other hazards

Note

- women of childbearing potential have to avoid any overexposure (limit values see chapter 8)

*1

*1 referring to:

Ribavirin

SECTION 3: Composition/information on ingredients

Characterization

medicinal product as part of a combination regimen for the treatment of chronic hepatitis C

Chemical name

- 1-β-D-Ribofuranosyl-1,2,4-triazole-3-carboxamide

*1

Ingredients

Concentration

Ribavirin

54.95 %

CAS: 36791-04-5

Microcrystalline cellulose

20.6 %

CAS: 9004-34-6

Corn starch

15.1 %

CAS: 9005-25-8

Magnesium stearate

~ 1 %

CAS: 557-04-0

*1 referring to:

Ribavirin

SECTION 4: First aid measures

4.1. Description of first aid measures

- | | |
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| Eye contact | - rinse immediately with tap water for 10 minutes - open eyelids forcibly
- consult a physician |
| Skin contact | - remove immediately contaminated clothes, wash affected skin with water and soap |
| Inhalation | - remove the casualty to fresh air and keep him/her calm
- get medical treatment |

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

- | | |
|------|----------------------------|
| Note | - no information available |
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4.3. Indication of any immediate medical attention and special treatment needed

- | | |
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| Note to physician | - treat symptomatically
- after accidental exposure women should get medical advice from a physician |
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SECTION 5: Firefighting measures

5.1. Extinguishing media

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| Suitable extinguishing media | - water spray jet, dry powder, foam, carbon dioxide |
| Flash point (liquid) | not applicable |
| Unsuitable extinguishing media | - full water jet |

5.2. Special hazards arising from the substance or mixture

- | | |
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| Specific hazards | - consider dust explosion hazard
- formation of toxic and corrosive combustion gases (nitrogen oxides (NO _x)) possible |
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5.3. Advice for firefighters

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| Protection of fire-fighters | - use self-contained breathing apparatus |
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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| Personal precautions | - avoid exposure |
|----------------------|------------------|

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6.2. Environmental precautions

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| Environmental protection | <ul style="list-style-type: none">- 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 | <ul style="list-style-type: none">- collect solids (avoid dust formation) and hand over to waste removal- clean contaminated areas with little ethanol |
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

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| Technical measures | <ul style="list-style-type: none">- avoid formation and deposition of dust |
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7.2. Conditions for safe storage, including any incompatibilities

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|---------------------|---|
| Validity | <ul style="list-style-type: none">- 4 years |
| Packaging materials | <ul style="list-style-type: none">- high density polyethylene (HDPE) bottles with a child-resistant polypropylene screw cap |

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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| Threshold value (USA) air | <ul style="list-style-type: none">- ACGIH-TLV: 10 mg/m³ *2- ACGIH-TLV: 10 mg/m³ (not classifiable as a human carcinogen) *3- OSHA-PEL: 5 mg/m³ (respirable fraction) *3- OSHA-PEL: 15 mg/m³ (total dust) *3- NIOSH-REL: 5 mg/m³ (respirable fraction) *3- NIOSH-REL: 10 mg/m³ (total dust) *3- ACGIH-TLV: 10 mg/m³ *4- OSHA-PEL: 5 mg/m³ (respirable dust fraction) *4- OSHA-PEL: 15 mg/m³ (total dust) *4- NIOSH-REL: 5 mg/m³ (respirable dust fraction) *4- NIOSH-REL: 10 mg/m³ (total dust) *4 |
| Threshold value (Roche) air | <ul style="list-style-type: none">- IOEL (Internal Occupational Exposure Limit): 0.002 mg/m³ *1 |

8.2. Exposure controls

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| Respiratory protection | <ul style="list-style-type: none">- Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.- in case of open handling of larger quantities or accidental release: particle mask or respirator with independent air supply |
|------------------------|--|

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Hand protection	- protective gloves (eg made of neoprene, nitrile or butyl rubber)	
Eye protection	- safety glasses	
Analytics	- sampling on teflon filter and chemical determination (HPLC)	*1
*1 referring to:	Ribavirin	
*2 referring to:	Magnesium stearate	
*3 referring to:	Corn starch	
*4 referring to:	Microcrystalline cellulose	

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	light pink	
Form	oval, biconvex tablet	
Solubility	142'000 mg/l, water (25 °C)	*1
	easily soluble, ethanol	*1
		*1
Partition coefficient	log P _{ow} -2.29 (n-octanol/water; pH 5, 7 & 9 20 °C) (Shake Flask Method, OECD No. 107)	*1
pH value (25 °C)	4.0 to 6.5 (2 %)	*1
Melting temperature	166 to 176 °C	*1

9.2. Other information

Note	- no information available
*1 referring to:	Ribavirin

SECTION 10: Stability and reactivity

10.1. Reactivity

Note	- no information available
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10.2. Chemical stability

Stability	- stable under normal conditions
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10.3. Possibility of hazardous reactions

Note	- no information available
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COPEGUS(R) F.C. Tablets (200 mg)

10.4. Conditions to avoid

Note - no information available

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- LD ₅₀	2'700	mg/kg	(oral, rat)	*1
	- LD ₅₀	2'000	mg/kg	(oral, mouse)	*1
Local effects	- respiratory tract:	irritant			*1
	- eye:	irritant			*1
Mutagenicity	-	mutagenic (various in vitro test systems)			*1
Reproductive toxicity	-	teratogenic and embryotoxic (several species)			*1
	-	reduction of fertility in the animal model (several species)			*1
Note	-	possible side effects: hemolytical anemia			*1
	-	virostatic agent			*1
	-	excretion is mainly renal			*1
	-	daily dose: 1'000 to 1'200 mg/d			*1
	-	elimination half-life (after a single dose): 2 d			*1
	-	elimination half-life (after multiple dose): 12 d			*1
Potential Health Effects	-	Exposure: Ingestion			
	-	Carcinogenicity: formulation not listed by NTP, IARC or OSHA			

*1 referring to: Ribavirin

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	-	barely toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)			
		EC ₅₀ (72 h) > 100 mg/l			
		NOEC (72 h) 100 mg/l			
		(OECD No. 201)			*1

COPEGUS(R) F.C. Tablets (200 mg)

- barely toxic for planktonic crustaceans (*Daphnia magna*)
EC₅₀ (48 h) > 100 mg/l
NOEC (48 h) 100 mg/l
(OECD No. 202) *1
- barely toxic for fish (zebrafish)
EC₅₀ (96 h) > 100 mg/l
NOEC (96 h) 100 mg/l
(OECD No. 203) *1
- barely toxic for microorganisms (activated sludge)
EC₅₀ (3 h) > 1000 mg/l
(Activated Sludge Respir. Inhib. Test, OECD No. 209) *1

12.2. Persistence and degradability

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| Ready biodegradability | <ul style="list-style-type: none"> - not readily biodegradable
the product is biodegradable after lengthy adaptation
15 %, 28 d
57 %, 63 d
(DOC Die-Away Test, OECD No. 301A) | *1 |
| Inherent biodegradability | <ul style="list-style-type: none"> - inherently biodegradable
38 %, 28 d
(Zahn-Wellens test, OECD No. 302 B) | *1 |

12.3. Bioaccumulative potential

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| Note | <ul style="list-style-type: none"> - no information available |
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12.4. Mobility in soil

- | | |
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| Note | <ul style="list-style-type: none"> - no information available |
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12.5. Results of PBT and vPvB assessment

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| Note | <ul style="list-style-type: none"> - no information available |
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12.6. Other adverse effects

- | | |
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| Note | <ul style="list-style-type: none"> - no information available |
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*1 referring to:	Ribavirin
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SECTION 13: Disposal considerations

13.1. Waste treatment methods

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| Waste from residues | <ul style="list-style-type: none"> - return to supplier or hand over to authorized disposal company - observe local/national regulations regarding waste disposal - incinerate in qualified installation with flue gas scrubbing - DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter. |
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SECTION 14: Transport information

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| Note | <ul style="list-style-type: none"> - not classified by transport regulations, proper shipping name non-regulated |
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SECTION 15: Regulatory information

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

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|------------------------|--|
| TSCA Status | <ul style="list-style-type: none"> - FDA Exemption - not on inventory |
| Reporting Requirements | <ul style="list-style-type: none"> - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material. - In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials. - State and local regulations vary and may impose additional reporting requirements. |

SECTION 16: Other information

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| Note | <ul style="list-style-type: none"> - Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user. |
| Edition documentation | <ul style="list-style-type: none"> - changes from previous version in sections 2, 13, 16 |

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.