

**1. Product and Company Identification**

Product name	COPEGUS(R) F.C. Tablets (200 mg)	
Product code	CSE-2027	
Use	- Copegus is an antiviral medication for chronic Hepatitis C.	
Company information	Enquiries:	Local representation:
	Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America	
	Phone	001-973/235 50 00
	E-Mail	info.sds@roche.com
	US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300	

2. Hazards identification**Emergency Overview**

Form	solid
Color	pink
Hazard Overview	<ul style="list-style-type: none">- May cause birth defects based on information on related materials- May cause reproductive systems effects based on information on related materials
Potential Health Effects	<ul style="list-style-type: none">- Exposure: Ingestion, Eye contact- Target Organs: respiratory tract, skin, eyes, mucous membranes, gastrointestinal system- Acute Effects: May cause eye irritation., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite., May cause respiratory effects., Signs and symptoms may include difficulty in breathing, coughing, wheezing, irritation (inflammation) and respiratory arrest.- Chronic Effects: No adverse effects known- Carcinogenicity: formulation not listed by NTP, IARC or OSHA

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Additional Health Information	- Reproductive Toxicity: May cause birth defects based on animal data. May cause reproductive system effects based on animal data. *1
	- Since this material may affect reproductive capabilities and the developing fetus, females and males planning to have a child and pregnant women should exercise caution regarding exposure. *1
	- It is also advisable for nursing mothers to exercise caution regarding exposure. *1
Note	- women of childbearing potential have to avoid any overexposure (limit values see chapter 8) *1

*1 referring to: Ribavirin

3. Composition/Information on ingredients

Characterization	final product
Ingredients	Concentration
Ribavirin CAS: 36791-04-5	~ 57 %
Microcrystalline cellulose CAS: 9004-34-6	~ 2 %
Corn starch CAS: 9005-25-8	~ 16 %
Sodium starch glycolate CAS: 9063-38-1	~ 5 %
Magnesium stearate CAS: 557-04-0	~ 1 %

4. First-aid measures

Eye contact	- in case of contact with eyes rinse thoroughly with plenty of water and get medical advice
Skin contact	- remove immediately contaminated clothes, wash affected skin with plenty of water
Inhalation	- in case of inhalation remove to fresh air and seek medical aid
Ingestion	- consult physician

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5. Fire-fighting measures

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	not applicable
Specific hazards	- Toxic emissions may be given off in a fire
Protection of fire-fighters	- use self-contained breathing apparatus
Special method of fire-fighting	- cool endangered containers with water spray

6. Accidental release measures

Personal precautions	- ensure adequate ventilation
Environmental protection	- avoid release to the environment
Methods for cleaning up	<ul style="list-style-type: none">- Scoop or shovel spilled material into a suitable labeled open head drum- Secure the drum cover and move the container to a safe holding area- Clean spill area thoroughly- Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal.- Check area for residual material and repeat clean up if detected

7. Handling and storage

Handling

Technical measures	<ul style="list-style-type: none">- local exhaust ventilation necessary- avoid dust formation; consider dust explosion hazard
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Storage

Storage conditions	<ul style="list-style-type: none">- keep containers tightly closed- room temperature- store in a dry place
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8. Exposure controls/Personal protection

Engineering Measures	- see 7.	
Threshold value (USA) air	- ACGIH-TLV: 10 mg/m ³ (not classifiable as a human carcinogen)	*2
	- OSHA-PEL: 5 mg/m ³ (respirable fraction)	*2
	- OSHA-PEL: 15 mg/m ³ (total dust)	*2
	- NIOSH-REL: 5 mg/m ³ (respirable fraction)	*2
	- NIOSH-REL: 10 mg/m ³ (total dust)	*2
	- ACGIH-TLV: 10 mg/m ³	*3
	- OSHA-PEL: 5 mg/m ³ (respirable fraction)	*3
	- OSHA-PEL: 15 mg/m ³ (total dust)	*3
	- NIOSH-REL: 5 mg/m ³ (respirable fraction)	*3
	- NIOSH-REL: 10 mg/m ³ (total dust)	*3
	- ACGIH-TLV: 10 mg/m ³	*4
	- OSHA-PEL: 5 mg/m ³ (respirable dust fraction)	*4
	- OSHA-PEL: 15 mg/m ³ (total dust)	*4
	- NIOSH-REL: 5 mg/m ³ (respirable dust fraction)	*4
	- NIOSH-REL: 10 mg/m ³ (total dust)	*4
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 5 µg/m ³	*1

Personal protective equipment

Respiratory protection	- 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.
	- respiratory protection not necessary
Hand protection	- protective gloves
Eye protection	- safety glasses
Body protection	- protective clothing

*1 referring to:	Ribavirin
*2 referring to:	Corn starch
*3 referring to:	Sodium starch glycolate
*4 referring to:	Microcrystalline cellulose

9. Physical and chemical properties

Color	pink
Form	solid

10. Stability and reactivity

Stability	- stable under normal conditions
Conditions to avoid	- None known
Materials to avoid	- None known

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11. Toxicological information

Acute toxicity	- LD ₅₀	2'700	mg/kg	(oral, rat)	*1
	- LD ₅₀	1'300	mg/kg	(i.p., mouse)	*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
Reproduction toxicity	- teratogenic and embryotoxic (several species)				*1
	- reduction of fertility in the animal model (several species)				*1
*1 referring to:	Ribavirin				

12. Ecological information

Ready biodegradability	- 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	- inherently biodegradable				
	38 %, 28 d				
	(Zahn-Wellens test, OECD No. 302 B)				*1
Ecotoxicity	- barely toxic for microorganisms (activated sludge)				
	EC ₅₀ (3 h) > 1000 mg/l				
	(Activated Sludge Respir. Inhib. Test, OECD No. 209)				*1
	- barely toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)				
	EC ₅₀ (72 h) > 100 mg/l				
	NOEC (72 h) 100 mg/l				
	(OECD No. 201)				*1
	- barely toxic for planktonic crustaceans (Daphnia magna)				
	EC ₅₀ (48 h) > 100 mg/l				
	NOEC (48 h) 100 mg/l				
	(OECD No. 202)				*1
	- barely toxic for fish (zebrafish)				
	EC ₅₀ (96 h) > 100 mg/l				
	NOEC (96 h) 100 mg/l				
	(OECD No. 203)				*1
*1 referring to:	Ribavirin				

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13. Disposal considerations

Waste from residues	<ul style="list-style-type: none">- incinerate in qualified installation with flue gas scrubbing- observe local/national regulations regarding waste disposal- 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.
Contaminated packaging	<ul style="list-style-type: none">- Empty containers must be triple rinsed prior to disposal, recycling or reuse.
RCRA waste	<ul style="list-style-type: none">- not regulated under RCRA

14. Transport information

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

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 enter a waterway or into soil, or 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.

16. Other information

Edition documentation	<ul style="list-style-type: none">- changes from previous version in sections 13
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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.