Safety Data Sheet **ACT**

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	ACT
Product code	04 0457 8

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 Phone +41-61/688 54 80 Fax +41-61/681 72 76 E-Mail info.sds@roche.com	Local representation:

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

Health Hazards:
3.4Respiratory or skin sensitization (Category 1)
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Signalword: Danger

Label:

Precautionary statements:
- P260 Do not breathe dust
- P280 Wear protective gloves/ protective clothing / eye protection / face protection.
- P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
- P312 Call a POISON CENTER or doctor/physician if you feel unwell.
- P304 + P341 IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.

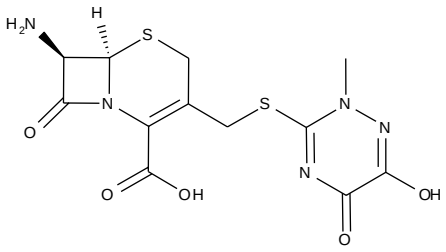
2.3. Other hazards

Note
- may form explosible dust-air mixture if dispersed

SECTION 3: Composition/information on ingredients

Characterization	chemical intermediate product of the Ceftriaxone synthesis
Chemical name	- (6R,7R)-7-Amino-3-[[[2,5-dihydro-6-hydroxy-2-methyl-5-oxo-1,2,4-triazin-3-yl]-thio]methyl]-8-oxo-5-thia-1-aza-bicyclo[4.2.0]oct-2-ene-2-carboxylic acid
Synonyms	- 7-Amino-8-oxo-3-{[(1,2,5,6-tetrahydro-2-methyl-5,6-dioxo-as-triazine-3-yl)-thio]-methyl}-5-thia-1-azabicyclo(4.2.0)-oct-2-ene-2-carboxylic acid - Aminocephalosporyl-thiotriazinone
CAS number	58909-56-1
EINECS number	261-491-7
Roche number	Ro0135268-000
Empirical formula	$C_{12}H_{13}N_5O_5S_2$

Molecular mass	371.39 g/mol



SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	- rinse immediately with tap water for at least 20 minutes - open eyelids forcibly - consult a physician
Skin contact	- remove contaminated clothes, wash affected skin with water and soap - do not use any solvents - consult physician
Inhalation	- 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	- no information available

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

Note to physician	- treat symptomatically - in case of strong sensitization against Cephalosporines anaphylaxis and asthma are possible weak cases: - Antihistaminica i.v. in case of asthma topical steroids and inhalative ß-Mimetica severe cases: - Adrenalin 0.3 - 0.5 mg i.v. - Antihistaminica i.v. - high dosage of steroids i.v. - in case of asthma additional inhalation with topical steroids and ß-Mimetica

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide

5.2. Special hazards arising from the substance or mixture

Specific hazards	- formation of toxic and corrosive combustion gases (nitrogen oxides, sulfur oxides) possible - consider dust explosion hazard

5.3. Advice for firefighters

Protection of fire-fighters	- precipitate gases/vapours/mists with water spray

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	- prevent any exposure

6.2. Environmental precautions

Environmental protection	- do not allow to enter drains or waterways - if the substance reaches waters or the sewer system, inform the competent authority

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	- collect solids (avoid dust formation) and hand over to waste removal - clean contaminated area/containers with a alkaline cleaner

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures	- processing only in closed rooms with reduced pressure and high efficiency particulate air filter (HEPA filter; GMP) - decontamination of the working surface, containers and protective clothes after work - local exhaust ventilation necessary - take precautionary measures against electrostatic charging - avoid dust formation; high dust explosion hazard
Suitable materials	- glass, aluminium, enamel, polyethylene - stainless steel

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	- cool - store under inert gas
Validity	- 18 months, 2 to 8 °C

Packaging materials	- in sealed containers - tightly closing; material: glass, aluminium, enamel, polyethylene, stainless steel
Note	- highly active substance: risk of cross contamination - avoid open handling

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Note	- no information available

8.2. Exposure controls

General protective and hygiene measures	- instruction of employees mandatory - shower after work recommended
Respiratory protection	- in case of open handling or accidental release: particle mask or respirator with independent air supply
Hand protection	- protective gloves (neoprene, nitrile or butyl rubber)
Eye protection	- safety glasses
Body protection	- full protective clothing with external breathing air supply (respiratory-, eye-, skin- and body protection), decontamination of protective clothing through full-dress shower after work
Analytics	- air: sampling on filter, desorption with water/acetonitrile; HPLC analysis - surfaces: wipe test with paper filter, desorption with water/acetonitrile; HPLC analysis
Remarks	- allergic persons should possibly be excluded from any occupational to ACT (evaluation of aptitude by physician) - particle mask, protective gloves and safety eyeglasses may be adequate for lab work involving low quantities

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour	white to yellowish
Form	powder partly with lumps
Solubility	virtually insoluble, water

9.2. Other information

Bulk density	~ 0.3 g/cm^3

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Note - no information available

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid
- light
- air
- humidity

10.5. Incompatible materials

Materials to avoid - acids, bases, oxidizing agents

10.6. Hazardous decomposition products

Note - strong exothermic decomposition above 70°C

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- LD_{50}	> 2’500	mg/kg	(oral, mouse)
	- LD_{50}	> 2’500	mg/kg	(oral, rat)

Local effects - no information available

Sensitization - strongly sensitizing (man)

Mutagenicity - no information available

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

Note	- persons sensitized to cephalosporin or penicillin may show allergic symptoms like skin reactions (exanthema), urticaria, asthma, rhino-conjunctivitis and hermatological alterations

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- barely toxic for algae (Selenastrum capricornutum) EbC_{50} (72 h) > 100 mg/l ErC_{50} (72 h) > 100 mg/l NOEC (72 h) 100 mg/l (OECD No. 201) - barely toxic for planktonic crustaceans (Daphnia magna) EC_{50} (48 h) > 100 mg/l NOEC (48 h) 100 mg/l (OECD No. 202)

12.2. Persistence and degradability

Ready biodegradability	- not readily biodegradable < 10 %, 28 days (CO_2 Evolution Test, Modified Sturm Test, OECD No. 301B)

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

Air pollution	- observe local/national regulations
Note	- highly active antibiotic - strictly avoid contamination of the environment

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

Safety-lab number	-	BS-2116
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.