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Safety Data Sheet acc. to OSHA HCS

Printing date 07/21/2023

Revision date 07/21/2023

1 Identification

· Product identifier

· Trade name: PCSK9 (human) Monoclonal Antibody (Clone 15A6)

· Synonym NARC-1

· Article number: 10218

· Application of the substance / the mixture

This product is for research use - Not for human or veterinary diagnostic or therapeutic use.

· Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Cayman Chemical Co. 1180 E. Ellsworth Rd. Ann Arbor, MI 48108

USA

· Information department: Product safety department

Emergency telephone number:

During normal opening times: +1 (734) 971-3335

US/CANADA: 800-424-9300

Outside US/CANADA: 703-741-5970

2 Hazard(s) identification

· Classification of the substance or mixture

The product is not classified, according to the Globally Harmonized System (GHS).

- · Label elements
- · GHS label elements None
- · Hazard pictograms None
- · Signal word None
- · Hazard statements None
- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 0 Fire = 1 Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = 0 Fire = 1 Reactivity = 0

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- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable. · **vPvB:** Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · **Description:** Mixture of the substances listed below with nonhazardous additions.

<u> </u>		
 Dangerous compone 	ents:	
CAS: 56-81-5 RTECS: MA8050000	Glycerol	50.0%
· Other ingredients		
CAS: 7732-18-5 RTECS: ZC0110000	Water	48.7%
CAS: 7647-14-5 RTECS: VZ4725000	Sodium chloride	0.8%
	PCSK9 (human) Monoclonal Antibody (Clone 15A6)	<0.2%
CAS: 7558-79-4 RTECS: WC4500000	Sodium phosphate, Dibasic	0.14%
CAS: 9048-46-8 RTECS: AY9296000	Albumin, bovine	0.1%
CAS: 7447-40-7 RTECS: TS8050000	Potassium chloride	0.02%
CAS: 7778-77-0 RTECS: TC6615500	Potassium phosphate, Monobasic	0.02%
CAS: 26628-22-8 RTECS: VY8050000	Sodium azide	0.02%

4 First-aid measures

- Description of first aid measures
- · General information: No special measures required.
- After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.
- Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- Indication of any immediate medical attention and special treatment needed No further relevant information available.

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5 Fire-fighting measures

- · Extinguishing media
- Suitable extinguishing agents:

Use fire fighting measures that suit the environment.

A solid water stream may be inefficient.

- · Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- · Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

Protective Action Criteria for Chemicals

· PAC-1:		
56-81-5	Glycerol	45 mg/m³
7778-77-0	Potassium phosphate, Monobasic	9.6 mg/m³
26628-22-8	Sodium azide	
· PAC-2:		
56-81-5	Glycerol	180 mg/m³
7778-77-0	Potassium phosphate, Monobasic	110 mg/m³
26628-22-8	Sodium azide	
· PAC-3:		
56-81-5	Glycerol	1,100 mg/m ³
7778-77-0	Potassium phosphate, Monobasic	630 mg/m³
26628-22-8	Sodium azide	5.3 mg/m³

7 Handling and storage

- · Handling:
- · Precautions for safe handling No special measures required.
- Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- Storage: Store in accordance with information listed on the product insert.
- Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · Specific end use(s) No further relevant information available.

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8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see section 7.
- · Control parameters
- · Components with limit values that require monitoring at the workplace:

56-81-5 Glycerol

PEL Long-term value: 15* 5** mg/m³ mist; *total dust **respirable fraction

TLV TLV withdrawn-insufficient data human occup. exp.

- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- Personal protective equipment:
- General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

- · Breathing equipment: Not required.
- · Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Not required.

9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Liquid

Color: According to product specification

· Odor: Characteristic

• Storage Buffer PBS, pH 7.2, with 50% glycerol, 0.1% BSA, and 0.02%

sodium azide

· Odor threshold: Not determined.

• Formulation 500 µg of affinity-purified monoclonal antibody

· pH-value at 20 °C (68 °F): 7.2

· Change in condition

Melting point/Melting range: Undetermined.
Boiling point/Boiling range: 100 °C (212 °F)

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Flash point:	(Contd. from page 199 °C (390.2 °F)
<u> </u>	,
Flammability (solid, gaseous):	Not determined.
Auto igniting:	400 °C (752 °F)
Decomposition temperature:	Not determined.
Ignition temperature:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits: Lower: Upper:	Not determined. Not determined.
Vapor pressure at 20 °C (68 °F): Vapor pressure at 50 °C (122 °F):	23 hPa (17.3 mm Hg) ~0 hPa
Density: Relative density Vapor density Evaporation rate	Not determined. Not determined. Not applicable. Not applicable.
Solubility in / Miscibility with Water:	Soluble.
Partition coefficient (n-octanol/wate	er): Not determined.
Viscosity: Dynamic: Kinematic:	Not applicable. Not applicable.
Solvent content:	
Organic solvents:	50.0 %
Water:	48.7 %
VOC content:	0.00 %
Other information	No further relevant information available.

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- · Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

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11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:

· LD/LC50 values that are relevant for classification:		
56-81-5 Glycero	I	
Oral	LD50	12,600 mg/kg (rat)
Irritation of skin	Irritation	500 mg/24h (rabbit) mild
Irritation of eyes	Irritation	500 mg/24h (rabbit) mild
	Intraperitoneal LD50	4,420 mg/kg (rat)
	Subcutaneous LD50	100 mg/kg (rat)

- · Primary irritant effect:
- on the skin: No irritant effect.on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
- Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

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· Other adverse effects No further relevant information available.

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13 Disposal considerations

- · Waste treatment methods
- · Recommendation: Smaller quantities can be disposed of with household waste.
- · Uncleaned packagings:
- **Recommendation:** Disposal must be made according to official regulations.
- · Recommended cleansing agent: Water, if necessary with cleansing agents.

Transport information	
UN-Number DOT, IMDG, IATA	UN1759
UN proper shipping name	
DOT	Corrosive solids, n.o.s. (Glycerol)
IMDG IATA	CORROSIVE SOLID, N.O.S. (Glycerol) Corrosive solid, n.o.s. (Glycerol)
Transport hazard class(es)	Corrosive solid, 11.0.3. (Glycerol)
DOT	
CORROSIVE	
Class	8 Corrosive substances
Label	8
IMDG, IATA	
Class	8 Corrosive substances
Label	8
Packing group DOT, IMDG, IATA	III
Environmental hazards:	Not applicable.
Special precautions for user	Warning: Corrosive substances
Hazard identification number (Kemler code):	
EMS Number: Stowage Category	F-A,S-B A
Stowage Category	^

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Transport/Additional information:	
DOT	
Quantity limitations	On passenger aircraft/rail: 25 kg On cargo aircraft only: 100 kg
IMDG	
Limited quantities (LQ) Excepted quantities (EQ)	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
IATA Remarks:	When sold in quantities of less than or equal to 1 ml or 1 g, with an Excepted Quantity Code of E1, E2, E4, or E5, this item meets the De Minim Quantities exemption, per IATA 2.6.10. Therefore packaging does not have to be labeled a Dangerous Goods/Excepted Quantity.
UN "Model Regulation":	UN 1759 CORROSIVE SOLID, N.O.S. (GLYCEROL 8, III

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.
- · Sara

Sala				
· Section 355	(extremely hazardous substances):			
26628-22-8	Sodium azide			
· Section 313	(Specific toxic chemical listings):			
26628-22-8	Sodium azide			
· TSCA (Toxi	· TSCA (Toxic Substances Control Act):			
56-81-5	Glycerol	ACTIVE		
7732-18-5	Water	ACTIVE		
7647-14-5	Sodium chloride	ACTIVE		
7558-79-4	Sodium phosphate, Dibasic	ACTIVE		
9048-46-8	Albumin, bovine	ACTIVE		
7447-40-7	Potassium chloride	ACTIVE		
7778-77-0	Potassium phosphate, Monobasic	ACTIVE		
26628-22-8	Sodium azide	ACTIVE		
· Hazardous Air Pollutants				

None of the ingredients is listed.

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

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· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

TLV (Threshold Limit Value)

26628-22-8 Sodium azide

A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

All chemicals may pose unknown hazards and should be used with caution. This SDS applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. Cayman Chemical Company assumes no responsibility for incidental or consequential damages, including lost profits, arising from the use of these data. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Cayman Chemical Company assumes no responsibility for the completeness or accuracy of the information contained herein.

- · Department issuing SDS: Environment protection department.
- · Contact: -
- Date of preparation / last revision 07/21/2023
- · Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, ÉU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit

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