

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/16/2020

Revision date 08/16/2020

1 Identification

- **Product identifier**
- **Trade name: Acetyl Lysine Monoclonal Antibody (Clone RM101)**
- **Synonym ACE**
- **Article number: 32125**
- **Application of the substance / the mixture**
API intended for use in a product approved in a NDA, ANDA, or equivalent.
For research use only - not for human or veterinary 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)**



- **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	1	Fire = 1
REACTIVITY	0	Reactivity = 0

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

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/16/2020

Revision date 08/16/2020

Trade name: Acetyl Lysine Monoclonal Antibody (Clone RM101)

(Contd. from page 1)

3 Composition/information on ingredients

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

- **Dangerous components:**

CAS: 56-81-5 RTECS: MA8050000	Glycerol	50.0%
CAS: 9048-46-8 RTECS: MT6446000	Albumin, bovine	1.0%

- **Other ingredients**

CAS: 7732-18-5 RTECS: ZC0110000	Water	47.914%
CAS: 7647-14-5 RTECS: VZ4725000	Sodium chloride	0.85%
CAS: 7558-79-4 RTECS: WC4500000	Sodium phosphate, Dibasic	0.106%
CAS: 26628-22-8 RTECS: VY8050000	Sodium azide	0.09%
CAS: 7778-77-0 RTECS: TC6615500	Potassium phosphate, Monobasic	0.03%
	Acetyl Lysine Monoclonal Antibody (Clone RM101)	0.01%

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**
May cause anemia, cough, CNS depression, drowsiness, headache, heart damage, lassitude (weakness, exhaustion), liver damage, narcosis, reproductive effects, teratogenic effects.
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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.

US

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/16/2020

Revision date 08/16/2020

Trade name: Acetyl Lysine Monoclonal Antibody (Clone RM101)

(Contd. from page 2)

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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/m ³
26628-22-8	Sodium azide	0.026 mg/m ³
7778-77-0	Potassium phosphate, Monobasic	9.6 mg/m ³

· PAC-2:

56-81-5	Glycerol	180 mg/m ³
26628-22-8	Sodium azide	0.29 mg/m ³
7778-77-0	Potassium phosphate, Monobasic	110 mg/m ³

· PAC-3:

56-81-5	Glycerol	1,100 mg/m ³
26628-22-8	Sodium azide	5.3 mg/m ³
7778-77-0	Potassium phosphate, Monobasic	630 mg/m ³

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**
Keep container tightly closed.
Store in accordance with information listed on the product insert.
- **Storage:**
- **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.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

(Contd. on page 4)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/16/2020

Revision date 08/16/2020

Trade name: Acetyl Lysine Monoclonal Antibody (Clone RM101)

(Contd. from page 3)

- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

56-81-5 Glycerol

PEL	Long-term value: 15* 5** mg/m ³ 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:** Goggles recommended during refilling.

9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form: Fluid

Color: According to product specification

- **Odor:** Characteristic

- **Storage Buffer:** PBS with 50% glycerol, 1% BSA, and 0.09% sodium azide

- **Odor threshold:** Not determined.

- **Formulation:** 100 µg of protein A-affinity purified monoclonal antibody

- **pH-value:** Not determined.

- **Change in condition**

Melting point/Melting range: Undetermined.

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

- **Flash point:** 199 °C (390.2 °F)

- **Flammability (solid, gaseous):** Not applicable.

- **Decomposition temperature:** Not determined.

(Contd. on page 5)

us

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/16/2020

Revision date 08/16/2020

Trade name: Acetyl Lysine Monoclonal Antibody (Clone RM101)

(Contd. from page 4)

· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure at 20 °C (68 °F):	23 hPa (17.3 mm Hg)
· Density at 20 °C (68 °F):	0.99795–1.00205 g/cm ³ (8.32789–8.36211 lbs/gal)
· Bulk density:	998–1,002 kg/m ³
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Fully miscible.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	50.0 %
Water:	47.9 %
VOC content:	0.00 %
	0.0 g/l / 0.00 lb/gal
Solids content:	1.1 %
· 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.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

ATE (Acute Toxicity Estimate)

Oral	LD50	50,000 mg/kg
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(Contd. on page 6)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/16/2020

Revision date 08/16/2020

Trade name: Acetyl Lysine Monoclonal Antibody (Clone RM101)

(Contd. from page 5)

56-81-5 Glycerol		
Oral	LD50	12,600 mg/kg (rat)
Irritation of skin	Irritation	500 mg/24h (rabbit)
Irritation of eyes	Irritation	500 mg/24h (rabbit)
	Intraperitoneal LD50	4,420 mg/kg (rat)
	Subcutaneous LD50	100 mg/kg (rat)
9048-46-8 Albumin, bovine		
	Intraperitoneal TDLO	0.2 pph (mouse)
26628-22-8 Sodium azide		
Oral	LDLO	27 mg/kg (rat)
	TDLO	3 ml/kg (wmn)
	LD50	27 mg/kg (rat)
	Subcutaneous LD50	45,100 µg/kg (rat)
Dermal	LD50	50 mg/kg (rat)
		20 mg/kg (rabbit)
Inhalative	LC50	37 mg/m ³ (rat)
	Subcutaneous LD50	45,100 µg/kg (rat)
	Interperitoneal LDLO	30 mg/kg (rat)
	Intraperitoneal LD50	28 mg/kg (mouse)
	Subcutaneous LD50	45 mg/kg (rat)
	Data	5,500 mg/kg (mouse)

- **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.

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/16/2020

Revision date 08/16/2020

Trade name: Acetyl Lysine Monoclonal Antibody (Clone RM101)

(Contd. from page 6)

- **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.
- **Other adverse effects** No further relevant information available.

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.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | |
| · DOT, IMDG, IATA | not regulated |
| · UN proper shipping name | |
| · DOT, IMDG, IATA | not regulated |
| · Transport hazard class(es) | |
| · DOT, ADN, IMDG, IATA | |
| · Class | not regulated |
| · Packing group | |
| · DOT, IMDG, IATA | not regulated |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | not regulated |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

· **Section 355 (extremely hazardous substances):**

26628-22-8	Sodium azide
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· **Section 313 (Specific toxic chemical listings):**

26628-22-8	Sodium azide
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(Contd. on page 8)

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/16/2020

Revision date 08/16/2020

Trade name: Acetyl Lysine Monoclonal Antibody (Clone RM101)

(Contd. from page 7)

· TSCA (Toxic Substances Control Act):		
56-81-5	Glycerol	ACTIVE
7732-18-5	Water	ACTIVE
9048-46-8	Albumin, bovine	ACTIVE
7647-14-5	Sodium chloride	ACTIVE
7558-79-4	Sodium phosphate, Dibasic	ACTIVE
26628-22-8	Sodium azide	ACTIVE
7778-77-0	Potassium phosphate, Monobasic	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.

· **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 established by ACGIH)**
26628-22-8 | Sodium azide | A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

- **GHS label elements** None
- **Hazard pictograms** None
- **Signal word** None
- **Hazard statements** None
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** Environment protection department.
- **Contact:** -
- **Date of preparation / last revision** 08/16/2020 / -

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods
 DOT: US Department of Transportation
 IATA: International Air Transport Association
 ACGIH: American Conference of Governmental Industrial Hygienists
 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)

(Contd. on page 9)

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/16/2020

Revision date 08/16/2020

Trade name: Acetyl Lysine Monoclonal Antibody (Clone RM101)

(Contd. from page 8)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

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

*** Data compared to the previous version altered.**

US