

SAFETY DATA SHEET

Product name	Product reference
Epinephrine	AG002K

R

Epinephrine

Safety Data Sheet acc. to OSHA HCS

Printing date 10/25/2023

Version Number 8

Reviewed on 10/25/2023

1 Identification

- **Product identifier**
- **Trade name:** Epinephrine
- **Article number:** AG002K
- **Application of the substance / the mixture** In vitro medical device for professional use
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
HYPHEN BioMed
155 rue d'Eragny
F-95000 NEUVILLE-SUR-OISE
FRANCE
- **Information department:**
info@hyphen-biomed.com
+33/1/34 40 65 10
- **Emergency telephone number:**
INFOTRAC emergency phone number (for USA, Puerto Rico and Canada only): 1-800-535-5053
(24-hours)

2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS06 Skull and crossbones

Acute Toxicity - Oral 2 H300 Fatal if swallowed.

- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS06

- **Signal word** Danger
- **Hazard-determining components of labeling:**
epinephrine hydrogen tartrate
- **Hazard statements**
Fatal if swallowed.
- **Precautionary statements**
Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
If swallowed: Immediately call a poison center/doctor.
Rinse mouth.
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

(Contd. on page 2)

Safety Data Sheet acc. to OSHA HCS

Printing date 10/25/2023

Version Number 8

Reviewed on 10/25/2023

Trade name: Epinephrine

· **vPvB:** Not applicable.

(Contd. of page 1)

3 Composition/information on ingredients

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

· **Dangerous components:**

51-42-3	epinephrine hydrogen tartrate	<5%
---------	-------------------------------	-----

4 First-aid measures

- **Description of first aid measures**
- **General information:**
Immediately remove any clothing soiled by the product.
Seek immediate medical advice.
- **After inhalation:**
In case of unconsciousness place patient stably in side position for transportation.
Supply fresh air and to be sure call for a doctor.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:**
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** Do not induce vomiting; immediately call for medical help.
- **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.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **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**
Wear protective clothing.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
- **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.

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/25/2023

Version Number 8

Reviewed on 10/25/2023

Trade name: Epinephrine

(Contd. of page 2)

· **Protective Action Criteria for Chemicals**

· **PAC-1:**

77-86-1	trometamol	18 mg/m ³
---------	------------	----------------------

· **PAC-2:**

77-86-1	trometamol	190 mg/m ³
---------	------------	-----------------------

· **PAC-3:**

77-86-1	trometamol	1,200 mg/m ³
---------	------------	-------------------------

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Thorough dedusting.
Open and handle receptacle with care.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **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:** 2 - 8°C
- **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 section 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Do not eat or drink while working.
- **Breathing equipment:**
Suitable respiratory protective device recommended.
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**



Protective gloves

(Contd. on page 4)

Safety Data Sheet acc. to OSHA HCS

Printing date 10/25/2023

Version Number 8

Reviewed on 10/25/2023

Trade name: Epinephrine

(Contd. of page 3)

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.

· **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:** Face protection

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form: Like powder

Color: White

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

· **Flash point:** Not applicable.

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

· **Decomposition temperature:** Not determined.

· **Ignition temperature:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

· **Vapor pressure:** Not determined.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapor density** Not determined.

· **Evaporation rate** Not applicable.

· **Solubility in / Miscibility with**

Water: Not determined.

· **Partition coefficient (n-octanol/water):** Not determined.

(Contd. on page 5)

Safety Data Sheet acc. to OSHA HCS

Printing date 10/25/2023

Version Number 8

Reviewed on 10/25/2023

Trade name: Epinephrine

(Contd. of page 4)

· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
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.

11 Toxicological information

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

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

ATE (Acute Toxicity Estimate)

Oral	LD50	23.4 mg/kg
------	------	------------

- **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 shows the following dangers according to internally approved calculation methods for preparations:
Very toxic

- **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.

(Contd. on page 6)

Safety Data Sheet acc. to OSHA HCS

Printing date 10/25/2023

Version Number 8

Reviewed on 10/25/2023

Trade name: Epinephrine

(Contd. of page 5)

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 2 (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
Avoid transfer into the environment.
- **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:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:**
Disposal must be made according to official regulations.
Dispose of packaging according to regulations on the disposal of packagings.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- | | |
|----------------------------------|---|
| · UN-Number | |
| · DOT, IMDG, IATA | UN2811 |
| · UN proper shipping name | |
| · DOT | Toxic solids, organic, n.o.s. (epinephrine hydrogen tartrate) |
| · IMDG | TOXIC SOLID, ORGANIC, N.O.S. (epinephrine hydrogen tartrate) |
| · IATA | Toxic solid, organic, n.o.s. (epinephrine hydrogen tartrate) |

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/25/2023

Version Number 8

Reviewed on 10/25/2023

Trade name: Epinephrine

(Contd. of page 6)

· **Transport hazard class(es)**

· **DOT**



· **Class**

6.1 Toxic substances

· **Label**

6.1

· **IMDG, IATA**



· **Class**

6.1 Toxic substances

· **Label**

6.1

· **Packing group**

· **DOT, IMDG, IATA**

II

· **Environmental hazards:**

Not applicable.

· **Special precautions for user**

Warning: Toxic substances

· **Hazard identification number (Kemler code):**

60

· **EMS Number:**

F-A,S-A

· **Stowage Category**

B

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable.

· **Transport/Additional information:**

· **DOT**

· **Quantity limitations**

On passenger aircraft/rail: 25 kg
On cargo aircraft only: 100 kg

· **IMDG**

· **Limited quantities (LQ)**

500 g

· **Excepted quantities (EQ)**

Code: E4

Maximum net quantity per inner packaging: 1 g

Maximum net quantity per outer packaging: 500 g

· **UN "Model Regulation":**

UN 2811 TOXIC SOLID, ORGANIC, N.O.S.
(EPINEPHRINE HYDROGEN TARTRATE), 6.1, II

15 Regulatory information

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

No further relevant information available.

(Contd. on page 8)

Safety Data Sheet acc. to OSHA HCS

Printing date 10/25/2023

Version Number 8

Reviewed on 10/25/2023

Trade name: Epinephrine

(Contd. of page 7)

· **Sara**

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

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

7647-14-5	sodium chloride	ACTIVE
77-86-1	trometamol	ACTIVE
50-81-7	ascorbic acid	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)**

None of the ingredients is listed.

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

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS06

· **Signal word** Danger

· **Hazard-determining components of labeling:**

epinephrine hydrogen tartrate

· **Hazard statements**

Fatal if swallowed.

· **Precautionary statements**

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

If swallowed: Immediately call a poison center/doctor.

(Contd. on page 9)

Safety Data Sheet acc. to OSHA HCS

Printing date 10/25/2023

Version Number 8

Reviewed on 10/25/2023

Trade name: Epinephrine

(Contd. of page 8)

Rinse mouth.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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.

· **Contact:**

· **Date of preparation / last revision** 10/25/2023

· **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)

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

Acute Toxicity - Oral 2: Acute toxicity – Category 2

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