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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Adrenaline tartrate

> Adrenalini tartras Adrenalinetartraat Adrénaline (tartrate d') Adrenalinhydrogentartrat

N° CAS: 51-42-3 N° EC: 200-097-1

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: Magis-Pharma NV

> Neerlandweg 24 2610 Wilrijk Belgium

Telephone: (+32) (0)3 457 11 76 Email: info@magis-pharma.be Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation: Belgisch Antigifcentrum Centre Antipoisons Belge

Telephone: (+32) (0)70 245 245 (Service 24/7)

Web page: www.antigifcentrum.be www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute toxicity, oral (category 1) H300 Acute toxicity, dermal (category H310

Skin corrosion/irritation (category H315

Serious eye damage/eye irritation H319

(category 2)

Acute toxicity, inhalation

(category 1)

H330

Specific target organ toxicity,

single exposure; Respiratory tract

H335

irritation (category 3)

2.2 Label elements

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Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):





Signal word(s): Danger

Hazard statements:

H300 Fatal if swallowed

H310 Fatal in contact with skin
H315 Causes skin irritation

H319 Causes serious eye irritation

H330 Fatal if inhaled

H335 May cause respiratory irritation

Precautionary statements:

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P262 Do not get in eyes, on skin, or on clothing.

P264 Wash ... thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P284 [In case of inadequate ventilation] wear respiratory protection.
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor/...

P302 + P350 Not applicable.

P302 + P352 IF ON SKIN: Wash with plenty of water/...

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses,

if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor/...
P312 Call a POISON CENTER/doctor/... if you feel unwell.
P320 Specific treatment is urgent (see ... on this label).

P321 Specific treatment (see ... on this label).

P322 Not applicable. P330 Rinse mouth.

P332 + P313 If skin irritation occurs: Get medical advice/attention.
P337 + P313 If eye irritation persists: Get medical advice/attention.
P361 Take off immediately all contaminated clothing.

P362 Take off contaminated clothing.

P363 Wash contaminated clothing before reuse.

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

P405 Store locked up.

P501 Dispose of contents/container to...

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Additional applicable label

elements:



2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Adrenaline tartrate

IUPAC name: (2R,3R)-2,3-dihydroxybutanedioic acid;4-[(1R)-1-hydroxy-2-

(methylamino)ethyl]benzene-1,2-diol

Synonyms: Epinephrine Bitartrate

N° CAS: 51-42-3 N° EC: 200-097-1 Molecular Formula: $C_{13}H_{19}NO_9$

Content: 98.5% to 101.0% (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: When in doubt or if symptoms are observed, get medical advice.

After inhalation: No special measures are necessary.

After skin contact: Wash immediately with: Water and soap Change contaminated, saturated clothing.

Wash contaminated clothing prior to re-use.

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye

irritation consult an ophthalmologist.

After ingestion: Call a physician in any case! Do NOT induce vomiting. If major quantity of dust is

swallowed or inhaled, immediately drink: Water

Self-protection of the first

aider: Not applicable.

4.2 Most important symptoms and effects, both acute and delayed

The following symptoms may occur: No known symptoms to date.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Not available.
Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires:

Protection against fire:

Hazardous combustion products:

Not available.

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Protective equipment: Avoid contact with skin, eyes and clothes. Use personal protection equipment.

For emergency responders

Not available.

6.2 Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains. Make sure spills can be contained, e.g. in sump pallets or kerbed areas. In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

6.3 Methods and material for containment and cleaning up

For containment: Collect in closed and suitable containers for disposal. Treat the recovered material as prescribed in the section on waste disposal.

For cleaning up: Take up carefully when dry.

6.4 Reference to other sections

See protective measures under point 7 and 8.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Personal protection:

Technical protective measures:

Handling:

Not available.

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

Conditions for safe storage, including any

incompatibilities:

Keep/Store only in original container.

Storage – away from: Not available.

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7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

Eye/face protection: Eye glasses with side protection

Skin protection: The quality of the protective gloves resistant to chemicals must be chosen as a

function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. DIN-/EN-Norms EN ISO 374 DIN EN 420 Suitable material NBR (Nitrile

rubber) PVA (Polyvinyl alcohol) PVC (polyvinyl chloride).

Hand protection: Breakthrough time (maximum wearing time) : > 60 m.

Thickness of the glove material: > 0,5 mm

Respiratory protection: If technical exhaust or ventilation measures are not possible or insufficient,

respiratory protection must be worn. Suitable respiratory protection apparatus Full-

/half-/quarter-face masks (DIN EN 136/140) Filtering device (full mask or

mouthpiece) with filter: ABEK-P3

Thermal hazards: Not determined.

Environmental exposure control

See section 7. No additional measures necessary.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or greyish – white, crystalline powder

Odour: Not available. Odour threshold: Not available. pH: Not available. Melting/freezing point: Not available. Not available. Initial boiling point: Boiling range: Not available. Flash point: Not available. Evaporation rate: Not available. Flammability (solid/gas): Not available.

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Upper/lower flammability or

explosive limits:

Not available.

Vapour pressure: Not available.
Vapour density: Not available.
Relative density: Not available.

Solubility: Freely soluble in water, slightly soluble in ethanol (96%)

Solubility in water: Not available.

Partition coefficient Not available.

(n-octanol/water):

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

Viscosity: Not available.

Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Stable under normal conditions of use

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Strong oxidizers

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:

Skin corrosion/irritation:

Not available.

Serious eye damage/irritation:

Respiratory/skin sensitisation:

Not available.

Not available.

Not available.

Not available.

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Carcinogenicity: Not available.

Reproductive toxicity: Not available.

Summary of evaluation of the

CMR properties:

Not available.

STOT-single exposure: Not available.

STOT-repeated exposure: Prolonged or repeated contact with skin or mucous membrane result in irritation

symptoms such as redness, blistering, dermatitis, etc.

Aspiration Hazard: Not available.

Other: Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:

Skin contact:

Not available.

Inhalation:

Not available.

Ingestion:

Not available.

Not available.

Not available.

Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Harmless to aquatic organisms up to the tested concentration.

12.2 Persistence and degradability

Biodegradable.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Delivery to an approved waste disposal company. Contaminated packages must be completely emptied and can be reused following proper cleaning. Handle contaminated packages in the same way as the substance itself.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

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ADR/RID(Land),IMDG(Sea),

IATA/ICAO (Air):

UN 2811

14.2 UN proper shipping name

ADR/RID(Land),IMDG(Sea), IATA/ICAO (Air):

TOXIC SOLID, ORGANIC, N.O.S. (Epinephrine hydrogen tartrate)

14.3 Transport hazard class(es)

ADR/RID(Land),IMDG(Sea),

IATA/ICAO (Air):

Land transport (ADR/RID)

Class(es): 6.1

Classification code: T2

Hazard identification number (Kemler No.): 66

Tunnel restriction code: C/E Special provisions: LQ 0 · E 5

Hazard label(s): 6.1 Sea transport (IMDG)

Class(es): 6.1 EmS-No.: F-A / S-A

Special provisions: LQ 0 · E 5

Hazard label(s): 6.1

Air transport (ICAO-TI / IATA-DGR)

Class(es) : 6.1

Special provisions: E 5 Hazard label(s): 6.1

14.4 Packing group

ADR/RID(Land),IMDG(Sea),

IATA/ICAO (Air):

14.5 Environmental hazards ADR/RID(Land),IMDG(Sea),

IATA/ICAO (Air):

Not classified.

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol: Not applicable. Risk phrases: Not applicable. Safety phrases: Not applicable.

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15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR: European Agreement concerning the International Carriage of Dangerous Goods by

Road

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

EC (number): European Community (number)

IATA: International Air Transport Association
ICAO: International Civil Aviation Organization

IMDG: International Maritime Code for Dangerous Goods
 IUPAC: International Union of Pure and Applied Chemistry
 PBT: Persistent, Bioaccumulative and Toxic substance

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail

STOT: Specific Target Organ Toxicity
UN (number): United Nations (number)

vPvB: very Persistent and very Bioaccumalative

16.3 Key literature references/sources for data

European Chemicals Agency.

https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

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