According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

FORM-06-14-01 (V00) Page 1/8

20/10/2022

ΕN

Publication: Revision: XX/XX/XXXX

Version: 00



NATRII DIHYDROGENOPHOSPHAS **DIHYDRICUS**

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

1.1 Product identifier

Product name: Sodium dihydrogen phosphate dihydrate

> Natrii dihydrogenophosphas dihydricus Natriumdiwaterstoffosfaat dihydraat Phosphate monosodique dihydraté Natriumdihydrogenphosphat-Dihydrat

N° CAS: 13472-35-0 N° EC: 603-853-2

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: FAC SECUNDUM ARTEM NV

Oostmalsebaan 1c (unit 5)

2960 Sint-Lenaarts

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

The substance is not classified according to Regulation (EC) 1272/2008 (CLP).

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s): Not applicable. Signal word(s): Not applicable. Hazard statements: Not applicable. Precautionary statements: Not applicable. Additional applicable label Not applicable.

elements:

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

FORM-06-14-01 (V00)

Page 2/8

ΕN

Publication: 20/10/2022 Revision: XX/XX/XXXX

Version: 00



NATRII DIHYDROGENOPHOSPHAS DIHYDRICUS

2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Sodium dihydrogen phosphate dihydrate

IUPAC name: Phosphoric acid, sodium salt, hydrate (1:1:2)

Synonyms: Sodium phosphate monobasic dihydrate

Phosphoric acid, monosodium salt, dihydrate

 N° CAS:
 13472-35-0

 N° EC:
 603-853-2

 Molecular Formula:
 NaH2PO4,2H2O

Content: 98.0 per cent to 100.5 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Consult a doctor. Show the safety data sheet to the doctor on duty.

After inhalation: Take to fresh air. If breathing is irregular, call a doctor immediately. Only give

artificial respiration if breathing stops or under medical supervision.

After skin contact: Wash immediately with plenty of soap and water for at least 15 minutes. Remove all

contaminated clothing immediately. Get medical attention if irritation develops and

persists.

After eye contact: Remove contact lenses and rinse immediately with plenty of water, including under

the eyelids, for at least 15 minutes. Get medical attention.

After ingestion: If conscious, give the victim plenty of water to drink. Never give anything by mouth

to an unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

There are no known acute or delayed effects from exposure to the product.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam, dry powder, carbon dioxide, sand, water fog.

Neighbouring fires (containers exposed to fire): Water spray or

water mist.

Unsuitable extinguishing media: Direct water jet.

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

NATRII DIHYDROGENOPHOSPHAS
DIHYDRICUS

FORM-06-14-01 (V00)

Page 3/8

ΕN

Publication: 20/10/2022 Revision: XX/XX/XXXX

Version: 00



5.2 Special hazards arising from the substance/mixture

Avoid breathing combustion product. Product is combustible and when dust is dispersed in air in sufficient concentrations and in the presence of an ignition source, may give rise to explosive reactions. Fire may develop or be driven by the solid, possibly escaping from the container, when it reaches high temperatures or by contact with ignition sources.

5.3 Advice for firefighters

Surrounding fires: Cool containers with water to prevent decomposition of product

and development of potential health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues

in accordance with current regulations.

Protection against fire: Helmet with visor, flame retardant clothing (jacket and trousers with

straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

If vapours from breathing or dust are released into the air, wear respiratory protection.

For emergency responders

If vapours from breathing or dust are released into the air, wear respiratory protection.

6.2 Environmental precautions

Avoid penetration of products into sewers, surface water, ground water.

6.3 Methods and material for containment and cleaning up

Suffocate with soil or inert material. Collect most of the material and remove the residue with water jets, follow the recommendations in section 13.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Keep the product in packaging made of material identical to the

original.

Personal protection: Not available.

Technical protective measures: Not available.

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

FORM-06-14-01 (V00)

Page 4/8

ΕN

Publication: 20/10/2022 Revision: XX/XX/XXXX

Version: 00



NATRII DIHYDROGENOPHOSPHAS DIHYDRICUS

Handling: Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Keep the product in packaging made of material identical to the

original.

Conditions for safe storage, including any

incompatibilities:

The product does not require special storage measures. Store

containers in a cool, dry place.

Storage – away from: Not available.

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

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

Hygiene measures: Handle with appropriate industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after breaks and after the end of the working day.

Individual protection measures

Eye/face protection:

No protection is required for this product.

No protection is required for this product.

Hand protection:

No protection is required for this product.

Respiratory protection:

No protection is required for this product.

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or almost white powder or colourless crystals.

Odour: Odourless.

Odour threshold: Not available.

pH: 4.0 – 5.0 (10 %)

Melting/freezing point: 100 °C

Initial boiling point: Not available.

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

FORM-06-14-01 (V00)

Page 5/8

ΕN

Publication: 20/10/2022 Revision: XX/XX/XXXX

Version: 00



NATRII DIHYDROGENOPHOSPHAS **DIHYDRICUS**

Boiling range: Not available.

Flash point: Not available. Evaporation rate: Not available. Not available. Flammability (solid/gas): Upper/lower flammability or

explosive limits:

Not available.

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

Very slightly soluble in ethanol (96 per cent). Solubility:

Solubility in water: Very soluble in water (900 g/l).

Partition coefficient

(n-octanol/water):

Not available.

Not available. Auto-ignition temperature: Decomposition temperature: Not available. Not available. Viscosity: Explosive properties: Not available. Oxidising properties: Not available.

9.2 Other information

Density (20 °C): 1.001 g/ml

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions.

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

The product does not present the possibility of hazardous reactions.

10.4 Conditions to avoid

None in particular.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

FORM-06-14-01 (V00) Page 6/8

20/10/2022

ΕN

Revision: XX/XX/XXXX

Version: 00

Publication:



NATRII DIHYDROGENOPHOSPHAS
DIHYDRICUS

Acute toxicity:

Not available.

Skin corrosion/irritation:

Not available.

Serious eye damage/irritation:

Respiratory/skin sensitisation:

Not available.

Germ cell mutagenicity:

Not available.

Carcinogenicity:

Not available.

Reproductive toxicity:

Not available.

CMR properties:

Summary of evaluation of the

STOT-single exposure: Not available.
STOT-repeated exposure: Not available.
Aspiration Hazard: Not available.

Other: There are no known health related events due to exposure to the product. In any

case, it is recommended to comply with the rules of good industrial hygiene.

11.2 Additional information on potential adverse human health effects and symptoms

Not available.

Eye contact:

Skin contact:

Inhalation:

Ingestion:

Aspiration:

Not available.

Not available.

Not available.

Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

According to available data, the product does not contain PBT or vPvB substances in concentrations above 0.10 %.

12.6 Other adverse effects

Use in accordance with good laboratory practice, avoid dispersal into the environment. Inform the competent authorities if the product contaminates groundwater, sewage, soil or vegetation.

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

FORM-06-14-01 (V00) Page 7/8

20/10/2022

ΕN

Publication: Revision: XX/XX/XXXX

Version: 00



NATRII DIHYDROGENOPHOSPHAS **DIHYDRICUS**

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

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

Not classified.

IATA/ICAO (Air):

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

14.2 UN proper shipping name

Not classified.

IATA/ICAO (Air):

14.3 Transport hazard class(es)

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

Not classified.

IATA/ICAO (Air):

14.4 Packing group

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

Not classified.

IATA/ICAO (Air):

14.5 Environmental hazards

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

Not classified.

IATA/ICAO (Air):

14.6 Special precautions for user

It is not dangerous in transport.

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

Not available.

14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

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.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

NATRII DIHYDROGENOPHOSPHAS
DIHYDRICUS

FORM-06-14-01 (V00) Page 8/8

ΕN

Publication: 20/10/2022

XX/XX/XXXX

Version: 00

Revision:



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 GoodsIUPAC: International Union of Pure and Applied ChemistryPBT: 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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According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

NATRII DIHYDROGENOPHOSPHAS

DIHYDRICUS

FORM-06-14-01 (V00)

Page 9/8

ΕN

Publication: 20/10/2022 Revision: XX/XX/XXXX

Version: 00



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16.8 Department issuing MSDS

Quality Department FAC SECUNDUM ARTEM NV info@magis-pharma.be