(in accordance with Regulation (EU) 2020/878)



# 90790-Sodium monobasic phosphate 2hto

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

#### 1.1 Product identifier.

Product Name: Sodium monobasic phosphate 2hto

90790 Product Code:

Chemical Name: Phosphoric acid, sodium salt, hydrate (1:1:2)

CAS No: 13472-35-0

Registration No: 01-2119489796-13-0042

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against.

Excipient pharmaceutical use

#### Uses advised against:

Uses other than those recommended.

# 1.3 Details of the supplier of the safety data sheet.

**GUINAMA** Company: Address: C/ Oslo Nº3

46185 La Pobla de Vallbona City:

Province: Valencia

Telephone: +34961869090 / 902119816

Fax: +34961850352 E-mail: ventas@quinama.com Web: www.guinama.com

1.4 Emergency telephone number: +34961869090 / 902119816 (Only available during office hours; Monday-Friday; 08:00-

18:00)

# **SECTION 2: HAZARDS IDENTIFICATION.**

# 2.1 Classification of the substance or mixture.

The product is not classified as hazardous within the meaning of Regulation (EC) No 1272/2008.

# 2.2 Label elements.

Este producto no esta clasificado como peligroso según el Reglamento CE 1272/2008.

# 2.3 Other hazards.

The substance is not PBT The substance is not vPvB

Substance does not have endocrine disrupting properties.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

# **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.**

# 3.1 Substances.

			(*)Classification - Regulation (EC) No 1272/2008	
Identifiers	Name	Name Concentrate Classifi		Specifics concentration limits and Acute toxicity estimate
CAS No: 13472-35-0	Phosphoric acid, sodium salt, hydrate (1:1:2)	1 - 10 %	Eye Irrit. 2, H319	-

#### 3.2 Mixtures.

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Not applicable.

# **SECTION 4: FIRST AID MEASURES.**

#### 4.1 Description of first aid measures.

Due to the composition and type of the substances present in the product, no particular warnings are necessary.

#### Inhalation.

If breathing stops, seek emergency medical attention. Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

#### Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.

#### Skin contact.

Remove contaminated clothing.

# Ingestion.

Keep calm. NEVER induce vomiting.

# 4.2 Most important symptoms and effects, both acute and delayed.

No known acute or delayed effects from exposure to the product.

#### 4.3 Indication of any immediate medical attention and special treatment needed.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

# **SECTION 5: FIREFIGHTING MEASURES.**

# 5.1 Extinguishing media.

# Suitable extinguishing media:

Extinguisher powder or CO2. In case of more serious fires, also alcohol-resistant foam and water spray.

#### **Unsuitable extinguishing media:**

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

#### 5.2 Special hazards arising from the substance or mixture.

#### Special risks.

Exposure to combustion or decomposition products can be harmful to your health.

# 5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account.

# Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

# **SECTION 6: ACCIDENTAL RELEASE MEASURES.**

# 6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

#### 6.2 Environmental precautions.

Product not classified as hazardous for the environment, avoid spillage as much as possible.

#### 6.3 Methods and material for containment and cleaning up.

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Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

#### 6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

#### **SECTION 7: HANDLING AND STORAGE.**

# 7.1 Precautions for safe handling.

The product does not require special handling measures, the following general measures are recommended:

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

# 7.2 Conditions for safe storage, including any incompatibilities.

The product does not require special storage measures. As general storage measures, sources of heat, radiation, electricity and contact with food should be avoided.

Keep away from oxidising agents and from highly acidic or alkaline materials.

Store the containers between 15 and 25 ° C, in a dry and well-ventilated place.

Store according to local legislation. Observe indications on the label. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

#### 7.3 Specific end use(s).

Not available.

# **SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.**

#### 8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

# 8.2 Exposure controls.

# **Measures of a technical nature:**

Concentration:	100 %				
Uses:	Excipient pharmaceutical use				
Breathing protection:					
If the recommended	technical measures are observed, no individual protection equipment is necessary.				
Hand protection:					
If the product is hand	dled correctly, no individual protection equipment is necessary.				
Eye protection:					
PPE: Characteristics:	Protective goggles against particle impacts.  «CE» marking, category II. Eye protector against dust and smoke.				
CEN standards:	EN 165, EN 166, EN 167, EN 168				
Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions.				
Observations:	Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, scraping etc.				
Skin protection:					
PPE:	Work footwear.				
Characteristics:	«CE» marking, category II.				
CEN standards:	EN ISO 13287, EN 20347				

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Maintenance: This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should

not be used by other people.

Observations: Work footwear for professional use includes protection elements aimed at protecting users against any

injury resulting from an accident

# **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.**

# 9.1 Information on basic physical and chemical properties.

Physical state: Solid Colour: Colorless Odour: Odorless

Odour threshold: Not applicable/Not available due to the nature/properties of the product

Melting point: 60 °C

Freezing point: Not applicable/Not available due to the nature/properties of the product

Boiling point or initial boiling point and boiling range: Not applicable/Not available due to the nature/properties of the product

Flammability: Not flammable

Lower explosion limit: Not applicable/Not available due to the nature/properties of the product Upper explosion limit: Not applicable/Not available due to the nature/properties of the product

Flash point: Not applicable/Not available due to the nature/properties of the product

Auto-ignition temperature: Not applicable/Not available due to the nature/properties of the product Decomposition temperature: Not applicable/Not available due to the nature/properties of the product pH: 4.5

рп. т.э

Kinematic viscosity: Not applicable/Not available due to the nature/properties of the product

Solubility: Not applicable/Not available due to the nature/properties of the product

Hydrosolubility: 850 kg/m3

Liposolubility: Not applicable/Not available due to the nature/properties of the product

Partition coefficient n-octanol/water (log value): -3,95861

Vapour pressure: 0 Pa

Absolute density: Not applicable/Not available due to the nature/properties of the product Relative density: Not applicable/Not available due to the nature/properties of the product Relative vapour density: Not applicable/Not available due to the nature/properties of the product Particle characteristics: Not applicable/Not available due to the nature/properties of the product

#### 9.2 Other information

Not applicable/Not available due to the nature/properties of the product

# **SECTION 10: STABILITY AND REACTIVITY.**

# 10.1 Reactivity.

No relevant data available.

# 10.2 Chemical stability.

Avoid heating. Loss of coordination waters when heating.

# 10.3 Possibility of hazardous reactions.

No dangerous reactions known

# 10.4 Conditions to avoid.

avoid heating

# 10.5 Incompatible materials.

No further relevant data available.

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10.6 Hazardous decomposition products.

phosphorus oxide sodium oxide

# **SECTION 11: TOXICOLOGICAL INFORMATION.**

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008.

#### Toxicological information.

Name	Acute toxicity			
Name	Туре	Test	Kind	Value
	Oral	LD50	Rat	8290 mg/kg [1]
Phosphoric acid, sodium salt, hydrate (1:1:2)		[1] Toxicological Data, compiled by the National Institute of Health (NIH), USA, selected and distributed by Technical Database Services (TDS), New York, 2009		
	Dermal	LD50 [1] (sustan	Rabbit cia anhidra)	>7940 mg/kg (-) [1]
CAS No: 13472-35-0 EC No:	Inhalation			

a) acute toxicity;

Not conclusive data for classification.

b) skin corrosion/irritation;

Not conclusive data for classification.

c) serious eye damage/irritation;

Based on available data, the classification criteria are not met.

d) respiratory or skin sensitisation;

Not conclusive data for classification.

e) germ cell mutagenicity;

Not conclusive data for classification.

f) carcinogenicity;

Not conclusive data for classification.

g) reproductive toxicity;

Not conclusive data for classification.

h) STOT-single exposure;

Not conclusive data for classification.

i) STOT-repeated exposure;

Not conclusive data for classification.

j) aspiration hazard;

Not conclusive data for classification.

# 11.2 Information on other hazards.

# **Endocrine disrupting properties**

This product does not contain components with endocrine-disrupting properties with effects on human health.

# Other information

There is no information available on other adverse health effects.

# **SECTION 12: ECOLOGICAL INFORMATION.**

# 12.1 Toxicity.

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Name	Ecotoxicity			
Name	Туре	Test	Kind	Value
	Fish	LC0 [1] -	peces	2400 mg/L (48h) [1]
Phosphoric acid, sodium salt, hydrate (1:1:2)	Aquatic invertebrates			
CAS No: 13472-35-0 EC No:	Aquatic plants			

#### 12.2 Persistence and degradability.

No information is available regarding the biodegradability

No information is available on the degradability

No information is available about persistence and degradability of the product.

### 12.3 Bioaccumulative potential.

Information about the bioaccumulation.

Name	Bioaccumulation			
Name	Log Pow	BCF	NOECs	Level
Phosphoric acid, sodium salt, hydrate (1:1:2)	-395861	-	-	Very low
CAS No: 13472-35-0 EC No:				

# 12.4 Mobility in soil.

No information is available about the mobility in soil.

The product must not be allowed to go into sewers or waterways.

Prevent penetration into the ground.

# 12.5 Results of PBT and vPvB assessment.

The substance does not meet the criteria for PBT or vPvB according to Regulation (EC) no. 1907/2006, annex XIII

# 12.6 Endocrine disrupting properties.

This product doesn't contain components with environmental endocrine disrupting properties.

# 12.7 Other adverse effects.

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

Risk level for water 1 (self-classification): slightly dangerous for water. In undiluted or unneutralized state, do not allow to infiltrate into groundwater, surface water or sewage.

# **SECTION 13: DISPOSAL CONSIDERATIONS.**

#### 13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.

Follow the provisions of Directive 2008/98/EC regarding waste management.

# **SECTION 14: TRANSPORT INFORMATION.**

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

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# ABSOLUTA CALIDAD

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#### 14.1 UN number or ID number.

Transportation is not dangerous.

# 14.2 UN proper shipping name.

Description:

ADR/RID: Not classified as hazardous for transport. IMDG: Not classified as hazardous for transport.

ICAO/IATA: Not classified as hazardous for transport.

#### 14.3 Transport hazard class(es).

Transportation is not dangerous.

#### 14.4 Packing group.

Transportation is not dangerous.

#### 14.5 Environmental hazards.

Transportation is not dangerous.

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): Not applicable.

#### 14.6 Special precautions for user.

Transportation is not dangerous.

# 14.7 Maritime transport in bulk according to IMO instruments.

Not classified as hazardous for transport.

# **SECTION 15: REGULATORY INFORMATION.**

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

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

# 15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

### **SECTION 16: OTHER INFORMATION.**

Classification codes:

Eye Irrit. 2: Eye irritation, Category 2

Changes regarding to the previous version:

- Changes in the information of the supplier (SECTION 1.3).
- Changes in the composition of the product (SECTION 3.2).
- Modifications in the first aid measures (SECTION 4.1).
- Elimination of toxicity values (SECTION 11.1).
- Elimination of ecological information values (SECTION 12.1).
- Elimination of ecological information values (SECTION 12.3).

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards On basis of test data Health hazards Calculation method Environmental hazards Calculation method

It is recommended that the product only be employed for the purposes advised.

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#### Information on the TSCA Inventory (Toxic Substances Control Act) USA:

CAS No	Name	State
13472-35-0	Phosphoric acid, sodium salt, hydrate (1:1:2)	

Risk classification system NFPA 704:



Health hazard: 2 (Hazardous)

Flammability: 0 (Will not burn)

Reactivity: 0 (Stable)

Abbreviations and acronyms used:

BCF: Bioconcentration factor.

European Committee for Standardization. CEN: EC50: Half maximal effective concentration. PPE: Personal protection equipment. LC50: Lethal concentration, 50%. LD50: Lethal dose, 50%.

NOEC: No observed effect concentration.

Key literature references and sources for data:

http://eur-lex.europa.eu/homepage.html

http://echa.europa.eu/ Regulation (EU) 2020/878.

Regulation (EC) No 1907/2006.

Regulation (EC) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.