

# PHOSPHAX

ACID NEUTRALIZER FOR AUTOMATIC WASHING MACHINES AND RENOVATION OF SURGICAL INSTRUMENTS

SURGICAL INSTRUMENTS



AUTOMATIC WASHING MACHINES



## ■ PRODUCT BENEFITS

- Double descaling action: dissolution of scale deposits and prevention of new deposit formation
- Neutralization of detergent used during the cleaning process
- Disintegration of residual foam before the final rinse
- Renovation of surgical instrument to give it a shiny appearance



**Fb** Franklab®  
notre expertise l'Ultra-Propreté



# PHOSPHAX

## ACID NEUTRALIZER FOR AUTOMATIC WASHING MACHINES AND RENOVATION OF SURGICAL INSTRUMENTS

### INSTRUCTIONS FOR USE

#### ACID NEUTRALIZATION IN DISINFECTING WASHER



##### LDI Intermediary rinse cycle settings:

- Recommended concentration:.....0.3 to 1% depending on detergent and water hardness
- Recommended temperature:.....40 to 50°C
- Recommended time contact:.....2 to 4 minutes

#### SURGICAL INSTRUMENTS RENOVATION IN AUTOMATIC WASHING MACHINES



- Recommended concentration:.....0.05 to 1%
- Recommended temperature:.....50°C
- Recommended time contact:.....5 to 15 minutes

#### SURGICAL INSTRUMENTS RENOVATION BY SOAKING

- Recommended concentration:.....5 to 10% depending on the surgical instruments aspect
- Recommended temperature:.....20 to 35°C
- Recommended time contact:.....5 to 15 minutes

Surgical instruments renovation must be followed by a lubrication in order to reprotect instruments by creating a paraffin protective layer on the stainless steel surface : LUBRIX Spray (TDS 1020.B).

### PRECAUTIONS OF USE

See (SDS010317)

### FEATURES

- Aspect: **Liquid**
- Color: **Colorless**
- pH at 0.3%: **2.0**
- pH at 1%: **1.7**
- pH at 5%: **1.3**
- pH at 10%: **<1**
- Expiration date: **4 years**

### COMPOSITION

- Phosphoric acid
- Other excipients

### PACKAGING

- ① Box of 4 x 5L .....ref. **1031720**
- ② Box of 2 x10L .....ref. **1031722**
- ③ Box of 3 low cans of 5L .....ref. **1031715**



Hazardous product - Follow precautions of use. Always read label and product information before use. Medical Device Class 1.

## PHOSPHAX

### SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 453/2010)

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

##### 1.1. Product identifier

Product name: PHOSPHAX

Product code: 010317

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

Acid neutralizing for automatic washing machines.

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

Registered company name: FRANKLAB

Address: 3 avenue des Frênes.78180.MONTIGNY LE BRETONNEUX.FRANCE.

Telephone: +33 1 39 44 93 40. Fax: +33 1 39 44 93 41.

contact@franklab.com

www.franklab.com

##### 1.4. Emergency telephone number: +33 1 40 44 30 00

Association/Organization: INRS Paris.

#### SECTION 2: HAZARDS IDENTIFICATION

##### 2.1. Classification of the substance or mixture

###### In compliance with EC regulation No. 1272/2008 and its amendments

Skin corrosion, Category 1A (Skin Corr. 1A, H314).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site

This mixture does not present a hazard to the environment. Ecological damages are not known or expected under normal uses.

##### 2.2. Label elements

###### In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard Pictograms:



GHS05

Signal Word:

DANGER

Product identifiers:

015-011-00-6

PHOSPHORIC ACID

Hazard statements:

H314

Causes severe skin burns and eye damage.

Precautionary statements - Prevention:

P280

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

Precautionary statements - Response:

P303 + P361 + P353

IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+351+338

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 or doctor/physician.

##### 2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC)  $\geq 0.1\%$  published by the European Chemicals Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>

The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

## PHOSPHAX

### SECTION 3: COMPOSITION/INFORMATIONS ON INGREDIENTS

#### 3.2. Mixtures

##### Composition:

Identification	(EC) 1272/2008	Note	%
INDEX: 015-011-00-6	GHS05	B	25 <= x % < 50
CAS: 7664-38-2	Dgr	[1]	
EC: 231-633-2	Skin Corr. 1B, H314		
REACH: 01-2119485924-24-xxxx			
PHOSPHORIC ACID			

##### Information on ingredients:

[1] Substance for which maximum workplace exposure limits are available.

### SECTION 4: FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

#### 4.1. Description of first aid measures

##### In the event of inhalation:

Remove to fresh air and keep at rest in a position comfortable for breathing.

##### In the event of splashes or contact with eyes:

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.

Regardless of the initial state, refer the patient to an ophthalmologist and show the label

##### In the event of splashes or contact with skin:

Remove/Take off immediately all contaminated clothing.

Watch out for any remaining product between skin and clothing, watches, shoes, etc.

If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted or the patient transferred to hospital.

##### In the event of swallowing:

Do not give the patient anything orally.

Seek medical attention, showing the label.

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

No data available.

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

No data available.

### SECTION 5: FIREFIGHTING MEASURES

Non-flammable.

#### 5.1. Extinguishing media

##### Suitable methods of extinction

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

##### Unsuitable methods of extinction

No data available.

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

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed:

- carbon monoxide (CO)

- carbon dioxide (CO<sub>2</sub>)

#### 5.3. Advice for firefighters

Use self-contained breathing apparatus and full protective gear.



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### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

##### For non first aid worker

Avoid any contact with the skin and eyes

##### For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

#### 6.2. Environmental precautions

Contain and control the leaks with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste.  
Prevent any material from entering drains or waterways.

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

Neutralize with an alkaline decontaminant, such as an aqueous solution of sodium carbonate or similar.  
If the ground is contaminated, once the product has been recovered by sponging with an inert and non-combustible absorbent material, wash the contaminated area in plenty of water.

#### 6.4. Reference to other sections

No data available.

### SECTION 7: HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the mixture is handled.

#### 7.1. Precautions for safe handling

Always wash hands after handling.  
Remove and wash contaminated clothing before re-using

##### Fire prevention:

Prevent access by unauthorized personnel.

##### Recommended equipment and procedures:

For personal protection, see section 8.  
Observe precautions stated on label and also industrial safety regulations.

##### Prohibited equipments and procedures:

No smoking, eating or drinking in areas where the mixture is used.

#### 7.2. Conditions for safe storage, including any incompatibilities

Keep away from heat.  
Keep container tightly closed.

##### Storage

Store at temperatures exceeding 3°C.

##### Packaging

Always keep in packaging made of an identical material to the original.

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

Professional use only.  
Consult section 1 for the product use.

### SECTION 8: EXPOSURE CONTROLS/PERSONNAL PROTECTION

#### 8.1. Control parameters

Occupational exposure limits:  
- European Union (2009/161/UE,2006/15/CE,2000/39/CE,98/24/CE):

CAS	VME-mg/m3:	VME-ppm:	VLE-mg/m3:	VLE-ppm:	Notes:
7664-38-2	1	-	2	-	-

- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010):

CAS	TWA:	STEL:	Ceiling:	Definition:	Criteria:
7664-38-2	1mg/m3	3mg/m3	-	-	-

- France (INRS-ED984: 2012):

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CAS	VME-ppm:	VME-mg/m3:	VLE-ppm:	VLE-mg/m3:	Notes:	TMP No:
7664-38-2	0.2	1	0.5	2	-	-

### - Mexico

CAS	TWA:	STEL:	Ceiling:	Definition:	Criteria:
7664-38-2	1mg/m3	-	-	-	-

## 8.2. Exposure controls

### Personal protection measures, such as personal protective equipment

Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

### - Eye/face protection

Avoid contact with eyes.

Use eye protectors designed to protect against liquid splashes.

Before handling, wear safety goggles with protective sides accordance with standard EN166.

Prescription glasses are not considered as protection.

Individuals wearing contact lenses should wear prescription glasses during work where they may be exposed to irritant vapours.

### - Hand protection

Use suitable protective gloves that are resistant to chemical agents in accordance with standard NF EN374.

### - Body protection

Avoid skin contact.

Wear suitable protective clothing.

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed

### - Respiratory protection

If the ventilation is insufficient, wear appropriate breathing apparatus

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

#### General information

Physical state:

Fluid liquid.

#### Important health, safety and environmental information

pH:

<1

Strongly acidic.

Flash point interval:

Not applicable.

Vapour pressure (50°C):

Lower than 110kPa (1.10 bar).

Density:

> 1

Water solubility:

Soluble.

### 9.2. Other information

No data available.

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### SECTION 10: STABILITY AND REACTIVITY

#### 10.1. Reactivity

*No dangerous reactions if handling and storage conditions are respected.*

#### 10.2. Chemical stability

*This mixture is stable under the recommended handling and storage conditions in section 7.*

#### 10.3. Possibility of hazardous reactions

*Do not mix with other products, especially hypochlorites.*

#### 10.4. Conditions to avoid

*- frost*

#### 10.5. Incompatible materials

*Do not mix with other chemicals.*

#### 10.6. Hazardous decomposition products

*The thermal decomposition may release/form:*

- carbon monoxide (CO)*
- carbon dioxide (CO<sub>2</sub>)*

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### SECTION 11 : TOXICOLOGICAL INFORMATION

#### 11.1. Information on toxicological effects

##### 11.1.1. Substances

*No toxicological data available for the substances.*

##### 11.1.2. Mixture

###### **Skin corrosion/irritation:**

*Corrosive classification is based on an extreme pH value.*

###### **Serious damage to eyes/eye irritation:**

*Corrosive classification is based on an extreme pH value.*

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### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1. Toxicity

##### 12.1.2. Mixtures

*No aquatic toxicity data available for the mixture.*

#### 12.2. Persistence and degradability

*No data available.*

#### 12.3. Bioaccumulative potential

*No data available.*

#### 12.4. Mobility in soil

*No data available.*

#### 12.5. Results of PBT and vPvB assessment

*No data available.*

#### 12.6. Other adverse effects

*No data available.*

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### SECTION 13: DISPOSAL CONSIDERATIONS

*Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.*

#### 13.1. Waste treatment methods

*Do not pour into drains or waterways.*

##### **Waste:**

*Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.*

*Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.*

*Do not contaminate the ground or water with waste, do not dispose of waste into the environment.*

**PHOSPHAX**

**Soiled packaging:**

Empty container completely. Keep label(s) on container.  
 Give to a certified disposal contractor.

**SECTION 14: TRANSPORT INFORMATION**

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2013 - IMDG 2012 - ICAO/IATA 2014).

**14.1. UN number**

1805

**14.2. UN proper shipping name**

UN1805=PHOSPHORIC ACID SOLUTION

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

- Classification:



8

**14.4. Packing group**

III

**14.5. Environmental hazards**

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**14.6. Special precautions for user**

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	8	C1	III	8	80	5L	-	E1	3	E

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ
	8	-	III	5L	F-A,S-B	223	E1

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	Note	EQ
	8	-	III	852	5L	856	60L	A3 A803	E1
	8	-	III	Y841	1L	-	-	A3 A803	E1

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

No data available.

**SECTION 15: REGULATION INFORMATION**

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

**- Classification and labeling information included in section 2:**

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 487/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 758/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 944/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 605/2014

**- Container information:**

No data available.

**- Particular provisions :**

No data available.

**15.2. Chemical safety assessment**

No data available.

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### SECTION 16: OTHER INFORMATION

*Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.*

*The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.*

*It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.*

*The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.*

#### **Wording of the phrases mentioned in section 3:**

H314 Causes severe skin burns and eye damage.

#### **Abbreviations:**

ADR: European agreement concerning the international carriage of dangerous goods by Road.

IMDG: International Maritime Dangerous Goods.

IATA: International Air Transport Association.

ICAO: International Civil Aviation Organization

RID: Regulations concerning the International carriage of Dangerous goods by rail.

GHS05: Corrosion



## DECLARATION OF CONFORMITY

The manufacturer: FRANKLAB  
Z.A. De L'Observatoire  
3 Avenue de Frênes  
78180 Montigny-Le-Bretonneux  
FRANCE

Hereby declares that the following product:

### **PHOSPHAX**

Class I Medical device according to rule 1 of annex VIII of the European Medical Device Regulation 2017/745.

Is manufactured and delivered in accordance with the following regulations:

**European Medical Device Regulation 2017/745 (April 5<sup>th</sup>, 2017)**  
**Public Health Code: Part 5 Book II**

This statement of conformity is based on Technical File (DT PHOSPHAX) constituted according to the annex II of the European Medical Device Regulation 2017/745.

The product is placed on the market with following packaging:

### **PHOSPHAX (Basic UDI-DI : 37013875050MV)**

- 5L Can Ref. : 1031705
- Low 5L Can Ref. : 1031705B
- 10L Can Ref. : 1031711
- 20L Can Ref. : 1031721
- 200L Drum Ref. : 1031789
- 200L Drum with drumtainer Ref. : 10317128

26<sup>th</sup> September 2022,

Nicolas VARAY  
President

