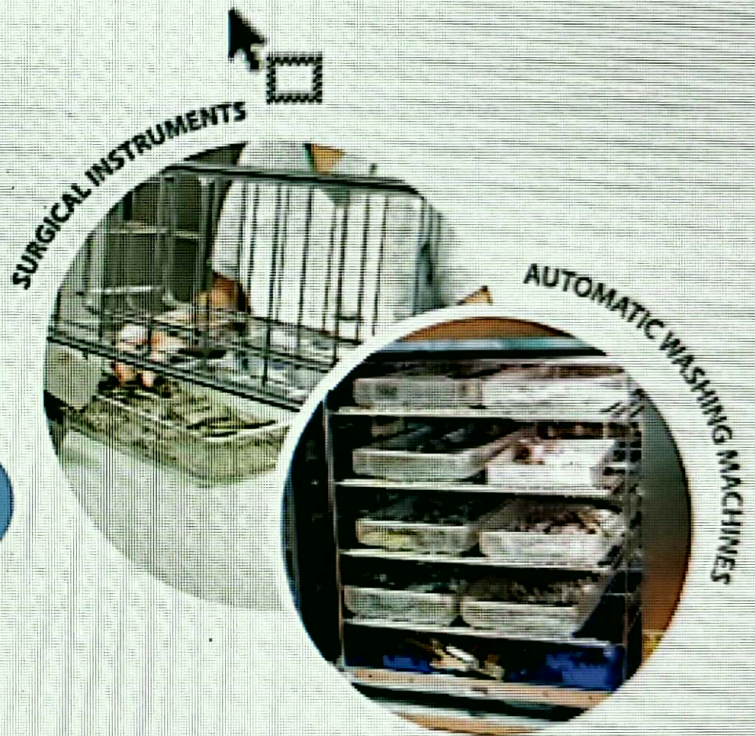


TFD 7

ALKALINE DETERGENT FOR AUTOMATIC WASHING MACHINES



■ PRODUCT BENEFITS

- Elimination of different type of secretion, proteins and greases generally dropped on surgical instruments.
- Can be used in ultrasound vats
- Compatibility with a wide range of materials: stainless steel, viton, silicone, PVC, polypropylene...
- Effectiveness guaranteed even in hard water

Fb Franklab
notre expertise l'Ultra-Propreté



CE



www.franklab.com

ALKALINE DETERGENT FOR AUTOMATIC WASHING MACHINES

INSTRUCTIONS FOR USE

LDI cleaning cycle settings:

- Recommended concentration: 0.5 to 1%
- Recommended temperature: 50 to 60°C
- Recommended time contact: 4 minutes

Concentrations rate can be adapted according to the installation type (washing machine, high-pressure cleaning...) and according to the soil.

Mechanical stirring and heat enhance the detergent action.

Product to associate during the cycle:

Intermediary rinse:

PHOSPHAX (TDS 050.B) : acid neutralizer

Final rinse:

RINCE L7 (TDS 1060.B) : rinse additive and neutral active drying

C-NET 2 (TDS 820.B) : rinse additive and neutral active drying

PRECAUTIONS OF USE

See (SDS 010208)

FEATURES

- Form: Liquid
- Color: Colorless to pale yellow
- Pure pH: 12.9 ■ Density: 1,115
- pH at 0.5%: 11.0 ■ pH at 1%: 11.8
- Expiration date: 3 years

COMPOSITION

- Sequestrants
- Non-ionic surfactants
- Potassium hydroxide
- Other excipients

PACKAGING

- Box of 3 low cans x 5 Lref. 1020815
- Box of 4 x 5 Lref. 1020820
- Box of 2 x 10 Lref. 1020822
- Can of 20 Lref. 1020821



Responsible product - Full responsibility of use. Always read label and product instructions before use. Medical Device Class I.

TFD 7

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: TFD 7

Product code: 010208

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

Liquid detergent for autoscrubber

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 for the environment. No harm to the environment is known or predictable under normal conditions of uses

2.2. Label elements

Detergent mixture (see section 15).

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

Hazard pictograms:



GHS05

Signal word

DANGER

Product identifiers:

EC 227-743-5

ETHYLENEDIAMINETETRAACETATE TETRAPOTASSIUM

EC 215-181-3

POTASSIUM HYDROXYDE

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): Take off immediately all contaminated clothing. Rinse skin with water/shower.

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.

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 annex XIII of the REACH regulations EC 1907/2006.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

TFD 7

3.2. Mixtures:

Composition:

Identification	(CE) 1272/2008	Nota	%
CAS: 5964-35-2 EC: 227-743-5 TETRAPOTASSIUM ETHYLENEDIAMINETETRAACETATE	GHS07, GHS05 Dgr Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Acute Tox. 4, H332		2.5 <= x % < 10
CAS: 1310-58-3 EC: 215-181-3 REACH: 01-2119487136-33-xxxx POTASSIUM HYDROXYDE	GHS07, GHS05 Dgr Acute Tox. 4, H302 Skin Corr. 1A, H314	[1]	2.5 <= x % < 10
CAS: 7722-88-5 EC: 231-767-1 REACH: 01-2119489794-17-0001 TETRASODIUM PYROPHOSPHATE	GHS07, GHS05 Dgr Acute Tox. 4, H302 Eye Dam. 1, H318	[1]	0 <= x % < 2.5

Information on the component:

[1] Substance for which there are exposure limit values in the workplace.

SECTION 4: FIRST AID MESURES

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 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 him the label.

In the event of splashes or contact with skin:

Remove any soiled or splashed clothing immediately.

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

If allergic manifestation, consult a doctor.

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 immediately, 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.

TFD 7

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.

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 (CO₂)

5.3. Firefighter advice

Use self-contained breathing apparatus and full protective gear.

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 or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

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 labour safety regulations.

Prohibited equipment and procedures:

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

7.2. Conditions for safe storage, including any incompatibilities

Keep the container tightly closed.

Storage

Store in a frost-free area

Packaging:

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

TFD 7

7.3. Specific end use(s)

Professional use only.

Consult section 1 for the product use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Occupational exposure limit values

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

CAS	TWA:	STEL:	Ceiling:	Définition:	Critères:
1310-58-3	-	-	2 mg/m ³	-	-

- France (INRS - ED984 :2012):

CAS	VME -ppm:	VME-mg/m ³ :	VLE-ppm:	VLE-mg/m ³ :	Notes:	TMPN°:
1310-58-3	-	-	-	2	-	-

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.

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

- 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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information:

Aspect: Fluid liquid.

Important health, safety and environmental information:

pH: 13.30

Strong base

Flash point: Not applicable.

Vapour pressure (50°C): Lower than 110 kPa (1.10 bar).

Relative density: > 1

Solubility: Soluble in water.

9.2. Other information

No data available.

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

TFD 7

No data available.

10.4. Conditions to avoid

Avoid:

- frost

10.5. Incompatible materials

Do not mix with other products

10.6. Hazardous decomposition products

The thermal decomposition may release/form:

- carbon monoxide (CO)
- carbon dioxide (CO₂)

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Substances

Acute toxicity:

TETRAPOTASSIUM ETHYLENEDIAMINETETRAACETATE (CAS: 5964-35-2)
inhalation route (dust/mist): 1 < CL₅₀ <= 5 mg/l

TETRASODIUM PYROPHOSPHATE (CAS: 7722-88-5)
Oral route: DL₅₀ = 1624 mg/kg
Species: Rat
OECD Guideline 425 (Acute Oral Toxicity - Dose Adjustment Method)

11.1.2. Mixture

Skin corrosion/ skin irritation:

The corrosive classification is based on an extreme pH value.

Severe eye damage/eye irritation:

The corrosive classification is based on an extreme pH value.

Substance(s) described in an INRS (Institut National de Recherche et de Sécurité) toxicological data sheet:

- Hydroxyde de potassium et solutions aqueuses (CAS 1310-58-3): Voir la fiche toxicologique n° 35.

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.

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.

TFD 7

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 2017 - IMDG 2016- OACI/IATA 2017).

14.1. UN Number

1814

14.2. UN proper shipping name

UN1814= POTASSIUM HYDROXIDE SOLUTION

14.3. Transport hazard class(es)

- Classification:



8

14.4. Packing group

III

14.5. Environmental hazards

-

14.6. Special precautions for user

15	ADR/	Classe	Code	Group	Label	Ident.	QL	Dispo.	EQ	Cat.	Tunnel
		8	C5	III	8	80	5 L	-	E1	3	E

IMDG	Classe	2°Label	Group	QL	FS	Dispo.	EQ
	8	-	III	5 L	F-A,S-B	223	E1

IATA	Classe	2°Etia.	Group	Passenger	Passenger	Carao	Carao	note	EQ
	8	-	III	852	5 L	856	60L	A3 A803	E1
	8	-	III	Y841	1 L	-	-	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.

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

No data available.

SECTION 15: REGULATORY INFORMATION

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

- Classification and labelling 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.

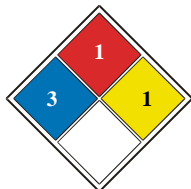
TFD 7

- Labelling for detergents (EC Regulation No. 648/2004,907/2006):

- - less than 5 %: phosphates
- - less than 5 %: non-ionic surfactants
- - less than 5 %: EDTA and salts

- U.S. Standard System for the Identification of Product Hazards for Emergency Response (NFPA 704) :

NFPA 704 Label : Health=3 Flammability=1 Instability/Responsiveness =1 Specific risk=none



15.2. Chemical safety assessment

No data available.

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:

H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H332	Harmful if inhaled.

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 Organisation.

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:

TFD7

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 5th, 2017)
Public Health Code: Part 5 Book II

This statement of conformity is based on Technical File (DT Générique 3) constituted according to the annex II of the European Medical Device Regulation 2017/745. The product is placed on the market with following packaging:

TFD7 (Basic UDI-ID: 37013875020ML)

- | | |
|-----------------------------|-----------------|
| • 5L Can | Ref. : 1020805 |
| • Low 5L Can | Ref. : 1020805B |
| • 10L Can | Ref. : 1020811 |
| • 20L Can | Ref. : 1020821 |
| • 200L Drum | Ref. : 1020889 |
| • 200L Drum with drumtainer | Ref. : 10208128 |

26th September 2022,

FRANKLAB SAS
3 av. des Frênes - ZA de l'Observatoire
78180 MONTIGNY LE BRETONNEUX
Tél. 01 39 44 93 40 - Fax 01 39 44 93 41
@internet : <http://www.franklab.com>
RC Versailles 306 563 206 - APE 2041Z

Nicolas VARAY
President

