

RINCE L7

RINSE ADDITIVE AND NEUTRAL ACTIVE DRYING

SURGICAL INSTRUMENTS



AUTOMATIC WASHING MACHINE



■ PRODUCT BENEFITS

- Neutral pH
- Silicone free
- Rinse additive for the LDI final rinsing cycle Additif to boost the drying process
- Rapid elimination of traces of moisture on instruments which are immediately dry and ready to be sterilised
- Bring a shiny appearance to instruments and improve articulation condition

Fb Franklab
notre expertise l'Ultra-Propreté



www.sterifrance.com

RINCE L7

RINSE ADDITIVE AND NEUTRAL ACTIVE DRYING

INSTRUCTIONS FOR USE

- LDI final rinse cycle settings:
 - Recommended concentration:0.03 to 0.1%
 - Recommended temperature:90 to 93°C
 - Recommended time contact :.....3 minutes

Final rinsing cycle must be performed at 93°C during 3 minutes (A0=3000) to ensure a thermal disinfection.

- Product to associate during the cycle:
 - Cleaning phase:
 - TFD Premium (TDS 1730.B):inactivating prions detergent
 - ENZYMEX L7 (TDS 790.B):enzymatic detergent
 - TFD 7 (TDS 020.B):alkaline detergent
 - Intermediary rinsing:
 - PHOSPHAX (TDS 050.B):acid neutralizer

PRECAUTIONS OF USE

See (SDS010329)

FEATURES

- Aspect: Liquid
- Color: Yellow orange
- pH at 0.1%: 7
- Expiration date: 2 years

COMPOSITION

- Non-ionic surfactants
- Rinse and dry activator agents
- Sequestrants

PACKAGING

- Box of 4 x 5Lref. 1032920
- Box of 2 x 10Lref. 1032922
- Box of 3 low cans of 5Lref. 1032915 (on demand)



Medical device Class 1.

Fb Franklab
notre expertise l'Ultra-Propreté

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RINCE L7

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: RINCE L7
Product code: 010329

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

Rinse additive and neutral active drying 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.

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 human health apart from potential occupational exposure limit values (see sections 3 and 8).
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.

Additional labels :
EUH210 Safety data sheet available on request.

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.

SECTION 3: COMPOSITION/INFORMATIONS ON INGREDIENTS

3.2. Mixtures

Composition:

Identification	(EC) 1272/2008	Note	%
CAS: 3207-22-6 EC: 250-913-5 SODIUM CUMENE SULFONATE	GHS07 Dgr Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335		2.5 \leq x % < 10
CAS: 68439-51-0 LAURYL, MYRISTYL ALCOHOL, ETHOXYLATED, PROPOXYLATED	Aquatic Chronic 3, H412		2.5 \leq x % < 10

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

RINCE L7

In the event of splashes or contact with eyes:

Immediately wash thoroughly with water.

In the event of splashes or contact with skin:

Wash thoroughly with water.

In the event of swallowing:

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 (CO₂)

5.3. Advice for firefighters

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 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

Wash thoroughly the spill area with 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.

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.

RINCE L7

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed.

Storage

Store in a frost-free place.

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/PERSONAL PROTECTION

8.1. Control parameters

No data available.

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 EN166.

- Hand protection

Use suitable protective gloves if prolonged or repeated skin contact.

- Body protection

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

Does not apply under normal use

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: 6.00

Neutral.

Flash point interval: Not relevant.

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

Density: > 1

Water solubility: Soluble.

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

No data available.

10.4. Conditions to avoid

RINCE L7

- 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 (CO₂)

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Substances

Acute toxicity:

LAURYL, MYRISTYL ALCOHOL, ETHOXYLATED, PROPOXYLATED (CAS: 68439-51-0)
Other guidelines

SODIUM CUMENE SULFONATE (CAS: 32073-22-6)

Oral route:

LD50> 2000mg/kg
Species: Rat

Skin corrosion/irritation:

LAURYL, MYRISTYL ALCOHOL, ETHOXYLATED, PROPOXYLATED (CAS: 68439-51-0)

Irritation:

No effects were observed.
Average score <1.5
OECD Guideline 471 (Bacterial Reverse Mutation Test)

Mutagenicity on germ cells :

LAURYL, MYRISTYL ALCOHOL, ETHOXYLATED, PROPOXYLATED (CAS: 68439-51-0)

No mutagenic effect.
OECD Guideline 471 (Bacterial Reverse Mutation Test)

11.1.2. Mixture

No toxicological data available for the mixture.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

12.1.1. Substances

LAURYL, MYRISTYL ALCOHOL, ETHOXYLATED, PROPOXYLATED (CAS: 68439-51-0)

Fish toxicity:

Duration of exposure: 96h

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

12.2.1. Substances

LAURYL, MYRISTYL ALCOHOL, ETHOXYLATED, PROPOXYLATED (CAS: 68439-51-0)

Biodegradability:

no degradability data is available, the substance is considered as not degrading quickly.

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.

RINCE L7

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.

Soiled packaging:

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

SECTION 14: TRANSPORT INFORMATION

Exempted from Transport labeling.

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).

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.

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:

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.

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.



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:

RINCE L7

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 RINCE L7) constituted according to the annex II of the European Medical Device Regulation 2017/745.

The product is placed on the market with following packaging:

RINCE L7 (Basic UDI-ID: 3701387510608P)

- | | |
|-----------------------------|-----------------|
| • 5L Can | Ref. : 1032905 |
| • Low 5L Can | Ref. : 1032905B |
| • 10L Can | Ref. : 1032911 |
| • 20L Can | Ref. : 1032921 |
| • 200L Drum | Ref. : 1032989 |
| • 200L Drum with drumtainer | Ref. : 10329128 |

26th September 2022,

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