

VIRO'WIPES

Șervețele de curățare și sporicide impregnate

MD TREATMENT



WIPES



■ BENEFICIILE PRODUSULUI

- Activ de la 2 min. (EN 16615)
- Curățarea și dezinfectarea dispozitivelor medicale
- Activitate dezinfectantă de nivel înalt* (soluție impregnată)
- Curățarea și dezinfecția suprafețelor în contact cu alimentele (clătire cu apă)
- Activ pe Clostridium Difficile (soluție impregnată)

QUATERNARY
AMMONIUM
FREE

**See disinfectant properties on the back*

Fb Franklab®
notre expertise l'Ultra-Propreté



READY-TO-
USE

CE
0459



www.sterifrance.com

VIRO'WIPES Șervețele de curățare și sporicide impregnate

INSTRUCȚIUNI DE FOLOSIRE

1 Utilizarea șervețelor:

- Purtați mănuși și îndepărtați capacul și sigiliul de protecție
- Introduceți primul șervețel din centrul rolei prin distribuitorul de alimentare cu capac și puneți capacul.

Utilizarea:

1- Folosind un șervețel proaspăt, curățați și dezinfectați bine zona necesară.

2- Timp de contact : Respectați timpul de contact în funcție de activitatea antimicrobiană necesară

3- Nu clătiți*

*Clătirea nu este necesară decât dacă este specificat de instrucțiunile producătorului de podele sau când intră în contact cu pielea sau mucoasa.

4- Aruncă șervețelul

5- Închideți capacul după fiecare utilizare.

6- Repetați ori de câte ori este necesar.

PROPRIETĂȚI DEZINFECTANTE

Activitate	Standard	Timp de contact *
Bactericid (1)	EN 16615 ⁽²⁾	2 min. (dc)
	EN 13727	2 min. (cc) / 5 min. (dc)
	EN 1276	5 min. (dc)
	EN 13697	5 min. (dc)
	EN 14561	5 min. (cc and dc)
Levuricid (1)	EN 16615 ⁽²⁾	2 min. (dc)
	EN 13624	5 min. (cc and dc)
	EN 1650	5 min. (dc)
	EN 13697	5 min. (dc)
	EN 14562	5 min. (cc) / 10 min. (dc)
Fungicid (1)	EN 13624	5 min. (cc) / 10 min. (dc)
	EN 14562	5 min. (cc) / 10 min. (dc)
Virucid (1)	EN 14476 <i>Murine Norovirus</i>	2 min. (cc) and 5 min. (dc)
	EN 14476 <i>Adenovirus</i>	5 min. (cc) and 10 min. (dc)
	EN 14476 <i>Poliovirus</i>	5 min. (cc) and 10 min. (dc)
	EN 14476 <i>Active on Rotavirus</i>	10 min. (dc)
Tuberculocid (1)	EN 14348 <i>Mycobacterium terrae</i>	5 min. (cc) and 10 min. (dc)
	EN 14563 <i>Mycobacterium terrae</i>	5 min. (cc)
Mycobactericid (1)	EN 14348 <i>Mycobacterium avium</i>	10 min. (cc)
Sporicid (1)	EN 17126 <i>Bacillus subtilis</i>	10 min. (cc)
	EN 17126 <i>Bacillus cereus</i>	15 min. (cc)
	EN 13704 <i>Clostridium difficile</i>	15 min. (dc)

*Standarde realizate pentru Condiții de Curățare (CC) și/sau Condiții Murdare (DC)(7) Activitatea soluției impregnate
(2) Activitatea șervețelului impregnat

PRECAUȚII DE UTILIZARE

Vezi fișa de date desecuritate

CARACTERISTICI

- Aspect : Șervețele albe
- pH soluției impregnate : 7

COMPOSITION

- Amestec etanol/izopropanol
- Surfactant amfoteric
- Alchilamină în soluție hidroalcoolică
- Excipienți

AMBALAJ

① Box of 12 canisters of 150 wipes.....ref. 23120L

①



Hazardous product - Follow precautions of use. Read label and product information before use. Medical device Class IIB.

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

1.1. Product identifier

Product name: **VIROWIPES**
Product code: **231L**

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

Virucidal disinfectant cleaner

1.3. Information concerning the supplier of the safety data sheet

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 40
contact@sterifrance.com
www.sterifrance.com

1.4. Emergency number: +33 (0)1 40 44 30 00.

Company/Organization: INRS Paris.

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

According to Regulation (EC) No. 1272/2008 and its adaptations.

Flammable liquid, Category 3 (Flam. Liq. 3, H226).

Eye Irritation, Category 2 (Eye Irrit. 2, H319).

Specific Target Organ Toxicity (Single exposure), Category 3 (STOT SE 3, H336).

This mixture is not an environmental hazard. No harm to the environment is known or expected under normal conditions of use.

2.2. Labelling elements

In accordance with Regulation (EC) No 1272/2008 and its adaptations.

Hazard pictograms:



GHS07



GHS02

Signal word:

DANGER

Product identifier:

603-117-00-0

PROPAN-2-OL

Hazard statements and additional hazard information:

H226 Flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

Precautionary statements - Prevention:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

Precautionary statements - Response:

P305 + P351 + P338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.

P337 + P313 If the eye irritation persists; get medical advice/attention.

Precautionary statements - Storage:

P403 + P235 Store in a well-ventilated place. Keep cool.

2.3. Other hazards

The mixture does not contain any 'Substances of Very High Concern' (SVHC) >= 0.1% published by the European Chemicals Agency (ECHA) according to article 57 of REACH: <https://echa.europa.eu/en/candidate-list-table>. Refer to section 3 to identify the substances concerned.

The mixture does not meet the criteria for PBT or vPvB mixtures according to Annex XIII of REACH Regulation (EC) No 1907/2006.

The mixture does not contain substances >= 0.1% with endocrine disrupting properties in accordance with the criteria in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Mixtures

Composition:

Identification	(CE) 1272/2008	Nota	%
CAS: 64-17-5 EC: 200-578-6 REACH: 01-2119457610-43-xxxx ETHYL ALCOHOL	GHS02, GHS07 Dgr Eye Irrit. 2, H319 Flam. Liq. 2, H225	[1]	25 ≤ x % < 50
INDEX: 603-117-00-0 CAS: 67-63-0 EC: 200-661-7 PROPAN-2-OL	GHS02, GHS07 Dgr Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336	[1]	10 ≤ x % < 25
CAS: 2372-82-9 EC: 219-145-8 N-(3-AMINOPROPYL)-N-DODECYLPROPAN E-1,3-DIAMINE	GHS06, GHS05, GHS09, GHS08 Dgr Acute Tox. 3, H301 Skin Corr. 1B, H314 Eye Dam. 1, H318 STOT RE 2, H373 Aquatic Acute 1, H400 M Acute = 1 Aquatic Chronic 1, H410 M Chronic = 1		0 ≤ x % < 2.5

Information on ingredients:

(Full text of H-phrases: see section 16)

[1] Substance for which there are occupational exposure limit values.

SECTION 4: FIRST AID MEASURES

In general, if in doubt or if symptoms persist, always seek medical attention.
NEVER induce swallowing to an unconscious person.

4.1. Description of first aid measures

In case of inhalation:

In case of massive inhalation, move patient to fresh air, keep warm and at rest.

If the person is unconscious, place him/her in the lateral safety position. Notify a doctor in all cases to determine the need for monitoring and symptomatic treatment in a hospital.

If breathing is irregular or stopped, perform artificial respiration and seek medical attention.

In case of eye contact:

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

If pain, redness or visual discomfort appears, consult an ophthalmologist.

If swallowed:

Seek medical attention and present the label.

4.2. Main symptoms and effects, acute and delayed

No data available.

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

No data available.

SECTION 5: FIRE FIGHTING MEASURES

Flammable.

Dry chemical, carbon dioxide and other extinguishing gases are suitable for small fires.

5.1. Extinguishing media

Cool containers in the vicinity of the flames to avoid the risk of bursting for pressurized containers.

Suitable extinguishing media

Prevent firefighting effluents from entering sewers or waterways.

5.2. Special hazards arising from the substance or mixture

A fire will often produce thick black smoke. Exposure to decomposition products may cause health hazards.
Do not breathe fumes.

In case of fire, the following may form:

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

5.3. Advice to firefighters

Responders will be equipped with self-contained breathing apparatus.

SECTION 6: MEASURES TO BE TAKEN IN CASE OF ACCIDENTAL DISPERSION

6.1. Personal precautions, protective equipment and emergency procedures

Refer to protective measures listed in sections 7 and 8.

For non-first aid workers

Avoid breathing vapours.

Avoid contact with skin and eyes.

If large quantities are spilled, evacuate personnel leaving only trained operators with protective equipment.

For first aid workers

Responders will be equipped with appropriate personal protective equipment (see section 8).

6.2. Precautions for the protection of the environment

Contain and collect spills with non-combustible absorbent materials, e.g. sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Prevent entry into sewers or waterways.

6.3. Methods and equipment for containment and clean-up

Clean up preferably with a detergent, avoid the use of solvents

6.4. Reference to other sections

No data available.

SECTION 7: HANDLING AND STORAGE

The requirements for storage rooms are applicable to workshops where the mixture is handled.

7.1. Precautions for safe handling

Wash hands after each use.

Remove and wash contaminated clothing before reuse.

Fire Prevention:

Handle in well ventilated areas.

Prevent the creation of flammable or explosive concentrations in the air and avoid vapour concentrations above the occupational exposure limit values.

Avoid accumulation of electrostatic charges with grounded connections.

The mixture may be electrostatically charged: always ground when transferring. Wear antistatic shoes and clothing and make floors of non-conductive material.

Use the mixture in areas without open flames or other sources of ignition and have protected electrical equipment.

Keep containers tightly closed and away from sources of heat, sparks and open flame.

Do not use tools that may cause sparks. Do not smoke.

Do not allow access to unauthorized persons.

Recommended equipment and procedures:

For personal protection, see section 8.

Observe the precautions indicated on the label as well as occupational health and safety regulations.

Avoid inhalation of vapours.

Avoid inhalation of vapours. Carry out any suitable industrial operation in a closed apparatus.

Provide vapor extraction at the source of emission, as well as general ventilation of the premises.

Also provide respiratory protection equipment for certain short-term, exceptional work or for emergency interventions.

In all cases, capture emissions at the source.

Avoid contact of the mixture with the eyes.

Prohibited equipment and procedures:

Smoking, eating, and drinking are prohibited in the areas where the mixture is used.

7.2. Conditions necessary for safe storage, taking into account possible incompatibilities

No data available.

Storage

Keep container tightly closed in a dry, well-ventilated place.

Keep away from all sources of ignition – Do not smoke.

Keep away from all sources of ignition, heat and direct sunlight.

Avoid accumulation of electrostatic charges.

Packaging

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

7.3. Specific end use(s)

No data available.

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	TLV-TWA:	STEL:	TLV-C:	Definition:	Criteria:
64-17-5		1000 ppm		A3	
67-63-0	200 ppm	400 ppm		A4; BEI	

- France (INRS - ED984 / 2020-1546):

CAS	TLV-TWA-ppm	TLV-TWA-mg/m3	TLV-C-ppm	TLV-C-mg/m3	Notes:	TOD NO.
64-17-5	1000	1900	5000	9500	-	84
67-63-0	-	-	400	980	-	84

-Mexico

CAS	TLV-TWA:	STEL:	TLV-C:	Definition:	Criteria:
64-17-5	1000ppm	-	-	-	-
67-63-0	400 ppm	500 ppm	-	-	-

8.2. Exposure Controls

Personal protective measures, such as personal protective equipment

Use clean and properly maintained personal protective equipment.

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

During use, do not eat, drink or smoke. Remove and wash contaminated clothing before reuse. Provide adequate ventilation, especially in confined areas.

Eye / face protection

Avoid contact with eyes.

Use eye protection designed to protect against liquid splashes.

Before any handling, it is necessary to wear goggles with side protection in accordance with the NF EN166 standard.

In case of increased danger, use a face shield for face protection.

Wearing prescription glasses does not constitute protection.

It is recommended that contact lens wearers use corrective lenses while working in areas where they may be exposed to irritating vapours.

Provide eyewash fountains in areas where the product is handled on a regular basis.

Hand protection

Use protective gloves that are resistant to chemical agents in accordance with the standard EN ISO 374-1.

The selection of gloves must be made according to the application and the duration of use at the workstation.

Protective gloves must be chosen according to the workstation: other chemical products that may be handled, physical protection required (cut, puncture, thermal protection), dexterity required.

Type of gloves recommended:

- Natural latex
- Nitrile rubber (Butadiene-acrylonitrile copolymer (NBR))
- PVC (Polyvinyl chloride)
- Butyl rubber (Isobutylene-isoprene copolymer)

Body protection

Personnel should wear regularly laundered work clothes.

After contact with the product, all soiled parts of the body should be washed.

Respiratory protection

Avoid inhalation of vapours.

In case of insufficient ventilation, wear suitable respiratory equipment.

When workers are confronted with concentrations above the exposure limits, they must wear an appropriate and approved respiratory protective device.

Anti-gas and vapor filter(s) (Combined filters) in compliance with the NF EN 14387/A1 standard:

- A1 (Brown)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on essential physical and chemical properties

Physical state:

Physical state: Solid (pre-impregnated wipes).

Colour

Not specified.

Odour

Odour threshold: Not specified.

Freezing point

Freezing point/interval: Not specified.

Boiling point or initial boiling point and boiling range

Boiling point/boiling range: Not applicable.

Flammability

Flammability (solid, gas): Not specified.

Lower and upper explosion limits

Explosion hazards, lower explosion limit (%): Not specified.

Explosion hazards, upper explosion limit (%): Not specified.

Flash point

Flash point range: 23.60°C.

Auto-ignition temperature

Auto-ignition point/range: Not applicable.

Decomposition temperature

Decomposition point/range: Not applicable.

pH

pH in aqueous solution: Not specified.

pH: 7.00

Neutral

Kinematic viscosity

Viscosity: Not specified.

Viscosity: 7 mm²/s ≤ v ≤ 14 mm²/s (40°C)

Solubility

Water solubility: Soluble.

Lipid solubility: Not specified.

Partition coefficient n-octanol/water (log value)

Partition coefficient n-octanol/water: Not specified.

Vapor pressure

Vapor pressure (50°C): Less than 110 kPa (1.10 bar).

Density and/or relative density

Density: <1

Relative vapor density

Vapor density: Not specified.

9.2. Other information

No data available.

9.2.1. Information concerning physical hazard classes

No data available.

9.2.2. Other safety data

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Any device likely to produce a flame or to bring to high temperature a metallic surface (burners, electric arcs, ovens...) will be banned from the premises.

Avoid:

- accumulation of electrostatic charges
- warming up
- heat
- flames and hot surfaces
- freezing

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

Thermal decomposition may release/form:

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

SECTION 11: TOXICOLOGICAL INFORMATION**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

May cause reversible eye effects, such as eye irritation that is completely reversible within a 21-day observation period. Narcotic effects may occur, such as drowsiness, narcosis, decreased alertness, loss of reflexes, lack of coordination or vertigo.

They may also manifest themselves as severe headaches or nausea and lead to impaired judgement, dizziness irritability, fatigue or memory problems.

11.1.1. Substances

No toxicological information is available on the substances.

11.1.2. Mixture

No toxicological information is available on the mixture.

11.2. Information on other hazards

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

- Ethanol (CAS 64-17-5): See toxicological data sheet NO. 48.
- Propane-2-ol (CAS 67-63-0): See the toxicological sheet NO. 66.

SECTION 12: ECOLOGICAL INFORMATION**12.1. Toxicity****12.1.2 Mixtures**

No aquatic toxicity information is available on the mixture.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulation potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessments

No data available.

12.6. Endocrine disrupting properties

No data available.

12.7. Other adverse effects

No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

Appropriate waste management of the mixture and/or its container shall be determined in accordance with the provisions of Directive 2008/98/EC.

13.1. Methods for waste disposal

Do not discharge into drains or waterways.

Waste:

Waste management shall be carried out without endangering human health and without harming the environment, and in particular without creating a risk to water, air, soil, wildlife or plants.

Recycle or dispose of in accordance with applicable laws, preferably through a licensed collector or company.

Do not contaminate soil or water with waste, do not dispose of it in the environment.

Contaminated packaging:

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

Hand over to an approved disposal agent.

SECTION 14: TRANSPORT INFORMATION

Transport the product in accordance with the provisions of ADR for road, RID for rail, IMDG for sea, and ICAO/IATA for air transport (ADR 2021 - IMDG 2020 [40-20] - ICAO/IATA 2022 [63]).

14.1. UN number or identification number

1993

14.2. Proper shipping name of the UN

UN1993=FLAMMABLE LIQUID, N.O.S.

(ethyl alcohol)

14.3. Transport hazard class(es)

- Classification:



3

14.4. Packing group

III

14.5. Environmental hazards

-

14.6. Special precautions to be taken by the user

ADR/RID	Class	Code	Group	Label	Ident.	LQ	Dispo.	EQ	Cat.	Tunnel
	3	F1	III	3	30	5 Kg	274 601	E1	3	D/E

IMDG	Class	2°Label	Group	LQ	FS	Dispo.	EQ	Stowage and Handling	Separation
	3	-	III	5 Kg	F-E. S-E	223 274 955	E1	Category A	-

IATA	Class	2°Label	Groupe	Passenger	Passenger	Cargo	Cargo	note	EQ
	3	-	III	355	60 Kg	366	220 Kg	A3	E1
	3	-	III	Y344	10 Kg	-	-	A3	E1

For limited quantities of dangerous goods, see ADR and IMDG Chapter 3.4 and IATA Part 2.7.

For excepted quantities of dangerous goods, see ADR and IMDG chapter 3.5 and IATA part 2.6.

14.7. Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: REGULATORY INFORMATION

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

- Classification and labelling information under section 2:

The following regulations have been taken into account:

- Regulation (EC) No 1272/2008 amended by Regulation (EU) No 2021/643 (ATP 16)
- Regulation (EC) No 1272/2008 amended by Regulation (EU) No 2021/849 (ATP 17)

- Packaging information:

The mixture does not contain any substance subject to restriction under Annex XVII of REACH Regulation (EC) No 1907/2006:
<https://echa.europa.eu/substances-restricted-under-reach>.

- Particular provisions:

No data available.

- Tables of occupational diseases according to the French Labour Code:

TOD NO.	Wording
84	Conditions caused by liquid organic solvents for professional use:
84	liquid aliphatic or cyclic saturated or unsaturated hydrocarbons and mixtures thereof; liquid halogenated hydrocarbons; nitro derivatives of aliphatic hydrocarbons; alcohols, glycols, glycol ethers; ketones; aliphatic and cyclic ethers, including tetrahydrofuran; esters; dimethylformamide and dimethylacetamide; acetonitrile and propionitrile; pyridine; dimethyl sulfone, dimethyl sulfoxide.

- Nomenclature of classified installations (Version 50 bis of February 2021, taking into account the provisions of the 2012/18/EU directive known as Seveso 3):

ICPE NO.	Name of the section	Regime	Radius
4331	Category 2 or category 3 flammable liquids excluding section 4330. The total quantity likely to be present in the installations including underground cavities being:		
	1. Greater than or equal to 1,000 t	A	2
	2. Greater than or equal to 100 t but less than 1,000 t	E	
	3. Greater than or equal to 50 t but less than 100 t	DC	
	Low threshold quantity as defined in article R. 511-10: 5,000 t.		
	High threshold quantity as defined in article R. 511-10: 50,000 t.		

Regime = A: authorization; E: registration; D: declaration; S: public utility easement; C: subject to periodic inspection as provided for in article L. 512-11 of the environmental code.

Radius = Radius of display in kilometres.

15.2. Chemical Safety Assessment

No data available.

SECTION 16: OTHER INFORMATION

As the working conditions of the user are not known to us, the information given in this safety data sheet is based on the state of our knowledge and on national and EU regulations.

The mixture must not be used for purposes other than those specified in section 1 without first obtaining written handling instructions.

It is always the responsibility of the user to take all necessary measures to meet the requirements of local laws and regulations.

The information given in this safety data sheet should be regarded as a description of the safety requirements for this mixture and not as a guarantee of its properties.

Wording of H and EUH phrases:

H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
H373	May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Abbreviations:

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals.

STEL: Short-term exposure limit

TLV-TWA: Threshold limit value – time-weighted average

TOD: Tables of Occupational Diseases (France)

TLV-C: Threshold limit value – ceiling limit.

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.

GHS02: Flame.

GHS07: Exclamation mark.

PBT: Persistent, bioaccumulative and toxic substances.

vPvB: Very persistent and very bioaccumulative.

SVHC: Substance of Very High Concern.



AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
						franklab			
DM000436587	DETERGENT PENTRU CURĂȚAREA SUPRAFEȚELOR DISPOZITIVELOR MEDICALE	DDN SURF	1 L, DOSING BOTTLE	1076016	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000041	24-02-2023
DM000436588	DETERGENT PENTRU CURĂȚAREA SUPRAFEȚELOR DISPOZITIVELOR MEDICALE	DDN SURF	5 L, CANISTRE	1076020	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000041	24-02-2023
DM000426558	SERVEȚELE DEZINFECTANTE	VIRO*WIPES	150 BUC.	23120L139	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000022	31-01-2023
DM000388406	DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	ENZYMEX P, 2KG	10317128	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388376	DETERGENT	FRANKLAB®	RINCE L7, 200L, DRUM	1092989	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388367	DETERGENT	FRANKLAB®	PHOSPHAX, LOW 5L, CAN	1031705B	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388368	DETERGENT	FRANKLAB®	PHOSPHAX, 10L, CAN	1031711	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388403	DEZINFECTANT ȘI DETERGENT PENTRU DISPOZITIVE MEDICALE	FRANKLAB®	ENZYMEX L9, 5L	1031711	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388369	DETERGENT	FRANKLAB®	PHOSPHAX, 20L, CAN	1031721	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022
DM000388374	DETERGENT	FRANKLAB®	RINCE L7, 10L, CAN	1092911	Franta	FRANKLAB	SOFRAGRUP S.R.L.	Rg04-000271	15-11-2022

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1 2 3 4

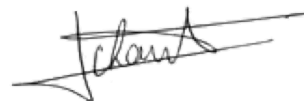


Содержит([Producatorul], 'franklab').

EQUIVALENCE VIRO'WIPES

Formula code	FRANKLAB Designation	Packaging	FRANKLAB Commercial reference
F1031V2	Viro'Wipes	12 canisters of 150 wipes	23120L

Julien CHARRAT
General Manager / CEO



TEST REPORT

FUNGICIDAL ACTIVITY OF THE F1031V2 PRODUCT ACCORDING TO THE EN 14562 STANDARD

Delivered to: Ms CHAKCHOUK

For : **FRANKLAB**
3 avenue des Frênes
78180 MONTIGNY LE BRETONNEUX
FRANCE



Date of request: 06/23/2021

Study number: n°167D34-2021-21

FUNGICIDAL TESTS:

According to the European standard EN 14562 (September 2006) – Chemical disinfectants and antiseptics. Quantitative surface test for the evaluation of fungicidal or yeasticidal activity in the medical area (phase 2, step 2).

Tests using the F1031V2 product against 2 reference strains: *Candida albicans* and *Aspergillus brasiliensis*.

This test report included 7 pages.

Study completion date: 12/03/2021

Stephanie MOROT-BIZOT
PhD in microbiology
Study director

A handwritten signature in black ink, appearing to be 'S. Morot-Bizot'.

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1. PERFORMING LABORATORY

APEX BIOSOLUTIONS
4, rue des Grandes Pièces
Zone EURESPACE
25 770 SERRE LES SAPINS
FRANCE

2. PRODUCT IDENTITY

Product	Batch N°
F1031V2	7443

Expiration date: Non communicated

Manufacturer: FRANKLAB

Manufacturing date: Non communicated

Storage conditions: as recommended by the manufacturer.

Active substances: ethanol, propanol, alkylamine

Appearance of the product : liquid, colorless

Diluent recommended by the manufacturer: none, ready-to-use product

Date of receipt: 06/24/2021

Date of the study: from 07/16/2021 to 07/26/2021

3. EXPERIMENTAL CONDITIONS

Final concentrations of the product: 100%

Method: dilution-neutralization

Exposure time: 5 min – 10 min - 15 min

Temperature using during the assays: 20°C

Organic soil load: dirty conditions, BSA 3 g/L and sheep erythrocytes 3 mL/L.

Diluent used for the microbial suspensions: trypton salt solution, sterile.

Strain : *Candida albicans*, CIP 48.72, batch 265.09 (ATCC 10231) and *Aspergillus brasiliensis* CIP 1431.83 batch n°252.09 - Institut Pasteur.

Media and growth conditions: MEA (Malt Extract Agar), at 30°C ± 1°C.

Stop solution: glass carriers in 10 ml of neutralizer [tween 80 (30g/l) and egg yolk (5%)].

4. VALIDATIONS AND ASSAYS

See results sheets.

– *C. albicans*, R = 4,03

– *A. brasiliensis*, R = 4,04

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■ SARL au capital de 10 000 € ■ RCS BESANÇON ■ N° SIRET 51786053200012 ■ N° TVA intra FR 23517860532 ■
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5. CONCLUSION

According to the EN 14562 (September 2006), the assays performed with the F1031V2 product:

- Demonstrated a fungicidal activity when the F1031V2 product is used from the 100% concentration against the two reference strains, for an exposure time of 10 minutes at 20°C, in dirty conditions (BSA 3 g/L + sheep erythrocytes 3 mL/L)

6. SHEETS OF RESULTS

Attached below.

Methodology:

- To be valid:

- $1,5 \times 10^8 \text{ CFU/mL} \leq N \leq 5 \times 10^8 \text{ CFU/mL}$
- $8,17 \leq \text{Log} N \leq 8,70$
- $1,4 \times 10^6 \text{ CFU/mL} \leq N_w \leq \lg N - 1,3$
- $R \geq 4$ for a product to be yeasticide

In the following tables:

- VC: number of CFU per ml
- $1E-XX = 1 \times 10^{-XX}$
- N: number of CFU of the fungicidal suspension per mL
- Log N: decimal logarithm of the fungicidal suspension.
- N_w = water control (number of viable cells after exposure time with water).
- N_a : number of viable cells after exposure time with the product.
- Log N_a : decimal logarithm of N_a .
- R = logarithmic reduction of the fungicidal suspension after exposure time with the product ($\log R = \log N_w - \log N_a$).

7. RESULTS – *Candida albicans*

Suspension of validation	Validation A		Validation B		Validation C		Trial suspension		Water control		Concentrations (v/v)					
	VC1 VC2		VC1 VC2		VC1 VC2		VC1 VC2		VC1 VC2		5 min		10 min		15 min	
	VC1	VC2	VC1	VC2	VC1	VC2	VC1	VC2	Nw	VC1	VC2	VC1	VC2	VC1	VC2	VC1
102	111	104	98	91	90	87	1.10 ⁻⁶	258	253	228	225	1.10 ⁰	81	93	22	23
\bar{x}	106,5	\bar{x}	101,0	\bar{x}	\bar{x}	88,5	1.10 ⁻⁷	27	26	1.10 ⁻⁴	27	1.10 ⁻¹	11	10	3	0
30 ≤ Nv0 ≤ 160	× yes <input type="checkbox"/> no		A ≥ 0,5 * Nv0		B ≥ 0,5 * Nv0		Log N	8,41	Log Nw	6,36	Log Na	2,94	2,35	<2,15	<2,15	<2,15
× yes <input type="checkbox"/> no	× yes <input type="checkbox"/> no		× yes <input type="checkbox"/> no		× yes <input type="checkbox"/> no		× yes <input type="checkbox"/> no		Log R		3,42	4,01	>4,21	>4,21	>4,21	>4,21

*Candida albicans*8. REPETITION – *Candida albicans*

Suspension of validation	Validation A		Validation B		Validation C		Trial suspension		Water control		Concentrations (v/v)					
	VC1 VC2		VC1 VC2		VC1 VC2		VC1 VC2		VC1 VC2		5 min		10 min		15 min	
	VC1	VC2	VC1	VC2	VC1	VC2	VC1	VC2	Nw	VC1	VC2	VC1	VC2	VC1	VC2	VC1
101	96	91	93	99	86	83	1.10 ⁻⁶	243	251	260	253	1.10 ⁰	100	96	22	0
\bar{x}	98,5	\bar{x}	92,0	\bar{x}	\bar{x}	84,5	1.10 ⁻⁷	28	27	1.10 ⁻⁴	28	1.10 ⁻¹	11	11	3	0
30 ≤ Nv0 ≤ 160	× yes <input type="checkbox"/> no		A ≥ 0,5 * Nv0		B ≥ 0,5 * Nv0		Log N	8,40	Log Nw	6,41	Log Na	2,99	2,36	<2,15	<2,15	<2,15
× yes <input type="checkbox"/> no	× yes <input type="checkbox"/> no		× yes <input type="checkbox"/> no		× yes <input type="checkbox"/> no		× yes <input type="checkbox"/> no		Log R		3,42	4,05	>4,26	>4,26	>4,26	>4,26

Candida albicans

9. RESULTS – *Aspergillus brasiliensis*

Suspension of validation			Validation A		Validation B		Validation C		Trial suspension				Water control			Concentrations (v/v)							
																Nw		5 min		10 min		15 min	
													VC1	VC2	VC1			VC2	VC1	VC2	VC1	VC2	VC1
66	68		60	57	59	61	55	55	1.10 ⁻⁶	160	154	1.10 ⁻³	158	160	1.10 ⁰	77	79	15	16	0	0		
\bar{X}	67,0		\bar{X}	58,5	\bar{X}	60,0	\bar{X}	55,0	1.10 ⁻⁷	19	16	1.10 ⁻⁴	18	17	1.10 ⁻¹	9	8	2	2	0	0		
30 ≤ Nv0 ≤ 160			A ≥ 0,5 * Nv0		B ≥ 0,5 * Nv0		C ≥ 0,5 * Nv0		N	8,20		Log Nw		6,21	Log Na	2,89		2,19		<2,15			
× yes <input type="checkbox"/> no			× yes <input type="checkbox"/> no		× yes <input type="checkbox"/> no		× yes <input type="checkbox"/> no								Log R	3,32		4,02		>4,06			
Aspergillus brasiliensis																							

10. REPETITIONS – *Aspergillus brasiliensis*

Suspension of validation			Validation A		Validation B		Validation C		Trial suspension			Water control			Concentrations (v/v)								
												Nw			5 min		10 min		15 min				
VC1	VC2		VC1	VC2	VC1	VC2	VC1	VC2		VC1	VC2		VC1	VC2	VC1	VC2	VC1	VC2					
68	73		80	73	75	77	62	60	1.10 ⁻⁶	>165	>165	1.10 ⁻³	>165	>165	1.10 ⁰	88	93	18	18	0	0		
\bar{X}	70,5		\bar{X}	76,5	\bar{X}	76,0	\bar{X}	61,0	1.10 ⁻⁷	18	20	1.10 ⁻⁴	21	19	1.10 ⁻¹	13	12	3	3	0	0		
30 ≤ Nv0 ≤ 160			A ≥ 0,5 * Nv0		B ≥ 0,5 * Nv0		C ≥ 0,5 * Nv0		Log N			Log Nw			6,30		2,96		2,26		<2,15		
× yes <input type="checkbox"/> no			× yes <input type="checkbox"/> no		× yes <input type="checkbox"/> no		× yes <input type="checkbox"/> no								Log R		3,34		4,04		>4,15		
Aspergillus brasiliensis																							

11. TECHNICAL APPENDIX

MEDIA

MEA (Malt Extract Agar), Dominique DUTSCHER, ref. 777304, batch n° n°712042

DILUENT

Trypton-Salt Solution

Per liter of distilled water:

- Trypton, Dominique Dutscher, ref. 777472, batch #090633 1,00
- Sodium Chloride, Grosseron, ref. 9020401, batch #FR08 085 793 8,50

Final pH at 25°C : $7,0 \pm 0,2$

NEUTRALIZER

Per liter of distilled water:

Tween 80, Sigma Aldrich, ref 59924, batch BCBJ6978V 30 g

Egg yolk 5 g

ORGANIC SOIL LOAD

Bovine Albumin Sera (powder), Dominique Dutscher, ref. 871001, batch #D1304039

Sheep erythrocytes, Analytic Lab, ref. 08449, batch# bcbj3984V

GLASS CARRIERS – blades of frosted glass 15 x 60 mm, 1 mm thick – Thermo scientific/ Menzel-Gläser
– ref. 100 OTM, batch #01 1794389.

4. Information about sample reception

- Date of reception of the sample 2022/09/02.
- Date of reception of order with test conditions 2022/09/01.
- Aspect of the received sample Transparent liquid in plastic package.

5. Method of assay and its validation

EN 14561: 2007 Standard.

- Method Dilution-neutralization.
- Neutralizer Tryptone 5 g/L, yeast extract, 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1 g/L, sodium bisulphite 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponin 30 g/L.

6. Experimental conditions

- Assay period 2022/09/25 to 2022/09/29.
- Solvent of the product used in the assay .. Sterile distilled water.
- Product concentrations for the assay Pure (100%), 50% and 0.1%.
- Aspect of the dilutions of the product Transparent liquid.
- Contact time 5 minutes.
- Assay temperature $+20^{\circ}\text{C} \pm 1^{\circ}\text{C}$.
- Interfering substance Bovine serum albumin 3 g/L + 3 mL/L erythrocytes.
- Stability of the mixture (product diluted in sterile distilled water) Stable.
- Incubation temperature $+36^{\circ}\text{C} \pm 1^{\circ}\text{C}$
- Drying time of the slides *P.aeruginosa*: 22 minutes.
S.aureus: 23 minutes.
E.hirae: 21 minutes.
- Identification of the strains used:
 - *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442).
 - *Staphylococcus aureus* (CECT 239 = ATCC 6538).
 - *Enterococcus hirae* (CECT 4081 = ATCC 10541).

7. Results of the assay

- Assay of validation See tables 1, 2, 3, 5, 6, 7, 9, 10 and 11.
- Evaluation of bactericidal activity See tables 4, 8 and 12.
- Number of replicates per assay organism ... 1.

8. Special remarks

- All controls and validation were between the basic limits.
- At least one concentration of the sample showed a log reduction lower than 5 log.
- At least one concentration of the sample showed a log reduction higher than 5 log.
- There was not any precipitation during the assay procedure (the assay mixtures were homogeneous).

9. Conclusion

The product **F1031V2**, batch 7833, when it is pure (100%), **shows bactericidal activity** after 5 minutes at $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$, under dirty conditions (bovine serum albumin 3 g/L + 3 mL/L erythrocytes.), for the reference strains *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442), *Staphylococcus aureus* (CECT 239 = ATCC 6538) and *Enterococcus hirae* (CECT 4081 = ATCC 10541), when tested as required by **EN 14561: 2007 Standard**.

Note: The results obtained correspond to the sample received in the laboratory.

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Bétera (Valencia), September 30, 2022.

HUGUET LOPEZ,
ALVARO (FIRMA)

Signed. Álvaro Huguet
Responsible Technician
(Investigator)

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials and reagents, following the Good Laboratory Practices (GLPs) as well and the final report contains the primary data obtained.

**TORRELLAS MARCÓ,
MAX (FIRMA)**

Signed. Max Torrellas
Responsible for the Laboratory Area
(Study Director)

**ESTEBAN BERMUDEZ,
ENCARNACION PILAR
(FIRMA)**

Signed. Encarnación Esteban
Technical Director
(Quality Assurance Director)

Reference

- **EN 14561 : 2007.** Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area. Test method and requirements (phase 2, step2). AENOR.

Results of the assay with *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442).

Seeding: Pour plates. No. of plates: 1/mL. Drying time of the slide: 22 minutes.

Table 1.-Validation and controls.

Suspension of validation (N_{v0})				Control of experimental conditions (A)				Control of the neutralizer (B)				Validation of the method (C) Sample concentration: Pure (100%)			
Counts per plate		V_{c1}	V_{c2}	Counts per plate		V_{c1}	V_{c2}	Counts per plate		V_{c1}	V_{c2}	Counts per plate		V_{c1}	V_{c2}
52	56	52	56	49	46	49	46	39	42	39	42	47	49	47	49
$30 \leq X \text{ of } N_{v0} \leq 160?$ $X = 54$				$X \text{ of } A \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ $X = 47.5$				$X \text{ of } B \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ $X = 40.5$				$X \text{ of } C \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ $X = 48$			
Yes				Yes				Yes				Yes			

Table 2.-Suspension of the assay.

Suspension of assay (N)	N	Counts per plate		V_{c1}	V_{c2}	$X_{wm} = 2.23 \times 10^9$ $\lg N = 9.35$ $9.17 \leq \lg N \leq 9.7?$ Yes
	10^{-7}	229	216	229	216	
	10^{-8}	22	23	22	23	

Table 3.-Water control.

Water control (N_w)	N_w	Counts per plate		V_{c1}	V_{c2}	$X_{wm} \times 10 = 9.60 \times 10^7$ $\lg N_w = 7.98$ $7.15 \leq \lg N_w \leq (\lg N - 1.3)?$ Yes
	10^{-5}	93	99	93	99	

Table 4.-Results of the activity assays with the sample.

Sample concentration	Dilution	Counts per plate		V_{c1}	V_{c2}	$\lg Na = \lg (X \text{ o } X_{wm}) + 1$	$\lg R (\lg N_w = 7.98)$	Time of contact (min)
Pure (100%)	10^0	0	0	<14	<14	<2.15	>5.83	5
	10^{-1}	0	0	<14	<14			
	10^{-2}	0	0	<14	<14			
	10^{-3}	0	0	<14	<14			
50%	10^0	0	0	<14	<14	<2.15	>5.83	5
	10^{-1}	0	0	<14	<14			
	10^{-2}	0	0	<14	<14			
	10^{-3}	0	0	<14	<14			
0.1%	10^0	>330	>330	>330	>330	> 6.52	<1.46	5
	10^{-1}	>330	>330	>330	>330			
	10^{-2}	>330	>330	>330	>330			
	10^{-3}	>330	>330	>330	>330			

Results of the assay with *Staphylococcus aureus* (CECT 239 = ATCC 6538).

Seeding: Pour plates. No. of plates: 1/mL. Drying time of the slide: 23 minutes.

Table 5.-Validation and controls.

Suspension of validation (N_{v0})				Control of experimental conditions (A)				Control of the neutralizer (B)				Validation of the method (C) Sample concentration: Pure (100%).			
Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2	Counts per plate		Vc_1	Vc_2
109	112	109	112	93	98	93	98	97	105	97	105	89	96	89	96
$30 \leq X \text{ of } N_{v0} \leq 160?$ $X = 110.5$				$X \text{ of } A \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ $X = 95.5$				$X \text{ of } B \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ $X = 101$				$X \text{ of } C \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ $X = 92.5$			
Yes				Yes				Yes				Yes			

Table 6.-Suspension of the assay.

Suspension of assay (N)	N	Counts per plate		Vc_1	Vc_2	$X_{wm} = 4.45 \times 10^9$ $\lg N = 9.65$ $9.17 \leq \lg N \leq 9.7?$ Yes
	10^{-7}	>330	>330	>330	>330	
	10^{-8}	46	43	46	43	

Table 7.-Water control.

Water control (N_w)	N_w	Counts per plate		Vc_1	Vc_2	$X_{wm} \times 10 = 3.90 \times 10^7$ $\lg N_w = 7.59$ $7.15 \leq \lg N_w \leq (\lg N - 1.3)?$ Yes
	10^{-5}	38	40	38	40	

Table 8.-Results of the activity assays with the sample.

Sample concentration (%)	Dilution	Counts per plate		Vc_1	Vc_2	$\lg Na = \lg (X \text{ o } X_{wm}) + 1$	$\lg R (\lg N_w = 7.59)$	Time of contact (min)
Pure (100%)	10^0	0	0	<14	<14	<2.15	>5.44	5
	10^{-1}	0	0	<14	<14			
	10^{-2}	0	0	<14	<14			
	10^{-3}	0	0	<14	<14			
50%	10^0	0	0	<14	<14	<2.15	>5.44	5
	10^{-1}	0	0	<14	<14			
	10^{-2}	0	0	<14	<14			
	10^{-3}	0	0	<14	<14			
0.1%	10^0	>330	>330	>330	>330	> 6.52	<1.07	5
	10^{-1}	>330	>330	>330	>330			
	10^{-2}	>330	>330	>330	>330			
	10^{-3}	>330	>330	>330	>330			

Results of the assay with *Enterococcus hirae* (CECT 4081 = ATCC 10541).

Seeding: Pour plates. No. of plates: 1/mL. Drying time of the slide: 21 minutes.

Table 9.-Validation and controls.

Suspension of validation (N_{v0})				Control of experimental conditions (A)				Control of the neutralizer (B)				Validation of the method (C) Sample concentration: Pure (100%)			
Counts per plate		V_{c1}	V_{c2}	Counts per plate		V_{c1}	V_{c2}	Counts per plate		V_{c1}	V_{c2}	Counts per plate		V_{c1}	V_{c2}
46	50	46	50	39	37	39	37	40	38	40	38	35	38	35	38
$30 \leq X \text{ of } N_{v0} \leq 160?$ $X = 48$				$X \text{ of } A \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ $X = 38$				$X \text{ of } B \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ $X = 39$				$X \text{ of } C \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ $X = 36.5$			
Yes				Yes				Yes				Yes			

Table 10.-Suspension of the assay.

Suspension of assay (N)	N	Counts per plate		V_{c1}	V_{c2}	$X_{wm} = 1.97 \times 10^9$ $\lg N = 9.29$ $9.17 \leq \lg N \leq 9.7?$ Yes
	10^{-7}	181	176	181	176	
	10^{-8}	18	18	18	18	

Table 11.-Water control.

Water control (N_w)	N_w	Counts per plate		V_{c1}	V_{c2}	$X_{wm} \times 10 = 8.60 \times 10^7$ $\lg N_w = 7.94$ $7.15 \leq \lg N_w \leq (\lg N - 1.3)?$ Yes
	10^{-5}	82	90	82	90	

Table 12.-Results of the activity assays with the sample.

Sample concentration (%)	Dilution	Counts per plate		V_{c1}	V_{c2}	$\lg Na = \lg (X_o X_{wm}) + 1$	$\lg R (\lg N_w = 7.94)$	Time of contact (min)
Pure (100%)	10^0	0	0	<14	<14	< 2.15	>5.79	5
	10^{-1}	0	0	<14	<14			
	10^{-2}	0	0	<14	<14			
	10^{-3}	0	0	<14	<14			
50%	10^0	0	0	<14	<14	< 2.15	>5.79	5
	10^{-1}	0	0	<14	<14			
	10^{-2}	0	0	<14	<14			
	10^{-3}	0	0	<14	<14			
0.1%	10^0	>330	>330	>330	>330	> 6.52	< 1.42	5
	10^{-1}	>330	>330	>330	>330			
	10^{-2}	>330	>330	>330	>330			
	10^{-3}	>330	>330	>330	>330			

Explanations:

Vc = Count per mL (one or more plates).

X = mean of Vc_1 and Vc_2 .

X_{wm} = ponderated mean of X ;

R (reduction) = $(\lg R = \log N_w - \log Na)$.

If $Na < 140$, $\log R = > [\log N_w - 2,15]$