exeol sept first

Neutral pH disinfectant detergent

- Solution to be diluted for cleaning and disinfection by immersion of invasive and non-invasive reusable medical devices before sterilisation or final disinfection

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Instructions for use

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NU-EXEOL SEPT FIRST-EN-01_2025-09 (M2-3)

To receive notifications of updates to the product file (Safety Data Sheet, Technical Data Sheet and/or Protocol), register on our website using this QR Code.

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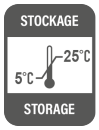
Definition of symbols used in documentation

Symbol/ Pictogram	Meaning
CE 0459	Specifies that the Medical Device marketed by Sodel is compliant with Regulation (EU) 2017/745 and that the technical documentation has been assessed by the notified body GMED (0459)
MD	Indicates that the product is a Medical Device
UDI	Indicates the Unique Device Identifier in Datamatrix or Barcode form, and in readable format
REF	Specifies the product catalogue Reference
LOT	Indicates the product Batch Number
	Indicates the Expiry date
	Indicates the email address to which the request should be sent to receive the product's Instructions For Use
	Identifies the manufacturer / marketing authority and related contact details
	Indicates that the product must be stored between 5°C and 25°C
	Indicates that the box is sensitive to moisture
	Indicates that the product must be diluted before use

Symbol/ Pictogram	Meaning
	Indicates use by manual dipping / immersion
	Indicates that the product can be used in an ultrasonic soaking tank
	Indicates that the medical devices must be rinsed before being disinfected, sterilised or reused
	Indicates that the wearing of protective gloves is mandatory
	Indicates that the wearing of protective clothing is mandatory
	Indicates that the wearing of protective goggles is mandatory
	Indicates that the product causes severe skin burns and eye damage
	Indicates that the product is very toxic to aquatic life with long lasting effects

Presentation

Field of application

- **exeol sept first** is intended for cleaning and disinfection by immersion of invasive and non-invasive reusable medical devices, before sterilisation or final disinfection.

Target users

- Use only by healthcare professionals in hospitals or similar settings and in the context of reprocessing reusable medical devices in accordance with the recommendations of their manufacturers. These users are trained in the use of hygiene products by supervising professionals with knowledge acquired through an appropriate diploma.

Product advantages

- Active in 10 min. at a dilution rate of 0.4% (bactericidal, yeasticidal and virucidal against enveloped viruses).
- Active in 30 min. with a 1% dilution on *Mycobacterium terrae* (tuberculocidal).
- Proven detergency performance on biofilm in accordance to standard NF EN ISO 15883-5: 2021.
- Combination of easily biodegradable complexing agents for metal and alkaline earth ions: increased detergency for hard water.
- neutral pH.

Commercial presentations

- Box 6 x 1L dosing bottle 20mL: EXS0043
- Box 4 x 5L + 1 x 20mL pump: EXS0088

Accessories adapted and characteristics

Accessories supplied by Sodel in 4 x 5L box

- 1 dosing pump of 20 mL: AC0016

Accessories used on the users' initiative

- Dosing pumps not supplied by Sodel: tube sufficiently long to reach the bottom of the container; Diameter of the cap to be screwed onto the 5L container: 43mm (= DIN 37); dosage enabling a solution concentration of 0.4% and/or 1%.

- Dilution units: dosage enabling a solution concentration of 0.4% and/or 1%.

- Soaking tank: made of stainless steel, polypropylene or other materials tested as compatible or recognised as inert (e.g.: Corian); fitted with a lid; preferably graduated.

- Ultrasonic tank: stainless steel tank, preferably graduated; fitted with a lid; ultrasonic frequency of up to 40 kHz; ultrasonic power of up to 360 watts.

  The **exeol sept first** 0.4% and 1% diluted solution is stable after use in ultrasonic tanks according to reports RPDILU2024_F3315_001 (2024-02-12) and RPSTABDILU2024_F3315_043 (2024-06-05) respectively.

It is the user's responsibility to ensure that the accessory selected is efficient and suitable for the product **exeol sept first** depending on information provided by the manufacturer of the accessory, by the manufacturer of the processed reusable medical device and by Sodel.

Regulatory information

Information according to Regulation (EU) 2017/745 (Medical Device)

- **exeol sept first** is a class IIa medical device.
- CE marking obtained in 2023

  CE 0459

  MD
- As a class IIa medical device, the labelling and technical documentation of **exeol sept first** meet the requirements of Annex I of Regulation (EU) 2017/745.
- Any serious incident that has occurred in relation to the medical device must be reported to Sodel and to the competent authority of the Member State in which the user and/or patient is established.
- (Indirect) expected clinical benefits:
  - Prevent healthcare-associated infection rates and in particular, the main disabling hospital-acquired infections.
  - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs.

Traceability information

The product labelling indicates the UDI, product reference, batch number and the expiry date of each production run, as follows:

UDI (01)EAN(17)YYMMDD(10)ySxxNzzzz

REF EXSXXXXxx

LOT aSxxNzzzz

YYYY-MM-DD

Definition of traceability data:

EXSXXXXxx = item code:

- EXS = exeol santé range;
- XXXX = incremented code;

- xx = Language or country code.

aSxxNzzzz = batch number:

- y = last digit of the year;
- Wxx = week number;
- Nzzzz = incremented number.

YYYY-MM-DD = expiry date:

- YYYY = year;
- MM = month;
- DD = day.

Definition of UDI data (Datamatrix):

→ (01) = 0EAN13 or EAN14 or IUD-ID

→ (17) = expiry date:

- YY = last 2 digits of the year;
- MM = month;
- DD = day.

→ (10) = batch number:

- y = last digit of the year;
- Wxx = week number;
- Nzzzz = incremented number.

IUD-ID of **exeol sept first**:

1L dosing bottle	:	EXS0043Z1 : 03268240055229
Box 6 x 1L dosing bottle	:	EXS0043Z1 : 13268240055226
5L container	:	EXS0088Z1 : 03268240055236
Box 4 x 5L + 1 pump	:	EXS0088Z1 : 13268240055233

Information in accordance with Regulation (EC) 1272/2008 (CLP)

- Wear protective gloves, protective clothing, eye protection, face protection.

- Refer to the Safety data sheet (SDS) available on *www.exeol.fr*
-

Use

Direction for use

- **1L dosing bottle:**

  Remove the cap and press the sides of the bottle to obtain the desired dose.

  Depending on the required activity spectrum, dilute the dose obtained with water at room temperature: 0.4% (4mL/L) or 1% (10mL/L).

  Close the bottle after use.

- **5L container:**

  When using for the first time, remove the tamper-proof ring before unscrewing the cap. Attach the 20mL pump to the container and prime it. Do not use the dose obtained before the pump is fully primed.

  Using the dosing pump, depending on the required activity spectrum, dilute the concentrate with water at room temperature: 0.4% (4mL/L) or 1% (10mL/L).

- The diluted and unused solution can be stored in a covered soaking tank for 72h.

- **Use:**

  1. Open and disassemble the medical devices and place them in the solution, ensuring that they are completely immersed.
  2. Contact time: 10 min. (at 0.4%) or 30 min. (at 1%), depending on the required activity spectrum.

     Observe the recommended contact time.
  3. Clean, brush, swab and irrigate the channels as necessary.
  4. Remove the medical devices, rinse thoroughly with water.

  Used solution must be changed after each use.

exeol sept first can be used in ultrasonic soaking tanks.

Cautionary notes

- All the information relating to safety is compiled in the safety data sheet (SDS), available on the website *www.exeol.fr*.
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- This information is the same as that listed on the label of the product **exeol sept first**:

DANGER. Contains:Didecyldimethylammonium chloride; Methanesulphonic acid; Alcohols, C9-11, ethoxylated. Causes severe skin burns and eye damage. Very toxic to aquatic life with long lasting effects. Avoid release to the environment. Wear protective gloves, protective clothing, eye protection, face protection. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER, a doctor. Collect spillage. Dispose of contents and container to hazardous or special waste collection point, in accordance with local regulation.

Restrictions / Warnings

Restrictions on use

- Do not mix with other products.
- Use long-sleeved gloves.
- Do not use directly on the patient.
- Do not use in a washer-disinfector.
- If in doubt about compatibility with the treated surface, carry out a test on a small surface beforehand.

Warnings for use

- Keep the container tightly closed in its original packaging and labelling.
- Before use, check the expiry date on the label.
- If you have any doubts concerning the way to use the product, please contact the sales department.

- If you have any doubts concerning the appearance of the solution or if it has been stored under non-recommended environmental conditions, do not use the product and dispose of it.
- If the label is damaged, set the container aside from the rest and inform the sales department.

Handling - First-time use - Storage

- The packaging should be stored tightly closed, at a temperature between +5°C and +25°C, in a well-ventilated place.
- If the product is, under accidental conditions and for an extended period, close to an intense source of heat, it is preferable not to reuse the product, as its qualities, properties and characteristics could be deteriorated.
- The product's expiry date before opening is 2 years from the date of manufacture when **exeol sept first** is stored in accordance with the conditions described above and in the safety data sheet (SDS) available on *www.exeol.fr* :

	**Expiry date**
	2 years after the date of manufacture, indicated on the label as: YYYY-MM-DD (Year-Month-Day)

- Close the packaging immediately after use to preserve the qualities, properties and characteristics of **exeol sept first**.
- Shelf life after opening: 12 months.

Accidental release – Disposal

Disposal of container

- Empty the container completely without rinsing it.
- Keep the label on the packaging.
- Dispose of in accordance with legal requirements. Avoid release to the environment.
- Product waste is to be disposed of without endangering human health and without harming the environment, in particular without creating a risk to water, air, soil, fauna or flora.

Disposal of residues

- Dispose of in accordance with legal requirements. Prevent entry into storm water systems or watercourses. Avoid release to the environment.
- Product waste is to be disposed of without endangering human health and without harming the environment, in particular without creating a risk to water, air, soil, fauna or flora.

Disposal of the soaking tank

- Effluent disposal is carried out in accordance with current legislation and without endangering human health and without harming the environment, in particular without creating a risk to water, air, soil, fauna or flora. Accordingly, the bath may be disposed of in the effluent treatment system of a hospital. It should be noted, however, that the hospital is fully responsible for the effluents which it discharges and must ensure the compatibility of its overall effluent with its discharge outlet (wastewater treatment plant) and in accordance with the prefectoral decree in effect (authorisation to operate).

Toxicovigilance

- The formula of **exeol sept first** is registered on the European Poison Center portal (PCN).
- UFI code to be communicated to European Poison Centers:

UFI: 6SF9-70M0-T00R-S6F7

Physico-chemical data

Composition

Didecyldimethylammonium chloride, non-ionic surfactant, sequestering agent, dye, fragrance and excipients.

Physico-chemical characteristics

- pure pH: 7.1 - 8.1
- pH at 0.4%: 6 - 7

  pH at 1%: 6.7 - 7.7
- Fragrance*: Lemon
- Colour: Blue

**Synthetic fragrance*

Microbiological data

exeol sept first est bactericidal, yeasticidal, active on *Candida auris*, virucidal against enveloped viruses such as HBV, HCV, HIV, Herpes virus, Coronavirus... et tuberculocidal.

Tests to determine bactericidal activity

Standard EN 13727: 2012+A2 (October 2015)

Test conditions	
Strain(s):	*Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae, Escherichia coli*
Interfering substance(s):	Dirty conditions
Concentration(s):	0.4%
Contact time:	5 minutes
Temperature:	20°C ± 1°C

Report:2022-904 / 22 23 00052

Conclusion: The product under test **exeol sept first** demonstrated bactericidal activity for Instrument Disinfection (≥ 5 log reduction), according to the EN 13727:2012+A2:2015, at 20±1 °C, under dirty conditions when tested at product concentrations:

- 0.5% for 5, 10 and 15 minutes contact time using as test organisms the reference strains: *Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae, Escherichia coli*.
- 0.4% for 5, 10 and 15 minutes contact time using as test organisms the reference strains: *Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae, Escherichia coli*.

Standard EN 14561 (May 2006)

Test conditions	
Strain(s):	*Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae*
Interfering substance(s):	Dirty conditions
Concentration(s):	0.4%
Contact time:	10 minutes
Temperature:	20°C ± 1°C

Report:2022-904 / 22 23 00053

Conclusion: The product under test **exeol sept first** demonstrated bactericidal activity (≥ 5 log reduction), according to the EN 14561:2006, at 20±1 °C, under dirty conditions when tested at product concentrations:

- 0.5% for 5, 10 and 15 minutes contact time using as test organisms the referenced strains: *Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae*.
- 0.4% for 10 and 15 minutes contact time using as test organisms the referenced strains: *Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae*.

Tests to determine yeasticidal activity

EN 13624 standard (November 2021)

Test conditions	
Strain(s):	*Candida albicans*
Interfering substance(s):	Dirty conditions
Concentration(s):	0.4%
Contact time:	5 minutes
Temperature:	20°C ± 1°C

Report:2022-904 / 22 23 00051_v02

Conclusion: The product under test **exeol sept first** demonstrated yeasticidal activity for instrument disinfection (≥ 4 log reduction) according to EN 13624:2021, at 20 ± 1 °C, under dirty conditions when tested at product concentrations:

- 0.5% for 5, 10 and 15 minutes contact time using as test organisms the reference strain: *Candida albicans*.
- 0.4% for 5, 10 and 15 minutes contact time using as test organisms the reference strain: *Candida albicans*.

EN 14562 standard (May 2006)

Test conditions	
Strain(s):	*Candida albicans*
Interfering substance(s):	Dirty conditions
Concentration(s):	0.4%
Contact time:	5 minutes
Temperature:	20°C ± 1°C

Report:2022-904 / 22 23 00054

Conclusion: The product under test **exeol sept first** demonstrated yeasticidal activity (≥ 4 log reduction) according to EN 14562:2006, at 20 ± 1 °C, under dirty conditions when tested at product concentration:

- 0.5% for 5, 10 and 15 minutes contact time using as test organisms the reference strain: *Candida albicans*.
- 0.4% for 5, 10 and 15 minutes contact time using as test organisms the reference strain: *Candida albicans*.

Tests to determine yeasticidal activity on *Candida auris*

EN 13624 standard (November 2021)

Test conditions	
Strain(s):	*Candida auris*
Interfering substance(s):	Dirty conditions
Concentration(s):	0.4%
Contact time:	5 minutes
Temperature:	20°C ± 1°C

Report:2023-7748/23 23 00104

Conclusion: The product under test **exeol sept first** demonstrated yeasticidal activity for specific purpose according to EN 13624:2021 (≥ 4 log reduction), under dirty conditions, at 20±1 °C, when tested at product concentrations:

- 0.5% for 5 and 10 minutes contact time using as test organism the reference strain: *Candida auris*.
- 0.4% for 5 and 10 minutes contact time using as test organism the reference strain: *Candida auris*.

EN 14562 standard (May 2006)

Test conditions	
Strain(s):	*Candida auris*
Interfering substance(s):	Dirty conditions
Concentration(s):	0.4%
Contact time:	5 minutes
Temperature:	20°C ± 1°C

Report:2023-7748/23 23 00105

Conclusion: The product under test **exeol sept first** demonstrated yeasticidal activity for specific purpose (≥ 4 log reduction) according to EN 14562:2006, at 20±1 °C, under dirty conditions when tested at product concentration:

- 0.5% for 5 and 10 minutes contact time using as test organism the reference strain: *Candida albicans.*
- 0.4% for 5 and 10 minutes contact time using as test organism the reference strain: *Candida albicans*.

Tests to determine virucidal activity

NF EN 14476+A2 standard (July 2019) on the vaccinia virus

Test conditions	
Strain(s):	Vaccinia virus *Elstree* strain
Interfering substance(s):	Dirty conditions
Concentration(s):	0.4%
Contact time:	10 minutes
Temperature:	20°C ± 1°C

Report:2022/0506-01

Conclusion: The Formula **exeol sept first** is active (reduction ≥ 4 log of the viral titer) at the concentrations 0.4% and 0.5% after 10 minutes of exposure time at 20°C, according to the standard NF EN 14476+A2 (July 2019), in dirty conditions against the Vaccinia Virus strain Elstree.

NF EN 17111 standard (October 2018) on the vaccinia virus

Test conditions	
Strain(s):	Vaccinia virus *Elstree* strain
Interfering substance(s):	Dirty conditions
Concentration(s):	0.4%
Contact time:	10 minutes
Temperature:	20°C ± 1°C

Report:22-1936

Conclusion: According to standard NF EN 17111 (2018), **exeol sept first** for medical instrument disinfection in dirty condition - has a virucidal activity at the concentration test 0.5% and 0.4% for the contact time 10 min ± 10 s against Vaccinia virus (enveloped viruses).

Tests to determine tuberculocidal activity

Standard NF EN 14348 (June 2005)

Test conditions	
Strain(s):	*Mycobacterium terrae*
Interfering substance(s):	Dirty conditions
Concentration(s):	1%
Contact time:	30 minutes
Temperature:	20°C ± 1°C

Report:345D106-2023-03

Conclusion: According to the NF EN 14348 standard (June 2005), the assays performed with **exeol sept first** demonstrated a tuberculocidal activity against *Mycobacterium terrae* reference strain for an exposure time of 30 min at 20°C, in dirty conditions (3 g/L BSA + 3 mL/L SE) from the concentration of 1.0% (v/v).

Standard NF EN 14563 (February 2009)

Test conditions	
Strain(s):	*Mycobacterium terrae*
Interfering substance(s):	Dirty conditions
Concentration(s):	1%
Contact time:	30 minutes
Temperature:	20°C ± 1°C

Report:345D106-2023-04

Conclusion: According to the NF EN 14563 standard (February 2009), **exeol sept first** demonstrated a mycobactericidal activity against *Mycobacterium terrae* strain for an exposure time of 30 min at 20°C, in dirty conditions from the concentration of 1.0%.

Detergency performance data

Study of detergency performance by measuring residual proteins

- **Utilisation sans agitation :**

Report:RPDERT2022_F3315_014 (2022-12-05)

Purpose of assay: The detergent soaking performance of an disinfectant detergent product is evaluated by its ability to desorb proteinaceous soil (citrated blood) previously deposited and dried on a hard surface. The detergency performance is determined by measuring the residual proteins still present on the surface compared to the initial amount deposited. The results are stated as a percentage of detergency performance.

Conclusion: According to the operating conditions, the detergency performance of the product **exeol sept first**, Neutral pH disinfectant detergent, diluted to 0.4% in tap water is evaluated to 71.2%.

This performance of detergence is equivalent to the leading product (evaluated at 67.6% in a 0.5% dilution), whereas the latter was tested at a concentration 25% higher than the product **exeol sept first**.

- **Use in ultrasonic tanks:**

Report:RPDERT2024_F3315_028 (2024-04-17)

Purpose of assay: The detergent soaking performance of an disinfectant detergent product is evaluated by its ability to desorb proteinaceous soil (citrated blood) previously deposited and dried on a hard surface. The detergency performance is determined by measuring the residual proteins still present on the surface compared to the initial amount deposited. The results are stated as a percentage of detergency performance. The aim of this study is to verify that the performance of the disinfectant detergent **exeol sept first** is not affected by use in an ultrasonic bath.

Conclusion: Depending on the operating conditions used, the detergent performance of **exeol sept first** is not affected by exposure to ultrasound. The disinfectant detergent **exeol sept first** is compatible with use in ultrasonic baths.

Assessment of cleaning efficiency against Biofilm in accordance with standard NF EN ISO 15883-5: 2021

Report:3692.SOD.23 - V2 (2023-09-14)

Purpose of assay: Evaluate the cleaning efficacy of the detergent **exeol sept first** against mono-bacterial biofilm of *Pseudomonas aeruginosa* CIP A22 formed on PTFE tube by measuring proteins and total organic carbon (TOC) remaining on the inner surface of the tube. The biocidal activity of the product against biofilm was also tested by measuring the reduction of the number of viable cells present on PTFE tube. Tests are performed with and without pre-treatment.

Conclusion: The product **exeol sept first**, when diluted at 0.4% (v/v), in 10 minutes contact time at 20°C ± 1°C with a flow rate of 250 ml/min allows to reduce the amount of proteins and TOC present in the *Pseudomonas aeruginosa* CIP A22 biofilm below the alert level (< 3.0 µg/cm² and < 6.0 µg/cm² respectively) defined in ISO 15883-5:2021 and AAMI ST98 when tests are performed with pretreatment.

The product **exeol sept first**, when diluted at 0.4% (v/v), in 10 minutes contact time at 20°C ± 1°C with a flow rate of 250 ml/min allows to reduce the amount of proteins and TOC present in the *Pseudomonas aeruginosa* CIP A22 biofilm below the alert level (< 6.4 µg/cm² and < 12.0 µg/cm² respectively) defined in ISO 15883-5:2021 and AAMI ST98 when tests are performed without pretreatment.

Moreover, in the same tests conditions, the product **exeol sept first** allows to reduce the number of viable cells present in the *Pseudomonas aeruginosa* CIP A22 biofilm (by removal and/or inactivation) 8.1 log (CFU/cm²) when tests are performed with pretreatment and 7.8 log (CFU/cm²) when tests are performed without pretreatment.

Compatibility data

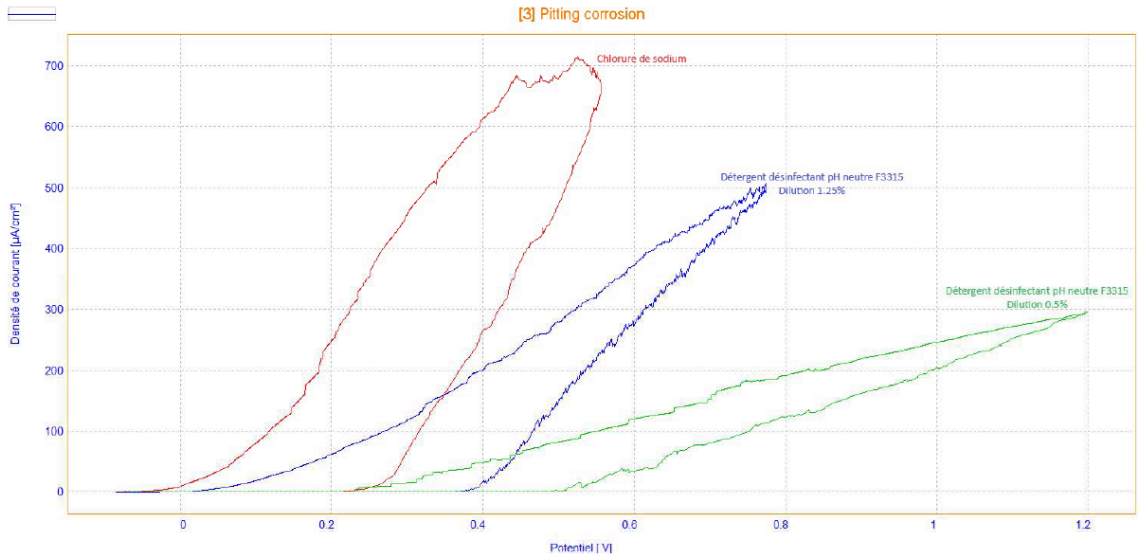
Study of corrosive action (electrochemical evaluation) according to standard NF S94-402-1 (May 2004)

Report:RPELEC2024_F3315_036 (2024-05-06)

Purpose of the study: Electrochemical test methods are designed to assess the pitting corrosion power of a product on a predefined metallic material. The corrosive power of a detergent, disinfectant or disinfectant detergent will be characterised by the value of its pitting and repassivation potentials (chronoamperometry).

Test results:

Parameters	Neutral pH disinfectant detergent exeol sept first		Sodium chloride solution (negative control sample)
	0.5% dilution (0.4% plus 25%)	1.25% dilution (1% plus 25%)	
Pitting potential	*512 mV*	*388 mV*	*256 mV*
Repassivation potential	*234 mV*	*148 mV*	*39 mV*



Conclusion: The pitting (512 mV at 0.5% dilution and 388 mV at 1.25% dilution) and repassivation (234 mV at 0.5% dilution and 148 mV at 1.25% dilution) values obtained for the neutral pH

disinfectant detergent **exeol sept first** demonstrate that this product is not corrosive to stainless steel, the material used in reusable metal medical-surgical instruments. Two parameters enable us to confirm this result: the pitting and repassivation potential values with more electropositive values compared to sodium chloride.

Study of material compatibility

Material immersion test for 8 days at +22°C ± 3°C

Report:RPCOMP2024_F3315_034 (2024-05-06)

Purpose of assay: Verification of the compatibility of the pH neutral disinfectant detergent **exeol sept first**, with respect to a given material ensures that it does not alter the material to which it is applied during its use. This usage and accelerated ageing simulation make it possible to detect any degradation process and the resulting damage profile.

Conclusion: According to the results associated with the compatibility test conditions carried out, the pH neutral disinfectant detergent **exeol sept first** shows compatibility with the following materials as follows:

PVC	COMPATIBLE
PMMA	COMPATIBLE
ABS	COMPATIBLE
HDPE	COMPATIBLE
PP	COMPATIBLE
PET	COMPATIBLE
Anodised aluminium	COMPATIBLE
Copper	COMPATIBLE

Immersion test on stainless steel instruments for 72 hours at +22°C ± 3°C

Report:RPCOMP2024_F3315_055 (2024-06-25)

Purpose of the study: Check the compatibility of the neutral pH disinfectant detergent **exeol sept first** on stainless steel instruments under real conditions of use after soaking the instruments for up to 72 hours.

Conclusion: Selon les résultats associés aux conditions d'essai de compatibilité réalisées, le détergent désinfectant pH neutre **exeol sept first** dilué à 0,4% présente une compatibilité avec les instruments inox jusqu'à un trempage de 72 heures.

Compatibility assessment of FUJIFILM and PENTAX endoscope components

Report:3388.SOD.22.2 - V2 (2022-06-13)

Purpose of assay: Evaluate the compatibility of Fujifilm endoscope components and Pentax endoscopes with **exeol sept first** diluted at 0.6% after 20 cycles of immersion (80 hours). This accelerated compatibility study represents 320 cleaning cycles of 15 minutes.

Conclusion: Results of the tests performed demonstrate the good compatibility of external surfaces of spare parts of FUJIFILM endoscopes and PENTAX bronchoscope and gastroscope when submitted to 20 cycles of immersion in **exeol sept first**, representing 320 cleaning cycles of 15 minutes.

Visual examination of external surfaces and comparison between untreated surface (control before the test to treated surfaces (assays) does not show any cosmetic or mechanical modification of the:

- Distal end,
- Control handle,
- Biopsy channel input,
- Contact point between control handle and insertion tube, and
- Spare parts of FUJIFILM endoscopes.