DISINFECTANTS
Catalogue

GBL
Gül Biyoloji Laboratuvarı
www.gbl.com.tr/en
Foreword

GBL Gül Biyoloji Laboratory, founded 1990, specializes in two main product groups: microbiological culture media and disinfectants.

GBL Gül Biyoloji Laboratory, as an ISO 9001:2008 and ISO 13485:2012 Quality Management System certified company, manages all of its processes from production to marketing, from research and development purchasing.

The strict quality-control procedures used to test our disinfectants, namely via microbiological culture media, allow us access to objective scientific evidence as regards the efficacy of our products.

European tests related to disinfectant products are being performed and published by our quality control laboratory for each batch. In addition, our products are periodically tested.

Our R&D laboratory surveys the new trends in our sector and constantly tries to add new products and packages to our portfolio. Every customer need and demand is evaluated separately and carefully so as to be met in the best way possible.

After 28 years of experience in the Turkish market, GBL Gül Biyoloji Laboratory is now ready to meet with its target international partners and clientele.

By using GBL® branded disinfectants, you will easily meet the international standards at a reasonable cost, you will feel warm Turkish hospitality in our customer service and you will recognize the speed and flexibility of a SME (small medium size enterprise) in our export operations.

Eager to serve you in your disinfection products needs!

Yours faithfully,

Mustafa Çetin Özbudun
Managing Partner
GBL®
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GBL® Gül Biyoloji Laboratuvarı founded 1990 by MD. Sait Hulusi Özbudun is an İSTANBUL Turkey based company manufacturing "in vitro diagnostic products (IVD)", "medical device disinfectants (MDD)" and "biocidal products". All of our process (research, design, development, production, quality control, marketing and sales) are certificated ISO 9001:2008 and ISO 13485:2012. All of our products (IVD and MDD) are CE marked.

The product groups (MD and biocidal products) we are producing are stated below;

- Hand disinfectants; alcohol and non-alcohol based, liquid or gel forms, various packaging alternatives
- Hemodialysis devices terminal disinfectants and decalcifiers (various formulae based on citric acid, peracetic acid and hypochlorite)
- Endoscope, surgical and medical devices high level disinfectants (various formulae based on glutaraldehyde, ortho-phthalaldehyde, peracetic acid and without aldehydes)
- Enzymatic cleaners for surgical instruments and endoscopes (3 enzymes based)
- Ground and surface disinfectants and disinfectant cleaners; baby incubator, hemodialysis machine surface, LCD monitor etc...

Our Vision

Our vision is to supply hospitals and laboratories with high quality service and products for a reasonable price, to perform all kinds of research, design, development, production, quality control, marketing and sales activities according to international standards, to be Turkey's most sustainably developing, innovative company in our scope of activity, who's products are preferred above all others.

Our Mission

- To satisfy the needs and exceed the expectations of our customers with our products
- To create a working environment where our staff security, personal development and financial interests are held to the fore.
- To build long-lasting, honest, principled business relations based on mutual interest
- To make sure our partners have steadily increasing company shares.
- To help close our country’s foreign trade deficit.
Certificates

ISO 9001:2008
Quality Management System Certificate

ISO 13485:2012
Quality Management System Certificate for Medical Device

Quality Assurance System According to MDD

Other certificates:
- Working Permission Certificate by Ministry of Labour
- Industrial Organisation Certificate by Ministry of Science, Industry and Technology
- First Class Non-Sanitary Organisation by Dudullu Organisation Industrial Zone Authority
- Working Permission Certificate by Ministry of Environment
- Capacity Report by Istanbul Chamber of Industry
- Quality Management System Certificate: ISO 13485: 2012 (Kiwa Certification Services Inc.)
- CE Certificate for Medical Devices (Kiwa Certification Services Inc.)
- CE Declarations for IVD and MDD products
- Biocidal Products Certificates for several products
- Free Sales Certificates by Turkish Ministry of Health
- Certified and authorized technical staff by Turkish Standardisation Institute to prepare Safety Data Sheets
**ADDRESS**

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### Hazard Symbols

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- **GHS 01** Explosive
- **GHS 02** Flammable
- **GHS 03** Oxidizing
- **GHS 04** Pressurized gases
- **GHS 05** Corrosive
- **GHS 06** Toxic
- **GHS 07** Irritant
- **GHS 08** Harmful
- **GHS 09** Harmful to the environment
Labelling

1. Trademark
2. Product Name
3. Intended Use
4. Hazard and Precautionary
5. Warning Symbols
6. REF Number
7. Ingredients
8. LOT Number
9. Production Date
10. Expiration Date
11. Hazard Symbols
12. Product Volume
13. Manufacturer Informations
Anyone handling laboratory chemicals should be fully aware of the potential risks involved and take appropriate safety measures before actually working with the substances. These safety measures include the technical handling of chemicals, the personal safety for people working with them as well as environmental considerations. GBL's MSDS provide these essential informations.

Dynamic Information Conforming to EU Legislation


In the Official Language of Your Country

It is not sufficient to issue the MSDS in English for all countries. Each EU Member State, and increasingly also non-EU countries, require that any hazardous product sold to them must be accompanied by MSDS in the official local official language(s).
SKIN AND HAND DISINFECTION
SKIN AND HAND DISINFECTION

In clinical routine, the human hand is the most important instrument to keep clean. Medical professionals who are continuously in contact with equipment and patients require adequate and ongoing antiseptic protection.

In most cases, nosocomial infections are transmitted via our hands.

Therefore, hand hygiene is the most important preventative tool. Hand hygiene products have been designed and formulated to care for and protect the natural moisture of fragile skin. It is internationally agreed that alcohol-based disinfectants are the most efficient formula against pathogens transmitted by our hands. There are many studies proving that hydroalcoholic products decrease the MRSA level in hospitals. GBL Gül Biyoloji Laboratory offers various skin and hand disinfectants for this most complex and important hygiene area.

OUR BRANDS

CHLORHEX™: Skin and Hand Disinfectant with Chlorhexidine Gluconate
HANDIFAST™ CH: Disinfectant Liquid Soap with Chlorexidine
MANOCHOL™ EP-70: Alcohol Based Skin and Hand Disinfectant
MANOCHOL™ GEL: Skin and hand disinfectant; Gel
ROSACREAM™: Protective Cream for Irritated Hands
**6162 - CHLORHEX™**
Skin and Hand Disinfectant with Chlorhexidine Gluconate

**COMPOSITION**
Chlorhexidine gluconate (2%), isopropyl alcohol (70%), distilled water.

**MICROBIOLOGICAL PROPERTIES**
Bactericide, tuberculocide, fungicide and virucide.

**PACKAGING**
500 ml bottles with screwed pump
1 liter bottles with screwed pump

Hygienic treatment and surgical disinfection of hands by rubbing.
- Chlorhexidine based ready-to-use formula.
- Hypo-allergenic and free of colourants.
- Broad antimicrobial spectrum in 30 seconds.
- Hygienic treatment according to EN 1500; 3 ml / 30 seconds.
- Surgical disinfection according to EN 12791; 2x3 ml / 1,50 minutes.

**6163 - HANDIFAST™ CH**
Disinfectant Liquid Soap with Chlorhexidine

**COMPOSITION**
Chlorhexidine digluconate (4%), benzalkonium chloride (0,5%), didecyl dimethyl ammonium chloride (0,25%), betaine, skin protection agents, skin softening agents, electrolytes, moisturizer agents, lubricants, antioxidant agents allantoin, lanolin, glycerol and distilled water.

**MICROBIOLOGICAL PROPERTIES**
Bactericide, tuberculocide, fungicide and virucide.

**PACKAGING**
500 ml bottles with screwed pump
1 liter bottles with screwed pump

- Antiseptic soap for hygienic handwash and general body cleansing.
- Chlorhexidine based formula.
- Hypo-allergenic and free of colourants.
- Effective against MRSA, multi drug resistant bacteria and viruses.
- Hygienic hand washing according to EN 1499; 3 ml / 1 minute (2 pump squirts 3 ml)
- Surgical hand washing according to EN 12791; 2x3 ml / 5 minutes.
The Good Hand Washing Guide
Let's all do the 6 steps.

1- Palm to palm.

2- Right palm over back of left hand and left palm over back of right hand.

3- Palm to palm fingers interlaced.

4- Clasp fingers to rub back of fingers interlaced.

5- Rotational rubbing of right thumb clasped in left palm and vice versa.

6- Finger tips together rubbing into palms. DO NOT FORGET to include wrists and dry well, preferably using paper towels if available.
6215 - MANOCHOL™ EP-70
Alcohol Based Skin and Hand Disinfectant

Skin and hand disinfectant; Alcohol-based hygienic treatment and surgical disinfection of hands. Formulated for surgical and hygienic hand disinfection.

Very effective against; effective against bacteria (Tb, MRSA, VRE), fungi and viruses (incl. HBV, HCV, HIV, polio, herpes simplex, adeno, rota, noro and vaccinia)

Increased skin compatibility; pH 5,50 SKIN FRIENDLY. Dermatologically tested. Suitable for frequent use.

Meets CDC Guideline for Hand Hygiene in Healthcare Settings.

Conforms to CEN standards; EN 13727, EN 1500 (3ml/30 seconds hygienic treatment) and EN 12791 (2x3ml/1,50 minutes surgical disinfection). Dosage and application time acc. to new DGH M guidelines; Hygienic hand disinfection 30 seconds, surgical hand disinfection 3 minutes!

"Biocidal Product Certificate" by Turkish Ministry of Health.

COMPOSITION
Ethyl alcohol 96% (45%), isopropyl alcohol (25%), antioxidants, surfactants, lubricants, moisturizers, lanolin and glycerin.

MICROBIOLOGICAL PROPERTIES
Bactericide, tuberculocide, fungicide and virucide.

PACKAGING
- 100 ml bottle
- 250 ml bottle with spray pump
- 500 ml bottle with screwed pump
- 1 liter bottle with screwed pump

Alcohol-based ready-to-use formula
Hypo-allergenic.
Broad antimicrobial spectrum in 30 seconds
Hygienic treatment according to EN 1500; 3 ml / 30 seconds
Surgical disinfection according to EN 12791; 2x3 ml / 1,50 minutes
6035 - MANOCHOL™ GEL
Skin and Hand Disinfectant; Gel

**COMPOSITION**
Ethanol (70%), isopropyl alcohol, emollients and other skin-care agents and excipients. Free of aldehyde, phenol, quaternary ammonium salts.

**MICROBIOLOGICAL PROPERTIES**
Bactericide, tuberculocide, fungicide and virucide.

**PACKAGING**
- 250 ml bottle with screwed pump
- 500 ml bottle with screwed pump
- 1 liter bottle with screwed pump
- 1 liter pouch

- Hygienic treatment of hands by rubbing.
- Alcohol-based ready-to-use formula.
- Hypo-allergenic.
- Broad antimicrobial spectrum in 30 seconds.
- Hygienic treatment according to EN 1500; 3 ml / 30 seconds.

6028 - ROSACREAM™
Protective Cream for Irritated Hands

**COMPOSITION**
Alpha bisabolol, allantoin, benzophenone, cetyl Cetearyl, alcohol, citric acid, dimethicone, glyceril mono stearate, glycerine, liquid paraffin, magnesium nitrate, methylchloroisothiasolinone, olive oil, perfumes, pro vitamin B5, stearic acid, triethanolamine, vitamin C, vitamin E, zinc oxide.

**PACKAGING**
- 500 ml bottle with screwed pump

- Formula without paraben
- Non greasy
- Rapid penetration
- Hypo-allergenic.
Hand disinfection according to the European Standard EN 1500

1. Cleanse between fingers
2. Turn hands in different directions
3. Cleanse fingernails
4. Cleanse wrist and forearm
5. Turn hands in different directions
6. Cleanse fingernails
FLOOR AND SURFACE DISINFECTIONS
FLOOR AND SURFACE DISINFECTIONS

All environmental surfaces contribute to cross contamination (contacts and exchanges between healthcare staff / surfaces / medical devices / patients).

Disinfection of non-critical surfaces in hospital can be a strong barrier against possible infections. The use of disinfection products for the non-critical surfaces increases neither cost nor work.

GBL branded floor and surface disinfectants, with their short contact and quick drying time help healthcare staff to accomplish hygiene standards and reach their targets in an effective and economic way.

OUR BRANDS

LUTARO™: Floor Disinfectant; Concentrated
SURFACTO™ EP-60+: Quick Surface Disinfectant; Alcohol Based
SURFACTO™ DIAPP: Premature Baby Incubator Disinfectant
SURFACTO™ NEUTRAL: Hemodialysis Machine Surface Disinfectant
SURFACTO™ QAS: Medical Device Surface Cleaner Disinfectant; Alcohol-Free
**6011 - LUTARO™**
Floor Disinfectant; Concentrated

**COMPOSITION**
Didecyl dimethyl ammonium chloride (8.5%), benzalkonium chloride (7%), isopropyl alcohol (4%), deionized water.

**MICROBIOLOGICAL PROPERTIES**
Bactericide, tuberculocide, fungicide and virucide.

**PACKAGING**
1L dosing bottle
5L canister

- Cleaning and disinfection of walls, floors and surfaces (operating theatres, high risk areas, care services...)
- Free of aldehyde.
- 0.50 % concentration.
- No rinsing.
- Proven efficiency against hospital strains.
- Broad antimicrobial spectrum in 15 minutes.
- Broad compatibility materials / surfacings.

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**6019 - SURFACTO™ EP-60+**
Quick Surface Disinfectant; Alcohol Based

**COMPOSITION**
Didecyl dimethyl ammonium chloride (0,05%), benzalkonium chloride (0,05%), ethanol 96% (47%), chlorhexidine digluconate solution 20% (0,5%), isopropanol (13%), pH adjuster (0,01%), corrosion inhibitors (0,20%), deionized water.

**MICROBIOLOGICAL PROPERTIES**
Bactericide, mycobactericide, fungicide and virucide.

**PACKAGING**
1 liter bottle with sprayer.

- Alcohol-based ready-to-use formula
- Aldehyde free
- No rinsing
- Does not leave trace or a greasy film
- Broad antimicrobial spectrum in 30 seconds
- Quick disinfection of medical devices, in operating theatres, high-risk units, examining rooms, care units
6001 - SURFACTO™ DIAPP
Premature Baby Incubator Disinfectant

Multipurpose disinfectant/decontaminant cleaner to be used on hard, non-porous surfaces. Suitable for neonatal units, isolation areas, surgical suites and other critical care areas where cross-contamination control is important.

Surfacto™ DIAPP is effective in cleaning and disinfecting the interior and exterior surfaces of infant incubators and bassinets, exterior surfaces of anesthesia machines and respiratory therapy equipment surfaces, operating room tables and lights which are made of plastic, stainless steel, plexiglass and glass.

COMPOSITION
Benzethonium chloride (2-{2-(4-Diisobutylphenoxy)ethoxy}ethyl)dimethylbenzylammonium chloride (0.3%), Isopropyl alcohol (17%), ethanol 96%, anticorrosive agents, antioxidants, stabilising agents, distilled water. Free of benzalkonium chloride and other quaternary ammonium compounds, aldehyde and phenol, buffers, other alcohols.

MICROBIOLOGICAL PROPERTIES
Bactericide, mycobactericide, fungicide and virucide.

PACKAGING
1 liter bottle with sprayer

Ready-to-use formula
Aldehyde and phenol free
No rinsing
Does not leave trace or a greasy film
Broad antimicrobial spectrum in 3 minutes (for tuberculocidal activity 5 minutes)
Broad material compatibility
**6009 - SURFACTO™ NEUTRAL**

Hemodialysis Machine Surface Disinfectant

*Surface disinfectant for haemodialysis machines in between treatments. Suitable for efficient disinfection and cleansing of dialysis machine surfaces.*

**COMPOSITION**

Alkyl dimethyl benzyl ammonium chloride (0.1%), dodecyl trimethyl ammonium bromide, propylene glycol, benzotriazole, ethanol 96%, antioxidants, stabilizing agents. Free of glutaraldehyde, formaldehyde, buffers, and other phenol derivatives.

**MICROBIOLOGICAL PROPERTIES**

Bactericide, fungicide and virucide.

**PACKAGING**

1 liter bottle with sprayer

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**6007 - SURFACTO™ QAS**

Medical Device Surface Cleaner Disinfectant; Alcohol-Free

*Alcohol-free rapid cleaner disinfectant based on quaternary ammonium compounds. Especially suitable for alcohol-sensitive equipment and medical devices.*

**COMPOSITION**

Didecyl dimethyl ammonium chloride (0.06%), alkyl dimethyl benzyl ammonium chloride (0.1%), chlorhexidine digluconate (0.11%), antioxidant agents, stabilizing agents, distilled water, other auxiliary agents, perfume. Free of other phenol derivatives, aldehyde and phosphate.

**MICROBIOLOGICAL PROPERTIES**

Bactericide, mycobactericide, fungicide and virucide.

**PACKAGING**

1 liter bottle with sprayers
CLEANING AND MAINTENANCE

Surface disinfectant for haemodialysis machines in between treatments.

Suitable for efficient disinfection and cleansing of dialysis machine surfaces.
CLEANING AND MAINTENANCE

Using a pre-disinfectant product (a detergent with disinfectant properties or vice versa) helps reduce the micro-organism population (bacteria, yeast, mould, virus and mycobacteria), during medical device treatment. Using a pre-disinfectant is necessary for improved disinfection activity. It helps to facilitate the disinfectant action of later sterilization and high level disinfection steps. Moreover, using a pre-disinfectant product reduces cross-contamination risks (“instrument/instrument” direct contamination or “instrument/user/instrument” indirect contamination). Final benefit of using a pre-disinfectant product is that it reduces the risk of contaminated product disposal into the natural environment.

Our formulae reduce substances hazardous for humans and excludes the use of CMR (carcinogenic, mutagenic and reprotoxic) classified substances.

GBL branded products contain corrosion inhibitors, they are non-corrosive when used according to protocol.

The combination of surfactants and enzymes makes for a high-performance detergent. Protocols and posters available on request.

OUR BRANDS

WARECLEAN™ EC : Enzymatic Cleaner Disinfectant; Concentrated
LIQUISEPT™ QAS CON : Instrument Disinfectnat Cleaner; Concentrated
WARECLEAN™ RC : Rust and Stain Remover; Concentrated
PURICIDE™ CR : Cleaner for Lab Glassware; Concentrated
LUBISERVE™ : Instrument Lubricant and Rust Inhibitor; Ready-to-use
6160 - WARECLEAN™ EC
Enzymatic Cleaner Disinfectant; Concentrated

Enzymatic cleaner disinfectant; 0,25-1%. Cleaning and pre-disinfection of medico-surgical instruments, medical devices, thermosensitive instrumentation, endoscopes. Suitable for soaking baths, ultrasonic bins and automatic washing machines.

COMPOSITION
Glycerol, isopropanol, ethanol (96%), EDTA, urea, trisodium phosphate, citric acid monohydrate, linear alkyl benzene sulfonic acid, sodium lauryl ether sulphate, potassium nitrate, sodium nitrate, sodium hydroxide, enzymatic complex (amylase, lipase, protease), defoamer, lemon scent, demineralized water.

MICROBIOLOGICAL PROPERTIES
Bactericide, yeasticide, virucide in 15 minutes.

PACKAGING
1 liter dosing bottle
5 liter canister + dosing pump

Concentrated product; 0,25% - 1% depending on protein residues level
High level detergence with 3 enzymes based formula: protease, lipase, amylase.
Effective between 5-15 minutes
Without chlorine and aldehyde
Not foaming, suitable for washing machines and ultrason bins
6018 - LIQUISEPT QAS CON
Instrument Disinfectant Cleaner; Concentrated

Instrument disinfectant cleaner; 0.5-1%. Cleaning and pre-disinfection of medico-surgical instruments, medical devices, thermosensitive instruments, endoscopes. Suitable for soaking baths, ultrasonic bins and automatic washing machines.

COMPOSITION
Didecyl dimethyl ammonium chloride (6%), alkyl dimethyl benzyl ammonium chloride (5%), isopropanol (5%), detergents, chelating agents, defoamer, thickening agents, emulsion agents, enzymatic complex (amylase, lipase, protease), buffers, corrosion inhibitors, stabilizing agents and lemon scent. Without aldehyde and phenol.

MICROBIOLOGICAL PROPERTIES
Bactericide, fungicide, tuberculocide and virucide.

PACKAGING
1 liter dosing bottle
5 liter canister + dosing pump
6170 - WARECLEAN™ RC
Rust And Stain Remover; Concentrated

**COMPOSITION**
Non-ionic detergents, phosphoric acid, phosphates, EDTA, butyl glycol, isopropyl alcohol, preservative agents, antioxidant agents, stabilizing agents, distilled water.

**PACKAGING**
1 liter dosing bottle
5 liter canister each + dosing pump

Wareclean RC removes rust, stains, spotting and corrosion.
Restores instrument’s original finish.
Non-corrosive; will not harm stainless steel.
Save money by restoring instruments instead of replacing or repairing them.
Routine use of Wareclean RC will increase the life and enhance the efficiency of stainless steel instruments.
Restores articulation to box-locks and joints.
Makes instruments look like new.

6145 - PURICIDE™ CR
Cleaner for Lab Glassware; Concentrated

**COMPOSITION**
Dichromate salts 100 g/l, sulfuric acid 250 ml/l.

**MICROBIOLOGICAL PROPERTIES**
Bactericide, fungicide, tuberculocide.

**PACKAGING**
1 liter bottle with pump

PURICIDE CR removes rust, stains, spotting and corrosion.
Non-corrosive; will not harm special lab glassware.
Save money by restoring lab glassware instead of replacing it.
Makes lab glassware look like new.
Exceptional manual laboratory glassware cleaner.
**COMPOSITION**

Liquid paraffin, preservative agents, antioxidants, corrosion inhibitors, isopropyl alcohol, butyl glycol.

**PACKAGING**

1 liter spray bottle

**6130 - LUBRISERVE™**

Instrument lubricant and rust inhibitor; ready-to-use.

*LUBRISERVE* is a silicone free non-toxic and non-sticky mineral oil lubricant forming a protective barrier on surgical instruments. *LUBRISERVE* prevents rusting, staining. Used routinely *LUBRISERVE* will reduce repair and replacement costs.

**IMPORTANCE OF CLEANING**

Factors that affect the efficacy of both disinfection and sterilization include prior cleaning of the object; organic and inorganic load present; type and level of microbial contamination; concentration of and exposure time to the germicide; physical nature of the object (e.g., crevices, hinges, and lumens); presence of biofilms; temperature and pH of the disinfection process; and in some cases, relative humidity of the sterilization process (e.g., ethylene oxide).

Cleaning is the removal of foreign material (e.g., soil, and organic material) from objects and is normally accomplished using water with detergents or enzymatic products. Thorough cleaning is required before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes. Also, if soiled materials dry or bake onto the instruments, the removal process becomes more difficult and the disinfection or sterilization process less effective or ineffective. Surgical instruments should be presoaked or rinsed to prevent drying of blood and to soften or remove blood from the instruments.

In general, endoscope disinfection or sterilization with a liquid chemical sterilant involves five steps after leak testing:

1. **Clean:** Mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and a detergent or enzymatic cleaners (leak testing is recommended for endoscopes before immersion).

2. **Disinfect:** Immerse endoscope in high-level disinfectant (or chemical sterilant) and perfuse (eliminates air pockets and ensures contact of the germicide with the internal channels) disinfectant into all accessible channels, such as the suction/biopsy channel and air/water channel and expose for a time recommended for specific products.

3. **Rinse:** Rinse the endoscope and all channels with sterile water, filtered water (commonly used with AERs) or tap water (i.e., high-quality potable water that meets federal clean water standards at the point of use).

4. **Dry:** Rinse the insertion tube and inner channels with alcohol, and dry with forced air after disinfection and before storage.
A Guide for Manual Reprocessing of Flexible Immersible Endoscopes

1- PRECLEANING
Wipe debris from insertion tube. Suction enzymatic detergent through the scope after each use until free of debris. Alternate enzymatic detergent and air. Flush air/water channel per manufacturer’s instructions. Attach water resistant cap to video scope. Transport scope separately from accessories in covered container to reprocessing room. Suction enzymatic detergent through biopsy/suction channel until solution is free of debris. Alternate suctioning enzymatic detergent and air several times. Finish with air. Flush air/water channels per manufacturer’s instructions. Attach soaking cap to video scope. Transport scope separately from accessories in covered containers to reprocessing area.

2- LEAK TEST
Remove adapters and valves. Inflate scope before submerging in water. Visually inspect and leak test scope per manufacturer’s instructions. If damage is detected, contact the manufacturer or repair facility for instructions.

3- MANUAL CLEANING
Immerse scope in enzymatic detergent when performing all subsequent steps. Wash all debris from exterior of scope. Clean inside all valve openings and elevators. Brush entire suction/accessory channel system including the body, insertion tube and the light guide (umbilical) tube. Repeat until free of debris. Use appropriate adapters to access all channels.

4- RINSING
Rinse removable parts with clean water. Rinse scope and repeatedly flush all channels. Use appropriate channel adapters where necessary. Purge all water from all channels. Wipe the exterior of scope dry and remove parts using soft, clean, lint-free cloth or sponge. Expel all rinse water by repeatedly flushing all channels with air.

5- HIGH-LEVEL DISINFECTION
Completely immerse scope, removable parts and cleaning apparatus/tools in high-level disinfectant. Inject high-level disinfectant into all channels until solution exits opposite ends of each channel. Cover disinfectant soaking tray with tight-fitting lid. Soak scope for appropriate time and temperature in disinfectant as indicated on the label. Metrex also suggests that customers consult authoritative protocols and guidelines, such as ASTM 1518, ASGE, SAGN, APIC and AORN. After soaking, use channel cleaning adapters to flush air repeatedly through all channels to remove disinfectant. Leave channel cleaning adapters attached for rinse cycle.

6- FINAL RINSE
Thoroughly rinse exterior of the scope, removable parts and cleaning apparatus with large amounts of water as indicated on disinfectant label. Flush all channels with large amounts of water. Purge all channels with air using the channel cleaning adapters.

7- DRYING
Flush all channels with 70% Isopropyl or Ethyl alcohol followed by air. Dry exterior of scope, valves, etc., using clean, lint-free cloth. Dry channels following manufacturer’s instruction. Dry the inside of the suction and air/water valve housings and connections on the light guide connector.

8- STORAGE
Store valves and accessories separately from scopes. Store with ETO venting cap in place and/or video soaking cap removed. Hang reprocessed scope vertically so insertion tube and umbilicus do not touch bottom of cabinet and are not looped.

Disinfectants Catalogue
Rev. No: 02 / Rev. Date: 26.02.2018
HIGH LEVEL DISINFECTION
HIGH LEVEL DISINFECTION

Our products are developed in accordance with the latest scientific findings and legal requirements. Our main focus is patient and personnel safety as well as long-term maintenance of the instruments.

GBL® branded instrument disinfection products meet the quality and efficacy requirements of the European Standards. Efficacy tests against relevant organisms are being performed periodically.

Increased demands on decontamination make material compatibility just as important as broad spectrum disinfection efficiency. GBL® offers reliable preparations with short contact times. The entire GBL product portfolio is developed to meet the most up-to-date scientific principles and meets all legal requirements.

OUR BRANDS

SANITAROSA™ OPA  : Endoscope Disinfectant; Ortho-Phthalaldehyde 0,55%
SANITAROSA™ GA  : Medical Instrument Disinfectant; Glutaraldehyde 2%, with Activator
SANITAROSA™ GA ACTIVE  : Medical Instrument Disinfectant; Glutaraldehyde 2%, Ready-To-Use
PEROXY™ HLD  : Surgical Instrument Disinfectant; Peracetic Acid, Concentrated
6026 - SANITAROSA™ OPA
Endoscope Disinfectant; Ortho-Phthalaldehyde 0,55%

SANITAROSA™ OPA solution is a convenient, ready-to-use, high-level disinfectant that provides a broad spectrum microbiological activity. It can disinfect a wide range of endoscopes and other heat sensitive semi-critical medical devices. SANITAROSA™ OPA solution is ideal for both automated and manual instrument reprocessing. It is designed for use in central processing, gastrointestinal departments, surgery centers, and other areas where high-level disinfection is required.

COMPOSITION
Orto-phthalaldehyde (0,55%), benzotriazole, buffers, antioxidant and stabilising agents. Does not contain quaternary ammonium salts, chlorine, phenol.

MICROBIOLOGICAL PROPERTIES
Vegetative organisms, fungi, nonenveloped viruses, enveloped viruses.

PACKAGING
4 cans, 5 L each.
Testing strips of ortho-phthalaldehyde rate (box of 25)
Glycine; 32 grams

SANITAROSA OPA Solution Material Compatibility
Noncorrosive SANITAROSA OPA solution offers excellent material compatibility which can significantly reduce instrument damage and repair costs. It works quickly and safely to disinfect metal and nonmetal devices as well as plastic devices and elastomers.

Offering high standards for purity when used for manual or automatic reprocessing
Tested and cleared for use with the most widely used endoscopes
Safe for patients, healthcare professionals, and instruments
Long-lasting efficacy reprocessing of more devices per canister than glutaraldehyde2
2-year unopened shelf-life; 75-day shelf life after opening the bottle
Quickly disinfects for improved productivity—more endoscopes can be processed in less time1
Works within minutes and provides broad spectrum killing power, even in the presence of human serum.
Requires no activation or mixing
5-minute soak time at 25°C in automatic endoscope reproprocessors*
12-minute soak time at 20°C for manual reprocessing
Minimizes exposure to fumes, odor, or irritation
Substantial reductions in instrument repair and replacement costs are possible with SANITAROSA OPA solution.
6128 - PEROXY™ HLD
Surgical Instrument Disinfectant; Peracetic Acid, Concentrated
Concentrate disinfectant based on peracetic acid for flexible endoscopes and heat-sensitive instruments.

COMPOSITION
Peracetic acid solution (PAA) (> 5 %), hydrogen peroxide, acetic acid, stabilizing agents, corrosion inhibitors, RO water.

MICROBIOLOGICAL PROPERTIES
Bactericide, fungicide, virucide and sporicide.

PACKAGING
5 liter can
MICROBIOLOGICAL PROPERTIES
Glutaraldehyde solution 20 g/L, corrosion inhibitors, cationic detergent, distilled water. Without perfume and colourant.

Bactericide, fungicide, tuberculocide, virucide and sporicide.

4 cans, 5 L each
Testing strips of glutaraldehyde rate (25x4)
Activator 500 ml x 1

COMPOSITION
Glutaraldehyde solution (2 %), stabilising agents, non-ionic detergents, buffers, corrosion inhibitors, distilled water. Does not contain acetate, borat, phosphate, anionic and cationic detergent, colourant.

MICROBIOLOGICAL PROPERTIES
Bactericide, fungicide, tuberculocide, virucide and sporicide.

Does not require activation!

pH 7.5-8.5 after activation
Active against bacteria, yeasts, moulds, viruses any mycobacteria in 10 minutes
Active against spores of bacteria in 1 hour.

6002 - SANITAROSA™ GA
Medical Instrument Disinfectant; Glutaraldehyde 2%, with Activator
High-level disinfection of medical devices, surgical equipment, endoscopic and thermosensitive equipment.

6071 - SANITAROSA™ GA ACTIVE
Medical Instrument Disinfectant; Glutaraldehyde 2%; Ready-To-Use

pH 7.5-8.5 after activation
Active against bacteria, yeasts, moulds, viruses any mycobacteria in 10 minutes
Active against spores of bacteria in 1 hour.

COMPOSITION
Glutaraldehyde solution 20 g/L, corrosion inhibitors, cationic detergent, distilled water. Without perfume and colourant.

Bactericide, fungicide, tuberculocide, virucide and sporicide.

4 cans, 5 L each
Testing strips of glutaraldehyde rate (25x4)
Activator 500 ml x 1

7001 - GBL® ROSACHEM™
GA MEC Test Strips
COLOUR SCALE
After 20 seconds

INACTIVE
ACTIVE
HEMODIALYSIS MACHINE DISINFECTION
HEMODIALYSIS MACHINE DISINFECTION

GBL Gül Biyoloji Laboratuvari offers a complete range of disinfectants for hemodialysis centers. We have been manufacturing disinfectants for hemodialysis machines for 28 years.

Processes are managed and audited according to ISO 9001: 2008 and ISO 13485: 2012 quality management system standards. Moreover, strict quality control procedures, including tests of microbiological effectiveness according to European norms, are carried out in our laboratory.

Our canister mouth and cap are specially designed for hemodialysis machines (DIN 51). Strong references for our products being used for many years in the Turkish market can be submitted upon request.

OUR BRANDS

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6106 - CITRO PLUS™
Hemodialysis Machine Disinfectant; Citric Acid 21%

Thermochemical disinfectant for haemodialysis machines with proportional mixing system and recirculation function. CITRO PLUS is a very strong and effective disinfectant because of the synergistic effects of its ingredients.

**COMPOSITION**
Citric acid (21 %), lactic acid, malic acid, buffers, preservative agents, distilled water. Does not contain phenol and phenol derivates, glutaraldehyde, quaternary ammonium salts, active chlorine and other halogen compounds.

**MICROBIOLOGICAL PROPERTIES**
A 3% CITRO PLUS solution is bactericidal, fungicidal and virucidal above 60°C.

**PACKAGING**
5 liter canister

- pH value 2,50 +/- 0,3
- Dissolves blood residue
- Perfectly removes CaCO₃
- Disinfection and decalcification in one process
- Natural materials used as active ingredients: citric acid, malic acid, lactic acid
- Biodegradable, non-toxic.
- Safe for health and environment
- Light lemon scent, colourless
6123 - PEROXY PLUS™
Hemodialysis Machine Disinfectant; Peracetic Acid Based

Cold disinfectant for haemodialysis machines with proportional mixing system and recirculation function. PEROXY PLUS™ can be used also as cold disinfectant for water treatment devices and circuit pipes. The absence of PEROXY PLUS™ has to be detected by test strips to be sure that no residue is left behind

**COMPOSITION**
Peracetic acid solution (PAA)(3,5%), hydrogen peroxide, asetic acid, stabilising agents, corrosion inhibitors, distilled water. Does not contain phenol and phenol derivates, formaldehyde, glutaraldehyde, quaternary ammonium salts, active chlorine ve other halogenic compounds.

**MICROBIOLOGICAL PROPERTIES**
Broad spectrum of microbiological activity at low concentrations and with a short exposure time. PEROXY PLUS is bactericidal, fungicidal, sporicidal and virucidal.

**PACKAGING**
5 liter canister

- Non-toxic decomposition.
- Low pH value easily achieves decalcification.
- After PEROXY PLUS use, you can easily remove it by rinsing with water.
- Safe for health and environment.

6338 - CITROTAL 100™
Hemodialysis Machine Disinfectant; Sodium Hypochloride Based

**COMPOSITION**
Sodium hypochlorite (5%), active chlorine. Potassium metasilicate, potassium hydroxide and demineralised water

**MICROBIOLOGICAL PROPERTIES**
Bactericidal, fungicidal and virucidal.

**PACKAGING**
5 liter canister

- Reduces biofilms, cleans and degreases.
6009 - SURFACTO™ NEUTRAL
Hemodialysis Machine Surface Disinfectant

*Surface disinfectant for haemodialysis machines in between treatments.*
*Suitable for efficient disinfection and cleansing of dialysis machine surfaces.*

**COMPOSITION**
- Alkyl dimethyl benzyl ammonium chloride (0.1%), dodecyl trimethyl ammonium bromide, propylene glycol, benzotriazole, ethanol 96%, antioxidants, stabilizing agents.
- Free of glutaraldehyde, formaldehyde, buffers, and other phenol derivatives.

**MICROBIOLOGICAL PROPERTIES**
- Bactericide, fungicide and virucide.

**PACKAGING**
- 1 liter bottle with sprayer
- 5 liter canister

![Image of Surfacto Neutral bottle]

**Additional Features**
- Ready-to-use formula with corrosion inhibitor.
- Formula compatible with acrylic, glass and PVC.
- Aldehyde and phenol free.
- Extremely effective disinfectant with cleansing properties.
- Biodegradable, harmless for the environment, safe for humans.
- Does not leave trace or a greasy film.
- Broad antimicrobial spectrum in 1 minute.

6127 - PEROXY PLUS™ RP
Cold Sterilant For Dialyzer Reprocessing

*GBL Peroxy Plus RP Cold Sterilant is indicated for the in vitro cleaning and sterilizing of hollow fiber dialyzers for dialyzer reprocessing systems. GBL Peroxy Plus RP Cold Sterilant also may be used for disinfecting dialysis equipment (e.g. kidney machines) and supplies (e.g. prot caps).*

**COMPOSITION**
- Peracetic acid solution (PAA)(3.5 %), hydrogen peroxide, asetic acid, stabilising agents, corrosion inhibitors, distilled water.
- Does not contain phenol and phenol derivates, formaldehyde, glutaraldehyde, quaternary ammonium salts, active chlorine ve other halogenic compounds.

**MICROBIOLOGICAL PROPERTIES**
- Broad spectrum of microbiological activity at low concentrations and with a short exposure time. PEROXY PLUS is bactericidal, fungicidal, sporicidal and virucidal.

**PACKAGING**
- 5 liter canister

![Image of Peroxy Plus RP canister]
6102 - CITRO-BRA
Hemodialysis Machine Disinfectant ; Citric Acid Based 50%

Thermochemical disinfectant for hemodialysis machines with proportional mixing system and recirculation function. Disinfection and decalcification in just one process.

**COMPOSITION**
Citric acid 50%, buffers, preservative agents, distilled water. Does not contain phenol and phenol derivatives, glutaraldehyde, quaternary ammonium salts, active chlorine and other halogen compounds.

**MICROBIOLOGICAL PROPERTIES**
Bactericidal, fungicidal and virucidal.

**PACKAGING**
5 liter canister.

\[\text{pH value } 1.50 \pm 0.5\]

6105 - CITRO-GAM
Hemodialysis Machine Disinfectant ; Citric Acid Based 30%

Thermochemical disinfectant for hemodialysis machines with proportional mixing system and recirculation function. Disinfection and decalcification in one process.

**COMPOSITION**
Citric acid 30%, buffers, preservative agents, distilled water. Does not contain phenol and phenol derivatives, glutaraldehyde, quaternary ammonium salts, active chlorine and other halogen compounds.

**MICROBIOLOGICAL PROPERTIES**
Bactericidal, fungicidal and sporocidal.

**PACKAGING**
5 liter canister.

\[\text{pH value } 1.80 \pm 0.5\]
Surface disinfectant for haemodialysis machines in between treatments.

Suitable for efficient disinfection and cleansing of dialysis machine surfaces.
**6334 - ROSACHEM™**  
**Sodium Hypochloride Solution**

Sodium hypochlorite is now used in endodontics during root canal treatments. It is the medicament of choice due to its efficacy against pathogenic organisms and pulp digestion. Its concentration for use in endodontics today varies from 0.5% to 5.25%. At low concentrations it will dissolve mainly necrotic tissue; whereas at higher concentrations tissue dissolution is better but it also dissolves vital tissue, a generally undesirable effect. It has been shown that clinical effectiveness does not increase conclusively for concentrations higher than 1%.

**COMPOSITION**

Sodium hypochlorite 5% + / - 0.5 active chlorinated, sodium carbonate 50 g / l

**PACKAGING**

100 ml HDPE Bottle  
250 ml HDPE Bottle  
500 ml HDPE Bottle

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**6337 - ROSACHEM™**  
**Canal Cleaner with EDTA; Concentrated**

Dentists and endodontists use EDTA solutions to remove inorganic debris (smear layer) and lubricate the canals in endodontics.

Dentists and endodontists use EDTA solutions to remove inorganic debris (smear layer) and lubricate the canals in endodontics. This procedure helps prepare root canals for obturation. Furthermore, EDTA solutions with the addition of a surfactant loosen up calcifications inside a root canal and allow instrumentation (canals shaping) and facilitate apical advancement of a file in a tight/calcified root canal towards the apex.

**COMPOSITION**

Ethylene diamine tetraacetic acid sodium salt, sodium hydroxide, preservatives and distilled water. The concentration of EDTA is minimum 15%.

**PACKAGING**

250 ml HDPE Bottle  
500 ml HDPE Bottle
6026 - SANITAROSA™ OPA
Endoscope Disinfectant; Ortho-Phthalaldehyde 0,55 %

SANITAROSA™ OPA solution is a convenient, ready-to-use, high-level disinfectant that provides a broad spectrum microbiological activity. It can disinfect a wide range of endoscopes and other heat sensitive semi-critical medical devices. SANITAROSA OPA solution is ideal for both automated and manual instrument reprocessing. It is designed for use in central processing, gastrointestinal departments, surgery centers, and other areas where high-level disinfection is required.

**COMPOSITION**
Orto-phthalaldehyde (0,55 %), benzotriazole, buffers, antioxidant and stabilising agents. Does not contain quaternary ammonium salts, chlorine, phenol.

**MICROBIOLOGICAL PROPERTIES**
Vegetative organisms, fungi, nonenveloped viruses, enveloped viruses.

**PACKAGING**
4 cans, 5 L each. 12 cans, 1 L each.
Testing strips of ortho-phthaldehyde rate (box of 25)
Glycine; 32 grams

**SANITAROSA OPA Solution Material Compatibility**
Noncorrosive SANITAROSA OPA solution offers excellent material compatibility which can significantly reduce instrument damage and repair costs. It works quickly and safely to disinfect metal and nonmetal devices as well as plastic devices and elastomers.
6018 - ASPIRATION SA
Concentrated disinfectant for treatment of suction systems

COMPOSITION
Didecyl dimethyl ammonium chloride (6%), alkyl dimethyl benzyl ammonium chloride (5%), isopropanol (5%), detergents, chelating agents, defoamer, thickening agents, emulsion agents, enzymatic complex (amylase, lipase, protease), buffers, corrosion inhibitors, stabilizing agents and lemon scent. Without aldehyde and phenol.

MICROBIOLOGICAL PROPERTIES
Bactericide, fungicide, tuberculocide and virucide.

PACKAGING
1 liter dosing bottles
5 liter can with dosing pump

Without CMR (carcinogenic, mutagenic and reprotoxic) classified substances.
Concentrated product; 1 %
Broad antimicrobial efficacy in 15 minutes
Without chlorine and aldehyde.
Not foaming, suitable for washing machines and ultrason bins
Can be prepared with hot or cold water
Neutral pH: broad compatibility materials
Includes rich corrosion inhibitors; does not damage medical devices

6215 - MANOCHOL™ EP-70
Alcohol Based Skin and Hand Disinfectant

COMPOSITION
Ethyl alcohol 96% (45%), isopropyl alcohol (25%), antioxidants, surfactants, lubricants, moisturizers, lanolin and glycerin.

MICROBIOLOGICAL PROPERTIES
Bactericide, tuberculocide, fungicide and virucide.

PACKAGING
100 ml bottle
250 ml bottle with spray pump
500 ml bottle with screwed pump
1 liter bottle with screwed pump
**Glossary**

**Action level**: Concentration of a regulated substance (e.g., ethylene oxide, formaldehyde) within the employee breathing zone, above which OSHA requirements apply.

**Activation of a sterilant**: Process of mixing the contents of a chemical sterilant that come in two containers (small vial with the activator solution; container of the chemical) Keeping the two chemicals separate until use extends the shelf life of the chemicals.

**Aeration**: Method by which ethylene oxide (EtO) is removed from EtO-sterilized items by warm air circulation in an enclosed cabinet specifically designed for this purpose.

**Antimicrobial agent**: Any agent that kills or suppresses the growth of microorganisms.

**Antiseptic**: Substance that prevents or arrests the growth or action of microorganisms by inhibiting their activity or by destroying them. The term is used especially for preparations applied topically to living tissue.

**Asepsis**: Prevention of contact with microorganisms.

**Autoclave**: Device that sterilizes instruments or other objects using steam under pressure. The length of time required for sterilization depends on temperature, vacuum, and pressure.

**Bacterial count**: Method of estimating the number of bacteria per unit sample. The term also refers to the estimated number of bacteria per unit sample, usually expressed as number of colony-forming units.

**Bactericide**: Agent that kills bacteria.

**Bioburden**: Number and types of viable microorganisms with which an item is contaminated; also called bioload or microbial load.

**Biofilm**: Accumulated mass of bacteria and extracellular material that is tightly adhered to a surface and cannot be easily removed.

**Biologic Indicator**: device for monitoring the sterilization process. The device consists of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the sterilization process being monitored. Biologic indicators are intended to demonstrate whether conditions were adequate to achieve sterilization. A negative biologic indicator does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.

**Bleach**: Household bleach (5.25% or 6.00%-6.15% sodium hypochlorite depending on manufacturer) usually diluted in water at 1:10 or 1:100. Approximate dilutions are 1.5 cups of bleach in a gallon of water for a 1:10 dilution (~6,000 ppm) and 0.25 cup of bleach in a gallon of water for a 1:100 dilution (~600 ppm). Sodium hypochlorite products that make pesticidal claims, such as sanitization or disinfection, must be registered by EPA and be labeled with an EPA Registration Number.

**Bowie-Dick test**: Diagnostic test of a sterilizer's ability to remove air from the chamber of a prevacuum steam sterilizer. The air-removal or Bowie-Dick test is not a test for sterilization.

**Ceiling limit**: Concentration of an airborne chemical contaminant that should not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling must be assessed as a 15-minute time-weighted average exposure.

**Centigrade or Celsius**: A temperature scale (0°C = freezing point of water; 100°C = boiling point of water at sea level). Equivalents mentioned in the guideline are as follows: 20°C = 68°F; 25°C = 77°F; 121°C = 250°F; 132°C = 270°F; 134°C = 273°F.

For other temperatures the formula is: \( F_o = (C_o \times 9/5) + 32 \) or \( C_o = (F_o - 32) \times 5/9 \).

Central processing or Central service department: the department within a health-care facility that processes, issues, and controls professional supplies and equipment, both sterile and nonsterile, for some or all patient-care areas of the facility.

**Challenge test pack**: Pack used in installation, qualification, and ongoing quality assurance testing of health-care facility sterilizers.

**Chemical Indicator**: device for monitoring a sterilization process. The device is designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators are intended to detect potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The "pass" response of a chemical indicator does not prove the item accompanied by the indicator is necessarily sterile. The Association for the Advancement of Medical Instrumentation has defined five classes of chemical indicators: Class 1 (process indicator); Class 2 (Bowie-Dick test indicator); Class 3 (single-parameter indicator); Class 4 (multi-parameter indicator); and Class 5 (integrating indicator).

**Contact time**: Time a disinfectant is in direct contact with the surface or item to be disinfected. For surface disinfection, this period is framed by the application to the surface until complete drying has occurred.

**Container system, rigid container**: sterilization containment device designed to hold medical devices for sterilization, storage, transportation, and aseptic presentation of contents.

**Contaminated**: State of having actual or potential contact with microorganisms. As used in health care, the term generally refers to the presence of microorganisms that could produce disease or infection.

**Control, positive**: Biologic indicator, from the same lot as a test biologic indicator, that is left unexposed to the sterilization cycle and then incubated to verify the viability of the test biologic indicator.

**Cleaning**: Removal, usually with detergent and water or enzyme cleaner and water, of adherent visible soil, blood, protein substances, microorganisms and other debris from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.
**Culture**: growth of microorganisms in or on a nutrient medium; to grow microorganisms in or on such a medium.

**Culture medium**: substance or preparation used to grow and cultivate microorganisms.

**Cup**: 8 fluid ounces.

**Decontamination**: according to OSHA, “the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal” [29 CFR 1910.1030]. In health-care facilities, the term generally refers to all pathogenic organisms.

**Decontamination area**: area of a health-care facility designated for collection, retention, and cleaning of soiled and/or contaminated items.

**Detergent**: cleaning agent that makes no antimicrobial claims on the label. They comprise a hydrophilic component and a lipophilic component and can be divided into four types: anionic, cationic, amphoteric, and non-ionic detergents.

**Disinfectant**: usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial spores. It refers to substances applied to inanimate objects. EPA groups disinfectants by product label claims of “limited,” “general,” or “hospital” disinfection.

**Disinfection**: thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).

**D value**: time or radiation dose required to inactivate 90% of a population of the test microorganism under stated exposure conditions.

**Endoscope**: an instrument that allows examination and treatment of the interior of the body canals and hollow organs.

**Enzyme cleaner**: a solution used before disinfecting instruments to improve removal of organic material (e.g., proteases to assist in removing protein).

**EPA Registration Number or EPA Reg. No.**: a hyphenated, two- or three-part number assigned by EPA to identify each germicidal product registered within the United States. The first number is the company identification number, the second is the specific product number, and the third (when present) is the company identification number for a supplemental registrant.

**Exposure time**: period in a sterilization process during which items are exposed to the sterilant at the specified sterilization parameters. For example, in a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature.

**Flash sterilization**: process designed for the steam sterilization of unwrapped patient-care items for immediate use (or placed in a specially designed, covered, rigid container to allow for rapid penetration of steam).

**Fungicide**: agent that destroys fungi (including yeasts) and/or fungal spores pathogenic to humans or other animals in the inanimate environment.

**General disinfectant**: EPA-registered disinfectant labeled for use against both gram-negative and gram-positive bacteria. Efficacy is demonstrated against both Salmonella choleraesuis and Staphylococcus aureus. Also called broad-spectrum disinfectant.

**Germicide**: agent that destroys microorganisms, especially pathogenic organisms.

**Germicidal detergent**: detergent that also is EPA-registered as a disinfectant.

**High-level disinfectant**: agent capable of killing bacterial spores when used in sufficient concentration under suitable conditions. It therefore is expected to kill all other microorganisms.

**Hospital disinfectant**: disinfectant registered for use in hospitals, clinics, dental offices, and any other medical-related facility. Efficacy is demonstrated against Salmonella choleraesuis, Staphylococcus aureus, and Pseudomonas aeruginosa. EPA has registered approximately 1,200 hospital disinfectants.

**Huck towel**: all-cotton surgical towel with a honey-comb weave; both warp and fill yarns are tightly twisted. Huck towels can be used to prepare biologic indicator challenge test packs.

**Implantable device**: according to FDA, “device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more” [21 CFR 812.3(d)].

**Inanimate surface**: nonliving surface (e.g., floors, walls, furniture).

**Incubator**: apparatus for maintaining a constant and suitable temperature for the growth and cultivation of microorganisms.

**Infectious microorganisms**: microorganisms capable of producing disease in appropriate hosts.

**Inorganic and organic load**: naturally occurring or artificially placed inorganic (e.g., metal salts) or organic (e.g., proteins) contaminants on a medical device before exposure to a microbicidal process.

**Intermediate-level disinfectant**: agent that destroys all vegetative bacteria, including tubercle bacilli, lipid and some nonlipid viruses, and fungi, but not bacterial spores.

**Limited disinfectant**: disinfectant registered for use against a specific major group of organisms (gram-negative or gram-positive bacteria). Efficacy has been demonstrated in laboratory tests against either Salmonella choleraesuis or Staphylococcus aureus bacteria.

**Lipid virus**: virus surrounded by an envelope of lipoprotein in addition to the usual core of nucleic acid surrounded by a coat of protein. This type of virus (e.g., HIV) is generally easily inactivated by many types of disinfectants. Also called enveloped or lipophilic virus.
Low-level disinfectant: agent that destroys all vegetative bacteria (except tubercle bacilli), lipid viruses, some nonlipid viruses, and some fungi, but not bacterial spores.

Mechanical indicator: devices that monitor the sterilization process (e.g., graphs, gauges, printouts).

Medical device: instrument, apparatus, material, or other article, whether used alone or in combination, including software necessary for its application, intended by the manufacturer to be used for human beings for diagnosis, prevention, monitoring treatment, or alleviation of disease; diagnosis, monitoring, treatment, or alleviation of or compensation for an injury or handicap; investigation, replacement, or modification of the anatomy or of a physiologic process; or control of conception and that does not achieve its primary intended action in or on the human body by pharmacologic, immunologic, or metabolic means but might be assisted in its function by such means.

Microbicidal activity: the minimum concentration of a liquid chemical germicide needed to achieve the claimed microbicidal activity as determined by dose-response testing. Sometimes used interchangeably with minimum recommended concentration.

Musklin: loosely woven (by convention, 140 threads per square inch), 100% cotton cloth. Formerly used as a wrap for sterile packs or a surgical drape. Fabric wraps used currently consist of a cotton-polyester blend.

Mycobacteria: bacteria with a thick, waxy coat that makes them more resistant to chemical germicides than other types of vegetative bacteria.

Nonlipid viruses: generally considered more resistant to inactivation than lipid viruses. Also called nonenveloped or hydrophilic viruses.

One-step disinfection process: simultaneous cleaning and disinfection of a noncritical surface or item.

Pasteurization: process developed by Louis Pasteur of heating milk, wine, or other liquids to 65–77°C (or the equivalent) for approximately 30 minutes to kill or markedly reduce the number of pathogenic and spoilage organisms other than bacterial spores.

Parametric release: declaration that a product is sterile on the basis of physical and/or chemical process data rather than on sample testing or biologic indicator results.

Penicilinder: carriers inoculated with the test bacteria for in vitro tests of germicides. Can be constructed of stainless steel, porcelain, glass, or other materials and are approximately 8 x 10 mm in diameter.

Permissible exposure limit (PEL): time-weighted average maximum concentration of an air contaminant to which a worker can be exposed, according to OSHA standards. Usually calculated over 8 hours, with exposure considered over a 40-hour work week.

Personal protective equipment (PPE): specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts) not intended to function as protection against a hazard are not considered to be PPE.

Parts per million (ppm): common measurement for concentrations by volume of trace contaminant gases in the air (or chemicals in a liquid); 1 volume of contaminated gas per 1 million volumes of contaminated air or 1¢ in $10,000 both equal 1 ppm. Parts per million = µg/mL or mg/L.

Prions: transmissible pathogenic agents that cause a variety of neurodegenerative diseases of humans and animals, including sheep and goats, bovine spongiform encephalopathy in cattle, and Creutzfeldt-Jakob disease in humans. They are unlike any other infectious pathogens because they are composed of an abnormal conformational isofrom of a normal cellular protein, the prion protein (PrP). Prions are extremely resistant to inactivation by sterilization processes and disinfecting agents.

Process challenge device (PCD): item designed to simulate product to be sterilized and to constitute a defined challenge to the sterilization process and used to assess the effective performance of the process. A PCD is a challenge test pack or test tray that contains a biologic indicator, a Class 5 integrating indicator, or an enzyme-only indicator.

QUAT: abbreviation for quaternary ammonium compound, a surface-active, water-soluble disinfecting substance that has four carbon atoms linked to a nitrogen atom through covalent bonds.

Recommended exposure limit (REL): occupational exposure limit recommended by NIOSH as being protective of worker health and safety over a working lifetime. Frequently expressed as a 40-hour time-weighted-average exposure for up to 10 hours per day during a 40-work week.

Reprocess: method to ensure proper disinfection or sterilization; can include: cleaning, inspection, wrapping, sterilizing, and storing.

Sanitizer: agent that reduces the number of bacterial contaminants to safe levels as judged by public health requirements. Commonly used with substances applied to inanimate objects. According to the protocol for the official sanitizer test, a sanitizer is a chemical that kills 99.999% of the specific test bacteria in 30 seconds under the conditions of the test.

Shelf life: length of time an undiluted or use dilution of a product can remain active and effective. Also refers to the length of time a sterilized product (e.g., sterile instrument set) is expected to remain sterile.

Spaulding classification: strategy for reprocessing contaminated medical devices. The system classifies a medical device as critical, semicritical, or noncritical on the basis of risk to patient safety from contamination on a device. The system also established three levels of germicidal activity (sterilization, high-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semicritical, and noncritical).
Spore: relatively water-poor round or elliptical resting cell consisting of condensed cytoplasm and nucleus surrounded by an impervious cell wall or coat. Spores are relatively resistant to disinfectant and sterilant activity and drying conditions (specifically in the genera Bacillus and Clostridium).

Spore strip: paper strip impregnated with a known population of spores that meets the definition of biological indicators.

Steam quality: steam characteristic reflecting the dryness fraction (weight of dry steam in a mixture of dry saturated steam and entrained water) and the level of noncondensable gas (air or other gas that will not condense under the conditions of temperature and pressure used during the sterilization process). The dryness fraction (i.e., the proportion of completely dry steam in the steam being considered) should not fall below 97%.

Steam sterilization: sterilization process that uses saturated steam under pressure for a specified exposure time and at a specified temperature, as the sterilizing agent.

Steam sterilization, dynamic air removal type: one of two types of sterilization cycles in which air is removed from the chamber and the load by a series of pressure and vacuum excursions (prevacuum cycle) or by a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush-pressure-pulse cycle).

Sterile or Sterility: state of being free from all living microorganisms. In practice, usually described as a probability function, e.g., as the probability of a microorganism surviving sterilization being one in one million.

Sterility assurance level (SAL): probability of a viable microorganism being present on a product unit after sterilization. Usually expressed as 10–6; a SAL of 10–6 means <1/1 million chance that a single viable microorganism is present on a sterilized item. A SAL of 10–6 generally is accepted as appropriate for items intended to contact compromised tissue (i.e., tissue that has lost the integrity of the natural body barriers). The sterilizer manufacturer is responsible for ensuring the sterilizer can achieve the desired SAL. The user is responsible for monitoring the performance of the sterilizer to ensure it is operating in conformance to the manufacturer’s recommendations.

Sterilization: validated process used to render a product free of all forms of viable microorganisms. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability. Although this probability can be reduced to a very low number, it can never be reduced to zero.

Sterilization area: area of a health-care facility designed to house sterilization equipment, such as steam ethylene oxide, hydrogen peroxide gas plasma, or ozone sterilizers.

Sterilizer: apparatus used to sterilize medical devices, equipment, or supplies by direct exposure to the sterilizing agent. Sterilizer, gravity-displacement type: type of steam sterilizer in which incoming steam displaces residual air through a port or drain in or near the bottom (usually) of the sterilizer chamber. Typical operating temperatures are 121–123°C (250–254°F) and 132–135°C (270–275°F).

Sterilizer, prevacuum type: type of steam sterilizer that depends on one or more pressure and vacuum excursions at the beginning of the cycle to remove air. This method of operation results in shorter cycle times for wrapped items because of the rapid removal of air from the chamber and the load by the vacuum system and because of the usually higher operating temperature (132–135°C [270–275°F]; 141–144°C [285–291°F]). This type of sterilizer generally provides for shorter exposure time and accelerated drying of fabric loads by pulling a further vacuum at the end of the sterilizing cycle.

Sterilizer, steam-flush pressure-pulse type: type of sterilizer in which a repeated sequence consisting of a steam flush and a pressure pulse removes air from the sterilizing chamber and processed materials using steam at above atmospheric pressure (no vacuum is required). Like a prevacuum sterilizer, a steam-flush pressure-pulse sterilizer rapidly removes air from the sterilizing chamber and wrapped items; however, the system is not susceptible to air leaks because air is removed with the sterilizing chamber pressure at above atmospheric pressure. Typical operating temperatures are 121–123°C (250–254°F), 132–135°C (270–275°F), and 141–144°C (285–291°F).

Surfactant: agent that reduces the surface tension of water or the tension at the interface between water and another liquid; a wetting agent found in many sterilants and disinfectants.

Tabletop steam sterilizer: a compact gravity-displacement steam sterilizer that has a chamber volume of not more than 2 cubic feet and that generates its own steam when distilled or deionized water is added.

Time-weighted average (TWA): an average of all the concentrations of a chemical to which a worker has been exposed during a specific sampling time, reported as an average over the sampling time. For example, the permissible exposure limit for ethylene oxide is 1 ppm as an 8-hour TWA. Exposures above the ppm limit are permitted if they are compensated for by equal or longer exposures below the limit during the 8-hour workday as long as they do not exceed the ceiling limit; short-term exposure limit; or, in the case of ethylene oxide, excursion limit of 5 ppm averaged over a 15-minute sampling period.

Tuberculocide: an EPA-classified hospital disinfectant that also kills Mycobacterium tuberculosis (tubercle bacilli). EPA has registered approximately 200 tuberculocides. Such agents also are called mycobactericides.

Use-life: the length of time a diluted product can remain active and effective. The stability of the chemical and the storage conditions (e.g., temperature and presence of air, light, organic matter, or metals).

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EN 1040: Basic bactericidal activity – Phase 1/Step 1. Suspension test in 5 minutes (or 1, 15, 30 and 60 minutes), at +20°C (or others with 10°C in–terval) – Microbial reduction > 105.

EN 1372: Bactericidal activity – Phase 2/Step 1 - Medical. Quantitative suspension test in 60 minutes (or 5, 15 and 30 minutes), at +20°C (or others with 10°C interval), in the presence of interfering substances (CC: 0.3 g/L albumin + 30°f hard water; DC: 3 g/L albumin + 3 ml/L erythrocytes + 30°f hard water; or others) - Microbial reduction > 105.

EN 1276: Bactericidal activity – Phase 2/Step 1 - Industry. Quantitative suspension test in 5 minutes (or other additional), at +20°C (or others with 10°C interval), in the presence of interfering substances (CC: 0.3 g/L albumin + 30°f hard water; DC: 3 g/L albumin + 30°f hard water; or others) - Microbial reduction > 105.

EN 14561: Bactericidal activity – Phase 2/Step 2 - Medical. Quantitative carrier test by immersion in 60 minutes (or 5, 15 and 30 minutes), at +20°C (or others with 10°C interval), in the presence of interfering substances (CC: 0.3 g/L albumin + 30°f hard water; DC: 3 g/L albumin + 3 ml/L erythrocytes + 30°f hard water; or others) - Microbial reduction > 105.

EN 13697: Bactericidal activity – Phase 2/Step 2 - Industry. Quantitative carrier test in 60 minutes (or 5, 15, 30 and 60 minutes), at +20°C (or others with 10°C interval), in the presence of interfering substances (CC: 0.3 g/L albumin + 30°f hard water; DC: 3 g/L albumin + 3 ml/L erythrocytes + 30°f hard water; or others) - Microbial reduction > 104.

EN 14348: Mycobactericidal / tuberculocidal activity – Phase 2 / Step 1 - Medical. Quantitative suspension test in 60 minutes (or 5, 15 and 30 minutes) at +20°C (or others with 10°C interval) in the presence of interfering substances (CC: 0.3 g/L albumin + 30°f hard water; DC: 3 g/L albumin + 3 ml/L erythrocytes + 30°f hard water; or others) – Microbial reduction > 105.

EN 13697: Bactericidal activity – Phase 2/Step 2 - Industry. Quantitative carrier test in 5 minutes (or 1, 15, 30 and 60 minutes), at +20°C (or +4, +10 and +40°C), in the presence of interfering substances (CC: 0.3 g/L albumin + 30°f hard water; DC: 3 g/L albumin + 3 ml/L erythrocytes + 30°f hard water; or others) - Microbial reduction > 105.

EN 14563: Fungicidal/yeasticidal activity – Phase 2/Step 1 - Medical. Quantitative suspension test in 60 minutes (or 5, 15 and 30 minutes) at +20°C (or others with 10°C interval), in the presence of interfering substances (CC: 0.3 g/L albumin + 30°f hard water; DC: 3 g/L albumin + 3 ml/L erythrocytes + 30°f hard water; or others) - Microbial reduction > 104.

EN 13624: Fungicidal/yeasticidal activity – Phase 2/Step 1 - Medical. Quantitative suspension test in 60 minutes (or 5, 15 and 30 minutes), at +20°C (or others with 10°C interval), in the presence of interfering substances (CC: 0.3 g/L albumin + 30°f hard water; DC: 3 g/L albumin + 3 ml/L erythrocytes + 30°f hard water; or others) - Microbial reduction > 104.

EN 1650: Fungicidal/yeasticidal activity – Phase 2/Step 1 - Industry. Quantitative suspension test in 15 minutes (or 5, 15 and 30 minutes), at +20°C (or +4, +10 and +40°C), in the presence of interfering substances (CC: 0.3 g/L albumin + 30°f hard water; DC: 3 g/L albumin + 30°f hard water; or others) - Microbial reduction > 104.

EN 14562: Fungicidal/yeasticidal activity – Phase 2/Step 2 - Medical. Quantitative carrier test by immersion in 60 minutes (or 5, 15 and 30 minutes), at +20°C (or others with 10°C interval), in the presence of interfering substances (CC: 0.3 g/L albumin + 30°f hard water; DC: 3 g/L albumin + 3 ml/L erythrocytes + 30°f hard water; or others) - Microbial reduction > 104.

EN 13697: Fungicidal/yeasticidal activity – Phase 2/Step 2 - Industry. Quantitative carrier test in 15 minutes (or 1, 5, 30 and 60 minutes), at +20°C (or +4, +10 and +40°C), in the presence of interfering substances (CC: 0.3 g/L albumin + 30°f hard water; DC: 3 g/L albumin + 30°f hard water; or others) - Microbial reduction > 104.

EN 14476+A1: Virucidal activity – Phase 2/Step 1 - Medical. Quantitative test in 60 minutes (or 5, 15 and 30 minutes) or in 30 seconds / 1 minute (or 3 minutes) for hands, at +20°C (or +60°C for machine product), in the presence of interfering substances (CC: 0.3 g/L albumin + 30°f hard water; DC: 3 g/L al–bumin + 30°f hard water; or buffered solution with phosphates for hands) – Viral reduction > 104. 

Activity on viruses: Adaptation of the EN 14476+A1 standard – Viral reduction > 104. HIV-1, PRV (assessment of activity on HBV), BVDV (surrogate of HCV), Herpes virus, Rotavirus, Norovirus, Coronavirus (SARS), Influenza virus A H1N1 and H5N1.

EN 13704: Sporicidal activity – Phase 2/Step 1 - Industry. Quantitative suspension test in 60 minutes (or 5, 15 and 30 minutes), at +20°C (or +4, +10, +40 and +75°C), in the presence of interfering substances (CC: 0.3 g/L albumin + 30°f hard water; DC: 3 g/L albumin + 30°f hard water; or others) - Microbial reduction > 103.
Activity on viruses: Adaptation of the EN 14476+A1 standard – Viral reduction > 10⁴. HIV-1, PRV (assessment of activity on HBV), BVDV (surrogate of HCV), Herpes virus, Rotavirus, Norovirus, Coronavirus (SARS), Influenza virus A H1N1 and H5N1.

EN 13704: Sporicidal activity – Phase 2/Step 1 - Industry. Quantitative suspension test in 60 minutes (or 5, 15 and 30 minutes), at +20°C (or +4, +10, +40 and +75°C), in the presence of interfering substances (CC: 0.3 g/L albumin + 30°f hard water; DC: 3 g/L albumin + 30°f hard water; or others) – Microbial reduction > 10³.

EN 1499: Hygienic Hand wash  – Phase 2/Step 2. Test on voluntaries with hands artificially contaminated with Escherichia coli K12, in the practical conditions of use, in 30 or 60 seconds. The reduction factor obtained is compared to those obtained in the same conditions with a standard washing (CODEX plain soap).

EN 1500: Hygienic Hand rubbing  – Phase 2/Step 2. Test on voluntaries with hands artificially contaminated with Escherichia coli K12, in the practical conditions of use, in 30 or 60 seconds. The reduction factor obtained is compared to those obtained in the same conditions with a standard washing (60% propanol-2).

EN 12791: Surgical disinfection of hands – Phase 2/Step 2. Test on natural flora of voluntaries. Assessment of the immediate effect and 3 hours after disinfection. The reduction factor obtained is compared to those obtained in the same conditions with a standard washing (60% propanol-2).

NF T 72-281: Airborne disinfection of surfaces - Determination of bactericidal and/or fungicidal and/or sporicidal activity. Quantitative carrier test ay +20°C and from 50 to 75% of relative humidity (or others according to the airborne process) – Microbial reduction > 10⁵ (bacteria); 10⁴ (yeasts/moulds); 10³ (spores of bacteria). Effectiveness of antimicrobial preservation Method from European Pharmacopoeia. Determination of anti-microbial efficiency of preservation agent.

NF S 94-402-1 (mai 2004); Electrochemical study of pitting corrosion of a product for the treatment of medico-surgical instrumentation in stainless steel. Compatibility with materials and medical devices. Verification of the compatibility of a product for the treatment of medico-surgical instrumentation by analysis of the medical devices and/or materials surface state after their contact with the product

Degreasing Cleaning Power (DCP): Determination of degreasing and detergent effectiveness of detergent or detergent/ disinfectant product on a biological soiling, rich in proteins and greasy materials, spread on a plate in stainless steel or PTFE. Biofilm: Studies of detergent effectiveness and antimicrobial action of a detergent and/or disinfectant product on monobacterial biofilm. Study of enzymatic activity of detergent and/or disinfectant product in the real conditions of use.
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