





CONTENTS

I. INTRODUCTION	3
II. PRODUCT INFORMANTION	4
1. GENERAL INFIRMATION OF OPHICLEAN	4
(1) Composition	4
(2) Physical properties	4
2. EFFICACY OF OPHICLEAN	4
3. SAFETY OF OPHICLEAN- Toxicity	6
4. STABILITY TEST OF OPHICLEAN	6
5. MATERIAL COMPATIBILITY OF OPHICLEAN	7
6. RINSING INSTRUCTIONS	8
(1) Rinsing Procedure	8
(2) Sterile water rinse	8
(3) Potable water rinse	9
7. DIRECTIONS FOR USE	
(1) Manual operation	
(2) Auto endoscope preprocessors	
(3) Efficacy test method of OPHICLEAN	
8.STORAGE AND PRECAUTION	
(1) Warning	
(2) General precautions	13
(3) First aid measures	13
(4) Disposal	13
(5) Packing and shelf-life	14
III. CONCLUTION	15
IV. REFERENCE	16

I. INTRODUCTION

Gastro-intestinal endoscopy plays an important role in the diagnosis and treatment of various diseases that may occur in the gastro-intestinal tract. As the interest in health has increased recently, endoscopy has increased rapidly, and the risk of infection has also become an important issue. Although the endoscope is easily contaminated by the patient's body fluids or blood, it is difficult to thoroughly clean due to the complicated structure of the endoscope, so that infection can be spread if used without appropriate reprocessing.¹⁾

Disinfection is a process of reducing or eliminating microorganisms, which is carried out to prevent the propagation of pathogenic microorganisms to patients due to the use of medical devices or instruments. Medical devices and instruments should be selected according to the purpose and materials of use, and proper disinfection methods should be applied to correct mechanism of disinfection, economic loss, infection risk and environmental pollution.

OPA formulations are widely used as disinfectants to complement the disadvantages of other disinfectants. When OPA type disinfectant is used, it can be opened and used without needing to be activated. It is effective even in the presence of organic matter. OPA formulation is disinfectant for medical instruments, instruments and devices and is used for disinfection of various medical instruments including flexible endoscope. When disinfected, a high level of disinfection that can kill general bacteria, viruses and Mycobacterium tuberculosis within 5 minutes can be realized. OPA preparations are reduced in irritation to workers as compared to GA preparations, so that skin irritation, skin sensitization, and light sensitization are both negative results. Further, disinfection can be performed while confirming whether the preliminary washing and rinsing are carried out reliably. OPA preparations, unlike GA preparations, are low in the action of protein coagulation, so they can be easily removed with enzymes and detergents even if they are colored by organic compounds.

🛈 Huons Medicare

II. PRODUCT INFORMANTION

1. GENERAL INFIRMATION OF OPHICLEAN

(1) Composition

Active ingredient :	ortho-phthalaldehyde	0.55%
Inert ingredients :	Buffering agents etc.	A proper quantity
Solvent :	Purified water	A proper quantity

(2) Physical properties

- Description : Clear, pale blue liquid
- OPHICLEAN is used as undiluted solution.
- pH : 7.2 ~ 7.8

2. EFFICACY OF OPHICLEAN

OPHICLEAN is an aldehyde disinfectant, in which two aldehyde groups mediate a double bond and five carbon groups form an aromatic ring. Aromatic rings show that *ortho*-phthalaldehyde easily penetrates the lipid-rich extracellular layer and binds to proteins having primary amines, thereby excellently disinfecting gram-negative bacteria. Amino acids, and microorganisms, and it has efficacy against bacteria, viruses, fungi, and spore depending on contact time, temperature, and concentration. In addition, the effect of stabilizing the cell outer membrane and cell wall of vegetable organic matter, and is relatively less toxic.³⁾

OPHICLEAN has a wide range of active against bacteria, fungi, tuberculosis, viruses, and spore. The results of the test results of OPHICLEAN are shown in the table below.

Institute	Test organism	Contact time
	Bacteria	
	Staphylococcus aureus ATCC 6538	5 min
	Escherichia coli ATCC 25922	5 min
KTR	Salmonella typhimurium ATCC 13311	5 min
(Korea testing& research	Super bacteria	
institute)	MRSA ATCC 33591	5 min
	VRE ATCC 51299	5 min
	Fungi	
	Candida albicans ATCC 10231	5 min
	Bacteria	
	Staphylococcus aureus ATCC 6538	1 min
	Pseudomonas aeruginosa ATCC 15442	1 min
	Enterococcus hirae ATCC 10541	1 min
	Fungi	
Hygiene –Nord (Germany)	Candida albicans ATCC 10231	1 min
	Aspergillus brasiliensis ATCC 16404	1 min
	Mycobacteria	
	Mycobacterium terrae ATCC 15755	1 min
	Mycobacterium avium ATCC 15769	1 min
	Virus	
labor orders (Cormany)	Poliovirus	5 min
labor-enders (Germany)	Adenovirus	5 min
	Murine Norovirus	5 min
	Mycobacteria	
Hoseo University (Korea)	Mycobacterium bovis ATCC 35737	5 min
	<i>H37Rv</i> ATCC 25618	5 min
	H37Ra ATCC 25177	5 min
	M.avium ATCC 700898	5 min
Korea National Tuberculosis	M.intracellulare ATCC 13950	5 min
Association	M.kansasii ATCC 12478	5 min
	M.abscessus ATCC 19977	5 min
	M.tuberculosis I	5 min
	M.tuberculosis II	5 min
Institute of Animal Medicare	Spore	
(Korea)	Bacillus subtilis ATCC 6633	32 hr

Table 1. In-vitro testing



3. SAFETY OF OPHICLEAN- Toxicity

The toxicological evaluation of OP	HICLEAN was made according to HSDB data.
------------------------------------	--

Testing Method	Animal	Result	
Acute oral toxicity	Rat	LD ₅₀ >2,000mg/kg	Low toxicity
Acute dermal toxicity	Rabbit	LD ₅₀ >2,000mg/kg	Low toxicity
Skin irritation	Rabbit	Mild irritation	
Eye irritation	Rabbit	Mild irritation	
Skin sensitization	Rabbit	Mild irritation	

* Source : Toxnet

**LD50 : Lethal dose 50

4. STABILITY TEST OF OPHICLEAN

Stability of *O*-phthalaldehyde in OPHICLEAN for open-bottle shelf-life (78 days)



After opening, the solution remaining in the container may be stored for up to 78 day (providing the 78 days does not extend past the expiration date on the container) until used.

5. MATERIAL COMPATIBILITY OF OPHICLEAN

0.55% OPA solution has been found to be compatible with the ma	aterials shown below.
--	-----------------------

METALS ^a	PLASTICS ^e	ELASTOMERS ^e	ADHESIVES ^e
Aluminum	Polymethylmethacrylate (Acrylic)	Polychloroprene (Neoprene)	Cyanoacrylate ^h
Anodized aluminum ^b	Nylon	Kraton G	EPO-TEK 301 Epoxy ^h
Brass	Polyethylene terephthalate (Polyester)	Polyurethane	EPO-TEK 353 Epoxy
Carbon steel	Polystyrene	Silicone rubber ^f	
Chrome plated brass ^b	Polyvinylchloride (PVC) ^f	Natural Rubber Latex	
Chrome plated steel ²	Acrylonitrile/butadiene/s tyrene		
Copper	Polysulfone		
Nickel plate brass ^b	Polycarbonate ^g		
Nickel sliver alloy ^b	Polyethylene		
Stainless steel ^c	Polypropylene		
Titanium	Acetyl		
Tungsten carbide ^b	PTFE		
Vanadium steel ⁴	Polyamide		

a) Exposed to 31 days (744 hours) of continuous contact with 0.55% OPA solution with no effect unless otherwise noted.

- b) Show signs of surface discoloration at 7 days of greater.
- c) Most grades tested show no effect. Others may exhibit discoloration at 7 days of greater. Stainless steel 440 shows rust at 14 days immersion.
- d) Treated with 500 cycles of 0.55% OPA Solution. Surface breakdown noted after 150 cycles (25 hour total contact.)
- e) Exposed 7 days of continuous contact with 0.55% OPA Solution with no effect unless otherwise noted.
- f) Some grades or applications ones exhibit discoloration.
- g) Some sonic welded parts may exhibit crazing.
- h) Some loss in shear strength, but show no signs of severe degradation.
- * Olympus, Pentax, and Fujinon endoscopes are compatible 0.55% OPA Solution.



6. RINSING INSTRUCTIONS

(1) Rinsing Procedure

a) Manual Processing :

- Following removal from OPHICLAEN Solution, thoroughly rinse the semi-critical medical device by immersing it completely in a large volume of water. Use sterile water unless potable water is acceptable. See item (2) or (3) below.
- Keep the device totally immersed for a minimum of 1 minute in duration, unless a longer time is specified by the reusable device manufacturer.
- Manually flush all lumens with large volumes (not less than 100 mL) of rinse water unless otherwise noted by the device manufacturer.
- Repeat the procedure TWO (2) additional times, for a total of THREE (3) RINSES, with large volumes of fresh water to remove OPHICLAEN[®] Solution residues. Residues may cause serious side effects. SEE WARNINGS. THREE (3) SEPARATE, LARGE VOLUME WATER IMMERSION RINSES ARE REQUIRED.
- Refer to the reusable semi-critical medical device manufacturer's labeling for additional rinsing instructions.

b) Automated Processing :

- Select a rinse cycle on an automatic endoscope reprocessor that has been validated for use with this product.
- Ensure that the automated rinse cycle selected will thoroughly rinse the semi-critical medical device including all lumens with large volumes of sterile or potable water equivalent to the reusable device manufacturer's recommendations.
- Verify that each rinse is a minimum of 1 minute in duration unless the reusable device manufacturer specifies a longer time. Ensure that a fresh volume of water is used for each rinse. Do not reuse the water for rinsing or any other purpose.
- Refer to the reusable device manufacturer's labeling for additional rinsing instructions.

(2) Sterile water rinse

The following devices should be rinsed with sterile water, using sterile technique when rinsing and handling:

Devices intended for use in normally sterile areas of the body.

Devices intended for use in know immunocompromised patients, or potentially immunocompromised patients based on institutional procedures (e.g., high risk population served).

When practical, bronchoscopes, due to a risk of contamination from potable water supply. Although microorganisms in this type of water system are not normally pathogenic in patients with healthy immune systems, AIDS patients or other immunocompromised individuals may be placed at high risk of infection by these opportunistic microorganisms.

边 Huons Medicare

(3) Potable water rinse

For all other devices, a sterile water rinse is recommended when practical. Otherwise, potable tap water rinse is acceptable. When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the device or medical equipment with microorganisms which may be present in potable water supplies. Water treatment systems, such as softeners or deionizers, may add microorganisms to the treated water to the extent that microbial content of the water at the point of use could exceed that of the pretreated drinking water. To ensure proper water quality, adherence to maintenance of the water treatment system(s) is recommended.

The use of a bacterial retentive (0.2 micron) filter system may eliminate or greatly reduce the amount of these waterborne bacteria from the potable water source. Contact the manufacturer of the filter or UV system for instructions on preventative maintenance and periodic replacement of the filter to avoid colonization or formation of biofilms in the filter.



7. DIRECTIONS FOR USE

- OPHICLEAN is used as undiluted solution.
- After using endoscopes and medical instruments, it is washed with enzymatic detergent or neutral detergent. OPHICLEAN Solution is compatible with enzymatic detergent which is mild in pH, low forming and easily rinsed from equipment (TBXzyme® Enzymatic Detergent). Detergents that are either highly acidic or alkaline are not recommended as cleaning agents.
- Endoscopes and instruments that have been disinfected with OPHICLEAN must be rinsed with sterile water or potable water.
- Endoscope cleaning and disinfection are performed in the following order. Before the disinfection, leak test should be executed to stop disinfection immediately if there is a leak.

(1) Manual operation



(clothes, hand washing)



5.) Disinfection (5 min)



1. Advance preparations 2. Recovery of instrument and arrangement



6. Cleaning after soaking & rinsing



3. Pre cleaning (detergent)



Checking oddity



4. Checking the waterleakage and inspection



8. Dry and arrangement (alcohol),

(2) Auto endoscope preprocessors



1. Advance preparations (clothes, hand washing)



5. Automatic disinfection & Sterilization, rinse



2. Pre cleaning (Regular detergent)



6. Dry and arrangement (alcohol)



3. Setting in cleaning machine



7. Storage



4. Checking the water leakage and inspection



Concentration of this product during its reuse life must be verified by the OPHICLEAN Solution Test Strip prior to each use to determine that the concentration of *ortho*-phthalaldehyde is above the MEC of 0.3%. OPHICLEAN Solution may be used and reused within the limitations indicated above for up to a maximum of 14 days. OPHICLEAN Solution must be discarded after 14 days, even if the OPHICLEAN[®] Solution Test Strip indicates a concentration above the MEC. In an automatic washer / disinfector, it is necessary to pay attention to the replacement cycle because it is likely to be diluted by the structure of the device as well as the concentration with time.

(3) Efficacy test method of OPHICLEAN

The reusable OPHICLEAN solution should be checked for the minimum effective concentration (0.3%) before use because the concentration will decrease and the effect will decrease due to long-term use and repeated use.

Test strip	How to use	Read results
<section-header></section-header>	 1) 1 pc strip is immersed into prepared OPHICLEAN during 2 seconds, then take out. 2) Strip is kept vertical like pic-1 in the form of indicator edge will touch napkin. 3) In 60 second, determine test result by comparing color that given on strip tube of below. 	PASS FAIL

* Detro OPA solution test strips

8.STORAGE AND PRECAUTION

(1) Warning

- Rarely can cause allergic reactions. Most allergies occur when a health care worker uses the product in a poorly ventilated room or does not have adequate personal protective equipment.
- Contact with eyes may cause irritation and may result in temporary discoloration if applied on skin. Repeated skin contact may cause irritability. In case of eye contact, rinse immediately with plenty of water for at least 15 minutes and consult a physician.
- In case of contact with skin, flush immediately with water. Do not spray or aerosol with this product.
- Avoid contamination by food. Ingestion may cause irritation or chemical burns on the mouth, throat, esophagus and on. Drink large quantities of water and get immediate medical attention. If the mucous membrane is damaged by being exposed to the mouth, stomach washing can't be performed.
- Avoid outbreaks of orthophthaldehyde vapors, as they may cause irritation to the respiratory tract and eyes. You may feel stinging in the nose and throat, and may cause secretions, coughing, and chest pain. It can aggravate asthma or bronchitis. If an adverse reaction occurs by inhaling steam, allow fresh air to be inhaled. If breathing is difficult, oxygen is supplied by qualified forgiveness. Medical attention is needed if symptoms persist.
- Use in semi-critical instrument should be part of the proven cleaning process supplied by the equipment manufacturer.

🛈 Huons Medicare

Always follow the recommendations (Special Instructions for TEE) and directions for use rinsing instructions for Transesophageal Echocardiography (TEE). Failure to follow this precisely can cause chemical burns, irritability, and coloration in the mouth, throat, esophagus and stomach.

(2) General precautions

- OPHICLEAN should not be applied to medical devices used for sterilization parts of the human body, such as cataract surgical instruments.
- OPHICLEAN should be used in well ventilated areas.
- Contaminated reusable equipment should be thoroughly cleaned prior to disinfection. Residual contamination of soil or lubricants reduces the effectiveness of the disinfectant.
- When disinfecting the appliance, wear gloves of appropriate type and length, eye protection, and waterproof surgical clothing. When using latex rubber gloves, the user must wear double gloves, or change them frequently.
- The user must follow the instruction manual. The instruction manual affects safety and efficacy.
- The manufacturer of a reusable device should provide the user with a validated application process when using the product.
- The use of an automatic endoscopic flushing device should be part of a validated procedure. The contact condition is 5 minutes at 25 degrees.
- Test strips are used to determine the concentration of ortho-phthalaldehyde prior to use.
- The active component of OPHICLEAN, ortho-phthalaldehyde, is less irritating than glutaraldehyde(GA). However, adequate ventilation and protective equipment is required for the safety of staff.

(3) First aid measures

- In case of eye contact, rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
- In case of skin contact, wash off with soap and plenty of water.
- If inhaled, if breathed in, move person into fresh air.
- If inhaled, if not breathing, give artificial respiration.
- If inhaled, consult a physician.
- Never give anything by mouth to an unconscious person.
- If swallowed, rinse mouth with water.

(4) Disposal

Check state and local disposal regulations. Glycine (free base) may be used as a neutralizer for OPHICLEAN Solution prior to disposal, if required. A minimum of 25 grams of glycine (free base) should be used to neutralize one gallon of OPHICLEAN Solution. The minimum

边 Huons Medicare

recommended neutralization time is one hour. Discard residual solution into drain. Flush drain thoroughly with water.

(5) Packing and shelf-life

- Packing unit : 4 L X 4 / Box
- Storage information: 15~30 °C
- Shelf- life : 24 months



III. CONCLUTION

The role of disinfectants is important for proper endoscope disinfection. The ideal disinfectant have to good efficacy, short disinfection time within 10 minutes, low toxicity and does not cause endoscopic damage.

OPHICLEAN can be used directly as undiluted solution and exhibits rapid effect to kill most strains in 5 minutes. In addition, it exhibits mild irritation of eye and skin compared to other disinfectants, and is also compatible with the most popular endoscopes on the market.

🛈 Huons Medicare

IV. REFERENCE

- 1. [Understandable infection control] (2006), p55-80, The Korean Journal
- 2. KCDC (2014), "Disinfection and sterilization instructions at medical institutions"
- 3. 「Types and characteristics of disinfectants」 The Korean Journal of Gastrointestinal Endoscopy
- 4. The Korean society of digestive endoscopy(2016), "Disinfection and sterilization instructions at medical institutions"
- 5. Selection and proper use of endoscopic disinfectants: centered on high-level disinfectants, The Korean Journal
- 6. "Types and characteristics of disinfectants(2007)", The Korean Journal
- 7. Cidex opa solution instruction

Authorized Representative: KTR Europe GmbH

Mergenthalerallee 77, Eschborn, Hessen, 65760, Germany Tel : +49(0)6196-887170 **Manufacturer: Huons Medicare Co., Ltd.** 22, Noksansandan 165-ro, Gangseo-gu, Busan Korea T+82 51 831 1030 F+82 51 831 1040

