VOLUME 16, NUMBER 6 JUNE 1995

An Official Journal of The Society for Healthcare Epidemiology of America

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY™

Continued inside.

The Real Facts About Glutaraldehyde

Glutaraldehyde solutions have been proven effective for over 30 years. *The praise in medical circles for glutaraldehyde's efficacy and safety led to quick acceptance. Glutaraldehyde's ability to reliably disinfect and sterilize medical instruments generated high confidence. And lasting confidence. Recently, however, that confidence is being questioned in certain corners. To make an informed judgement, consider the facts presented below.*

High Level Disinfection or Sterilization?

Currently there is universal acceptance of high level disinfection for semi-critical devices such as flexible endoscopes.[1] This acceptance comes from both government and professional organizations, including the FDA, CDC, AORN, APIC, SGNA, and ASGE. As one group stated, "The apparent consensus is that high-level disinfection, if meticulously and consistently done, gives a high degree of patient safety; this appears to be the current standard worldwide."[1]

"Although the value of sterilization of semi-critical items may seem obvious, evidence that sterilization reduces the risk of infection is lacking."[2] The incidence of post-endoscopic infections has been estimated to be 1 in approximately 1.8 million gastrointestinal procedures.[3]

Fast Acting, Compatible, Reusable and Cost Effective

Glutaraldehyde is the most commonly used liquid chemical germicide for heat-sensitive medical devices such as endoscopes. It provides *quick high level disinfection* for fast instrument turnaround time. However, manufacturers' recommendations for specific high level disinfection times vary with formulation and usage. Their complete product directions should be referred to before use.

Data from a variety of sources clearly indicate that reducing the bioburden challenge by thorough cleaning prior to high level disinfection or sterilization results in greater efficacy in less time. For example, the APIC Guideline for Selection and Use of Disinfectants recommends 20 minutes at room temperature as the minimum exposure time for a 2% glutaraldehyde to achieve high level disinfection following cleaning. However, because manufacturers have no control over user's cleaning technique, and regulatory agencies currently do not recognize a protocol that considers the effects of cleaning on label claims[4], specific label statements *cannot* be made with regard to the potential decrease in soak time and temperature following cleaning.

Glutaraldehyde can also be used to *sterilize* heat-sensitive instruments when ETO or steam sterilization is not appropriate.

Compared to other liquid chemical germicides used for high level disinfection and sterilization, alkaline glutaraldehyde has the best *compatibility with a wide range of materials.*[2] It is non-corrosive to instruments, including delicate endoscopic instrumentation. Furthermore, glutaraldehyde is reusable up to 14 or 28 days.[4] This makes it the most *cost effective* product available for high level disinfection.

In addition, glutaraldehyde may be used in automated endoscope reprocessors to reduce health care worker exposure, and reduce the variability of processing instrumentation in manual tray systems.

Effectiveness Can Be Tested Before Each Use

Glutaraldehyde solutions *can be tested and documented* prior to each use to verify that the effective concentration is still present. This provides the end user with a margin of safety by offering a reliable way to detect unintentional dilution or contamination of the glutaraldehydesolution.

Hard Evidence Favors Glutaraldehyde's Safety For Health Care Workers

Although glutaraldehyde can be irritating to the eyes, respiratory tract and skin, precautions can easily be undertaken to prevent these short term effects by donning appropriate protective clothing (such as high quality rubber latex gloves, protective eye wear and fluid resistant gowns) and the implementation of environmental controls that allow for adequate ventilation.[4] However, even upon exposure at ambient temperatures to vapor concentrations in excess of the 0.2 ppm threshold limit value, *no evidence of acute or subchronic toxicity has been found in studies on animal models.*[5-7]

"Glutaraldehyde does not meet the criteria for classification as a mutagen . . . [or] . . . carcinogen . . . A number of studies have no evidence of teratogenicity."[8] Studies conducted to date have shown glutaraldehyde ***not*** *to be a* ***suspected carcinogen.*** Although glutaraldehyde is frequently confused with formaldehyde, its chemical and toxicological properties are significantly different. OSHA, the International Agency for Research on Cancer (IARC), and the National Toxicology Program (NTP) do not list glutaraldehyde as a carcinogen.

In addition, studies conducted to date have shown glutaraldehyde *not to cause birth defects.*[9] However, as a normal precaution, pregnant women working around glutaraldehyde or other chemicals should inform their obstetricians.

Prominent Endoscope Companies Recommend Glutaraldehyde††††

For over 30 years, prominent endoscope companies such as Olympus, Karl Storz, Stryker Endoscopy, CIRCON ACMI, Pentax and Fujinon have recommended alkaline glutaraldehyde solutions as safe to, use with their delicate endoscopic instrumentation.

Third party studies confirm this recommendation. "In particular, they (glutaraldehyde solutions) are preferred for the disinfection of gastrointestinal endoscopes."[10]

Glutaraldehyde Meets U.S. EPA Regulations For Non-Hazardous Waste

In compliance with U.S. EPA regulations, glutaraldehyde *may be disposed down the drain* as an ordinary domestic waste.††††† Further, by the time the drain-disposed solutions reach the wastewater treatment system, they are diluted to well below 10 ppm glutaraldehyde. At this low concentration, glutaraldehyde will not have detrimental effects on functioning wastewater treatment systems.

The fact is, sewage microorganisms readily biodegrade glutaraldehyde, initially to glutaric acid, a naturally occurring compound, and then ultimately to carbon dioxide and water.

The FDA Now Regulates Glutaraldehyde's Claims

The FDA now regulates the efficacy claims of high level disinfectants/sterilants. All manufacturers of high level disinfectants/sterilants used with medical devices are currently required to submit for 510(k) clearance with the FDA.

"Chemical germicides should be registered with the U.S. Environmental Protection Agency and cleared for marketing by the U.S. Food and Drug Administration."[11] The FDA 510(k) clearance process assures that similar glutaraldehyde products will have comparable high level disinfection claims.

Glutaraldehyde Is A Long-Running Success Story

Today, glutaraldehyde continues to pass one of the most important safety tests health care workers rely upon – the test of time.

How To Get More Information

If you would like to learn more about glutaraldehyde, ask your Johnson & Johnson Medical, Inc. Account Manager about our educational programs, including *The Use of Glutaraldehyde in the Health Care Environment,* a videotape that allows for 2 contact hours, and *Just The Facts,* a publication that discusses important issues about high level disinfection and sterilization. If you would like *technical* assistance, please call 1-800-423-5850.

†Rigid endoscopes are considered to be a critical device and should be sterilized versus high level disinfected before each use, if feasible. When sterilization is not feasible, high level disinfection is acceptable. This is consistent with the Center for Disease Control guidelines for decontamination and cleaning laparoscopes, endoscopes and respiratory therapy equipment in their Department of Health and Human Services "Guidelines for Prevention and Control of Nosocomial Infection," and the "APIC Guideline for Selection and Use of Disinfectants."

†† Provided the glutaraldehyde solution passes test strip verification of minimum effective concentration (MEC).

†††During the 1970s, the American Conference of Governmental Industrial Hygienists (ACGIH) adopted a threshold limit value (TLV) ceiling limit of 0.2 ppm of glutaraldehyde for the atmosphere in work environments. The ceiling limit may be achieved by "any reasonable combination of engineering controls, work practices, and personal protective equipment." Code of Federal Regulations 29 C.F.R. 1910.1000 CH.XVII. Strive to achieve a minimum of 10 air exchanges per hour.

††††While surfactant containing glutaraldehyde solutions are NOT generally recommended for use with rigid endoscopes used in electrosurgical procedures, major scope manufacturers have found surfactant containing glutaraldehyde solutions to be compatible with their flexible endoscopes.

†††††Please note that some state and local authorities may have additional restrictions on drain disposal of specific wastes.

1. Bond WW. Center for Disease Control, Biological Indicators for a Liquid Chemical Sterilizer: A Solution to the Instrument Reprocessing Problem? *Infect Contr Hosp Epidemiol.* 1993; 14:311.
2. Rutula W. APIC Guideline for Selection and Use of Disinfectants, *Am J Inf Contr.* p 104.
3. Transmission of Infection by Gastrointestinal Endoscopy, *ASGE.* 1993;39:885-886.
4. Rutula W, et al. FDA Labeling Requirements for Disinfection of Endoscopes: A Counterpoint. *Infect Contr Hosp Epidemiol.* 1995;231-235.
5. Ballantyne B. Review of Toxicological Studies and Human Health Effects - Glutaraldehyde, *Union Carbide Corp.* 1986:x-s.
6.Greenspan B, Ballantyne B, Fowler E, Snellings W. Subchronic Inhalation Study of Glutaraldehyde, *Toxicologist* 1985;5:29.
7. Karl F. National Toxicology Program Technical Report on Toxicity Studies of Glutaraldehyde - Administered by Inhalation to F344/N Rats and B6C3F Mice, *NIH Publication 93-3348.* 1993.
8. Worksafe Australia. Priority Existing Chemical Number 3, Glutaraldehyde. July, 1994.
9. Ema M, Itami T, Kawasaki H. Teratological Assessment of Glutaraldehyde in Rats by Gastric Intubation, *Teratology Letters.* 1992;63:147-153.
10. Bailly JL. Activity of Glutaraldehyde at Low Concentrations (≤ 2%) against Poliovirus and its Relevance to Gastrointestinal Endoscope Disinfection Procedures, *Applied and Environmental Microbiology.* April, 1991.
11. Proposed Recommended Practices for Chemical Disinfection, *AORN J.* 1994;464.

Johnson & Johnson
MEDICAL INC.

EDITORIAL OFFICES
Vanderbilt University School of Medicine
A-1131 Medical Center North
Nashville, TN 37232-2637
(615) 343-1095; (615) 343-1882 (FAX)
Email: iche@mcmail.vanderbilt.edu

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY®

SLACK Incorporated
6900 Grove Road
Thorofare, New Jersey 08086
(609) 848-1000

Vice President/Group Publisher
Richard N. Roash

Publisher
John C. Carter

Editorial Director
Jennifer Kilpatrick

Production Editor
Shirley P. Strunk, ELS

Assistant Editor
Eileen C. Anderer

Circulation Manager
Lester J. Robeson, CCCP

Production Director
Christine Malin

Production Coordinator
Joanne Patterson

Publishing Director/ Advertising
Wayne McCourt

Pharmaceutical Group Sales Director
Michael LoPresti

Advertising Sales Representative
Jennine Kane

Classified/Recruitment Sales Manager
Michele Burch

Vol. 16 No. 6 June 1995

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY™

CONTENTS

Continued from cover.

PUBLISHER: Infection Control and Hospital Epidemiology (ISSN-0899-823X, Canadian GST#129780466) is published exclusively by SLACK Incorporated 12 times a year Address: 6900 Grove Rd., Thorofare, NJ 08086. Telephone: (609) 848-1000.

SUBSCRIPTIONS: Requests should be addressed to the publisher (except Japan). In Japan, contact Woodbell Incorporated, 4-22-11, Kitakasai, Edogawaku, Tokyo 134, Japan. Subscription rates in the United States and possessions: Individual: One year-$95.00; Two years-$130.00; Three years-$160.00; Institutional: One year-$105.00; Two years-$145.00; Three years-$185.00. Fellows: $35 per year with proof of training status. Canada: $18.00 additional each year plus 7% for Canadian Goods & Services tax; all other countries: $36.00 additional each year Single copies of current issues may be obtained for $15.00, United States and possessions: $30.00 all other countries.

CHANGE OF ADDRESS: Notice should be sent to the publisher six weeks in advance of effective date. Include old and new addresses with zip codes. The publisher cannot accept responsibility for undelivered copies. Second-class postage is paid at Thorofare, New Jersey 08086, and additional entry points. POSTMASTER: Send address changes to SLACK Incorporated. 6900 Grove Rd., Thorofare, NJ 08086.

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY is listed in Index Medicos. Current Contents---Clinical Practice, Hospital Literature Index. Cumulative Index to Nursing & Allied Health Literature. Nursing Abstracts, Laboratory Performance Information Exchange System. and RNdex Top 100.