Occupational Health Hazards of Select High Level Disinfectants & Sterilants

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INTRODUCTION

Though the FDA provides a listing of various properties of several common high level disinfectants and sterilants, we noted that there has been lack of scientific information on the occupational health hazards when working with these high level disinfectants and chemical sterilants.

To varying degrees, when information was available, the sources have not been readily available or accessible. Recognized regulatory authorities such as the FDA, NIOSH, OSHA, and international sources have also been inconsistent in their efforts in identifying, evaluating, and providing recommendations for their control.

We also developed a simple template for controlling these hazards.

OBJECTIVES AND METHODS

To better understand the hazards of several commonly used disinfectants as well as the control methods the research project was initiated in 2002. The chemicals we evaluated were glutaraldehyde, orthophthaldehyde, peroxyacetic (or peracetic) acid, & hydrogen peroxide.

Information and data were collected through a series of: meetings, literature reviews of medical, toxicologic and industrial hygiene journals, data-2mining, collection of hundreds of air samples, collaboration with North American and European colleagues, as well as ongoing meetings with AIHA's Healthcare & Control Banding Working Groups.

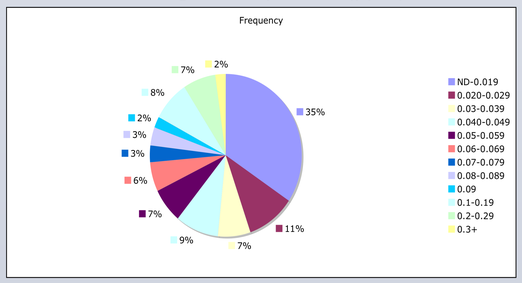
We also held discussions with users, chemical manufacturers, analytical laboratories, and instrument manufacturers.

RESULTS

Followed by the American Conference of Governmental Industrial Hygienists (ACGIH) lowering the Threshold Limit Value (TLV) to 0.05 ppm as a Ceiling, the need arose to have sampling and analytical method that took the TLV into consideration. Though US OSHA did not have an occupational exposure standard (Permissible Exposure Limit or PEL) for glutaraldehyde, their analytical laboratory laboratory initiated the development of a more sensitive sampling and analytical method (SAM).

When the final stages of this process came to a halt, we evaluated the method and with the assistance of a NIOSH contract laboratory, initiated collection and analysis of samples where process exposures were evaluated at intervals as low as 1 minute. Exposures during fresh pouring processes approximating or exceeding the TLV occurred approximately 50% of the time. This data called the results from earlier scientific papers describing short term exposures into question.

Pouring Rate Exposures (ppm)



RESULTS

Based upon the new TLV, enhanced regulatory actions of glutaraldehyde in assorted jurisdictions, a lack of odor with perceived lower health effects, orthophthaldehyde (OPA, 0.55% concentration) entered the worldwide market. With no occupational exposure limits (or analytical methods), OPA gained market share. In a brief time period reports of anaphylactic shock, primarily associated with bladder cancer patients surfaced. The primarily manufacturer of OPA solutions changed their MSDSs and, through the FDA's efforts, stated that OPA was contra-indicated in bladder patients.

24 USA bladder cancer patients were reported with anaphylactic shock in December 2005, increasing to 58 cumulatively by November 2007 (FDA). A NIOSH team reviewed the FDA's MAUDE database and identified a significantly higher number of OPA adverse health reports compared to glutaraldehyde among patients and workers. Worldwide, significantly more OPA related health effects surfaced. At NIOSH's request, OPA was placed on the National Occupational Research Agenda (NORA) in 2007. NIOSH has yet to publish any information on OPA.

Incidence Of PATIENT Related Reactions Reported In FDA's MAUDE Database

	OPA				GLUTARALDEHYDE			
	Allergic Rxn	Anaph-ylaxis	Diffi-culty Breath-ing	Head-ache, Burns, Irrita-tion	Allergic Rxn	Anaph-ylaxis	Difficulty Breath-ing	Head-ache, Burns, Irrita-tion
2001	1	1	0	0	0	0	0	0
2002	3	3	0	0	0	0	0	1
2003	10	11	0	0	0	0	0	4
2004	17	24	0	1	0	0	0	8
2005	16	9	0	0	5	0	0	0
2006	1	5	0	1	0	0	0	1
2007	0	5	0	1	0	0	0	0
2008	6	3	0	2	0	0	0	0
Totals	54	61	0	5	5	0	0	14

Incidence of WORKER Related Reactions Reported in FDA's MAUDE Database

	OPA				GLUTARALDEHYDE			
	Allergic Rxn	Anaph-ylaxis	Diffi-culty Breath-ing	Head-ache, Burns, Irrita-tion	Allergic Rxn	Anaph-ylaxis	Diffi-culty Breath-ing	Head-ache, Burns, Irrita-tion
2001	3	0	1	6	1	0	0	1
2002	18	0	0	4	9	0	1	8
2003	16	0	0	5	1	0	0	3
2004	29	1	0	7	5	0	0	7
2005	107	4	3	2	3	1	1	13
2006	25	0	1	5	0	0	0	4
2007	19	0	1	19	0	0	0	2
2008	20	0	12	5	2	0	2	6
Totals	237	5	18	53	21	1	4	44

RESULTS

Based on a review of the literature the following table provides a summary of toxicological concerns associated with select high-level disinfectants and sterilants.

	Glutaraldehyde	Ortho-phthaladehyde	Hydrogen Peroxide	Peracetic Acid
Typical Use Concentration	2-4%	0.55%	7.35%	0.23%
Respiratory Sensitization	Yes (asthmagen)	Yes	No Data	No Data
Respiratory Irritation	Yes	Yes	Yes (>10%)	Yes (Pungent Odor)
Dermal Sensitization	Yes, Allergic Dermatitis	Yes(Allergic Reaction)	Non-Sensitizing	Non-Sensitizing
Skin/Eye Irritation	Yes, (1-2%),Irreversible eye irritant	Yes	Yes, Skin and Eye	Yes
Cytoxicity	Cytotoxic (2.5%)	Cytotoxic (0.6%)	Limited Data	Limited Data

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AGGIH, TLV Documentation for Peracetic Acid 2014

The Association for the Advancement of Medical Instrumentation standard ANSI/AAMI ST58: *Chemical Sterilization And High-level Disinfection In Health Care Facilities (2013)*, contains detailed information and guidance on the selection and safe use of these chemicals. From this document the following should be health and safety considerations for use of such products:

a) To what extent has toxicity testing been performed?

b) Has a copy of the SDS (formerly known as MSDS) been provided?

c) What are the potential short and long-term adverse health effects of overexposure to the chemical sterilant/high-level disinfectant?

d) Is the chemical sterilant/HLD potentially toxic to personnel? In what way? Are there toxic vapors or toxic byproducts? Does the chemical sterilant/high-level disinfectant react with certain materials (e.g., cleaning agents, adhesives) to form toxic products?

e) At what level of exposure is the chemical sterilant/high-level disinfectant toxic to humans? By what route of exposure (skin contact, inhalation, eye)? Are there occupational exposure levels (OELs)? Are there adequate exposure monitoring standards?

f) How can the hazards be suitably controlled (engineering, administrative, ppe)?

g) How would the user be able to detect toxicity problems? What are the adverse health effects?

h) What PPE is required? Do the chemical sterilant/high-level disinfectant manufacturer's written IFU indicate that special types of gloves are required when working with the product?

i) Is environmental or personnel monitoring required or recommended by OSHA, NIOSH, ACGIH®, or necessitated by the potentially hazardous nature of the sterilant? If so, what are the methods?

j) Are there specific IFU that explain how toxic conditions or reactions can be avoided during use? For example, must time, temperature, or humidity be controlled? Should a local exhaust hood be used?

k) Are special storage conditions necessary for the chemical sterilant/HLD or processed items?

l) Does the chemical sterilant/disinfectant leave residues on processed items that could be toxic to patients or health care personnel? Is there a method of reducing residues on processed items to nontoxic levels? If it is necessary to aerate processed items, what are the time and temperature parameters? How can adequate aeration be monitored and ensured? If rinsing is necessary, what tests have been performed by the manufacturer to document that the recommended rinse process will adequately remove residues?

m) Is sensitization or tissue irritation a potential health effect? What controls can be instituted for sensitive and at risk employees? Is there a medical management plan?

n) Are there physical hazards such as fire or explosion?

o) Can heat or other environmental conditions cause chemical changes in the chemical sterilant/high-level disinfectant that would result in other hazards?

p) What precautions should be taken in the disposal of the LCS/HLD? Even if the product itself is not toxic when discarded, can it react with other substances (in the sewer, for example) to form new volatile or toxic products? Are there applicable federal, state, or local regulations?

q) What level of in-service instruction or other personnel training in the safe use of the chemical sterilization system does the manufacturer provide?

r) What level of testing has been done to determine that processed devices remain safe for patient use after repeated processing?

s) Is it necessary to retain employee health records? If so, for how long?

t) Where will the eyewash & shower station be located? Are existing eyewash & shower stations placed appropriately, and are they suitable for the chemical sterilant/high-level disinfectant?

u) What types of environmental controls need to be instituted for spills & disposal?

CONCLUSIONS

- Carefully evaluate jobs, components, work practices, & all exposures
- Use meaningful exposure characterizations in developing hazard/control bands. Unknown and lightly characterized substances warrant more caution
- Understand and train workers of the need to be careful
  - Not smelling anything does not mean the environment is safe
- Appropriate work practices, ventilation, & ppe, especially while working around sensitizers is critical. Surveys have shown FDA guidelines and sound industrial hygiene hazard control practices are not being followed
- Consider chemical substitution as a method of hazard control
- Encourage instrument manufacturers to review/update chemical compatibility
- Comprehensively report incidents to FDA, NIOSH, manufacturer, others
- Encourage NIOSH to complete their NORA project on a timely basis
- When characterizing exposures for peroxyacetic acid, report your findings (especially those that are inconsistent) to NIOSH, professional organizations, laboratories, and your colleagues via reports, papers, publications, and public presentations
- Consider medical removal for higher risk individuals
- Follow the manufacturer's recommendations when handling all chemicals
- Consider requesting FDA and EPA develop more standardized testing and reporting protocols for high level disinfectants and chemical sterilants

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