RespiCide® GP
Disinfecting Solution

TECHNICAL INFORMATION

- Introduction
- Efficacy
- Safety
- Materials Compatibility
- Features & Benefits
- Product Comparison

INTRODUCTION

Patient-ready rubber and plastic CPAP and respiratory equipment such as breathing masks, tubing, connecting adapters and canisters are devices that require cleaning and disinfection prior to reuse. These devices are considered non-critical medical devices because they normally only come in contact with intact skin. The process of disinfection for non-critical devices requires equipment to be cleaned using a validated cleaning procedure, and rinsed to remove sanitizer that could be harmful to humans. Liquid chemical germicides used to reprocess breathing masks, tubing, adapters and canisters should not alter the appearance or function of the device or be retained on equipment.

RespiCide GP Disinfecting Solution is an EPA registered single use disinfectant formulated to disinfect non-metal, heat sensitive, reusable, non-critical medical equipment. The product is packaged as two components; a fluid component consisting of 2% chlorine dioxide precursor and an activator component. One gallon of disinfecting solution is prepared by adding 4 ounces of RespiCide GP Solution to 124 ounces of water followed by the addition of 1 heaping tablespoon of activator. Allow 15 minutes for RespiCide GP Disinfecting Solution to become effective before treating equipment. Disinfection is complete in 5 minutes at 20°C. Equipment is removed from the disinfecting solution, rinsed with water and allowed to air dry before being reused. The disinfecting solution is discarded and fresh solution is prepared for the next disinfection procedure.

RespiCide GP Disinfecting Solution was developed by BC Medical Products, a Division of Bio-Cide International, Inc.. The product was specially formulated to address the odor, staining, disinfection time and temperature and reuse issues associated with aldehyde-based products. Field trial results indicated a preference for RespiCide GP Disinfecting Solution over each test site's currently used product.

MICROBIOLOGICAL DATA

Objective To test the microbiological effectiveness of RespiCide GP Disinfecting Solution using test methods required by the Environmental Protection Agency (EPA) for registration approval and in simulated use testing.

Results

Test Method	Test Organism (s)	Kill Time at 20°C*
Quantitative Tuberculocidal Test	Mycobacterium bovis	5 minutes
EPA Virucidal Testing (DIS/TSS-7, November 1981)	Poliovirus Type 2	5 minutes
	Herpes simplex 1	5 minutes
	Coxsackie virus	5 minutes
	Rhino virus	5 minutes
	Cytomegalovirus	5 minutes
	Respiratory syncytial virus	5 minutes
AOAC Use Dilution Test	Pseudomonas aeruginosa	5 minutes
	Staphylococcus aureus	5 minutes
	Salmonella choleraesuis	5 minutes
AOAC Fungicidal Test	Trichophyton mentagrophytes	5 minutes
Simulated Use Test**	Pseudomonas aeruginosa	5 minutes
	Staphylococcus aureus	5 minutes

* Efficacy testing was conducted on RespiCide GP Disinfecting Solution at 32:1 dilution.

** Simulated use testing was conducted on inoculated plastic breathing masks. Bacterial cells were dried onto the breathing masks at 37°C in vacuo. Treatment time was 5 minutes at 20°C. R.S. Tanner, Ph.D., Professor of Microbiology, "Activity of RespiCide GP Disinfecting Solution Against Pseudomonas aeruginosa and Staphylococcus aureus on Breathing Masks", The University of Oklahoma, May 31, 2003

Conclusion

Microbiological efficacy test results support the 5-minute effectiveness label claim for RespiCide GP Disinfecting Solution against the test organisms shown in the above table.

TOXICITY TESTING

Objective To measure the oral and dermal toxicity and skin and eye irritation of RespiCide GP Disinfecting Solution. Testing was performed to determine the potential toxicological affects of exposure to RespiCide GP Disinfecting Solution.

Results

Toxicology Test	Results
Primary Dermal Irritation	Non-irritating
Acute Dermal Toxicity	Dermal LD_{50} >2g/kg body weight
Ocular Irritation	Mildly irritating, Class III rating
Acute Oral Toxicity	Male-Oral LD_{50} 4g/kg body weight Female-Oral LD_{50} 3.5g/kg body weight Overall-Oral LD_{50} 3.75g/kg body weight
Skin Sensitization	Non-sensitizing
Cytotoxicity	Non-cytotoxic (Score = 0)

Conclusion

The results of the toxicity testing showed RespiCide GP Disinfecting Solution to be non-toxic. The product has a Class III Toxicity Rating, which requires only a precautionary statement of "CAUTION".

MATERIALS COMPATIBILITY

Objective To evaluate materials compatibility behavior of rubber and plastic breathing equipment with RespiCide GP Disinfecting Solution in laboratory studies and field trials.

Procedures

LABORATORY STUDY

1. The material compatibility of RespiCide GP Disinfecting Solution was evaluated by immersing a variety of rubber and plastic facemasks, tubing and connectors in the test solution for 3 hours, twice a day for twenty days at ambient temperatures, which is equivalent to at least 1,440 simulated disinfection cycles.
2. The test samples were removed from the test solution, washed with tap water, air-dried and visually inspected for surface damage, color changes and assessed for odor by olfaction after each treatment.
3. The results were compared with those obtained from identical sets of equipment exposed to tap water.

FIELD TRIAL

1. RespiCide GP Disinfecting Solution was used in three sleep labs for 3.5 months to disinfect their rubber and plastic facemasks, tubing, canisters and connectors. Equipment contact time/treatment was a minimum of 5 minutes.
2. Lab personnel noted appearance of equipment after each treatment. Patients reported any effect of treated facemasks on nasal passages, skin and eyes.

Results

Both studies showed that RespiCide GP Disinfecting Solution did not alter the surfaces of any of the test equipment. Tubing, canisters and connectors remained unchanged in color. In the field trial, some mild yellowing or pink discolorations were observed with some facemasks but the discolorations did not become increasingly intense with additional cycles. In all cases, the change was not considered a negative and was reported to be less than they observed with their current disinfecting solution products. In the laboratory study only a silicon gel filled mask became yellowed after repeated cycles. A non-silicon gel masked remained unchanged during the entire 20 days. Extracts from the silicon gel mask were assessed for cytotoxicity, however no cytotoxicity was found (Grade=0).

Conclusion

RespiCide GP Disinfecting Solution when used as directed does not produce any undesirable affects on the appearance, performance or odor properties of rubber and plastic respiratory equipment such as: facemasks, tubing, canisters and connectors.

FEATURES AND BENEFITS

FEATURES	BENEFITS
Effectiveness	Disinfection in 5 minutes at 20°C. Bactericidal, Fungicidal, Virucidal, and Tuberculocidal.
Safety	No aldehydes. Low level of active ingredient. Class III Toxicity Rating, requires only a precautionary statement of "Caution".
User-Friendly	Low odor. Non-staining. Sold as a concentrate. Diluted with tap water. Easily handled. Requires minimal storage space.
Liability	Single use, no effectiveness monitoring records required – fresh solution per treatment.
Materials Compatibility	Does not damage or stain rubber/plastic medical equipment. Does not contain surfactants. Easily rinsed with water, no retention of product. Does not fix protein to equipment.
Disposability	Can be discarded without special precautions. No organic residues.
Cost Efficient	Less than $2.00 per use-dilution gallon. No additional costs; i.e., effectiveness monitoring tests, fume hoods or heaters.

PRODUCT COMPARISON

Characteristic	CIDEX®	CIDEX OPA®	Control III Elite®	RespiCide GP®
Active Ingredient	Glutaraldehyde	O-phthalaldehyde	Dual Quat	Chlorine Dioxide
Mode of action	Denatures protein	Denatures protein	Cell-Disruption/Denaturation	Oxidant
MEC[1] (disinfection)	1.5%	0.3%	0.21%	0.0005% (5 ppm)
Packaging	Use-diln. (4 gal/case)	Ready to Use (4 gal/case)	Ready to Use (4 gal/case)	Concentrate (128 gal/case)
Activator	Yes	No	No	Yes
Efficacy Disinfection Sterilization	 45 min @ 25°C 10 hrs @ 20°C	 12 min @ 20°C 32 hrs @ 20°C	 10 min na	 5 min @ 20°C na
Safety Statement	Danger	Warning	Warning	Caution
Surfactants	None	None	Yes	None
Recommended Use	14-Day Reuse	14-Day Reuse	Single Use	Single Use
Effectiveness Test	Required	Required	Yes	na
Materials Compatibility Rubber/Plastic Metals	 Retains Odor Good	 Retains Odor Good	 Good[2] Good	 Good na
Odor/Eye Irritation	Strong	Low	Minimal	Minimal
Staining (skin)	Yes	Yes	No	No

1. MEC = minimum effective concentration 2. Requires thorough rinsing with water to remove soap

CONCLUSION

RespiCide GP Disinfecting Solution is a safe, economical, low odor, non-staining, fast acting, and materials compatible disinfectant. RespiCide GP Disinfecting Solution offers benefits over products currently used to disinfect heat sensitive, reusable, non-critical medical equipment.

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