Review of Necessary Practices for EPA Submission of a Hospital Disinfectant Using Good Laboratory Practice (GLP) Disinfectant Study Summaries of a Hospital Disinfection System

Dr. Helene M. Paxton, MS, MT (ASCP),PhD, CIC, Infection Preventionist

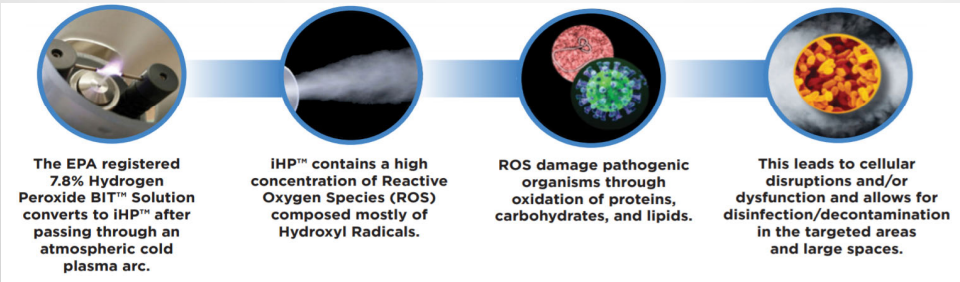
Journal of ABSA International
2017, Vol. 22(4) 172-180
ª ABSA International 2017

Disclosures:

Tomi Environmental Scientific Advisory Board; Trinity Health System Employee
All Opinions are expressed are my own

A New Approach: The First EPA Registered Solution + Equipment Combination that Provides the Unique Technology of Hydrogen Peroxide Ionization called SteraMist™.

The iHP™ Process:



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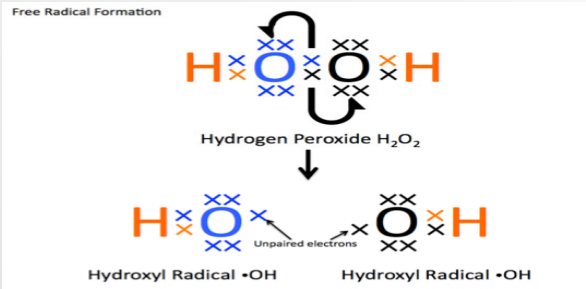

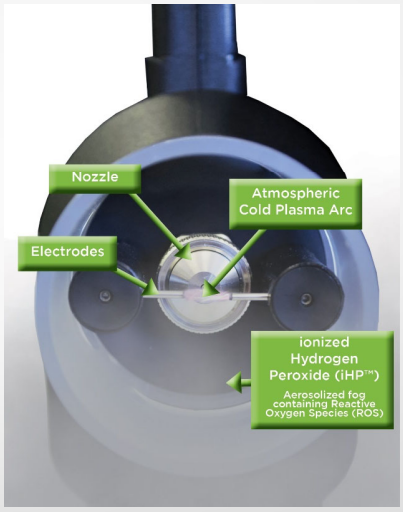

The iHP™ Process

- The SteraMist™ converts the BIT™ solution into a **Reactive Oxygen Species (ROS)** after passing through an atmospheric cold plasma arc.
- H_2O_2 converted by plasma science.
- **iHP™ contains a high concentration of Reactive Oxygen Species (ROS) composed mostly of Hydroxyl Radicals**.
- Does not contaminate the environment with any toxic by-products.

All Hospital Disinfectants Must Be EPA Registered

All disinfectants and pesticides marketed for use in United States must meet safety requirements as described in OCSPP 810.2200, (*1) Applicability.*

The following guideline describes test methods that the EPA believes will generally satisfy testing requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, et seq.) and the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a).

It addresses testing to demonstrate the effectiveness of antimicrobial pesticides bearing claims as disinfectants, fungicides, virucides, and tuberculocides. (EPA 712-C-07-074)

Table 1. Methodology used for testing organisms as defined. TOMI[1,2] EPA registered products only.[1,2]

Organism	Study Title	Study Completion Date	EPA Product Performance Guidelines	method
Pseudomonas aeruginosa (ATCC 15442)	AOAC Germicidal Spray Method	05 FEB 2015	OCSPP 810.2200	AOAC 961.02
Pseudomonas aeruginosa (ATCC 15442)	Efficacy of a Disinfectant Applied to a Room via a Fogging, Misting or Vaporizing Device for Disinfection	05 FEB 2015	OCSPP 810.2200	Modified Method AOAC 961.02
Staphylococcus aureus (ATCC 6538)	AOAC Germicidal Spray Method	05 FEB 2015	OCSPP 810.2200	AOAC 961.02
Staphylococcus aureus (ATCC 6538)	Efficacy of a Disinfectant Applied to a Room via a Fogging, Misting or Vaporizing Device for Disinfection	06 FEB 2015	OCSPP 810.2200	Modified Method AOAC 961.02
Methicillin Resistant *Staphylococcus aureus*-MRSA (ATCC 33592)	AOAC Germicidal Spray Method	04 MAR 2015	OCSPP 810.2200	Modified method AOAC 961.02
Clostridium difficile (C. diff) spores (ATCC 43598)	Efficacy of a Disinfectant Applied to a Room via a Fogging, Misting, or Vaporizing Device for Disinfection of *C. difficile* spores	16 SEP 2015	OCSPP 810.2100	QCT2 Method: ASTM E2197, ASTM E2839[2]
H1N1 Influenza A (ATCC VR-1469)	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces	02 MAR 2015	OCSPP 810.2200	ASTM E1053
Salmonella enterica (ATCC 10708)	Hard Surface Room Disinfection via a Fogging Device against Salmonella	13 OCT 2016	OCSPP 810.2200	Modified Method AOAC 961.02
Salmonella enterica (ATCC 10708)	AOAC Germicidal Spray Products Test Method Modified for Handheld Spraying Device	12 SEP 2016	OCSPP 810.2200	Modified Method AOAC 961.02
Feline calicivirus, Strain F-9, (ATCC VR-782)	AOAC Germicidal Spray Products Test Method Modified for Use with a Fogging Device and Viruses	13 OCT 2016	OCSPP 810.2200	Modified Method AOAC 961.02

Note. MB methods from EPA are specifically referenced in OCSPP citations and are not separately listed.

Process of getting EPA Registered is a difficult, time consuming, and expensive.

1. Find an Accredited Lab
2. Receive an EPA approved Protocol
3. Run R&D Tests
4. Run GLP Tests

Process Continued....

5. Pass GLP Tests
6. Receive Final Report
7. Submit Revised Registration and Final GLP Report Studies to the EPA
8. Discuss, Review, and Edit Revised Registration with the EPA
9. Wait 90 days for Review

Methods: In the Dip Studies...

- Study carriers are inoculated with **specific organisms** with **three** different lots of disinfectant, one lot being older than 60 days old; 60 carriers per organism are used, and dipped into solution, per specified time.

Results

- With 59/60 carriers being negative for the organism after disinfectant treatment to be considered acceptable.

In Aerosolized Studies...per EPA Defined Protocol

- For each bacterial and viral organism, the cultures are grown per protocol.
- Coated onto carriers, usually glass microscope slides.
- Carriers are inoculated, and dried per protocols.

Protocols Continued…

- Sprayed solution is applied to the carriers using the Equipment for 5 seconds/ 0.0929 m^2 ($1ft^2$) at 24 inches with a contact time of 7 minutes or solution is fogged to fill a space with a contact time of 15 minutes.
- Technology is fairly temperature and humidity independent. Humidity is held at 16.7-27% relative humidity and temperature is held at 20 $\pm$ 2 ^{o} C depending on organism being tested.
- The carriers are transferred using sterile technique to neutralizing solution, incubated and examined for growth.

GLP Tables for Disinfectant

Test Organism	Test Substance	Test Organism	Sample Dilution	Number of Carriers		
				Exposed	Showing Growth	Confirmed as Test Organism
Pseudomonas aeruginosa (ATCC 15442)	Binary Ionization Technology® (BIT™) Solution Batch# OJ30A1	Pseudomonas aeruginosa (ATCC 15442)	Ready to Use	60	0	0
Staphylococcus aureus (ATCC 6538)		**Staphylococcus aureus (ATCC 6538)**		60	0	0

***Clostridium difficile* spores - CFU on Filter: CFU/Carrier (Log $_{10}$)**		
Binary Ionization Technology® (BIT™) Solution Lot: OJ30A1	Binary Ionization Technology® (BIT™) Solution Lot: OJ02A1	Binary Ionization Technology® (BIT™) Solution Lot: OL11A1
Average Log_{10}: <0.00	Average Log_{10}: <0.08	Average Log_{10}: <0.03
Log_{10} Reduction: >6.33	Log_{10} Reduction: >6.42	Log_{10} Reduction: >6.47

Other GLP Studies for Disinfectants

- TES01120614. **FLU A for H1N1** pages 3---12 modifications included (7);
- TES01030716.RDT page 3 for ***Mycobacterium bovis*** (8);
- Protocol Number P1619 pages 25---38 for ***Salmonella enterica*** and protocol modifications page 10 (10);
- Microchem Laboratory Protocols NG7535 for ***Norovirus*** (11).

Other GLP Studies for Disinfectants "THE GOLD STANDARD"

- Protocol MRID 488313---03 (field study) pages 2---4 for ***Geobacillus stearothermophilus spores*** (9);

In Conclusion…

- The EPA aerosolized studies are very difficult to perform as compared to dip test technology where carriers are simply immersed in the disinfectant solution for a period of time and evaluated.

- **These studies are the first to demonstrate the combination of disinfection solution and the effect of the dispersal method with the *RESULTING EFFECT ON THE KILLING EFFICACY FOR MULTIPLE ORGANISMS*.**

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Thank you!