SAFETY OF GOLDSHIELD:

A question that often arises is, what agency regulates the approval claims of antimicrobial and disinfectant products for hospital use? Succinctly, the Environmental Protection Agency has authority for all surfaces, textiles and equipment. The FDA regulates the application of these materials for products deemed to be medical devices or intrusive devices, such as wound care dressings and catheters, respectively.

A prerequisite of receiving approval claims on any product at the Environmental Protection Agency, is the evaluation of toxicity data, such as cyto-toxicity, skin irritation, sensitivity, and inhalation. The EPA evaluates this data and makes recommendations to the safety claims the manufacturer wants to include in their labeling. These "Master Labels" are then submitted to the EPA with the recommended changes and are approved or disapproved.

The data is based on efficacy testing derived from Good Laboratory Practice ["GLP"] standards and in accordance with the acceptable protocols of the EPA and FDA. From their analysis they determine how benign or harmful a material is, resulting in claims being allowed or not.

Of great concern to the EPA is the safety of any product classified as a pesticide e.g. they kill pests [organisms such as bacteria, and fungi] with direct contact with human skin. Clearly their concern would be the proximity of chemicals applied to textiles, which would be exposed to ones skin. Under the strictest of reviews, Goldshield® is approved for **diapers, sheets, pillow cases, air filters, woman and men's underwear** and other direct human contact applications on textiles, such as towels. This becomes reassuring to the end user or customer, because these claims are articulated in the labeling of the product. For example, Comet™ a widely used household disinfectant has a precautionary statement: "HAZARDOURS TO HUMANS AND ANMIALS", Goldshield®75 has on its label: KEEP OUT OF REACH OF CHILDREN as the EPA determined that the toxicity data did not warrant any other precautionary statements, such as those indicating that the material is hazardous to humans and animals.

It should be also noted that Goldshield® 5, with dilution recommendations, and Goldshield®75, the ready-to-use product, are approved for home consumption, hospitals, daycare centers, churches and other institutions.

In terms of why it is so benign, is important to understand that unlike any other water stable product, including paints and coatings, Goldshield® bonds to the surface or substrate and does not leach off. This is important, as all other disinfecting chemicals leave trace amounts of organics on the surfaces, which become mobile and have been known to cause allergies and other inhalation toxicity issues. Goldshield® does not, as the bond prevents it to become mobile and the residual component provides long term protection. Furthermore, the Quaternary Ammonium Compounds ("QAC's") contained in the ingredient have been used in the past for wound care dressings. Although Goldshield® has not pursued that application yet, management intends to.

The toxicity data that is submitted to the EPA and FDA is based on protocols these agencies have accepted, generally derived from AOAC or ASTM, and conducted under GLP. Below are results of some studies evaluating the cytotoxicity issues that were conducted on a treated material with 2.5% of the active, an amount that we generally never use, as 0.75%-1.0% are sufficient to provide the kind of efficacy most facilities are seeking.

Sensitivity: "

Under the conditions of this study, the test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

Irritation:

Appendix 1 - Classification System For Skin Reaction

REACTION	NUMERICAL GRADING
Erythema and Eschar Formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Edema Formation	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond exposure area)	4
Total possible score for irritation	8

NOTE: Other adverse changes at the skin sites shall be recorded and reported

IRRITATION RESPONSE CATEGORIES IN THE RABBIT

RESPONSE CATEGORY	MEAN SCORE
Negligible	0.0 to 0.4
Slight	0.5 to 1.9
Moderate	2.0 to 4.9
Severe	5.0 to 8.0

Results:

Appendix 2 - Dermal Observations

Rabbit Number/ Gender	Weight (kg)	Group	Observation	Interval (hours)							
				1		24		48		72	
				Left	Right	Left	Right	Left	Right	Left	Right
56851 Male	2.3	Test	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
		Control	Erythema	0	1	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
56852 Male	2.4	Test	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
		Control	Erythema	1	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
56853 Male	2.5	Test	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0
		Control	Erythema	0	0	0	0	0	0	0	0
			Edema	0	0	0	0	0	0	0	0

Left = Intact site
Right = Abraded site

Inhalation:

"RESULTS

1. LC_{50}
The LC_{50} of the extract of Goldshield Procedural Material, Lot/Batch# 1 (one) is greater than 2.1 *mg/L*.
2. Mortality
All animals survived the four hour 2.1 *mg/L* exposure.
3. Systemic Observations (Table 1)
Coating of the fur with test article extract was noted during the 4 hour exposure. All animals appeared normal one hour after dosing to day 14.
4. Body Weights (Table 2)
Body weight changes were normal.
5. Necropsy Findings (Table 3)
Necropsy results were normal.
1765"

Cytotoxicity:

Under the conditions of this study, the test article showed evidence of causing slight cell lysis or toxicity. The tests article met the requirements of the ISO since the grade was less than a grade 2 (mild reactivity). The negative a control and the positive control performed as anticipated.

Salts would cause the same toxicity and nothing here to be concerned about.

Goldshield® Agent:

Sharon Harper RN, MSN, LNC
24x7 Infection Control
Goldshield Representative
Sharon@24x7infectioncontrol.com
www.24x7infectioncontrol.com
 # 843.696.6830