

**CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION
PUBLIC REPORT 2008-3**

Active Ingredient: Poly-D-Glucosamine
Tracking ID Numbers 221525

DESCRIPTION OF ACTION

Chem Tex Laboratories submitted an application to the Department of Pesticide Regulation (DPR) for California registration of Bac-Shield, EPA Reg. No. 81446-1. Bac-Shield is an anti-microbial agent, which is an alternate brand name and identical to ChitoSante, EPA Reg. No. 81446-1. Bac-Shield contains the new pesticide active ingredient poly-D-glucosamine. Bac-Shield is labeled for treatment of textiles, carpet, and paper products for prevention of bacterial, mold, mildew, and fungal growth.

DPR evaluated the product label and the submitted data for Bac-Shield and found them acceptable to support conditional registration. Precautionary and first aid statements and other protective measures on the product label adequately mitigate the potential health risks to users. The data adequately substantiates Bac-Shield's effective anti-bacterial and anti-fungal qualities. DPR does not expect significant adverse environmental impacts to result from registration of Bac-Shield.

BACKGROUND

Registrant: Chem Tex Laboratories
Common name: Poly-D-glucosamine (chitosan)
Chemical name: Poly-D-glucosamine
Brand name: Bac-Shield
Uses: Antimicrobial
Pests controlled: Bacteria, mold, mildew, and fungi
Type of registration: Conditional Registration

On March 7, 2007, the U.S. Environmental Protection Agency (U.S. EPA) granted full registration to Chem Tex Laboratories for ChitoSante. Bac-Shield, which is identical to ChitoSante, is an aqueous liquid formulation containing 6.0% Poly-D-glucosamine. Bac-Shield is intended for the control of non-health related bacteria, mold, mildew, and fungus that cause odor, stains, discoloration, decay, and deterioration of paper and fabric products. Bac-Shield is labeled for commercial and industrial uses for treatment of paper and textiles including carpet. It is also labeled for use by professional applicators for treatment of vehicle interiors, and for domestic uses for home laundry treatment. Poly-D-glucosamine is produced commercially by deacetylation of chitin, which is the structural element in the exoskeleton (outer shell) of crustaceans such as crabs and shrimp. Poly-D-glucosamine molecules are positively charged and readily bind to and weaken the barrier function of the microbial cellular membrane.

SCIENTIFIC REVIEW

A. Chemistry

Chem Tex Laboratories submitted chemistry studies for Bac-Shield. DPR evaluated the submitted studies and determined that the product chemistry data supported registration of Bac-Shield. Chem Tex Laboratories did not submit data addressing residue in food and animal feed. Bac-Shield is a microbicide labeled for treatment of paper and fabrics, and when used as directed, DPR does not expect poly-D-glucosamine to come in contact with feed or food contact surfaces. Also, in accordance with California Notice 2004-7, DPR no longer requires these data.

1. Product Chemistry: The product chemistry results are summarized in Table 1.

Table 1. Physical and Chemical Properties of Bac-Shield	
Properties	Values
Physical state	White to pale yellow liquid
Odor	Slight sea-side odor
Density	1.05 grams (g)/milliliter (ml)
pH	4.5 ± 0.5
Solubility	Soluble in water
Viscosity	Water at 20° C
Storage stability	Stable between 18° C and 26° C

2. Environmental Fate: Bac-Shield is a microbicide labeled for treatment of paper and fabrics. Food and Agricultural Code section 13141, et seq., requires the submission of environmental fate data for agricultural use products. As Bac-Shield was not proposed to be registered for agricultural use, environmental fate data were not required.

B. Toxicology

Chem Tex Laboratories submitted adequate toxicology studies to conduct complete toxicological evaluations of poly-D-glucosamine. DPR evaluated the submitted data to determine the potential for adverse health effects. The product label adequately identifies the potential acute toxicity hazards indicated by the data reviewed. The first aid statements are adequate for the indicated acute toxicity hazards. The acute toxicity parameters for poly-D-glucosamine are summarized in Table 2 on page 3.

Table 2. Summary of Acute Toxicity of ChitoSante*

Type of Study	Acute Toxicity Values**	Acute Toxicity Category
Acute oral	LD ₅₀ > 5 g/kg	IV
Acute dermal	LD ₅₀ > 5 g/kg	IV
Acute inhalation	LC ₅₀ > 2.07 mg/l	IV
Primary eye irritation	N/A	III
Primary dermal irritation	N/A	IV
Dermal sensitization	N/A	Not a dermal sensitizer
Signal word	N/A	CAUTION

* Toxicity testing was conducted with ChitoSante, which contains 6.0% poly-D-glucosamine.
**Acute Toxicity Values expressed as:
LD₅₀ = Lethal dose that kills 50% of the test population
LC₅₀ = Lethal environmental concentration that kills 50% of the test population
N/A = Not applicable

Chem Tex Laboratories did not submit chronic toxicology data in support of poly-D-glucosamine. Poly-D-glucosamine (chitosan) is on the U.S. Food and Drug Administration (FDA) list of food additives generally recognized as safe (GRAS). Poly-D-glucosamine is a biochemical, and is produced from chitin, the structural element in the exoskeleton of crustaceans such as crabs and shrimp. Because poly-D-glucosamine is on the FDA GRAS list, and is classified as a biochemical, it is exempt from the data requirements of the Birth Defects Prevention Act (Food and Agricultural Code section 13121).

DPR prioritizes pesticide active ingredients for risk assessment based on of the nature the potential adverse health effects, the number of potential adverse effects, the number of species affected, no observable effect levels (NOELs), the potential for human exposure, use patterns, and other similar factors. Based on these criteria, pesticides with the greatest potential for health problems are placed in high priority, with other chemicals being in moderate or low priority. At this time, DPR has not prioritized poly-D-glucosamine for risk assessment. The purpose of the risk assessment would be to appraise the potential for poly-D-glucosamine to cause adverse health effects in humans if exposed to the pesticide through legal use.

C. Health & Safety

DPR compared the medical management information of the Bac-Shield label to the acute toxicity study results. DPR found that the product label bears all required statements and warnings

regarding safety to handlers and other persons who may be exposed to the pesticide. The product label bears adequate First Aid statements.

D. Fish & Wildlife

Bac-Shield is a microbicide labeled for treatment of textiles, carpet, and paper products to inhibit the growth of odor causing bacterium, mold, mildew, and fungi. When used as directed, DPR does not expect poly-D-glucosamine to be released into the environment. Consequently, fish and wildlife data are not required.

E. Efficacy & Phytotoxicity

Chem Tex Laboratories submitted efficacy data derived from Bac-Shield tested against *Enterobacter aerogenes*, *Klebsiella pneumoniae*, *Staphylococcus aureus*, *Trichophyton rubrum*, *Aspergillus niger*, *Chaetomium globosum*, *Penicillium varians*, *Stachybotrys chartarum*, and *Trichoderma viride*. Test results demonstrate product efficacy at the label recommended use range of 1-2% Bac-Shield per weight of treated material. Submitted data are adequate to support conditional registration of Bac-Shield. Conditional registration is contingent upon the submission of simulated in-use data demonstrating product effectiveness for treatment of carpet at the label recommended use rate of 6 ounces per gallon.

ALTERNATIVES

Poly-D-glucosamine is a biochemical produced from chitin. Bac-Shield is an antimicrobial product that inhibits the growth of bacteria, mold, mildew and fungi that can cause odors, discoloration, and deterioration of paper and fabric products, including carpet. Poly-D-glucosamine has very low mammalian toxicity, and is on the FDA list of food additives generally recognized as safe. A number of other active ingredients are registered for use on fabrics and carpets for control of odor causing microorganisms. However, an effective integrated pest management strategy requires the flexibility of a number of comparable, but not exactly equivalent, pesticides in order to reduce the development of resistance. Additionally, the use of a less toxic active ingredient such as poly-D-glucosamine minimizes the adverse effects to humans and the environment.

CONCLUSION

DPR evaluated the product label and scientific data submitted to support the registration of Bac-Shield. The label and data were found acceptable to support conditional registration until December 31, 2008. The acute health risks to humans from exposure to poly-D-glucosamine are minimal due to its low mammalian toxicity. The precautionary and first aid statements on the product label mitigate potential health risks to persons who may be exposed to this pesticide. If a risk assessment conducted by DPR determines that exposure to poly-D-glucosamine may result in unacceptable margins of exposure, further restrictions will be placed on the use of poly-D-glucosamine at that time. Conditional registration of Bac-shield is contingent upon the

submission of simulated in-use data demonstrating product effectiveness for treatment of carpet at the label recommended use rate of 6 ounces per gallon. Chem-Tex Laboratories must submit the required data or documentation that the testing is under way by December 31, 2008, or the registration for Bac-Shield will not be renewed for 2009.