

CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION

PUBLIC REPORT 2004-03 N-butyl-1,2-benzisothiazolin-3-one Tracking ID 202131 N

DESCRIPTION OF ACTION

Avecia Incorporated submitted an application seeking California registration of Vanquish 100 Antimicrobial, U.S. EPA Reg. No. 72674-2, to control bacteria and fungi in natural rubber and plastic products. Vanquish 100 Antimicrobial contains the new active ingredient N-butyl-1,2-benzisothiazolin-3-one. Vanquish 100 Antimicrobial was registered unconditionally by the United States Environmental Protection Agency (U.S. EPA) on April 24, 2003.

The Department of Pesticide Regulation (DPR) evaluated the product label and scientific data supporting registration of the product and found them acceptable to support conditional registration. The acute health risks from exposure to N-butyl-1,2-benzisothiazolin-3-one are potentially significant due primarily to its corrosive nature to the skin. However, the precautionary and first aid statements on the product label, as well as label directions requiring personal protective equipment (PPE) and other protective measures adequately mitigate the potential health risks to persons who may come in contact with the pesticide. DPR does not expect significant adverse environmental impacts to result from registration of this product.

BACKGROUND

Registrant: Avecia Incorporated
Common name: None
Chemical name: N-butyl-1,2-benzisothiazolin-3-one
Brand name: Vanquish 100 Antimicrobial
Uses: Protection of natural rubber and plastic products
Pests controlled: bacteria and fungi
Type of registration: Conditional registration for 18 months

Vanquish 100 Antimicrobial is an antimicrobial/antifungal additive to preserve items made of natural rubber and plastic. Vanquish 100 Antimicrobial is applied during the manufacturing process to prevent bio-degradation by algal, bacteria and fungal organisms. It can provide protection for the surfaces of products from staining, the generation of objectionable odors, and premature failure of the product. Some of the items recommended for treatment are: coated fabrics, floor coverings, pool liners, outdoor furniture, foam seat cushions, and caulks and sealants. As a liquid, Vanquish 100 Antimicrobial is applied during the manufacturing process at a rate of 0.03-1.0% of the weight of the final product. The application rate will depend on the susceptibility of the product to micro-degradation, species involved, environmental conditions the product is going to be used in, and length of time protection is needed. Vanquish 100 Antimicrobial can also be used to formulate antimicrobial products. Products intended to be

used for handling food/feed or drinking water or toys should not be treated with Vanquish 100 Antimicrobial.

SCIENTIFIC REVIEW

A. Chemistry

1. Product Chemistry: DPR evaluated the submitted chemistry studies for Vanquish 100 Antimicrobial and the results are summarized in the following table.

Table I. Physical and Chemical Properties of Vanquish 100 Antimicrobial

Properties	Values
Physical state	Liquid
Color	Brown
Odor	None
Flash point	178° C (+/-5° C)
Specific gravity	1.17
Solubility (water)	< 0.5 parts per million (ppm)
Vapor pressure	1.13 X 10 ⁻⁴ mm Hg at 25° C
pH	2.77
Storage stability	Unknown

A one-year storage stability study is needed to complete the chemistry evaluation.

2. Residues in Food and Animal Feed: The Vanquish 100 Antimicrobial label does not include any food or feed uses. Therefore, residue data are not required to support registration of the product.

3. Environmental Fate: Vanquish 100 Antimicrobial is an antimicrobial/antifungal additive applied during the manufacturing of rubber and plastic items to prevent bio-degradation by algal, bacteria and fungal organisms. Because N-butyl-1,2-benzisothiazolin-3-one becomes an integral part of these items, the use results in no exposure to the environment. Environmental fate studies are not required for pesticide products with this type of use pattern.

B. Toxicology

Avecia Incorporated submitted adequate toxicity studies to conduct a complete toxicological evaluation of Vanquish 100 Antimicrobial. DPR evaluated the submitted data to ascertain the potential for adverse health effects. The estimated acute toxicity parameters for Vanquish 100 Antimicrobial are summarized in Table II.

Table II. Estimated Acute Toxicity of Vanquish 100 Antimicrobial

Type of Study	Acute Toxicity Values	Acute Toxicity Category
Acute oral	LD ₅₀ (M/F)>2000 mg/kg	III
Acute dermal	LD ₅₀ (M/F) >2000 mg/kg	III
Acute inhalation	LC ₅₀ (F)>0.100 mg/L	II
Primary eye irritation	N/A	Study not submitted
Primary dermal irritation	N/A	I
Dermal sensitization	N/A	Possible dermal sensitizer
Signal word	N/A	DANGER

DPR's evaluation of the acute toxicity studies indicates that exposure to Vanquish 100 Antimicrobial can cause irreversible damage to the skin. The product label bears a warning identifying the product as being corrosive to the skin and the "signal word" is DANGER. The precautionary language on the product label adequately identifies all acute toxicity hazards noted in the studies.

DPR found the submitted toxicology studies adequate to satisfy the data requirements of the Birth Defects Prevention Act (SB 950). The results from one of the two chromosomal aberration studies indicate a possible adverse health effect. A neurotoxicity study is not required at this time. At this time, N-butyl-1,2-benzisothiazolin-3-one has not been prioritized for risk assessment. DPR prioritizes pesticide active ingredients for risk assessment based on the nature of the potential adverse health effects, number of potential adverse health effects, number of species affected, NOELs, potential for human exposure, use patterns, and similar factors. Based on these criteria, pesticides with the greatest potential for health problems are placed in high priority, with other chemicals being placed in moderate or low priority. The purpose of the risk assessment will be to appraise the potential for N-butyl-1,2-benzisothiazolin-3-one to cause adverse health effects in humans if exposed to the pesticide as the result of a legal use.

C. Health & Safety

An evaluation of the medical management information on the Vanquish 100 Antimicrobial label and the acute toxicity study results indicate that the product label bears all of the required statements and warnings regarding safety for workers during the use of the product. The product label bears an adequate first aid statement and the following PPE are required to be worn by workers handling Vanquish 100 Antimicrobial: goggles or face shield and rubber gloves, and a National Institute of Occupational Safety and Health (NIOSH) certified respirator if adequate ventilation is not present.

D. Fish & Wildlife

Vanquish 100 Antimicrobial is an antimicrobial/antifungal additive applied during the manufacturing of rubber and plastic products to prevent bio-degradation by algal, bacteria and fungal organisms. Because N-butyl-1,2-benzisothiazolin-3-one becomes an integral part of these products, the use results in no exposure to the environment. Fish and wildlife studies are not required for pesticide products with this type of use pattern.

The Vanquish 100 Antimicrobial label bears a warning indicating that the product is toxic to fish. The label warns the user not to discharge effluent containing this product into lakes streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge.

E. Efficacy & Phytotoxicity

Avecia Incorporated submitted data generated from several trials where treated plastic and rubber were manufactured into final use products such as coated fabrics, floor coverings, tarpaulins, synthetic leather, swimming pool liners, appliance gaskets, sealants, caulks and other household items. The treated specimens were exposed to mixed fungi and bacteria inoculum for 28 days at 21° C. The caulks and sealants were also exposed to leaching during the test period. The results indicate that Vanquish 100 Antimicrobial can provide control of these organisms over a short period of time. The treated articles were not re-inoculated over the period of the trial.

DPR has determined that additional efficacy data are needed to confirm the control of fungi, and Gram positive and Gram negative bacteria on coated fabric or awnings, sealants, caulks, adhesives, vinyl wall coverings, and bath mats manufactured from treated plastic and rubber. Additional data are needed to evaluate the control of problem algae on swimming pool liners and ornamental pond liners manufactured from plastic treated with N-butyl-1,2-benzisothiazolin-3-one. Also in-use data on major types of “treated articles” manufactured from treated PVC, polyurethane, silicones, polyesters, and acrylics are needed to demonstrate the effectiveness of the subject product in preserving these plastics against loss of mechanical strength, flexibility, adhesive strength or appearance of these articles during their expected use-life.

More data are needed to confirm the ability of Vanquish 100 Antimicrobial to control fungi and bacteria over the expected service life of the treated article. These trials should also evaluate the effect of leaching on efficacy for appropriate products through the observed period.

ALTERNATIVES

The purpose of making plastic and rubber products impregnated with n-butyl-1,2-benzisothiazolin-3-one is to prevent premature product failure and the production of odors and staining. N-butyl-1,2-benzisothiazolin-3-one is one of a few chemicals that can added during the manufacturing process to provide these benefits. Failure to treat various products constructed with plastic and rubber can lead to the aforementioned problems.

CONCLUSION

DPR evaluated the product label and scientific data submitted to support the registration of Vanquish 100 Antimicrobial and found them acceptable to support registration. The acute health risks to humans from exposure to N-butyl-1,2-benzisothiazolin-3-one are mitigated by the

precautionary and first aid statements on the product label, as well as by the required PPE and other protective measures. If, a risk assessment is conducted and DPR determines that exposure to N-butyl-1,2-benzisothiazolin-3-one may result in unacceptable margins of exposure, further restrictions will be placed on the use of N-butyl-1,2-benzisothiazolin-3-one at that time. When used in accordance with label directions, the product will be effective for its intended use.

DPR is granting an 18-month conditional registration for Vanquish 100 Antimicrobial. The registrant is required to conduct and submit a one-year storage stability study. In addition, the registrant is required to submit efficacy data showing the control of fungi and bacteria over the expected service life of various treated articles. The trials must also evaluate the effect of leaching on efficacy for appropriate products through the observed period.