

Chitosan  
PC Code: 128930

DP Number(s): 386109  
EPA Reg. or File Symbol No. 83729-1



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

**OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION/OFFICE OF PESTICIDE PROGRAMS**

**MEMORANDUM**

**DATE:** 4/19/2011

**SUBJECT:** Science review of efficacy data for label amendment of registered product, YEA! Yield Enhancing Agent, EPA Ref. No. 83729-1, containing 0.25% w/w of Chitosan, as its active ingredient.

**Decision Numbers:** 444246  
**DP Numbers:** 386109  
**EPA File Symbol Numbers:** 83729-1  
**Chemical Class:** Biochemical  
**PC Code:** 128930  
**CAS Number:** 9012-76-4  
**Tolerance Exemptions:** 180.1072  
**MRID Numbers:** 483519-01

**FROM:** Clara Fuentes, Ph.D. Entomologist  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

A handwritten signature in black ink, appearing to be "Clara Fuentes", written over a horizontal line.

**TO:** Gina Casciano, Regulatory Action Leader  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

**ACTION REQUESTED**

AgriHouse, Inc. is submitting efficacy data in MRID 483519-01 in support of label amendment for registered product, YEA! Yield Enhancing Agent, EPA Ref. No. 83729-1, containing 0.25% w/w of Chitosan as its active ingredient. The product is used to promote plant growth, boost seed germination, and enhance plant vigor and quality in grasses, trees, ornamental and agricultural crops. The proposed label amendment indicates that the product promotes induced plant resistance and offers protection against three species of tree beetles, and plant pathogens, virus and fungi.

\*Inert ingredient information may be entitled to confidential treatment\*

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## **RECOMMENDATIONS AND CONCLUSIONS**

### Product Chemistry:

The CSF needs to be revised and upgraded. The following deficiencies were identified:

1. The percent by weight of active ingredient listed on the CSF is inconsistent with the concentration stated on the product label. The concentration listed on the CSF is 2.50 % w/w, and the concentration stated on the product label is 0.25%.
2. The name of the product is not listed on column 3 in the CSF, and it should be.
3. The amounts of active and inert ingredients are not listed on the CSF. The amount, in units of weight, of each component in the formulation needs to be listed on 13 a) in the CSF.
4. The CAS number for [REDACTED] is not listed on the CS, and it needs to be.
5. The name of the active ingredient on the label should be consistent with that listed on the CSF. The name of the active ingredient listed on the CSF is Poly-D-Glucosamin, and the name of the active ingredient on the label is Chitosan. The registrant needs to resolve this discrepancy concerning the use of different synonyms for referring to the active ingredient on the CSF and product label.

### Product Performance:

Unacceptable. The submitted data volume is not product specific and fails to support label claims concerning the efficacy of the product when used as recommended by label directions. The submitted data volume in MRID 483619-01 is supplemental information about performance and biological properties of the active ingredient, Chitosan. To upgrade the required efficacy data to acceptable, the registrant needs to address the following deficiencies:

1. There is no data to support the performance of the product when applied at the rates specified in the amended label.
2. The registrant needs to provide data showing the performance of the product in terms of yield increase relative to negative controls when applied at the specified rates for each crop type.
3. The registrant needs to provide data showing the efficacy of the product against target pests when applied as intended for use. The efficacy of product applications on target pests, as

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recommended on label instructions for use, should be measured against comparable levels of same pest infestations on negative control treatments.

## **STUDY SUMMARIES**

The registrant submitted data from the scientific published literature documenting that Chitosan is a biodegradable, naturally occurring substance that can be successfully employed to enhance plant vigor and ameliorate the adverse effects of plant pathogens, viruses and fungi, and some species on tree beetles on plant growth and yield production. There is enough information from the public literature on the mechanism for induce plant resistance by Chitosan, and its ability to protect many types of plants from disease vectors and insect damage. The information contained in MRID 483519-01 is useful, but supplemental because it is not product specific. It does not explain how the optimal application rates recommended on the label were determined, and the level of pest suppression and yield production generated under those application rates. The Agency needs to know level of efficacy due to treatments in order to support the application rates recommended on the product label.

cc: Reviewer: Clara Fuentes; RAL: Chris Pfeifer, BPPD Chron File, IHAD/ARS  
FT, PY-S: date: 4 / 19 /11