

6



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

JUN 04 2009

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM**DATE:** June 4, 2009**SUBJECT:** Science Review in Support of the Registration of YEA! Yield Enhancing Agent, Containing 0.25% Chitosan (Poly-*D*-Glucosamine) As Its Active Ingredient.**Decision Number:** 401006**DP Number:** 364826**EPA Registration Number:** 83729-1**Chemical Class:** Biochemical**PC Code:** 128930**CAS Number:** 9012-76-4**Active Ingredient Tolerance Exemptions:** 40 CFR 180.1072**MRID Numbers:** 47745201, 47731702-47731703**FROM:** Angela L. Gonzales, Biologist *Angela L. Gonzales*
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)**TO:** Leonard Cole, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)**THE FOLLOWING CONTAINS CONFIDENTIAL BUSINESS INFORMATION****ACTION REQUESTED**

In response to the request for additional information discussed in a memorandum from A. L. Gonzales to L. Cole dated April 13, 2009 and relayed in a letter from BPPD to the registrant dated April 14, 2009, the registrant has submitted a revised proposed label, a revised Confidential Statement of Formula (CSF), product chemistry data and information in MRID 47745201, human toxicology information in MRID 47731702 and efficacy data and information in MRID 47731703.

Chitosan
PC Code: 128930

DP Number: 364826
EPA Reg. No.: 83729-1

RECOMMENDATIONS AND CONCLUSIONS

1. The product chemistry submission is ACCEPTABLE, pending resolution of the deficiencies identified below.

1a. The value provided in box 7 "Pounds/Gal or Bulk Density" on the CSF does not match the value provided in MRID 47745201. The registrant must resolve this discrepancy.

1b. The value provided in box 8 "pH) on the CSF does not match the value provided in MRID 47745201. The registrant must resolve this discrepancy.

1c. The storage stability and corrosion characteristics study must be submitted upon completion.

2. The toxicology submission is ACCEPTABLE.

3. The product performance data are SUPPLEMENTAL.

3a. Two studies were submitted in MRID 47731703. It is unclear to the reviewer if the EP was tested in the first study because its name is not mentioned in the study (of the three names noted by the registrant, YEA!, BEYOND and ODC). This study cannot be used in support of product efficacy until it is demonstrated that the product was actually employed in the study.

3b. A table was provided on the last page of MRID 47731703. It is unclear as to which study this table belongs. The registrant must provide this information.

3c. Based on the information provided, it appears that the product is beneficial in reducing ethanol development associated with post harvest treatment of citrus when used as a foliar and soil treatment together. It is unknown based on the available data if the product is as effective when used as a foliar treatment alone. The information provided in the table on the last page of MRID 47731703 (study unknown at this time) indicates that the product's efficacy is not significantly different from the untreated control. The data provided regarding efficacy of the product (yield increase, slowing of senescence, etc.) following foliar application to citrus are still insufficient to support adding foliar application to the product label. A detailed foliar-application only study employing the product used according to label instructions should be submitted.

Note to RAL:

1. The registrant has added language referring to the National Organic Program (NOP) on the label. The product must be reviewed by BPPD prior to allowing this language on the label.

Chitosan
PC Code: 128930

DP Number: 364826
EPA Reg. No.: 83729-1

STUDY SUMMARIES

Product Chemistry (MRID 47745201)

Acceptable product physical and chemical properties were submitted in MRID 47745201 and are summarized in Table 1 below. A storage stability and corrosion characteristics study is underway and will be submitted upon completion. On the CSF, the values provided for density and pH do not comply with the values provided in MRID 47745201. The registrant also confirmed that the new (revised) formulation does replace the old basic formulation; there is no alternate formulation.

OPPTS Guideline No.	Property	Description of Result	MRID
830.6302	Color	Light brown; lightens slightly as the formulation ages	47745201
830.6303	Physical State	Liquid	47745201
830.6304	Odor	Not required for EP	
830.6313	Stability to Normal and Elevated Temperatures, Metals and Metal Ions	Not required for EP	
830.6315	Flammability	Product does not contain combustible liquids	47745201
830.6317	Storage Stability	Study in progress	47745201
830.6319	Miscibility	Product is not to be diluted with petroleum solvents	47745201
830.6320	Corrosion Characteristics	Study in progress	47745201
830.7000	pH	6.1 (increases slightly as the formulation ages)	47745201
830.7050	UV/Visible Light Absorption	Not required for EP	
830.7100	Viscosity	0.986 centistokes 25°C	47745201
830.7200	Melting Point/Range	Not required for EP	
830.7220	Boiling Point/Range	Not required for EP	
830.7300	Density	0.996 g/mL at 25°C	47745201
830.7520	Particle Size, Fiber Length and Diameter Distribution	Not required for EP	
830.7550 830.7560 830.7570	Partition Coefficient (n-Octanol/Water)	Not required for EP	
830.7840	Water Solubility	Not required for EP	
830.7950	Vapor Pressure	Not required for EP	

Inert ingredient information may be entitled to confidential treatment

4

Chitosan
PC Code: 128930

DP Number: 364826
EPA Reg. No.: 83729-1

Toxicology (MRID 47731702)

Potential changes in the toxicological properties of the revised formulation were adequately addressed. The acute toxicity of the EP is not expected to change due to the low concentration of the new inert ingredient, [REDACTED] and because of its low toxicity. Although the chemical can be a skin irritant, its presence at a low concentration is not expected to change the current acute toxicity classification for the product. Moreover, the pH of the revised formulation (pH = 6.1) is higher (closer to being neutral) than that of the old formulation (pH = 4.3) and therefore increase in toxicity is not expected when compared to the toxicity of the old formulation. Additionally, the concentrations of the active ingredient and the other inert ingredient, [REDACTED] have remained the same.

Product Performance (MRID 47731703)

The two unpublished studies originally cited and discussed in the memorandum from A. L. Gonzales to L. Cole dated April 13, 2009 were submitted in MRID 47731703. It is unclear to the reviewer if the EP was tested in the first study because its name is not mentioned in the study (of the three names noted by the registrant, YEA!, BEYOND and ODC). This study cannot be used in support of product efficacy until it is demonstrated that the product was actually employed in the study.

In the second study, which was conducted using ODC, soil drip applications together with a foliar application were employed; there was no foliar treatment alone. It was concluded that the treatment worked effectively, by reducing ethanol development associated with post harvest treatment of fruit and that the treated fruit did not exhibit the signs of aging normally seen in gassed (with ethylene) fruit.

A table was provided on the last page of MRID 47731703. It is unclear as to which study this table belongs. Additionally, it is noted that data on the product, Beyond, with respect to treatment on oranges was provided in this table and that the results were not significantly different than the untreated controls for the parameters of internal quality, color during degreening, grade, or decay.

Based on the information provided, it appears that the product is beneficial in reducing ethanol development associated with post harvest treatment of citrus when used as a foliar and soil treatment together. It is unknown based on the available data if the product is as effective when used as a foliar treatment alone. The information provided in the table on the last page of MRID 47731703 (study unknown at this time) indicates that the product's efficacy is not significantly different from the untreated control. The information regarding efficacy of the product (yield increase, slowing of senescence) following foliar application to citrus is insufficient to support adding foliar application to the product label.

cc: Angela L. Gonzales, L. Cole, BPPD Science Review File, IHAD/ARS
A. L. Gonzales, FT, PY-S: 6/4/09



13544

R173800

Chemical Name: Chitosan

PC Code: 128930

HED File Code: 41500 BPPD Tox/Chem

Memo Date: 6/4/2009

File ID: DPD364826

Accession #: 000-00-0130

HED Records Reference Center

10/13/2009