

DATE OUT: 27 Sept 2007

SUBJECT: **PRODUCT CHEMISTRY REVIEW** MP [] EP [x]
DP BARCODE No.: D335153
Reg. File Symbol No.: 264-RNLL
PRODUCT NAME: USF 0728 325 SC Fungicide
COMPANY: Bayer CropScience LP
Decision No.: 371935 PC CODE: 129112, 113961
FOOD USE: [x] Integrated Formulation []

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Bruce F. Kitchens
27 Sept 2007
SKB
9/27/07

INTRODUCTION:

The registrant, Bayer CropScience LP, is submitting an application to register the proposed end-use product, USF 0728 325 SC Fungicide. The active ingredients in this product are Trifloxystrobin and Prothioconazole at label nominal concentrations of 13.7 and 16.0% a.i., respectively. This product is intended for use as a sugar beet fungicide. In support of this request, the registrant has submitted a basic Confidential Statement of Formula (CSF) dated 25 Oct 2006, a draft label, and product chemistry data contained in MRID#469746-01. The Technical Review Branch (TRB) has been asked to review this submission.

SUMMARY OF FINDINGS

TRB has reviewed this submission and reports the following findings:

1. This product is produced from registered sources of the active ingredients.
2. All inert ingredients are cleared for use in formulated pesticide products. In addition, all inert ingredients are exempt from the requirement of a food tolerance.
3. The nominal concentration of the active ingredient listed on the proposed CSF and the draft label are the same.
4. The draft label contains the appropriate storage and disposal statements.
5. The active ingredient's certified limits as proposed on the basic CSF are acceptable.

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. The basic formula CSF for the proposed end-use product, USF 0728 325 SC Fungicide dated 25 Oct 2006 is acceptable.
2. This submission (MRID# 469746-01) satisfies the data requirements as specified in 40 CFR 158.155, 158.160, 158.165, 158.167, 158.175, and 158.180 with respect to product identity and composition, description of materials used to produce the product, description of formulation process, discussion of formation of impurities, certified limits, and enforcement analytical method.
3. Except for storage stability/corrosion characteristics studies, the remaining product chemistry Group B data (MRID# 469746-01) adequately fulfill the data requirements. The registrant indicated that studies are in progress to satisfy the storage stability and corrosion characteristics data requirements. Inform the registrant that these data must be submitted to the Agency for evaluation.

PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A)

Subgroup A – Product Identity and Composition	<u>Data Required Fulfilled</u>	<u>MRID No.</u>
830.1550. Chemical Identity	Y	469746-01
830.1600. Beginning Materials	Y	469746-01
830.1650. Formulation Process	Y	469746-01
830.1670. Discussion of Impurities	Y	469746-01
830.1700. Preliminary Analysis	NR	
830.1750. Certified Limits	Y	see 11/25/06
830.1800. Enforcement Analytical Method	Y	469746-01

Enforcement Analytical Method: (MRID No. 469746-01)

The active ingredients, Trifloxystrobin and Prothioconazole, were determined by high performance liquid chromatography (HPLC) using ultraviolet detection (UV). Butyrophenone was used as an internal standard by analytical method AM003605F1. Quantitation of samples was made by comparing the peak areas of the sample and the corresponding analytical standards. The method was validated for linearity, accuracy, specificity, and stability.