6-15-92 RcF

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

JUN 15 1992

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Triadimefon. Case # 2700. Waiver and Extension Requests: Storage Stability Data and Processing Study. No MRID #. CBRS # 9851. DP Barcode: D177806.

FROM: Leung Cheng, Chemist
Special Review Section II
Chemistry Branch II - Reregistration Support
Health Effects Division (H7509C)

THROUGH: Francis Suhre, Section Head
Chemistry Branch II - Reregistration Support
Health Effects Division (H7509C)

TO: Mark Wilhite, Review Manager
Accelerated Reregistration Branch
Special Review/Reregistration Division (H7508W)

In a letter dated July 31, 1991, Mobay Agricultural Chemicals Division requested waiving storage stability data requirement for wet and dry pomace, wheat middlings, garbanzos (including chick peas), and raspberries, and waiving processing data for barley. At the same time, Mobay requested an extension for the submission of the wheat processing study. A draft label (with English translation) of Bayleton® 25% WP which had removed the use on almonds was also submitted.

Triadimefon is a List B chemical. The full chemical name is 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl-2-butanone. A Phase IV review was completed 1/24/91 (S. Funk).

Storage Stability (GDLN # 171-4(e))

According the Phase IV review, storage stability studies must be conducted on all crops and processed products for which a field trial and/or processing study has been (or will be) conducted, as well as representative livestock commodities.

Mobay responded that storage stability data for the parent compound, KWG 0519 (triadimenol or Baytan®), KWG 1323 (1-(4-chlorophenoxy)-3-methyl-3-hydroxymethyl-1-(1H-1,2,4-triazol-1-yl)-

2-butanone) and KWG 1342 (1-(4-chlorophenoxy)-3-methyl-3-hydroxymethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanol) had recently been submitted on wheat forage, wheat grain, grapes and tomatoes up to a period of 24 months. No data on almonds are provided because use on almonds is being deleted. Citing the Phase III Technical Guidance document (12/24/89), and based on the storage stability data (to be) developed for similar or representative crops, the company is requesting a waiver for this requirement for dry and wet grape pomace (extrapolating from raisins, raisin waste and juice); wheat middlings (from bran, flour and shorts); chick peas (from wheat, grapes and tomatoes); and raspberries (from wheat, grapes and tomatoes). The Phase III Technical Guidance document considers this requirement satisfied once the storage stability has been demonstrated in an oilseed crop (e.g., soybeans), a fruit (e.g., citrus) and a non-oily grain (e.g., wheat) and their by-products, provided storage conditions and duration for the crops of interest are similar.

We agree with Mobay.

Barley Processing Study (GDLN 171-4(1))

Mobay has requested to waive the processing data for barley. The company states that they have committed to conduct a processing study on wheat which, according to the Guidance document, is translatable to barley. We agree.

The company also has requested an extension for the wheat processing study because of the requirement of a new wheat metabolism study (due July, 1993) and potential method development (projected July 1994 submission date should new metabolites are uncovered and require regulation in the new metabolism study). Their projected completion date for the wheat residue field trials and processing study is July 1996.

Metabolites likely to require regulation should be identified by the registrant prior to completion of the metabolism study, and analytical method development can be initiated. Furthermore, metabolism studies, analytical method development, and field trial/processing studies in general need not be carried out sequentially. Study due dates are determined considering this. The registrant has provided no rationale why this case is special or unique requiring a time extension. CBRS recommends against the requested time extension. In any event, granting a time extension request is in the purview of SRRD.

CONCLUSIONS AND RECOMMENDATION

1. Storage Stability (GDLN # 171-4(e))

Mobay's arguments for waiving storage stability data for dry and wet pomace, wheat middlings, garbanzos and raspberries are acceptable. The Phase III Technical Guidance document considers this requirement satisfied once the storage stability has been demonstrated in an oilseed crop (e.g., soybeans), a fruit (e.g., citrus) and a non-oily grain (e.g., wheat) and their by-products, provided storage conditions and duration for the crops of interest are similar.

2. Barley Processing Study (GDLN 171-4(l))

The barley processing study is waived as long as there is an acceptable wheat processing study. Mobay has requested a time extension for conducting the wheat processing study because of the need of a new wheat metabolism study and potential method development.

Metabolites likely to require regulation should be identified by the registrant prior to completion of the metabolism study, and analytical method development can be initiated. Furthermore, metabolism studies, analytical method development, and field trial/ processing studies in general need not be carried out sequentially. Study due dates are determined considering this. The registrant has provided no rationale why this case is special or unique requiring a time extension. CBRS recommends against the requested time extension. In any event, granting a time extension request is in the purview of SRRD.

CBRS notes that the draft label contains crops (sugarcane and coffee) that are not listed in 40 CFR 180.410. Changes are needed.

cc:Circ, RF, List B File, Cheng, PIB/FOD
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