

OPP Chemistry Document

Subject: Case No. 2625; Chemical No. 035603
Document Phase 4 Response -- ReRegistration

Class:

Product 830.1550 Product Identity and composition
Chem: 830.1600 Description of materials used to produce the product
830.1620 Description of production process
830.1700 Preliminary analysis
830.1750 Certified limits
830.1800 Enforcement analytical method
830.6302 Color
830.6303 Physical state
830.6304 Odor
830.6313 Stability to normal and elevated temperatures, metals, and metal ions
830.7000 pH
830.7220 Boiling point/boiling range
830.7300 Density/relative density/bulk density
830.7550 Partition coefficient (n-octanol/water), shake flask method
830.7560 Partition coefficient (n-octanol/water), generator column method
830.7570 Partition coefficient (n-octanol/water), estimation by liquid chromatography
830.7840 Water solubility: Column elution method, shake flask method
830.7860 Water solubility, generator column method
830.7950 Vapor pressure

Residue 860.1300 Nature of the residue - plants, livestock
Chem: 860.1340 Residue analytical method
860.1380 Storage stability data
860.1480 Meat/milk/poultry/eggs
860.1500 Crop field trials
860.1520 Processed food/feed

Biochemicals:

DP Barcode:

MRIDs: 41612001, 41612001, 41612001, 41612002, 41612002, 41612002, 41612003, 41612003, 41612003, 41612003, 41612003, 41612003

PC Codes: 035603 2-(Thiocyanomethylthio)benzothiazole

Actives/Inerts

CAS #:

Commodities: Oats; Wheat; Barley; Corn; Safflower; Cotton; Sorghum, Grain; Beet, Sugar; Rice

Administrative #:

Reviewers: Andrew Rathman

Review Andrew Rathman

Approver:

Approved on: March 11, 1991

WP Document:  - Tcmtb_003.wpd

Case No. 2625
Chemical No. 035603

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Transmitted to HED on 10/30/90

Case name: TCMTB

Chemical Name(s): 2-(Thiocyanomethylthio)benzothiazole

Data submitter(s): Buckman Lab

CRM: Virginia Dietrich

Phone #: 308-8057

Issues/flags:

This action contains a request for a DATA WAIVER (X)
TIME EXTENSION ()
ALTERED/DELETED USE ()

Other:

Branch: CBRS, Phase 4 Review Team

Reviewed by: Leung Cheng Date: _____

cc: Circ, RF, List B
File, Cheng, Grim
(EFED), FOD/ISB

Approvals:

Section Head: Andrew R. Rathman Date: _____

Branch Approval: Edward Zager Date: _____

Response, by Guideline

Guideline #: 171-4(a) Description: Nature of residue - plants
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a
candidate for Phase 5 review?: N/A
Data Waiver() Time Extension() Other ()
Data Waiver/Time Extension (If applicable) Granted? (Y/N):

Discussion: The registrant indicated in its Phase II response
that Buckman Lab intended to conduct this study.

Data gap: The registrant must provide three new plant
metabolism studies, one each on corn or wheat,
cotton and sugar beets. TCMTB labelled in a non-
labile part of the molecule should be applied to the
seeds of these three crops reflecting the currently
registered use including the maximum treatment rate.
If no uptake of activity is found in the aerial
portion and/or edible root portion of the growing
crop, then these uses may be considered non-food.
However, if activity occurs in the aerial and/or
edible root portions of the crop, adequate
characterization of the metabolites/degradates is
required and these uses will be considered food uses
requiring tolerances. In this case, the plant
material from the metabolism study should be tested
using the data collection method(s) and enforcement
analytical method(s).

Guideline #: 171-4(b) Description: Nature of residue - animals
Is requirement applicable? (Y/N): I (decision cannot be made at
this time)
Does the summary/available information indicate that the MRID is a
candidate for Phase 5 review?: N/A
Data Waiver(X) Time Extension() Other ()
Data Waiver/Time Extension (If applicable) Granted? (Y/N): I

Discussion: The registrant requested in its Phase II submission
a waiver for this data requirement because the
labels restrict feed use. Judging from the list of
crops permitted for use, most of feed items can not
be restricted from a practical standpoint. This
data requirement can only be waived if radiotracer
studies show no uptake of activity in plants.

Data gap: Should animal metabolism studies be required, the
registrant must provide a livestock (poultry,

ruminants) metabolism study. TCMTB labelled in a non-labile part of the molecule should be fed to the livestock for a minimum of three days. Orally treated test animals must be sacrificed within 24 hours of the final dose. The dose administered and the specific activity should be high enough to allow for adequate identification of the metabolites/degradates. The tissues from the metabolism study should be tested using the data collection method(s) and enforcement analytical method(s).

Guideline #: 171-4(c) Description: Res. analyt. method - plant
Is requirement applicable? (Y/N): I
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Data Waiver() Time Extension() Other ()
Data Waiver/Time Extension (If applicable) Granted? (Y/N):

Discussion: This requirement is put on RESERVE pending results from the plant metabolism studies. Should it be determined that the label uses are food uses, then the following data gap applies.

Data gap: The registrant must submit data collection and regulatory analytical method(s) for the determination of TCMTB and any toxic metabolites in/on plant matrices. Any regulatory methods submitted will require an independent method validation as described in PR Notice 88-5 (July 15, 1988). TCMTB and its metabolites must be tested through multiresidue Protocol(s) B, C, D, and E.

If method validations of the multiresidue methods are found to be necessary, representative plant matrices must be tested.

Guideline #: 171-4(d) Description: Res. anal. method - animals
Is requirement applicable? (Y/N): I
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Data Waiver() Time Extension() Other ()
Data Waiver/Time Extension (If applicable) Granted? (Y/N):

Discussion: This requirement is put on RESERVE pending results from the crop residue trials and animal metabolism studies. Should this study be required, the following data gap applies.

Data gap: The registrant must submit data collection and regulatory analytical method(s) for the determination of TCMTB and any toxic metabolites in/on animal commodities. Any regulatory methods submitted will require an independent method validation as described in PR Notice 88-5 (July 15, 1988). TCMTB and its metabolites must be tested through multiresidue Protocol(s) B, C, D, and E.

If method validations of the multiresidue methods are found to be necessary, representative animal matrices must be tested.

Guideline #: 171-4(e) Description: Storage stability
Is requirement applicable? (Y/N): I
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Data Waiver(X) Time Extension() Other ()
Data Waiver/Time Extension (If applicable) Granted? (Y/N): I

Discussion: The registrant requested a waiver in its Phase II submission. This data requirement is put on RESERVE pending plant metabolism studies results. Should the results show uptake of TCMTB residues, then the following data gap applies.

Data gap: 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. Use of field-weathered samples is strongly recommended. Storage conditions must reflect the storage conditions of the treated samples (from the field trial and processing studies) with respect to temperature, length of storage, containers, lighting, etc. If there are any metabolites and/or degradates that may be included in the tolerance expressions, then they must be tested as well. The chosen intervals must allow for unforeseen delays in sample storage.

Guideline #: 171-4(f) Description: Mag. res. - potable water
Is requirement applicable? (Y/N): N

Guideline #: 171-4(g) Description: Magnitude residue - fish
Is requirement applicable? (Y/N): N

Guideline #: 171-4(h) Description: Mag. res. - irrigated crop
Is requirement applicable? (Y/N): N

Guideline #: 171-4(i) Description: Mag. res. - food handling
Is requirement applicable? (Y/N): N

Guideline #: 171-4(j) Description: Mag. meat/milk/poultry/eggs
Is requirement applicable? (Y/N): I
Does the summary/available information indicate that the MRID is a
candidate for Phase 5 review?: N/A
Data Waiver(X) Time Extension() Other ()
Data Waiver/Time Extension (If applicable) Granted? (Y/N): I

Discussion: The registrant requested a waiver in its Phase II submission. This data requirement is put on RESERVE pending plant metabolism studies results. Should the results show uptake of TCMTB residues, then the following data gap applies.

Data gap: TCMTB residues must be fed to dairy cattle and/or poultry for a minimum of 28 days or until residues plateau in the milk or eggs, whichever is longer. Following oral treatment, test animals should be sacrificed within 24 hours of the final dose. Animals should be fed at 1x, 3x and 10x the anticipated dietary burden. Feeding levels should be determined based on the latest crop residue data generated or to be generated. When determining the feeding levels the registrant should consider the maximum crop residue levels possible and the dietary burden based on Table II Subdivision O - Residue Chemistry Guidelines.

Guideline #: 171-4(k) Description: Crop field trials
Is requirement applicable? (Y/N): I
Does the summary/available information indicate that the MRID is a
candidate for Phase 5 review?: N/A
Data Waiver(X) Time Extension() Other ()
Data Waiver/Time Extension (If applicable) Granted? (Y/N): I

Discussion: The registrant requested a waiver with respect to this data requirement in its Phase II submission. This requirement is put on RESERVE until plant metabolism studies results are available. Should the results show uptake of TCMTB in plants, the following data gap applies.

Data gap: Data depicting residues of TCMTB and the regulated metabolites in/on the following rac's must be submitted: barley, corn, cotton, oats, rice safflower, sorghum, sugar beets and wheat. Seeds must be treated at the maximum label rates reflecting various application method or timing (eg, slurry, at planting).

Guideline #: 171-4(1) Description: Processing - barley bran, hulls, flour, pearl barley; corn starch, crude oil, refined oil (wet milling), grits, meal, flour, crude oil, refined oil (dry milling); cottonseed meal, hulls, soapstock, crude oil, refined oil; oat flour, hulls, rolled oats; polished rice, bran, hulls; safflower meal, crude oil, refined oil; sorghum starch, flour; sugar beet molasses, refined sugar, dry pulp; wheat bran, flour, middlings, shorts

Is requirement applicable? (Y/N): I

Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A

Data Waiver(X) Time Extension() Other ()

Data Waiver/Time Extension (If applicable) Granted? (Y/N): I

Discussion: The registrant requested a waiver with respect to this data requirement in its Phase II submission. This requirement is put on RESERVE until results from the nature of the residue (plant metabolism) studies are available. Should the results show detectable residues in plants, the following data gap applies.

Data gap: A processing study must each be conducted for barley, corn, cotton, rice, safflower, sorghum sugar beets and wheat. RAC's bearing detectable residues of the parent and the regulated metabolites should be processed into processed products (as indicated above) to determine the residue concentration or reduction factor(s). If residues below the sensitivity of the method are found, exaggerated treatment rates will be required. Processing data for oats may be translated from wheat and barley.

PRODUCT CHEMISTRY

Case Name: TCMTB
 Chemical Name(s): 2-(Thiocyanomethylthio)benzothiazole
 Registrant: Buckman Lab

Guideline Number	Is requirement applicable?	Does summary or available information indicate MRID is a candidate for Phase 5 review?	Are additional data required?	MRID Number
61-1	Y	Y	N	41612001
61-2 (a)	Y	P	Y ^a	41612001
61-2 (b)	Y	Y	N	41612001
62-1	Y	Y	N	41612002
62-2	Y	P	Y ^b	41612002
62-3	Y	Y	N	41612002
63-2	Y	Y	N	41612003
63-3	Y	Y	N	41612003
63-4	Y	Y	N	41612003
63-5	N/A			
63-6	Y	U	Y ^c	
63-7	Y	Y	N	41612003
63-8	Y	P	Y ^d	41612003
63-9	Y	Y	N	41612003
63-10	N/A			
63-11	Y	N/A	Y ^e	
63-12	Y	Y	N	41612003
63-13	Y	U	Y ^f	

Key: Y=yes; N=no; I=a decision cannot be made at this time;
 S=fully satisfies requirement; P=partially; N/A=not applicable; U=unsatisfactory.

^a a description of the equipment used in the manufacture of TCMTB; a detailed description of the synthesis of the key starting material

^b upper certified limits for the impurities

^c highest temperature reached before decomposition

^d solubility in nonpolar organic solvents to be submitted

^e octanol/water partition coefficient to be submitted

^f stability towards metal, metal ions, sunlight, and at room and elevated temperatures