



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

JUL 30 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Addendum to Residue Data for Captan Seed Treatments; EPA
Reg. No. 10182-293; MRID No. 414684-01; DEB No. 6691

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ICI Americas, Inc. has submitted an addendum to residue studies previously submitted (MRID Nos. 411491-01 through -04 and 413061-01 and -02) in response to DEB comments (C. Olinger 10/6/89, 1/29/90). Magnitude of residue studies for captan seed treatments were required in the Data Call-In notice of April 29, 1985. The requirements, as specified in the DCI are as follows:

"EPA requires residue data for captan and THPI for representative crops to support low level tolerances covering seed treatments. Residue data for crops grown from treated seed must be submitted for corn, soybeans, potatoes, rice or a small grain, and two of the vegetables having seed treatments."

Based on the Use Index information compiled for the Registration Standard, captan formulations are registered for use as slurry, dry, seed piece (potato), and/or planter box seed treatments at a variety of rates and formulations. The following commodities have registered uses of captan seed treatments (DEB is not aware of any cancellation of any of these uses): alfalfa, barley, beans, beets, broccoli, Brussel sprouts, cabbage, cantaloupe, carrots, cauliflower, clover, collards, sweet corn, field corn, cotton, cucumber, eggplant, flax, grasses, kale,

lentils, lespedeza, millet, muskmelons, mustard, oats, okra, onions, peanuts, peas, pepper, potato (seed piece), pumpkins, radishes, rape, rice, rutabagas, rye, safflower, sesame, sorghum, soybeans, spinach, squash, sugar beets, sunflower, Swiss chard, tomatoes, trefoil, turnips, watermelons, and wheat.

Conclusions

1. The deficiencies regarding the beet top and wheat forage storage stability studies have been resolved. Captan and THPI residues are stable for 8 mos. in beet tops and 6 mos. in wheat forage. Sufficient data are available supporting the use of captan as a seed treatment on sugar beets.
2. Additional storage stability data have been presented for corn grain and several other commodities. In the absence of detailed study information, DEB cannot provide conclusions regarding the storage stability of captan and THPI on corn grain.
3. DEB reserves judgement on translation of storage stability of other RAC's to wheat grain until the final storage stability studies are reviewed.
4. The deficiencies regarding the soybean seed treatment magnitude of residue studies have been resolved. Sufficient data are available supporting the use of captan as a seed treatment on soybeans.

Recommendations

Deficiencies regarding magnitude of residue data for seed treatments using captan have not been completely resolved as outlined in items two and three above. Specifically deficiencies from the supporting storage stability data for wheat and corn grain need to be addressed. The Captan Task Force should submit the complete results from the final storage stability studies 2 and 3. Interim results have been previously reviewed by DEB (L. Probst 12/19/89). Once this information has been received and reviewed favorably DEB should be able to consider the seed treatment data requirements completed. Currently the seed treatment residue data requirements are satisfied for soybeans, beets, spinach, and potatoes. (Refer to memorandum by N. Gray 4/22/88 for potato seed piece data.)

Based on the residue data submitted DEB could recommend for the following new tolerances for captan and its metabolite tetrahydrophthalimide at a level of 0.1 ppm (the combined limits of determination) if proposed by the Captan Task Force: cotton, flax, lentils, okra, peanuts, radishes, rape, safflower, sesame,

sugar beets, sunflowers, and Swiss chard. DEB could recommend for a **reduction** in tolerances for captan and its metabolite tetrahydrophthalimide for the following commodities to 0.1 ppm from established levels if proposed by the Captan Task Force: beets, broccoli, Brussel sprouts, cabbage, cantaloupe, carrots, cauliflower, collards, cotton, cucumber, eggplant, honeydew melon, kale, muskmelon, mustard greens, onion (dry bulb), onion (green), pea, pepper, pumpkin, rutabaga, soybean, spinach, squash, tomato, turnip, and watermelon. Interim tolerances have been established for beans and potatoes. DEB could recommend for reduction of the tolerances for captan and its metabolite tetrahydrophthalimide to 0.1 ppm for beans and 0.5 ppm for potatoes (N. Gray 4/22/88). DEB will reserve judgement on proposing new tolerances, or reducing established tolerances, on the following commodities until the requested storage stability data outlined above have been submitted: alfalfa, barley, clover, grasses, lespedeza, millet, oats, rice, rye, sorghum, trefoil, and wheat.

Detailed Considerations

Deficiencies are restated below along with the registrant's response.

Deficiency #3, (C. Olinger 10/6/89)

"Storage stability data covering the samples analyzed here are sufficient for most crops. However additional information is needed for corn grain and beet tops."

Deficiency 3b, (C. Olinger 1/29/90)

"Insufficient information regarding the wheat forage stability study was provided to conclusively determine the maximum stability interval. No THPI stability data are available."

Deficiency 3c, (C. Olinger 1/29/90)

"No stability data are available for wheat grain. The registrant's intention to translate corn grain data is not appropriate."

Registrant Response

The registrant has provided the protocol used in the storage stability study on beet tops and wheat forage. Because the analytical method specifies maceration on the day of the extraction, the RAC was coarsely chopped while frozen and fortified with standard solution while the sample container was setting on dry ice. The fortified samples were stored frozen prior to analysis. Treated samples were stored frozen.

The THPI results reported were expressed as captan equivalents for the wheat forage stability samples. This was not specified in the original data submitted.

The registrant has provided additional storage stability data for corn grain. They claim stability on corn grain for up to 12 months, showing 92% recovery for captan (expressed as captan equivalents) and 92% recovery for THPI.

The registrant cited additional data showing stability through 12 months for several RAC's and processed products. Based on the demonstrated stability on RAC's in 9 different crop groupings, the registrant believes these data should support the magnitude of residue study for wheat grain, the samples from which were stored for 3 months prior to extraction. The data used to support their discussion is summarized below.

<u>Commodity or Processed Product</u>	<u>Study</u>	<u>Interval (months)</u>	<u>Captan % Recovery*</u>	<u>THPI % Recovery</u>
Almonds	3	12	73	90
Apples	1	14	111	-
Apples	3	12	71	79
Apple juice	2	15	91	-
Applesauce	3	9	70	76
Cherry	2	12	78	-
Corn Grain	3	12	92	92
Cucumber	1	14	83	-
Grape Dry Pomace	3	12	70	89
Potatoes	2	15	67	-
Potatoes	3	12	74	80
Raisins	3	12	75	77
Spinach	3	12	87	94
Strawberry	1	14	81	-
Tomatoes	2	12	79	-
Tomatoes	3	12	87	74
Tomato Dry Pomace	3	12	87	82
Tomato Sauce	3	12	72	87

*Reported as captan equivalents.

The data above are from storage stability studies for commodities which were not chopped or processed prior to storage.

DEB Comments

The description of the sample preparation, storage, and analysis of the beet top and wheat forage stability studies is adequate. Based on the original study data and this addendum, it can be concluded that the stability of captan and THPI in beet tops is 8 months and wheat forage, 6 months.

The registrant has presented additional data for corn grain. Since the raw data have not been included in the subject addendum DEB cannot concur with the registrants conclusion that captan and THPI residues are stable in corn grain for 12 months.

Storage stability studies were previously reviewed by DEB (L. Probst 12/19/89). The data reviewed showed wide variation in

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storage stabilities, and it appeared that the extent of the degradation depended upon the RAC and the extent to which it had been processed. Some of the data presented were interim results, and had only been stored three months. Based on the information available, the reviewer concluded a storage stability of 3 months for several commodities and processed products.

ICI has included a data table in their submission listing the storage stability for these RAC's or processed products as 12 months. DEB cannot concur with these storage stability intervals until the complete study has been reviewed. Noticeably absent from this list are soybean grain, which DEB had concluded a stability of only 3 months, and data for commodities which had been processed prior to fortification such as almonds, corn grain, and spinach.

DEB reserves judgement on translation of the storage stability data from numerous RAC's to wheat grain. The final storage stability report from studies 2 and 3 will have to be reviewed. From a preliminary review (of the data table in the addendum) it appears that commodities which have not been macerated prior to being placed into storage demonstrate greater stability. Since treated samples were not macerated prior to storage, storage stability data from the fortified whole commodities are probably more representative of the storage conditions. DEB will consider translation of data from the other RAC's once the final reports are reviewed and if it concurs with the storage stability intervals that the registrant has proposed.

Deficiency 4a, (C. Olinger 1/29/90)

"No residues were detected in soybean forage when seeds were treated at the maximum application rate. The data are not adequate since the interval between treatment and planting was unacceptably long."

Registrant Response

The registrant states that the report incorrectly listed the treatment for the 1988 trial seed rather than the 1989 seed. The seeds used in the 1989 field trials were treated in 1989 at a rate of 2.5 fl. oz./cwt. with Captan 400, the maximum application rate. This is equivalent to a theoretical rate of 780 ppm captan. ICI analyzed the treated seed for captan and THPI and found the seed used in the North Carolina trial contained 775 ppm captan and 8.9 ppm THPI while the seed used in the Illinois trial contained 820 ppm captan and 9.5 ppm THPI.

DEB Comments

The registrant has adequately addressed this deficiency. The interval between treatment and planting was appropriate. Detectable residues of captan and THPI in/on soybean forage are not

expected when soybean seed is treated at the maximum application rate. Sufficient data are available supporting the use of captan as a seed treatment on soybeans.

cc: CLOlinger (DEB), Circulate (7), Reg. Std. File, RF, SF,
RDSchmitt, C. Peterson (SRRD), C. Furlow (PIB/FOD)
H7509C:DEB:CLOlinger:clo:CM#2:Rm 803C:557-1406: 7/27/90
RDI: ARRathman: 7/30/90 EZager: 7/30/90