



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

July 28, 1999

MEMORANDUM

SUBJECT: TPTH: DETERMINATION OF RESIDUES IN AGED FIELD SAMPLES OF SUGAR BEET LEAVES AND INTERIM REPORT OF STORAGE STABILITY STUDY OF RESIDUES IN FORTIFIED SUGAR BEET LEAVES. MRIDs: 44840501 and 44840502; Reregistration Case: 0099; PC Code: 083601; DP Barcode: D256821.

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INTRODUCTION

Previously, HED determined that the Task Force needed to conduct a required two-year frozen storage stability study for the raw agricultural commodity (RAC) sugar beet leaves in support of sugar beet field trials. The Task Force submitted a study determining TPTH residues and its metabolites (MPTH and DPTH) in aged field samples of sugar beet leaves (MRID# 44840501) and an interim report for determining storage stability of TPTH (and metabolites) in sugar beet leaves (MRID# 44840502). The interim report was submitted for data generated up to and including the 6 month interval. Completed frozen stability data for TPTH is to be submitted to the Agency no later than April 10, 2000.

CONCLUSIONS

MRID: 44840501

Data indicate that total TPTH related residues in field trial samples originally analyzed in 1995 were stable under frozen storage for an additional 35 months at - 20 C in the dark.

MRID: 44840502

The data indicate that total TPTH residues are stable for up to 219 days at - 20 C in the dark. The registrant stated that further samples will be removed from storage and analyzed after 12, 18 and 24 months. Until the analyzed data from 6-24 months is submitted to the Agency for evaluation, guideline 830.1380 is still considered a deficiency. Frozen stability data for TPTH on sugar beet leaves should be submitted to the Agency no later than April 10, 2000.

DETAILED CONSIDERATIONS

MRID: 44840501 (Residues of TPTH and Metabolites in Aged Field Samples)

Samples were taken from 1993 field trials in order to determine the total TPTH related residue levels in samples of sugar beet leaves that were stored at approximately -20 C after harvest in order to obtain data on the storage stability of TPTH and its organotin metabolites in/on aged field samples. Samples were originally analyzed under analytical phase number PWT 1995 in 1995 at Huntingdon Life Sciences. Six samples, containing a range of TPTH levels, were selected for study. The GC analytical method was validated for sugar beet leaves at Huntingdon. The LOQ for total TPTH related residues was 0.03 ppm.

Procedural recoveries were analyzed concurrently with test samples; recoveries of the samples are shown in Table# 1.

Table #1. Procedural Recovery of TPTH (expressed as TPTH equivalents) in Aged Sugar Beat Leaves (RAC) .

Huntingdon Reference Number	Nominal Fortification Level of Total TPTH (ppm)	% Recovery
K95/0883	1.50	71
K95/0883	15.0	65

Mean: 68%

Table #2 shows the residues determined in aged sugar beet leaves (RAC) along with the residues determined originally. The results are corrected for procedural recovery.

Table #2. TPTH Residues in Aged Sugar Beet Leaves.

Lab Reference Number ¹	Storage Period (days) ²	From Study PWT 119			From this Study			% of Original Assay
		Observed Residue Level (ppm, as TPTH)	Mean Procedural Recovery (%)	Corrected Residue Level (ppm, as TPTH)	Observed Residue Level (ppm, as TPTH)	Mean Procedural Recovery (%)	Corrected Residue Level (ppm, as TPTH)	
K95/0894	1058	5.27	66	7.98	4.18	68	6.15	77
K95/0907	1058	3.74	66	5.67	3.72	68	5.47	96
K98/0292	1064	7.16	70	10.2	7.06	68	10.4	102
K98/0296	1064	9.08	70	13.0	7.87	68	11.6	89
K98/0301	1058	4.08	66	6.18	4.69	68	6.90	112
K98/0303	1064	11.3	70	16.1	12.2	68	17.9	111

¹New reference numbers from original numbering.

² Time period between study PWT 119 and this study.

These data indicate that residues did not decline 35 months after the original analysis (1995).

MRID: 44840502 (Interim Report: 0-6 months)

This interim report detailed the results obtained for the determination of the storage stability of TPTH (and DPTH and MPTH) in sugar beet leaves up to and including the 6 month interval and for the analytical method used. After 12, 18 and 24 months, further samples will be removed from storage and analyzed.

Samples of untreated sugar beet leaves were fortified with TPTH and its metabolites DPTH (in a dichloride form) and phenyltin hydroxide (in a trichloride form) stored in the dark at approximately -20 C. Samples were removed from storage after 0 days, and at 3 and 6 months. Samples were analyzed concurrently with samples fortified immediately prior to analysis.

The analytical work was performed by a section of Huntingdon Life Sciences Ltd in Huntingdon, England; the method of analysis was validated at Huntingdon under study number PWT 115. The LOQ for total TPTH related residues was 0.03 ppm.

Procedural recoveries from the samples are shown in Table #3; the mean recovery was 71%.

Table #3. Sugar Beet Recovery Data.

Huntingdon Reference Number	Nominal Fortification Level (Total TPTH, ppm)	Recovery (%)
K98/0387	9.0	67
K98/0387	9.0	72
K98/0387	9.0	74
K98/0387	9.0	76
K98/0387	9.0	66
K98/0387	9.0	68

Mean: 71%

Standard Deviation: 4.1%

Coefficient of Variation: 5.8T

Storage stability data are shown in Table #4. The results are corrected for control and procedural data.

Table #4. Storage Stability of TPTH in Sugar Beet Leaves (RAC).

Huntingdon Reference Number and Identity	Observed Residue Level (ppm)	Storage Period	Recovery in Freshly Fortified Sample		Recovery in Stored Sample (%)	Corrected Recovery in Stored Sample (%)
			(%)	Mean (%)		
Control	0.004	0 days	-	-	-	-
C + 9.05ppm 'Fresh' A	6.08	0 days	67	70	-	-
C + 9.05ppm 'Fresh' B	6.55	0 days	72	70	-	-
C + 9.05ppm 'Stored' A	6.62	0 days	-	-	73	104
C + 9.05ppm 'Stored' B	6.31	0 days	-	-	70	100
C + 9.05ppm 'Stored' C	6.37	0 days	-	-	70	100
Control	0.013	115 days	-	-	-	-
C + 9.79ppm 'Fresh' C	7.28	115 days	74	75	-	-
C + 9.79ppm 'Fresh' D	7.47	115 days	76	75	-	-
C + 9.05ppm 'Stored' A	6.84	115 days	-	-	75	100
C + 9.05ppm 'Stored' B	7.08	115 days	-	-	78	104
Control	0.018	219 days	-	-	-	-
C + 8.82ppm 'Fresh' A	5.88	219 days	66	67	-	-
C + 8.82ppm 'Fresh' B	6.03	219 days	68	67	-	-
C + 9.05ppm 'Stored' A	6.48	219 days	-	-	71	106
C + 9.05ppm 'Stored' B	6.25	219 days	-	-	69	103

The data from MRID 44840502 indicate that total TPTH residues are stable for up to 219 days at approximately -20 C in the dark. Data from 6-24 month intervals is forthcoming by the TPTH Task Force. Guideline requirement 830.1380 is considered a deficiency until the 6-24 month interval storage stability data is submitted, reviewed, and deemed acceptable by the Agency.

cc: S. Levy 7/28/99 (RRB3), S. Knizner 7/28/99 (RRB3)

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003294

Chemical:	Fentin hydroxide
PC Code:	083601
HED File Code	11000 Chemistry Reviews
Memo Date:	07/28/99
File ID:	DPD256821
Accession Number:	412-01-0084

HED Records Reference Center
01/23/2001