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

SEP 1 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Memorandum

Subject: Triphenyl Tin Hydroxide (TPTH): Amendment to 056227; Submitted in response to RCB memo of 9-4-86 (S. Hummel); MRID Nos. 401494-01 and 401494-02, RCB No. 2213.

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Thru: Edward Zager, Section Head
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With this amendment the registrant, M&T Chemicals Inc., has responded to several deficiencies cited in RCB's review of 9-4-86 (S. Hummel). The registrant's responses are detailed in two studies, entitled:

1. Triphenyltin Hydroxide - Responses to Question in the EPA Letter dated September 24, 1986 (Jacoby to Shelton). MRID No. 401494-01; and

2. Triphenyltin Hydroxide - Separation and determination of Phenyltin Species (C_aSnX_{4-a}) in Beef, Milk, Eggs and Poultry by Liquid Chromatography/Atomic Absorption Spectroscopy. MRID No. 401494-02.

The deficiencies outlined in our review of 9-4-86 are listed below, followed by the petitioner's response and RCB's comments.

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Deficiency 1:

According to the Registration Standard, the TPTH metabolites, diphenyltin oxide and monophenylstannoic acid should be included in the tolerance expression. We recommend that they be calculated as TPTH equivalents.

Registrant's Response:

The registrant has provided numerical factors (Mol. Wt. of TPTH/Mol. Wt. of Metabolite) for conversion of each metabolite to its corresponding TPTH equivalent, i.e:

diphenyltin oxide x 1.2704 = TPTH Equivalent

monophenylstannoic acid x 1.6041 = TPTH Equivalent

In addition the registrant has recalculated, as TPTH equivalents, previously submitted residue data for diphenyltin oxide and monophenylstannoic acid in or on sugar beets, carrots, peanut hulls, potatoes, and soybeans.

RCB's Comment:

We conclude that deficiency 1 has been resolved.

Deficiency 2:

The feeding restriction for peanut hulls is impractical and should be removed from the label.

Registrant's Response:

The registrant responded by citing RCB's previous review of a study protocol for TPTH residue field trials and storage stability (ID#18120, RCB No. 799, R. Loranger memo of 6-21-85). The applicability of that review to deficiency 2 was not specifically stated by the registrant.

RCB's Comment:

R. Loranger states in his 6-21-85 review, "The peanut protocol does not mention analysis of hulls and vines/hay. Analysis of the latter may be avoided by imposing a feeding restriction on the TPTH labels. Hulls must be analyzed since they are not under the control of the grower (i.e., not subjected to feeding restrictions)."

We conclude that deficiency 2 has not been resolved and reiterate our previous position, i.e., feeding restrictions for peanut hulls are impractical and should not appear on the label. Peanut hulls are not under the control of the grower. Additional labeling changes are needed as well. The label must state a maximum number of applications

of TPTH per season for each crop. Alternatively, residue data reflecting the maximum theoretical number of applications may be submitted. A tolerance for TPTH residues in or on peanut hulls has been established.

Deficiency 3:

The validation results included in this submission are in sharp contrast to the previously submitted validation data which showed residues in control samples approximately five times the level of residues in samples fortified at 50 ppb. The major change in the method is length of the fraction collected (reduced from three minute fractions to one minute fractions being collected). This major discrepancy must be explained.

Registrant's Response

The registrant cites tin contamination of reagents (dibasic sodium phosphate) and glassware (disposable glass culture tubes) as the reason for the high control values reported during the validation of Method TA-45. These contamination sources were eliminated during subsequent validation of methods TA-46, 47, and 48.

RCB's Comment:

The registrant's explanation of the high tin background and subsequent reduction of that background is supported by validation data provided in connection with methods TA-46, 47, 48, and 49.

We conclude that deficiency 3 is resolved.

Deficiency 4:

No data were submitted to demonstrate that other organotin pesticides will not interfere in this determination. These data are needed. Vendex [hexakis(B,B-dimethylphenethyl)-distannoxane] has a tolerance for residues on pecans. Both Vendex and cyhexatin (Plictran) have tolerances for residues on meat commodities.

Registrant's Response:

The registrant submitted HPLC chromatograms for Plictran (including its di- and monocyclohexyl metabolites) and Vendex. Using the HPLC parameters of the most recent versions of the method (not specifically stated), the retention times were:

Compound	HPLC Retention Time
Cyhexatin	113 minutes
dicyclohexyl metabolite	88 minutes
monocyclohexyl metabolite	68 minutes
Vendex	49 minutes

The registrant further states that since all TPTH chromatograms were less that 35 minutes, interferences from Plictran and Vendex residues are unlikely.

RCB's Comment

The HPLC retention times for TPTH and its metabolites as reported in Method TA-49 (Accession 266045) are:

Compound	HPLC Retention Time
ϕ_4Sn	5-6 minutes
ϕ_3SnOH	7-8 minutes
ϕ_2SnO	9-10 minutes
ϕ_1SnOOH	11-13 minutes
Bu_4Sn	19-21 minutes

Residues of Plictran and Vendex should not interfere with the HPLC assay of TPTH.

We conclude that deficiency 4 is resolved.

Deficiency 5:

This method (Method TA-45) would not be suitable for the analysis of TPTH and its metabolites in meat, milk, poultry, and eggs, since a base hydrolysis step has not been included. An analytical method for the analysis of TPTH and its metabolites in meat, milk, poultry, and eggs is still needed.

Registrant's Response

The registrant has submitted a method entitled:

Triphenyltin Hydroxide - Separation and Determination of Phenyltin Species ($\phi_a SnX_{4-a}$) in Beef, Milk, Eggs, and Poultry by Liquid Chromatography/Atomic Absorption Spectroscopy (M&T Method TA-50) (MRID No. 401494-02).

In addition the registrant states that extraction experiments indicate that a base hydrolysis is neither required nor beneficial with regard to the extraction of bound residues.

RCB's Comment

M&T Method TA-50 is similar to M&T Methods TA-43, TA-45, TA-46, TA-47, TA-48, and TA-49; these methods differ only in their sample workups, which are optimized for specific sample types. Methods TA-43 through TA-48 were previously reviewed by S. Hummel (TPTH S.F., memo of 9-4-86), and Method TA-49 by F. Suhre (TPTH S.F., memo of 5-1-87).

M&T Method TA-50 is applicable for assaying triphenyltin hydroxide, its degradation products (tetraphenyltin, diphenyltin oxide and phenylstannoic acid), and inorganic tin (as tetrabutyltin). 50 grams of chopped sample are extracted with 100 mL of tetrahydrofuran (THF) containing 0.01 g tartaric acid. Following filtration the sample is re-extracted (2x) with 50 mL of THF. The combined THF extract is passed through an alumina column (6 g) and the column eluent is concentrated to ca 10 mL. Tin compounds present in the concentrate are then converted to their corresponding tetraorganotin species by reacting with BuMgCl. Triphenyltin hydroxide (ϕ_3SnOH) converts to triphenylbutyltin (ϕ_3SnBu), diphenyltin oxide (ϕ_2SnO) converts to diphenyl dibutyltin (ϕ_2SnBu_2), phenyl stannoic acid ($\phi SnOOH$) converts to phenytributyltin ($\phi SnBu_3$), and inorganic tin (Sn) if present is converted to tetrabutyltin (Bu_4Sn). Tetraphenyltin (ϕ_4Sn) if present will remain as tetraphenyltin since it is already in the tetraorgano form. After conversion, the organotins are separated by reverse phase HPLC (C-8) and their respective fractions (1.5 mL) are collected and assayed for elemental tin by Graphite Furnace Atomic Absorption Spectroscopy. The method's limit of sensitivity is reported to be 0.05 ppm. Validation data (limits of sensitivity and recovery) reflecting fortification of control samples of meat, milk, poultry and eggs were not provided.

We conclude that deficiency 5 has only partially been resolved. Validation data reflecting fortification of meat, milk, egg, and poultry samples at appropriate levels are required. Furthermore, the registrant did not provide experimental data to support the contention that a base hydrolysis is neither required nor beneficial with regard to the extraction of bound residues. These data must be provided.

Deficiency 6:

The storage stability study included in this submission clearly shows that residues degrade rapidly when samples are stored at room temperature, although we question the calculations. The residue profile changes with time so that even if the residue analyses in this submission were done within three days of harvest, they would not be acceptable.

We suggest that samples be stored frozen from harvest until analysis. Another storage stability study will be needed using frozen samples. The conditions used in the storage

stability study should be the same as those used for the storage of the samples from harvest until analysis. Storage stability data are needed from soybeans or peanuts and from a root crop.

Registrant's Response

The registrant states that the storage stability study for soybeans was performed on samples stored at room temperature but that samples A through G on pages 61b, 62, and 63 of the validation report for Method TA-46 (Accession No. 263222) reflect a timed study on frozen samples. The registrant did not address the issue of a storage stability on a root crop.

RCB's Comment:

The residue data (samples A through G) as presented on pages 61b, 62, and 63 of the validation report for M&T Method TA-46 (Accession No. 263222) do not fulfill the criteria of a storage stability study. The criteria for a storage stability study are discussed in § 171-4 (c)(1)(ii) of the Residue Chemistry, Pesticide Assessment Guidelines, Subdivision O, as follows:

"Accepted procedures for maintaining sample integrity should be followed after taking the sample. Normally samples should be frozen as soon as possible and kept frozen until analysis. Information should be furnished on how samples are shipped and stored until analyzed. If samples are likely to be held in storage, storage stability data should be obtained by fortifying control samples, and analyzing at the end of the storage period. It is always advisable to have spiked storage stability samples available to allow for unforseen delays in analysis, and to verify results of analysis of check samples should reanalysis be necessary to verify possibly aberrant results."

Samples should be analyzed at the begining and end of the storage period and perferably at several intermediate times.

There is no sample history for samples A-G. There is no indication that samples A-G are fortified controls. In fact, there are 3 sets of samples A-G which appear to correspond to untreated controls and 2 levels of treated samples. There is no indication that the samples were analyzed more than once. The dates of analysis are missing.

In addition, the registrant needs to provide storage stability data on a root crop.

We conclude that deficiency 6 has not been resolved.

Deficiency 7:

Complete residue data should include field trials from all major growing areas for the crop and represent all typical growning seasons. The pesticide should be applied at the maximum registered or proposed rate, with maximum number of applications allowed per season. The crop should be harvested at the minimum PHI allowed on the label. Data for all types of applications allowed on the label should be made(ground, aerial, etc.). Exaggerated rate data may be needed.

Complete information on the field trials would include
- identification of responsible personnel from planting through writing the final report

- the type and variety of crop
- the formulation used, the formula, the EPA Reg. No., the percent active ingredient, and lbs. ai./gal if appropriate.
- the type of formulation used (WP, EC, G, etc.)
- any adjuvants or other pesticides used
- size of field trial plots
- developmental stage and general condition of the crop at harvest
- method of harvest
- method of assuring random, representative samples
- date of planting, pesticide application; number and timing of applications
- complete information on sample handling from harvest to the laboratory to analysis
  - details of any compositing or subsampling
  - were the samples trimmed, cleaned, etc. ?
  - condition of storage from harvest until shipping (temperature, humidity, etc.)
  - shipping container type, size, etc.
  - method of shipping, ambient or ice, etc.
  - dates samples entered storage in laboratory
  - any compositing or subsampling
- description of quality control measures

Details needed for evaluation of residue data are outlined in "Hazard Evaluation Division Standard Evaluation Procedure: Magnitude of the Residue: Crop Field Trials." We suggest that the registrant obtain a copy of this document through NTIS.

We note that residues for some fractions, where the signal is clearly more than the limit of detection (twice the standard deviation of the background), have not been calculated. This discrepancy should be explained.

Registrant's Response

The registrant has provided information with regards to handling samples from harvest to the laboratory to analysis, as folows:

- details of any compositing or subsampling

  Not discussed

- were the samples trimmed, cleaned, etc. ?

  All samples received were trimmed but not cleaned. Before analysis, samples were washed thoroughly with distilled water and chopped in an Osterizer blender to give sample uniformity

- condition of storage from harvest until shipping (temperature, humidity, etc.)

  Not discussed

- shipping container type, size, etc.

  All crops were received by M&T's Shipping Department packed in a "Lo Boy" thermal chest, packed with dry ice. "Lo Boy" is a product of Magna Mfg. Inc.; it is 9 1/4" deep, 20 3/4" long, and 13" wide.

- method of shipping, ambient or ice, etc.

  Dry ice

- dates samples entered storage in laboratory

  Day of receipt, the date of receipt for samples of pecans, potatoes, peanut and peanut hulls, sugar beets, carrots and soybeans were provided.

- any compositing or subsampling

  Not discussed

Regarding RCB's concern over apparent residues (fractions where the signal is clearly more than the limit of detection) not reported; the registrant states that residue levels in these samples are above the method's limit of detection but fall below the reliable detection limit of the method.

In addition to providing the above information, the registrant states that additional data will be submitted (Volumes I-IV) by Griffin Corp. These volumes consist of protocols and sample histories for field residue trials (peanuts, sugar beets,

pecans, potatoes, and carrots), and as such address many of the concerns expressed in deficiency 7. The Griffin Corp. submission (volumes I to IV) has been received by RCB and is currently in review.

RCB 's Comment:

We conclude that deficiency 7 is only partially resolved. Deficiency 7 will be discussed in our Review of the data submitted in Volumes I-IV, as cited above. Trimming and washing of samples should not be done. Samples should be rinsed only to remove surface soil.

Deficiency 7a.:

Residue data on soybeans are needed from geographically representative areas where soybeans are grown (refer to Agricultural Statistics). Data are needed from IL/IN, MN/IA, MD/AK, MI/OH, NE/KS, KY/TN, AL/MS/GA, and TX/LA.

No data were submitted on soybean processed fractions. These data are needed since finite residues are found on soybean grain. These fractions are meal hulls, soapstock, and crude and refined oil.

Registrant's Response:

The registrant states that the residue data provided for soybeans (Accession No. 263226) were solely for the purpose of validating the analytical method, and that additional residue data are currently being generated and will be submitted at a later date.

RCB 's Comment:

Deficiency 7a. was based on our assumption that the residue data provided in submission 263222 were meant to fulfill the data requirements for field trials on soybeans. This apparently was not the case. We note that the tolerance for soybeans is still pending.

Deficiency 7a. has not been resolved.

Deficiency 7b.:

The geographical representation of the carrot data appears to be adequate. However, residue data are needed reflecting multiple applications made every seven days beginning 6 weeks after planting. Data reflecting both ground and aerial application are needed.

Registrant's Response:

The registrant cites residue field studies being submitted by Griffin Corporation (Volume V 171-4 Residue Chemistry-Triphenyltin Hydroxide Protocols and Field History for Residue Field Trial on Carrots).

RCB's Comments

The residue field trials on carrots were poorly documented in the initial submission (Accession No. 263218). A study entitled: Triphenyltin Hydroxide - Protocols and Field History for Residues Field Trials on Carrots, has been recently submitted and is under review. This report appears to contain much of the required supporting data for the carrot field trials.

Conclusions concerning resolution of deficiency 7b will be discussed in connection with the review of the above referenced material.

Deficiency 7c.:

Even if the potato data are later determined to be acceptable, additional data are needed for spring/summer potatoes from FL, NC/VA, and CA. Data from ME, ND, WA, and ID will be sufficient for winter potatoes.

If finite residues are found in potatoes treated at exaggerated rate equal to the theoretical concentration factor for potatoes processing fractions, a potato processing study will be needed. Potato processed fractions are potato granules, potato chips, and dried potatoes.

Registrant's Response:

The registrant responded by stating that protocols which included geographic representation were submitted to the Agency and subsequently approved (R. Loranger, memo dated 6-21-85). Furthermore, that a potato processing study was not conducted since there were no detectable finite residues found at exaggerated application rates.

RCB's Comment:

The following comments regarding potatoes appear in RCB's (R. Loranger memo of 6-21-85) review of proposed field study protocols:

8. We concur with NE, NC, and NW regions to be included in the potato trials. Likely choices are ME, ND, ID, and WA.

10. For potatoes we note that the processed commodities to be analyzed are potato chips and either flakes or granules.

Agricultural Statistics (1985) categorized total U.S. potato production during 1984 on a seasonal basis as follows:

Winter	0.66%
Spring	5.5%
Summer	5.6%
Fall	88.25%

The states of ME, ND, WA, and ID accounted for 62% of the fall/winter potato harvest or 55% of the total US potato harvest, while FL, CA, NC, and VA accounted for 52% of the spring/summer potato harvest or 6% of the total US potato harvest.

Based on these statistics we conclude that potato field trials conducted in ME, ND, WA, and ID should be adequate, provided the maximum application rate and minimum PHI are the same for treated potatoes harvested in spring/winter and summer/fall.

Regarding the requirement for a potato processing study, if no residues are found on a raw agricultural commodity resulting from a residue field trial treated at the theoretical concentration factor or up to 5x, then no feed/food processing studies are required. The theoretical concentraction factor can be calculated by dividing the amount (weight or volume) of the processed commodity into the the amount of raw agricultural commodity from which it was produced. The largest theoretical concentration factor for a processed commodity used for food or feed is the minimum number by which the use rate must be multiplied to determine the acceptable exaggerated rate. Experience indicates that exaggerated rates above 5x are not useful in reflecting the normal residue burden on a crop.

A 2x exaggerated rate is not sufficient to waive the requirement of a potato processing study.

We concluded that deficiency 7c is partially resolved. ME, ND, WA, and ID provide adequate geographical representation of potato production in the US, provided the maximum application rate and minimum PHI are the same for treated potatoes harvested in spring/winter and summer/fall. However, an exaggerated field treatment rate of 2x is not adequate to waive the requirement of potato processing studies.

Deficiency 7d:

The sugar beet data appears to have adequate geographic representation.

If finite residues are found in sugar beets treated at an exaggerated rate equal to the theoretical concentration factor for sugar beet processing fractions, a sugar beet processing study will be needed. Sugar beet processed fractions are pulp, molasses, and refined sugar.

Registrant's Response:

The registrant states that residues of TPTH in sugar beets treated at exaggerated rates were below the analytical method's limit of detection.

RCB's Response:

Sugar beet residue data previously submitted (Accession No. 263221) reflect application rates of 1x and 2x.

An exaggerated application rate of 2x is not adequate to waive the requirement of a sugar beet processing study (See RCB's comment under deficiency 7c.).

We conclude that deficiency 7d. has not been resolved.

Deficiency 7e:

Even if the peanut hull data are later determined to be adequate, additional data are needed from TX. For adequate geographical representation, residue data are needed from AL/GA, NC/VA, and TX.

No residue data for peanut nut meats were submitted. These data are needed. No peanut processing study was submitted. These data are needed if finite residues are found in peanuts treated at exaggerated rate equal to the theoretical concentration factor for peanuts processing fractions, a peanut processing study will be needed. Peanut processed fractions are meal, soapstock, crude and refined oil.

Registrant's Response:

The registrant states that analytical methodology and residue data on peanut meat were submitted to the Agency ('Accession No. 266045).

RCB's Response:

A report describing analytical methodology plus TPTH residues on peanuts (meat) was recently reviewed (F. Suhre, memo of 5-1-87). Residue data from GA and VA reflects treatment at 1 and 2x the proposed application rate, no data were provided from TX, and no processing studies were included.

We conclude that deficiency 7e is only partially resolved. Residue data on peanuts (meat) were submitted, however, the data are not geographically representative of the peanut growing regions of the US. Field trials from TX are required. Furthermore peanut processing studies were not included. An exaggerated treatment rate of 2x is not adequate to waive the requirement of a peanut processing studies.

Deficiency 7f:

No residue data were submitted for pecans. These data are needed.

Registrant's Response:

The registrant states that analytical methodology and residue data on pecans were submitted to the Agency ('Accession No. 266046).

RCB 's Comment

A report describing analytical methodology plus TPTH residues on pecans was recently reviewed (F. Suhre, memo of 5-1-87), numerous deficiencies were cited.

We conclude that deficiency 7f (submission of pecan data) is resolved, provided the deficiencies cited in our review of those data are resolved (see, F. Suhre, TPTH S.F., memo of 5-1-87).

Deficiency 8

No conclusion can be made about residues in meat, milk, poultry, and eggs until deficiencies in the residue data are resolved.

Registrant's Reponse

The registrant did not specifically respond to this deficiency.

RCB 's Comment

We conclude that deficiency 8 is not resolved.

Conclusions

1. TPTH tolerances were initially established for the parent compound only. The Agency now considers the residues of concern in plants and animals to be intact TPTH, and its di- and monophenyltin hydroxides (or oxides). This conclusion appears in the TPTH Registration Standard. The registrant has now recalculated residue levels in terms of TPTH equivalents.

2. A current label for Supertin 4L must be provided, showing that the feeding restriction for peanut hulls has been removed. The label must include directions stating the maximum number of applications per season. Alternatively, residue data reflecting the maximum theoretical number of applications may be submitted.

3. Livestock feeding restrictions for peanut hulls are impractical and should not appear on the product label.

4. The organotin pesticides Plictran and Vendex should not interfere with the HPLC assay of TPTH and its di- and monophenyltin metabolites since their HPLC retention times are much longer than those of TPTH and its metabolites as analyzed.

5. We can draw no conclusions concerning the adequacy of Method TA-50, Separation and Determination of Phenyltin Species ($\phi_a SnX_4$-a) in Beef Milk, Eggs and Poultry by Liquid Chromatography/Atomic Absorption Spectroscopy (MRID No. 401494-02). The method was not adequately supported with validation data.

6. Methods TA-46 (soybeans), TA-47 (carrots potatoes, and sugar beets), TA-48 (peanut hulls), and TA-49 (peanut and pecans) appear to be adequate for assaying the TPTH residues of concern at 0.05 ppm in peanuts and pecans, and 0.01 ppm in carrots potatoes, sugar beets and soybeans. The registrant must submit a "non-confidential" copy of each analytical method so that a Method Try-Out (MTO) can be performed; ultimately methods must be available for enforcement of established tolerances.

7. Storage stability data to support soybeans, carrots, sugar beets, potatoes, pecans, and peanuts residue data are needed. Data on the storage stability of soybeans or peanuts and on a root crop would be sufficient to meet this requirement.

8 We can draw no conclusions concerning the adequacy of the residue field trials on peanuts, sugar beets, pecans, potatoes, and carrots until Volumes I-IV (see below), submitted by Griffin Corporation, are reviewed.

Vol. I - 171 4 Residue Chemistry - Triphenyltin Hydroxide Protocols and Field Histories for Residue Field Trials on Peanuts. (MRID No. 401493-01).

Vol. II - 171-4 Residue Chemistry - Triphenyltin Hydroxide Protocols and Field Histories for Residue Field Trials on Sugar beets. (MRID No. 401493-02).

Vol. III - 171-4 Residue Chemistry - Triphenyltin Hydroxide Protocols and Field Histories for Residue Field Trials on Pecans. (MRID No. 401493-03).

Vol. IV - 171-4 Residue Chemistry - Triphenyltin Hydroxide Protocols and Field Histories for Residue Field Trials on Potatoes. (MRID No. 401493-04).

Vol. V - 171-4 Residue Chemistry - Triphenyltin Hydroxide Protocols and Field Histories for Residue Field Trials on carrots. (MRID No. 401493-04).

This material is currently under review and will be discussed in our review of the Griffin submission.

9. We can draw no conclusions concerning the adequacy of the residue field trials on soybeans until additional data are submitted. The registrant states that the residue data provided for soybeans (Accession No. 263226) were solely for the purpose of validating the analytical method, and that additional residue data are currently being generated and will be submitted at a later date.

10. Processing studies (or a waiver from the requirement of a processing study) are required for soybeans, peanuts, sugar beets, and potatoes. Non-detectable residues at a 2X exaggerated rate is not sufficient to waive the requirement for processing studies. Treatment at an exaggerated rate equal to the theoretical concentration factor would be needed (and no residue detected).

11. We can draw no conclusions concerning secondary residues in meat, milk, poultry, and eggs until the deficiencies in the residue field trials, and the deficiencies in Method TA-50 for meat, milk, poultry and eggs have been resolved.

Recommendation

We recommend that the registrant (1) be informed of our comments; and (2) be advised to address all the unresolved deficiencies. We recommend that a copy of our review be sent to the registrant.

cc: R.F., Circu., F. Suhre, TPTH S.F., TPTH SRF (Hummel), Reg. Std. file, PMSD/ISB.
RDI:SH:8/31/87:RDS:9/1/87
TS-769:FBS:fbs:Rm.814:CM#2:557-1883:9/1/87