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EFGWB Out :

JUN 28 1993

To: Joanne Miller

Product Manager PM 23

Registration Division (H7505C)

From: Akiva D. Abramovitch, Ph.D., Head

Environmental Chemistry Review Section #3

Environmental Fate & Ground Water Branch/EFED (H7507C)

Thru: Henry Jacoby, Chief

Henry Jacoby, Chief
Environmental Fate & Ground Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of...

DP Barcode:	D183015		
Common Name:	Prodiamine	Trade name:	Endurance
Company Name:	Sandoz Agro, Inc.		
ID #:	055947-00041		
Purposa:	submission of leachin	g/adsorption/desorption	data on aged material

Type Product: Action Code: EFGWB #(s): Review Time:	herbicide	575	93-0001	
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Type Product: Action Code: FFGUR #/*).			1	
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STATUS OF STUDIES IN THIS PACKAGE: REQUIREMENTS:

STATUS

OF DATA

uideline #	MRID	Status ¹	
63-1	424832-01	U	

***************************************			16
			16
			16
			168
			165

¹Study Status Codes; ²Data Requirement Status Codes;

A=Acceptable U=Upgradeable C=Ancillary i=Invalid. S=Satisfied P=Partially satisfied N=Not satisfied R=Reserved.

1. CHEMICAL:

chemical name:

 N^3 , N^3 -Di- \underline{n} -propy1-2,4-dinitro-6-(trifluoromethy1)- \underline{m} -

phenylenediamine Prodiamine

common name: trade name:

Endurance

structure: **CAS #:**

29091-21-2 Shaughnessy #: 110201

NOZ

PHYSICAL/CHEMICAL CHARACTERISTICS are as follows:

physical state -- crystalline powder color -- dark yellow odor -- odorless m.p. -- 124-1250 C

vapor pressure -- 2.5 x 10⁻⁷ mm Hg at 25° C water solubility -- 0.05 ppm octanol/water coefficient (kow) -- 3.3 x 10⁴

- 2. TEST MATERIAL: described in DER
- 3. STUDY/ACTION TYPE: submission of data on leaching of soil-aged prodiamine
- 4. STUDY IDENTIFICATION:

Tong, R.T-M; Jain, R.; Moore, P.; and Atallah, Y. Soil Column Leaching of ¹⁴C-Prodiamine and its Soil Degradates. Performed and submitted by Sandoz Agro, Inc. Des Plaines, IL. project# 480425. dated 9/10/92, received EPA 9/21/92 under MRID# 424832-01.

5. REVIEWED BY:

> Typed Name: Title:

E. Brinson Conerly-Perks Chemist, Review Section 3 EFGWB/EFED/OPP

Organization:

6. APPROVED BY:

> Typed Name: Title: Organization:

Akiva Abramovitch

Section Head, Review Section 3 EFGWB/EFED/OPP

JUN 23 1993

7. CONCLUSIONS:

> The study is not acceptable at this time, because the material balance is not determinable from the data included in the report (unextractable material in the soil, in particular, was not included). It may be upgradeable if the additional information can be supplied. Prodiamine and its degradates do not appear to leach under the conditions of the experiment. A reference compound, alachlor, is mobile under the same conditions, as expected.

8. RECOMMENDATIONS:

> If possible, the applicant should resubmit the data in such a way that material balance may be easily discerned. It might be convenient to follow the same path as the fractionation scheme (figure 15), showing the relative amounts in each fraction.

9. **BACKGROUND:**

> Prodamine is a herbicide used to control the germination of grasses and broadleaf weeds in ornamentals and turf. Label directions indicate that it may be applied either to a cover crop (established turf) or to bare soil (around ornamental plants and in non-crop areas). The recommended label rate is up to 1.15 lb ai./A (1.15 ppm, 3" soil layer) per single application or 2.3 lb a.i./A/yr.

ENVIRONMENTAL FATE ASSESSMENT

The data requirements for the present uses of prodiamine have almost all been fulfilled by submission of data which were deemed acceptable when initially reviewed. It should be noted that some of these studies are more than ten years old. The one current data gap is that of mobility of aged material, reviewed in this document. These are not acceptable at this time but may be upgraded.

Available data on degradation, when considered in toto, depict a chemical which is relatively non-susceptible to most environmental degradative processes. In loam soil under aerobic conditions (t_k ca. 2 months), with one major degradate (prodiamine benzimidazole). A field dissipation study on turf indicates a t_k of a 1980 review, it is highly susceptible to photolysis in aqueous solution (t_k ca. 20 minutes). Although soil photolysis data are not required for current uses, an unacceptable study yields a t_k of 50-60 hours.

The parent is not mobile in laboratory studies; K_d values for adsorption were 19.5 for sand, 55 for silt loam, 182 for clay loam, and 399 for sandy loam, based on a 1980 review. Respective $K_{\rm qc}s$ were 19540, 10890, 9310, and 12860. Adsorption was clearly favored by high organic matter content. Neither parameter appeared to correlate with pH, but $K_{\rm qc}s$ were higher for sandier soils. The currently submitted (not acceptable, but upgradeable) data on aged material appears to support the conclusion that both parent and major degradate are not mobile, although specific quantities of material in leachate vs. soil could not be determined by this reviewer. The previously mentioned field study on turf also indicates that prodiamine is not mobile.

Fish bioaccumulation was significant (BCFs ca. 400 - 2000), and depuration was relatively slow (14 days).

GROUND WATER ASSESSMENT

Prodiamine is relatively persistent in the environment, based on the available field dissipation and other data. However, due to its lack of mobility, prodiamine does not appear likely to reach ground water. Though it is improbable that it would reach ground water, if it did, it would persist there, since photolysis, the major mode of degradation, would not occur. The mobility of the major degradate (prodiamine benzimidazole) also is low, and is described in the study report discussed in this review.

SURFACE WATER ASSESSMENT

Prodiamine does not appear to be a major threat to sunlight-exposed surface water since it photolyzes rapidly in water. Although the probability seems very low, any prodiamine which is present on soil affected by a runoff event could be carried on suspended particles to adjacent bodies of surface water. Once there, it would be expected to remain in the sediment and degrade/dissipate very slowly.

DATA BASE ASSESSMENT

The status of data requirements is as follows:

- <u>hydrolysis</u> -- <u>FULFILIED</u> 6/22/90 [Bowman and Fenessey, MRID #'s 406091-01 and 413594-01 -- $t_{1/2}$ > 6 months is indicated at all three pHs
- photolysis in water -- FULFILLED 5/13/80 [reference not indicated in that review] -- not done under current Guidelines. A short half life (ca. 20 min.) is indicated. The fulfilling study has not been rereviewed under current standards.
- soil photodegradation -- not fulfilled, but not required for present uses.
 For a full discussion of the status of this data requirement, see the attached previous review (7/20/92). Available data indicate a short half life (ca. 50-60 hours).

- aerobic soil metabolism -- FULFILLED 6/22/90 [Krueger and Butz, MRID #s 405934-24 and 413594-02]-- half-life ca. 2 mos, one major product
- anaerobic soil metabolism -- submitted study unacceptable as of 5/14/80,
 not required for this use

leaching/adsorption/desorption

PARENT -- FULFILLED 5/13/80 [reference not indicated in that review. A batch adsorption/desorption study (MRID 405934-25, which was probably not the fulfilling study) indicated K_d values of 19.5 to 399 for adsorption.

AGED MATERIAL -- not fulfilled -- The mobility of parent and primary degradate (prodiamine benzimidazole) is low, based on the study discussed in this review, and is described in detail in the study report discussed. The study is not acceptable at this time, but may be upgraded if the applicant can supply additional information to demonstrate an acceptable material balance. [Daly, MRID #s 405934-26 and 413594-03, previously reviewed, are not acceptable].

- turf terrestrial field dissipation -- FULFILLED 6/22/90 [Bade and Rosas, MRID# 413594-05] -- no leaching or significant dissipation noted.
- confined accumulation on rotational crops -- FULFILLED 5/14/80 [reference not indicated in that review] -- not done under current Guidelines -- not required for this use -- no significant accumulation except in root crops. Responsibility for this data requirement is now in HED.
- fish bioaccumulation -- FULFILLED by MRID# 417272-01 (reviewed 7/25/91), and additional data in MRID 405238-01. BCFs were 390 for fillet, 1200 for whole fish, and 2000 for viscera. Depuration was essentially complete in 14 days.
- 10. <u>DISCUSSION OF INDIVIDUAL TESTS OR STUDIES</u>: see DER
- 11. <u>COMPLETION OF ONE-LINER</u>: updated 1-liner attached
- 12. CBI APPENDIX: attached to DER

Hecewel July 1, 1993

DATA EVALUATION REVIEW 1

Study Type: leaching/adsorption/desorption -- aged material -- Guideline 163-1

II. Citation:

Tong, R.T-M; Jain, R.; Moore, P.; and Atallah, Y. Soil Column Leaching of ¹⁴C-Prodiamine and its Soil Degradates. Performed and submitted by Sandoz Agro, Inc, Des Plaines, IL. project# 480425. dated 9/10/92, received EPA 9/21/92 under MRID# 424832-01.

III. Reviewer:

> Typed Name: Title: Organization:

E. Brinson Conerly-Perks Chemist, Review Section 3 EFGWB/EFED/OPP

E.B. Coney- Fe es 6/23/93

IV. Conclusions:

The study is not acceptable as it stands, because material balance cannot be determined from the data provided. It may be upgradeable, if the applicant can provide the additional information, especially the unextractable material in the soil. At this time, it may be concluded that prodiamine and degradates do not appear to be mobile under the conditions of the experiment.

V. Materials and Methods:

ABSTRACT

The mobility of prodiamine (N², N³-Di-n-propyl-2, 4-dinitro-6-(trifluoromethyl)-1,3-benzenediamine) and 6-amino-benzimidzeole (6-amino-2-ethyl-7-nitro-1-propyl-5-trifluoromethyl-benzimidzeole) were characterized in Kenyon loam soil using the soil column method. The Kenyon loam soil is the same soil that was used for soil metabolism atody (MRID# 405934-24). This soil type was also used with aged and nonaged prodiamine to measure adsorption/desorption using the batch equilibrium method (MRID#s 405934-25, -25; 417272-02). Soil columns (30 cm in length) were packed with a bulk density range of 1.38-1.45 c/cm². All the columns were presaturated (by allowing them to stand in two liters of 0.01M caCl, solution until the moisture reached the top of each column). After the columns were saturated and drained, 48 gm (ca, 0.5 cm depth) of soil containing aerobically aged prodiamine (day 30) was added to the top of each column before dripping with at least 3.2 liters (20 inches column depth [ca. 1.5 column volume ?]) of 0.01 M CaCl, solution.

On average, 1.14% of the applied radiocarbon was detected in the leachate. 89.49% of the applied radiocarbon was found in the 'C-prodiamine treated soil columns. 98.32% of the radioactivity in the soil columns was present in the depth of 0 to 2 cm and 1.55% in the depth of 2 to 4 cm. These results indicate that prodiamine, its 6-amino-benzimidazole, and other metabolites were not mobile.

Soil in the columns was extracted with methanol to release the radiocarbon. Characterization of the methanol extract from the "C-prodiamine treated soil in the columns showed that the radiocarbon adsorbed onto the soil was identified as prodiamine, 6-amino-benzimidazole, 4-amino-benzimidazole, didespropyl prodiamine, and despropyl prodiamine. The percent of applied radiocarbon in the methanol extract ranged from 25.5-28.2% for prodiamine, 0.0-0.04 for didespropyl prodiamine, 2.5-3.8% for 6-amino-benzimidazole, and 4.1-6.3% for 4-amino-benzimidazole.

Following methanol extraction, the soil pellets were subjected to alkaline hydrolysis. This further released about 5.7% of the applied radiocarbon of which 3% was ethyl acetate extractable and 3.7% remained in the aqueous fraction. The analyses of the ethyl acetate fraction showed that about 2% of applied radiocarbon was located to the origin. The rest of the radiocarbon in the ethyl acetate extract consisted of minute amounts (each totalling less than 0.4% of applied) of didespropyl prodiamine, 6-amino-benzimidazole, despropyl prodiamine and

About 0.26%, 0.15%, and 0.02% of the applied radiocarbon in the leachate was characterized as prodiamine, 6-amino-benzimidazole and didespropyl prodiamine, respectively.

The radiocarbon in the leachates was quantified by liquid scintillation counting (LSC). The radiocarbon in soil (after leachate collection) was measured by combustion and LSC of aliquots from each soil depth. The material balance for the prodiamine treated columns averaged 90.85% of the applied radiocarbon.

For the soil columns treated with MC-alachlor (a reference herbicide), 35.89 (average) of the applied radiocarbon was in the leachate and 52.42% was in soil. The results indicate that alachlor and its metabolites ar relatively mobile. The material balance for MC-alachlor treated columns was 88.90% of the applied radiocarbon.

Materials:

test compound -- U-ring-labelled prodiamine , spec. act. 25.0 mCi/mmol, radiochemical purity 98% (by TLC), dissolved in acetone:ethanol 1:1; authentic standards of known metabolites. Reference alachlor had a spec. act of 220,160 dpm/ μ g

test soil -- Kenyon loam (characterization attached)

Methods:

All glassware was silanized. Moist field soil equivalent to 1000 gm dry soil was mixed with 3.1 mg of $^{14}\text{C-prodiamine}$ (3.1 ppm, equivalent to 2 lb/A incorporated in a 2 inch layer). The moisture level was 75% of 1/3 bar of field capacity and was maintained by addition of water on a weekly basis. The treated soil was incubated in darkness at 25 \pm 1°C for 30 days. The actual concentration of prodiamine in the moist soil at zero time was 2.31

A series of gas traps were employed to monitor 14CO2 (using 1.5 N KOH) and volatile organic compounds (using ethylene glycol) respectively. The trapping solutions (KOH and ethylene glycol) were changed on a weekly basis and radioassayed in duplicate.

The columns were prepared and presaturated by allowing them to stand in a bucket filled with $0.01~\mathrm{M}~\mathrm{CaCl_2}$ until moisture reached the top of the soil bucket filled with 0.01 M CaCl₂ until moisture reached the top of the soil columns. The columns were removed from the buckets and left undisturbed for 24 hours to allow excess liquid to drip off. The wet columns were then weighed to determine total pore volume. The conditioned columns were then treated (three each) with either ¹⁴C-prodiamine or ¹⁴C-alachlor. One column was left untreated as a control. Leaching was accomplished at a rate of less than 1 inch/hour (2.5 cm). After ca. 30 days, the rate of percolation had dropped to ca. 1.5 cm/hr, and an auxiliary tube was added to each column. The auxiliary tube allowed for an additional 10-15 cm of eluting fluid thus increasing pressure and therefore flow rate. Leaching was column. The auxiliary tube allowed for an additional 10-15 cm of eluting fluid, thus increasing pressure and therefore flow rate. Leaching was completed in ca. 80 days.

Leached columns were stored frozen until they were allowed to thaw overnight at room temperature before sectioning. They were divided into segments as follows: 0-2 (including treated soil), 2-4, 4-6, 6-12, 12-18, 18-24, and 24-30 cm. They were packed in dry ice for shipping to the analytical lab, and stored frozen until analysis.

material balance -- combined values for soil and leachate

soil -- total radiocarbon by combustion followed by LSC

leachates -- original leachates were subjected to a slight clean-up, and analyzed both by LSC and TLC

extracts -- LSC, followed by concentration and TLC; in addition, GC/MS was sometimes used. Standards and unknowns were visualized under UV light. Radioactivity was detected by a radioscanner.

TLC solvent systems:

I -- hexane: ethyl acetate, 70:30

II -- hexane:ethyl acetate, 80:20
III -- hexane:ethyl acetate:toluene, 65:30:5

IV -- ethyl acetate: isopropyl alcohol: formic acid:water, 60:30:5:5

VI. Study Author's Results and/or Conclusions:

RESULTS AS STATED BY THE AUTHOR

The mean value of the material balance of day 30 $^{14}\text{C-prodiamine}$ aerobically treated Kenyon loam soil was 103.17% (Table III). $^{14}\text{CO}_2$, which accounted for 1.25% of the applied radiocarbon, was the only trapped volatile. No other organic volatile was detected. Methanol extractable radioactivity accounted for 89.04% of the applied while the methanol unextractable radioactivity was 12.88% of the applied.

About 83.1%, 2.8%, 5.5%, and 3.1% of the methanol extractable radioactivity (day 30 soil sample) was prodiamine, despropyl prodiamine, didespropyl prodiamine and 6-amino benzimidazole, respectively (Table IV, Figure 2).

The moist soil (day 30) had a specific activity of 2.35 μg (2.054 μg + 0.297 μg) equivalents of ¹²C-prodiamine per gram (Table III).

The amount of radiocarbon in leachate from both ¹⁴C-prodiamine and ¹⁴C-alachlor treated columns is shown in Figure 3. On average, the amount of radioactivity in the leachate collected from ¹⁴C-prodiamine treated columns accounted for 1.14% of the applied radiocarbon (Table VI). In this study the rate of percolation became 1.5 ml/hour after about 1600 ml of the 0.01M CaCl₂ solution had leached through. Nonetheless, the low amount of radioactivity in the leachate demonstrated that prodiamine and its soil degradates were immobile. In contrast, 35.69% of the applied radioactivity in ¹⁴C-alachlor treated columns was observed in the leachate.

The leachate, collected from ¹⁴C-prodiamine treated soil columns, was first freeze-dried and then taken up by methanol prior to analysis by TLC. The results of the TLC analysis are given in Tables VII-a and b, and Figures 4 and 5. 0.53% (average) of the applied radiocarbon was located at the origin of the TLC plate (Appendix II). In addition 0.26% of applied radiocarbon was identified as prodiamine and 0.15% of applied radiocarbon as 6-amino benzimidazole.

After collection of leachate, aliquots of soil from each section of $^{14}\text{C-prodiamine}$ or $^{14}\text{C-alachlor}$ treated columns were combusted to obtain the total radiocarbon. The distribution of radioactivity in each depth of $^{14}\text{C-prodiamine}$ and $^{14}\text{C-alachlor}$ treated soil columns is provided in tables VIII and IX.,

Most (87.99\$) of the applied radiocarbon obtained in $^{14}\text{C-prodiamine}$ treated soil columns was located at the depth of 0-2 cm. Small amounts, 1.38 and 0.11% of the applied radiocarbon, was found at the depths of 2-4 and 4-6 cm of the soil column, respectively. None of the radioactivity was observed at the depth of 6-30 cm.

In ¹⁴C-alachlor treated soil columns, 30.59% of the applied radiocarbon was obtained at the depth of 0-2 cm. Lower amounts, 14.14, 3.49, 2.10, 0.83, 0.46, and 0.80% of the applied radiocarbon, were located at the depths of 2-4, 4-6, 6-12, 12-18, 18-24, and 24-30 cm, respectively. The results indicate that alachlor and its metabolites were relatively mobile and leached through the soil column during the study period.

The amount of methanol extractable radiocarbon from various depths of $^{14}\mathrm{C}$ -prodiamine treated soil columns is given in Table X. On average, 40.33% of the applied radiocarbon of the $^{14}\mathrm{C}$ -prodiamine treated soil was methanol extractable. Over 99.6% of the methanol extractable radiocarbon was obtained in the depth of 0-2 cm. The characterization of the methanol extracts, in three TLC solvent systems for $^{14}\mathrm{C}$ -prodiamine treated columns at the depth of 0-2 cm, is given in Figures 6-a and b, 7-a to c and 8-a to c. The percent of applied radiocarbon in the methanol extract ranged from 25.5-28.2% for prodiamine, 0.0-1.4% for despropyl prodiamine, 0.0-0.4% for didespropyl prodiamine, 2.5-3.8% for 6-aminobenzimidazole, 1.7-3.3% at origin (Appendix II), and 4.1-6.3% for an unknown compound, respectively (Tables XI a-c). The unknown compound was further isolated and purified from a large soil sample and analyzed by GC-MS (Appendix III). The unknown compound was identified as 4-amino-benzimidazole. The $R_{\rm f}$ values of $^{14}\mathrm{C}$ -4-amino-benzimidazole, isomer of 6-amino-benzimidazole, in three different TLC solvent systems are reported in Table II. The concentration of 4-amino-benzimidazole is higher than that of 6-amino-benzimidazole at the end of this study. J.P. Krueger and R.G. Butz found a similar metabolic profile in the anaerobic soil metabolism of prodiamine study (Reference 1).

The methanol extracted soil pellets from one $^{14}\text{C-prodiamine}$ treated column were further hydrolyzed with 0.1 N KOH solution at $80\,^6\text{C}$ for 1 hour. The results of alkaline hydrolysis showed that an additional 6.7% (7.53 $\mu\text{g})$ of the applied hydrocarbon was released from soil pellets (Table XII). In the released radiocarbon, 3% (3.34 $\mu\text{g})$ of applied radiocarbon was ethyl acetate extractable and 3.7% (4.19 $\mu\text{g})$ of applied radiocarbon was left in the aqueous fraction (Table

XII). Characterization of the ethyl acetate extractable radiocarbon is shown in Table XIII a-c. 1.99-2.12% of the applied radiocarbon was located at the origin of the TLC plate when developed with three different solvent systems (Table XIII a-c, and Appendix II for characterization). 0.18-0.25% of the applied radiocarbon was didespropyl prodiamine and 0.25-0.35% of the applied radiocarbon was 6-aminobenzimidazole in the ethyl acetate extract (Table XIII a-c). Autoradiography of the ethyl acetate extract in different TLC solvent systems is given in Figures 9-11. The aqueous fraction of the alkaline hydrolysate was neutralized (with 0.1N HCl) and freeze-dried. The freeze-dried solids were extracted with methanol (3.68% of applied radiocarbon) and then water (0.2% of applied radiocarbon). Characterization of the methanol extractable radiocarbon from the aqueous fraction of the alkaline hydrolysate showed that all the radioactivity was located at the origin of the TLC plate, when using either of the following solvent systems: [hexane:ethyl acetate; 70:30 (I) or 80:20 (II)] (Figures 12-13). However, the methanol extractable radiocarbon from the aqueous fraction was diffused along the TLC plate, when using solvent system IV: ethyl acetate:isopropyl alcohol:formic acid:water (60:30:5:5, Table XIV and Figure 14). These results showed that the radiocarbon from the aqueous fraction of the alkaline hydrolysate did not match any of the reference standards.

Due to the low percentage of the radiocarbon located at origin of the TLC plates (which were applied with either methanol or ethyl acetate extracts from aged $^{14}\mathrm{C}$ -prodiamine treated soil columns and developed with two solvent systems (hexane:ethyl acetate, 70:30 and 80:20), the radiocarbon was scraped, combined and extracted with methanol before reapplying to a TLC plate. Further TLC characterization of the radiocarbon at the origin (in System III) is given in Appendix II, Table B and Figure B. The radiocarbon at the origin consisted of diffuse multiple bands. Each band was less than 1.6% of the applied radiocarbon. Bands in the R_{f} range of 0.82 to 1.00 may be multicomponent.

The results of the methanol extractable radiocarbon from various depths of 14 C-alachlor treated soils columns are given in Table XV. On average 15.15% of the applied radiocarbon was methanol extractable. The methanol extractable radiocarbon decreased with the increasing depth of the columns.

The mean value of the material balance of the three prodiamine treated columns was 90.85% of the applied radiocarbon (Table VI). 1.14% of the applied radiocarbon was in the leachate and 89.49% of the applied radiocarbon was in the soil. The mean value of the material balance of the ¹⁴C-alachlor treated soil columns was 88.90% of the applied radiocarbon (Table XVI). 35.69% of the applied radiocarbon was in the leachate and 52.42% of the applied radiocarbon was in the

CONCLUSIONS AS STATED BY THE AUTHOR

The results indicate that prodiamine, 6-amino benzimidazole and other metabolites were immobile and stayed at the surface of the soil column, close to the application site.

VII. Reviewer's Comments:

- 1) The data as presented does not contain, and does not allow this reviewer to determine, the actual material balance. Based on tables VII-IX, only ca. 50% of the applied material is accounted for in column fractions and leachate. The information may be available and only require formatting.
- The analytical techniques (TLC in three solvent systems) are only marginally acceptable. The two hexane:ethyl acetate solvent systems do not appear to move the compounds significantly from each other, that is, although the compounds do move somewhat further in the 70:30 mixture, the relative distances do not vary greatly, and the order of elution does not change. In addition, the other solvent also produces similar R_f values and the same order of elution. EFGWB strongly prefers such confirmatory identification methods as GC/MS analysis. Some GC analysis was done, but apparently not for all samples.

3) The elution process was lengthy, and may well have influenced the relative proportions of parent and degradate which were found. (This comment is an observation, not intended to be interpreted as an identified deficiency.)

VIII. CBI Information Addendum: attached

Page _	is not included in this copy. through 34 are not included in this copy.
	aterial not included contains the following type of mation:
	Identity of product inert ingredients.
	Identity of product impurities.
	Description of the product manufacturing process.
	Description of quality control procedures.
	Identity of the source of product ingredients.
	Sales or other commercial/financial information.
	A draft product label.
	The product confidential statement of formula.
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