105001

11-20-97

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 11/20/97

SUBJECT: **PP#8E3574; Human Health Risk Assessment for Terbufos in/on Coffee (Tolerances Expire 12/15/97).**

DP Barcode: D240347
PRAT Case#: 260426
Submission #: S532580
Caswell#: 131A
Chemical#: 105001 Class: Insecticide
Trade Name: None 40 CFR: 180.352
EPA Reg#: None (Product not registered in the US.)

TO: T. Levine/M. Mautz PM Team 04
Insecticide Branch/RD (7505C)

FROM: William D. Wassell, Chemist
Pamela M. Hurley, Toxicologist
RAB2/HED (7509C)

THRU: Richard Loranger, Branch Senior Scientist
RAB2/HED (7509C) R. Loranger

INTRODUCTION

Tolerances are established (40 CFR 180.352(a)) for residues of the insecticide terbufos (S-[[(1,1-dimethylethyl)thio]methyl]O,O-diethyl phosphorodithioate) and its cholinesterase-inhibiting metabolites (terbufoxon sulfoxide, and terbufoxon sulfone) in or on the following raw agricultural commodities (RAC's):

RAC	Tolerance (ppm)
Bananas	0.025
Beets, Sugar (Roots)	0.05
Beets, Sugar, (tops)	0.1
Corn, Field, Fodder	0.5
Corn, Field, Forage	0.5
Corn, Pop, Forage	0.5
Corn, Grain	0.05

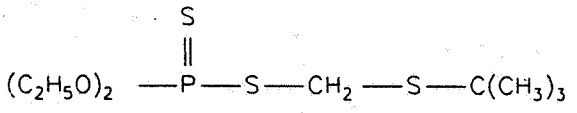
1/61

Corn, Sweet ...(CWHR)	0.05
Corn, Sweet, Forage	0.5
Corn, Sweet, Fodder	0.5
Sorghum, Fodder	0.5
Sorghum, Forage	0.5
Sorghum, Grain	0.05

A tolerance with an expiration date of 12/15/97 is established (40 CFR §180.352(b)) for residues of terbufos and its cholinesterase-inhibiting metabolites in or on coffee, beans at 0.05 ppm. There are no U.S. products registered for use on coffee.

The HED Chapter of the Reregistration Eligibility Decision Document (RED) for Terbufos has been issued (10/17/95, D.L. McCall). The HED Chapter of the RED did not address FQPA-specific concerns. The conclusions drawn in the HED Chapter of the RED are applicable to the expiring tolerance on coffee with the exception of sections pertaining to special sensitivity of infants and children, the reference dose (RfD) and risk estimates. **We note:** the RED recommended that tolerance levels for sorghum, fodder and sorghum, forage be increased to 1.0 ppm from 0.5 ppm.

The molecular structure of terbufos is:



Terbufos

I. EXECUTIVE SUMMARY

RAB2's estimates of chronic risk (water only) based upon EFED's highest estimates for terbufos in water exceed HED's level of concern. RAB2's estimates of chronic risk (food only) for the population subgroups of infants and children based upon tolerance level residues and percent crop treated data for terbufos are above HED's level of concern. The chronic risk (food only) estimate for the population subgroup U.S. Population is at an acceptable level (33% of the RfD).

We note: If anticipated residue estimates were utilized in place of tolerance level residues in the DRES analysis, the exposure estimates would decrease. RAB2 has not attempted to more highly refine our

chronic risk estimates for terbufos because highly refined acute risk estimates for this active ingredient (ai) are above our levels of concern.

RAB2's estimates of acute risk from water only based upon EFED's highest estimates for terbufos in water exceed HED's level of concern. RAB2's estimates of acute risk based upon tolerance level residues from food only for terbufos are above HED's level of concern.

The registrant's acute risk estimates (food only and food plus water) for all population subgroups except Women (13 yrs plus) based upon anticipated residues and Monte Carlo analysis are above HED's level of concern. **We Note: The registrant's analysis of acute risk was not extensively reviewed in conjunction with current action.**

An occupational exposure analysis is not required for this use on coffee as this use is not registered for domestic use. A residential exposure analysis is not required as terbufos is not registered for residential/homeowner use.

As acute risk estimates for most population subgroups exceed our levels of concern, HED recommends against the extension of the time-limited tolerance for residues of terbufos and its cholinesterase-inhibiting metabolites in or on coffee.

II. SCIENCE ASSESSMENT

1. Dose Response Assessment

a. Special Sensitivity to Infants and Children

On September 8, 1997, The Health Effects Division's Hazard Identification Assessment Review Committee determined that there are sufficient data available to adequately assess the potential for toxicity to young animals following pre- and/or post-natal exposure to terbufos. These include acceptable developmental toxicity studies in rats and rabbits as well as a 2-generation reproduction study in rats. In addition, no treatment-related effects in the reproductive organs were seen in subchronic and chronic studies conducted in mice, rats and dogs. The developmental toxicity studies in rats and rabbits showed no evidence of additional sensitivity to young rats or rabbits following pre- or postnatal exposure to terbufos and comparable NOELs were established for adults and offspring. Based upon a weight-of-the-evidence consideration of the data base, the Committee determined that a developmental neurotoxicity study in rats is not required.

For acute dietary risk assessment, the Committee determined that the **10x** factor to account for enhanced sensitivity of infants and children **(as**

required by FQPA) should be reduced to 3x. Therefore, **a Margin of Exposure of 300 is required** to ensure protection of these population subgroups from acute exposure to terbufos because:

(1) Lack of acute and subchronic neurotoxicity studies. Data on cholinesterase inhibition, FOB, and histopathology on the central and peripheral nervous system are not available for evaluation after a single exposure to terbufos.

(2) Lack of evaluation of a critical endpoint (i.e., measurement of cholinesterase activity) in the developmental or reproduction studies which would have yielded a comparison of this endpoint in adults and offsprings.

For chronic dietary risk assessment, the Committee determined that the **10x** factor to account for enhanced sensitivity of infants and children **(as required by FQPA) should be reduced to 3x for a total UF of 300** (i.e., 10 for inter-species variation x 10 for intra-species variation x 3 for FQPA) to ensure protection of these population subgroups from chronic exposure to terbufos. The UF of 300 is required because of the:

(1) Lack of acute and subchronic neurotoxicity studies. Data on cholinesterase inhibition, FOB, and histopathology on the central and peripheral nervous system are not available for evaluation after repeated exposures to terbufos.

(2) Lack of an evaluation of a critical endpoint (i.e., measurement of cholinesterase activity) in the developmental or reproduction studies which would have yielded a comparison of this endpoint in adults and offsprings.

Cholinesterase (ChE) activity was not measured in either the adults or the offspring in the developmental toxicity studies. In the reproduction study, ChE activity was measured only in adults and not in the pups. Therefore, no comparisons could be made for this endpoint between adults and offspring. In addition, data gaps exist for acute and subchronic neurotoxicity studies.

b. Reference Dose (RfD)

The endpoint for chronic dietary risk assessment is based on plasma cholinesterase inhibition observed at 0.015 mg/kg/day (LOEL) in a 28-day oral study in dogs. The NOEL was 0.005 mg/kg/day. The study was performed at dose levels of 0, 0.00125, 0.005 or 0.015 mg/kg/day given orally by capsule. A UF of 100 applied to the NOEL for all population subgroups other than infants and children; 10x each for inter and intra species variability. **Thus, an RfD of 0.00005 mg/kg/day was derived for**

all population subgroups other than infants and children.

For infants and children, the additional UF of 10 (required by FQPA) beyond the ones for inter and intra species variability is reduced to 3. **For infants and children, an additional uncertainty factor of 3 will be used with the RfD value for risk assessment of these population subgroups.**

The toxicological endpoints for terbufos are summarized in Table 1.

TABLE 1. Summary of Toxicological Endpoints for Terbufos

Exposure Duration	Exposure Route	Endpoint and Toxicological Effect
Acute	Dietary	NOEL: 0.005 mg/kg/day (inhibition of plasma cholinesterase activity at 0.015 mg/kg/day). MOE: 300 for infants and children population subgroups. MOE: 100 for all other population subgroups.
Short-Term (1-7 days) Occupational/Residential	Dermal	**Dermal**: NOEL: 0.005 mg/kg/day with 100% dermal absorption (inhibition of plasma cholinesterase activity at 0.015 mg/kg/day).
Intermediate-Term (one week to several months) Occupational/Residential	Dermal	**Dermal**: NOEL: 0.005 mg/kg/day with 100% dermal absorption (inhibition of plasma cholinesterase activity at 0.015 mg/kg/day).
[All time periods]	[Inhalation]	**Inhalation**:NOEL: 0.01 μg/L (significant decreases in plasma, RBC and brain cholinesterase at 0.04 μg/L).

Exposure Duration	Exposure Route	Endpoint and Toxicological Effect
Cancer	Dietary/Dermal/Inhalation	Classified as a group E: no evidence of carcinogenicity by the oral exposure route.
Chronic (non-cancer)	Dietary	RFD: 0.00005 mg/kg/day (NOEL of 0.005 mg/kg/day with UF of 100; plasma cholinesterase inhibition at 0.015 mg/kg/day) for population subgroups other than infants and children. For infants and children, an additional uncertainty factor of 3 will be used with the RfD for assessment of risk for these subgroups.

We Note: An occupational exposure analysis is not required for this use on coffee as this use is not registered for domestic use. A residential exposure analysis is not required as terbufos is not registered for residential/homeowner use.

2. Dietary Exposure and Risk Assessment/Characterization

a. Dietary Exposure (Food Sources)

The RACs (Raw Agricultural Commodities) and tolerances, used in the dietary risk assessment, were derived from 40 CFR 180.352 and the Tolerance Index System:

Commodity[1]:	Tolerance: (ppm)
Bananas	0.025
Coffee	0.05
Beets, Sugar (Roots)	0.05
Corn, Grain	0.05
Corn, Sweet	0.05

Tolerances for residues of terbufos and its chlinesterase-inhibiting

metabolites are pending in/on soybean grain (Memo, 2/17/89, F. Toghrol, PP#2F2608, DEB# 4466); peanut nutmeat, shells and oil (Memo, 5/20/88, W.T. Chin, PP#4F2996/8H5549, RCB # 3100); mustard and rape seed (Memo, 7/30/90, R.W. Cook, PP#3F2926).

b. Dietary Exposure (Drinking Water Source)

There is no Maximum Contaminant Level (MCL) established for residues of terbufos in drinking water. Health Advisory (HA) levels have been established for residues of terbufos in drinking water based upon an RfD of 0.00013 mg/kg/day with a drinking water equivalent level of 0.005 mg/L. They are as follows:

Lifetime level of 0.009 mg/L
Long-term level of 0.005 mg/L

This information was furnished by the EPA Safe Drinking Water Hotline (1-800-426-4791) on 10/06/97.

EFED has provided estimates of terbufos levels in ground and surface water (Memo, J. Breithaupt, 9/30/97). The highest residue estimate for chronic risk assessment was 8.7 ug/L (for ground water). This estimate was from a ground water monitoring study. The highest residue estimate for purposes of acute risk assessment was 21.7 ug/L (for surface water). This estimate was from simulation utilizing PRZM 2.3 (**P**esticide **R**oot **Z**one **M**odel). PRZM 2.3 simulates the transport of a pesticide off agricultural fields and is considered to overestimate actual drinking water concentrations for the active ingredient. We further note that 32 fish kills have been attributed to terbufos use. In order for fish kills to occur surface water concentrations were estimated to range from 0.77 to 20 ug/L. This concentration range is within the concentration range predicted by PRZM 2.3.

Current HED policy is to calculate a "Level of Concern" (LOC) for the active ingredient in water and compare this level to the **maximum** estimate for residues of the active ingredient in surface and/or ground water. The LOC for drinking water is defined as the concentration level at which the human health risk exceeds HED's level of concern. HED was unable to calculate a level of concern of terbufos in drinking water as our risk estimates for dietary exposure (food only) exceed HED's level of concern based upon both the chronic and acute dietary toxicological endpoints.

For chronic exposure based upon the highest estimate for terbufos in water:

The highest EFED estimate for terbufos in water is 8.7 ug/L (for

residues in ground water). This estimate was based on the proposed use rate for grain sorghum and/or sugar beets and SCI-GROW. Assuming no dietary exposure (food only) and estimating the risk level based upon 8.7 ug/L in water, the level of risk (from drinking water only) was calculated to occupy as much as **5220% of the RfD for children, 487% of the RfD for adult males and 580% of the RfD for adult females.**

For acute exposure based upon the highest estimate for terbufos in water:

We note: Acceptable MOE's for children are ≥300 and acceptable MOE's for adults are ≥100.

The highest EFED estimate for residues of terbufos in water is 21.7 ug/L for residues in surface water. This estimate was based on the label directions of grain sorghum and PRZM 2.3. Assuming no dietary exposure (food only) and estimating the risk level based upon 21.7 ug/L in water, the level of risk from drinking water only was calculated to have an **MOE of 0.005 for children, an MOE of 8.6 for adult males and an MOE of 6.9 for adult females.**

RAB2 concludes there is a concern for residues of terbufos in drinking water based upon both chronic and acute toxicological endpoints. This conclusion is based upon EFED's estimates for residues in ground and surface water.

c. Dietary Risk Assessment and Characterization

i. Chronic Risk

The endpoint for chronic dietary risk assessment is based on plasma cholinesterase inhibition observed at 0.015 mg/kg/day (LOEL) in a 28-day oral study in dogs. The NOEL was 0.005 mg/kg/day. A UF of 100 applied to the NOEL for all population subgroups other than infants and children. For infants and children, the additional UF of 10 (required by FQPA) is reduced to 3. Thus, for this population subgroup, the total UF is 300. **Thus, an RfD of 0.00005 mg/kg/day was derived for all population subgroups other than infants and children. For infants and children, an additional uncertainty factor of 3 will be used with the RfD value for assessment of risk for these groups.**

Assuming tolerance level residues and 100% of the crop treated, the total TMRC (Theoretical Maximum Residue Contributions) exposure for dietary exposure from terbufos for the U.S. population from established tolerances is estimated as being 0.000055 mg/kg bodyweight per day and

the risk estimate is 110% of the Reference Dose (RfD). The subgroups with the highest estimated dietary TMRC exposures/risks are as follows:

Subgroup:	**TMRC (mg/kg/day)**	**Percent RfD**
U.S. Population	0.000055	110%
Nursing Infants	0.000051	310%
Non-nursing Infants (< 1 Year Old)	0.00012	696%
Children (1 to 6 Years Old)	0.00013	790%
Children (7 to 12 Years Old)	0.000089	530%

Adjustments of the TMRC exposure, by inclusion of percent crop treated data for field corn; sweet corn; sorghum; and sugar beets, roots in the DRES analysis produced ARCs (Anticipated Residue Contributions) for the same subgroups and substantially lowered the estimates of chronic dietary exposure to terbufos. The total dietary ARC exposure of the U.S. population is estimated to be 0.000016 mg/kg bodyweight per day and the risk estimate was 33% of the RfD. The subgroups with the highest estimated dietary total ARC exposures/risks are as follows:

Subgroup:	**ARC (mg/kg/day)**	**Percent RfD**
Nursing Infants	0.000027	160%
Non-nursing Infants (< 1 Year Old)	0.000040	240%
Children (1 to 6 Years Old)	0.000039	230%
Children (7 to 12 Years Old)	0.000022	130%

The raw agricultural commodities which contribute the most ARC exposure/risk for U.S. populations from dietary terbufos are bananas, corn (all), and beets (sugar).

RAB2 concludes the chronic risk estimates (food only) utilizing percent crop treated data and tolerance level residues for terbufos exceed HED's level of concern. We note: If anticipated residue estimates were utilized in place of tolerance level residues in the DRES analysis, the exposure estimates would decrease. RAB2 has not attempted to more highly refine our chronic risk estimates for terbufos because highly refined acute risk estimates for this ai are above our levels of concern.

iii. Acute Dietary Risk

The acute dietary endpoint (one day) is based on the NOEL for plasma cholinesterase inhibition (0.005 mg/kg/day) in dogs. An MOE of ≥100 is considered acceptable for all population subgroups other than those for infants and children. For infants and children, the **10x** factor to account for enhanced sensitivity of infants and children **(as required by FQPA)** has been **reduced to 3x.** Therefore, **a Margin of Exposure of ≥300 is required** to ensure protection of this population from acute exposure to terbufos

Acute dietary exposure analysis estimates the distribution of single-day exposures for the U.S. population and certain subgroups. The analysis evaluates individual food consumption as reported by respondents in the 1977-78 Nationwide Food Consumption Survey and accumulates exposure to terbufos for each food commodity which has a terbufos tolerance. As such, the exposure estimate is a maximal estimate because it assumes that terbufos residues are present at the maximum legal limit in the entirety of the commodities in which they can occur.

The Margin of Exposure (MOE) for acute dietary risk was calculated for the U.S. population and for four population subgroups. The calculated MOEs using a NOEL of 0.005 mg/kg bodyweight/day were:

Population Groups:	**Percentile Pop.:**	**MOE:**
U.S. population	96th	25
Infants (<1 Year Old)	96th	10
Children (1-6 Years Old)	98th	10
Females (≥13 Years Old)	93rd	50
Males (≥ 13 Years Old)	91st	50

$$\text{Margin of Exposure (MOE)} = \frac{\text{NOEL}}{\text{exposure}}$$

RAB2 concludes our acute risk estimates (food only) for terbufos are above HED's level of concern of all population subgroups.

The petitioner has submitted the results (MRID No. 444070-01) of a Monte Carlo analysis in order to present a more realistic estimate of exposure. **This study was not extensively reviewed by RAB2 in conjunction with the current action.** The analysis was performed by Novigen Sciences Inc. The introduction of this report states that utilizing EPA's Tier 3 methodology (Monte Carlo) for acute exposure Margin's of Exposure (MOE's) up to the 99th percentile of exposure (food

only) were approximately 100 for all population subgroups.

HED requires the MOE's up to the 99.9th percentile to be at an acceptable exposure level. **For terbufos, the acceptable MOE's for adult population subgroups are to be ≥100. For children population subgroups, the acceptable MOE's are to be ≥300.**

MOE's at the 99.9th percentile are contained in Appendix 4 of the registrant's report. The MOE's at the 99.9th percentile (food only and food plus water) for various population subgroups are as follows:

Population Subgroup	MOE (food only)	MOE (food + water)
U.S. Population	83	**82**
Children (1 to 6 yrs)	43	**43**
Children (7 to 12 yrs)	82	**83**
All Infants	53	**51**
Women (13 yrs +)	151	**153**

RAB2 concludes the registrant's acute risk estimates (food only and food plus water) for all population subgroups except Women (13 yrs plus) are above HED's level of concern.

3. Occupational and Residential Exposure and Risk Assessment/Characterization

An occupational exposure analysis is not required for this use on coffee as this use is not registered for domestic use. A residential exposure analysis is not required as terbufos is not registered for residential/homeowner use.

4. Aggregate Exposure and Risk Assessment/Characterization

a. Chronic Aggregate Exposure and Risk

RAB2's estimates of chronic risk (water only) based upon EFED's highest estimates for terbufos in water exceed HED's level of concern. RAB2's estimates of chronic risk (food only) for the population subgroups of infants and children based upon tolerance level residues and percent crop treated data for terbufos are above HED's level of concern. Therefore, estimates of chronic aggregate risk (food plus water) also exceed HED's level of concern for these populations. The chronic risk

(food only) estimate for the population subgroup U.S. Population is at an acceptable level (33% of the RfD).

We note: If anticipated residue estimates were utilized in place of tolerance level residues in the DRES analysis, the exposure estimates would decrease. RAB2 has not attempted to more highly refine our chronic risk estimates for terbufos because highly refined acute risk estimates for this ai are above our levels of concern.

b. Acute Aggregate Exposure and Risk

RAB2's estimates of acute risk (water only) based upon EFED's highest estimates for terbufos in water exceed HED's level of concern. RAB2's estimates of acute risk (food only) based upon tolerance level residues for terbufos are above HED's level of concern.

The registrant's acute aggregate risk estimates (food plus water) based upon anticipated residue estimates and Monte Carlo analysis for all population subgroups except Women (13 yrs plus) are above HED's level of concern. **We Note: The registrant's analysis of acute risk was not extensively reviewed.**

As most acute risk estimates exceed our levels of concern, HED recommends against the extension of the time-limited tolerance for residues of terbufos and its cholinesterase-inhibiting metabolites in or on coffee.

5. Other Food Quality Protection Act Considerations

a. Cumulative Risk (standard language)

Terbufos is a member of the organophosphate class of insecticides. Some of the other members of this class include malathion, trichlorfon, naled, mevinphos, acephate and methyl and ethyl parathion (G.W. Ware, Fundamentals of Pesticides, 3rd edition, 1991).

Section 408(b)(2)(D)(v) of the Food Quality Protection Act of 1996 requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity". The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA

does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical-specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether terbufos has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that terbufos has a common mechanism of toxicity with other substances.

b. Endocrine disruption

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

Attachments (4): 1) The HED Chapter of the Reregistration Eligibility Decision Document (RED) for Prometryn (3/16/95 J.C.

Redden, Case #0467).
2) Chronic DRES Analyses (9/17/97).
3) Acute Dietary Analyses (excluding coffee) (3/22/95).
4) Acute Dietary Analyses (coffee only) (3/22/95).

cc with Attachments: W.D. Wassell (RAB2), P. Hurley (RAB2), PP#8E3574, RAB2, B. Steinwand (CEB1)

cc without Attachments: Caswell File, J. Breithaupt (EFED, 7507C), W.Hazel (RRB1, 7509C), L. Nisenson (SRRD, 7508C).

RDI: RAB2: 11/18/97.
Disk: WDW-10, File: Terbufos.2

Attachment 1

October 17, 1995
MEMORANDUM

SUBJECT: The Revised HED Chapter of the Reregistration Eligibility Decision Document (RED) for Terbufos, Case #0109 (PCCode 105001)

FROM: Deborah L. McCall
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

THRU: Karen Whitby, Ph.D., Acting Chief
Risk Characterization and Analysis Branch
Health Effects Division (7509C)
and
Stephanie Irene, Ph.D., Acting Director /s/
Health Effects Division (7509C)

TO: Jack Housenger, Chief
Special Review Branch
Special Review and Reregistration Division (7508W)

Attached is the Revised Human Health Assessment for the Terbufos Reregistration Eligibility Decision Document. This assessment completely replaces the previously issued chapter in 1994. The revised chapter includes the original assessments from P. McLauglin (TOX II), J. Bazuin (SAB), C. Swartz (CBRS) plus the revised Occupational Exposure Assessment from Al Nielsen (OREB, see Attachment I).

Terbufos is an organophosphate insecticide/nematicide applied as a granular formulation by soil incorporation, during planting or post-emergence of terrestrial food and feed crops. Tolerances for residues of terbufos and its metabolites in/on raw agricultural commodities are established in 40 CFR 180.352. A Reregistration

Standard for terbufos was issued in September 1988.

HED considers terbufos to be of concern for health effects from acute dietary exposure, particularly for infants and children. Margins of exposure (MOEs) are 25 for the general population and 13 for infants and children.

cc: A. Levy
A. Nielsen

Attachments:
I Revised Occupational/Residential Exposure Assessment

cc:mail	(with attachments)	Amy Farrell
cc:mail	(without attachments)	Alan Levy Al Nielson Christina Swartz Beth Doyle
cc:	(with attachments) (2)	Marvin Hawkins
cc:	(without attachments)	RCAB
disk	(with attachments)	RCAB

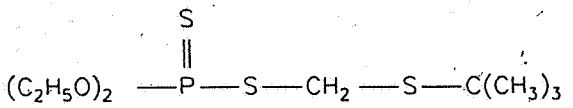
REVISED HUMAN HEALTH ASSESSMENT OF TERBUFOS

The Health Effects Division has conducted a thorough review of the scientific data base for terbufos, to support the reregistration eligibility decision for this pesticide. The findings are summarized below.

A. PRODUCT CHEMISTRY ASSESSMENT

1. Identification of the Active Ingredient

Terbufos (S-[[(1,1-dimethylethyl)thio]methyl]O,O-diethyl phosphorodithioate) is a restricted use organophosphate insecticide and nematicide. The molecular structure of terbufos is:



Terbufos

Other identifying characteristics and codes are:

Physical Properties:	Clear, slightly brown liquid
Empirical Formula:	$C_9H_{21}O_2PS_3$
Molecular Weight:	288.4
CAS Registry No.:	13071-79-9
Shaughnessy No.:	105001
Melting Point:	-15°C

2. Other Product Chemistry Issues

There is one manufacturing-use product for terbufos, referred to as the 85% technical (T) (EPA Reg. No. 241-241). All pertinent data requirements for the terbufos 85% MP/T (EPA Reg. No. 241-241) have been satisfied by the American Cyanamid in recent submissions (MRID Nos. 43147500, 43147501, 43147502 and

43147503).

B. HUMAN HEALTH ASSESSMENT

I. Toxicology Assessment

The toxicological data base on terbufos is adequate and will support reregistration eligibility.

a. Acute Toxicity

The acute toxicity values and categories for terbufos are summarized in the Table 1 below.

TABLE 1: Acute Toxicity (technical)

TEST	RESULTS	CATEGORY
Oral LD_{50} - rat	LD_{50} = Males 1.6-4.5; Females 1.3-9.0 mg/kg	I
Oral LD_{50} - mouse	LD_{50} = Males 3.5; Females 5.0-9.2 mg/kg	I
Oral LD_{50} - dog	LD_{50} = Males 4.5; Females 6.3 mg/kg	I
Inhalation LC_{50}	data gap	---
Dermal LD_{50} - rabbit	LD_{50} = Males 0.8-1.1; Females 0.93 mg/kg	I
Eye irritation - rabbit	100% deaths in 24 hours	
Dermal irritation - rabbit	100% deaths in 24 hours	

Terbufos has a high degree of acute toxicity when tested by various routes of administration using concentrations ranging from 86.0% to 97.7%. The LD_{50} values for terbufos in acute oral rat studies ranged from 1.6 to 4.5 mg/kg in males and 1.3 to 9.0 mg/kg in females (guideline 81-1). Similar oral LD_{50} values were obtained with terbufos in mice and dogs (MRID 00044957, 00037467, 00037471, 00035121). In several additional acute tests in mice,

the oral LD_{50} values for phosphorus-containing and nonphosphorus-containing metabolites of terbufos ranged from 1.1 to 14.0 mg/kg (Parkin, 1973).

The LD_{50} for terbufos from acute dermal rabbit studies ranged from 0.8 to 1.1 mg/kg in males and was 0.93 mg/kg in females (guideline 81-2; MRID(s): 00044957, 00037467, 00144805). There is no acute inhalation study available that is applicable to the guidelines. Confirmatory information from a two-week inhalation study in rats indicates mortality (2/10 females) and cholinesterase activity depression were found at a concentration of 0.0394 mg/m^3 (MRID 00258710). An acute inhalation study is required; however, the two-week study may be considered confirmatory because testing of end-use products addresses labeling concerns.

In primary eye and primary dermal irritation studies in rabbits, all animals died within 24 hours after dosing with 0.5 mL or less of terbufos (guidelines 81-4, 81-5; MRID 00044957, 00037467). No dermal sensitization study has been performed due to the acute lethality of terbufos. The compound was not neurotoxic when administered in a single oral dose of 40 mg/kg to hens in an acute delayed neurotoxicity study (guideline 81-7; MRID 00037472).

b. Subchronic Toxicity

Dietary administration of terbufos for three months to Sprague Dawley rats at concentrations of 0, 0.00625, 0.0125, 0.025, or 0.05 mg/kg/day resulted in a systemic NOEL of 0.0125 mg/kg/day. The systemic LOEL was 0.025 mg/kg/day based on increased liver weight and liver extramedullary hematopoiesis. Mesenteric and mandibular lymph node hyperplasia were found at the highest dose. The NOEL for cholinesterase (ChE) inhibition was 0.0125 mg/kg/day. The NOEL was based on 17% inhibition of plasma cholinesterase at concentrations in excess of 0.0125 mg/kg/day (guideline 82-1; MRID 00109446).

A 30 day dermal toxicity study with New Zealand white rabbits used doses of 0, 0.004, 0.02, or 0.10 mg/kg applied to intact and abraded skin (MRID 00085169). This study was determined to fulfill the toxicology requirements for guideline 82-2. The only effect found was slight erythema, which generally abated by the

end of the study, found at 0.1 mg/kg/day, the LOEL. Cholinesterase activity was not measured. The systemic NOEL was 0.02 mg/kg (guideline 82-2; MRID 00085169).

A 21-day inhalation study was performed with Sprague-Dawley rats. The rats were exposed in inhalation chambers to vapors of technical terbufos for 3 weeks at target concentrations of 0, 0.005, 0.01, 0.05 or 0.10 µg/L. The mean analytical concentrations were 0, 0.0117, 0.0243, 0.0458, or 0.0946 µg/L for males and 0, 0.0112, 0.0256, 0.0468, or 0.1001 µg/L for females. The highest dose tested (HDT) showed a statistically significant decrease in red blood cell (RBC), plasma and brain cholinesterase in male or female rats on day 21. The chamber concentrations were not well controlled and wide variations in daily concentrations were noted. Due to this fact the lowest mean chamber concentrations were selected for the NOEL and LOEL. The cholinesterase NOEL is 0.01 µg/L or 0.001 mg/kg/day (MRID 00258710). The cholinesterase LOEL is 0.04 µg/L based on significant decreases in plasma, RBC and brain cholinesterase in the 0.1 µg/L dose group. This study was not designed to satisfy the requirements of a subchronic toxicity test because of the short duration, the number of animals/group, no individual clinical data and the fact that no histopathology was performed. Therefore, this study presents supplementary data.

A 28-day oral toxicity study with dogs was performed to define the plasma cholinesterase effect levels that were not achieved in the one year oral beagle dog study (MRID 00161572). The study was performed at dose levels of 0, 0.00125, 0.005 or 0.015 mg/kg/day given orally by capsule. The plasma cholinesterase NOEL was 0.005 mg/kg/day (MRID 40374701). The plasma cholinesterase LOEL of 0.015 mg/kg/day was based on a 58-64% decrease in plasma cholinesterase in male and female dogs.

c. Chronic toxicity

A one-year oral toxicity study was performed in Charles River CD rats with terbufos doses of 0, 0.125, 0.5, or 1.0 ppm in the diet (equivalent to 0, 0.007, 0.028, or 0.055 mg/kg/day for males and 0, 0.009, 0.036 or 0.071 mg/kg/day for females) (guideline 83-1; MRID 40098602). The systemic NOEL was greater than 1.0 ppm (0.055 mg/kg/day). The NOEL for cholinesterase inhibition was 0.5 ppm (0.028 mg/kg/day), based upon reductions in brain and

plasma cholinesterase levels in both sexes at the next highest dose of 1.0 ppm.

In a one-year oral beagle dog study, the doses of terbufos administered by capsule were 0, 0.015, 0.06, 0.09, or 0.12 mg/kg/day (guideline 83-1; MRID 00161572). The systemic NOEL was ≥ 0.12 mg/kg/day, the highest dose tested. Initial higher doses of 0.024 and 0.048 mg/kg/day were reduced after the first 6-8 weeks of the study due to cholinergic-related behavioral signs, reduced food consumption and weight gain, depressed hematology parameters, and gross changes of congestion, edema and necrosis in the gastro-intestinal tract. A NOEL for plasma cholinesterase inhibition was not determined because plasma cholinesterase inhibition was found in all treated dose levels. Red blood cell (RBC) cholinesterase activity in male dogs was moderately reduced (≈ 20%) in the 0.09 and 0.12 mg/kg/day dose groups at week 13. This percent reduction in RBC activity was consistently observed at subsequent sampling periods. A similar pattern was observed in females with RBC cholinesterase activity being depressed slightly more during the 13 week period in the two highest dose groups. A NOEL for RBC cholinesterase inhibition was 0.06 mg/kg/day. Brain cholinesterase inhibition was more variable, but generally supported a depression of cholinesterase activity in the two high dose groups.

d. Carcinogenicity

Terbufos was examined for potential carcinogenic activity in rats and mice. Long Evans rats were given 0, 0.0125, 0.05 or 0.1 mg/kg/day in the diet initially, the levels were then raised to 0.2 and 0.4 mg/kg/day after 6 and 12 weeks, respectively, with the females at 0.4 mg/kg/day reduced back to 0.2 mg/kg/day after 16 weeks (guidelines 83-1, 83-2; 00049236). No neoplastic activity was observed after two years of dosing. In this study, the LOEL was 0.05 mg/kg/day for systemic toxicity, based on mortality and exophthalmia. Significant cholinesterase inhibition, in red blood cells and brain, was found at 0.05 mg/kg/day and at higher doses; in addition, there was inhibition in red blood cells at 0.0125 mg/kg/day. The NOEL for ChE inhibition was less than 0.0125 mg/kg/day.

In another study, dietary doses of 0, 0.45, 0.9 or 1.8 mg/kg/day of terbufos were administered to CD-1 mice for 18 months. No

carcinogenic effects were observed (guideline 83-2; 40098603). The systemic NOEL in this study appeared to be 0.9 mg/kg/day, based upon a slight increase in mortality and reduction in weight gain at 1.8 mg/kg/day in both sexes of mice. Terbufos has been classified by the HED RfD Committee as a Group E chemical.

e. Developmental Toxicity

Developmental toxicity studies with terbufos were conducted in rats and rabbits. Doses of 0, 0.05, 0.1 or 0.2 mg/kg/day were administered by gavage on gestation days 6-15 to COBS (CD) rats. The maternal toxicity NOEL in rats was greater than 0.2 mg/kg/day (highest dose tested) and the developmental toxicity NOEL was 0.1 mg/kg/day. The developmental toxicity LOEL of 0.2 mg/kg/day was based on increases in early fetal resorptions, the number of litters with 2 or more resorptions, and post-implantation losses (guideline 83-3; MRID 00147533).

In New Zealand white rabbits, doses of 0, 0.05, 0.10, 0.25, or 0.50 mg/kg/day were administered by gavage on gestation days 7-19. The maternal toxicity NOEL was 0.1 mg/kg/day and the LOEL was 0.25 mg/kg/day. Reduced weight gain and soft stools occurred at 0.25 mg/kg/day and at 0.5 mg/kg/day, the highest dose tested. The developmental toxicity NOEL was 0.25 mg/kg/day. The developmental toxicity LOEL was 0.5 mg/kg/day based on a slight reduction in fetal body weight and an increase in resorptions (guideline 83-3; MRID 40886301). No compound-related developmental effects were reported for external, visceral, or skeletal observations in either rats or rabbits with terbufos.

f. Reproductive Toxicity

A three-generation reproduction study in Long-Evans rats used doses of 0, 0.0125, or 0.05 mg/kg/day (MRID 00085172). The NOEL was 0.05 mg/kg/day as no adverse effects were shown. The study does not meet the requirements for guideline 83-4. However, no other study of this type is required, on the basis that higher doses would be expected to produce cholinesterase inhibition, as was found in chronic studies at slightly higher doses.

g. Mutagenicity

A dominant lethal study with terbufos was performed in rats to

test for structural chromosomal aberrations. A possible compound-related effect on fertility occurred in the high dose group (0.4 mg/kg), where the number of viable implants was reduced and implantation efficiency was lower (MRID 00161571). However, terbufos was not mutagenic in a variety of other studies when tested to cytotoxic levels. Those designed to detect gene mutations were the Ames reversion assay with S. typhimurium and E. coli strains (MRID 00063209) and the CHO/HGPRT assay in vitro (MRID 00133297). Tests for structural chromosomal aberrations included the Chinese hamster ovary cells in culture (MRID 00133296) and the in vitro cytogenetics assay in rats (MRID 00161570). Tests for other genotoxic effects were the rat hepatocyte primary culture/DNA repair test (MRID 00133298) and the effects on DNA repair in S. typhimurium and E. coli strains (MRID 00063209). (These studies fulfill the requirements of guideline 84.)

h. Metabolism

A metabolism study in rats (MRID 00087695) indicated that a single administration of 0.8 mg/kg of terbufos C14 in the diet to male rats results in 83% of the administered dose being excreted in the urine in the form of metabolites and 3.5% in the feces over 168 hours. There was no unusual localization of terbufos or its metabolites in tissues. Several metabolites of terbufos have been identified, including phosphorus-containing metabolites (esters of phosphorothioic and phosphorodithioic acids) and nonphosphorus metabolites (Parkin, 1973). Additional rat metabolism studies consisting of single oral low and high doses, and 14-day repeated oral exposure with the low dose are required to fulfill Agency requirements (Levy, 1990).

i. Toxicological Endpoints of Concern

The Reference Dose (RfD) for chronic oral exposure was determined to be 0.00005 mg/kg/day based on a NOEL of 0.005 mg/kg/day for plasma cholinesterase inhibition in a 28-day study in dogs. The 28-day and the 1 year dog studies should be considered co-critical studies; since the 28-day dog study was performed because the 1 year dog failed to demonstrate a plasma cholinesterase NOEL. The toxicological endpoint of concern is cholinesterase activity with plasma being the most sensitive indicator. A safety factor of 100 was utilized (10 for intra-

and interspecies variation each). The Joint Meeting on Pesticide Residues (JMPR) acceptable daily intake (ADI) is 0.0002 mg/kg (Summary of Toxicological Evaluations, IPCS, 1993). The ADI is based on a NOAEL of 0.016 mg/kg/day from a 3-generation reproduction study in rats.

The HED Less-than-Lifetime Committee met in January 1995 and identified the NOEL based on cholinesterase inhibition from the 28-day toxicity study in dogs as the endpoint of concern for the acute dietary, short and intermediate-term occupational/ residential dermal exposure scenarios (Ioannou, 1995). Short-term exposure is defined as a duration of 1 to 7 days for occupational/residential exposures. Intermediate exposure is defined as 1 week to several months for occupational/residential exposures. The Less-than-Lifetime Committee also identified the NOEL based on cholinesterase inhibition from the 21-day inhalation toxicity study in rats as the endpoint of concern for the short and intermediate-term occupational/residential inhalation exposure scenarios (Ioannou, 1995). In the absence of dermal absorption data, the Agency assumed 100% (default assumption).

II. EXPOSURE ASSESSMENT

a. Use Pattern

Terbufos is an organophosphate insecticide/nematicide. Terbufos is formulated as a granular product (15 and 20 percent active ingredient). Occupational exposure is expected, based upon the currently registered uses of this pesticide. Terbufos is applied at planting or postemergence to terrestrial food and feed crops. Crops treated are corn (field, pop, and sweet), grain sorghum, and sugar beets (including tops as a feed crop). All application methods require soil incorporation. Terbufos is applied to the soil as an in-furrow treatment (drill equipment, band treatment, or direct-incorporation treatment). The registrant is not supporting a previously registered aerial/broadcast treatment. Applications are made as often as twice per season. Based on the currently registered use-sites, terbufos is not used in a greenhouse. The maximum application rates are: for corn 1.97 lb ai/acre, for grain sorghum 3.92 lb ai/acre, and for sugar beets 4.35 lb ai/acre.

The mixer/loader/applicator exposure estimates are derived from the Pesticide Handlers Exposure Database (PHED V1.1). This data was used to calculate daily dermal and inhalation exposure for workers handling terbufos in treating the registered sites. The PHED data are based on two major exposure scenarios 1) loading the dry (granular) formulation and 2) applying the dry formulation with granular-spreader equipment.

b. Dietary Exposure

Residue chemistry data requirements are satisfied, with the exception of Guideline §165-2; additional confirmatory limited field trials are required to determine if rotational crop tolerances are necessary. Conclusions are summarized below.

§171-4 (a): Plant Metabolism: The 1983 Residue Chemistry Chapter, as well as the 1987 FRSTR and 1988 Guidance Document concluded that the qualitative nature of the residue in plants is adequately understood. Studies conducted on corn, sugar beets, soybeans, sorghum, cabbage, rape, and wheat indicate that the residues of concern in plants are terbufos and its phosphorylated (cholinesterase-inhibiting) metabolites (terbufoxon sulfoxide, and terbufoxon sulfone).

§171-4 (b): Animal Metabolism: The qualitative nature of the residue in poultry is adequately understood. Radioactive residues in poultry tissues and eggs were non-detectable following dosing of laying hens at up to 30X the maximum anticipated dietary burden. It was concluded that residues resulting from an anticipated 1X exposure would not exceed 0.01 ppm in poultry tissues and eggs.

The qualitative nature of the residue in ruminants is adequately understood. The residues of concern in ruminants are terbufos and its phosphorylated (cholinesterase-inhibiting) metabolites. Treatment of goats at exaggerated terbufos dose levels resulted in regulated terbufos residue levels of <0.01 ppm in milk, liver and kidney (MRID Nos. 43237801 and 43237802. CBRS Nos. 13803 and 13804).

§171-4 (c) and (d): Residue Analytical Methods-Plants and Animals: An adequate method is available for data collection and enforcement of terbufos tolerances in or on plant commodities.

The GLC/flame ionization-detection method for determining terbufos and its phosphorylated metabolites is described in PAM, Vol. II, as Method I. The hazardous reagent benzene is specified in this method.

Method M-1754, a modification of Method I in PAM that substitutes acetone for benzene and methylene chloride for chloroform, underwent a successful Residue Analytical Laboratory method validation trial and was forwarded to FDA for revision of PAM, Vol II.

§171-4 (e): Storage Stability: No additional storage stability data are required. The available storage stability data indicate that residues of terbufos, terbufoxon sulfoxide, and terbufoxon sulfone are stable in or on corn grain, forage, and fodder, sorghum grain, forage and fodder, and in or on sugar beet roots and tops stored at -10 °C for up to 2 years.

§171-4 (k): Magnitude of the Residue in Plants and Animals:

No additional residue data are required to support existing tolerances for terbufos residues in/on plant commodities; however, amended labels specifying a 150-day PHI for sugar beets and a 60-day PHI for sweet corn (K + CWHR) are required. Labels must be amended to specify a 50-day pre-grazing/feeding interval for sorghum forage, and a 100-day PHI for sorghum grain and fodder.

§171-4 (l): Magnitude of the Residue in Processed Commodities:

The requirements for corn and sorghum processing studies were waived by the Agency [CBRS No. 13593, C. Swartz, 5/5/94]. (The tolerance in the RAC should be used in assessing the dietary risk associated with corn processed fractions.)

§171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs:

Based on poultry metabolism data in which a 30X dose resulted in nondetectable (<0.01 ppm) residues in laying hen tissues and eggs, it was concluded that residues resulting from 1X the dietary burden would not be detectable in poultry tissues and

eggs. This is equivalent to classification of terbufos residues in poultry under 40 CFR §180.6(a)(3), and therefore no tolerances for terbufos residues in poultry commodities are required.

Based on a goat metabolism study (MRID 42576901) in which a 10X dose resulted in non-detectable (<0.01 ppm) regulated terbufos residues in meat, milk, liver and kidney, it was concluded that terbufos residues in meat and milk can be classified under 40 CFR §180.6(a)(3), i.e. there is no reasonable expectation of finite residues. No tolerances are required. Reserved ruminant feeding studies are not required.

§165-1 Confined Rotational Crops:

A confined rotational crop study was submitted and determined to be adequate to fulfill the data requirements for this guideline. A field rotational crop study was required, based on the results of the confined study.

§165-2 Field Rotational Crops:

The required field rotational crop studies were submitted. Rotated spring wheat, sugar beets, and cabbage were planted about 30 days after the corn field had been treated. Terbufos residues were less than 0.05 ppm in the tops and roots of beets, in whole cabbages, and in wheat grain; wheat straw contained residues of 0.10 ppm; spring wheat forage had residues of 0.15 ppm. Additional confirmatory limited field trials are required to determine if rotational crop tolerances are necessary because the limited field trials involved analysis of single samples for each crop matrix, and residues were found in wheat forage and straw.

c. Occupational-use products and homeowner-use products

At this time no products containing terbufos are intended primarily for homeowner use. All products containing terbufos are intended primarily for occupational use. None of the registered occupational uses are likely to involve applications at residential sites.

d. Handler Exposures & Assumptions

EPA has determined there is a potential exposure to mixers, loaders, applicators, or other handlers during usual use-patterns associated with terbufos. Of particular concern are dermal and inhalation exposures during loading of terbufos granular into hoppers and dermal and inhalation exposures during application. Mixer/loader/applicator (M/L/A) exposure data for terbufos were required during Phase IV of the reregistration process, since one or more toxicological criteria had been triggered at that time.

Exposure was estimated for handlers treating corn using typical- and maximum-size treated areas and typical and maximum application rates, since these data were available from the Corn Cluster Assessment (BEAD-supplied data). Typical application rates were not available for sugar beets or grain sorghum. Exposure was estimated for handlers treating these crops using typical- and maximum-size treated areas and maximum application rates (LUIS-supplied data).

Table 2 describes the simulated clothing/equipment used to calculate the exposure values reported in Tables 3 and 4. The dermal exposure scenarios are presented in Table 3 and the corresponding inhalation exposure assessment in Table 4. The footnotes summarize the caveats and parameters specific to each exposure scenario. Protection factors were applied, in some instances, to the dermal exposure data reported in Table 3 to simulate use of the following personal protective equipment:

- For loaders

  PPE represents loaders using open loading systems while wearing chemical-resistant gloves plus coveralls worn over long pants and long sleeve shirt;

  Engineering controls represent loaders using closed loading systems (lock 'n load) while wearing long pants and long-sleeve shirts. (Since actual exposure data were not available, a 90 percent protection factor was used to simulate Lock'N Load closed granular loading.)

- For applicators

  PPE represents applicators using open cab tractors while

wearing chemical-resistant gloves plus coveralls over long pants and long-sleeve shirts. (A 98 percent protection factor was used to back-calculate from enclosed-cab data to simulate an open-cab-tractor scenario.)

Engineering controls represent applicators using enclosed cabs while wearing long-sleeve shirts and long pants. (A 90 percent protection factor was used to back-calculate to simulate workers wearing no gloves while in an enclosed cab.)

Protection factors were applied to the inhalation exposure data reported in Table 4 to simulate use of the following personal protective equipment:

- For loaders

PPE represents loaders using open loading systems while wearing a respirator with an organic-vapor-removing cartridge and a prefilter approved for pesticides. (A 90 percent protection factor was used to simulate wearing the respirator.)

Engineering controls represent loaders using closed loading systems (lock 'n load) while wearing chemical-resistant gloves. (A 90 percent protection factor was used to simulate Lock & Load closed granular loading.)

- For applicators:

PPE represents applicators using open cab tractors while wearing a respirator with an organic-vapor-removing cartridge and a prefilter approved for pesticides. (A 90 percent protection factor was used to simulate wearing the respirator.)

Engineering controls represent applicators using enclosed cabs. (A 90 percent protection factor was used to simulate an enclosed-cab system with an air-filtration system equivalent to the organic-vapor cartridge respirator with a pesticide prefilter.)

TABLE 2: MIXER/LOADER/APPLICATOR EXPOSURE SCENARIO DESCRIPTION

Exposure Scenario (Number)	Data Source	Clothing Scenario		Equipment		Standard Assumptions[b] (8-hr work day)	Comments
		PPE	Engineering Controls	PPE	Engineering Controls		
Mixer/Loader Exposure							
Loading Granulars (I)	PHED V1.1	Coveralls over long sleeved shirt and long pants; chemical resistant gloves; respirator with organic vapor removing cartridge.	Long sleeved shirt and long pants; no gloves; no respirator	Open loading granulars	Closed loading granulars using a Lock & Load system	Loading for typical and maximum acreage and rates for sugar beets, grain sorghum, and corn	PPE: Dermal and inhalation acceptable grades. Dermal = 12 to 45 replicates; Inhalation = 58 replicates. Medium confidence in the dermal data. High confidence in the inhalation data. Engineering Controls: Dermal all grades; inhalation acceptable grades. Dermal = 10 to 78 replicates; Inhalation = 58 replicates. Low confidence in the dermal data. High confidence in the inhalation data.
Applicator Exposure							
Granular Row Planter (II)	PHED V1.1	Coveralls over long sleeved shirt and long pants; chemical resistant gloves; respirator with organic vapor removing cartridge.	Long sleeved shirt and long pants; no gloves; no respirator	Open cab tractor	Enclosed cab tractor	Application of typical and maximum acreage and rates for sugar beets, grain sorghum, and corn	PPE: Dermal and inhalation acceptable grades. Dermal = 2 to 17 replicates; Inhalation = 17 replicates. Low confidence in the dermal data. High confidence in the inhalation data. Engineering Controls: Dermal and inhalation acceptable grades. Dermal = 2 to 17 replicates; Inhalation = 17 replicates. Low confidence in the dermal data. High confidence in the inhalation data.

Clothing represents the exposure estimates used in Table 2.

Standard Assumptions based on an 8-hour work day as described in Table 2.

"Acceptable grades." as defined by OREB SOP for meeting Subdivision U Guidelines, are grades A and B for dermal, hand, and inhalation matrices. All grades that do not meet OREB's SOP are listed individually.

TABLE 3: DERMAL EXPOSURE MIXER/LOADER/APPLICATOR FOR TERBUFOS

Exposure Scenario (Number)	Dermal Exposure[a] (mg/lb ai)		Crop	Label Application Rates[b] (lb ai/acre)	Daily Acres Treated[c]	Daily Dermal Dose[d] (mg/kg/day)	
	PPE	Engineering Controls				PPE	Engineering Controls
			Mixer/Loader Exposure				
			Typical Acres Treated at Maximum Rates				
Granular Loaders (I)	0.003	0.001	Sugar Beets	4.35	69	0.013	0.0043
			Grain Sorghum	3.92		0.012	0.0039
			Corn	1.97		0.0058	0.0019
			Maximum Acres Treated at Maximum Rates				
			Sugar Beets	4.35	213	0.040	0.013
			Grain Sorghum	3.92		0.036	0.012
			Corn	1.97		0.018	0.0060
			Typical Acres Treated at Typical Rate				
			Corn	1.12	69	0.0033	0.0011
					100	0.0048	0.0016
			Maximum Acres Treated at Typical Rate				
			Corn	1.12	213	0.010	0.0034
			Applicator Exposure				
			Typical Acres Treated at Maximum Rates				
Granular Row Planters (II)	0.2	0.003	Sugar Beets	4.35	69	0.86	0.013
			Grain Sorghum	3.92		0.78	0.012
			Corn	1.97		0.39	0.0058
			Maximum Acres Treated at Maximum Rates				
			Sugar Beets	4.35	213	2.6	0.040
			Grain Sorghum	3.92		2.4	0.036
			Corn	1.97		1.2	0.018
			Typical Acres Treated at Typical Rate				
			Corn	1.12	69	0.22	0.0033
					100	0.32	0.0048
			Maximum Acres Treated at Typical Rates				
			Corn	1.12	213	0.68	0.010

[a] The PPE represents coveralls over long pants, long sleeved shirt, chemical resistant gloves while using open systems. The engineering controls represent long pants, long-sleeved shirt, no gloves and closed systems (i.e., Lock & Load or enclosed cabs).

[b] Maximum application rate based on labelled uses and LUIS report for terbufos.

[c] Acres treated are based on 8 row planters (69 acres/day) and 20 row planters (213 acres/day) and a typical application rate of 1.12 lb ai/A for corn.

[d] Daily Dermal Dose (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/acre)} * \text{Max. Treated}}{70 \text{ kg}}$

where:

application rates and acres treated can be typical or maximum as discussed in the text. Typical application rate is only available for corn.

TABLE 4: INHALATION EXPOSURE MIXER/LOADER/APPLICATOR FOR TERBUFOS

Exposure Scenario (Number)	Inhalation Exposure[a] (mg/lb ai)		Crop	Label Application Rates[b] (lb ai/acre)	Daily Acres Treated[c]	Daily Inhalation Dose[d] (mg/kg/day)
	PPE	Engineering Controls				
			Mixer/Loader Exposure			
			Typical Acres Treated at Maximum Rates			
Granular Loaders (I)	2×10^{-4}	2×10^{-4}	Sugar Beets	4.35	69	8.6×10^{-4}
			Grain Sorghum	3.92		7.8×10^{-4}
			Corn	1.97		3.9×10^{-4}
			Maximum Acres Treated at Maximum Rates			
			Sugar Beets	4.35	213	2.6×10^{-3}
			Grain Sorghum	3.92		2.4×10^{-3}
			Corn	1.97		1.2×10^{-3}
			Typical Acres Treated at Typical Rate			
			Corn	1.12	69	2.2×10^{-4}
					100	3.2×10^{-4}
			Maximum Acres Treated at Typical Rate			
			Corn	1.12	213	6.8×10^{-4}
			Applicator Exposure			
			Typical Acres Treated at Maximum Rates			
Granular Row Planters (II)	4×10^{-4}	4×10^{-4}	Sugar Beets	4.35	69	1.7×10^{-3}
			Grain Sorghum	3.92		1.6×10^{-3}
			Corn	1.97		7.8×10^{-4}
			Maximum Acres Treated at Maximum Rates			
			Sugar Beets	4.35	213	5.3×10^{-3}
			Grain Sorghum	3.92		4.8×10^{-3}
			Corn	1.97		2.4×10^{-3}
			Typical Acres Treated at Typical Rate			
			Corn	1.12	69	4.4×10^{-4}
					100	6.4×10^{-4}
			Maximum Acres Treated at Typical Rates			
			Corn	1.12	213	1.4×10^{-3}

[a] The PPE inhalation exposure values are for workers wearing organic vapor removing respirators (90 fold PF used). The engineering control values are for workers wearing no respirators, but loading and applying the pesticide within closed systems (i.e., Lock & Load or enclosed cab). Since the protection afforded by the respirator is equivalent to the Lock & Load or an enclosed cab with proper positive pressure filtration (i.e., inhalation exposure values are the same), only one set of daily dose and MOE are calculated.

[b] Maximum application rate based on labelled uses and LUIS report for terbufos.

[c] Acres treated are based on 8 row planters (69 acres/day) and 20 row planters (213 acres/day) and a typical application rate of 1.12 lb ai/A for corn.

[d] Daily Inhalation Dose (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/acre)} * \text{Max. Treated}}{70 \text{ kg}}$

where:

application rates and acres treated can be typical or maximum as discussed in the text. Typical application rate is only available for corn.

$$\text{NOEL} = 0.01 \text{ mg/m}^3 \left(\frac{0.01 \text{ mg/m}^3 \times 10 \text{ m}^3\text{/day}}{70 \text{ kg}} = 0.0014 \text{ mg/kg/day} \right)$$

where:

10 m^3 is the volume of air inhaled in a typical eight hour work day (OSHA Docket H-049, 1993)

Post-Application Exposures & Assumptions

EPA has determined the potential exposure to persons entering treated sites after application is minimal as long as: (1) the application is incorporated correctly, or (2) the reentry task does not involve contact with the soil subsurface.

THIS SECTION IS INCOMPLETE. IT CANNOT BE COMPLETED UNTIL HANDLER RISK-MITIGATION MEASURES ARE FINALIZED.

Post Application/Reentry/Exposure

Foliar residue dissipation data (132-1a) were required for aerial/broadcast applications in arid climates (i.e., rainfall less than 25 inches), according to the terbufos Registration Standard (September, 1988). A post-application reentry interval of 7 days was specified for broadcast applications without soil incorporation. The registrant is not supporting broadcast applications. Therefore, potential post-application/reentry exposures to terbufos applications are limited to granular terbufos soil incorporation treatments for which the 7 day REI will not be required.

No reentry data are required, since post-application foliar and soil exposures are likely to be minimal. For chemicals in this toxicity category (acute dermal I), the Worker Protection Standard PR Notice 93-7 Supplement Three-A requires an REI of 48 hours and an REI of 72 hours in arid (less than 25 inches of precipitation) climates. REIs provided in the Worker Protection Standards are expected to be adequate, because the aerial/broadcast applications are not supported by the registrant.

e. Incidence Data

Of the 28 organophosphates and carbamates examined in the Agency's Acute Worker Risk Strategy (AWRS), terbufos had one of the highest estimated dermal toxicities for a formulated product (8-10 mg/kg body weight for 15-20% granular formulations). Two deaths from ingestion of terbufos were reported in 1990 (EPA Region 5 report and American Association of Poison Control Centers Annual Report), but no deaths were reported from dermal exposure to terbufos. No deaths or poisonings have been reported in California since 1980, however no usage was reported for California either.

The American Association of Poison Control Centers maintains a Toxic Exposure Surveillance System which is one of the only available sources of data on terbufos poisoning. A total of 80 occupational exposures, 49 non-occupational exposures to adults, and 19 exposures in children under six years of age were reported to the Poison Control Center between 1985 and 1992. The 28 chemicals in the AWRS were ranked on the basis of percent with symptoms, life threatening effects, requirement for medical care, or hospitalization. Terbufos ranked fifth overall for occupational cases and third overall for non-occupational adults. However, when the frequency of symptoms, life-threatening symptoms, health care and hospitalization were adjusted for national estimates of use (pounds active ingredient), terbufos exhibited lower ratios than the median for other organophosphates and carbamates used in agriculture. This suggests that the incidence of terbufos poisonings in workers at risk may be low, though when over-exposed poisoning may be more likely to be serious.

III. RISK CHARACTERIZATION

a. Dietary Risk

i. Acute Risk Analysis

As previously stated the acute dietary endpoint (one day) is based on the NOEL for plasma cholinesterase inhibition (0.005 mg/kg/day) in dogs (MRID 40374701).

Acute dietary exposure analysis estimates the distribution of single-day exposures for the U.S. population and certain subgroups. The analysis evaluates individual food consumption as reported by respondents in the 1977-78 Nationwide Food Consumption Survey and accumulates exposure to terbufos for each food commodity which has a terbufos tolerance. As such, the exposure estimate is a maximal estimate because it assumes that terbufos residues are present at the maximum legal limit in the entirety of the commodities in which they can occur.

The RACs (Raw Agricultural Commodities) and tolerances, used in this assessment, were derived from 40 CFR 180.352 and the Tolerance Index System and are listed below and in Appendix A:

RAC	Tolerance (ppm)
Bananas	0.025
Coffee	0.05

Beets, Sugar (Roots)	0.05
Corn, Grain	0.05
Corn, Sweet	0.05
Sorghum, Grain	0.05

The Margin of Exposure (MOE) for acute dietary risk was calculated for the U.S. population and for four population subgroups. The calculated MOEs using a NOEL of 0.005 mg/kg bodyweight/day were:

Population Groups	Percentile Pop.	MOE
U.S. population	96th	25
Infants (Less Than One Year Old)	96th	10
Children (1-6 Years Old)	98th	10
Females (> or = 13 Years Old)	93rd	50
Males (> or = 13 Years Old)	91st	50

$$\text{Margin of Exposure} = \frac{\text{NOEL}}{\text{exposure}}$$

An acute Margin of Exposure (MOE) using a NOEL based on animal data that is ≥ 100 for the U.S. Population, or any of its subgroups that are analyzed by the DRES system, is generally considered not to be of concern. In the current analysis terbufos appears to present acute dietary risk concerns for all populations evaluated.

ii. Chronic Risk Analysis

As previously stated the Reference Dose (RfD) for chronic oral exposure was determined to be 0.00005 mg/kg/day based on a NOEL of 0.005 mg/kg/day for plasma cholinesterase inhibition in a 28 day oral study in dogs.

The total TMRC (Theoretical Maximum Residue Contributions) exposure for dietary exposure from terbufos for the U.S. population was estimated as being 0.000052 mg/kg bodyweight per day and the risk estimate was 104% of the Reference Dose (RfD). The subgroups with the highest estimated dietary TMRC exposures/risks were:

Subgroup	**TMRC Exposure**	**TMRC Risk**
U.S. Population	0.000055	110% RfD
Non-nursing Infants (< 1 Year Old)	0.000116	232% RfD
Children (1 to 6 Years Old)	0.000131	262% RfD
Children (7 to 12 Years Old)	0.000089	178% RfD

*mg/kg bodyweight per day

Adjustments of the TMRC exposure, by inclusion of percent crop treated data for Field Corn; Sweet Corn; Sorghum; and Sugar Beets, Roots in the DRES terbufos file to produce ARCs (Anticipated Residue Contributions) for the same subgroups, substantially lowered the estimates of chronic dietary exposure and risk to terbufos. The total dietary ARC exposure of the U.S. population was estimated as being 0.000016 mg/kg bodyweight per day and the risk estimate was 33% of the RfD. The subgroups with the highest estimated dietary total ARC exposures/risks were:

Subgroup	**ARC Exposure***	**ARC Risk**
Non-nursing Infants (<1 Year Old)	0.000040	81% RfD
Children (1 to 6 Years Old)	0.000039	77% RfD
Children (7 to 12 Years Old)	0.000022	44% RfD

*mg/kg bodyweight per day

A recently published FR notice for a tolerance in coffee was included in the above assessment. The raw agricultural commodities which contribute the most ARC exposure/risk for U.S. populations from dietary terbufos are; bananas, corn (all), and beets (sugar). Pending tolerances, especially for the RAC soybeans, increase the ARCs of the infant and children subgroups greater than the RfD.

For each of the subgroups with a total terbufos dietary ARC exposure (risk) estimate that exceeds the RfD, the total estimated ARC contributions of the commodities that currently have Pending tolerances, versus those that have Published tolerances, are as follows:

DIETARY RISK COMPARISON FOR PENDING AND PUBLISHED TOLERANCES

POPULATION GROUP	PENDING TOLERANCES		PUBLISHED TOLERANCES	
	EXPOSURE[1]	RISK[2]	EXPOSURE[1]	RISK[2]
Non-Nursing Infants (> yr)	0.000083	166	0.000040	81
Children (1-6 yr)	0.000045	90	0.000039	77

Children (7-12 yr)	0.000034	68	0.000022	44

[1] Exposure as mg/kg bodyweight per day.
[2] Risk as percent RfD.

Therefore, the Agency does not have concerns for chronic dietary exposure and resulting risk for uses being considered under reregistration.

b. Occupational Risk

EPA has determined there is potential exposure to mixers, loaders, applicators, or other handlers during usual use-patterns associated with terbufos. Of particular concern are dermal and inhalation exposures during loading the dry (granular) formulation and applying the dry formulation with granular-spreader equipment.

Table 2 describes the simulated clothing/equipment used to estimate risks. Margins of exposure (MOEs) for occupational exposure were calculated for handlers using a NOEL of 0.005 mg/kg/day for short and intermediate-term dermal exposure and a NOEL of 0.01 μg/L (0.0014 mg/kg/day) for short and intermediate-term inhalation exposure. The calculated dermal and inhalation MOEs are presented in Tables 5 and 6.

The estimated MOEs are all less than 100; with most being less than 5 for loaders and applicators of terbufos for all crop scenarios using both typical and maximum application rates and typical and maximum treated-area size. The MOEs for loaders and applicators are less than 100 even when engineering controls (closed loading system and enclosed cab with respiratory filtration system) are simulated. It should also be noted that <u>if</u> 50% dermal absorption was assumed the MOEs would still result in MOEs of less than 100.

Risk From Post-Application Exposures

[Note: the following sections need to be addressed with the registrant, because all scenarios yield MOEs less than 100.]

THIS RISK ASSESSMENT HAS BEEN POSTPONED PENDING THE OUTCOME OF THE HANDLER RISK-MITIGATION DECISION.

Additional Occupational/Residential Exposure Studies

Handler Studies

THIS DETERMINATION HAS BEEN POSTPONED PENDING THE OUTCOME OF THE HANDLER RISK-MITIGATION DECISION.

Post-Application Studies

THIS DETERMINATION HAS BEEN POSTPONED PENDING THE OUTCOME OF THE HANDLER RISK-MITIGATION DECISION.

TABLE 5: OCCUPATIONAL MARGINS OF EXPOSURE RESULTING FROM DERMAL EXPOSURE to TERBUFOS

Exposure Scenario (Number)	Crop	Daily Acres Treated[a]	Daily Dermal Dose[b] (mg/kg/day)		MOE (dermal)[d]	
			PPE[c]	Engineering Controls[c]	PPE[c]	Engineering Controls[c]
Mixer/Loader Exposure						
	Typical Acres Treated at Maximum Rates					
Granular Loaders (I)	Sugar Beets	69	0.013	0.0043	0.38	1.2
	Grain Sorghum		0.012	0.0039	0.42	1.3
	Corn		0.0058	0.0019	0.86	2.6
	Maximum Acres Treated at Maximum Rates					
	Sugar Beets	213	0.040	0.013	0.13	0.38
	Grain Sorghum		0.036	0.012	0.14	0.42
	Corn		0.018	0.0060	0.28	0.83
	Typical Acres Treated at Typical Rate					
	Corn	69	0.0033	0.0011	1.5	4.5
		100	0.0048	0.0016	1.0	3.1
	Maximum Acres Treated at Typical Rate					
	Corn	213	0.010	0.0034	0.50	1.5
Applicator Exposure						
	Typical Acres Treated at Maximum Rates					
Granular Row Planters (II)	Sugar Beets	69	0.86	0.013	0.0058	0.38
	Grain Sorghum		0.78	0.012	0.0064	0.42
	Corn		0.39	0.0058	0.013	0.86
	Maximum Acres Treated at Maximum Rates					
	Sugar Beets	213	2.6	0.040	0.0019	0.13
	Grain Sorghum		2.4	0.036	0.0021	0.14
	Corn		1.2	0.018	0.0042	0.28
	Typical Acres Treated at Typical Rate					
	Corn	69	0.22	0.0033	0.023	1.5
		100	0.32	0.0048	0.016	1.0
	Maximum Acres Treated at Typical Rates					
	Corn	213	0.68	0.010	0.0074	0.50

47

[a] Acres treated are based on 8 row planters (69 acres/day) and 20 row planters (213 acres/day) and a typical application rate of 1.12 lb ai/A for corn.

[b] Daily Dermal Dose (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/acre)} * \text{Max. Treated}}{70 \text{ kg}}$

where:

application rates and acres treated can be typical or maximum as discussed in the text. Typical application rate is only available for corn.

[c] The PPE represents coveralls over long pants, long sleeved shirt, chemical resistant gloves while using open systems. The engineering controls represent long pants, long-sleeved shirt, no gloves and closed systems (i.e., Lock & Load or enclosed cabs).

[d] MOE = NOEL / Daily Dermal Dose (mg/kg/day). NOEL = 0.005 mg/kg/day for oral study, dermal absorption data are not available, 100 percent is assumed.

hh

Table 6: OCCUPATIONAL MARGINS OF EXPOSURE RESULTING FROM INHALATION EXPOSURE to TERBUFOS

Exposure Scenario (Number)	Crop	Daily Acres Treated[a]	Daily Inhalation Dose[b,c] (mg/kg/day)	MOE (inhalation)[c,d]
Mixer/Loader Exposure				
	Typical Acres Treated at Maximum Rates			
Granular Loaders (I)	Sugar Beets	69	8.6×10^{-4}	1.6
	Grain Sorghum		7.8×10^{-4}	1.8
	Corn		3.9×10^{-4}	3.6
	Maximum Acres Treated at Maximum Rates			
	Sugar Beets	213	2.6×10^{-3}	0.54
	Grain Sorghum		2.4×10^{-3}	0.58
	Corn		1.2×10^{-3}	1.2
	Typical Acres Treated at Typical Rate			
	Corn	69	2.2×10^{-4}	6.4
		100	3.2×10^{-4}	4.4
	Maximum Acres Treated at Typical Rate			
	Corn	213	6.8×10^{-4}	2.1
Applicator Exposure				
	Typical Acres Treated at Maximum Rates			
Granular Row Planters (II)	Sugar Beets	69	1.7×10^{-3}	0.82
	Grain Sorghum		1.6×10^{-3}	0.88
	Corn		7.8×10^{-4}	1.8
	Maximum Acres Treated at Maximum Rates			
	Sugar Beets	213	5.3×10^{-3}	0.26
	Grain Sorghum		4.8×10^{-3}	0.29
	Corn		2.4×10^{-3}	0.58
	Typical Acres Treated at Typical Rate			
	Corn	69	4.4×10^{-4}	3.2
		100	6.4×10^{-4}	2.2
	Maximum Acres Treated at Typical Rates			
	Corn	213	1.4×10^{-3}	1.0

45

[a] Acres treated are based on 8 row planters (69 acres/day) and 20 row planters (213 acres/day) and a typical application rate of 1.12 lb ai/A for corn.

[b] Daily Inhalation Dose (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/acre)} * \text{Max. Treated}}{70 \text{ kg}}$

where:

application rates and acres treated can be typical or maximum as discussed in the text. Typical application rate is only available for corn.

[c] The PPE inhalation exposure values are for workers wearing organic vapor removing respirators (90 fold PF used). The engineering control values are for workers wearing no respirators, but loading and applying the pesticide within closed systems (i.e., Lock & Load or enclosed cab). Since the protection afforded by the respirator is equivalent to the Lock & Load or an enclosed cab with proper positive pressure filtration (i.e., inhalation exposure values are the same), only one set of daily dose and MOE are calculated.

[d] MOE = NOEL / Daily Inhalation Dose (mg/kg/day).

$$\text{NOEL} = 0.01 \text{ mg/m}^3 \left(\frac{0.01 \text{ mg/m}^3 \times 10 \text{ m}^3/\text{day}}{70 \text{ kg}} = 0.0014 \text{ mg/kg/day} \right)$$

where:

10 m^3 is the volume of air inhaled in a typical eight hour work day (OSHA Docket H-049, 1993)

Post-Application Risk

There is minimal potential for post-application exposure risk from the registered granular terbufos products under the requirements of the WPS when the product is applied according to label specifications. The post-application risk would be expected to be less than those risks associated with handler exposure. HED recommends retention of existing REIs (re-entry intervals), at 48 hours and 72 hours (arid regions) as currently required by the Worker Protection Standard PR Notice 93-7 for soil incorporated treatment by Terbufos. Personal protective equipment (PPE) selection for mixer/loaders/ applicators and other handlers is to be based on exposure to the end use product. Label statements to be included on all Terbufos labels are located on the Pesticide Worksheets--Parts One and Two: User Safety Statements, Application Restrictions, Entry Restrictions, Early Entry PPE, and Notification (Attached).

Data Requirements

Confirmatory data are required as follows:

1) Acute inhalation toxicity data (Guideline 81-3) are required.

2) Additional field rotational crop (Guideline 165-2) data are required to fulfill residue chemistry data requirements.

3) Label amendments are required (Guideline 171-4(e)) for the RAC(s) sugarbeets, sweet corn(K+CWHR) as well as for sorghum grain, fodder and forage.

REFERENCES

00035121 Parke, G. S. E.; Terrell, Y. (1976). Acute Toxicity Studies in Rats. Compound: Enlist Technical Insecticide (terbufos). Report No. 6E-3164. Unpublished Aceto Chemical Co., Inc. study prepared by Cannon Laboratories.

00037467 American Cyanamid Company (1972). Toxicity Data: O,O-Diethyl-S-(tert-butylthiomethyl) phosphorodithioate Technical, 85.8%. Report No. A-72-95. Unpublished study prepared by American Cyanamid Co.

00037471 Kretchmar, B. (1972). Report to American Cyanamid: Acute Oral Toxicity Studies with Two Samples in Female Albino Rats. Report No. A 1373. Unpublished American Cyanamid Co. study prepared by Industrial Bio-Test Laboratories.

00037472 Smith, J. H., Rosselet, C.; Cannelongo, B. (1972). A Neurotoxicity Study of AC 92,100, an Organic Phosphate Cholinesterase Inhibitor, in Hens. Report No. 72S-788. Unpublished American Cyanamid Co. study prepared by Bio/Dynamics, Inc.

00044957 American Cyanamid Company (1972). Toxicity Data of 0,0-Diethyl- S-(tert-butylthiomethyl) phosphorodithioate. Report No. A-72-3. Unpublished study prepared by American Cyanamid Co.

00049236 Rapp, W. R.; Wilson, N. H.; Mannion, M. (1974). A Three and Twenty-Four Month Oral Toxicity and Carcinogenicity Study of AC 92-100 in Rats. Report No. 71R-725. Unpublished American Cyanamid Co. study prepared by Bio/Dynamics, Inc.

00063209 Allen, J. S.; Johnson, E.; Wainwright, C (1977). Mutagenicity Testing of Technical Counter (R) Soil Insecticide (terbufos) in the Ames Test. Report No. AIR 5:419-431. Unpublished study prepared by American Cyanamid Co.

00085169 Kruger, R.; Feinman, H. 1973. 30-day Subacute Dermal Toxicity in Rabbits of AC-92100. Study No. 1611. Unpublished study prepared by FDRL and submitted by American Cyanamid.

00085172 Smith, J. M.; Kasner, J. A.; Wilson, N. H. (1972). A

Three Generation Reproduction Study of Pesticide AC 92,100 in Rats. Report No. 71R-727. Unpublished American Cyanamid Co. study prepared by Bio/Dynamics, Inc.

00087695 North, H. H. (1973). Counter Insecticide: Rat Metabolism of CL 92,100. Report No. 2-402. Unpublished study prepared by American Cyanamid Co.

00109446 Daly, I.; Rinehart, W.; Martin, A. (1979). A Three-Month Feeding Study of Counter terbufos Insecticide in Rats. Report No. 78-2343. Unpublished American Cyanamid Co. study prepared by Bio/Dynamics Inc.

00133296 Thilagar, A.; Kumaroo, P.; Kott, S. (1983). Chromosome Aberrations in Chinese Hamster Ovary Cells. Report No. T1906. 337006. Unpublished American Cyanamid Co. study prepared by Microbiological Associates, Inc.

00133297 Allen, J. S.; Johnson, E.; Fine, B. (1983). Mutagenicity Testing of AC 92,100 in the in vitro CHO/HGPRT Mutation Assay. Report No. 0402. Unpublished study prepared by American Cyanamid Co.

00133298 Godek, E.; Naismith, R.; Matthews, R. (1983). Rat Hepatocyte Primary Culture/DNA Repair Test. Report No. PH 311-AC-001-83. Unpublished American Cyanamid Co. study prepared by Pharmakon Research International, Inc.

00144805 Fisher, J. (1985). Rabbit Dermal LD_{50} (Intact Skin). Report No. A 85-54. Unpublished study prepared by American Cyanamid Co.

00147533 Rodwell, D. (1985). A teratology Study with AC 92,100 in Rats -Report No. WIL-35014. Unpublished study prepared by WIL Research Laboratories, Inc.

00161570 Putman, D. (1986). The Acute in vivo Cytogenetics Assay in Rats. Report No. T4277. 105002. Unpublished study prepared by Microbiological Associates Inc.

00161571 Mackenzie, K. (1986). Dominant Lethal Study with AC 92,100 in Rats: Final Report. Report No. 6123-137. Unpublished American Cyanamid Co. study prepared by Hazleton Laboratories America, Inc.

00161572 Shellenberger, T. (1986). One-Year Oral Toxicity Study

in Purebred Beagle Dogs with AC 92,100. Report No. 8414. Unpublished American Cyanamid Co. study prepared by Tegeris Laboratories, Inc.

00258710 Rusch, G. M.; Rinehart, W. E. (1980). A Two Week Inhalation Toxicity Study of Technical Counter terbufos in the Rat. Report No. 78-7168. Unpublished study prepared by Bio/dynamics Inc.

40098602 Daly, I. (1987). A One-Year Dietary Toxicity Study with AC 92,100 in Rats: Chronic Toxicity in Rats. Report No. 85-2964. Unpublished study prepared by Bio/Dynamics, Inc.

40098603 Shellenberger, T. (1986). Chronic Dietary Toxicity and Oncogenicity Study with AC 92,100 in Mice: Chronic Toxicity and Oncogenicity - Mouse. Report No. 8422. Unpublished study prepared by Tegeris Laboratories, Inc.

40374701 Shellenberger, T.E. 1987. 28-Day Oral Toxicity Study in the Dog with AC 92,100. Study No. 87-021. Unpublished study conducted by Tegeris Laboratories. Also MRID 40374702.

40886301 Hoberman, A. (1988). A Developmental Toxicity Study (Embryo-Fetal Toxicity Teratogenicity) Study with AC 92-100 in Rabbits. Report No. 101-008. Unpublished study prepared by Argus Research Laboratories, Inc.

Ioannou, M. (1995). Terbufos - Toxicology Endpoint Selection Document. U. S. EPA Memorandum dated January 19.

Levy, A.C. (1990). Terbufos (Counter 5G) - State of Minnesota Request for Emergency Use for Control of Flea Beetles on Rape. U. S. EPA Memorandum dated February 9.

Parkin, W. E. (1973). Request for Temporary Negligible Residue Tolerances for the Insecticide S-(tert-butylthio)-methyl-0,0-diethyl phosphorodithioate and its Cholinesterase Inhibiting Metabolites in or on Corn, Grain, Forage and Fodder at 0.05 ppm. U. S. EPA Memorandum dated February 6.

50

TERBUFOS TOLERANCE SUMMARY APPENDIX A

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under §180.352(a)			
Bananas	0.025	0.025	
Beets, sugar (roots)	0.05 (N)	0.05	The negligible residue designation (N) should be deleted. *Sugar beets (roots)*
Beets, sugar (tops)	0.1	0.1	*Sugar beets (tops)*
Corn, field, fodder	0.5	0.5	
Corn, field, forage	0.5	0.5	
Corn, pop, fodder	0.5	0.5	
Corn, pop, forage	0.5	0.5	
Corn, grain	0.05 (N)	0.05	The tolerance for "Corn, grain" should be replaced with separate tolerances for *Corn, field, grain* and *Corn, pop, grain* The negligible residue designation (N) should be deleted.
Corn, sweet (K+CWHR)	0.05 (N)	0.05	The negligible residue designation (N) should be deleted.
Corn, sweet, forage	0.5	0.5	
Corn, sweet, fodder	0.5	0.5	
Sorghum, fodder	0.5	1.0	
Sorghum, forage	0.5	1.0	
Sorghum, grain	0.05	0.05	
Tolerances listed under §180.352(b)			
Coffee beans, green	0.05	0.05	A proposal to extend the existing time-limited tolerance for an additional 2 years was issued in the FR [August 2, 1995; Volume 60, No. 148].

57

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Terbufos Caswell #131A CAS No. 13071-79-9 A.I. CODE: 105001 CFR No. 180.352	28d feeding- dog NOEL= 0.0050 mg/kg 0.00 ppm LEL= 0.0150 mg/kg 0.00 ppm ONCO: E (RfD/PR Committee)	Inhibition of plasma ChE. No evidence of carcinogenicity in rats or mice.	ADI UF -->300 OPP RfD= 0.000050 EPA RfD= 0.000050	No data gaps. 1-yr dog feeding study used as co-critical. LEL= 0.015 mg/kg (inhibition of plasma ChE); NOEL not established.	HED reassess 09/25/97 EPA deferred 06/22/88 WHO reviewed 1989 RfD/PR reviewed 09/25/97 RfD/PR reviewed 05/22/96 RfD/PR reviewed 05/23/96

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.000055	0.000076	152.640000	43.142000	0.000038	75.83400
U.S. POPULATION - SPRING SEASON	0.000052	0.000073	145.968000	42.180000	0.000037	73.87600
U.S. POPULATION - SUMMER SEASON	0.000056	0.000078	156.492000	43.828000	0.000039	77.01600
U.S. POPULATION - FALL SEASON	0.000053	0.000075	150.574000	43.910000	0.000038	76.54800
U.S. POPULATION - WINTER SEASON	0.000053	0.000074	148.054000	42.652000	0.000038	75.58600
NORTHEAST REGION	0.000047	0.000067	133.888000	40.472000	0.000035	70.64200
NORTH CENTRAL REGION	0.000054	0.000076	151.798000	43.772000	0.000038	76.80800
SOUTHERN REGION	0.000057	0.000078	155.592000	41.750000	0.000037	73.28000
WESTERN REGION	0.000056	0.000080	160.882000	48.240000	0.000043	85.41000
HISPANICS	0.000070	0.000090	180.962000	40.852000	0.000041	82.84000
NON-HISPANIC WHITES	0.000052	0.000074	147.922000	44.284000	0.000039	77.00000
NON-HISPANIC BLACKS	0.000057	0.000076	152.002000	37.166000	0.000032	64.40000
NON-HISPANIC OTHERS	0.000050	0.000070	140.182000	40.194000	0.000038	75.29600
NURSING INFANTS (< 1 YEAR OLD)	0.000051	0.000071	142.826000	40.796000	0.000048	95.36200
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000116	0.000199	397.922000	166.372000	0.000124	247.33800
FEMALES (13+ YEARS, PREGNANT)	0.000037	0.000052	103.606000	29.582000	0.000026	51.59600
FEMALES 13+ YEARS, NURSING	0.000041	0.000060	120.556000	39.458000	0.000033	65.50800
CHILDREN (1-6 YEARS OLD)	0.000131	0.000176	351.240000	89.794000	0.000084	167.12800
CHILDREN (7-12 YEARS OLD)	0.000089	0.000124	247.160000	68.364000	0.000056	112.82200
MALES (13-19 YEARS OLD)	0.000056	0.000079	157.196000	45.160000	0.000036	72.39000
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000047	0.000066	131.464000	36.508000	0.000030	60.57800
MALES (20 YEARS AND OLDER)	0.000038	0.000054	108.042000	33.034000	0.000029	57.93200
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000034	0.000049	97.452000	28.652000	0.000027	53.29600

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

Attachment 3

12

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 131A DATE: 11/18/97 PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Terbufos Caswell #131A CAS No. 13071-79-9 A.I. CODE: 105001 CFR No. 180.352	28d feeding- dog NOEL= 0.0050 mg/kg 0.00 ppm LEL= 0.0150 mg/kg 0.00 ppm ONCO: E (RfD/PR Committee)	Inhibition of plasma ChE. No evidence of carcinogenicity in rats or mice.	ADI UF -->300 OPP RfD= 0.000050 EPA RfD= 0.000050	No data gaps. 1-yr dog feeding study used as co-critical. LEL= 0.015 mg/kg (inhibition of plasma ChE); NOEL not established.	HED reassess 09/25/97 EPA deferred 06/22/88 WHO reviewed 1989 RfD/PR reviewed 09/25/97 RfD/PR reviewed 05/22/96 RfD/PR reviewed 05/23/96

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
06002AA	BANANAS-UNSPEC	22 COOKED-FRESH-BAKED	6E3409	P 0.025000	0.025000		100.00	0.025000
06002AB	BANANAS-FRESH	10 RAW-FRESH OR NFS	6E3409	P 0.025000	0.025000		100.00	0.025000
06002AB	BANANAS-FRESH	21 COOKED-NFS	6E3409	P 0.025000	0.025000		100.00	0.025000
06002AB	BANANAS-FRESH	31 COOKED-FRESH OR CANNED	6E3409	P 0.025000	0.025000		100.00	0.025000
06002DA	BANANAS-DRIED	10 RAW-FRESH OR NFS	6E3409	P 0.025000	0.025000		100.00	0.025000
06002DA	BANANAS-DRIED	21 COOKED-NFS	6E3409	P 0.025000	0.025000		100.00	0.025000
06016AA	PLANTAINS	21 COOKED-NFS	6E3409	P 0.025000	0.025000		100.00	0.025000
06016AA	PLANTAINS	23 COOKED-FRESH-BOILED	6E3409	P 0.025000	0.025000		100.00	0.025000
06016AA	PLANTAINS	25 COOKED-FRESH-FRIED	6E3409	P 0.025000	0.025000		100.00	0.025000
07002AA	COFFEE	21 COOKED-NFS	8E3574	P 0.050000	0.050000		100.00	0.050000
08028AA	MUSTARD SEED	11 RAW-FRESH-PICKLED,CORNED,OR CURED	3F2926	A 0.050000	0.050000		100.00	0.050000
08028AA	MUSTARD SEED	21 COOKED-NFS	3F2926	A 0.050000	0.050000		100.00	0.050000
15004AA	CORN,POP	21 COOKED-NFS	6F1657	P 0.050000	0.050000		100.00	0.050000
15005AA	CORN,SWEET	10 RAW-FRESH OR NFS	6F1657	P 0.050000	0.050000		9.00	0.004500
15005AA	CORN,SWEET	21 COOKED-NFS	6F1657	P 0.050000	0.050000		9.00	0.004500
15005AA	CORN,SWEET	31 COOKED-FRESH OR CANNED	6F1657	P 0.050000	0.050000		9.00	0.004500
15006AA	PEANUTS-WHOLE	10 RAW-FRESH OR NFS	4F2996	A 0.050000	0.050000		100.00	0.050000
15006AA	PEANUTS-WHOLE	21 COOKED-NFS	4F2996	A 0.050000	0.050000		100.00	0.050000
15006AA	PEANUTS-WHOLE	22 COOKED-FRESH-BAKED	4F2996	A 0.050000	0.050000		100.00	0.050000
24002EA	CORN,GRAIN-ENDO	10 RAW-FRESH OR NFS	6F1657	P 0.050000	0.050000		12.00	0.006000
24002EA	CORN,GRAIN-ENDO	21 COOKED-NFS	6F1657	P 0.050000	0.050000		12.00	0.006000
24002EA	CORN,GRAIN-ENDO	22 COOKED-FRESH-BAKED	6F1657	P 0.050000	0.050000		12.00	0.006000
24002EA	CORN,GRAIN-ENDO	23 COOKED-FRESH-BOILED	6F1657	P 0.050000	0.050000		12.00	0.006000
24002HA	CORN,GRAIN-BRAN	00 NOT SPECIFIED (NO CONSUMPTION)	6F1657	P 0.050000	0.050000		12.00	0.006000
24002SA	CORN SUGAR	10 RAW-FRESH OR NFS	6F1657	P 0.050000	0.050000		12.00	0.006000
24002SA	CORN SUGAR	21 COOKED-NFS	6F1657	P 0.050000	0.050000		12.00	0.006000
24002SA	CORN SUGAR	22 COOKED-FRESH-BAKED	6F1657	P 0.050000	0.050000		12.00	0.006000
24006AA	SORGHUM	00 NOT SPECIFIED (NO CONSUMPTION)	1F2540	P 0.050000	0.050000		3.00	0.001500
25002SA	BEET SUGAR	10 RAW-FRESH OR NFS	6F1657	P 0.050000	0.050000		29.00	0.014500
25002SA	BEET SUGAR	21 COOKED-NFS	6F1657	P 0.050000	0.050000		29.00	0.014500
25002SA	BEET SUGAR	22 COOKED-FRESH-BAKED	6F1657	P 0.050000	0.050000		29.00	0.014500
25002SA	BEET SUGAR	31 COOKED-FRESH OR CANNED	6F1657	P 0.050000	0.050000		29.00	0.014500
27002OA	CORN,GRAIN-OIL	18 PROCESSED OIL	6F1657	P 0.050000	0.050000		12.00	0.006000
27007OA	PEANUTS-OIL	18 PROCESSED OIL	8H5549	A 0.200000	0.200000		100.00	0.200000
27010OA	SOYBEANS-OIL	18 PROCESSED OIL	2F2608	A 0.050000	0.050000		100.00	0.050000
27017AA	RAPE SEED	00 NOT SPECIFIED (NO CONSUMPTION)	3F2926	A 0.050000	0.050000		100.00	0.050000
28023AA	SOYBEANS-UNSPEC	21 COOKED-NFS	2F2608	A 0.050000	0.050000		100.00	0.050000
28023AB	SOYBEANS-DRY	10 RAW-FRESH OR NFS	2F2608	A 0.050000	0.050000		100.00	0.050000
28023AB	SOYBEANS-DRY	21 COOKED-NFS	2F2608	A 0.050000	0.050000		100.00	0.050000
28023AB	SOYBEANS-DRY	23 COOKED-FRESH-BOILED	2F2608	A 0.050000	0.050000		100.00	0.050000

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Terbufos Caswell #131A CAS No. 13071-79-9 A.I. CODE: 105001 CFR No. 180.352	28d feeding- dog NOEL= 0.0050 mg/kg 0.00 ppm LEL= 0.0150 mg/kg 0.00 ppm ONCO: E (RfD/PR Committee)	Inhibition of plasma ChE. No evidence of carcinogenicity in rats or mice.	ADI UF -->300 OPP RfD= 0.000050 EPA RfD= 0.000050	No data gaps. 1-yr dog feeding study used as co-critical. LEL= 0.015 mg/kg (inhibition of plasma ChE); NOEL not established.	HED reassess 09/25/97 EPA deferred 06/22/88 WHO reviewed 1989 RfD/PR reviewed 09/25/97 RfD/PR reviewed 05/22/96 RfD/PR reviewed 05/23/96

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
28023AB	SOYBEANS-DRY	25 COOKED-FRESH-FRIED	2F2608	A 0.050000	0.050000		100.00	0.050000
28023AB	SOYBEANS-DRY	31 COOKED-FRESH OR CANNED	2F2608	A 0.050000	0.050000		100.00	0.050000
28023WA	SOY-FL, FULL FAT	21 COOKED-NFS	2F2608	A 0.050000	0.050000		100.00	0.050000
28023WA	SOY-FL, FULL FAT	22 COOKED-FRESH-BAKED	2F2608	A 0.050000	0.050000		100.00	0.050000
28023WA	SOY-FL, FULL FAT	31 COOKED-FRESH OR CANNED	2F2608	A 0.050000	0.050000		100.00	0.050000
28023WB	SOY-FL, LOW FAT	21 COOKED-NFS	2F2608	A 0.050000	0.050000		100.00	0.050000
28023WC	SOY-FL,DEFAT	10 RAW-FRESH OR NFS	2F2608	A 0.050000	0.050000		100.00	0.050000
28023WC	SOY-FL,DEFAT	21 COOKED-NFS	2F2608	A 0.050000	0.050000		100.00	0.050000
28023WC	SOY-FL,DEFAT	22 COOKED-FRESH-BAKED	2F2608	A 0.050000	0.050000		100.00	0.050000
28023WC	SOY-FL,DEFAT	51 COOKED-CANNED	2F2608	A 0.050000	0.050000		100.00	0.050000
28023WC	SOY-FL,DEFAT	53 COOKED-CANNED-BOILED	2F2608	A 0.050000	0.050000		100.00	0.050000

54

TOLERANCE ASSESSMENT SUMMARY FOR Terbufos DATE: 10/27/97
USING ANTICIPATED RESIDUES
CASWELL #131A

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.000016	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	32.686	% OF THE ADI.
NO NEW ANTICIPATED RESIDUES ARE IN THE FILE.		
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE CURRENT NEW PETITION HAVE AN ARC OF:	0.000022	MG/KG/DAY
THIS ARC WILL OCCUPY	43.148	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.000038	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	75.834	% OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: NURSING INFANTS (< 1 YEAR OLD)

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.000027	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	54.566	% OF THE ADI. x 3 = 164%
NO NEW ANTICIPATED RESIDUES ARE IN THE FILE.		
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE CURRENT NEW PETITION HAVE AN ARC OF:	0.000020	MG/KG/DAY
THIS ARC WILL OCCUPY	40.796	% OF THE ADI. x 3 = 122%
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.000048	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	95.362	% OF THE ADI. x 3 = 286%

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.000040	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	80.966	% OF THE ADI. x 3 = 243%
NO NEW ANTICIPATED RESIDUES ARE IN THE FILE.		
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE CURRENT NEW PETITION HAVE AN ARC OF:	0.000083	MG/KG/DAY
THIS ARC WILL OCCUPY	166.372	% OF THE ADI. x 3 = 499%
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.000124	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	247.338	% OF THE ADI. x 3 = 742%

TOLERANCE ASSESSMENT SUMMARY FOR Terbufos DATE: 10/27/97
USING ANTICIPATED RESIDUES
CASWELL #131A

ANALYSIS FOR POPULATION SUB-GROUP: CHILDREN (1-6 YEARS OLD)

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)			
RESULT IN AN ARC OF:	0.000039	MG/KG/DAY	X 3 = 232%
THE EXISTING ARC IS EQUIVALENT TO:	77.332	% OF THE ADI.	
NO NEW ANTICIPATED RESIDUES ARE IN THE FILE.			
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE			
CURRENT NEW PETITION HAVE AN ARC OF:	0.000045	MG/KG/DAY	X 3 = 269%
THIS ARC WILL OCCUPY	89.796	% OF THE ADI.	
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE			
CURRENT NEW PETITION) ARE GRANTED			
THE RESULTANT ARC WILL BE:	0.000084	MG/KG/DAY	X 3 = 501%
THE TOTAL ARC WILL OCCUPY	167.128	% OF THE ADI.	

ANALYSIS FOR POPULATION SUB-GROUP: CHILDREN (7-12 YEARS OLD)

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)			
RESULT IN AN ARC OF:	0.000022	MG/KG/DAY	X 3 = 133%
THE EXISTING ARC IS EQUIVALENT TO:	44.460	% OF THE ADI.	
NO NEW ANTICIPATED RESIDUES ARE IN THE FILE.			
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE			
CURRENT NEW PETITION HAVE AN ARC OF:	0.000034	MG/KG/DAY	X 3 = 205%
THIS ARC WILL OCCUPY	68.362	% OF THE ADI.	
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE			
CURRENT NEW PETITION) ARE GRANTED			
THE RESULTANT ARC WILL BE:	0.000056	MG/KG/DAY	X 3 = 338%
THE TOTAL ARC WILL OCCUPY	112.822	% OF THE ADI.	

DETAILED ACUTE ANALYSIS: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 15:17 Wednesday, March 22, 1995 7

	STUDY	RDV	NOEL	SF	STUDY TYPE	SPECIES	EFF. LEV.	CORE GRADE	DOC. NO.
*NAME: TERBUFOS	A	00000.0001		000100					
*CASWELL NO: 131A CFR NO: CFR180.352	B								
*CAS NO: 13071-79-9 SHAUGHNESSY NO: 105001	C								

*STATUS CODES:
*RDV INFO: The LD value used in this analysis is 0.0005 MG/KG of BODY WEIGHT/DAY
*FILE INFO: NEW ACTION: No User Modifications APPROVED:Data NOT Used PUBLISHED: Data Used

U.S. POP.--48 STATES

	ESTIMATED % OF POTENTIAL	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	
ESTIMATES BASED ON	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
PRIOR TOLERANCES:	99.20	0.000052	10.34
NEW TOLERANCES:	99.20	0.000052	10.34

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
PRIOR TOLERANCES:	100	14	4	1	1	0	0	0	0	0	0	0	0	0	0	0	0
NEW TOLERANCES:	100	14	4	1	1	0	0	0	0	0	0	0	0	0	0	0	0

MOE = 0.005 mg/kg/day ÷ 0.0005 mg/kg/day = 10

INFANTS(<1 YEAR)

	ESTIMATED % OF POTENTIAL	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	
ESTIMATES BASED ON	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
PRIOR TOLERANCES:	72.61	0.000138	27.52
NEW TOLERANCES:	72.61	0.000138	27.52

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
PRIOR TOLERANCES:	100	42	23	14	7	4	2	1	1	1	0	0	0	0	0	0	0
NEW TOLERANCES:	100	42	23	14	7	4	2	1	1	1	0	0	0	0	0	0	0

MOE = 0.005 mg/kg/day ÷ 0.001 mg/kg/day = 5

CHILDREN(1-6 YRS)

	ESTIMATED % OF POTENTIAL	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	
ESTIMATES BASED ON	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
PRIOR TOLERANCES:	99.77	0.000131	26.16
NEW TOLERANCES:	99.77	0.000131	26.16

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
PRIOR TOLERANCES:	100	47	20	9	4	2	1	1	0	0	0	0	0	0	0	0	0
NEW TOLERANCES:	100	47	20	9	4	2	1	1	0	0	0	0	0	0	0	0	0

MOE = 0.005 mg/kg/day ÷ 0.0008 mg/kg/day = 6

Attachment 5

57

DETAILED ACUTE ANALYSIS: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION

	STUDY	RDV	NOEL	SF	STUDY TYPE	SPECIES	EFF. LEV.	CORE GRADE	DOC. NO.
*NAME: TERBUFOS									
*CASWELL NO: 131A CFR NO: CFR180.352	A	00000.0001		000100					
*CAS NO: 13071-79-9 SHAUGHNESSY NO: 105001	B								
*STATUS CODES:	C								

*RDV INFO: The LD value used in this analysis is 0.0005 MG/KG of BODY WEIGHT/DAY

*FILE INFO: NEW ACTION: No User Modifications APPROVED:Data NOT Used' PUBLISHED: Data Used

FEMALES(13+ YRS)

	ESTIMATED % OF POTENTIAL	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	
ESTIMATES BASED ON	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
PRIOR TOLERANCES:	99.32	0.000034	6.70
NEW TOLERANCES:	99.32	0.000034	6.70

0

	ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=															
	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
PRIOR TOLERANCES:	100	6	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEW TOLERANCES:	100	6	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

MOE = 0.005 mg/kg/day ÷ 0.0003 mg/kg/day = 17

MALES(13+ YRS)

	ESTIMATED % OF POTENTIAL	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	
ESTIMATES BASED ON	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
PRIOR TOLERANCES:	99.80	0.000038	7.70
NEW TOLERANCES:	99.80	0.000038	7.70

0

	ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=															
	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
PRIOR TOLERANCES:	100	8	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEW TOLERANCES:	100	8	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

MOE = 0.005 mg/kg/day ÷ 0.0003 mg/kg/day = 17

58

DETAILED ACUTE ANALYSIS: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION

	STUDY	RDV	NOEL	SF	STUDY TYPE	SPECIES	EFF. LEV.	CORE GRADE	DOC. NO.
*NAME: TERBUFOS	A	00000.0001		000100					
*CASWELL NO: 131A CFR NO: CFR180.352	B								
*CAS NO: 13071-79-9 SHAUGHNESSY NO: 105001	C								

*STATUS CODES:
*RDV INFO: The LD value used in this analysis is 0.0005 MG/KG of BODY WEIGHT/DAY
*FILE INFO: NEW ACTION: No User Modifications APPROVED:Data NOT Used PUBLISHED: Data Used

LISTING OF RELEVANT FOODS, ORDERED BY MENU CATEGORY. MENU PATTERN = I
CHEMICAL IS ASSUMED TO BE UNIFORMLY DISTRIBUTED (WATER:OIL)

POPULATION = U.S. POP.--48 STATES FOOD CODE DESCRIPTION	NUMBER OF CONSUMER DAYS AS PERCENT OF POTENTIAL PERSON DAYS	TOLERANCE VALUE(PPM) & TYPE: PUBLISHED	APPROVED	NEW	FOOD CONTRIBUTION TO EXPOSURE (UG/KG BODY WT PER DAY): PRIOR TOL.	NEW TOL.
MENU CATEGORY 6: GRAINS(EXCL. RICE),SOYBEANS,VEG. OILS						
24002EA CORN,GRAIN-ENDOSPERM	38.88	0.0500D	0.0500D	0.0500D	0.021348	0.021348
24002HA CORN,GRAIN-BRAN	0.00	0.0500D	0.0500D	0.0500D	0.000000	0.000000
24006AA SORGHUM (INCLUDING MILO)	0.00	0.0500	0.0500	0.0500	0.000000	0.000000
27002OA CORN,GRAIN-OIL	96.73	0.0500D	0.0500D	0.0500D	0.001186	0.001186
MENU CATEGORY 9: OTHER VEGETABLES, INCL. BRASSICA						
15005AA CORN,SWEET	13.13	0.0500D	0.0500D	0.0500D	0.091194	0.091194
MENU CATEGORY 10: FRUITS						
06002AA BANANAS-UNSPECIFIED	0.22	0.0250	0.0250	0.0250	0.037835	0.037835
06002AB BANANAS-FRESH	13.64	0.0250	0.0250	0.0250	0.041515	0.041515
06002DA BANANAS-DRIED	0.05	0.0250	0.0250	0.0250	0.079483	0.079483
MENU CATEGORY 12: SUGARS						
24002SA CORN SUGAR	58.84	0.0500D	0.0500D	0.0500D	0.012467	0.012467
25002SA BEET SUGAR	97.50	0.0500D	0.0500D	0.0500D	0.017161	0.017161

POPULATION = INFANTS(<1 YEAR) FOOD CODE DESCRIPTION	NUMBER OF CONSUMER DAYS AS PERCENT OF POTENTIAL PERSON DAYS	TOLERANCE VALUE(PPM) & TYPE: PUBLISHED	APPROVED	NEW	FOOD CONTRIBUTION TO EXPOSURE (UG/KG BODY WT PER DAY): PRIOR TOL.	NEW TOL.
MENU CATEGORY 10: FRUITS						
06002AA BANANAS-UNSPECIFIED	0.10	0.0250	0.0250	0.0250	0.081124	0.081124
06002AB BANANAS-FRESH	29.09	0.0250	0.0250	0.0250	0.084079	0.084079
06002DA BANANAS-DRIED	2.63	0.0250	0.0250	0.0250	0.074402	0.074402
MENU CATEGORY 12: SUGARS						
24002SA CORN SUGAR	30.59	0.0500D	0.0500D	0.0500D	0.090188	0.090188
25002SA BEET SUGAR	54.45	0.0500D	0.0500D	0.0500D	0.030181	0.030181
MENU CATEGORY 22: OTHER VEGETABLES, EXCL. BRASSICA						
15005AA CORN,SWEET	18.47	0.0500D	0.0500D	0.0500D	0.095753	0.095753
MENU CATEGORY 25: GRAINS AND STARCHY VEGETABLES						
24002EA CORN,GRAIN-ENDOSPERM	28.58	0.0500D	0.0500D	0.0500D	0.039186	0.039186
24002HA CORN,GRAIN-BRAN	0.00	0.0500D	0.0500D	0.0500D	0.000000	0.000000
24006AA SORGHUM (INCLUDING MILO)	0.00	0.0500	0.0500	0.0500	0.000000	0.000000
27002OA CORN,GRAIN-OIL	28.06	0.0500D	0.0500D	0.0500D	0.001837	0.001837

DETAILED ACUTE ANALYSIS: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 16:00 Wednesday, March 22, 1995 7

	STUDY	RDV	NOEL	SF	STUDY TYPE	SPECIES	EFF. LEV.	CORE GRADE	DOC. NO.
*NAME: TERBUFOS	A	00000.0001		000100					
*CASWELL NO: 131A CFR NO: CFR180.352	B								
*CAS NO: 13071-79-9 SHAUGHNESSY NO: 105001	C								

*STATUS CODES:
*RDV INFO: The LD value used in this analysis is 0.0001 MG/KG of BODY WEIGHT/DAY
*FILE INFO: NEW ACTION: No User Modifications APPROVED:Data NOT Used PUBLISHED: Data Used

U.S. POP.--48 STATES

	ESTIMATED % OF POTENTIAL	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	
	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
ESTIMATES BASED ON PRIOR TOLERANCES:	44.31	0.000005	5.22
NEW TOLERANCES:	44.31	0.000005	5.22

0	ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=															
	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
PRIOR TOLERANCES:	100	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEW TOLERANCES:	100	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

MOE = 0.005 mg/kg/day ÷ 0.00004 mg/kg/day = 125

INFANTS(<1 YEAR)

	ESTIMATED % OF POTENTIAL	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	
	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
ESTIMATES BASED ON PRIOR TOLERANCES:	0.00	0.000000	0.00
NEW TOLERANCES:	0.00	0.000000	0.00

0	ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=															
	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
PRIOR TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEW TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

MOE = N/A

CHILDREN(1-6 YRS)

	ESTIMATED % OF POTENTIAL	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	
	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
ESTIMATES BASED ON PRIOR TOLERANCES:	0.74	0.000008	7.89
NEW TOLERANCES:	0.74	0.000008	7.89

0	ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=															
	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
PRIOR TOLERANCES:	100	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEW TOLERANCES:	100	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

MOE = 0.005 mg/kg/day ÷ 0.00004 mg/kg/day = 125

Attachment 7

97

		STUDY	RDV	NOEL	SF	STUDY TYPE	SPECIES	EFF. LEV.	CORE GRADE	DOC. NO.
*NAME: TERBUFOS										
*CASWELL NO: 131A	CFR NO: CFR180.352	A	00000.0001		000100					
*CAS NO: 13071-79-9	SHAUGHNESSY NO: 105001	B								
*STATUS CODES:		C								

*RDV INFO: The LD value used in this analysis is 0.0001 MG/KG, of BODY WEIGHT/DAY

*FILE INFO: NEW ACTION: No User Modifications APPROVED:Data NOT Used PUBLISHED: Data Used

FEMALES(13+ YRS)

ESTIMATES BASED ON	ESTIMATED % OF POTENTIAL: PERSON DAYS THAT ARE USER-DAYS	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY: MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
PRIOR TOLERANCES:	57.33	0.000005	5.48
NEW TOLERANCES:	57.33	0.000005	5.48

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
PRIOR TOLERANCES:	100	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEW TOLERANCES:	100	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

MOE = 0.005 mg/kg/day ÷ 0.00004 mg/kg/day = 125

MALES(13+ YRS)

ESTIMATES BASED ON	ESTIMATED % OF POTENTIAL: PERSON DAYS THAT ARE USER-DAYS	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY: MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
PRIOR TOLERANCES:	55.30	0.000005	4.86
NEW TOLERANCES:	55.30	0.000005	4.86

0 ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=

	0	.2	.4	.6	.8	1	1.2	1.4	1.6	1.8	2	3	4	5	10	15	20
PRIOR TOLERANCES:	100	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NEW TOLERANCES:	100	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

MOE = 0.005 mg/kg/day ÷ 0.00004 mg/kg/day = 125