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

JUN 13 1997

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Revised HED Chapter of the Reregistration Reregistration Eligibility Decision Document (RED) for Thiobencarb (Case number 2665; Chemical number 108401)

FROM: Paul Lewis, Biologist
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

Paul Lewis
6/13/97

THRU: Pauline Wagner, Chief
Reregistration Branch II
Health Effects Division (7509C)

TO: Dennis Deziel/Arnold Layne
Reregistration Branch I
Special Review and Reregistration Division (7509C)

Attached is the revised HED thiobencarb RED chapter. Chapter revisions reflect comments addressing the HED chapter based on a May 27, 1997 HED/SRRD thiobencarb RED team meeting. The comments and HED's response are provided below.

Comment: Page 4, carcinogenicity and page 9, carcinogenic classification. On page 4, mice were treated for 104 weeks in the carcinogenicity study. However, in the section addressing carcinogenic classification, the same study noted above indicated the animals were treated for 121 weeks.

Response: The study period was 121 weeks. This change was reflected in redline on page 4.

Comment: Page 4, carcinogenicity. Was decreased absolute and relative kidney weights occurring for males at 14 mg/kg/day as opposed to 19 mg/kg/day, as noted in the document?

Response: Decreased absolute and relative kidney weights occurred for males at 14 mg/kg/day and was reflected on page 4 by redline.

Comment: Page 16, magnitude of the residue in potable water analysis. Should a 14-day water holding interval be imposed following thiobencarb applications to rice fields only at the maximum

application rate?

Response: A 14-day water holding restriction should be imposed regardless of the application rate of thiobencarb. This change was reflected in redline on page 16.

Comment: Page 17, dietary sources from drinking water. Add a statement reflecting estimates on the environmental fate of thiobencarb were provided by EFED.

Response: This comment was reflected in redline.

Comment: Page 18, dietary sources from drinking water. Since GENEEC and STORET were not used in the risk assessment, they should be removed from the document.

Response: This change was reflected in the document on page 18.

Comment: Page 20, risk assessment. A stronger rationale is needed explaining why an inhalation risk assessment is not required since thiobencarb is Toxicity Category IV for acute inhalation .

Response: An inhalation risk assessment is not required since the LC_{50} of > 42.8 mg/L hour in an acute inhalation study placed thiobencarb in Toxicity Category IV and the degree of inhalation exposure is less than 1% of total occupational exposure. Changes were made on pages 20 and 31 in redline.

Comment: Page 22, acute dietary (food source) risk. What does high-end exposure mean?.

Response: High-end exposure represents exposure of the pesticide to 99.5% of the targeted population. This statement was added to the document in redline.

Comment: Pages 22-24, acute and chronic dietary (drinking water) risk. The acute and chronic drinking water risk assessment should reflect current OPP policy.

Response: Both risk assessments were revised in redline. Since a developmental endpoint was selected for acute dietary exposure, the subpopulation of concern are females (13+ years). This subpopulation are assumed to weigh 60 kg and consume 2 .0 liters of water per day (28.6 g/kg-body wt/day).

Comment: Page 24, chronic drinking water risk. Add a statement that the drinking water exposure estimate was not above the limit of detection of 0.1 ug/L.

Response: This change was reflected in the document in redline.

Comment: Pages 26-29, Tables 7 and 8. Only dermal unit exposure, daily dermal dose and dermal MOE were provided for applying sprays with a fixed-wing aircraft (enclosed cockpit), applying granulars with a fixed-wing aircraft (enclosed cockpit), applying sprays with a helicopter (enclosed cockpit) and applying granulars with a tractor-drawn spreader (enclosed cockpit);

baseline and additional PPE values were not provided.

Response: Exposure estimates for these exposure scenarios were generated by PHED and do not reflect either open cockpits or open cabs. Thus, baseline and additional PPE exposure estimates are not available.

Comment: Pages 26-29, Tables 7 and 8. Mixer/loader and applications risk estimates should be combined.

Response: HED estimates that typically, the mixer/loader and applicator will not be the same person. Thus, mixer/loader and applicator risk estimates should be considered separately.

Comment: Page 31, post-application. Provide greater information how intermediate-term exposure and risk were "roughly" estimated.

Response: These changes were made in redline.

Comment: Page 31, post-application. Post-application exposure studies will be addressed by the agricultural-reentry DCI.

Response: HED lacks appropriate post-application thiobencarb use information to assess whether the herbicide will be addressed by the agricultural-reentry DCI. Thus, no changes are necessary to the RED.

Comment: Page 33, FQPA considerations. Acute food/drinking water risk and acute/chronic drinking water risk should be additive in the document.

Response: Changes were made in the document in redline on pages 20 and 32 to reflect this comment. In addition, we added language addressing endocrine disruptor effects in redline on page 8.

Comment: Page 33, risk characterization. Is limiting the amount of acreage that can be treated in a day a reasonable risks mitigation measure? Handlers could apply the restricted/remaining quantity of chemical the next day.

Response: This statement was removed from the RED.

Comment: Page 33, risk characterization. A discussion addressing the confidence of MOE estimate should be provided.

Response. This change in the document was reflected in redline.

MEMORANDUM

SUBJECT: The HED Chapter of the Reregistration Eligibility Decision Document (RED) for Thiobencarb (Case number 2665; Chemical number 108401)

FROM: Paul Lewis, Biologist
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

THRU: Pauline Wagner, Chief
Reregistration Branch II
Health Effects Division (7509C)

and
Margaret Stasikowski, Director
Health Effects Division (7509C)

TO: Arnold Layne, Chief
Reregistration Branch I
Special Review and Reregistration Division (7509C)

Please find attached the Human Health Risk Assessment for the Thiobencarb Reregistration Eligibility Decision Document (RED). This chapter includes the Hazard Assessment from Stephen Dapson in TBII (Attachment I), the Occupational and Residential Exposure Assessment from Al Nielsen in OREB (Attachment II), Product and Residue Chemistry Assessment from David Miller in CBRS (Attachment III), and the Dietary Risk Analysis from Brian Steinwand in SAB (Attachment IV). If you have any questions concerning this document, please call Paul Lewis at 305-7398.

Attachments

pc (without attachments): A. Nielsen, OREB
S. Dapson, TBII
P. Deschamp, RCAB
D. Miller, CBRS
B. Steinwand, SAB

1. EXECUTIVE SUMMARY

Thiobencarb [S-((4-chlorophenyl)methyl)diethylcarbamothioate] is a thiocarbamate herbicide that is applied to rice, lettuce, celery and endives to control grasses and broadleaf weeds. It is applied as a liquid and granular using fixed-wing aircraft, helicopter, granular tractor-drawn spreader, and groundboom sprayer.

Thiobencarb is sold in the United States by Valent Corporation. There are five registered products: technical thiobencarb (EPA Reg. No. 63588-4; 97.4% a.i.), Valent Bolero 8 EC (EPA Reg. No. 59639-79), Valent Bolero 10 G (EPA Reg. No. 59639-80), Bolero 10 G (EPA Reg. No. 63588-5) and Bolero 8 EC (63588-6). Since thiobencarb is applied to food crops, EPA expects both dietary and occupational exposure (residential exposure is not expected since there are no residential uses).

II. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Thiobencarb [S-((4-chlorophenyl)methyl)diethylcarbamothioate] is a thiocarbamate pesticide.

1. Identification of Active Ingredient

Thiobencarb is a pale, yellow liquid with a boiling point of 126-129 C. Thiobencarb is readily soluble in most organic solvents and slightly soluble in water. Its empirical formula is $C_{12}H_{16}ClNOS$ and its molecular weight is 257.8.

2. Manufacturing-Use Products

A search of the Reference Files System (REFS) conducted on 10/18/95 identified a single thiobencarb technical product (T) registered to K-I Chemical U.S.A., Incorporated under Shaughnessy No. 108401; the 97.4% T (EPA Reg. No. 63588-4). The K-I Chemical 97.4% T was transferred from Chevron Chemical Co. (12/5/91). Only the K-I Chemical TGAI and 97.4% T are subject to a reregistration eligibility decision.

3. Regulatory Background

The Thiobencarb Phase IV Review (dated 4/15/91 by C. Olinger and S. Funk) determined that Chevron data submissions for all product chemistry data requirements met the acceptance criteria for Phase V review. The Chevron data are applicable to the K-I Chemical 97.4% T, provided that K-I Chemical confirms that the manufacturing process and site have not changed since the product transfer. Otherwise, all product chemistry data will be required for the K-I Chemical 97.4% T.

The current status of the product chemistry data requirements for K-I Chemical thiobencarb TGAI and 97.4% T is presented in Appendix 1. Refer to this table for a listing of the outstanding product chemistry data requirements.

4. Conclusions

All pertinent data requirements are satisfied for the thiobencarb TGAI 97.4% pending confirmation by K-I Chemical that the manufacturing process and location have not changed since the product was transferred from Chevron. Provided that the registrant certifies that the suppliers of beginning materials and the manufacturing process for the thiobencarb technical product have not changed or submits a complete updated product chemistry data package, HED has no objections to the reregistration of thiobencarb with respect to product chemistry data requirements.

B. Human Health Assessment

1. Hazard and Dose Response Assessment

At present, the available toxicological database for thiobencarb is adequate and will support reregistration eligibility for the currently registered uses.

a. Acute Toxicity

Thiobencarb has been tested for acute toxicity by the oral, dermal and inhalation routes of exposure. The results obtained in these studies, which are listed in Table 1, satisfy the acute toxicity data requirements.

Table 1. Acute Toxicity Values for Technical Thiobencarb

TEST	RESULTS	TOXICITY CATEGORY	PURITY
Oral LD_{50} - rat	Males: LD_{50} = 1033 (924-1155) mg/kg Females: LD_{50} = 1130 (1033-1247) mg/kg (MRID 42130701)	III	96.0%
Dermal LD_{50} - rabbit	LD_{50} > 2000 mg/kg (both sexes) (MRID 42130701)	III	96.0%
Inhalation LC_{50} - rat	LC_{50} > 42.8 mg/L (1 hour) (MRID 00040585, 00134976	IV	95.1%
Eye Irritation - rabbit	Slight irritation (MRID 00040581)	III	95.1%

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TEST	RESULTS	TOXICITY CATEGORY	PURITY
Dermal Irritation - rabbit	Slight irritation (MRID 00040583, 00081900)	IV	95.1%
Dermal Sensitization - guinea pig	Not a sensitizer (MRID 00161699)	NA	84.0%

b. Subchronic Toxicity

In a 21 day dermal study (MRID# 42893001, revision of MRID# 42003401), Sprague-Dawley rats received repeated dermal applications of Bolero® 8EC (85.2% a.i.) at doses of 0, 40, 160, or 500 mg/kg, 5 days per week, over a 22-day period. 36 animals of each sex were used, 6 animals/sex/dose for the 0, 40, 160 and 500 mg/kg dose plus an extra 6/sex/dose for the 0 and 500 mg/kg doses at recovery. There was a dose related increase in the incidence of skin irritation in treated versus control rats of both sexes. Six additional animals dosed with 0 and 500 mg/kg were held for 2 weeks following dosing as a recovery group. Reduced food intake with an associated reduction in body weight gain was observed in the mid- and high-dose groups. The reduction in body weight gain persisted in high-dose males in the recovery group. Statistically significant decreases in food efficiency were observed in mid-and high-dose males. For dermal toxicity, a NOEL was not observed and the LOEL was less than 40 mg/kg/day based on the skin irritation observed. For systemic toxicity, the NOEL was 40 mg/kg/day and the LOEL was 160 mg/kg/day based on decreases in body weight gain and food consumption in males and females, and statistically significant decreases in food efficiency in males.

Subchronic toxicity studies were conducted by Industrial Biotest (IBT) Laboratories and are classified as supplementary data, not adequate to satisfy Subdivision F guidelines. Therefore, the data requirements for subchronic studies in rats and dogs are satisfied by the chronic feeding studies in the rat and dog (see chronic toxicity and carcinogenicity section).

c. Chronic Toxicity

In a combined chronic toxicity/carcinogenicity feeding study (MRID# 00154506), Fischer 344 rats received 0, 20, 100 or 500 ppm (approximately 0, 1, 5, and 25 mg/kg/day by standard conversion methods) technical Bolero® (95.3% a.i.) in the diet for 2 years. Systemic toxicity was noted at 100 ppm and above as decreased body weight gain, food consumption and food efficiency. There was also an increase in blood urea nitrogen. However, no evidence of carcinogenicity at the dose levels tested was observed. For chronic toxicity, the NOEL was 1 mg/kg/day and the LOEL was 5 mg/kg/day based on decreased body weight gains, food consumption, food efficiency and increased blood

urea nitrogen.

In a chronic oral toxicity study (MRID# 00144742), Beagle dogs received 0, 1, 8, or 64 mg/kg/day of thiobencarb technical (Lot# SX-1381; Purity 96.3% a.i.) by capsule for 52 weeks. Systemic toxicity was noted in the high dose males as decreased body weight gains and increased absolute and relative kidney and liver weights in high dose males and females. There were decreases in serum albumin and protein in high dose males and females (a slight effect was noted in mid dose males). In addition, there were decreased erythrocyte counts and hemoglobin levels with a reduction in hematocrit in high dose males and females along with decreases in alanine aminotransferase and cholesterol levels in the high dose group. For systemic toxicity, the NOEL was 8 mg/kg/day and the LOEL was 64 mg/kg/day based on increased liver and kidney weights and decreased hematological and clinical chemistry parameters. Based on biologically significant depression in cholinesterase activity, for plasma cholinesterase, the NOEL was 1 mg/kg/day and the LOEL was 8 mg/kg/day; for erythrocyte cholinesterase, the NOEL was 8 mg/kg/day and the LOEL was 64 mg/kg/day; for brain cholinesterase the NOEL was equal to or greater than 64 mg/kg/day and the LOEL was greater than 64 mg/kg/day.

d. Carcinogenicity

In a carcinogenicity study (MRID# 00086004), B6C3F1 mice received 0, 25, 100, 400, or 1600 ppm (0, 3, 14, 56, and 235 mg/kg/day for males and 0, 5, 19, 75, and 302 mg/kg/day for females, respectively) technical Bolero® (93.7% a.i.) for 121 weeks. Systemic toxicity was noted at 14 mg/kg/day for males and 19 mg/kg/day for females and above as histopathological changes in the liver. These observations included an increased incidence of hepatocytic (glycogen) pallor; the high dose animals also had increased incidence of fatty vacuolization (moderate or marked mid-zonar). High dose males had marked fine fatty periacinar, vacuolization and increased relative heart and liver weights. At 14 mg/kg/day and above, males had decreased absolute and relative kidney weights, while high dose females had increased relative kidney weights. Upon gross examination, there was an increased incidence of pale foci of the lungs of high dose animals and pale livers in the high dose males (external examination showed abdominal swelling). There was also an increased incidence of focal epithelialization of the alveolar walls of the lungs with associated macrophages. In addition, high dose females had reduced body weight gains. There was no evidence of carcinogenicity in either sex at the dose levels tested. For chronic toxicity, the NOEL was 3 mg/kg/day for males and 5 mg/kg/day for females and the LOEL was 14 mg/kg/day for males and 19 mg/kg/day for females based on histopathological changes in the liver.

e. Developmental Toxicity

In a developmental toxicity study (MRID# 00115248), albino rats of the Sim: (SD) FBR (Sprague Dawley derived) strain received by oral gavage either 0, 5, 25, or 150

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mg/kg/day thiobencarb technical (97% a.i.) in Deionized Water/CMC/Tween 80 on days 6 through 19 of gestation. Maternal toxicity was observed as a treatment related decrease in body weight gains in the high dose group. There was no effect on food consumption; however, the high dose had lower food efficiency than the control group, an indicator of systemic toxicity. For maternal toxicity, the NOEL was 25 mg/kg/day and the LOEL was 150 mg/kg/day based on decreased body weight gains and decreased food efficiency. Developmental toxicity was noted as a slight increase in skeletal anomaly observations at the high dose mostly related to reduced ossification and an increase in runts in the high dose group. For developmental toxicity, the NOEL was 25 mg/kg/day and the LOEL was 150 mg/kg/day based on increased skeletal anomaly observations and an increase in the number of runts.

In another developmental toxicity study (MRID# 00164313), New Zealand white rabbits received 0, 20, 100, or 200 mg/kg/day technical thiobencarb (96.0% a.i,) by oral gavage from days 6 through 18 of gestation. Maternal toxicity was observed at 200 mg/kg/day as statistically significant increase in absolute and relative liver weights. For maternal toxicity, the NOEL was 100 mg/kg/day and the LOEL was 200 mg/kg/day based on increased liver weights. No developmental toxicity was observed at dose levels tested. For developmental toxicity, the NOEL was equal to or greater than 200 mg/kg/day and the LOEL was greater than 200 mg/kg/day. Based on the results of these studies, thiobencarb is not considered to be a developmental toxicant in rats or rabbits.

f. Reproductive Toxicity

In a multigeneration reproduction study (MRID# 40446201), Charles River CD rats received either 0, 2, 20, or 100 mg/kg/day Technical Bolero® (96.7% a.i.) by daily oral gavage in 0.5% CMC aqueous solution. Systemic toxicity was noted at 20 mg/kg/day and above based on enlargement of centrolobular hepatocytes (both generations) and hepatocyte single cell necrosis observed in both sexes of both generations including renal atrophic tubule consisting of regenerated epithelium. There were increased liver weights (absolute and relative) and increased kidney weights (absolute and relative) in the high dose group. There were also significant changes on body weights at 100 mg/kg/day and male kidney weights were increased in the high dose group. There were no effects on reproductive parameters. For Parental/Systemic toxicity, the NOEL was 2 mg/kg/day and the LOEL was 20 mg/kg/day based on histopathological changes of the liver and kidney. For reproductive toxicity, the NOEL was equal to or greater than 100 mg/kg/day and the LOEL was greater than 100 mg/kg/day.

g. Mutagenicity

Thiobencarb was evaluated in an Ames assay (MRID#s 00041174, 00084131 and 00135285) and was negative in tester strains TA100, TA98 and TA1537 at levels up to 50 ug/plate, both with and without metabolic activation.

Thiobencarb was negative in a dominant lethal assay in mice (MRID# 00084133 and 00135282), administered at a single oral dose of 600 mg/kg and at an oral dose of 300 mg/kg for 5 days.

In a clastogenicity test in human lymphocytes (MRID# 40352401), thiobencarb (96.0% a.i.) was tested at dose levels of 0, 5, 10, and 20 ug/ml without S9 activation and at dose levels of 0, 10, 20, and 40 ug/ml with S9 activation. No mutagenic activity was noted.

In a micronucleus test in mice (MRID# 40352402), thiobencarb (96.0% a.i.) was tested at dose levels of 0, 270, 540, and 1080 mg/kg in males and at dose levels of 0, 405, 810, and 1620 mg/kg in females, as a single oral dose. A dose related increase in micronuclei was noted, and was statistically significant in high dose males and in the two highest doses in females. Four consecutive daily doses of 540 mg/kg caused statistically significant increases in the incidence of micronuclei in both sexes. This was considered as a positive mutagenic response.

Thus, thiobencarb was shown to lack mutagenicity in three of the four mutagenicity tests conducted. No further testing is required at this time.

h. Metabolism

In a general metabolism study (MRID# 42340302), the disposition and metabolism of [Phenyl-U-^{14}C]-thiobencarb (Radiochemical Purity: not stated, but data in report, indicate acceptable purity of radiochemical; Specific Activity: 32.5 mCi/mmol prior to purification, specific activity following purification was not stated; Unlabeled Thiobencarb, (Purity: > 97.0%) was investigated in male and female Sprague-Dawley rats at a single low oral dose (30 mg/kg), repeated low oral doses (30 mg/kg x 14 days), and a single high dose (300 mg/kg). Thiobencarb was rapidly absorbed after oral administration as judged by the rate of excretion. No significant sex-related or dose group differences in absorption were noted. Excretion was relatively rapid at all doses tested, with a majority of radioactivity eliminated in the urine and feces by 48 hours. The extent of excretion was completed by 72 hours at the 300 mg/kg dose, but the mechanism responsible for this delay was not identified. No significant sex- or dose-related differences in urinary or fecal excretion of thiobencarb derived radioactivity were noted. Repeated low oral dosing did not affect elimination of thiobencarb in either male or female rats.

Fecal elimination of [Phenyl-U-^{14}C]-thiobencarb derived radioactivity was a minor route of excretion, and for urine, no significant sex- or dose-related differences in amount of radioactivity excreted by this route were observed. Residual levels of thiobencarb derived radioactivity were also minor (less than 0.5% of an administered dose).

Urinary and fecal metabolites of [Phenyl-U-^{14}C]-Thiobencarb were isolated and identified by HPLC, TLC, and mass spectral analysis. The major metabolite detected was the glycine conjugate 4-chlorohippuric acid, comprising between 74-81% of an administered dose in urine. Other metabolites detected included 4-chlorobenzyl methyl sulfoxide and -sulfone, des-ethyl thiobencarb, and 4-chlorobenzoic acid, each representing less than 10% of an administered dose of thiobencarb. A single high or repeated low oral dose did not significantly affect the urinary or fecal metabolite profile for thiobencarb in male or female rats.

i. Neurotoxicity

Acute Neurotoxicity

In an acute neurotoxicity study (MRID# 42987001, 43148202), male and female Sprague-Dawley rats received a single oral administration of thiobencarb (96.9%) at doses of 0, 100, 500 or 1000 mg/kg. Neurobehavioral evaluations, consisting of Functional Observational Battery (FOB) and motor activity, were conducted at pre-study, Day 0, at time of peak effect (4 hrs post-dosing), Day 7 and Day 14. At Day 15, animals were euthanized and neuropathological examination performed on control and high-dose animals (5/dose/sex). With the exception of one high-dose female, which died on Day 3 of the study, all other animals survived until terminal sacrifice. An increased incidence of clinical signs, consisting of red deposits around the noses and mouths of high-dose animals, was noted. Gait abnormalities (rocking, lurching and swaying) were observed in some high-dose females. No significant differences were noted in either the mean body weight or body weight gain of any of the treated animals. Neurobehavioral evaluation revealed treatment-related FOB and motor activity findings at the mid- and high-dose levels. The effects were, in general, transient and observed only at the peak time of effect (4 hrs post-dosing). Although the incidences of FOB findings were not significantly different from control values, when taken together, a consistent, treatment-related pattern of neurobehavioral effects becomes clear. These findings included gait abnormalities (lurching, swaying and rocking), impaired mobility and decreased sensory responses (approach, touch, startle, tail pinch and pupil responses). In high-dose males, the startle response achieved statistical significance when measured at the time of peak effect. Hindlimb resistance was reduced in high-dose animals. Mean body temperature was significantly decreased in all treated males and mid- and high dose females. Total and ambulatory motor activity, measured at the peak time of effect on Day 0, showed significant treatment-related decreases in all mid- and high-dose animals. No treatment-related gross or neuropathological findings were present. Brain weights and measurements of the treated animals were comparable to control values. Thus, for systemic toxicity, the NOEL was 100 mg/kg/day and the LOEL was 500 mg/kg based on increased clinical signs and gait abnormalities. For neurobehavioral toxicity, the NOEL was 100 mg/kg/day and the LOEL was 500 mg/kg based on gait abnormalities, decreased sensory responses, decreased body temperature and decreased motor activity.

Subchronic neurotoxicity

In a subchronic neurotoxicity study (MRID# 43001001), male and female Sprague-Dawley rats (10/sex/group) received oral administration of Bolero® 8EC at 0, 2, 20 or 100 mg/kg/day for 13 weeks. All animals survived until terminal sacrifice. Clinical signs were evident only within the first 4-hours post-dosing. During this time, there was an increased incidence of dried red material around the noses of all treated animals and dried tan or red material around the mouths of mid- and high-dose animals. Mean body weights and body weight gains of high-dose females were lower than controls. Food consumption was not affected by treatment. The absolute-and relative (to terminal body weight and brain weight) liver and kidney weights of high-dose males and females was statistically significantly increased. The relative (to the terminal body weight) liver weights of mid-dose males and the kidney weights of mid-dose females were statistically significantly increased. No clinical pathology was conducted. In addition, no treatment-related gross or neuropathological findings were present. Thus, for systemic toxicity, the NOEL was 2 mg/kg/day and the LOEL was 20 mg/kg/day based on increased clinical signs, decreased body weights, increased liver and kidney weights. For neurotoxicity, the NOEL was greater than 100 mg/kg/day (HDT) and a LOEL was not established.

j. Endocrine Disruptor Effects

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 disruptor effects.

k. Epidemiological Information

No cases of poisoning were located from any of the available databases on incidents related to the use of thiobencarb. EPA believes that this may be due partly to the relatively limited use of this chemical.

2. Toxicological Endpoints for Risk Assessment

a. Reference Dose (RfD)

The RfD/Peer Review Committee met on February 8, 1996, to discuss and

evaluate the existing and/or recently submitted toxicology data in support of the thiobencarb reregistration and to reassess the RfD for this chemical.

The Committee recommended that the existing RfD for thiobencarb remain unchanged. The RfD for this chemical was based on the two year rat feeding study (MRID# 00154506) with a NOEL of 20 ppm (1 mg/kg/day). At the next higher dose level of 100 ppm (5mg/kg/day), decreased body weights and increased blood urea nitrogen levels were observed. An uncertainty factor of 100 was applied to account for both inter-species extrapolation and intra-species variability. On this basis, the RfD was calculated by the Committee to be 0.01 mg/kg/day.

b. Carcinogenic Classification

The carcinogenic potential of thiobencarb was evaluated by the RfD/Peer Review Committee on February 8, 1996. The Committee considered the carcinogenicity phases of the combined chronic toxicity/carcinogenicity studies in rats (MRID# 00154506) and the carcinogenicity study in mice (MRID# 00086004) for carcinogenic classification.

The highest dose level tested in the rat (500 ppm, or 25 mg/kg/day) was considered to be adequate for carcinogenicity testing based on depression of cholinesterase activity and reduced body weight gain. The highest dose level tested in the mouse (1600 ppm, or 235 mg/kg/day in males and 302 mg/kg/day in females) was considered to be adequate based on body weight gain depression.

In rats, there was no treatment-related increase in tumors of any kind at any dose level. The Committee, therefore, concluded that the treatment did not alter the spontaneous tumor profile in this strain of rat.

In mice, adenomas and carcinomas of the harderian glands appeared to be increased in treated females (1, 2, 6, 5 and 7 tumors for the 0, 25, 10, 400 and 1600 ppm groups, respectively). However, the Committee noted several limitations with the study. First, the concurrent control incidence was lower than expected for females of this strain. This decreased incidence in the control group could possibly be due to chance and could not be precluded. Second, if a greater number of control mice had lived until completion of the study, more spontaneous tumors may have occurred, thus resulting in similar tumor incidence between treatment and control groups. Third, the study was carried out for 121 weeks, a significantly longer period than guideline requirements. Thus, the increased study length may have contributed to the appearance of tumors in treated females. Fourth, the Committee concluded that historical control incidence data from studies conducted for a significantly shorter duration should not be considered. The Committee reasoned that these shorter duration studies may not accurately depict tumor incidences because the tumor incidence would most likely be lower than what was observed in the studies used for carcinogenic classification. Thus, no historical control data were acceptable for

review by the Committee.

On this basis, the Committee recommended that thiobencarb be classified as Group D chemical (not classifiable as to human carcinogenicity).

c. Other Toxicological Endpoints

On April 30, 1996, the Agency's Office of Pesticide Program Health Effects Division Toxicity Endpoint Selection Committee (i.e. the TES Committee), met to discuss the toxicological endpoints to be used in various risk assessments for thiobencarb. A summary of the endpoints selected is provided in Table 2.

Dermal Absorption. In addition to the toxicological endpoints listed in Table 2, the TES Committee discussed the dermal absorption of thiobencarb.

Table 2. Summary of Toxicological Endpoints for Thiobencarb

TYPE OF EXPOSURE	NOEL	ENDPOINT
Acute Dietary (one day)	NOEL = 25 mg/kg/day established in a rat developmental toxicity study (MRID 00086873, 00093691 and 00115248)	Increases in incidence of reduced ossification and an increase in fetal runts.
Short-Term Occupational or Residential Exposure (one to seven days)	NOEL = 25 mg/kg/day established in a rat developmental toxicity study (MRID 00086873, 00093691 and 00115248).	Increases in the incidence of reduced ossification and an increase in fetal runts.
Intermediate-Term Occupational or Residential Exposure (one week to several months)	NOEL = 2 mg/kg/day for systemic toxicity established in a rat subchronic neurotoxicity study (MRID 430001001). This NOEL of 2 mg/kg/day is supported by a similar NOEL (2 mg/kg/day) established in the multigeneration reproduction study (MRID 40446201 and 409085701).	Histopathological changes in the liver and kidney.

In a dermal absorption study (MRID# 41215311), Sprague-Dawley® Crl:CD® (SD)BR male rats were dermally treated with either 0, 0.05, 0.5 or 5.0 mg/rat of ^{14}C-Thiobencarb (Radiochemical purity: 98.8%, Specific Activity: 359,092 dpm/ug) for exposure durations of 1, 2, 4, 10, or 24 hours (4 rats per dose per duration). The unlabeled compound used was Bolero® 8EC (Thiobencarb, Purity: 89% a.i.). This study may represent a worst-case scenario since the skin was washed approximately 1 hour prior to dosing rather than the recommended 24 hours (which would allow normal replacement of skin oils). Thus, this might tend to over-estimate absorption. Based on the results of the study, the Committee determined that thiobencarb is rapidly and continuously absorbed at doses of 5.0, 46.8 and 498 ug/cm^2 for exposure times up to 24 hours. Absorption at 10 hours was 60.2, 52.6, and 17.1% for the 5.0, 46.8 and 498 ug/cm^2 dose groups, respectively. Maximum absorption at 24 hours was 71.5, 72.6, and 41.75 for the 5.0, 46.8 and 498 ug/cm^2 dose groups, respectively. Urine was the primary route of excretion.

On this basis, the committee recommended that a dermal absorption factor of 60.2%, observed at 10 hours in a dermal absorption study (MRID# 41215311), be used for risk assessment purposes.

3. Exposure Assessment

Thiobencarb, S-((4-chlorophenyl)methyl)N,N-diethylcarbamothioate, is a herbicide used on rice, lettuce, celery and endives. The herbicide is applied preemergence or early postemergence to control grasses and broadleaf weeds. Thiobencarb is applied using a variety of equipment including fixed-wing aircraft, helicopter, granular tractor-drawn spreader, and groundboom sprayer. Application rates vary from 4 to 8 lbs ai/acre depending on the formulation and the target crop.

There are four registered end-use products: Valent Bolero® 8 EC (EPA Reg. No. 59639-79), Valent Bolero® 10 G (EPA Reg. No. 59639-80), Bolero® 10 G (EPA Reg. No. 63588-5) and Bolero® 8 EC (63588-6). Thus, the following exposure assessment is based on these products.

EPA expects both dietary (i.e. food and drinking water sources) and occupational exposure from the use of thiobencarb (there are no residential uses). Dietary exposure is expected to be both acute and chronic (i.e. one day and over a long-term period of time). Occupational exposure is expected to occur over a short to intermediate term (i.e. from one day to several months).

a. Dietary Exposure from Foods Sources

Regulatory Background

EPA completed the Thiobencarb Phase 4 Review on 4/15/91. A Thiobencarb Data-Call-

In (DCI) Notice was subsequently issued 8/13/91. HED has conducted Phase 5 Reviews of several residue chemistry studies that were submitted in response to the DCI as well as studies that were deemed acceptable during Phase 4 Review. Based on the available data, a risk assessment can be performed for this chemical.

Tolerances for residues of thiobencarb in/on plant and animal commodities [40 CFR §180.401(a) and (b)] are expressed in terms of the combined residues of thiobencarb and its chlorobenzyl and chlorophenyl moiety-containing metabolites. Primary metabolites of interest are: 4-Chlorobenzylmethylsulfone, 4-Chlorobenzoic acid, N-(4-Chlorobenzoyl)glycine, and 4-Chlorobenzylthio conjugates. Provided in Table 3 is the chemical structure of thiobencarb and the structures of its primary metabolites. Tolerances are established under 40 CFR §180.401(a) for: rice, grain at 0.2 ppm; rice, straw at 1.0 ppm; meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep at 0.2 ppm; eggs at 0.2 ppm; and milk at 0.05 ppm. Tolerances with regional registration, in accordance with 40 CFR §180.1(n), are established under 40 CFR §180.401(b) for celery, endive (escarole), and lettuce at 0.2 ppm each. Adequate methods are available for the enforcement of established tolerances.

Summary of Science Findings

i. Directions for Use

A REFS search conducted 10/18/95 identified four thiobencarb end-use products (EPs) registered to Valent U.S.A. Corporation and K-I Chemical U.S.A., Inc. under FIFRA Section 3 (as noted above), and 17 active SLNs registered under FIFRA Section 24(c) for use on food/feed crops. A list of thiobencarb EPs is presented in Table 4.

A comprehensive summary of registered food/feed use patterns for thiobencarb, based on the products registered to Valent U.S.A. Corporation, and all active SLN registrations is presented in Appendix 2. For the purposes of reregistration, label amendments are required for Valent's end-use products (EPA Reg. Nos. 59639-79 and 59639-80) to specify a 14-day water holding interval following thiobencarb application to rice fields. Additionally, the following use restrictions should be added to thiobencarb labels: "Do not use on rice paddies where commercial catfish or crayfish farming is practiced. Do not use adjacent to catfish or crayfish ponds."

A tabular summary of the residue chemistry science assessments for reregistration of thiobencarb is presented in Appendix 3. The conclusions listed in Appendix 3 regarding the reregistration eligibility of thiobencarb are based on the use patterns registered by the basic producer. All end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) must be amended such that they are consistent with the basic producer labels.

Table 3. Chemical structures of thiobencarb and its metabolites containing the chlorobenzyl and chlorophenyl moiety

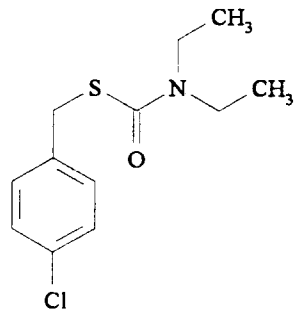
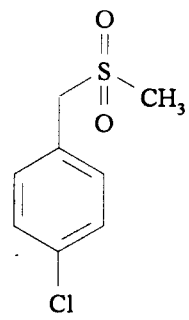
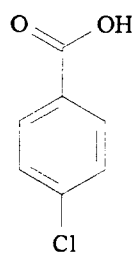
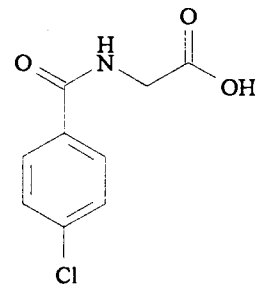
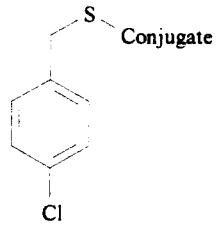
Compound: Chemical name	**Compound**: Chemical name
 Thiobencarb S-((4-Chlorophenyl)methyl)diethylcarbamothioate	 4-Chlorobenzylmethylsulfone
 4-Chlorobenzoic acid	 N-(4-Chlorobenzoyl)glycine
 4-Chlorobenzylthio conjugates	

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Table 4. Thiobencarb end-use products (EPs) with food/feed uses registered to Valent U.S.A. Corporation and K-I Chemical U.S.A., Inc.

EPA Reg. No.	Acceptance Date	Formulation	Product Name
EPs Registered to Valent U.S.A. Corporation			
59639-79 [1]	4/20/94	8 lb/gal EC	Bolero® 8EC (Herbicide)
59639-80 [2]	11/29/93	10% G	Bolero® 10 G (Herbicide)
EPs Registered to K-I Chemical U.S.A Inc.			
63588-5	2/94	10% G	Bolero® 10 G
63588-6	2/94	8 lb/gal EC	Bolero® 8EC

[1] EPA Reg. No 59639-79 is the parent label for the following Section 24(c) registrations: AR940002, AR940003, AR950004, CA930003, FL910003, FL930010, LA950005, MO930007, MO940005, MO950002, MS930009, MS930010, MS950007, and TX930023.

[2] EPA Reg. No. 59639-80 is the parent label for the following Section 24(c) registrations: AR940001, MS930011, and TX930024.

ii. Plant Metabolism

The qualitative nature of the residue in plants is adequately understood based on an acceptable study depicting the metabolism of thiobencarb in rice. On May 13, 1993, the HED Metabolism Committee determined that the current tolerance expression for residues of thiobencarb and its metabolites containing the chlorobenzyl and chlorophenyl moieties is appropriate.

iii. Animal Metabolism

For the purposes of reregistration and risk assessment, the qualitative nature of the residue in animals is adequately understood based on acceptable studies conducted on ruminants and in poultry. The residue of concern in eggs, milk, and poultry and livestock tissues include the parent thiobencarb and its metabolites containing the chlorobenzyl and chlorophenyl moieties. The current tolerance expression for animal commodities, as defined in 40 CFR §180.401(a), is adequate.

iv. Residue Analytical Methods - Plants and Animals

The requirements for residue analytical methods are fulfilled for the purposes of reregistration.

Adequate methods are available for enforcement and data collection purposes for both plant and animal commodities. Successful radiovalidation of the enforcement methods, using samples from the metabolism studies, has also been conducted. The 1/94 FDA PESTDATA database indicates that residues of thiobencarb are completely recovered (>80%) using multiresidue method Section 302 (Luke method; Protocol D), and variably recovered using method Section 304 (Mills, Onley, Gaither method; fatty food). The registrant has conducted multiresidue method trials with thiobencarb metabolites 4-chlorobenzylmethylsulfone and 4-chlorobenzylmethylsulfoxide using Protocol E and with 4-chlorobenzoic acid using Protocol B. HED has forwarded the results of these multiresidue trials to FDA for evaluation and inclusion in PAM Vol. I, Appendix I.

v. Storage Stability

Adequate storage stability data are available to support the established tolerances. Acceptable storage stability studies have been submitted for representative plant and animal commodities. The available plant and animal metabolism studies are also validated by adequate storage stability data.

vi. Magnitude of the Residue in Plants

The reregistration requirements for magnitude of the residue in/on plants are fulfilled for the following commodities: celery, endive, lettuce, and rice grain and straw. No additional data are required. Adequate field trial data, following treatments according to the maximum registered use patterns, have been submitted for the commodities listed above. The available data were submitted in conjunction with tolerance petitions for celery, endive, and lettuce (PP#5F3158), and rice grain and straw (PP#0F2322, 5G1582, 6F1763, and 2G1231), and are adequate to support reregistration requirements including tolerance reassessment.

vii. Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in the processed food/feed commodities of rice are fulfilled. An acceptable study depicting the potential for thiobencarb residues of concern to concentrate in rice processed fractions has been submitted and evaluated. The data indicate that the combined residues of thiobencarb and 4-chlorobenzylmethylsulfone did not concentrate in polished rice and bran processed from rice samples that received postemergence application of the registered 10% G formulation at an exaggerated rate (5x); however, the combined residues concentrated 2x in hulls. Although residue concentration was observed in hulls, the observed combined residues of thiobencarb and its metabolite (<0.06 ppm) in/on hulls following exaggerated rate treatment were below the established tolerance of 0.2 ppm for rice grain.

viii. Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

The reregistration requirements for magnitude of the residue in milk and livestock tissues as

well as in eggs and poultry tissues are fulfilled. There are no registered direct animal treatments of thiobencarb on cattle, goats, hogs, horses, poultry, or sheep.

The available dairy cattle and poultry feeding studies indicates that the combined residues of thiobencarb and its metabolites [4-chlorobenzoic acid, 4-chlorobenzyl-methylsulfone, and 4-chlorobenzylmethylsulfoxide] will not exceed the established tolerances.

ix. Magnitude of the Residue in Potable Water

The reregistration requirements for magnitude of the residue in water will be considered fulfilled when revisions are made to Valent's end-use product labels (EPA Reg. Nos. 59639-79 and 59639-80) to prohibit use of treated water for livestock watering or for drinking or irrigation for a specified time period after treatment. Based on the results of an acceptable magnitude of residue in potable water study (MRIDs 43404003, 43404004, and 43404005), thiobencarb and thiobencarbsulfoxide residues in runoff and receiving waters associated with rice fields did not fall to acceptable levels until 14 days after treatment. Thus, HED has determined that a 14-day water holding interval should be imposed following thiobencarb applications to rice fields ~~at the maximum registered rate~~. If the registrant does not wish to institute this label restriction, then a irrigated crop field trial and a drinking water intake study will be required.

The use of the thiobencarb granular formulation (Bolero® 10G, EPA Reg. No. 59639-80) in California is regulated under the Basin Plan for the Sacramento River Basin established by the California Regional Water Quality Control Board, Central Valley Region. A performance goal of 1.5 ppb is strictly monitored, and growers must adhere to a program of approved management practices, including a 30-day water holding restriction.

x. Nature and Magnitude of the Residue in Fish

The reregistration requirements for nature and magnitude of the residue in fish will be fulfilled when label revisions are made on Valent's end-use products (EPA Reg. Nos. 59639-79 and 59639-80) to specify the following use restrictions: "Do not use on rice paddies where commercial catfish or crayfish farming is practiced. Do not use adjacent to catfish or crayfish ponds."

xi. Magnitude of the Residue in Irrigated Crops

Data depicting the magnitude of the residue in irrigated crops are not required for reregistration purposes since the Agency is imposing a 14-day water holding interval.

xii. Magnitude of the Residue in Food-Handling Establishments

Thiobencarb is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

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xiii. Confined/Field Rotational Crops

Valent's thiobencarb end-use labels specify a 6-month plantback interval following rice and all other crops, except celery, endive and lettuce for which rotational crop plant-back intervals are 4-months. These currently specified plant-back intervals are appropriate.

xiv. Residue Information (for dietary risk assessment)

Tolerances for thiobencarb are published in 40 CFR 180.401(a) and (b). Tolerances have been established for rice grain at 0.2 ppm; meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep at 0.2 ppm; eggs at 0.2 ppm; and milk at 0.5 ppm. Tolerances with regional registrations are established for celery, endive, and lettuce at 0.2 ppm each. Tolerance level residues and 100 percent crop treated assumptions were made for all commodities. Anticipated residue information was not used for this analysis.

A summary of the residue information that was used in the dietary risk assessment is provided in Table 1 of Appendix 5.

b. Dietary Exposure from Drinking Water

Thiobencarb is not currently regulated under the Safe Drinking Water Act. Public water supply systems are not required to sample and analyze for thiobencarb. Thus, no maximum contaminant level (MCL) is established for thiobencarb in drinking water systems. An MCL is an action level as established by the EPA Office of Water to ensure the safety of drinking water. In addition, the lifetime Health Advisory (HA) for thiobencarb has not been established. Estimates of thiobencarb concentrations in well, ground water and surface water and the environmental fate of thiobencarb were prepared by the EFED.

Ground Water

Limited groundwater monitoring information is available for thiobencarb. The "Pesticide in Ground Water Database" (Hoheisel et al., 1992) reported sampling for thiobencarb in 270 wells in California and 65 wells in Missouri. Two detections of thiobencarb in ground water were reported in Missouri and at very low concentrations (0.2 - 0.3 ppb). However, no limit of detection (LOD) or limit of quantification (LOQ) were provided to normalize the data for non-detectable residues. This is an important consideration since thiobencarb was not detected in almost all wells sampled. Therefore, the groundwater sampling data are not usable for drinking water risk assessment purposes.

Surface Water

Thiobencarb has the potential to contaminate surface water from releases of rice paddy water

following thiobencarb applications or from spray drift associated with aerial or ground spray application to other registered sites.

EFED provided estimates of thiobencarb residues in surface water by utilizing the Generic Estimated Environmental Concentration program (GENEEC), EPA's Office of Water's STORET database and data from a California thiobencarb surface water monitoring study. However, the GENEEC and STORET data were not applicable to access thiobencarb in drinking water. First, GENEEC does not model for rice scearnios. According to EFED, almost 95% of all thiobencarb use is on rice. Thus, GENEEC exposure estimates are not applicable to most thiobencarb uses. Second, the STORET data were not normalized for non-detectable residues. Approximately 99% of samples collected to measure for thiobencarb indicated non-detectable residues. Therefore, due to limitations with the GENEEC and STORET data, the California surface water modeling study was the only applicable data to measure thiobencarb in surface water. In addition, results of a thiobencarb surface water monitoring studies in California (USEPA, 1997) are also available. The results of the California thiobencarb surface water monitoring data are provided below.

GENEEC model

The GENEEC model was used to estimate aquatic EEC concentrations for the thiobencarb lettuce, endive and celery uses (aquatic EEC concentration modeling for rice was not conducted because the Agency does not have a computer simulation model which will estimate concentrations for this use). The range of aquatic EECs was 140 mg/L (1.4×10^5 ppb) for 6 lb a.i. application rate and 180 mg/L (1.8×10^5 ppb) for the 8 lb a.i. application rate. Thiobencarb is expected to dissipate in pond water at an approximate rate of 0.4 - 0.6 mg/L/day (400 - 600 ppb/day). However, since GENEEC cannot model rice scenarios (almost 95% of all thiobencarb use is on rice), these exposure estimates are not applicable to most thiobencarb uses.

STORET database

Detection of thiobencarb was identified in eight states: California, Georgia, Maryland, North Carolina, Oregon, Oklahoma, Texas and Washington. However, detection of thiobencarb was only observed in two states where thiobencarb is used on rice, California and Texas. Thirty-nine positive detections were reported for 3,130 samples (approximately 1%) with a maximum concentration of 0.24 mg/L (240 ppb) and a mean concentration of 0.10 mg/L (100 ppb). Similar to the groundwater monitoring data discussed above, no LOD or LOQ were provided to normalize the STORET data for non-detectable residues. Therefore, the STORET data are not applicable for drinking water risk assessment purposes.

California Surface Water Monitoring study

Monitoring for residues of specific rice pesticides in surface water of California's Sacramento River basin was performed by the California Environmental Protection Agency (CAL EPA), sometimes in conjunction with the California Rice Industry Association, from 1993 to 1996. HED estimates that the City of Sacramento is the only locality in the US rice growing region relying on surfacewater as its source of drinking water (i.e. the city utilizes the Sacramento River as its source of drinking water).

In 1993, 17 samples were collected just before the intake to the Sacramento River drinking water treatment facility (the only year of the four year study that samples from this location were collected). No detections above a limit of detection of 0.1 ug/L were reported. However in 1993, due to substantial flow in the Sacramento River, water was diverted south of the sampling location via the Yolo Bypass. Thus, diverting water from the Sacramento River drinking water treatment facility may have contributed to thiobencarb levels below the limit of detection. Therefore, HED concludes that even though thiobencarb residues at the Sacramento River were below the limit of detection (0.1 ug/L), thiobencarb residues may be higher if water was not diverted via the Yolo Bypass.

c. Occupational Exposure

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete.

In the case of thiobencarb, EPA has determined that there is a toxicological concern and there is potential exposure to mixers, loaders, applicators, or other handlers during activities that would occur under the usual thiobencarb use scenarios. Also, there is potential exposure to persons reentering sites that have been treated with thiobencarb. Therefore, the Agency has assessed application and post-application exposure to thiobencarb.

At this time, products containing thiobencarb are intended primarily for occupational uses only and not for homeowner uses. Thus, this exposure assessment is limited to occupational uses only. Further, EPA expects that, based on the use patterns, exposure to thiobencarb will occur for a short to intermediate duration; chronic exposure is not expected. Finally, the Agency expects exposure to occur via the dermal and inhalation routes.

i. Handler Exposure

EPA has identified eight major exposure scenarios from the use patterns of thiobencarb for its occupational exposure assessment: (1a) mixing/loading liquids for aerial application; (1b)

mixing/loading liquids for groundboom application; (2a) loading granulars for fixed-wing aircraft; (2b) loading granulars for tractor-drawn spreader application; (3) applying sprays with a fixed-wing aircraft; (4) applying granulars with a fixed-wing aircraft; (5) applying sprays with a helicopter; (6) applying granulars with a tractor-drawn spreader; (7) applying sprays with groundboom equipment; and, (8) flagging aerial spray applications.

Potential dermal and inhalation baseline unit exposure (which are derived from PHED V. 1.1), along with corresponding calculated daily exposures, are presented in Table 5. No chemical-specific data were submitted. Baseline unit exposure is the PHED exposure estimate with just the clothing scenario that was provided in the PHED data base (i.e. the baseline clothing). Dermal exposure is several orders of magnitude greater than inhalation exposure.

Potential daily exposure is calculated using the following formula:

Daily exposure (mg ai /day) = Unit exp. (mg ai/lb ai) x Max. App. Rate (lb ai/ac) x Max. Area Trt. (ac/day)

Provided in Appendix 4 are the caveats, parameters and assumptions specific to each exposure scenario.

ii. Post-Application Exposure

Based on the use patterns of thiobencarb, EPA has determined that there is potential exposure for persons entering treated sites after application is complete. Workers may be entering treated areas to perform such tasks as scouting, thinning, hoeing or harvesting. However, there are no chemical-specific data available upon which to assess the risks from post-application exposures.

(d) Aggregate Exposure

In examining aggregate exposure, FQPA requires that EPA take into account available information concerning exposure from the pesticide residue in food and all other exposure for which there is reliable information. These other sources of exposure of the general population (including infants and children) to pesticides include residues in drinking water and non-occupational exposures, e.g. to pesticides used in and around the home and to sources not directly related to use of the pesticide such as Superfund sites or TRI emissions. Only food source and drinking water exposure were evaluated since no non-occupational use is expected.

4. Risk Assessment

EPA expects both dietary and occupational exposure from the use of thiobencarb (there are no residential uses). Dietary exposure occurs via the oral route while occupational exposure occurs via the dermal and inhalation routes. Since an acute inhalation study placed thiobencarb in Toxicity Category IV, an inhalation risk assessment was not initiated. When exposure estimates were derived, daily inhalation exposure (mg/day) was approximately 33% of daily absorbed

Table 5. Thiobencarb Baseline Unit Exposures and Daily Exposures (Short and Intermediate-Term)

Exposure Scenario (Number)	Crop	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (ug/lb ai)[b]	Application Rate (lb ai/acre)[c]	Daily Acres Treated[d]	Daily Absorbed Dermal Exposure (mg/day)[e]	Daily Inhalation Exposure (mg/day)[f]
Mixer/Loader Exposure							
Mixing/Loading Liquids for Aerial Application (1a)	Rice	2.9	1.2	4	350	2444.1	1.68
Mixing/Loading Liquids for Groundboom Application (1b)	Rice			4	80	558.7	0.38
	Endive/Lettuce			6		838.0	0.58
	Celery			8		1,117.3	0.77
Loading Granulars for Fixed-wing Aircraft Application (2a)	Rice	0.0076	1.7	4	350	6.6	2.3
Loading Granulars for Tractor-drawn Spreader Application (2b)	Rice				80	1.5	0.54
Applicator Exposure							
Applying Sprays with a Fixed-wing Aircraft (Enclosed Cockpit) (3)	Rice	See Eng. Controls	See Eng. Controls	4	350	See Eng. Controls	See Eng. Controls
Applying Granulars with a Fixed-wing Aircraft (Enclosed Cockpit) (4)	Rice	See Eng. Controls	See Eng. Controls	4	350	See Eng. Controls	See Eng. Controls
Applying Sprays with a Helicopter (Enclosed Cockpit) (5)	Rice	See Eng. Controls	See Eng. Controls	4	350	See Eng. Controls	See Eng. Controls
Applying Granulars with a Tractor-Drawn Spreader (Enclosed Cab) (6)	Rice	See Eng. Controls	See Eng. Controls	4	80	See Eng. Controls	See Eng. Controls
Applying Sprays with a Groundboom Sprayer (7)	Rice	0.015	0.7	4	80	2.9	0.22
	Endive/Lettuce			6		4.3	0.34
	Celery			8		5.8	0.45
Flagger Exposure							
Flagging Spray Applications (8)	Rice	0.01	0.28	4	350	8.4	0.39

a Baseline derm: posure represents long pants, long sleeve shirt, no gloves, open mixing/loading, and open c or. Baseline data are not available for aerial application and granular applications with a tr. awn spreader.
b Baseline inhalation exposure represents no respirator.
c Application rates are the maximum found in the thiobencarb labels [EPA Reg. Nos. 59639-79 and 59639-80].
d Daily acres treated are from EPA OREB estimates of acreage that could be treated in a single day for each exposure scenario of concern.
e Daily absorbed dermal exposure (mg/day) = Exposure (mg/lb ai) * Appl. rate (lb ai/A) * Acres Treated * Dermal Absorption Rate (60.2%)
f Daily inhalation exposure (mg/day) = Exposure (ug/lb ai) * (1mg/1000 ug)conversion * Appl. Rate (lb ai/A) * Acres Treated

dermal exposure (mg/day). In order to mitigate any potential risk from inhalation exposure, HED is recommending thiobencarb mixer/loaders to wear dust/mist filtering respirators (MSHA/NIOSH approval number prefix TC-23C). This would reduce inhalation exposure by approximately 80% for several exposure scenarios (i.e. loading granulars for fixed-wing aircraft application and loading granulars for tractor drawn spreader application).

Dietary exposure (food and drinking water sources) is expected to occur over an acute through chronic period. To assess the acute dietary risk, EPA calculates a margin of exposure (MOE), which is the ratio of the NOEL to exposure. To assess chronic risk, EPA calculated the percent of the reference dose [RfD] (i.e. % RfD) used.

a. Dietary Risk

i. Acute Dietary (Food Source) Risk

The Dietary Risk Evaluation System (DRES) acute analysis estimates the distribution of single-day exposure for the overall U.S. population and certain subgroups. It includes all published uses of thiobencarb, even those commodities that are being recommended for revocation. The analysis evaluates individual food consumption as reported by respondents in the USDA 1977-1978 Nationwide Food Consumption Survey and accumulates exposure to the chemical for each commodity.

The MOE is calculated by dividing the acute dietary NOEL (i.e. mg/kg/day) by the high-end exposure (see Table 2 of Appendix 5 for the exposure estimates). High-end exposure represents exposure of the pesticide to 99.5% of the targeted population. Because the endpoint of concern for acute dietary risk assessment is a developmental toxicity effect, the only subgroup of concern is females (13+ years). Generally, acute aggregated MOEs greater than 100 tend to cause no dietary concern when the data are compared to a toxicological endpoint from an animal study (such is the case for thiobencarb). Since the only subgroup of concern is females (13+) and represents an MOE = 8928 (as represented in Table 3 of Appendix 5), HED is not concerned with acute dietary risks from exposure to thiobencarb residues in food.

ii. Acute Dietary (Drinking Water) Risk

Due to limitations with available groundwater sampling data, no groundwater data are applicable for risk assessment purposes. Even though there is an absence of applicable groundwater data, based on the environmental fate of thiobencarb and the soil profile of rice fields as defined by EFED, HED does not believe that thiobencarb would be a concern to groundwater. First, thiobencarb is slightly persistent in water, generally not very mobile, tends to bind to soil organic matter, and doesn't desorb. Second, rice fields are usually underlain by a clay layer to restrict water movement through the soil and help contain the water in the flooded field. This clay layer will significantly limit the amount of leaching that occurs in rice fields (~~U.S.EPA, 1996g~~).

As noted above, approximately 95% of thiobencarb applications are made to rice. In addition, HED estimates that the City of Sacramento is the only locality in the US rice growing region utilizing surface water as its drinking water. Data from the California surface water monitoring study indicated thiobencarb residues were not above a limit of detection of 0.1 ug/L (0.1 ppb).

Thus, drinking water exposure was calculated using the following formula:

Exposure (mg/kg/day) = (ppb thiobencarb in the water consumed)(10^{-6})(28.6)

Thus, drinking water exposure = 2.86×10^{-6} mg/kg/day and a resulting MOE > 10,000. Therefore, HED is not concerned with acute drinking water risks from exposure to thiobencarb residues in drinking water.

Water consumption is defined as all water obtained from the household tap that is consumed either directly as a beverage or is used to prepare foods (mixing water with a can of soup) and beverages (diluting frozen juice concentrate). Since a developmental endpoint was selected for acute dietary exposure, the subpopulation of concern are females (13+ years). This subpopulation are assumed to weigh 60 kg and consume 2.0 liters of water per day (28.6 g/kg-body wt/day), the value used in the above equation. ~~Two generally accepted default values for water consumption are 2 liters per day (28.6 g/kg-body wt/day) or 1.5 liters per day (21.4 g/kg-body wt/day. The 22.6 g/kg-body wt/day used in this calculation was derived using water consumption values and self-reported body-weights obtained from USDA's 1977-1978 Nationwide Food Consumption Survey.~~

iii. Total Acute Dietary (Food Sources and Drinking Water)

To assess total acute dietary exposure and MOEs, the following formulas were utilized:

Total acute dietary exposure = acute food source exp. (high end exp.) [mg/kg/day] + drinking water exp. (high end exp.) [mg/kg/day]

Total acute dietary MOE= $\frac{\text{NOEL (mg/kg/day)}}{\text{total acute dietary exposure (mg/kg/day)}}$

Food source exposure (high end exposure) was 0.0028 mg/kg/day based on the high end exposure for females (13+ years) (Appendix 5; Table 3). Drinking water exposure (high end exposure) was 2.86×10^{-6} mg/kg/day based on surface water exposure as discussed previously. Thus, the total acute dietary MOE is 8920. Therefore, HED is not concerned with total acute dietary risks from exposure to thiobencarb.

iii. Chronic Dietary (Food Source) Risk

A DRES chronic exposure analysis was performed using tolerance level residues and a 100 percent crop treated assumption to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. A summary of the TMRCs and the % RfD values for the U.S. general population, non-nursing infants (<1 year old) children (1-6 years) and females (13+ years) are provided in Table 2 of Appendix 5. The chronic analysis for thiobencarb is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with thiobencarb.

As shown in Table 6, much less than 100% of the RfD is occupied by the dietary uses recommended through reregistration. Existing tolerances result in a TMRC which represents

12.8% of the RfD for the U.S. general population. The highest subgroup, Non-Nursing Infants (<1 year old), occupies 42.9% of the RfD. In addition, numerous conservative assumptions have been considered into this assessment. Thus, the actual % RfD is considered $\leq$ 42.9%. Therefore, HED is not concerned with chronic dietary risks from exposure to thiobencarb residues in food.

Table 6. Chronic Dietary (Food Source) Risk Evaluation for Thiobencarb

POPULATION SUBGROUP	Exposure (mg/kg/day)	%RfD (Chronic - noncancer)
General U.S. Population	0.001280	12.8
Non-nursing infants (< 1 year)	0.004294	42.9
Children (1-6 years)	0.002945	29.5
Females (13 + years)	0.001103	11.03

iv. Chronic Drinking Water Risk

As noted previously, due to limitations with available groundwater sampling data, no groundwater data are applicable for risk assessment purposes. However, even though there is an absence of applicable groundwater data, based on the environmental fate of thiobencarb and the soil profile of rice fields as defined by EFED, HED does not believe that thiobencarb would be a concern to groundwater.

HED utilized data from the California surface water monitoring study to access chronic drinking water exposure. A drinking water exposure estimate of 0.1 ug/L (i.e. 2.86×10^{-6} mg/kg/day) was used to assess chronic exposure (as was performed for acute drinking water exposure) since this is the only data available. As was noted previously in the acute drinking water exposure assessment, data from the California surface water monitoring study indicated thiobencarb residues were not above the a limit of detection of 0.1 ug/L. Thus, high end drinking water exposure was utilized for the chronic drinking water risk assessment and corresponds to a %RfD = 0.29. Therefore, HED is not concerned with chronic drinking water risks from exposure to thiobencarb in drinking water.

v. Total Chronic Dietary (Food Sources and Water) Risk

To assess total chronic dietary exposure and MOEs, the following formulas were utilized:

Total chronic dietary exposure (mg/kg/day) = food source chronic exp. (average exp.) [mg/kg/day] + drinking water exp. high end exp. *) [mg/kg/day]

$$\% \text{ RfD} = \frac{\text{total chronic dietary exposure (mg/kg/day)}}{\text{RfD (mg/kg/day)}}$$

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* High end exposure was used due to a lack of average exposure data.

Thus, this represents a percent RfD = 43.2%. Therefore, EPA is not concerned with total chronic dietary risks from exposure to thiobencarb.

vi. Dietary (food source and water) Carcinogenic Risk

Since thiobencarb is a Group D carcinogen (not classifiable as to human carcinogenicity), a dietary carcinogenic risk assessment is not required.

b. Occupational Risk

i. Handlers

The short-term and intermediate-term MOEs for thiobencarb calculated from Baseline and Risk Mitigation unit exposures are provided in Tables 7 and 8. Two types of risk mitigation were evaluated: (1) adding personal protective equipment (PPE) to the baseline clothing: and (2) instituting engineering controls (e.g. closed system). The unit exposure values for PPE and Engineering Controls are from PHED. As noted previously, an inhalation exposure assessment was not initated. Provided in Appendix 4 are the assumptions used for these calculations.

The daily dermal dose is calculated using a 60 kg body weight for short-term exposure and a 70 kg body weight for intermediate-term exposure. A 60 kg body weight is used for short-term exposure because this exposure is based on a developmental toxicity endpoint. The following formula was used to calculate the daily dermal dose:

Daily Dermal Dose (mg ai/kg/day) = Daily Dermal Exp. (mg ai/day) x 1/Body weight (kg) x 60.2% dermal absorption

These calculations of daily dermal dose of thiobencarb received by handlers are used to assess the dermal risk to those handlers. The short-term dermal MOEs were calculated using a dermal absorption rate of 60.2 percent and a NOEL of 25 mg/kg/day. The intermediate-term dermal MOEs were calculated using a dermal absorption rate of 60.2 percent and a NOEL of 2 mg/kg/day. The following formula was used for MOE calculations:

MOE = NOEL (mg/kg/day)/Daily Dermal Dose (mg/kg/day)

Short-term

EPA generally considers a MOE for occupational exposures of 100 to be protective of human health. The calculations of short-term risk estimates indicate that the MOEs are greater than 100 at **baseline** for the following scenarios:

- (2a) loading granulars for fixed-wing aircraft application;
- (2b) loading granulars for tractor drawn spreader application;
- (7) applying sprays with a groundboom sprayer; and,
- (8) flagging liquid aerial application.

Table 7. S' 'erm Dermal Risk Estimates for Thiobencarb (Baseline and Mitigation MOEs)

Exposure Scenario (Scen #)	Crop	Baseline Absorbed Dermal Dose (mg/kg/day)[a]	Baseline Absorbed Dermal MOE[b]	MOE Calculation Considering Risk Mitigation Measures					
				Additional PPE			Engineering Controls		
				Dermal Unit Exp. (mg/lb ai)	Daily Dermal Absorbed Dose[a] (mg/kg/day)	Dermal MOE[b]	Dermal Unit Exp. (mg/lb ai)	Daily Dermal Absorbed Dose[a] (mg/kg/day)	Dermal MOE[b]
Mixer/Loader Risk									
Mixing/Loading Liquids for Aerial Application (1a)	Rice	40.7	0.61	0.025	0.35	71	0.009	0.13	192
Mixing/Loading Liquids for Groundboom Application (1b)	Rice	9.3	3	0.043	0.14	179	NA	NA	NA
	Endive/ Lettuce	14.0	2	0.043	0.21	119			
	Celery	18.6	1	0.025	0.16	156			
Loading Granulars for Fixed-wing Application (2a)	Rice	0.11	227	NA	NA	NA	NA	NA	NA
Loading Granulars for Tractor-drawn Spreader Application (2b	Rice	0.025	1,000	NA	NA	NA	NA	NA	NA
Applicator Risk									
Applying Sprays with a Fixed-Wing Aircraft (Enclosed Cockpit) (3)	Rice	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.005	0.07	357
Applying Granulars with a Fixed-wing Aircraft (Enclosed Cockpit) (4)	Rice	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.0016	0.022	1136
Applying Sprays with a Helicopter (Enclosed Cab) (5)	Rice	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.0021	0.03	833
Applying Granulars with a Tractor-Drawn Spreader (Enclosed Cab) (6)	Rice	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.002	0.006	4,167
Applying Sprays with a Groundboom Sprayer (7)	Rice	0.048	521	NA	NA	NA	NA	NA	NA
	Endive/L ettuce	0.072	347						

Exp	Scenario (Scen #)	Crop	Baseline Absorbed Dermal Dose (mg/kg/day)[a]	Baseline Absorbed Dermal MOE[b]	MOE Calculation Considering Risk Mitigation Measures					
					Additional PPE			Engineering Controls		
					Dermal Unit Exp. (mg/lb ai)	Daily Dermal Absorbed Dose[a] (mg/kg/day)	Dermal MOE[b]	Dermal Unit Exp. (mg/lb ai)	Daily Dermal Absorbed Dose[a] (mg/kg/day)	Dermal MOE[b]
		Celery	0.097	258						
Flagger Risk										
	Flagging Spray Applications (8)	Rice	0.14	179	NA	NA	NA	NA	NA	NA

NA = Not applicable since the previous MOE exceeded 100.

[a] Absorbed Dermal Dose (mg/kg/day) = (daily absorbed dermal exposure (mg/day) / 60 kg).

[b] Dermal Absorbed MOE = NOEL (25 mg/kg/day) / daily dermal absorbed dose (mg/kg/day).

Additional PPE:

1a Double layer of clothing with chemical resistant gloves.

1b Single layer of clothing with chemical resistant gloves for rice (4lbs ai/acre) and endive/lettuce (6 lbs ai/acre).

1b Double layer of clothing with chemical resistant gloves for celery (8lbs ai/acre).

Engineering Controls:

1a Closed mixing system, single layer of clothing with chemical resistant gloves.

3 Enclosed cockpit, single layer clothing, no gloves.

4 Enclosed cockpit, single layer clothing, no gloves.

5 Enclosed cockpit, single layer clothing, no gloves.

6 Enclosed cab, single layer clothing, chemical resistant gloves.

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Table 8. Ir ediate-Term Dermal Risk Estimates for Thiobencarb

Exposure Scenario (Scen #)	Crop	Baseline Absorbed Dermal Dose (mg/kg/day)[a]	Baseline Absorbed Dermal MOE[b]	Risk Mitigation Measures					
				Additional PPE			Engineering Controls		
				Dermal Unit Exp. (mg/lb ai)	Daily Dermal Absorbed Dose[a] (mg/kg/day)	Dermal MOE[b]	Dermal Unit Exp. (mg/lb ai)	Daily Dermal Absorbed Dose[a] (mg/kg/day)	Dermal MOE[b]
Mixer/Loader Risk									
Mixing/Loading Liquids for Aerial Application (1a)	Rice	34.9	0.06	0.025	0.3	7	0.009	0.11	18
Mixing/Loading Liquids for Groundboom Application (1b)	Rice	8.0	0.25		0.07	29		0.02	100
	Endive/Lettuce	12.0	0.17		0.1	20		0.04	50
	Celery	16.0	0.13		0.14	14		0.05	40
Loading Granulars for Fixed-wing Aircraft Application (2a)	Rice	0.05	40	0.0031	0.037	54	None	None	None
Loading Granulars for Tractor-drawn Spreader Application (2b)	Rice	0.02	100	NA	NA	NA	NA	NA	NA
Applicator Risk									
Applying Sprays with a Fixed-Wing Aircraft (Enclosed Cockpit) (3)	Rice	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.005	0.06	33
Applying Granulars with a Fixed-wing Aircraft (Enclosed Cockpit) (4)	Rice	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.0016	0.019	105
Applying Sprays with a Helicopter (Enclosed Cockpit) (5)	Rice	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.0021	0.03	67
Applying Granulars with a Tractor-Drawn Spreader (Enclosed Cab) (6)	Rice	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.002	0.0055	364
Applying Sprays with a Groundboom Sprayer (7)	Rice	0.041	49	0.01	0.028	71	0.0067	0.018	111
	Endive/ Lettuce	0.061	33		0.041	49		0.028	71

Exp	Scenario (Scen #)	Crop	Baseline Absorbed Dermal Dose (mg/kg/day)[a]	Baseline Absorbed Dermal MOE[b]	Risk Mitigation Measures					
					Additional PPE			Engineering Controls		
					Dermal Unit Exp. (mg/lb ai)	Daily Dermal Absorbed Dose[a] (mg/kg/day)	Dermal MOE[b]	Dermal Unit Exp. (mg/lb ai)	Daily Dermal Absorbed Dose[a] (mg/kg/day)	Dermal MOE[b]
		Celery	0.083	24		0.055	36		0.037	54
Flagger Risk										
Flagging Spray Applications (8)		Rice	0.12	17	0.007	0.084	24	0.0002	0.0024	833

NA Not applicable since the previous MOE exceeded 100.
None No Engineering Controls exist for this scenario.
[a] Absorbed Dermal Dose (mg/kg/day) = (daily absorbed dermal exposure (mg/day) / 70 kg.
[b] Dermal Absorbed MOE = NOEL (2 mg/kg/day) / daily dermal absorbed dose (mg/kg/day).

Additional PPE:
1a Double layer of clothing with chemical resistant gloves.
1b Double layer of clothing with chemical resistant gloves.
2a Double layer of clothing with chemical resistant gloves.
7 Double layer of clothing with chemical resistant gloves.
8 Double layer of clothing with out chemical resistant gloves.

Engineering Controls:
1a Closed mixing system, single layer of clothing with chemical resistant gloves.
1b Closed mixing system, single layer of clothing with chemical resistant gloves.
3 Enclosed cockpit, single layer clothing, no gloves.
4 Enclosed cockpit, single layer clothing, no gloves.
5 Enclosed cockpit, single layer clothing, no gloves.
6 Enclosed cab single layer, chemical resistant gloves.
7 Enclosed cab, single layer clothing, no gloves.
8 Enclosed cab, single layer clothing, no gloves.

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The calculations of short-term risk estimates indicate that the MOEs are greater than 100 with **additional PPE** for (1b) mixing/loading liquids for groundboom sprayer application.

The calculations of short-term risk estimates indicate that the MOEs are greater than 100 with **engineering controls** for the following scenarios:

- (1a) mixing/loading liquids for aerial application;
- (3) applying liquid spray with a fixed-wing aircraft;
- (4) applying granulars with a fixed-wing aircraft;
- (5) applying liquid sprayer with a helicopter; and,
- (6) applying granulars with a tractor-drawn spreader.

The calculations of short-term risk estimates indicate that the MOEs are greater than 100 for all exposure scenarios employing maximum risk mitigation measures. Thus, no exposure scenarios utilizing risk mitigation measures indicate a risk of concern for short term exposure.

Intermediate-term

As noted above, EPA generally considers a MOE for occupational exposures of 100 or greater to be protective of human health. The calculations of intermediate-term dermal risk estimates indicate that MOEs are greater than 100 at **baseline** for (2b) loading granulars for tractor-drawn spreader application.

The calculations of intermediate-term risk estimates indicate that the MOEs are not greater than 100 with **additional PPE** for any exposure scenario.

The calculations of intermediate-term risk estimates indicate that the MOEs are greater than 100 with **engineering controls** for the following scenarios:

- (1b) mixing/loading liquids for groundboom sprayer application for rice (4 lbs ai/acre);
- (4) applying granulars with a fixed-wing aircraft;
- (6) applying granulars with a tractor-drawn spreader;
- (7) applying liquid spray with a groundboom sprayer for rice (4 lbs ai/acre) ; and
- (8) flagging liquid aerial applications.

Thus, even with the use of risk mitigation measures, the calculations of intermediate-term risk estimates indicate that the MOEs are not more than 100 for the following scenarios:

- (1a) mixing/loading liquids for aerial application;
- (1b) mixing/loading liquids for groundboom sprayer application for endive/lettuce (6 lbs ai/acre) and celery (8 lbs ai/acre);
- (2a) loading granulars for fixed-wing aircraft;
- (3) applying liquid spray with a fixed-wing aircraft;
- (5) applying liquid spray with a helicopter;
- (7) applying liquid spray with a groundboom sprayer for endive/lettuce (6 lbs ai/acre) and celery (8 lbs ai/acre);

Therefore, these exposure scenarios indicate a risk of concern even with the use of risk mitigation measures.

ii. Post-application

EPA estimated the intermediate-term exposure based on rough assumptions of foliar dislodgeable residues, transfer coefficients and maximum application rates and the risk that thiobencarb would pose during post-application activities in rice, lettuce, endive and celery fields. After conducting this rough estimate, there are some issues that need to be discussed with the registrant. These issues include determining reentry activities (i.e. scout, harvester) for each of the crops and estimating a re-entry interval for the specific crop related tasks.

c. Additional Occupational/Residential Exposure Studies

i. Handler Studies

EPA is requiring the following confirmatory data for handlers due to a lack of data for these exposure scenarios:

(3) baseline and PPE data for applying liquid spray with a fixed-wing aircraft. Only enclosed cockpit data are available;

(4) baseline and PPE data for applying granulars with a fixed-wing aircraft. Only enclosed cockpit data are available;

(5) baseline and PPE data for applying liquid spray with a helicopter. Only enclosed cockpit data are available; and,

(6) baseline and PPE data for applying granulars with a tractor-drawn spreader. Only enclosed cab data are available.

EPA needs to meet with the registrant concerning additional occupational/residential exposure studies and risk mitigation measures.

ii. Post-Application Studies

EPA needs to meet with the registrant concerning additional post-application exposure studies.

(d) Short-Term Residential Risk

Thiobencarb is not available for use in a residential setting. Thus, no non-occupational exposure to thiobencarb is expected.

(e). Cumulative Risk Assessments

Thiobencarb is structurally similar to thiocarbamate pesticides. Further, other pesticides may have common toxicity endpoints with thiobencarb. However, the Agency has not made a determination whether thiobencarb and any other pesticides have a common mode of toxicity and require a cumulative risk assessment. For the purpose of this Reregistration Eligibility Decision, the Agency has considered only risks from thiobencarb. If required, cumulative exposure and risks will be assessed when methodologies for determining common mode of toxicity and for performing cumulative risk assessment are finalized.

5. Risk Characterization

Short-term and intermediate-term handler MOE determinations were based on exposure estimates from surrogate chemical field studies submitted to the Pesticide Handlers Exposure Database (PHED) and from hazard identification for those exposure scenarios based on the weight-of-the-evidence of the toxicology database for thiobencarb.

A. Toxicity

For dermal absorption, the TESC determined the thiobencarb dermal absorption factor was 60% at 10 hours based on a rat dermal absorption study.

In terms of short-term exposure, the TESC selected the NOEL of 25 mg/kg/day established in a developmental toxicity study in rats. The LOEL of 150 mg/kg/day was based on increases in reduced ossification and runts in the fetuses of dams given oral administration of thiobencarb. This dose and endpoint was selected based on the assumption that the fetal effects can occur following short-term exposure (i.e., 1-7 days). In addition, the oral NOEL of 25 mg/kg/day is supported by the dermal NOEL of 40 mg/kg/day established in the 21-day dermal study when the 60% dermal absorption factor is utilized, as was demonstrated in this species. Thus, the comparable dermal dose is approximately 40 mg/kg/day [i.e. oral NOEL (25 mg/kg/day)/(0.6% dermal absorption) = 42 mg/kg/day]. In spite of the availability of a 21-day dermal toxicity study, the TESC did not use this study because: (i) the concern for the developmental effects seen in the oral rat study, (ii) developmental endpoints were not evaluated in the dermal rat study, and (iii) the high dermal absorption demonstrated in this species as well. The confidence in the toxicity studies for short-term exposure is high because all three studies were conducted in one species (rat) via different routes (oral and dermal) yielding comparable NOELs.

For intermediate-term exposure, the TESC selected the NOEL of 2 mg/kg/day established in the 2-generation reproduction study in rats. The LOEL of 20 mg/kg/day was based on the parental/systemic toxicity characterized as enlargement of the centrilobular heptocytes in both generations, hepatocyte single cell necrosis observed in both sexes of both generations, and renal

atrophic tubule consisting of regenerated epithelium. This NOEL is supported by the identical NOEL/LOEL established in the 90-day neurotoxicity study in rats; the NOEL was 2 mg/kg/day and the LOEL was 20 mg/kg/day based on systemic toxicity manifested as statistically significant increases in relative liver weights of male and kidney weights of female rats. The TESC noted that the alternations in organ weights seen in the subchronic study were corroborated with histopathological lesions in these organs (liver and kidneys) in the multi generation reproduction study indicating the liver and kidney to be target organs following intermediate exposure (i.e. up to several months) to thiobencarb-inducted toxicity. No kidney or liver histopathological effects were observed in the chronic feeding study in the rat. The toxicological significance for the lack of renal or liver lesions is not known at this time. However it is noted that the chronic feeding study was conducted in a different strain (i.e. Fisher) while the 2-generation reproduction study was done in Charles River and the subchronic neurotoxic study was conducted in Sprague-Dawley. This indicates a possible strain difference in sensitivity to thiobencarb.

B. Occupational Exposure

Short-term handler exposure MOEs are greater than 100. However, intermediate-term handler MOEs are less than 100 for several of the aerial and ground mixer/loader and applicator exposure scenarios. Most of the intermediate-term exposure scenarios having MOEs less than 100 are rated as high confidence for both dermal and inhalation exposure data. For example, the unit exposure for mixing/loading liquids for aerial application with a closed system (MOE = 18) is derived from four registrant submitted studies in PHED. There are 31 replicates for hand, 16 to 22 replicates for other dermal exposure, and 27 replicates for inhalation. From the 31 replicates in the PHED, only 138 samples (approximately 4%) had non-detectable residues. Dermal and inhalation exposure data are rated as high confidence based on the number of replicates and analytical grading criteria. The Agency's confidence in the unit exposure values are high because exposures are based on detectable residues from high confidence studies. Since detectable residues were observed, normalizing residue estimates to 1/2 the level of quantification or 1/2 the level of detection to account for non-detectable residues is not necessary. This provides additional support for HED's exposure estimates. In addition, most of the dermal data are from studies involving whole body dosimeters, which are generally a more accurate monitoring method than patch dosimetry. ~~Thus, HED's exposure estimates are reasonable.~~

The assumption of 350 and 80 acres treated for aerial and groundboom applications, respectively, are reasonable based on agricultural practices. ~~However, it may be feasible for the registrant to limit the amount of acreage that can be treated in a day or the amount of chemical handled in a given day.~~ Lowering the maximum application rate without compromising efficacy may contribute to raising intermediate-term MOE estimates. The confidence in the toxicity and handler exposure data provides support for handler MOE estimates. Thus, HED's MOE estimates appear reasonable.

~~6. Food Quality Protection Act (FQPA) Considerations~~

~~The FQPA of 1996 requires EPA to give special consideration to exposure of infants and children to pesticide residues in food in establishing tolerances. The Act also requires EPA to consider aggregate exposure to the pesticide residue, including all anticipated dietary exposure and other exposure for which there is reliable information, as well as cumulative effects from the pesticide and other substances that have a common mechanism of toxicity.~~

~~EPA performs a number of analyses to determine the risks from aggregate exposure to~~

pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. For many of these studies, a dose response relationship can be determined, which establishes a dose that causes adverse effects and doses causing no observable effects (the "no observed effect level" or "NOEL").

Once a study has been evaluated and the observed effect had been determined to be a threshold effect, EPA generally divides the NOEL from the most appropriate study by an uncertainty factor (usually 100) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risk to human health. An uncertainty factor (formerly called "safety factor") of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and also, that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive than other individuals or subgroups. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the studies and determines whether an additional uncertainty factor is warranted. Traditionally, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA.

For the purpose of assessing the prenatal toxicity of thiobencarb, EPA evaluated two developmental studies and one reproduction study. As EPA fully implements the requirements of FQPA, additional data related to the special sensitivity of young organisms may be required.

(a) Potential Risks to Infants and Children

i. Developmental and Reproductive Effects

There is no evidence of increased sensitivity of young animals to *in utero* exposure to thiobencarb. No developmental toxicity was noted in a prenatal developmental toxicity study in New Zealand white rabbits, although the highest dose tested was sufficient to elicit significant increases in maternal liver weight. In a prenatal developmental toxicity study in rats, developmental toxicity (an increase in the number of runted fetuses and skeletal anomalies that consisted primarily of reductions in ossification) occurred at the highest dose tested, in the presence of maternal toxicity (decreased body weight gain and food consumption). The multigeneration reproduction study in rats revealed no reproductive toxicity or toxicological effects in the offspring, although systemic toxicity, including increased liver and/or kidney weights with histopathological lesions of these organs and/or decreased body weight, was observed in the mid- and high-dose adults. Since these studies do not suggest any increased sensitivity to young animals following prenatal exposure to thiobencarb, an additional uncertainty factor for the potential increased sensitivity of infants and children is not deemed necessary by the Agency.

i. Acute/Chronic Food Source Risk

An acute dietary exposure analysis was performed using tolerance-level residues and assumption of 100 percent crop treated. Since the endpoint of concern for an acute dietary risk assessment is a developmental effect, the only subgroup of concern are females (13+) and represents a MOE = 8920. Thus, EPA is not concerned with acute dietary risks from exposure to

~~thiobencarb residues in food.~~

~~A chronic dietary exposure analysis was performed using tolerance-level residues and 100 percent crop treated information. This resulted in a theoretical maximum residue concentration which occupied 12.8% of the RfD for the US population. The highest subgroup, Non-Nursing Infants (<1 year old), occupied 42.9% of the RfD.~~

~~**ii. Acute/Chronic Drinking Water Risk**~~

~~Approximately 95% of thiobencarb use occurs on rice. In these regions (lower Mississippi Valley and Central Valley in California), ground water is relied upon almost exclusively (except the City of Sacramento) as the source of drinking water. In addition, thiobencarb environmental fate data as provided by EFED indicate that thiobencarb is slightly persistent in water, generally not very mobile, tends to bind to soil organic matter, and doesn't desorb. However, due to limitations with available groundwater sampling data, no groundwater data are applicable for risk assessment purposes. Data from a California surface water monitoring study conducted in the Sacramento River basin indicated that thiobencarb residues were not above a limit of detection of 0.1 ug/L (0.1 ppb). This corresponds to an MOE > 10,000 for acute drinking water exposure and a %RfD = 0.28% for chronic drinking water exposure. Thus, EPA is not concerned with exposure to thiobencarb in drinking water based on available information.~~

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Dietary

1. Tolerance Reassessment Summary

The tolerances for plant and animal commodities listed in 40 CFR §180.401(a) and (b) are expressed in terms of the combined residues of thiobencarb [S-[(4-chlorophenyl)-methyl]diethylcarbamothioate] and its metabolites containing the chlorobenzyl and chlorophenyl moiety. A summary of thiobencarb tolerance reassessments is presented in Table 10.

a. Tolerances Listed Under 40 CFR §180.401(a):

Sufficient data are available to ascertain the adequacy of the established tolerances for the following commodities listed in 40 CFR §180.401(a): cattle, fat; cattle, mbyp; cattle, meat; eggs; goats, fat; goats, mbyp; goats, meat; hogs, fat; hogs, mbyp; hogs, meat; horses, fat; horses, mbyp; horses, meat; milk; poultry, fat; poultry, mbyp; poultry, meat; rice, grain; rice, straw; sheep, fat; sheep, mbyp; sheep, and meat.

b. Tolerances Listed Under 40 CFR §180.401(b):

Sufficient data are available to ascertain the adequacy of the established tolerances with regional registration in accordance with 40 CFR §180.1(n), for the following commodities listed in 40 CFR §180.401(b): celery, endive (escarole), and lettuce.

2. Codex Harmonization

No maximum residue limits (MRLs) have been established by the Codex Alimentarius Commission for thiobencarb residues in/on raw agricultural, animal, or processed commodities. Therefore, no compatibility questions exist with respect to U.S. tolerances.

Table 10. Tolerance Reassessment Summary for Thiobencarb.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR 180.401(a):			
Cattle, fat	0.2	0.2	
Cattle, mbyp	0.2	0.2	
Cattle, meat	0.2	0.2	
Eggs	0.2	0.2	
Goats, fat	0.2	0.2	
Goats, mbyp	0.2	0.2	
Goats, meat	0.2	0.2	
Hogs, fat	0.2	0.2	
Hogs, mbyp	0.2	0.2	
Hogs, meat	0.2	0.2	
Horses, fat	0.2	0.2	
Horses, mbyp	0.2	0.2	
Horses, meat	0.2	0.2	
Milk	0.05	0.05	
Poultry, fat	0.2	0.2	
Poultry, mbyp	0.2	0.2	
Poultry, meat	0.2	0.2	
Rice, grain	0.2	0.2	
Rice, straw	1.0	1.0	
Sheep, fat	0.2	0.2	
Sheep, mbyp	0.2	0.2	
Sheep, meat	0.2	0.2	
Tolerances Listed Under 40 CFR 180.401(b):			
Celery	0.2	0.2	
Endive (escarole)	0.2	0.2	*[Endive/escarole]*
Lettuce	0.2	0.2	

B. Occupational

EPA is concerned about the risks posed to application workers who are involved in the following scenarios for intermediate term exposure (risks of concern are not evident for short-term exposure):

- (1a) mixing/loading liquids for aerial application (MOE = 18);
- (1b) mixing/loading liquids for groundboom sprayer application for endive/lettuce (6 lbs ai/acre) and celery (8 lbs ai/acre) (MOEs = 50 and 40, respectively);
- (2a) loading granulars for fixed-wing aircraft (MOE = 54);
- (3) applying liquid spray with a fixed-wing aircraft (MOE = 33);
- (5) applying liquid spray with a helicopter (MOE = 67);
- (7) applying liquid spray with a groundboom sprayer for endive/lettuce (6 lbs ai/acre) and celery (8 lbs ai/acre) (MOEs = 71 and 54, respectively);

V. ACTIONS REQUIRED BY THE REGISTRANTS (to be completed, pending a meeting with the registrants).

REFERENCES

Provided in the following list of references are the citation for specific documents (memorandum, etc.) that were cited in the text of this document.

U.S. EPA. 1996a. Memorandum from T. Campbell to A. Aikens. "Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Thiobencarb." November 6, 1996.

U.S EPA. 1996b. S. Dapson, Y. Ioannou and S. Irene. Thiobencarb Toxicology Endpoint Selection Document. May 15, 1996.

U.S. EPA. 1996c. Memorandum from G. Ghali to J. Miller. " RfD/Peer Review Report of Thiobencarb (Bolero®); S-[(4-Chlorophenyl) methyl] diethylcarbamothioate. June 10, 1996.

U.S. EPA. 1996d. Memorandum from B. Steinwand to M. Metzger. "Dietary Exposure Analysis for Thiobencarb in Support of the Reregistration Eligibility Decision." September 9, 1996.

The references listed below are for other documents used to write this document. The bibliographic citations for the toxicology MRIDs may be found in PDMS. For residue chemistry, all supporting documentation may be found in the reference section of the Chemistry memorandum (U.S. EPA, 1996f).

U.S. EPA. 1996e. Memorandum from S. Dapson to P. Deschamp and P. Lewis. "Toxicology Review for the Reregistration Eligibility Document on Thiobencarb." September 17, 1996.

U.S. EPA. 1996f. Memorandum from S. Knizner to P. Lewis and P. Deschamp. Thiobencarb. Chemistry Chapter of the Reregistration Eligibility Document Reregistration Case No. 2665 Chemical No. 108401 No MRID # DP Barcode 214611 CBRS #16685." January 31, 1996.

U.S. EPA. 1996g. Memorandum from F.N. Mastrota to J. Ellenberger. Transmittal of EFED's RED chapter for thiobencarb (Chemical # 108401, Case #2665, DP Barcode # D214608, D214609, and D214610), associated data reviews (DP Barcodes # D182567, D199775, D200554, D200560, D204352, D205496, and D208936), and EFED's recommendation for thiobencarb.

U.S. EPA. 1997. Memorandum from H. Nelson to P. Lewis and N. Mastrota. Review and Summary of California EPA/California Rice Industry Association Data on Thiobencarb in California Surface Waters, 1993-1996. February 13, 1997.

LIST OF APPENDICES

Appendix 1. Product Chemistry Data Summary.

Appendix 2. Food/Feed Use Patterns Subject to Reregistration for Thiobencarb (Case 2665)

Appendix 3. Residue Chemistry Science Assessments for Reregistration of Thiobencarb.

Appendix 4. Exposure Scenario Descriptions for Uses of Thiobencarb.

Appendix 5. Memorandum from B. Steinwand to M. Metzger. "Dietary Exposure Analysis for Thiobencarb in Support of the Reregistration Eligibility Decision." September 9, 1996 (U.S. EPA. 1996d).

APPENDIX 1

PRODUCT CHEMISTRY DATA SUMMARY

Case No. 2665
Chemical No. 108401
Case Name: Thiobencarb
Registrant: K-I Chemical U.S.A., Incorporated
Product(s): 97.4% T (EPA Reg. No. 63588-4)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [a]	MRID Number [b]
61-1	Product Identity and Disclosure of Ingredients	Y	41609001
61-2	Starting Materials and Manufacturing Process	Y	41609001
61-3	Discussion of Formation of Impurities	Y	41609001
62-1	Preliminary Analysis	Y	41609002
62-2	Certification of Ingredient Limits	Y	41609002, 41609010
62-3	Analytical Methods to Verify the Certified Limits	Y	41609002, 41609010
63-2	Color	Y	00140158, 41609003
63-3	Physical State	Y	00140158, 41609003
63-4	Odor	Y	00140158, 41609003
63-5	Melting Point	N/A [c]	
63-6	Boiling Point	Y	00140158
63-7	Density, Bulk Density or Specific Gravity	Y	41609003
63-8	Solubility	Y	00140158
63-9	Vapor Pressure	Y	00140158
63-10	Dissociation Constant	N/A [d]	
63-11	Octanol/Water Partition Coefficient	Y	00044507
63-12	pH	Y	41609003
63-13	Stability	Y	00140158, 41609003

[a] Y = Yes; N = No; N/A = Not Applicable. The above conclusions are tentative, pending confirmation by K-I Chemical that the manufacturing process and location for the 97.4% T have not changed since the product was transferred from Chevron. Otherwise, all product chemistry data will be required for the K-I Chemical TGAI/T.
[b] All citations were reviewed under CBRS No. 16591, D221503, 12/8/95, S. Knizner.
[c] Data are not required because the TGAI is a liquid at room temperature.
[d] Data are not required because the TGAI does not dissociate in water.

APPENDIX 2

Food/Feed Use Patterns Subject to Reregistration for Thiobencarb (Case 2665).

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations [1]
Celery					
Broadcast soil application Post-transplant Ground equipment	8 lb/gal EC [59639-79] [FL910003]	8 lb	Not Specified (NS)	NS	Use limited to celery grown on muck soil in FL. Application may be made in 20-40 gal/A. Feeding crop or crop remains to livestock or grazing in treated areas is prohibited. A 12-hour REI and a 70-day PHI have been established. A 4-month PBI has been established for crops other than celery, endive (escarole), and lettuce.
Endive/Escarole					
Broadcast or directed, shielded soil application Postplant (at seeding or post-transplant) Ground equipment	8 lb/gal EC [59639-79] [FL910003]	6 lb	NS	NS	Use limited to endive/escarole grown on muck soil in FL. Application may be made in 20-50 gal/A. Feeding crop or crop remains to livestock or grazing in treated areas is prohibited. A 12-hour REI and a 60-day PHI have been established. A 4-month PBI has been established for crops other than celery, endive (escarole), and lettuce.

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations [1]
Lettuce					
Broadcast or directed, shielded soil application Postplant (at seeding or post-transplant) Ground equipment	8 lb/gal EC [59639-79] [FL910003]	6 lb	NS	NS	Use limited to lettuce grown on muck soil in FL. Application may be made in 20-50 gal/A. Feeding crop or crop remains to livestock or grazing in treated areas is prohibited. A 12-hour REI and a 60-day PHI have been established. A 4-month PBI has been established for crops other than celery, endive (escarole), and lettuce.
Rice (dry-seeded)					
Broadcast spray application Late preemergence or early postemergence Ground or aerial equipment	8 lb/gal EC [59639-79]	4 lb	1	Not Applicable (NA)	Application may be made in a minimum of 10 gal/A using ground or aerial equipment. Application may be made alone or as a tank mix with other herbicides. Application to rice paddies where commercial catfish or crayfish farming is practiced and use adjacent to catfish ponds are prohibited. A 12-hour REI and a 6-month PBI have been established. A maximum seasonal rate of 4 lb ai/A is in effect.
Split broadcast spray application Late preemergence/early postemergence Ground or aerial equipment	8 lb/gal EC [59639-79] [MO930007]	2 lb	2	10-14	

(continued; footnotes follow)

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations [1]
Rice (dry-seeded) *continued*					
Broadcast spray application Late preemergence or early postemergence Ground or aerial equipment	8 lb/gal EC [AR940002] [MS930010] [TX930023]	4 lb	NS	NS	Use limited to AR, MS, and TX. Application may be made in a minimum of 10 gal/A using ground or aerial equipment. Application may be made alone or as a tank mix with other herbicides. Use in fields where fall farming of crayfish is practiced is prohibited. Drift onto catfish, crayfish, shrimp, or minnow ponds is not permitted. A 6-month PBI has been established. A maximum seasonal rate of 4 lb ai/A is in effect.
Split broadcast spray application Late preemergence/early postemergence or Early postemergence/late postemergence Ground or aerial equipment	8 lb/gal EC [AR940002] [MS930010] [TX930023]	2 lb	2	10-14	
Broadcast spray application Late preemergence or early postemergence Ground or aerial equipment	8 lb/gal EC [FL930010]	4 lb	NS	NS	Use limited to FL. Application may be made in a minimum of 10 gal/A using aerial equipment and 20 gal/A using ground equipment. A 6-month PBI has been established.

(continued; footnotes follow)

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations [1]
Rice (dry-seeded) *continued*					
Broadcast spray application Late preemergence Ground or aerial equipment	8 lb/gal EC [MO930007]	4 lb	NS	NS	Use limited to MO. Application may be made in a minimum of 10 gal/A using ground or aerial equipment. Use in fields where fall farming of crayfish will be practiced is prohibited. Drift onto catfish, crayfish, shrimp, or minnow ponds is not permitted. A 6-month PBI has been established. A maximum seasonal rate of 4 lb ai/A is in effect.
Broadcast spray application Delayed preemergence Ground or aerial equipment	8 lb/gal EC [MS950007]	4 lb	NS	NS	Use limited to MS. Application may be made in a minimum of 10 gal/A using ground or aerial equipment. Application may be made alone or as a tank mix with other herbicides. Application to rice paddies where commercial catfish or crayfish farming is practiced is prohibited. Drift onto catfish, crayfish, shrimp, or minnow ponds is not permitted. A maximum seasonal rate of 4 lb ai/A is in effect.

(continued; footnotes follow)

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations [1]
Rice (dry-seeded) *continued*					
Split broadcast spray application Delayed preemergence/postemergence Ground or aerial equipment	8 lb/gal EC [MS950007]	2 lb	2	NS	Tank mix use limited to MS. Application may be made in a minimum of 10 gal/A using ground or aerial equipment. Application to rice paddies where commercial catfish or crayfish farming is practiced is prohibited. Drift onto catfish, crayfish, shrimp, or minnow ponds is not permitted. A maximum seasonal rate of 4 lb ai/A is in effect.
Broadcast spray application Early postemergence Ground or aerial equipment	8 lb/gal EC [MS930010]	4 lb	NS	NS	Tank mix use limited to MS. Application may be made in a minimum of 10 gal/A using ground or aerial equipment. Use in fields where fall farming of crayfish will be practiced is prohibited. Drift onto catfish, crayfish, shrimp, or minnow ponds is not permitted. A 6-month PBI has been established. A maximum seasonal rate of 4 lb ai/A is in effect.

(continued; footnotes follow)

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations [1]
Rice (dry-seeded) *continued*					
Broadcast spray application Early postemergence Ground or aerial equipment	8 lb/gal EC [AR940003] [MO930007]	3 lb	NS	NS	Tank mix use limited to AR and MO. Application may be made in a minimum of 10 gal/A using ground or aerial equipment. Use in fields where fall farming of crayfish will be practiced is prohibited. Drift onto catfish, crayfish, shrimp, or minnow ponds is not permitted. A 6-month PBI has been established. A maximum seasonal rate of 4 lb ai/A is in effect.
Split broadcast spray application Early postemergence/late postemergence Ground or aerial equipment	8 lb/gal EC [MS930010]	2 lb	2	NS	Tank mix use limited to MS. Application may be made in a minimum of 10 gal/A using ground or aerial equipment. Use in fields where fall farming of crayfish will be practiced is prohibited. Drift onto catfish, crayfish, shrimp, or minnow ponds is not permitted. A 6-month PBI has been established. A maximum seasonal rate of 4 lb ai/A is in effect.

(continued; footnotes follow)

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations [1]
Rice (dry-seeded) *continued*					
Split broadcast spray application Early postemergence/postflood Ground or aerial equipment	8 lb/gal EC [AR940002] [MS930010]	2 lb	2	NS	Tank mix use limited to AR and MS. Application may be made in a minimum of 10 gal/A using ground or aerial equipment. Use in fields where fall farming of crayfish will be practiced is prohibited. Drift onto catfish, crayfish, shrimp, or minnow ponds is not permitted. A 6-month PBI have been established. A maximum seasonal rate of 4 lb ai/A is in effect.

(continued; footnotes follow)

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations [1]
Rice (water-seeded)					
Broadcast spray application Preplant (nonflood) Ground or aerial equipment	8 lb/gal EC [AR940002] [MS930010] [TX930023]	4 lb	NS	NS	Tank mix use limited to AR, MS, and TX. Application may be made in a minimum of 10 gal/A using ground or aerial equipment. Use in fields where fall farming of crayfish will be practiced is prohibited. Drift onto catfish, crayfish, shrimp, or minnow ponds is not permitted. A 6-month PBI has been established. A maximum seasonal rate of 4 lb ai/A is in effect.
Split broadcast spray application Preplant/early postemergence (nonflood) or Preplant/postflood or Early postemergence/postflood Ground or aerial equipment	8 lb/gal EC [AR940002] [MS930010] [TX930023]	2 lb	2	NS	

(continued; footnotes follow)

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations [1]
Rice (water-seeded) *continued*					
Broadcast spray application Late preemergence Ground or aerial equipment	8 lb/gal EC [CA930003]	4 lb	1	NA	For use in CA on non-flooded fields only. Application may be made in a minimum of 5 gal/A using ground or aerial equipment. Use in fields where fall farming of crayfish will be practiced and use adjacent to catfish ponds are prohibited. A 6-month PBI has been established. A maximum seasonal rate of 4 lb ai/A is in effect.
Broadcast spray application Early postemergence Ground or aerial equipment	8 lb/gal EC [59639-79]	3 lb	NS	NS	For use on non-flooded fields only. Application may be made in a minimum of 10 gal/A using ground or aerial equipment. Application may be made alone or as a tank mix with other herbicides. Application to rice paddies where commercial catfish or crayfish farming is practiced and use adjacent to catfish ponds are prohibited. A 12-hour REI and a 6-month PBI have been established. A maximum seasonal rate of 4 lb ai/A is in effect.

(continued; footnotes follow)

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations [1]
Rice (water-seeded) *continued*					
Broadcast spray application Early postemergence Ground or aerial equipment	8 lb/gal EC [AR940002] [AR940003] [MO930007] [MS930010] [TX930023]	3 lb	NS	NS	Tank mix use limited to AR, MO, MS, and TX on non-flooded fields only. Application may be made in a minimum of 10 gal/A using ground or aerial equipment. Use in fields where fall farming of crayfish will be practiced is prohibited. Drift onto catfish, crayfish, shrimp, or minnow ponds is not permitted. A 6-month PBI has been established. A maximum seasonal rate of 4 lb ai/A is in effect.
Broadcast spray application Postemergence (after flooding when rice is in the expanded two-leaf stage)	10% G [59639-80]	4 lb	1	NA	Use limited to CA. Use in fields where fall farming of crayfish will be practiced and use adjacent to catfish ponds are prohibited. A 12-hour REI and a 6-month PBI have been established.
	10% G [AR940001] [MS930011] [TX930024]	4 lb	NS	NS	Use limited to AR, MS, and TX.

(continued; footnotes follow)

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations [1]
Rice (drill-seeded)					
Broadcast spray application Preplant or late preemergence Ground or aerial equipment	8 lb/gal EC [AR940002] [MS930010]	4 lb	NS	NS	Tank mix use limited to AR and MS. Application may be made in a minimum of 10 gal/A using ground or aerial equipment. Use in fields where fall farming of crayfish will be practiced is prohibited. Drift onto catfish, crayfish, shrimp, or minnow ponds is not permitted. A 6-month PBI has been established. A maximum seasonal rate of 4 lb ai/A is in effect.
Split broadcast spray application Preplant/early postemergence or Late preemergence/early postemergence Ground or aerial equipment	8 lb/gal EC [AR940002] [MS930010]	2 lb	2	NS	
Broadcast spray application Delayed preemergence Ground or aerial equipment	8 lb/gal EC [MO940005]	4 lb	NS	NS	Tank mix use limited to MO. Application may be made in a minimum of 10 gal/A using ground or aerial equipment. Application to rice paddies where commercial catfish or crayfish farming is practiced is prohibited. Drift onto catfish, crayfish, shrimp, or minnow ponds is not permitted. A maximum seasonal rate of 4 lb ai/A is in effect.

(continued; footnotes follow)

Site Application Type Application Timing Application Equipment	Form [EPA Reg. No.]	Max. Single Application Rate (ai)	Max. # Apps.	Min. Retreatment Interval (Days)	Use Limitations [1]
Rice (drill-seeded) *continued*					
Split broadcast spray application Delayed preemergence/early postemergence Ground or aerial equipment	8 lb/gal EC [MO940005]	2 lb	2	NS	Tank mix use limited to MO. Application may be made in a minimum of 10 gal/A using ground or aerial equipment. Application to rice paddies where commercial catfish or crayfish farming is practiced is prohibited. Drift onto catfish, crayfish, shrimp, or minnow ponds is not permitted. A maximum seasonal rate of 4 lb ai/A is in effect.

APPENDIX 3

Residue Chemistry Science Assessments for Reregistration of Thiobencarb

GLN: Data Requirements	Current Tolerance(s), ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
171-3: Directions for Use	N/A = Not Applicable	Yes [2]	See Table A
171-4 (a): Plant Metabolism	N/A	No	42384701 [3]
171-4 (b): Animal Metabolism	N/A	No	*92182051* [4], *92182072* [4], 42340301 [5], 43404002 [6]
171-4 (c/d): Residue Analytical Methods			
- Plant commodities	N/A	No	*92182052* [7], *92182073* [7], 43075402 [8]
- Animal commodities	N/A	No	*92182052* [7], *92182073* [7], 43492301 [9]
171-4 (e): Storage Stability	N/A	No	42003405 [10], 42384702 [3], 42962802 [11], 43182501 [12]
171-4 (k): Magnitude of the Residue in Plants			
Leafy Vegetables (Except Brassica Vegetables) Group			
- Celery	0.2 [§180.401(b)]	No	00142476 [13], 00152879 [13], 40774601 [13], 40774602 [13]
- Endive	0.2 [§180.401(b)]	No	00142476 [13], 00152879 [13], 40774601 [13], 40774602 [13]

GLN: Data Requirements	Current Tolerance(s), ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
- Lettuce	0.2 [§180.401(b)]	No	00142476 [13], 152879 [13], 40774601 [13], 40774602 [13]
Cereal Grains Group			
- Rice grain	0.2, rice grain [§180.401(a)]	No	*92182068* [14], *92182080* [14]
Forage, Fodder, Hay, and Straw of Cereal Grains Group			
- Rice straw	1, rice grain [§180.401(a)]	No	*92182068* [14], *92182080* [14]
171-4 (l): Magnitude of the Residues in Processed Food/Feed			
- Rice	--	No	*92182069* [15], *92182081* [15], 42987002 [16]
171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs			
- Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	0.05, milk; 0.2, fat, meat, and mbyp of cattle, goats, hogs, horses, and sheep [§180.401(a)]	No	*92182053* [17], *92182074* [17], 42962801 [11]
- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	0.2, eggs, fat, meat, and mbyp of poultry	No	*92182053* [17] *92182074* [17], 42962802 [11]
171-4 (f): Nature and Magnitude of the Residue in Potable Water	--	No [18]	*92182066* [19] *92182078* [19], 42981801 [20], 43404003 [21], 43404004 [21], 43404005 [21]
171-4 (g): Nature and Magnitude of the Residue in Fish	--	No [22]	*92182067* [23], *92182079* [23]

GLN: Data Requirements	Current Tolerance(s), ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
171-4 (h): Nature and Magnitude of the Residue in Irrigated Crops	--	No [24]	
171-4 (i): Magnitude of the Residue in Food Handling Establishments	N/A	No	
165-1: Rotational Crops (Confined)	--		
165-2: Rotational Crops (Field)	--	No	00073826[25], 41609011[26]

1. *Italicized* references were reviewed in the Thiobencarb Phase IV Review by C. Olinger and S. Funk dated 4/15/91 and/or in conjunction with one or more of the following petitions for rice grain and straw: PP#0F2322, PP#5G1582, PP#6F1763, and PP#2G1231. All other references were reviewed as noted.

2. Label amendments are required for Valent's end-use products (EPA Reg. Nos. 59639-79 and 59639-80) to specify a 25-day water holding interval following thiobencarb application to rice fields. Additionally, the following use restrictions should be added to thiobencarb labels: "Do not use on rice paddies where catfish or crayfish farming is practiced. Do not use adjacent to catfish or crayfish ponds."

3. CBRS No. 10220, DP Barcode D180633, 3/1/93, S. Knizner.

4. MRIDs 92182051 and 92182072 are a summary and reformat, respectively, of MRID 00040935.

5. CBRS No. 10090, DP Barcode D179319, 1/29/93, S. Knizner.

6. CBRS Nos. 14681 and 14721, DP Barcode D209308, 4/11/95, S. Knizner.

7. MRIDs 92182052 and 92182073 are a summary and reformat, respectively of MRIDs 00040950, 00042023, 00042026, 00042027, 00042028, 00072529, 00086773.

8. This submission, pertaining to the analysis of thiobencarb metabolites [4-chlorobenzylmethylsulfone, 4-chlorobenzylmethylsulfoxide, and 4-chlorobenzoic acid] using multiresidue method Protocols B and E, was forwarded by CBRS to FDA for evaluation and inclusion in PAM Vol. I, Appendix I (L. Edwards to B. McMahon, 3/15/94).

9. CBRS No. 14890, DP Barcode D210516, 12/19/95, S. Knizner.

Table B *(continued)*.

10. CBRS No. 8567, DP Barcode D168623, 10/26/92, C. Olinger.

11. CBRS No. 12709, DP Barcode D196131, 4/12/94, F. Suhre.

12. CBRS No. 13540, DP Barcode D201833, 5/9/94, S. Knizner.

13. See various reviews under PP#5F3158, including:
CBTS Nos. 6857 and 6858, 8/14/90, E. Haeberer;
CBTS No. 6196, 2/7/90, D. Edwards;
CBTS Nos. 5738 and 5739, 10/27/89, D. Edwards;
CBTS Nos. 5278 and 5279, 5/9/89, D. Edwards;
CBTS No. 428, 12/5/88, N. Dodd; and
CBTS No. 10, 3/17/86, V. Boyd.

14. MRIDs 92182068 and 92182080 are a summary and reformat, respectively, of MRIDs 00042024, 00042029, and 00124278.

15. MRIDs 92182069 and 92182081 are a summary and reformat, respectively, of MRIDs 00042024 and 00042029.

16. CBRS No. 12825, DP Barcode D196589, 4/11/94, F. Suhre.

17. MRIDs 92182053 and 92182074 are a summary and reformat, respectively, of MRID 00044528.

18. The reregistration requirements for magnitude of the residue in water will be fulfilled when label revisions are made to Valent's end-use products to preclude livestock watering or use for drinking or irrigation for a specified time period after treatment.

19. MRIDs 92182066 and 92182078 are a summary and reformat, respectively, of MRIDs 00133563 and 00139049.

20. CBRS No. 12826, DP Barcode D196735, 12/10/93, R. Perfetti.

21. CBRS No. 14657, DP Barcode D208937, 7/31/95, S. Knizner.

The reregistration requirements for the nature and magnitude of the residue in fish will be fulfilled when label revisions are made to Valent's end-use products prohibiting use of thiobencarb on rice paddies where commercial catfish or crayfish farming is practiced, and on areas adjacent to catfish or crayfish ponds. Refer to endnote 2 for appropriate wording of recommended label revisions.

Table B *(continued)*.

23. MRIDs 92182067 and 92182079 are a summary and reformat, respectively, of MRIDs 00133563, 00139049, and 00155428.

24. Data depicting the magnitude of the residue in irrigated crops are not required for reregistration purposes. Valent's thiobencarb end-use products contain restrictions that prohibit the use of water drained directly from treated rice fields for use in irrigating other crops.

25. S.Creeger, 9/11/86. This review also noted that previous EFED memoranda (dated 12/13/82 and 7/18/83) established additional plant back intervals. These plant back intervals are acceptable.

26. H.Manning, 4/29/91, DP Barcode D157129 and S.Knizner, 1/25/96, CBRS No. 16727, DP Barcode D222095.

APPENDIX 4
Exposure Scenario Descriptions for Uses of Thiobencarb

The following table provides the assumptions that were used in developing the daily exposure estimates for the thiobencarb exposure assessment. For all exposure scenarios, the unit exposure values were derived from PHED V. 1.1

Exposure Scenario (Number)	Standard Assumptions [a] (8-hr work day)	Comments[b]
Mixer/Loader Descriptors		
Mixing/Loading Liquid Formulations (1a and 1b))	350 acres for aerial, 80 acres for groundboom	**Baseline:** "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 53 replicates; Dermal = 25 to 122 replicates; Inhalation = 85 replicates. High confidence in dermal and inhalation data. **PPE:** "Best Available" grades: Hands and dermal acceptable grades. Hands = 59 replicates; Dermal = 25 to 122 replicates. High confidence in dermal data. **Engineering Controls:** "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 31 replicates; Dermal = 16 to 22 replicates; Inhalation = 27 replicates. High confidence in dermal and inhalation data. PHED data used for baseline, no Protection Factors (PFs) were necessary. A 50% PF was used for PPE to represent double layer of clothing. Gloves were worn during use of engineering controls.

Exposure Scenario (Number)	Standard Assumptions [a] (8-hr work day)	Comments[b]
Mixing/Loading Granulars (2a and b)	80 acres for tractor-drawn spreader	**Baseline:** "Best Available" grades: Hands = all grades; dermal and inhalation acceptable grades. Hands = 10 replicates; dermal = 29 to 36 replicates; inhalation = 58 replicates. Low confidence in dermal data; high confidence for inhalation data. **PPE:** "Best Available" grades: Hands and dermal= acceptable grades. Hands = 45 replicates; dermal = 29 to 36 replicates. High confidence for dermal. PHED data used for baseline, no PFs were necessary. A 50% PF was used for PPE to represent double layer of clothing.

Exposure Scenario (Number)	Standard Assumptions [a] (8-hr work day)	Comments[b]
Applicator Descriptors		
Applying Sprays with a Fixed-wing Aircraft (Enclosed Cockpit) (3)	350 acres	**Engineering Controls:** "Best Available" grades: Hands = acceptable grades; dermal, and inhalation A,B,C grades. Hands = 34 replicates; dermal = 24 to 48 replicates; inhalation = 23 replicates. Medium confidence in dermal and inhalation data. PHED data used no PFs were necessary.
Applying Granulars with a Fixed-wing Aircraft (4)	350 acres	**Engineering Controls:** "Best Available" grades: Hands and inhalation = all data; Dermal = Grade C. Hands = 4 replicates; dermal = 9 to 13 replicates; inhalation = 13 replicates. Low confidence in dermal and inhalation data. PHED data used no PFs were necessary.
Applying Sprays with a Helicopter (Enclosed Cockpit) (5)	350 acres	**Engineering Controls:** "Best Available" grades: Hands and dermal = A,B,C grades; inhalation acceptable grades. Hands = 2 replicates; dermal = 3 replicates; inhalation = 3 replicates. Low confidence in dermal and inhalation data. PHED data used no PFs were necessary.

Exposure Scenario (Number)	Standard Assumptions [a] (8-hr work day)	Comments[b]
Applying Granulars with a Tractor-drawn Spreader (Enclosed Cab) (6)	80 acres	**Engineering Controls:** "Best Available" grades: Hands, dermal and inhalation = acceptable grades. Hands = 17 replicates; dermal = 27 to 29 replicates; and inhalation = 37 replicates. High confidence in dermal and inhalation data. PHED data used for engineering controls no PFs were necessary. Only data for the glove scenario are available.
Applying Sprays with a Groundboom Sprayer (7)	80 acres	**Baseline:** "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 29 replicates; Dermal = 32 to 42 replicates; Inhalation = 22 replicates. High confidence in dermal and inhalation data. **PPE:** "Best Available" grades: Hands = A,B,C grades; dermal = acceptable grades. Hands = 21 replicates; Dermal = 32 to 42 replicates. Medium confidence in dermal data. **Engineering Controls:** "Best Available" grades: Hands and dermal = A,B,C grades; inhalation acceptable grades. Hands = 16 replicates; Dermal = 20 to 31 replicates; Inhalation = 16 replicates. Medium confidence in dermal data and high confidence in inhalation data. PHED data used for baseline, no PFs were necessary. a 50% PF was used for PPE to represent a double layer of clothing.
Flagger Descriptors		

Exposure Scenario (Number)	Standard Assumptions [a] (8-hr work day)	Comments[b]
Flagging Spray Applications (8)	350 acres	**Baseline:** "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 16 replicates; Dermal = 16 to 18 replicates; Inhalation = 18 replicates. High confidence in dermal and inhalation data. A 50% PF was added for PPE to represent a double layer of clothing. A 98% PF was added for Engineering controls to represent an enclosed cab.

[a] Standard Assumptions based on an 8-hour work day as estimated by OREB. BEAD data were not available.

[b] "Best Available" grades are defined by OREB SOP for meeting Subdivision U Guidelines. Best available grades are assigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B, and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:

High = grades A and B and 15 or more replicates per body part
Medium = grades A, B, and C and 15 or more replicates per body part
Low = grades A, B, C, D, and E or any combination of grades with less than 15 replicates

1. REI = Restricted entry interval. PHI = Preharvest interval. PBI = Plantback interval.

13544

012621

Chemical:	**Thiobencarb**
PC Code:	**108401**
HED File Code	**11000 Chemistry Reviews**
Memo Date:	**09/09/96**
File ID:	**00000000**
Accession Number:	**412-02-0005**

HED Records Reference Center
10/25/2001

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

SEP - 9 1996

PC 108401

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SEP - 9 1996

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Thiobencarb in Support of the Reregistration Eligibility Decision.

FROM: Brian Steinwand
Dietary Risk Evaluation Section
Science Analysis Branch/HED (7509C)

Through: Elizabeth Doyle, Section Head
Dietary Risk Evaluation Section
SAB/Health Effects Division

E. A. Doyle

TO: Mike Metzger, Chief
Risk Characterization Analysis Branch
Health Effects Division (7509C)

Action Requested

Provide a dietary exposure analysis to estimate the chronic and acute dietary exposure and risk from thiobencarb for uses which are being supported through reregistration.

Discussion

Toxicological Endpoint:

The Reference Dose (RfD) used in the analysis is 0.01 mg/kg bwt/day, based on a NOEL of 1.0 mg/kg bwt/day (LEL of 5 mg/kg/day) from a two year rat feeding study with an uncertainty factor of 100 that demonstrated decreased body weights, food consumption and food efficiency and increased blood urea nitrogen as an endpoint (See IRIS). The RfD value has been approved by both the HED (2/8/96) and Agency (4/15/87) RfD committees.

The Health Effects Division Carcinogenicity Peer Review Committee (CPRC) has determined thiobencarb to be a class D carcinogen (not classifiable as to human carcinogenicity).

The endpoint for acute dietary risk assessment is the developmental NOEL of 25 mg/kg bwt/day.

Residue Information

Tolerances for thiobencarb residues in/on agricultural and animal commodities are published in 40 CFR §180.401(a) and (b). Tolerances have been established for rice, grain at 0.2 ppm; meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep at 0.2 ppm; eggs at 0.2 ppm; and milk at 0.5 ppm. Tolerances with regional registrations are established for celery, endive, and lettuce at 0.2 ppm each. Tolerance level residues and 100 percent crop treated assumptions were made for all commodities. No anticipated residue (AR) information was used in this analysis.

Results

A summary of the residue information included in this analysis is attached as Table 1. A DRES chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. Summaries of the TMRCs and their representations as percentages of the Reference Dose (RfD) are included as Table 2. The results of the acute analysis are attached as Table 3.

Existing tolerances result in a TMRC which represents 12.8% of the RfD for the U.S. general population. The highest subgroup, Non-Nursing Infants (<1 year old) occupies 42.9% of the RfD.

The chronic analysis for thiobencarb is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with thiobencarb. Based on the risk estimates calculated in this analysis, it appears that chronic dietary risk from the uses recommended through reregistration, is not of concern.

Acute Exposure:

The Margin of Exposure (MOE) is a measure of how close the high end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). Generally, acute dietary margins of exposure greater than 100 tend to cause no dietary concern when results are compared to animal-derived data. Because the endpoint of concern for acute dietary risk assessment is a developmental effect, the only subgroup of concern is females (13+). The MOE for this subgroup (8928) demonstrates no acute concern considering the proposed tolerances.

Attachments

cc: DRES; Caswell 207DA

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Thiobencarb (Bolero) Caswell #207DA CAS No. 28249-77-6 A.I. CODE: 108401 CFR No. 180.401	2yr. feeding- rat NOEL= 1.0000 mg/kg 20.00 ppm LEL= 5.0000 mg/kg 100.00 ppm ONCO: D (RfD/PR Committee)	Decreased body weights, food consumption & food efficiency; Increased blood urea nitrogen. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.010000 EPA RfD= 0.010000	No data gaps.	HED reviewed 02/11/86 EPA pending 08/05/86 HED reassess 03/20/87 EPA verified 04/15/87 RfD/PR reviewed 02/08/96 On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
13002AA	CELERY	5F3158			0.200000
13013AA	LETTUCE-LEAFY VARIETIES	5F3158			0.200000
13015AA	ENDIVE,CURLEY AND ESCAROLE	5F3158			0.200000
13020AA	LETTUCE-UNSPECIFIED	5F3158			0.200000
13045AA	LETTUCE-HEAD VARIETIES	5F3158			0.200000
24004AA	RICE-ROUGH	0F2322			0.200000
24004AB	RICE-MILLED	0F2322			0.200000
50000DB	MILK-NON-FAT SOLIDS	0F2322			0.050000
50000FA	MILK-FAT SOLIDS	0F2322			0.050000
50000SA	MILK SUGAR (LACTOSE)	0F2322			0.050000
53001BA	BEEF-MEAT BYPRODUCTS	0F2322			0.200000
53001BB	BEEF(ORGAN MEATS)-OTHER	0F2322			0.200000
53001DA	BEEF-DRIED	0F2322			0.200000
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	0F2322			0.200000
53001KA	BEEF(ORGAN MEATS)-KIDNEY	0F2322			0.200000
53001LA	BEEF(ORGAN MEATS)-LIVER	0F2322			0.200000
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0F2322			0.200000
53002BA	GOAT-MEAT BYPRODUCTS	0F2322			0.200000
53002BB	GOAT(ORGAN MEATS)-OTHER	0F2322			0.200000
53002FA	GOAT(BONELESS)-FAT	0F2322			0.200000
53002KA	GOAT(ORGAN MEATS)-KIDNEY	0F2322			0.200000
53002LA	GOAT(ORGAN MEATS)-LIVER	0F2322			0.200000
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0F2322			0.200000
53003AA	HORSE	0F2322			0.200000
53005BA	SHEEP-MEAT BYPRODUCTS	0F2322			0.200000
53005BB	SHEEP(ORGAN MEATS)-OTHER	0F2322			0.200000
53005FA	SHEEP(BONELESS)-FAT	0F2322			0.200000
53005KA	SHEEP(ORGAN MEATS)-KIDNEY	0F2322			0.200000
53005LA	SHEEP(ORGAN MEATS)-LIVER	0F2322			0.200000
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT	0F2322			0.200000
53006BA	PORK-MEAT BYPRODUCTS	0F2322			0.200000
53006BB	PORK(ORGAN MEATS)-OTHER	0F2322			0.200000
53006FA	PORK(BONELESS)-FAT (INCLUDING LARD)	0F2322			0.200000
53006KA	PORK(ORGAN MEATS)-KIDNEY	0F2322			0.200000
53006LA	PORK(ORGAN MEATS)-LIVER	0F2322			0.200000
53006MA	PORK(BONELESS)-LEAN (W/O REMOVEABLE FAT)	0F2322			0.200000
55008BA	TURKEY-BYPRODUCTS	0F2322			0.200000
55008LA	TURKEY-GIBLETS (LIVER)	0F2322			0.200000
55008MA	TURKEY-FLESH(W/O SKIN, W/O BONES)	0F2322			0.200000
55008MB	TURKEY-FLESH(+SKIN,W/O BONES)	0F2322			0.200000

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Thiobencarb (Bolero) Caswell #207DA CAS No. 28249-77-6 A.I. CODE: 108401 CFR No. 180.401	2yr feeding- rat NOEL= 1.0000 mg/kg 20.00 ppm LEL= 5.0000 mg/kg 100.00 ppm ONCO: D (RfD/PR Committee)	Decreased body weights, food consumption & food efficiency; Increased blood urea nitrogen. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.010000 EPA RfD= 0.010000	No data gaps.	HED reviewed 02/11/86 EPA pending 08/05/86 HED reassess 03/20/87 EPA verified 04/15/87 RfD/PR reviewed 02/08/96 On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
55008MC	TURKEY-UNSPECIFIED	0F2322			0.200000
55013BA	POULTRY,OTHER-BYPRODUCTS	0F2322			0.200000
55013LA	POULTRY,OTHER-GIBLETS(LIVER)	0F2322			0.200000
55013MA	POULTRY,OTHER-FLESH (+SKIN,W/O BONES)	0F2322			0.200000
55014AA	EGGS-WHOLE	0F2322			0.200000
55014AB	EGGS-WHITE ONLY	0F2322			0.200000
55014AC	EGGS-YOLK ONLY	0F2322			0.200000
55015BA	CHICKEN-BYPRODUCTS	0F2322			0.200000
55015LA	CHICKEN-GIBLETS(LIVER)	0F2322			0.200000
55015MA	CHICKEN-FLESH(W/O SKIN,W/O BONES)	0F2322			0.200000
55015MB	CHICKEN-FLESH(+SKIN,W/O BONES)	0F2322			0.200000

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Thiobencarb (Bolero) Caswell #207DA CAS No. 28249-77-6 A.I. CODE: 108401 CFR No. 180.401	2yr feeding- rat NOEL= 1.0000 mg/kg 20.00 ppm LEL= 5.0000 mg/kg 100.00 ppm ONCO: D (RfD/PR Committee)	Decreased body weights, food consumption & food efficiency; Increased blood urea nitrogen. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.010000 EPA RfD= 0.010000	No data gaps.	HED reviewed 02/11/86 EPA pending 08/05/86 HED reassess 03/20/87 EPA verified 04/15/87 RfD/PR reviewed 02/08/96 On IRIS.

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	0.001280	0.001280	12.797260	0.000000		
U.S. POPULATION - SPRING SEASON	0.001243	0.001243	12.434000	0.000000		
U.S. POPULATION - SUMMER SEASON	0.001280	0.001280	12.796390	0.000000		
U.S. POPULATION - FALL SEASON	0.001309	0.001309	13.093630	0.000000		
U.S. POPULATION - WINTER SEASON	0.001287	0.001287	12.866340	0.000000		
NORTHEAST REGION	0.001313	0.001313	13.130740	0.000000		
NORTH CENTRAL REGION	0.001284	0.001284	12.836710	0.000000		
SOUTHERN REGION	0.001200	0.001200	11.998230	0.000000		
WESTERN REGION	0.001368	0.001368	13.677180	0.000000		
HISPANICS	0.001656	0.001656	16.562670	0.000000		
NON-HISPANIC WHITES	0.001249	0.001249	12.486000	0.000000		
NON-HISPANIC BLACKS	0.001269	0.001269	12.686040	0.000000		
NON-HISPANIC OTHERS	0.001582	0.001582	15.821090	0.000000		
NURSING INFANTS (< 1 YEAR OLD)	0.001202	0.001202	12.024630	0.000000		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.004294	0.004294	42.942550	0.000000		
FEMALES (13+ YEARS, PREGNANT)	0.000920	0.000920	9.202000	0.000000		
FEMALES 13+ YEARS, NURSING	0.001103	0.001103	11.032810	0.000000		
CHILDREN (1-6 YEARS OLD)	0.002945	0.002945	29.451340	0.000000		
CHILDREN (7-12 YEARS OLD)	0.001941	0.001941	19.411530	0.000000		
MALES (13-19 YEARS OLD)	0.001362	0.001362	13.620040	0.000000		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.001080	0.001080	10.804950	0.000000		
MALES (20 YEARS AND OLDER)	0.000966	0.000966	9.658160	0.000000		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000831	0.000831	8.307230	0.000000		

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

TABLE 3

1DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 14:38 Friday, August 23, 1996 28

*NAME: BOLERO	STUDY	RDV	NOEL	SF	STUDY TYPE	SPECIES	EFF. LEV.	CORE GRADE	DOC. NO.*
*CASWELL NO: 207DA CFR NO: CFR .	A								*
*CAS NO: SHAUGHNESSY NO: 180401	B								*
*STATUS CODES:	C								*
*RDV INFO: The LD value used in this analysis is 0.002 MG/KG of BODY WEIGHT/DAY									*
*FILE INFO: No Tolerance Data Are Used--Without User Modifications.								AR DATA:	No User Modifications*

-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
TOLERANCES:	0.00	0.000000	0.00
ANTICIPATED RESIDUES:	99.78	0.000877	43.85

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
TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTICIPATED RESIDUES:	100	85	50	21	8	3	1	0	0	0	0	0	0	0	0	0	0

Females (13+ Years:

Exposure = RDV x X
= 0.002 x 1.4
High End Exposure = 0.0028

MOE = Noel + Exposure
= 25.0 mg/kg/day + 0.0028 mg/kg/day
MOE = 8928

207DA	13002AA10	0.2000	CELERY
207DA	13002AA21	0.2000	CELERY
207DA	13013AA10	0.2000	LETTUCE-LEAFY
207DA	13015AA10	0.2000	ENDIVE
207DA	13015AA21	0.2000	ENDIVE
207DA	13020AA10	0.2000	LETTUCE-UNSPEC
207DA	13045AA10	0.2000	LETTUCE-HEAD
207DA	13045AA21	0.2000	LETTUCE-HEAD
207DA	24004AA21	0.2000	RICE-ROUGH
207DA	24004AA23	0.2000	RICE-ROUGH
207DA	24004AB21	0.2000	RICE-MILLED
207DA	24004AB22	0.2000	RICE-MILLED
207DA	24004AB23	0.2000	RICE-MILLED
207DA	24004AB31	0.2000	RICE-MILLED
207DA	50000DB10	0.0500	MILK-NON-FAT SOL
207DA	50000DB21	0.0500	MILK-NON-FAT SOL
207DA	50000DB51	0.0500	MILK-NON-FAT SOL
207DA	50000FA10	0.0500	MILK-FAT SOLIDS
207DA	50000FA21	0.0500	MILK-FAT SOLIDS
207DA	50000FA51	0.0500	MILK-FAT SOLIDS
207DA	50000SA21	0.0500	MILK SUG (LACT)
207DA	50000SA51	0.0500	MILK SUG (LACT)
207DA	53001BA21	0.2000	BEEF-MEAT BYP
207DA	53001BA26	0.2000	BEEF-MEAT BYP
207DA	53001BB21	0.2000	BEEF-OTH ORGAN
207DA	53001BB51	0.2000	BEEF-OTH ORGAN
207DA	53001DA21	0.2000	BEEF-DRIED
207DA	53001FA10	0.2000	BEEF-FAT
207DA	53001FA21	0.2000	BEEF-FAT
207DA	53001FA22	0.2000	BEEF-FAT
207DA	53001FA23	0.2000	BEEF-FAT
207DA	53001FA24	0.2000	BEEF-FAT
207DA	53001FA25	0.2000	BEEF-FAT
207DA	53001KA21	0.2000	BEEF-KIDNEY
207DA	53001LA25	0.2000	BEEF-LIVER
207DA	53001LA31	0.2000	BEEF-LIVER
207DA	53001MA10	0.2000	BEEF-LEAN
207DA	53001MA21	0.2000	BEEF-LEAN
207DA	53001MA22	0.2000	BEEF-LEAN
207DA	53001MA23	0.2000	BEEF-LEAN
207DA	53001MA24	0.2000	BEEF-LEAN
207DA	53002BA00	0.2000	GOAT-MEAT BYP
207DA	53002BB00	0.2000	GOAT-OTH ORGAN
207DA	53002FA23	0.2000	GOAT-FAT
207DA	53002FA25	0.2000	GOAT-FAT
207DA	53002KA00	0.2000	GOAT-KIDNEY
207DA	53002LA00	0.2000	GOAT-LIVER
207DA	53002MA23	0.2000	GOAT-LEAN
207DA	53002MA25	0.2000	GOAT-LEAN
207DA	53003AA00	0.2000	HORSE
207DA	53005BA21	0.2000	SHEEP-MEAT BYP
207DA	53005BB21	0.2000	SHEEP-OTH ORGAN
207DA	53005FA21	0.2000	SHEEP-FAT
207DA	53005KA21	0.2000	SHEEP-KIDNEY
207DA	53005LA00	0.2000	SHEEP-LIVER
207DA	53005MA21	0.2000	SHEEP-LEAN
207DA	53005MA31	0.2000	SHEEP-LEAN
207DA	53006BA21	0.2000	PORK-MEAT BYP
207DA	53006BB21	0.2000	PORK-OTH ORGAN
207DA	53006BB26	0.2000	PORK-OTH ORGAN
207DA	53006FA10	0.2000	PORK-FAT
207DA	53006FA21	0.2000	PORK-FAT
207DA	53006FA23	0.2000	PORK-FAT
207DA	53006FA25	0.2000	PORK-FAT
207DA	53006FA26	0.2000	PORK-FAT
207DA	53006KA21	0.2000	PORK-KIDNEY
207DA	53006LA21	0.2000	PORK-LIVER
207DA	53006LA25	0.2000	PORK-LIVER
207DA	53006MA21	0.2000	PORK-LEAN
207DA	53006MA25	0.2000	PORK-LEAN
207DA	53006MA26	0.2000	PORK-LEAN
207DA	55008BA21	0.2000	TURKEY-BYP
207DA	55008BA26	0.2000	TURKEY-BYP
207DA	55008LA21	0.2000	TURKEY ORGAN
207DA	55008LA25	0.2000	TURKEY ORGAN
207DA	55008MA21	0.2000	TURKEY W/O SKIN
207DA	55008MA31	0.2000	TURKEY W/O SKIN
207DA	55008MA62	0.2000	TURKEY W/O SKIN
207DA	55008MB21	0.2000	TURKEY+SKIN
207DA	55008MB25	0.2000	TURKEY+SKIN
207DA	55008MC21	0.2000	TURKEY-UNSPEC
207DA	55013BA00	0.2000	POULTRY,OTH-BYP
207DA	55013LA25	0.2000	POULTRY,ORGAN
207DA	55013MA21	0.2000	POULTRY,OTHER
207DA	55014AA10	0.2000	EGGS-WHOLE
207DA	55014AA21	0.2000	EGGS-WHOLE
207DA	55014AA22	0.2000	EGGS-WHOLE
207DA	55014AA23	0.2000	EGGS-WHOLE
207DA	55014AA25	0.2000	EGGS-WHOLE
207DA	55014AB10	0.2000	EGGS-WHITE ONLY
207DA	55014AB21	0.2000	EGGS-WHITE ONLY
207DA	55014AB22	0.2000	EGGS-WHITE ONLY
207DA	55014AB62	0.2000	EGGS-WHITE ONLY
207DA	55014AB81	0.2000	EGGS-WHITE ONLY
207DA	55014AC10	0.2000	EGGS-YOLK ONLY
207DA	55014AC21	0.2000	EGGS-YOLK ONLY
207DA	55014AC25	0.2000	EGGS-YOLK ONLY
207DA	55014AC31	0.2000	EGGS-YOLK ONLY
207DA	55015BA00	0.2000	CHICKEN-BYP
207DA	55015LA21	0.2000	CHICKEN-ORGAN
207DA	55015LA25	0.2000	CHICKEN-ORGAN
207DA	55015LA26	0.2000	CHICKEN-ORGAN
207DA	55015MA21	0.2000	CHICKEN-W/O SKIN
207DA	55015MA22	0.2000	CHICKEN-W/O SKIN

207DA	55015MA25	0.2000	CHICKEN-W/O SKIN
207DA	55015MA31	0.2000	CHICKEN-W/O SKIN
207DA	55015MA53	0.2000	CHICKEN-W/O SKIN
207DA	55015MB21	0.2000	CHICKEN+SKIN
207DA	55015MB25	0.2000	CHICKEN+SKIN