



R.E.D. FACTS

Thiobencarb

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet the safety standard of the FQPA and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 2665, Thiobencarb.

Use Profile

Thiobencarb is a systemic, pre-emergence herbicide that acts by inhibiting shoots of emerging seedlings. It is used to control grasses, sedge and broadleaf weeds in food crops such as rice (represents 95% of use), lettuce, celery, and endive. Formulations include a liquid and a granular. Thiobencarb may be applied using ground spray equipment or by aircraft.

Regulatory History

Thiobencarb was first registered for use on rice in 1982. In 1991, thiobencarb was issued regional tolerances for use on celery, endives, and lettuce in the State of Florida.

Currently, there are five products containing thiobencarb registered under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act. They consist of one technical (manufacturing use) product containing 97.4% active ingredient, two emulsifiable concentrate end-use products each containing 84.0% active ingredient, and two granular end-use products each containing 10.0% active ingredient.

Human Health Assessment

Toxicity

In studies using laboratory animals, thiobencarb generally has been shown to be of low acute toxicity. It is slightly toxic by the oral and dermal route and has been placed in category III for these effects. It is practically non-toxic by the inhalation route and for eye irritation, and has been placed in Toxicity Category IV (the lowest of four categories) for these effects. Thiobencarb also tested negative for mutagenicity.

Dietary Exposure

People may be exposed to residues of thiobencarb through the diet. Tolerances have been established for celery, lettuce, endive (escarole), rice (grain and straw), and for animal commodities including milk and eggs, and the fat, meat, and meat by-products of cattle, hogs, poultry, sheep, goats and horses (please see 40 CFR 180.401(a) and (b)). EPA has reassessed the thiobencarb tolerances and found that they are acceptable.

Occupational and Residential Exposure

Exposure to homeowners is not expected since there are no residential uses. Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to thiobencarb during and after normal agricultural use.

The risks calculated from intermediate-term exposures to thiobencarb indicate that risks from exposures to granular formulations (loading and applying) are lower than those from exposures to the liquid formulation/spray applications. For the granular formulations, the MOEs exceed 100 for all scenarios (except loading to support aerial application) with the addition of personal protective equipment. For many of the liquid formulation/spray application scenarios, the MOEs do not reach 100, even with engineering controls.

Granular Formulations: The Agency believes the risks resulting from intermediate-term exposures to the granular formulation are overestimated due to the use of a 60.2 percent dermal absorption value for the granular scenarios. In general, dermal absorption of granular formulations has been found to be significantly lower than for liquid formulations. Therefore, the Agency has determined that risks to handlers of granular formulations will be adequately mitigated with the addition of personal protective equipment.

Liquid Formulations: The Agency believes that risks resulting from intermediate-term exposures to persons handling liquid formulations are overestimated due to limitations with the hazard identification and the dose-response assessment for the intermediate-term endpoint, particularly in light of the absence of serious effects to these target organs in either the subchronic neurotoxicity or rat chronic feeding study, which suggest the lack of a deleterious response to thiobencarb by the kidney and/or liver. The Agency believes that risks to handlers using liquid formulations will be adequately mitigated with the used of engineering controls and personal protective equipment.

Human Risk Assessment

Thiobencarb generally is of low acute toxicity, and has been classified in Group D (not classifiable as to human carcinogenicity). Food crop uses are registered including rice, lettuce, endive and escarole. However, dietary exposure to thiobencarb residues in foods is extremely low, as is the cancer risk posed to the general population.

Of greater concern is the risk posed to thiobencarb handlers, particularly mixers/loaders/applicators, and field workers who come into contact with treated crops following application of this pesticide. Exposure and risk to workers will be mitigated by the use of PPE required by the WPS, supplemented by engineering controls as required by this RED.

For post-application workers, since no dislodgable foliar residue studies or concurrent dermal samples were submitted to the EPA for thiobencarb to measure postapplication reentry, a rough surrogate postapplication assessment was performed as a default. Only the short-term endpoint (25 mg/kg/day) was used for the risk assessment, since EPA does not anticipate that intermediate-term exposures (i.e., 7 days or more of exposure) are likely to occur for post-application workers for these crops in early-stage development. EPA assumed in the surrogate assessment that dermal absorption would be significantly lower than the 60.2 percent used in the handler assessment, since dermal exposure would be to dry residues. The surrogate postapplication risk assessment indicated that at all application rates (i.e., 4-8 pounds active ingredient per acre), risks would be acceptable to post-application workers entering treated areas to perform tasks such as scouting, thinning, or hoeing, provided entry is postponed for 24 hours following application.

FQPA Considerations

The FQPA of 1996 amended the FFDCFA by setting a new safety standard for the establishment of tolerances and directs the EPA to consider available information concerning the susceptibility of infants and children to pesticide residues in food. Based on the review of available data and the absence of incident or epidemiological data for thiobencarb, an additional safety factor for the protection of children is not necessary. The FQPA also requires EPA to consider aggregate exposure to the pesticide residue,

including all anticipated dietary exposure and other exposures 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 has assessed the dietary risk posed by thiobencarb. In assessing chronic dietary risk, EPA estimates that thiobencarb residues in food sources account for $\leq 42.9\%$ of the RfD, and include the highest-at-risk subgroup, non-nursing infants. In drinking water thiobencarb residues account for 0.29% of the RfD. Thus, the aggregate exposures from all sources of thiobencarb (in this case, only dietary and drinking water exposures are relevant) account for 43.2% of the RfD. Therefore, the Agency concludes that aggregate risks for the general population resulting from thiobencarb uses are not of concern.

EPA estimates that thiobencarb residues in the diet of infants and children account for 42.9% of the RfD (29.5 for children 1-5) and residues in drinking water account for 0.29% of the RfD. Thus the aggregate exposure from all sources of thiobencarb account for 43.2% of the RfD for infants and children. Therefore, the Agency concludes that aggregate risks for infants and children resulting from uses of thiobencarb are not of concern.

Environmental Assessment

Environmental Fate

Thiobencarb is slightly persistent in water, generally not very mobile, tends to bind to soil organic matter, and doesn't desorb. Generally, thiobencarb is stable to degradation by hydrolysis and is stable under anaerobic aquatic conditions. Thiobencarb meets the persistence and mobility triggers for classification as a restricted-use chemical for groundwater concerns, but not the detections triggers. The Agency believes that ground water concerns do not warrant use restrictions. Furthermore, due to the binding nature of the active ingredient, any thiobencarb that may reach surface water will be predominantly bound with suspended solids and sediments. Standard coagulation and flocculation processes used in plants are expected to remove most of the suspended solids and sediments from the water, thereby removing most of the potential risk of thiobencarb in drinking water.

Ecological Effects

Use of liquid formulations of thiobencarb pose some acute risk to mammals. The acute risk to birds is minimal. Use of liquid formulations pose a high chronic risk to birds and mammals.

Use of thiobencarb on rice in the southeast US poses a high risk of chronic effects to freshwater and estuarine aquatic invertebrates, including shrimp and mollusks. There is also likely a high risk of chronic effects to fish, but additional data are needed to confirm this. This use of thiobencarb also poses a high risk of acute effects to fish and aquatic invertebrates in

certain high-exposure situations. Additionally, use of thiobencarb on rice in California poses a risk of causing chronic effects to aquatic organisms in the smaller drains and waterways, but not in the larger rivers. Thiobencarb use poses minimal risk of acute effects to fish and aquatic invertebrates. Minimal risk of both acute and chronic effects is expected for all estuarine organisms in California. Spray drift from aerial application of liquid thiobencarb on rice poses a high risk to nontarget terrestrial and semiaquatic plants. Drift of granular thiobencarb and spraying of liquid thiobencarb applied with ground equipment pose minimal risk to these plants. All uses of thiobencarb on rice may pose a risk of killing emerging seedlings of aquatic plants, especially aquatic grasses. Use of thiobencarb on rice may pose a risk to aquatic algae in the southeast US and in smaller drains and waterways in California.

Use of thiobencarb on celery, lettuce, and endive in Florida poses a high risk of causing chronic effects to fish, freshwater invertebrates, and estuarine invertebrates, including shrimp. Additionally, this use poses a high risk of causing acute effects to freshwater and estuarine invertebrates, including oysters and shrimp. Use of thiobencarb on celery, lettuce, and endive in Florida poses a high risk to terrestrial plants, semiaquatic plants, and algae. It may also pose a risk to emerging seedlings of vascular aquatic plants.

Environmental Risk Characterization

Of particular concern to the Agency is the high risk of chronic effects to fish and freshwater invertebrates, including shrimp and mollusks, and the high risk of causing acute effects to freshwater and invertebrates, and the water quality risks posed by the chemical.

Risk Mitigation

To lessen worker risk, and ecological and water quality risks posed by thiobencarb, EPA is requiring the following mitigation measures from registrants of thiobencarb-containing products.

To protect handlers:

- For liquid formulations: mixers and loaders must use closed systems in addition to wearing a chemical-resistant apron, chemical-resistant gloves, long-sleeve shirt, long pants, shoes, and socks. Applicators and flaggers must use enclosed cabs or cockpits and wear long-sleeve shirt, long pants, shoes, and socks.
- For granular formulations: loaders must wear a chemical-resistant apron, chemical-resistant gloves, long-sleeve shirt, long pants, shoes, and socks. Applicators and flaggers must wear chemical-resistant gloves, long-sleeve shirt, long pants, shoes, and socks.

To protect workers:

- A restricted-entry interval of 24 hours is being imposed. Early entry workers must wear coveralls, chemical-resistant gloves, shoes, and socks.

To protect non-target organisms:

- Application restrictions are being mandated in the states of Louisiana and Texas. In Louisiana, thiobencarb application will not be allowed south of the Intracoastal Waterway. In Texas, thiobencarb application will not be allowed within two miles inland from the shorelines of Galveston Bay, and not within two miles of Matagorda Bay.
- Include label warnings preventing application to rice fields with catfish/crayfish farming, and preventing application to rice fields adjacent to catfish or crayfish ponds.
- Where weather conditions permit, it is required that flood waters not be released within 14 days.
- Require that thiobencarb not be applied within 24 hours of rainfall, or when heavy rain is expected to occur within 24 hours.
- Require that thiobencarb not be mixed/loaded or otherwise handled within 100 feet of aquatic habitat.
- Continue existing label warnings addressing environmental hazards, such as restricting application aerially within one mile of the St. Francis Floodway where the Fat Pocketbook Pearly Mussel is known to occur. Comparable warnings would be appropriate where use on rice can expose other threatened and endangered mussels.
- Work with the EPA to reassess in the Fall of 1998 thiobencarb use on leafy vegetables in Florida based on the results of the currently ongoing environmental monitoring study for muck soils in Florida from the U.S. Geological Survey's National Water Quality Assessment Program (NAWQA).

**Additional Data
Required**

EPA is requiring the following additional generic studies for thiobencarb to confirm its regulatory assessments and conclusions:

- *Dermal Penetration Study [GLN 85-2];*
- *Life-Cycle Freshwater Fish Study [GLN 72-5];*
- *Avian Subacute Toxicity Study [GLN 71-2(b)];*
- *Avian Reproduction Study [GLN 71-4(b)];*
- *Seedling Emergence Testing Study [GLN 123-1(a)];*

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling

All thiobencarb end-use products must comply with EPA's current

Changes Required

pesticide product labeling requirements and with the following requirements:

Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

"Only for formulation into an Herbicide for the following use(s):rice weed control in California, Louisiana, Texas, Mississippi, Missouri and Arkansas, and lettuce, endive and celery weed control in Florida."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

- (a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."
- (b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

Labeling Requirements for End-Use Products

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

PPE and Engineering Control Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain thiobencarb:

- Revise the product labeling to adopt the handler personal protective equipment/engineering control requirements set forth in this section.
- Remove any conflicting PPE requirements on the current labeling.

For **multiple-active-ingredient** end-use products that contain thiobencarb:

- Compare the handler personal protective equipment/engineering control requirements set forth in this section to the requirements on the current labeling.

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- Retain the more protective requirements. (For guidance on which requirements are considered more protective, see PR Notice 93-7.)

Active-Ingredient Specific Engineering Control Requirements

EPA is establishing active-ingredient specific engineering controls for some occupational uses of thiobencarb end-use products.

For liquid formulations:

"Mixers and loaders are required to use closed systems. The closed system must be used in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4))."

"Applicators and flaggers are required to use enclosed cabs or enclosed cockpits. The closed system must be used in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(5-6))."

Active-Ingredient Specific Personal Protective Equipment Requirements

EPA is establishing active-ingredient specific personal protective equipment requirements for all occupational uses of thiobencarb end-use products.

For liquid formulations:

"In addition to using closed systems, mixers and loaders must wear:

- long-sleeved shirt and long pants,
- chemical-resistant gloves*,
- socks plus shoes, and
- chemical-resistant apron."

"Applicators and flaggers using enclosed cabs or cockpits must wear:

- long-sleeved shirt and long pants, and
- socks plus shoes."

"For other handling activities and in case of a spill or other emergency exposure, handlers must wear:

- coveralls over long-sleeved shirt and long pants,
- chemical-resistant gloves*,
- chemical-resistant footwear, and
- chemical-resistant apron when cleaning equipment."

*For the glove statement, use the statement established for thiobencarb through the instructions in Supplement Three of PR Notice 93-7.

For granular formulations:

"Applicators and other handlers must wear:

- long-sleeved shirt and long pants,
- chemical-resistant gloves*,
- shoes plus socks
- chemical-resistant apron when loading formulation into equipment or cleaning equipment."

*For the glove statement, use the statement established for thiobencarb through the instructions in Supplement Three of PR Notice 93-7.

a. Entry Restrictions

For **sole-active-ingredient** end-use products that contain thiobencarb:

- Revise the product labeling to adopt the entry restrictions set forth in this section.
- Remove any conflicting entry restrictions on the current labeling.

For **multiple-active-ingredient** end-use products that contain thiobencarb:

- Compare the entry restrictions set forth in this section to the entry restrictions on the current labeling.
- Retain the more protective restrictions. (A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled.")

Restricted-entry interval: A 24-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all thiobencarb end-use products.

Early-Entry Personal Protective Equipment (PPE): The PPE required for early entry is:

- coveralls,
- chemical-resistant gloves, and
- shoes plus socks.

Other Labeling Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing thiobencarb:

i. Application Restrictions

“Do not apply this product in a way that will contact workers or other persons, either directly or indirectly or through drift. Only protected handlers may be in the area during application.”

“Do not apply this product south of the Intracoastal Waterway in Louisiana.”

“Do not apply this product within two (2) miles from the shorelines of Matagorda Bay in Texas.”

“Do not apply this product within two (2) miles from the shorelines of Galveston Bay in Texas.”

“Do not apply this product to rice fields with catfish/crayfish farming.”

“Do not apply this product on rice fields adjacent to catfish or crayfish ponds.”

“When applying to rice fields, do not release permanent flood water within 14-days of application of this product (where weather permits).”

“Avoid application of this product within 24 hours of rainfall, or when heavy rain is expected to occur within 24 hours.”

“Do not mix/load or otherwise handle this product within 100 feet of aquatic habitat.”

ii. User Safety Requirements

“Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”

“Follow manufacturer’s instructions for cleaning/maintaining PPE. If there are not such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.”

iii. User Safety Recommendations

“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.”

“Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.”

“Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”

iv. Spray Drift Labeling

The following language must be placed on each product label that can be applied aurally:

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.

The following Aerial Drift Reduction Advisory Information must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

1. The distance of the outer most nozzles on the boom must not exceed $\frac{3}{4}$ the length of the wingspan or rotor.
2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they should be observed.

It is recommended that the applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.

The following aerial drift reduction advisory information must be contained in the product labeling:

[This section is advisory in nature and does not supersede the mandatory label requirements.]

INFORMATION ON DROPLET SIZE: The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE

- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

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- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.
 - Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.
 - Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.
 - Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.
 - Maintenance of Nozzles - periodic inspection and subsequent replacement of nozzles to ensure proper chemical application is recommended.

BOOM LENGTH: For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

APPLICATION HEIGHT: Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT: When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)

WIND: Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY: When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS: Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS: The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

Regulatory Conclusion

The use of currently registered products containing thiobencarb in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Thiobencarb products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for thiobencarb during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet are available on the Internet. See <http://www.epa.gov/REDS>.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the thiobencarb RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, thethiobencarb RED, or reregistration of individual products containing thiobencarb], please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week.