

Q16. Is there any reason for concern about the inert ingredients used in Sonar?

A16. Inert ingredients are those components of the product that do not exhibit herbicidal activity; that is, the components other than Sonar. Water is the primary inert ingredient in Sonar A.S., making up approximately 45% of the formulation. The second largest (approximately 10%) inert is propylene glycol, a compound used in facial creams and other health and beauty products. Other inert ingredients are added to serve as wetters, dispersants, and thickeners in the formulation. Trace amounts of an antifoaming agent and a preservative are also added. The primary inert ingredient in the pelleted formulation -- Sonar SRP -- is clay, which makes up approximately 89% of the formulation. Small amounts of a binder or coating solution are also added to reduce the dustiness of the pellets. None of the inert ingredients in Sonar formulations are on the USEPA's list of "Inerts of Toxicological Concern" or list of "Potentially Toxic Inerts/High Priority for Testing." Thus, there is no reason for concern about the inert ingredients used in Sonar.

Q17. Is it important to follow label directions for use and disposal of Sonar?

A17. Yes. It is a violation of federal law to use products, including Sonar, in a manner inconsistent with product labeling or to improperly dispose of excess products or rinsate. Although the results of extensive toxicity testing in the laboratory and in field trials indicate a low order of toxicity to non-target plants, animals, and people, Sonar, like all chemicals, will cause adverse effects at sufficiently high exposure levels. Failure to follow label directions for use and disposal of Sonar could result in environmental levels that exceed the tolerances for Sonar established to be protective of human health and the health of pets, livestock and other wildlife. In addition, improper use of Sonar could result in unintended damage to non-target plants.

Q18. If Sonar is used in conformance with label directions, is there any reason to be concerned that Sonar will pose risk to human health or the environment?

A18. As discussed in the answers to the previous questions, results of laboratory and field studies and extensive use experience with Sonar in a wide range of water bodies strongly support the conclusion that Sonar will pose negligible risks to human health and the environment when used in conformance with label directions.

In summary, it can be said that Sonar has a favorable toxicological profile for humans. It has an overall low relative toxicity and it is not a carcinogen, mutagen or reproductive toxicant. Sonar also has a very good environmental profile for an aquatic product because of: 1) its low toxicity to non-target organisms; 2) its non-persistent behavior when applied to water bodies (i.e., it readily breaks down to carbon, hydrogen, oxygen, nitrogen and fluorine); and 3) its low bioaccumulation potential, which means it does not build up in the body or in the food chain.

by the U.S. Fish and Wildlife Service, Florida Department of Environmental Protection, and the Florida Game and Fresh Water Fish Commission.

Sonar has also been used in other environmentally sensitive areas such as Disney World, Ducks Unlimited MARSH projects, Sea World, state and federal parks, and numerous fish and waterfowl management areas.

Q14. What is it that makes Sonar an effective aquatic herbicide while being a compound of relatively low toxicity to humans?

A14. Sonar inhibits a plant's ability to make food. Specifically, Sonar inhibits carotenoid synthesis, a process specific only to plants. Carotenoids (yellow, orange and red pigments) are an important part of the plant's photosynthetic (food making) system. These pigments protect the plant's green pigments (called chlorophyll) from photodegradation or breakdown by sunlight. When carotenoid synthesis is inhibited, the chlorophyll is gradually destroyed by sunlight. As a plant's chlorophyll decreases, so does its capacity to produce carbohydrates (its food source) through photosynthesis. Without the ability to produce carbohydrates, the plant dies.

Humans do not have carotenoid pigments. Therefore, the property of Sonar that makes it an effective herbicide at low doses does not affect the human body.

Q15. Will Sonar have an adverse effect on water quality?

A15. Extensive testing of a wide range of water bodies has shown no significant changes in water quality after Sonar treatment. In fact, Sonar has a practical advantage over certain other aquatic herbicides in this area. Specifically, the dissolved oxygen content of the water does not change significantly following Sonar treatment because the relatively slow herbicidal activity of the product permits a gradual decay of the treated vegetation. Maintaining adequate dissolved oxygen levels is critical to fish and other aquatic animals, which require oxygen to survive. This contrasts with the changes in water quality that can arise from the application of certain other aquatic herbicides that are "fast-acting." The sudden addition of large amounts of decaying plant matter to the water body can lead to decreased oxygen levels and result in a fish kill. To avoid depressions in dissolved oxygen content, label directions for certain "fast-acting" aquatic herbicides recommend that only portions of areas of dense weeds be treated at a time. Because Sonar does not have any substantial impact on dissolved oxygen, it is possible to treat an entire water body with Sonar at one time.

In addition, Sonar has been monitored in water, plants and fish during field trials. This provides first-hand information on residue levels in the environment following application of Sonar.

Q12. What do these investigations reveal?

- A12. A combination of the toxicity studies and residue monitoring data reveals that Sonar poses negligible risks to aquatic animals including fish, wildlife, pets, and livestock when used according to label directions.

As was done with laboratory mammals, toxicity studies were conducted to establish a dietary no-observed-effect level (NOEL) for birds. This maximum, non-toxic chronic dose is 1,000 ppm in the diet. One thousand (1,000) ppm is 2,500 times the highest average concentration of total residue found in fish (0.40 ppm), about 2,100 times the highest concentration found in aquatic plants (0.47 ppm), and about 11,500 times the highest average concentration of Sonar found in the water at field trial sites (0.087 ppm). Because the residue levels in these "bird food" items are so far below the NOEL, it can be concluded is that there are negligible risks to birds that might be exposed to Sonar in their diet following application of Sonar.

The highest average Sonar concentration found in Sonar-treated water is below the lowest NOEL values for both short and long term exposures from freshwater and marine fish. Honey bees and earthworms are not particularly sensitive to Sonar. Sonar caused no deaths in honey bees when they were dusted directly with the herbicide, and earthworms were not affected when they were placed in soil containing more than 100 ppm Sonar.

Extensive testing of Sonar in laboratory animals used to assess potential risks to human health indicates that a large safety margin exists for mammalian species in general. Thus, Sonar poses negligible risk to pets, livestock, and mammalian wildlife that might drink from water treated with Sonar.

Q13. Can Sonar be used in environmentally sensitive areas?

- A13. Sonar has been used in a wide range of aquatic environments in the United States without incident for almost 10 years. Florida canals and rivers are examples of environmentally sensitive areas that have been treated with Sonar. Some sites are habitats for the endangered Florida manatee. Although toxicity testing data for the manatee, or for other endangered species, cannot be collected directly, questions about whether Sonar treatment will pose any significant risk to the manatee can be answered with results of the mammalian toxicity studies.

The Florida manatee is an aquatic mammal that consumes up to 20% (one-fifth) of its body weight per day in aquatic plants. Treatment of canal water with Sonar according to label directions is expected to result in a maximum Sonar concentration of 0.15 ppm in the water and from 0.8 to 2.6 ppm in aquatic plants. Calculations show that it would be impossible for a manatee to ingest enough Sonar in its diet to cause any adverse effects, based on results of laboratory studies in other mammals. To reach the maximum non-toxic dose or NOEL for sensitive mammalian species, a manatee would have to drink more than 40 times its body weight per day in treated water, or eat at least 3 to 10 times its body weight per day in aquatic plants. This calculation indicates that treatment with Sonar in manatee habitats -- as one example of an environmentally sensitive area -- will pose negligible risk. In fact, application to Florida canals and rivers has been approved

Q9. How complete is the toxicology information upon which this conclusion rests?

A9. All toxicity studies required by the USEPA to obtain registration approval for Sonar have been completed.

Q10. What about the people who apply Sonar -- are they at risk?

A10. The Sonar label states that individuals who use Sonar should avoid breathing spray mist or contact with skin, eyes, or clothing; should wash thoroughly with soap and water after handling; and should wash exposed clothing before reuse. These precautions are the minimum recommendations for the application of any pesticide. If Sonar is used according to label instructions, exposures to the product should be minimal and use should pose negligible risks to applicators.

Sonar has been shown to be of low acute toxicity in laboratory animal studies (that is, toxicity from a high dose exposure for a short period of time). Therefore, any exposure to the product (even undiluted) that might occur during use is unlikely to lead to adverse effects as long as label instructions are followed. As discussed in Question #7, Sonar's label carries the signal word CAUTION which corresponds to the USEPA's lowest acute toxicity rating category.

Studies in laboratory animals show that the lethal dose from a single oral exposure of Sonar is greater than 10,000 mg/kg. To put this into perspective, an adult would have to drink over one million gallons of Sonar-treated water (at the 0.15 [150 ppb] ppm maximum allowable limit) to receive a dose of 10,000 mg/kg; a 20-kg child would have to drink approximately 350,000 gallons.

Because applicators are more likely to contact the undiluted material than the general population, questions about the toxicity of Sonar following direct skin contact have been raised. A laboratory study of the toxicity of an 80 percent solution of Sonar applied to rabbit skin (a standard model to predict effects in humans) suggests that Sonar is minimally toxic by this route. In this study, when Sonar was repeatedly applied to the skin of rabbits for 21 days (in the largest amounts that could be applied practically), there were no signs of toxicity and only slight skin irritation was observed. Further, the dermal administration of the 80 percent solution of Sonar did not induce sensitization in guinea pigs.

Q11. Has there been any investigation of the possible harmful effects of Sonar on fish, wildlife, pets and livestock?

A11. The toxicity of Sonar has been investigated in laboratory studies in birds (including the bobwhite quail and mallard duck), in the honey bee (as a representative insect) and in the earthworm (as a representative soil organism), in five different species of freshwater and marine fish, and in other aquatic animals. These studies have involved exposures to high concentrations for brief periods as well as exposures lasting as long as an entire lifetime, including during reproduction.

Extensive studies have also been performed to evaluate the effects of Sonar on various aquatic and terrestrial plants (both those considered undesirable aquatic weeds and those native plants that we wish to protect). Studies in laboratory animals designed primarily to assess potential health risk in humans are also relevant to the assessment of potential health effects in mammalian wildlife, livestock, and pets.

Investigations of the toxicity of Sonar have been performed in laboratory animals under a variety of exposure conditions, including exposure to very high doses for short periods (acute studies), as well as repeated exposures to lower doses (which are still far in excess of any exposures that humans might actually receive) throughout the lifetime of the laboratory animals (chronic studies). Other special studies have been performed to evaluate the potential for Sonar to cause reproductive effects, cancer, and genetic damage. Study results indicate a low order of toxicity to mammalian species following acute exposures and repeat-dose exposures for up to a lifetime. In addition, repeated doses of Sonar did not result in the development of tumors, adverse effects on reproduction or on development of offspring, or genetic damage.

In characterizing the toxicity of a compound and its safety margin for exposures of humans and wildlife, toxicologists attempt to identify the maximum dose at which a chemical produces no toxicity. Another way of stating this is how much of the chemical can an organism be exposed to before it reaches a toxic level (recall from the footnote to the introduction on page 1 that all substances are toxic at some dose or level). This maximum non-toxic dose is usually established by studies in laboratory animals and is reported as the "no-observed-effect level" or NOEL. The dietary NOEL for Sonar (that is, the highest dose at which no adverse effects were observed in laboratory animals fed Sonar) is approximately 8 milligrams of Sonar per kilogram of body weight per day, abbreviated 8 mg/kg/day. This NOEL was derived from a study in rats that were fed Sonar in their regular diets every day for their entire two-year lifetime.

To put this NOEL into perspective, a 70-kg adult (about 150 pounds) would have to drink over 1,000 gallons of water containing the maximum legally allowable concentration of Sonar in potable water (0.15 ppm) daily for a significant portion of their lifetime to receive a dose equivalent to the 8 mg/kg/day NOEL. At most, adults drink about 2 quarts (one-half gallon) of water daily, which means that even if a person was drinking water with the maximum legally allowable concentration of Sonar, their margin of safety would still be at least 2,000. Similarly, a 20-kg child (about 40 pounds) would have to drink approximately 285 gallons of Sonar-treated water every day to receive a dose equivalent to the NOEL. Because children drink only about one quart of water daily, this provides a safety margin of greater than 1,000.

The above example calculation of safety margins is based on the assumption that potable water will contain levels of Sonar at its maximum allowable concentration of 0.15 ppm (150 ppb). In fact, the Sonar concentration achieved under typical applications is closer to 0.02 ppm (20 ppb), thereby providing a safety margin seven times greater. The point is that adults and children who drink water from potable water sources that have been treated with Sonar according to label instructions are at negligible risk.

Similarly, the levels of Sonar allowed in various food products pose negligible risk to human health. For example, even if Sonar were present at the maximum allowable limit of 0.05 ppm in meat, poultry, eggs, and milk, a 70-kg adult would have to consume almost 25,000 pounds of these foods daily (and again for a significant portion of a lifetime) to receive a dose equivalent to the dietary NOEL for Sonar. A child would have to consume over 7,000 pounds of these foods daily.

Because Sonar is used only intermittently in any one area, and because it disappears from the environment, there is virtually no way that anyone will be exposed continuously for a lifetime. Because the NOEL derives from a study involving daily exposures for a lifetime, the actual safety margin for people is, in fact, much greater than is suggested by the above illustrative examples.

forage crops. Consumption by livestock of Sonar-treated water and crops irrigated with Sonar-treated water was shown to result in negligible levels of Sonar in lean meat and milk. Sonar-treated water can be used immediately for watering livestock.

To ensure that residue levels of Sonar pose no significant risk, USEPA has established tolerances, or maximum legally allowable levels, in water, fish, crops irrigated with Sonar-treated water, and other agricultural products (including eggs, milk, meat, and chicken). For example, the 0.15 ppm (150 ppb) concentration in water mentioned in the answer to Question #1 is the tolerance limit for water that is used for drinking. The recommended application rates of Sonar (detailed on the label) are established to ensure the product will do its job and that tolerance limits won't be exceeded.

Q6. How might people come into contact with Sonar after it is applied to an aquatic site?

A6. People could come into contact with Sonar by swimming in water bodies treated with the herbicide, by drinking water from treated lakes or reservoirs, by consuming game fish taken from treated waters, and by consuming meat, poultry, eggs or milk from livestock that were provided water from treated surface water sources.

Q7. Is it likely that people will be harmed because of those contacts?

A7. Extensive studies have demonstrated that contact with Sonar poses negligible health risks when the herbicide is used according to label instructions. The label for Sonar carries no restrictions for swimming or fishing in treated water or against drinking water treated with Sonar. Sonar does not build up in the body.

The conclusion that Sonar poses negligible health risks is evidenced by USEPA's toxicity rating for Sonar. The USEPA classifies herbicides according to their acute toxicity or potential adverse health effects and requires that a "signal word" indicating the relative toxicity of the herbicide be prominently displayed on the product label. Every herbicide carries such a signal word. The most acutely toxic herbicide category requires the signal word DANGER. However, if the product is especially toxic, the additional word POISON is displayed. Herbicides of moderate acute toxicity require the signal word WARNING. The least toxic products require the signal word CAUTION. Sonar labels display the word CAUTION, the USEPA's lowest acute toxicity rating category.

Q8. How do we know that humans are not likely to experience any harmful effects from Sonar's temporary presence in the environment?

A8. Companies that develop new herbicides are required to: 1) conduct extensive investigations of the toxicology of their product in laboratory animals; 2) characterize the ways by which people may contact the herbicide after it has been applied to an aquatic site; 3) determine the amount of exposure resulting from these possible contacts; and 4) demonstrate the fate of the herbicide in the environment. Before USEPA will register a herbicide, the Agency must establish with a high degree of certainty that an ample safety margin exists between the level to which people may be exposed and the level at which adverse effects have been observed in the toxicology studies.

- A2. Federal law requires that an aquatic herbicide be registered with the USEPA before it can be shipped or sold in the United States. To obtain registration, manufacturers are required to conduct numerous studies (i.e., over 120 studies depending upon the intended uses) and to submit a thorough and extensive data set to USEPA to demonstrate that, under its conditions of use, the product will not pose a significant risk to human health and the environment and that the herbicide is effective against the target weeds or plants.

Individual states can establish registration standards that are more strict than federal standards, but not less strict.

- Q3. What types of information must be submitted to regulatory agencies before a herbicide is registered?**

- A3. To register a herbicide, the manufacturer must submit information that falls into the following categories: product chemistry (for example, solubility, volatility, flammability and impurities), environmental fate (for example, how the substance degrades in the environment), mammalian toxicology (studies in laboratory animals used to assess potential health risks to humans), and wildlife and aquatic (for example, bird and fish) toxicology. If there are any residues in the environment, their levels must be determined. A manufacturer also conducts studies of product performance (or efficacy as a herbicide).

- Q4. Have all of the data required for registration of Sonar been submitted to regulatory agencies, and have those agencies found the data acceptable?**

- A4. The data required for registration of Sonar by the USEPA is complete and has been accepted by the USEPA and by all states.

- Q5. What happens to Sonar when it is used according to approved labeling -- that is, what is its environmental fate or what happens to Sonar once it is released or applied to the water?**

- A5. Tests under field conditions show that Sonar disappears from treated water in a matter of weeks or months, depending on a number of environmental factors such as sunlight, water temperature and depth. In lakes, reservoirs, rivers and canals where only a portion of the water body is treated, dilution reduces the level of Sonar relatively quickly following application.

Sonar does not persist in the environment. Its disappearance from aquatic environments is accomplished by several processes. First, the plants that are being treated absorb Sonar, thereby removing a portion of it from the water. Second, Sonar degrades or breaks down in the presence of sunlight by a process called "photodegradation." Photodegradation is the primary process contributing to the loss of Sonar from water. Third, adsorption of Sonar to hydrosol (sediments) also contributes to its loss from water. As Sonar is released from hydrosol back into the water, it is photodegraded.

Study results indicate that Sonar has a low bioaccumulation potential and therefore is not a threat to the food chain. Specifically, studies have shown that Sonar does not accumulate in fish tissue to any significant degree. The relatively small amounts of Sonar that may be taken up by fish following application are eliminated as the Sonar levels in water decline. In a study of crops irrigated with Sonar-treated water, no residues of Sonar were found in any human food crops, and only very low levels were detected in certain

SONAR*
An Effective Herbicide That Poses
Negligible Risk To Human Health
And The Environment

Sonar is a highly effective aquatic herbicide used to selectively manage undesirable aquatic vegetation in freshwater ponds, lakes, reservoirs, rivers and canals. Sonar is absorbed through the leaves, shoots, and roots of susceptible plants, and destroys the plant by interfering with its ability to make and use food. As with any substance introduced into the environment, concerns arise about possible harmful effects on humans who may come into contact with it, and about its effects on wildlife and plants that we wish to protect and preserve. The following discussion, presented in a "Question and Answer" format, provides information regarding Sonar and evidence that Sonar presents negligible risk¹ to human health and the environment when applied according to its legally allowed uses and label directions.

Q1. What are the legally approved uses of Sonar?

- A1. Sonar has been approved for use by the U.S. Environmental Protection Agency (USEPA) since 1986 for the management of aquatic vegetation in freshwater ponds, lakes, reservoirs, drainage canals, irrigation canals and rivers. Two different formulations have been approved for use -- an aqueous suspension known as Sonar A.S. (USEPA Registration Number 67690-4) and a pellet form known as Sonar SRP (USEPA Registration Number 67690-3). There are no USEPA restrictions on the use of Sonar-treated water for swimming or fishing when used according to label directions. The Agency has approved Sonar's application in water used for drinking as long as residue levels do not exceed 0.15 parts per million (ppm) or 150 part per billion (ppb). For reference, one (1) ppm can be considered equivalent to roughly one second in 12 days or one foot in 200 miles, and (0.1) ppm can be considered approximately equal to one second in 120 days or one foot in 2,000 miles.

Sonar's USEPA-approved labeling states that in lakes and reservoirs that serve as drinking water sources, Sonar A.S. and Sonar SRP applications can be made up to within one-fourth mile (1,320 feet) of a potable water intake. For the control of Eurasian watermilfoil, curlyleaf pondweed and hydrilla where treatment concentrations are 0.01 to 0.02 ppm (10 to 20 ppb), this set-back distance of one-fourth mile from a potable water intake is not required. Note that these effective treatment concentrations are well below the 0.15 ppm (150 ppb) allowable limit in water used for drinking.

Local public agencies may require permits for use of a herbicide in public waters. Therefore, the Sonar label states that the user must consult appropriate state or local water authorities before applying the herbicide.

Q2. How does a product such as Sonar gain approval for use? (How does it become registered?)

¹Throughout this document, we use the phrases "negligible risk" or "no significant risk." We use these terms because it is beyond the capabilities of science to prove that a substance is absolutely safe, i.e., that the substance poses no risk whatsoever. Any substances, be it aspirin, table salt, caffeine, or household cleaning products, will cause adverse health effects at sufficiently high doses. Normal exposures to such substances in our daily lives, however, are well below those associated with adverse health effects. At some exposure, risks are so small that, for all practical purposes, no risk exists. We consider such risks to be negligible or insignificant.