



Roundup Pro[®] Herbicide Technical Fact Sheet

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INTRODUCTION

Roundup Pro[®] herbicide is widely used to control weeds and brush in professional vegetation management situations such as roadsides, railroad rights of way, turf management and landscaping. Roundup Pro is part of Monsanto's family of glyphosate herbicides, made up of more than 90 brands used in agricultural, industrial and residential markets in more than 130 countries worldwide. Various wildlife habitat restoration groups use Roundup Pro or similar herbicides in the restoration and management of habitat and refuge areas.

The active ingredient in Roundup Pro, glyphosate, is absorbed into the green vegetation and is translocated throughout the plant, including the roots. Glyphosate works by inhibiting production of an enzyme that is essential to formation of essential amino acids in plants. Obvious signs of treatment may not be visible for one to four days in annual weeds and for up to seven days or more in perennials. Visible effects include gradual wilting or yellowing followed by complete browning and deterioration of plant tissue, and ultimate decomposition of the underground roots and rhizomes. Since Roundup Pro works only on plants that have emerged through the soil, it will not affect seeds in the soil that have not yet sprouted. When desirable vegetation is in close proximity to weeds, care must be exercised to keep Roundup Pro off of green plant tissues.

INGREDIENTS

The active ingredient in Roundup Pro herbicide is the isopropylamine salt of glyphosate, which makes up 41 percent of the formulation. The non-herbicidally active or inert ingredients are water and a surfactant blend, which is added to aid penetration of the active ingredient through leaf surfaces. The concentrated formulation is diluted with water before application. Most vegetation management situations call for a spray solution of Roundup Pro herbicide that is more than 98 percent water.

HEALTH AND SAFETY STUDIES

Toxicological testing with laboratory animals serves as a model for evaluating the potential of a substance to cause adverse effects in humans. Roundup Pro herbicide has been evaluated in numerous studies with laboratory animals and wildlife species, using exposure levels far greater than the levels that might occur from normal use of the herbicide.

In 2000, three internationally recognized toxicologists published a safety evaluation and risk assessment of glyphosate. They concluded that glyphosate has low acute toxicity, is not a carcinogen, does not adversely affect reproduction and development, and does not bioaccumulate in mammals.¹

• Acute Toxicity Tests

Acute exposure includes oral, dermal and inhalation routes, as well as the potential for skin or eye irritation. Glyphosate, the active ingredient in Roundup Pro herbicide, is rated by the U.S. Environmental Protection Agency (EPA) as Category IV for acute oral and dermal toxicity based on tests conducted on laboratory animals. Tables 1 and 2 summarize mammalian toxicity and irritation data from laboratory studies conducted with Roundup Pro herbicide.

Table 1. Roundup Pro Mammalian Acute Toxicity Data

Toxicity Endpoint ²	Animal	LC ₅₀ or LD ₅₀	U.S. EPA Category ³
Oral LD ₅₀	Rat	> 5000 mg/kg bw	IV
Dermal LD ₅₀	Rabbit	> 5000 mg/kg bw	IV
Inhalation LC ₅₀	Rat	2.7 mg/L	n/a

¹ Williams GM, Kroes R, Munro IC (2000) Safety evaluation and risk assessment of the herbicide Roundup and its active ingredient, glyphosate, for humans. *Reg Toxicol Pharmacol* 31(2):117-165.

² The LD₅₀/LC₅₀ is the dose/concentration that produces mortality in 50% of the test animals. The units are mg/kg body weight for oral and dermal studies, and mg/L air for inhalation studies.

³ The U.S. EPA has established acute toxicity categories generally ranging from slight to moderate to severe, with Category I being most severe and Category IV being the least.

Table 2. Roundup Pro Irritation and Allergy Data

Test	Animal	Classification	EPA Category
Eye irritation	Rabbit	Slightly irritating	III
Skin irritation	Rabbit	Essentially non-irritating	IV
Skin allergy	Guinea pig	Non-allergenic	n/a

The U.S. EPA requires all herbicide labels to contain either a Danger, Warning or Caution signal word. The signal word alerts the user to the severity of the potential hazard associated with acute exposure to the product. Roundup Pro herbicide carries a “Caution” signal word. The Caution signal word is allowed by the U.S. EPA only for products assigned to one of the acute toxicity categories of lowest potential hazard, Category III or IV.

• Long Term Toxicity Tests

Long-term toxicological studies have been conducted to determine the effects of prolonged exposure to glyphosate. High doses of glyphosate were administered on a daily basis for the average lifetime (two years) of rats and mice and for one year for dogs. Few effects were observed in rats and mice in these studies, and when effects were observed, they were present only at very high levels. No treatment-related effects were seen at any dose in the dog study.

• Carcinogenicity Tests

The results from extensive, chronic toxicology tests resulted in a U.S. EPA cancer classification of glyphosate as a “Category E,” or “evidence of non-carcinogenicity for humans,” the most favorable rating granted. This rating is based on a thorough review of results from extensive toxicological testing required by the Agency. This classification has only been given to a limited number of pesticide active ingredients.

• Mutagenicity Tests

An extensive battery of mutagenicity assays designed to evaluate three major endpoints -- gene mutations, chromosome aberrations and DNA damage and repair – has been conducted with glyphosate. The results of these studies show that glyphosate does not interfere with the genetic makeup of cells.

• Reproductive Tests

Studies have shown that the glyphosate does not cause birth defects or reproductive problems in laboratory animals. In a study in which glyphosate was fed continuously to rats over two generations, weight reductions were seen only at a very high dose level. Lower dose levels in this study and in a three-generation study in rats did not affect the offspring, nor were any adverse effects observed in the ability of those offspring to develop into normal adults.

• Residential Exposure

The U.S. EPA evaluated potential residential exposure to glyphosate. Based on the low acute toxicity and the lack of other toxicological concerns, the EPA concluded that “exposures from residential uses of glyphosate are not expected to pose undue risks”.⁴

WILDLIFE SAFETY STUDIES

The acute toxicity of Roundup Pro herbicide and glyphosate to terrestrial and aquatic wildlife has been extensively evaluated, with laboratory and field results indicating low acute toxicity and low risk from direct exposure. The scientific literature contains hundreds of articles addressing this topic.⁵ In 2000, a comprehensive ecotoxicological risk assessment was published for glyphosate.⁶ The authors concluded that the use of glyphosate does not pose an unreasonable risk of adverse effects to non-target species, when used according to label directions.

⁴ Federal Register. (2002) Notice. Vol. 67, page 18894, April 17.

⁵ Sullivan DS, Sullivan TP (2000) Non-target impacts of the herbicide glyphosate: A compendium of references and abstracts. 5th Edition. Applied Mammal Research Institute, Summerland, British Columbia, Canada.

⁶ Giesy JP, Dobson S, Solomon KR (2000) Ecotoxicological risk assessment for Roundup herbicide. Reviews of Environmental Contamination and Toxicology 167: 35-120.

• **Aquatic Wildlife**

Roundup Pro herbicide is not labeled for direct application to water and any such application would be a violation of federal law and strictly prohibited. However, it is possible that small amounts could inadvertently reach surface water via drift during application or movement of soil after application. Thus, Roundup Pro has been evaluated for toxicity to aquatic species.

Roundup Pro herbicide has been classified as “slightly toxic” to aquatic invertebrates and “moderately toxic” to fish based on acute toxicity studies with standard aquatic test species. Glyphosate has been tested in additional aquatic species. Table 3 summarizes the results of laboratory testing with Roundup Pro herbicide and glyphosate for aquatic species.

Table 3:
Acute Aquatic Toxicity Data from Laboratory Studies

Species, Endpoint ⁷	LC ₅₀ or EC ₅₀ (mg/L)	EPA Classification
Roundup Pro herbicide		
Bluegill sunfish 96-hr LC ₅₀	7.3	Moderately toxic
Rainbow trout 96-hr LC ₅₀	5.4	Moderately toxic
<i>Daphnia magna</i> 48-hr EC ₅₀	11	Slightly toxic
Glyphosate		
Green Algae 7-d EC ₅₀	13.8	Slightly toxic
Sheepshead minnow 96-hr LC ₅₀	>1000	Practically non-toxic
Grass shrimp 96-hr LC ₅₀	281	“
Mysid shrimp 96-hr LC ₅₀	> 1,000	“
Sea urchin 96-hr LC ₅₀	> 1,000	“
Fiddler crab 96-hr LC ₅₀	934	“

Based on these results and predicted aquatic concentrations, when Roundup Pro is used according to label directions, aquatic concentrations are not expected to reach levels that would be harmful to aquatic species.

⁷ The LC₅₀ is the concentration that produces mortality in 50% of the test organisms. The EC₅₀ is the concentration that produces effects (such as inhibition of growth or immobilization) in 50% of the test organisms.

• **Terrestrial Wildlife**

Laboratory studies indicate that Roundup Pro herbicide is not expected to result in adverse effects to earthworms and honeybees (following acute exposure) or avian species, such as mallard ducks or bobwhite quail (following dietary exposure) when used according to label directions. Table 4 summarizes the results of laboratory testing with terrestrial species.

Table 4:
Acute Terrestrial Toxicity Data from Laboratory Studies

Species, Endpoint ⁸	Value	EPA Classification
Roundup Pro herbicide		
Earthworm 14-d LD ₅₀	> 1250 mg/kg dry soil	Practically non-toxic
Bobwhite quail 5-d dietary LC ₅₀	> 5620 mg/kg diet	“
Mallard duck 5-d dietary LC ₅₀	> 5620 mg/kg diet	“
Honey bee 48-hr Oral LD ₅₀	> 100 µg/bee	Practically non-toxic
48-hr Contact LD ₅₀	> 100 µg/bee	“

In addition to the studies summarized above, numerous lab and field studies with glyphosate and other glyphosate herbicides have been conducted on non-target species such as birds, deer mice, voles, chipmunks and various aquatic organisms. For example, this diverse testing included specific tests on the ability of birds to lay eggs, the hatchability of eggs, the survival of chicks, and the thickness of the egg shells, following glyphosate exposure. Based on an extensive review, the U.S. EPA has determined that the effects of glyphosate (when used according to label directions) on birds, mammals, fish and invertebrates are minimal.⁹

⁸ The LC₅₀/LD₅₀ is the concentration/dose that produces mortality in 50% of the test organisms.

⁹ U.S. EPA. (1993) Reregistration Eligibility Decision (RED) document for Glyphosate. EPA 738-R-93-014. URL: http://www.epa.gov/oppsrrd1/REDS/old_rede/glyphosate.pdf.

ENVIRONMENTAL FATE STUDIES

The favorable environmental fate characteristics of glyphosate, the active ingredient in Roundup Pro herbicide, are well established.

Glyphosate binds tightly to most types of soil until it is degraded. This tight binding means that it is not absorbed by roots from soil. This binding also results in an extremely low potential for glyphosate to move into groundwater.

Over time, glyphosate undergoes microbial degradation in soil, sediment and natural waters, under both aerobic and anaerobic conditions. The typical time for half of the glyphosate to dissipate (the half-life) is less than 40 days in soil. The major metabolite formed is aminomethylphosphonic acid (AMPA), which is also degraded by microbial processes over time. Glyphosate and AMPA are ultimately metabolized to carbon dioxide, inorganic phosphate, and other naturally occurring compounds. There is no credible evidence that the presence of glyphosate in soil at expected environmental concentrations causes extended adverse effects to microbial processes in soil.

In the event that glyphosate reaches surface water, it dissipates from surface water by two primary mechanisms. It quickly partitions from water into sediment, and then is microbially degraded over time in both the water and the sediment. In flowing waters, factors such as tributary dilution and dispersion contribute to the dissipation of glyphosate.

The dissipation of glyphosate in sterile and non-sterile water has been extensively studied. A review of the available dissipation field studies concluded that 50% of the concentration of glyphosate initially found in water dissipates within time periods ranging from a few days to two weeks.¹⁰

Extremely Low Volatility

Glyphosate, the active ingredient in Roundup Pro herbicide, has extremely low volatility. That means that Roundup Pro herbicide will not produce vapors that could move through air after application and damage non-target vegetation.

Water Quality

Detections of glyphosate in surface water and groundwater have occasionally been reported. These levels are not considered a health or environmental concern.

In the United States, a maximum contaminant level (MCL) of 700 µg/L has been established by the U.S. EPA as a health-based upper legal limit for glyphosate in drinking water.¹¹ The California Environmental Protection Agency has established a public health goal (PHG) for glyphosate in drinking water of 1000 µg/L.¹² These levels are considered to be protective of human health for potential exposure to glyphosate residues in drinking water.

Glyphosate has rarely been detected in drinking water, and there are no known exceedances of these drinking water standards. This is not surprising since it binds tightly to soil and degrades completely over time into naturally occurring substances.

The World Health Organization reviewed water quality data for glyphosate and stated:

“It was concluded that because of its low toxicity, the health-based value derived for glyphosate was orders of magnitude higher than glyphosate concentrations normally found in drinking water. Under usual conditions, therefore, the presence of glyphosate in drinking water does not represent a hazard to human health.”¹³

¹⁰ Giesy JP, Dobson S, Solomon KR (2000) Ecotoxicological risk assessment for Roundup herbicide. *Reviews of Environmental Contamination and Toxicology* 167: 35-120.

¹¹ U.S. EPA. (2000) Drinking water standards and health advisories. EPA 822-B-00-001. Office of Water, U.S. Environmental Protection Agency. URL: <http://www.epa.gov/waterscience/drinking/standards/dwstandards.pdf>

¹² California EPA. (1997) Public health goal for glyphosate in drinking water. Pesticide and Environmental Toxicology Section, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. URL: http://www.oehha.ca.gov/water/phg/pdf/glypho_c.pdf

¹³ Rolling Revisions of WHO Guidelines for Drinking Water Quality Report of Working Group Meeting on Chemical Substances for the Updating of WHO Guidelines for Drinking Water Quality. 22-26 April, 1997.

Bioaccumulation

Aquatic Species: In laboratory studies conducted with several aquatic species, glyphosate bioconcentration factors were less than or equal to 12, indicating that glyphosate has a low potential for bioaccumulation in aquatic animals. The low bioconcentration factors are a result of glyphosate being readily soluble in water, and therefore subject to rapid elimination from organisms in water.

Terrestrial Species: Studies conducted with laboratory mammals indicate that glyphosate is poorly absorbed when ingested. Any absorbed glyphosate is rapidly eliminated, resulting in minimal tissue retention. Feeding studies with chickens, cows and pigs have shown extremely low to no residues in meat and fat following repeated exposures. Negligible residues have also been reported in wild animals such as voles, chipmunks, hares and moose after feeding in treated areas.

ECOSYSTEM STUDIES

Because Monsanto's glyphosate herbicides are widely used throughout the world, ecosystem studies have been conducted to assess what effect, if any, the active ingredient had on an ecosystem.^{14,15,16}

A recently published compendium of references on the non-target impacts of glyphosate cites more than 750 peer-reviewed studies.¹⁷ These studies address the impacts on environmental parameters such as birds, fish, amphibians, water quality, soils, and biodiversity. Some of the studies were conducted with formulations containing surfactants, others with sprayed glyphosate and water. The overwhelming conclusion of these studies is clear; aside from the intended removal of vegetation, when used according to label directions, glyphosate products have little, if any, impact on terrestrial and aquatic animals or on ecosystems in which the animals live.

Habitat Restoration

Because of glyphosate's effectiveness and favorable environmental profile, several of Monsanto's glyphosate formulations, including Roundup Pro, have been used to protect and restore wildlife habitat in locations throughout the world, including the Florida Everglades and the Galapagos Islands. Members of groups as diverse as Quail Unlimited, Ducks Unlimited, and the National Audubon Society, The Nature Conservancy and the Society for Ecological Restoration have used glyphosate formulations in various preservation and restoration projects.

SUMMARY

Extensive toxicological studies have been conducted on glyphosate, the active ingredient in Roundup Pro herbicide. The results of these studies in animals have demonstrated that glyphosate does not cause cancer, birth defects, mutagenic effects, neurotoxic effects or reproductive toxicity.

In addition, toxicological studies with Roundup Pro herbicide demonstrate that it has very low toxicity to birds and mammals and slight to moderate toxicity to aquatic invertebrates and fish.

The results of thorough environmental studies indicate that application of glyphosate herbicides in accordance with the label does not pose an unreasonable risk of adverse effects to wildlife and the environment.

¹⁴ Forest Pest Management Institute. (1989) Proceedings of the Carnation Creek Herbicide Workshop. Sault Ste-Marie, Ontario, Ministry of Forests, Research Branch.

¹⁵ Newton M, Howard KM, Kelpsas BR, Danhaus R, Lottman CM, Dubelman S. (1984) Fate of Glyphosate in an Oregon forest Ecosystem, *Journal of Agricultural and Food Chemistry*, 32(5): 1144-1151.

¹⁶ Lautenschlager RA, Bell FAN, Wagner RG, Reynolds PE. (1998) The Fallingsnow Ecosystem Project: Documenting the consequences of conifer release alternatives. *Journal of Forestry* 96(1):20-27.

¹⁷ Sullivan DS, Sullivan TP (2000) Non-target impacts of the herbicide glyphosate: A compendium of references and abstracts. 5th Edition. Applied Mammal Research Institute, Summerland, British Columbia, Canada.