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# Tolerance Reassessment Eligibility Decision for Urea Sulfate

June 2005

Tolerance Reassessment Eligibility Decision

Urea Sulfate

Special Review and Reregistration Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
1801 South Bell Street  
Arlington, VA 22202

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## Background:

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act called for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or the Agency) to assess the current tolerances. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and, to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act (FQPA) was signed into law. FQPA amends FIFRA to require tolerance reassessment during reregistration. In addition, FQPA requires that all active ingredients first registered after 1984 would also be reevaluated to reassess their current tolerances, by 2006. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity.

In this document, the current exemption from the requirement for a tolerance for urea sulfate is being reassessed in order to meet FQPA standards. This document represents the Lower Risk Pesticide Chemical Focus Group's (LRPCFG) Tolerance Reassessment Eligibility Decision (TRED) on urea sulfate (monocarbamide dihydrogen sulfate). Urea sulfate is used both as an herbicide and desiccant (each current label actually lists this active ingredient as 1-aminomethanamide dihydrogen tetraoxosulfate). This active ingredient was first registered in 1987.

The Agency has determined that urea sulfate readily degrades to urea and sulfuric acid and/or sulfate ions in the environment and in the human body. Therefore, this tolerance reassessment for the active ingredient urea sulfate is based on the recent tolerance reassessments performed on both urea and sulfuric acid and its salts. Urea tolerances were reassessed under the 2002 TRED for urea, while the active and inert tolerances for sulfuric acid were reassessed through the LRPCFG's assessment of mineral acids and their ammonium, calcium, ferrous, ferric, magnesium, potassium, sodium, and/or zinc salts (7/24/2002). In addition, the Mineral Acids TRED relied on information from the 1993 Mineral Acids Reregistration Eligibility Decision (RED).

## **I. Executive Summary:**

Urea sulfate is used primarily as an active ingredient in herbicides and desiccants on agricultural crops. Five products are currently registered with urea sulfate as an active ingredient, three of which contain urea sulfate as the only active ingredient. According to an EPA Pesticide Fact Sheet, "Acute toxicology data indicate that the chemical is extremely caustic and corrosive. The appropriate toxicity category is I (DANGER), based on primary eye and skin irritation studies. Chronic toxicology and environmental fate data requirements are waived." Since urea sulfate readily degrades to urea and sulfuric acid and/or sulfate ions in the environment and in the human body, the Agency used the tolerance reassessments for urea and sulfuric acid (sulfate salts) to reassess the tolerance for urea sulfate.

The urea TRED states that "Based on the hazard assessment of urea, exposures to this compound resulting from reasonably anticipated patterns of usage present a reasonable certainty of no harm to

human health. Given the low toxicity of urea, a more detailed assessment of risks resulting from exposure to urea, when used either as a frost protectant or pesticide inert ingredient, is not necessary based on the hazard assessment of urea, exposures to this compound resulting from reasonably anticipated patterns of usage were not believed to present a reasonable certainty of harm to human health.”

According to the Mineral Acids RED, sulfuric acid has registered food uses. However, because sulfuric acid rapidly degrades in the environment to sulfate ions, which are of no toxicological concern, sulfuric acid has been granted an exemption from tolerance requirements. While it was determined that the use of sulfuric acid as a potato vine desiccant might result in dermal and inhalation exposure to workers, all other uses of pesticide products containing sulfuric acid were determined to not pose unreasonable risks or adverse effects to humans or the environment. According to LRPCFG’s TRED for Mineral Acids and their Salts, when exposed to liquids, the salts of sulfuric acid would dissociate to the respective metal cation and the sulfate anion. That TRED reported that there was not any available information for the sulfate ion or any of the salts of sulfuric acid that would indicate a human health hazard to the general public or any population subgroup resulting from either the EPA-regulated uses or the FDA GRAS uses, and that no additional information was needed to assess the safety of the sulfuric acid or any of its salts.

Based on the findings in the TREDs for both urea and sulfuric acid (sulfate salts), and the dissociation of urea sulfate to each of these resulting products, it has been determined that the use of products containing only urea sulfate as the active ingredient would not present a human health hazard to the general public. Products containing urea sulfate in addition to other active ingredients (ethephon and glyphosate or any other mixed active ingredient products which might become registered in the future) would need to be assessed as part of those respective REDs and/or TREDs for those active ingredients, but it is determined in this TRED that urea sulfate alone may be reassessed as not presenting an unreasonable risk to humans or the environment. Furthermore, the current exemption from the requirement of a tolerance for urea sulfate has been reassessed and meets the reasonable certainty of no harm as defined by FQPA.

## **II. Use Information:**

### **Urea Sulfate**

Urea sulfate (CAS Number 21351-39-3) has several synonyms: 1-aminomethanamide dihydrogen tetraoxosulfate (the name listed as the active ingredient on all the current labels); monocarbamide dihydrogen sulfate; Enquik; N-TAC Desiccant; sulfuric acid monourea; sulfuric acid, monourea adduct; urea sulfuric acid monoadduct; and urea sulfate (1:1). As mentioned above, urea sulfate is used primarily as an active ingredient in herbicides and desiccants on agricultural crops (PC Code 128961). The first urea sulfate product was registered in 1987. The sole registrant listed in OPPIN Query is Entek Corporation. Recently, Griffin LLC purchased Entek, and DuPont Crop Protection is a primary owner of Griffin, so DuPont is now considered to be the registrant for the urea sulfate products.

Five products are currently registered with urea sulfate as an active ingredient, 3 of which contain urea sulfate as the only active ingredient (See Table 1). Each of the current products is formulated as soluble concentrates, except for one, Enquik MP (68891-6), which is a Manufacturing Use product. All of the products with urea sulfate as the sole active ingredient are listed as containing 79% ai, although two other products also contain other active ingredients. In addition, there is currently one SLN (FL960011), while the OPP REFS lists 18 other SLNs, which have been cancelled, as well as 4 SLNs, which have been withdrawn.

Table 1. Registered Products Being Reassessed Containing Urea Sulfate					
Registration Number	Registration Name	Percent Urea Sulfate	Other Active Ingredients	Formulation Type	Date first registered
68891-1	SuperQuik™	79	None	soluble concentrate	30 Dec, 1987
68891-4	WilThin Blossom Thinner	79	None	soluble concentrate	12 Jan, 1995
68891-6	Enquik MP	79	None	formulation intermediate	2 Feb, 1996
68891-7	ETK-2201	58.6	18.3% ethephon	soluble concentrate	1 Feb, 1996
68891-8	ETK-2301 Herbicide	71.1	9.6% glyphosate	soluble concentrate	18 Dec, 1996
FL960011	Enquik	79	None	soluble concentrate	22 Oct, 1992

The BEAD Screening Level Usage Analysis (SLUA) in Appendix A indicates that most of the urea sulfate is applied to cotton, that is, the ETK-2201 product (also know as CottonQuik), a product also containing ethephon. DuPont has submitted confidential sales data to the Agency indicating that their records, as well as those of Entek, indicate that ETK-2201 is the only product which has any sales over the last few years.

The tolerance exemption being reassessed in this document, with the respective citation in the Code of Federal Regulations (CFR), and the use pattern as an active ingredient are listed in Table 2. Specifically, the tolerance expression at 40 CFR 180.1084 is stated as follows: “monocarbamide dihydrogen sulfate is exempted from the requirement of a tolerance when used as an herbicide or desiccant in or on all raw agricultural commodities.”

Table 2. Exemption from the Requirement for a Tolerance Being Reassessed for Urea Sulfate				
Tolerance Exemption Expression	CAS No.	40 CFR	PC Code	Use Pattern
<b>Active Ingredient</b>				
“monocarbamide dihydrogen sulfate”	21351-39-3	180.1084	128961	as an herbicide or desiccant

Urea

Urea was registered by EPA in 1995 for use as a frost protectant pesticide under the trade name Enfrost. Enfrost is a 43% liquid formulation of urea that may be applied commercially to a wide variety of field crops, vegetables, fruit trees and ornamentals to reduce frost damage. There are currently no residential uses for urea as a pesticide product. Enfrost is the only currently registered pesticide product containing urea as an active ingredient, but Enfrost has not been actively produced or sold by the registrant, Entek Corporation, since 1995. However, according to the Urea TRED (EPA, 2002a), the registrant maintains active registration of Enfrost for potential future production and use.

In addition, urea is used as an inert pesticide ingredient as a stabilizer, inhibitor, or intensifier. Also,

several million tons of urea are produced annually for use in fertilizer and as an animal feed supplement, with some of the urea being added as a fertilizer in pesticidal products. Moreover, urea is used in the manufacture of dyes, fire retardant paints, plasticizers, and stabilizers for explosives (EPA, 2002a).

The tolerance exemptions reassessed for urea, with the respective citation in the Code of Federal Regulations (CFR), and the use pattern as an active and inert ingredient are listed in Table 3.

<b>Table 3. Exemption from the Requirement for a Tolerance Reassessed in the 2002 Urea TRED</b>				
Tolerance Exemption Expression	CAS No.	40 CFR	PC Code	Use Pattern
urea	57-13-6	<b>Active Ingredient</b>		
		180.1117	085702	frost protectant
		<b>Inert Ingredient</b>		
		180.1001 (c), (d), (e)	885702	stabilizer, inhibitor, or intensifier

Sulfuric Acid and its Salts

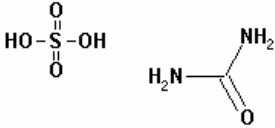
As an active ingredient in pesticides, sulfuric acid is used as a desiccant, and it is also used to kill bacteria on potatoes, in milking equipment, and within food processing areas. It was first registered as a desiccant/herbicide in the U.S. as early as 1971 and was exempted from the requirement for a residue tolerance for this use (40 CFR 180.1019). A food processing sanitizer product, containing sulfuric acid as well as other active ingredients, was registered in 1992. Sulfuric acid as an active ingredient was evaluated in the 1993 Mineral Acids RED (EPA, 1993). In addition, sulfuric acid is registered for use as an inert ingredient in certain pesticide products. It is primarily used as a pH control agent and is included at concentrations of up to 0.1% of the pesticide formulation, according to the Sulfuric Acid and its Salts TRED (EPA, 2002b).

The tolerance exemption reassessed for sulfuric acid, with the respective citation in the Code of Federal Regulations (CFR), and the use pattern as an active ingredient are listed in Table 4.

<b>Table 4. Exemption from the Requirement for a Tolerance Reassessed in the 2002 Mineral Acids (Sulfuric Acid) TRED</b>				
Tolerance Exemption Expression	CAS No.	40 CFR	PC Code	Use Pattern
sulfuric acid	7664-93-9	<b>Active Ingredient</b>		
		180.1019	078001	used to kill bacteria on potatoes, milking equipment and in food processing areas; as a desiccant
		<b>Inert Ingredient</b>		
		180.1001(c)	878001	pH control agent

### III. Physical/Chemical Properties:

The physical and chemical properties of urea sulfate are provided in Table 5. This information was obtained from the profiles in TOXNET (ChemIDplus) and CambridgeSoft (ChemFinder), as well as various MSDS sheets for urea sulfate/monocarbamide dihydrogen sulfate.

Table 5. Physical/Chemical Properties of Urea Sulfate		References
Structure		ChemIDplus Lite (2004)
Chemical Name	urea sulfate; uronium hydrogen sulphate	MSDS (2004)
Molecular formula	CH <sub>4</sub> N <sub>2</sub> O · H <sub>2</sub> SO <sub>4</sub>	
Color/Form	Clear to slightly hazy liquid	
Odor	odorless	
Boiling point	Decomposes (110°C or 230°F)	
Melting point	5.6°C (42°F) Salt out temp.	
Density/Specific Gravity	12.65 lbs/gal; 1.52 (Water =1)	
pH	1 (for a 10% solution in water)	
Solubilities	Easily soluble in cold water, hot water	
Volatility	18% (w/w)	

### IV. Hazard Characterization:

#### A. Toxicity

Acute toxicity studies were conducted to support registration of urea sulfate. Table 6 provides the information available on the acute toxicity of urea sulfate. Currently, there are no chronic toxicity studies available for urea sulfate. According to an EPA Pesticide Fact Sheet (EPA, 1987), chronic toxicity studies were waived in accordance with provisions of 40 CFR 162.45 (c).



**Table 6. Acute Toxicity Profile for Urea Sulfate (monocarbamide dihydrogen sulfate)**

Study Type	Species	Results	Toxicity Category	Reference
Acute Oral	Rat	1,200 mg/kg (male) 350 mg/kg (female)	II	EPA Pesticide Fact Sheet (1987)
Acute Dermal	Rabbit	>2 g/kg Study terminated at 48 hrs because of extreme caustic action and dermal necrosis.	Not determined	
Acute Inhalation	Rat	>10.8 mg/L	III	
Primary Eye Irritation	Rabbit	Severe corneal involvement, grade 4 chemosis of conjunctivae at 24 hrs.	I	
Primary Skin Irritation	Rabbit	Caustic on intact and abraded skin at 24 hours. Study was terminated at 24 hours after similar results were obtained with 1:4 v/v dilution with water	I	

For urea, the acute toxicity studies were submitted by the registrant. These acute studies indicated that the registered product for urea (i.e., the frost protectant) was a slight eye irritant and had a low toxicity to animals. In addition, there were other studies cited from the available literature. In subchronic studies, no severe toxicity was observed for urea in dogs, and no adverse organ pathology was found. In addition, animal studies provided no evidence of adverse chronic or carcinogenic effects, nor developmental or teratogenic effects.

For sulfuric acid, the available toxicity studies indicate that is corrosive to the eyes and skin and is toxic via the inhalation route. However, sulfuric acid readily degrades in the environment to sulfate ions. In addition, studies conducted with the salts of sulfuric acids indicate that these salts are not of toxicologic concern, especially since these salts dissociate in water into the respective metal cation and the sulfate anion.

**B. Metabolism**

The Agency has determined that urea sulfate rapidly degrades to urea and sulfuric acid and/or sulfate ions in the human body. Thus, the data requirements for the higher tier toxicity studies have all been waived by the Agency, and there are no repeated dose toxicity studies available for urea sulfate.

**C. Special Considerations for Infants and Children**

Data from repeated dosing toxicity studies with animals does not exist for urea sulfate. However, urea sulfate readily degrades to urea and sulfuric acid and/or the sulfate ion in the body. Based on the toxicity data reviewed in this tolerance assessment documents for urea and for sulfuric acid and its salts, there are no adverse effects that would be expected in infants and children for urea sulfate. For urea, animal studies provide no evidence of developmental nor teratogenic effects. In an aqueous environment, sulfuric acid rapidly ionizes to sulfate ions which are of no toxicological concern to infants and children. For these reasons, a safety factor analysis has not been used to assess the risks resulting from the use of urea sulfate; therefore, an additional tenfold safety factor for the protection of infants and children is

unnecessary.

#### **V. Exposure Assessment:**

The Agency has determined that urea sulfate breaks down readily into both urea and sulfuric acid and/or sulfate ion in the human body. Since the risks have already been assessed for these various other chemicals, it is not necessary to repeat these other risk assessments to reassess the food-use tolerance for urea sulfate. The conclusions of the RED documents for urea and mineral acids (sulfuric acid), as well as the TRED documents for urea and the mineral acids (sulfuric acid and its salts), indicate that these chemicals have been determined to not present unacceptable risks to humans or the environment.

#### **VI. Dietary Exposure:**

Based on the dissociation of urea sulfate in the human body to urea and sulfuric acid and/or sulfate ion, the Agency has determined that only a qualitative dietary assessment is needed, based on the results of the REDs and TREDs for these constituent products. Thus, the Agency has determined that there are no dietary risk concerns, whether from the ingestion of food or water or both, for urea sulfate (or at least for the consumption of products containing urea sulfate as the sole active ingredient).

#### **VII. Aggregate Assessment:**

In examining aggregate exposure, FFDCa section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). In developing this tolerance assessment document for urea sulfate, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given the lack of human health concerns associated with exposure to this chemical, as well as its constituent products (urea and sulfuric acid and/or sulfate ions).

#### **VIII. Cumulative Exposure:**

Section 408(b)(2)(D)(v) of the FFDCa requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” If chemicals are structurally related and all are low toxicity chemicals, then the risks either separately or combined should also be low.

EPA does not have, at this time, available data to determine whether urea sulfate has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to urea sulfate and any other substances, and urea sulfate does not appear to produce a toxic metabolite produced by other substances.

For the purposes of this tolerance action, therefore, EPA has assumed that urea sulfate does not have a common mechanism of toxicity with other substances. For information regarding the Agency’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have

a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

## **IX. Risk Characterization:**

As mentioned above, the Agency has been determined that urea sulfate readily breaks down into urea and sulfuric acid and/or sulfate ion in the environment and in the human body. Assessments performed on both these substituent compounds indicate no reasonable certainty of harm to human health from either the EPA-registered uses or the FDA-GRAS uses. Therefore, it has been determined that the use of products containing urea sulfate (as the sole active ingredient) also would not present a human health hazard to the general public.

## **X. Environmental Fate/Ecotoxicity/Drinking Water Considerations:**

### Urea Sulfate

All of the environmental fate data requirements for urea sulfate have been waived by the Agency because the environmental fate is so well known for its two substituent compounds, urea and sulfuric acid. In addition, many of the ecotoxicity data requirements have also been waived. It has also been determined that the use of products containing urea sulfate is not expected to impact groundwater, according to a document prepared by the New York State Department of Environmental Conservation regarding the uses of various urea sulfate end-use products (EPA, 1997).

### Urea

Available data from literature reviews show that urea degrades rapidly in most soils, with it generally hydrolyzed to ammonium through soil urease activity. In various soils, the hydrolysis may near completion within 24 hours; however, the rate of hydrolysis can be much slower depending upon soil type, moisture content, and urea formulation. Soil adsorption studies show that urea sorbs very weakly to soil; therefore, leaching is possible. Ultimate degradation of urea produces ammonia and carbon dioxide as volatile products. Biodegradation is expected to be the major fate process in the aquatic ecosystem. The rate of biodegradation generally decreases with decreasing temperatures. Naturally-occurring phytoplankton increases the degradation rate, because phytoplankton can use urea as a nitrogen source. In phytoplankton-rich waters, degradation occurs much faster in sunlight than in the dark. Abiotic hydrolysis of urea occurs very slowly in relation to biotic hydrolysis (EPA, 2002a).

### Sulfuric Acid

Sulfuric acid generally dissolves in the environment and release sulfate ions and hydrogen ions, and these hydrogen ions, in turn, increases the acidity of the soil or water (EPA, 1993). The extent of the increased acidity depends on the amount of the neutralizing ions present, the buffering capacity, and the amount of dilution possible.

## **XI. References**

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Appendix 1. BEAD Screening Level Usage Analysis  
for Urea Sulfate for Agricultural Uses and Other Information

**Urea Sulfate (128961)**  
**Screening Level Usage Analysis (SLUA)**  
**Date: 6/2/05**

**What is a Screening Level Usage Analysis (SLUA)?**

- Available estimates of pesticide usage data for a particular active ingredient that is used on **agricultural** crops in the United States.

**What does it contain?**

- Pesticide usage data for a **single** active ingredient only.
- Agricultural use sites (crops) that the pesticide is *reported* to be used on.
- Available pesticide usage information (i.e., does not include all of the United States).
- Annual percent of crop treated (**average & maximum**) for each agricultural crop.
- Average annual pounds of the pesticide applied for each agricultural crop (i.e., for the states surveyed, not for the entire United States).

**What assumptions can I make about the reported data?**

- **Average pounds of active ingredient applied** - Values are calculated by merging pesticide usage data sources together; averaging by year, averaging across all years, & then rounding. *Note: If the estimated value is less than 500, then that value is labeled <500. Estimated values between 500 & <1,000,000 are rounded to 1 significant digit. Estimated values of 1,000,000 or greater are rounded to 2 significant digits.)*
- **Average percent of crop treated** - Values are calculated by merging data sources together; averaging by year, averaging across all years, & rounding to the nearest multiple of 5. *Note: If the estimated value is less than 1, then the value is labeled <1.*
- **Maximum percent of crop treated** - Value is the single maximum value reported across all data sources, across all years, & rounded up to the nearest multiple of 5. *Note: If the estimated value is less than 2.5, then the value is labeled <2.5.*

**What are the data sources used?**

- **USDA-NASS** (United States Department of Agriculture's National Agricultural Statistics Service) – pesticide usage data from 1998 to 2003.
- **NCFAP** (National Center for Food and Agricultural Policy) – pesticide usage data from 1997 & is *only* used if data is not available from the other sources.
- **Private pesticide market research** – pesticide usage data from 1998 to 2003.
- California DPR data can be requested separately.

**What are the limitations to the data?**

- Additional registered uses may exist but are not included because the available surveys do not report usage (e.g., small acreage crops).
- Lack of reported usage data for the pesticide on a crop **does not imply** zero usage.
- Usage data on a particular site may be noted in data sources, but **not quantified**. In these instances, the site would not be reported in the SLUA.
- Non-agricultural use sites (e.g., turf, post-harvest, mosquito control, etc.) are not reported in the SLUA. A separate request must be made to receive these estimates.

Wednesday, June 1, 2005 15:24

Screening Level Estimates of Agricultural Uses of Urea Sulfate (128961)  
Sorted Alphabetically

	<u>Crop</u>	<u>Lbs. A.I.</u>	<u>Percent Crop Treated</u>	
			<u>Avg.</u>	<u>Max.</u>
1	Apples	9,000	<1	<2.5
2	Cotton	3,000,000	5	10
3	Peppers	200,000	5	5
4	Tomatoes	80,000	<1	<2.5

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All numbers rounded.

'<2.5' indicates less than 2.5 percent of crop is treated.