Docket Number: EPA-HQ-OPP-2007-0202
www.regulations.gov

Urea Sulfate Summary Document
Registration Review: Initial Docket
August 2007

Case Number 7213

Approved by: _____

Peter Caulkins, Ph.D.
Acting Director
Special Review and Reregistration Division

Date: 7/23/07

TABLE OF CONTENTS

Page #

I. PRELIMINARY WORK PLAN

Urea Sulfate

Introduction

The Food Quality Protection Act of 1996 amendments to the Federal Fungicide Insecticide and Rodenticide Act (FIFRA) mandated a new program: registration review. All pesticides distributed or sold in the United States generally must be registered by the United States Environmental Protection Agency (the Agency) based on scientific data showing that they will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. The new registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the new registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can continue to be used safely. Information on this program is provided at http://www.epa.gov/oppsrrd1/registration_review/.

The Agency has begun to implement the new registration review program, and plans to review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state clearly what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision.

Anticipated Risk Assessment and Data Needs

The Agency anticipates conducting a comprehensive ecological risk assessment which will include an endangered species risk assessment. The Agency does not expect to conduct an additional human health risk assessment. At this time, the Agency does not anticipate that additional data will be needed.

Ecological Risk

- A screening level ecological risk assessment has not been conducted for urea sulfate. Only "hazard assessments" on the agricultural uses of urea sulfate have been completed (1989).
- Urea sulfate rapidly dissociates to urea and sulfuric acid and/or sulfate ions. Sulfate ions were not evaluated because they are not expected to pose a significant ecological risk.
- Based on the previously conducted hazard assessments, sulfuric acid resulting from the use of urea sulfate may pose a risk to terrestrial wildlife and also could lower the pH of very small and shallow water bodies with a low buffering capacity, and therefore may harm aquatic organisms. These issues will be explored further in Registration Review.
- The Environmental Fate and Effects Division (EFED) will use the hazard assessments and the supporting data as a resource for completing an ecological

risk assessment. The Agency will also consider the 1989 U.S. Fish and Wildlife Service Biological Opinion which discusses the use of urea sulfate on several vegetables, fruits, and nut tree crops.

- The planned ecological risk assessment will allow the Agency to determine whether urea sulfate's use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitat. If the assessment indicates that urea sulfate "may affect" a listed species or its designated critical habitat, the assessment will be refined. The refined assessment will allow the Agency to determine whether use of urea sulfate is "likely to adversely affect" the species or critical habitat or "not likely to adversely affect" the species or critical habitat. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (the Services), as appropriate.
- The Agency does not foresee requiring any additional ecological effects or environmental fate studies prior to conducting the planned assessments. The Agency will however conduct a search of the open literature to ensure that all best available science is utilized. The Agency uses the ECOTOX database as its mechanism for searching the open literature for ecological effects information. ECOTOX integrates three previously independent databases – AQUIRE, PHYTOTOX, and TERRETOX – into a system which includes toxicity data derived predominately from the peer-reviewed literature, for aquatic life, terrestrial plants, and terrestrial wildlife.

Human Health Risk

- The Agency does not anticipate the need for new dietary and occupational risk assessments because the risks do not exceed the Agency's level of concern.
- The Agency does not expect to require additional data for urea sulfate.
- Several product chemistry studies have not been reviewed and will be evaluated later in the process.

Timeline

EPA has created the following estimated timeline for the completion of the urea sulfate registration review.

Activities	Estimated Completion
Phase 1: Opening the docket	
Open Public Comment Period for Urea Sulfate Docket	Aug. 2007
Close Public Comment Period	Nov. 2007
Phase 2: Case Development	
Develop Final Work Plan (FWP)	Jan. 2008
Open Public Comment Period for Preliminary Risk Assessments	3rd Quarter 2009
Close Public Comment Period	4th Quarter 2009
Phase 3: Registration Review Decision	
Open Public Comment Period for Proposed Reg. Review Decision	1st Quarter 2010
Close Public Comment Period	2nd Quarter 2010
Final Decision and Begin Post-Decision Follow-up	2010
Total (years)	3

Guidance for Commenters

The public is invited to comment on EPA's preliminary registration review work plan and rationale. The Agency will carefully consider all comments as well as any additional information or data provided prior to issuing a final work plan for the urea sulfate case.

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Levels (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern. Urea sulfate is exempt from the requirement of a tolerance, and there are no Codex MRLs; so trade irritants are not expected for urea sulfate.

Stakeholders are also specifically asked to provide information and data in the following areas:

1. Use or potential use distribution (*e.g.*, acreage and geographical distribution of relevant uses).
2. Use history.
3. Median and 90th percentile reported use rates (lbs. a.i./acre) from usage data—national, state, and county.
4. Application timing (date of first application and application intervals) by use—national, state, and county.

5. Typical application interval (days).
6. Usage/use information for non-agricultural uses (*e.g.*, golf course, athletic fields, ornamentals).
7. Directly acquired county-level usage data (not derived from state level data).
    a. maximum reported use rate (lbs. a.i./acre) from usage data—country
    b. percent crop treated—county
    c. median and 90th percentile number of applications—county
    d. total pounds per year—county
    e. the year the pesticide was last used in the county/sub-county area
    f. the years in which the pesticide was applied in the county/sub-county area
8. Sub-county crop location data.
9. State or local restrictions.
10. Ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency.
11. Monitoring data.
12. Urea Sulfate is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at http://oaspub.epa.gov/tmdl/waters_list.impairments?p_impid=3. The Agency invites submission of water quality data for this chemical. To the extent possible, data should conform to the quality standards in Appendix A of the "OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process" information provided at http://www.epa.gov/oppsrrd1/registration_review/water_quality.htm., in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

Next Steps

After the comment period closes, the Agency will prepare a Final Work Plan for this pesticide.

II. FACT SHEET

Background Information

- Urea Sulfate Registration Review Case Number: 7213
- Urea Sulfate PC Code: 128961, CAS#: 21351-39-3
- Technical Registrant: DuPont
- One technical product, and two end-use products (end-use products contain other active ingredients—ethephon and glyphosate).
- First product registered in 1987.
- Not subject to reregistration; thus, no Reregistration Eligibility Decision (RED) is available.
- Tolerances were reassessed as per FQPA in the Tolerance Reassessment Decision (TRED) completed in June 2005.
- Urea sulfate rapidly dissociates to urea and sulfuric acid and/or sulfate ions. Urea has been designated by FDA as Generally Recognized as Safe (GRAS), see 21 CFR 184.1923. In addition, sulfuric acid has been designated as GRAS for some uses when present in low concentrations.
- Special Review and Reregistration Division (SRRD), Chemical Review Manager (CRM): Andrea Carone, carone.andrea@epa.gov
- Registration Division (RD), Product Manager (PM): Jim Tompkins, tompkins.jim@epa.gov

Use & Usage Information (For additional details, please refer to the BEAD Appendix A document in the urea sulfate docket.)

- Urea sulfate can be used as an herbicide, desiccant, and harvest-aid on various crops and non-crops including:
  - Crops: Alfalfa, apples, barley, berries, citrus, corn, cotton, grass seed, oats, peanut, peppermint, potatoes, rice, tomatoes, tree fruit, tropical fruit, soybean, spearmint, vegetables, and wheat.
  - Non-crops: Farmstead weed control, conservation reserve program, forestry site preparation, rights of way, ornamentals, nursery stock, Christmas tree plantings, pastures, fallow and reduced tillage systems.
- Approximately 3,080,000 pounds of urea sulfate are used annually. The highest usage is on cotton, potatoes, tomatoes, and apples. Less than 1% of the crop of apples, potatoes, and tomatoes are treated.
- Currently there are no residential uses.
- Urea sulfate is formulated as a soluble concentrate/liquid.
- Urea sulfate may be applied by boom sprayer, high volume ground sprayer, low volume sprayer, hand held sprayer, wiper application, shielded applicator, and aircraft.

Recent Actions

- A TRED was completed June 14, 2005 and reassessed the tolerance exemption in or on all raw agricultural commodities when the product is used as an herbicide or a desiccant (40 CFR 180.1084).

- On July 18, 2006 three products were cancelled—SuperQuik, WilThin Blossom Thinner, and Enquik. This included one special local needs product.
- A new label for the technical was accepted in February 2007. Entek was the technical registrant until the company was purchased by Griffin LLC. DuPont owns Griffin LLC. The revised technical label has DuPont as the sole technical registrant.

Ecological Risk Assessment Status: Please refer to Section III of this document, Ecological Risk Assessment Problem Formulation, for a detailed discussion of the anticipated ecological risk assessment needs. Since urea sulfate rapidly dissociates to urea and sulfuric acid and/or sulfate ions, EFED looked at the assessments of the constituent products—urea and sulfuric acid. Sulfate ions were not evaluated because they are not expected to pose a significant ecological risk. Below is a summary of the findings:

Urea Sulfate

- Urea sulfate is slightly to practically non-toxic to birds and fish.
- In a simulated avian field study birds directly exposed to spray applications of urea sulfate showed eye and foot damage.
- There are no registrant-submitted studies for urea sulfate that address chronic mammalian toxicity, chronic fish toxicity, or chronic aquatic invertebrate toxicity. However, because of its fate properties, chronic exposure is not expected. Nevertheless, an open literature search is planned.
- There are also no acute aquatic invertebrate or macrophyte toxicity data for urea sulfate. A literature search is planned.

Urea

- Urea is practically non-toxic to freshwater fish, freshwater invertebrates, and birds.
- There are no registrant-submitted studies for urea that address environmental fate. However, available data illustrates that urea degrades rapidly in most soils, and therefore is not expected to leach into groundwater.

Sulfuric Acid

- The Agency will use open literature data and information gleaned from studies with urea sulfate to assess the ecotoxicological effects of sulfuric acid. In addition, there are two sulfuric acid studies pending review by the Agency: 1) a simulated ephemeral pond study, and 2) an irrigation water study, where the systems were titrated with urea dihydrogen sulfate.
- Based on the previously conducted hazard assessments, sulfuric acid resulting from the use of urea sulfate may pose a risk to terrestrial wildlife and also could lower the pH of very small and shallow water bodies with a low buffering capacity, and therefore may harm aquatic organisms.

Human Health Risk Assessment Status: Please refer to Section IV of this document, Human Health Effects Scoping Document, for a detailed discussion of the anticipated risk assessment needs for human health. Below is a summary of the findings:

Dietary (Food and Water):

- There are no dietary risks that exceed the Agency's level of concern (LOC).

Residential

- There are no residential uses for urea sulfate.

Occupational

- Assessments completed on urea and sulfuric acid and/or sulfate ion indicate that occupational scenarios did not result in risks of concern.

Data Call-In (DCI) Status

- No outstanding DCIs.

Tolerances

- Urea sulfate is exempt from the requirement of a tolerance in or on raw agricultural commodities when used as an herbicide or desiccant (40 CFR 180.1084).
- No MRLs for urea sulfate have been established or proposed by Codex for any agricultural commodities.

Labels

- A list of registration numbers is included below and the labels can be obtained from the Pesticide Product Label System (PPLS) website: http://oaspub.epa.gov/pestlab1/ppls.home.

Urea Sulfate Registrations

Registration Number	Product Name	Company	Active Ingredient
352-673	Urea Sulfate-MP	Dupont	Urea Sulfate
352-674 (68891-7)	ETK-2201	Dupont	Urea Sulfate and Ethephon
352-675 (68891-8)	ETK-2301	Dupont	Urea Sulfate and Glyphosate

III. ECOLOGICAL RISK ASSESSMENT PROBLEM FORMULATION

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

PC Code: 128961
DP Barcode: D337144
Date: July 20, 2007

MEMORANDUM

Subject: Registration Review Preliminary Problem Formulation for the Ecological Risk Assessment of Urea Sulfate

To: Andrea Carone, Risk Manager
Mail Code: 7508P
Special Review and Reregistration Division
Office of Pesticide Programs

From: Fred Jenkins, MS, Biologist
Ibrahim Abdel-Saheb, Ph.D., Environmental Scientist
Environmental Risk Branch 2
Environmental Fate and Effects Division
Office of Pesticide Programs

Through: Dana Spatz, Acting Chief
Environmental Risk Branch 2
Environmental Fate and Effects Division
Office of Pesticide Programs

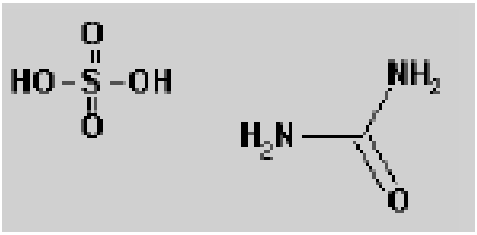
Attached is the Environmental Fate and Effects Division's (EFED) preliminary problem formulation for the ecological risk assessment to be conducted as a part of the Registration Review of the agricultural uses of urea sulfate as a desiccant and an active ingredient in herbicides.

REGISTRATION REVIEW

ECOLOGICAL RISK ASSESSMENT
PRELIMINARY PROBLEM FORMULATION FOR:

UREA SULFATE

$$CH_4N_2O \cdot H_2SO_4$$



PREPARED BY:

Fred Jenkins, MS, Biologist
Ibrahim Abdel-Saheb, Ph.D., Environmental Scientist
Environmental Risk Branch 2
Environmental Fate and Effects Division
Office of Pesticide Programs

APPROVED BY:

Dana Spatz, Acting Chief
Environmental Risk Branch 2
Environmental Fate and Effects Division
Office of Pesticide Programs

STRESSOR SOURCE AND DISTRIBUTION

Urea sulfate (CAS Number 21351-39-3) is an active ingredient in herbicides and is used as a desiccant on agricultural crops. According to the Office of Pesticide Programs Information Network (OPPIN) two products are currently registered with urea sulfate as an active ingredient. These products are ETK-2301 and ETK-2201. Table 1 displays further details regarding both of these products. ETK-2201 is used as a cotton harvest aid/defoliant and ETK-2301 is used as an herbicide on a large variety of crops listed in Table 2. Table 3 displays the screening level estimates of the 1999 thru 2005 agricultural uses of Urea Sulfate conducted by the Office of Pesticde Programs Biological and Economic Analysis Division (BEAD). This analysis was based on data from the US Department of Agriculture's National Agricultural Statistics Service (NASS). This analysis indicates that although urea sulfate is registered for use on a multitude of different crops, the actual usage of this chemical during recent years has been predominantly limited to apples, cotton, potatoes, and tomatoes.

Based on the conclusions of the Ecological Effects Branch Hazard Assessment dated 1984, EFED currently surmises that the sulfuric acid acts as the primary herbicidal active ingredient for the urea sulfate products. The sulfuric acid apparently acts via the catalyzation of hydrolysis of cellulose which results in the dissolution of the vegetative tissue. Urea sulfate readily dissociates to urea and sulfuric acid. Therefore, this preliminary problem formulation will evaluate the potential ecological effects of urea, and sulfuric acid individually. Both urea and sulfuric acid are registered pesticides.

Table 1. Registered Products of Urea Sulfate (according to OPPIN [1])

Reg. Number	Product Name	Percent Urea Sulfate	Other Active Ingredients	Formulation Type	Specific Use	Date first registered
68891-7	ETK-2201	58.6	18.3% ethephon	Soluble concentrate	Cotton harvest aid/defoliant only	Feb. 1996
68891-8	ETK-2301	71.1	9.6% glyphosate	Soluble concentrate	Herbicide on a variety of crops	Dec. 1996

[1] **Note: OPPIN (Office of Pesticide Programs Information Network)**:

Table 2. ETK-2301 Use Crops	
Type Crops	**Crops**
Row Crops	Corn, Cotton, Peanuts, and Soybeans
Forage Legumes	Alfalfa, Peanuts, and Soybeans
Cereal Grains	Barley, Oats, Millets, Rice, Rye, Triticale, and Wheat (All)
Tree Fruits	Apple, Apricot, Cherry, Nectarine, Olive, Peach, Pear, Plum, Plumcot, and Prune
Tree Nuts	Almond, Beechnut, Brazil Nut, Butternut, Cashew, Chestnut, Filbert, Hickory Nuts, Macadamia Nut, Pecan, Pistachio, and Walnut
Vine Crops	Grapes
Tropical Crops	Avocado, Banana, Coffee, Dates, Figs, Guava, Papaya, Passion Fruit, Persimmon, Pineapple, Plantain,
Vegetables	Asparagus, Beans (All), Broccoli (All), Brussels Sprouts, Cabbage (All), Chinese Cabbage, Cantalope, Cauliflower, Casaba Melon, Celery, Chard Swiss, Collard, Crenshaw Melon, Cucumber, Eggplant, Endive, Garlic, Gourds, Honeydew Melon, Honey Melon, Kale, Kohlrabi, Leek, Lettuce, Mango Melon, Melons (All) Muskmelon, Mustard Greens, Onion (All), Parsley, Peas (All), Pepper (All), Persian Melon, Potato, Pumpkin, Rape Greens, Rhubarb, Spinach (All), Squash (Winter, Summer), Sugarbeet, Tomatillo, Tomato, and Watermelon.

Table 3. Screening Level Estimates of Agricultural Uses of Urea Sulfate (BEAD, October 2006)			
Crop	Lbs. A.I.	Percent Crop Treated *	
		Avg.	Max.
Apples	10,000	<1	<2.5
Cotton	2,900,000	5	10
Potatoes	90,000	< 1	< 2.5
Tomatoes	80,000	<1	<2.5

Notes:
* All numbers rounded. '<2.5' and < 1indicates less than 2.5 percent of crop and 1 percent of crop respectively is treated.

INTEGRATION OF AVAILABLE INFORMATION

The following Agency risk assessment documents available in the Office of Pesticides Program Regulatory Docket serve as the basis for this preliminary problem formulation:

> U.S. EPA, June 2005 Tolerance Reassessment Eligibility Decision (TRED) Document for Urea Sulfate
>
> U.S. EPA Pesticide Registration Decision (RED) document for Mineral Acids (The mineral acids include four different active ingredients including sulfuric acid, the herbicidal active ingredient of urea sulfate. Each of the active ingredients was evaluated independently within the RED document. The evaluation of sulfuric acid in the Mineral Acids RED will be used as a resource for this preliminary problem formulation).
>
> U.S. EPA Ecological Effects Branch, September 1989. Risk Assessment for Terrestrial Organisms Exposed to Enquik
>
> Ecological Effects Branch, February 21, 1989. Urea Sulfate - Review of Proposed Registration of New Crops and Expansion of Geographic Areas from Previous Label

ECOLOGICAL EFFECTS

TOXICITY STUDIES

Registrant Submitted Studies for Urea Sulfate

The registrant submitted studies include one fish acute toxicity study, an acute oral rat toxicity test, two avian acute dietary studies, one aquatic plant toxicity study, and three terrestrial plant toxicity studies including a vegetative vigor study, a seedling emergence study, and a seed germination study. Also, one simulated avian field study has been submitted by the registrant.

The acute toxicity studies testing fish, birds, and mammals demonstrated that urea sulfate is slightly to practically nontoxic to these organisms. The results of the plant toxicity studies were as follows. The vegetative vigor results demonstrated that the tomato was the most sensitive species with an EC_{50} of 12 lb a.i. /acre for fresh and dry weights. The most sensitive NOECs for these parameters were 1.2 and 4.7 lbs. a.i. /acre for tomato and radish respectively. The seed germination study demonstrated that seed germination was not inhibited by more than 9.7% in any of 10 plant species tested. The NOEAC of this study was > 37.5 lb a.i./acre. The results of the seedling emergence study showed that seedling emergence was not inhibited anymore than 14% among any of the species tested. The algal toxicity study demonstrated a *Selenastrum capricornutum* EC_{50} of 11.5 ppm. The results of the avian simulated field study demonstrated that birds exposed to

spray applications of urea sulfate displayed significant eye and foot damage that may be pronounced for birds exposed to direct applications of undiluted urea sulfate. The results also concluded that diluted urea sulfate causes some, but much less, damage.

Data demonstrating the toxicity of urea sulfate to aquatic invertebrates have not been submitted. However, the Agency presumes that urea sulfate will not pose a significant toxic concern to aquatic invertebrates based on the following rationale. The available registrant submitted toxicity data demonstrate that urea sulfate has low acute toxicity (only slightly to practically nontoxic) to birds, mammals, and fish. Since urea sulfate has demonstrated low toxicity to all animals tested, it is expected to also demonstrate low toxicity to aquatic invertebrates. In addition, urea sulfate degrades rapidly into urea and sulfuric acid, neither of which is expected to pose a significant risk to aquatic invertebrates because; 1) urea has been shown to be practically nontoxic to aquatic invertebrates (see below, *Registrant Submitted Studies for Urea*) and 2) sulfuric acid is expected to readily dissociate into sulfate ions which are innately nontoxic.

Registrant Submitted Studies for Urea

There are four registrant submitted ecotoxicity studies for urea. These include two freshwater fish acute toxicity studies, one freshwater invertebrate study, and one avian acute dietary toxicity study. These studies indicate that urea is practically nontoxic to freshwater fish, freshwater invertebrates, and birds (birds practically nontoxic on an acute dietary basis).

Registrant Submitted Studies for Sulfuric Acid

The registrant has not submitted any data to evaluate the ecotoxicological effects of sulfuric acid independently as an active ingredient. However, because sulfuric acid is expected to readily dissociate into innately non-toxic sulfate ions, EFED does not expect sulfuric acid to pose a significant toxicological hazard to nontarget organisms. Additionally, available aquatic toxicity data based on a preliminary search of the EPA ECOTOX database indicates that sulfuric acid is only slightly acutely toxic to fish and aquatic invertebrates (Table 4). Furthermore, the available registrant submitted studies testing urea sulfate contained up to 49% sulfuric acid, and these studies also demonstrated low toxicity to terrestrial and aquatic animals. Therefore, because of the low toxicity of sulfuric acid as demonstrated by the studies evaluated thus far and the available registrant submitted studies testing urea sulfate, EFED does not believe it necessary to require additional toxicity data for sulfuric acid.

Table 4. Results Preliminary ECOTOX Database Search				
Species (Common name)	Test Duration (Days)	LC_{50} (ppm)	Test Type	ECOTOX Reference
Carcinus maenas (Green or Europeon shore crab)	2	70-80 (slightly toxic)	Saltwater lab	906
Crangon crangon (Common shrimp, sand shrimp	2	70-80 (slightly toxic)	Saltwater lab	906
Pandalus (Aesop shrimp montagui)	2	42.5 (slightly toxic)	Saltwater lab	906
Daphnia magna (Water flea)	7	20 (slightly toxic)	Freshwater	916
Cerastoderma edule (Cockle)	2	200-500 (slightly toxic)	Saltwater	906
Fish				
Species (Common name)	Test Duration (Days)	LC_{50} (ppm)	Test Type	ECOTOX Reference
Agonus cataphractus Hooknose	2	80-90 (slightly toxic)	Saltwater Lab	906
Gambusia affinis Western mosquitofish	4	42 (slightly toxic)	Freshwater Lab	508
Platichthys flesus (Starry, european flounder)	2	100-330 (slightly toxic)	Saltwater Lab	906

INCIDENT REPORTS

According to Office of Pesticides Program Ecological Incident Information System (EIIS), there is one incident in Kern County California reportedly classified as a possible incident resulting from use of a Lorsban pesticide tank mix which included urea and sulfate as ingredients. The total ingredients in the Lorsban tank mix included zinc sulfate, manganese sulfate, urea, potassium nitrate, manganese nitrate. The Lorsban tank mix was applied to a tangelo crop on April 4, 2001. The tangelos began exhibiting ridging symptoms. The ridging lowered the grade of the fruit which consequently lowered the potential economic gains of the crop. Insufficient evidence was available to determine if urea sulfate or one of the other ingredients in the tank mixture caused the ridging.

EXPOSURE CHARACTERISTICS

Urea

EFED has no registrant submitted fate data for urea. Information on the environmental fate, as summarized in the Hazardous Substances Data Bank (http://toxnet.nlm.nih.gov/) and cited in previous EFED reviews may be found below.

Biodegradation is expected to be the major fate process in the aquatic ecosystem. Various screening studies have demonstrated that urea can biodegrade readily with the release of CO_2 and ammonia. The rate of biodegradation generally decreases with decreasing temperatures; under cold winter-like conditions, biodegradation may be relatively slow (0-6% per day). The presence of naturally-occurring phytoplankton increases the degradation rate because phytoplankton uses urea as a nitrogen source and because urea is decomposed by phytoplankton via photosynthesis. In phytoplankton-rich waters, degradation occurs much faster in sunlight than in the dark.

If released to air, a vapor pressure of 1.20×10^{-5} mm Hg at 25 ^{0}C, indicates urea will exist in both the vapor and particulate phases in the ambient atmosphere. Vapor-phase urea will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 9.6 hrs. Particulate-phase urea will be removed from the atmosphere by wet and dry deposition.

In various soils, the hydrolysis may near completion within 24 hours. Abiotic hydrolysis of urea occurs very slowly in relation to biotic hydrolysis. Abiotic hydrolysis yields ammonium carbamate which decomposes to form CO_2 and ammonia; the enzyme urease catalyzes urea hydrolysis.

In one photodegradation study using a silica gel adsorbent, only 0.2% of applied urea photomineralized after a 17-hr irradiation with a UV lamp (>290 nm).

The adsorption of urea was measured in six different British soils with organic carbon contents ranging from 1.76 to 36.5%; no adsorption was measurable in five of the soils; in the sixth soil (36.5% organic carbon), a K_{OC} of 8 can be determined from the measured Freundlich isotherm.

BCF values of 1 and <10 suggest bioconcentration in aquatic organisms is low.

There appears to be no drinking water concerns for urea. Because of the low toxicity of urea and the subsequent lack of toxicity endpoints for use in risk assessment, drinking water levels of comparison (DWLOCs) were not calculated for urea (http://www.epa.gov/pesticides/reregistration/REDs/urea_tred.htm).

In conclusion, available data from literature reviews show that urea degrades rapidly in most soils. Soil adsorption studies have demonstrated that urea adsorbs very weakly to

soil; however, because urea degrades rapidly, leaching to groundwater in appreciable amounts is not expected. Ultimate urea degradation produces ammonia and CO_2.

Sulfuric Acid

The mineral acids generally dissociate and release hydrogen ions in the environment; thus increasing the pH of soil and water. Sulfuric acid will ultimately react with calcium and magnesium in water to form sulfate salts.

Two studies had been previously submitted, one being a simulated ephemeral pond study, consisting of 5 gallon buckets, 6 inches of soil (8 various types) and 6 inches of distilled water. Enquik had been sprayed at a rate of 50 gal/A and 100 gal/A.

The data indicated that there was little difference between the ponds treated with the 50 gal/A, and the ponds (buckets) treated with 100 gal/A. All treated buckets plummeted to a pH of approximately 2.5 within the first day of treatment. One soil indicated that the pH did not go higher than 5 until 21 days postapplication. In a second study, 12 irrigation waters, collected from California and Arizona irrigation systems, were titrated with Urea dihydrogen sulfate (N-TAC DESSICANT) to a pH of 4.5. The data indicate that an average of 33 gallons of N-TAC/A in 6 inches of water will lower the pH to 4.5. The actual values ranged from 11 gallons to 42 gallons of N-TAC/A in 6 inches water were required to lower the pH to 4.5.

It is important to note that these studies were conducted in only 6 inches of water. The studies are pending review by EFED.

Monitoring Data:

EFED has no monitoring data on the concentrations of urea sulfate, urea or sulfuric acid in surface or groundwater.

CHARACTERISTICS OF ECOSYSTEMS POTENTIALLY AT RISK

As previously mentioned, urea sulfate readily dissociates to urea and sulfuric acid and/or sulfate ions in the environment. Therefore, this preliminary problem formulation will evaluate urea and sulfuric acid. The sulfate ions will not be evaluated because they aren't expected to pose significant ecological risk, due to their innately non-toxic nature and their naturally abundant occurrences in the environment.

For urea sulfate and pesticides in general, the ecosystems at greatest risk are those in close proximity to the use areas. These would include agricultural fields (surrounding non-agricultural terrestrial habitats) and water bodies directly adjacent to treated fields that may receive chemical residues via drift, volatilization, and/or runoff. Within water bodies, the water column, sediments, and pore water are all compartments of concern.

Organisms of concern include birds, mammals, reptiles, fish, and terrestrial and aquatic invertebrates, plants, and amphibians. The assessment endpoints are intended to reflect population sustainability and community structure within ecosystems and hence relate back to ecosystems at risk. If risks are expected for given species/taxa based on the screening-level assessment, then risks might be expected to translate to higher levels of biological organization.

ASSESSMENT ENDPOINTS

Assessment endpoints are defined as "explicit expressions of the actual environmental value that is to be protected." Defining an assessment endpoint involves two steps: 1) identifying the valued attributes of the environment that are considered to be at risk; and 2) operationally defining the assessment endpoint in terms of an ecological entity (i.e., a community of fish and aquatic invertebrates) and its attributes (i.e., survival and reproduction). Therefore, selection of the assessment endpoints is based on valued entities (i.e., ecological receptors), the ecosystems potentially at risk, the migration pathways of pesticides, and the routes by which ecological receptors are exposed to pesticide-related contamination. The selection of clearly defined assessment endpoints is important because they provide direction and boundaries in the risk assessment for addressing risk management issues of concern. Changes to assessment endpoints are typically estimated from the available toxicity studies, which are used as the measures of effects to characterize potential ecological risks associated with exposure to a pesticide, such as urea sulfate.

The most sensitive toxicity endpoints are used from surrogate test species to estimate treatment-related direct effects on acute mortality and chronic reproductive, growth and survival assessment endpoints. Toxicity tests are intended to determine effects of pesticide exposure on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, sub-acute, and reproduction studies and are typically arranged in a hierarchical or tiered system that progresses from basic laboratory tests to applied field studies. The toxicity studies are used to evaluate the potential of a pesticide to cause adverse effects, to determine whether further testing is required, and to determine the need for precautionary label statements to minimize the potential adverse effects to non-target animals and plants. The following is a summarization of the most sensitive endpoints from the available ecotoxicity data.

Urea Sulfate Most Sensitive Endpoints

Birds

The acute toxicity studies demonstrated that urea sulfate is practically non-toxic to birds. (studies demonstrated no mortalities to test birds). Thus, there are no acute toxicity endpoints for birds.

Mammals

The most sensitive mammalian acute oral toxicity endpoint was a rat acute oral LD_{50} of > 5000 mg/kg.

Fish

The most sensitive fish acute toxicity endpoint for urea sulfate is a Three spine Stickleback LC_{50} of 80 ppm (ACC072861).

Aquatic Invertebrates

Urea sulfate toxicity endpoints have not been determined for aquatic invertebrates.

Aquatic plants

The most sensitive algal toxicity endpoint for urea sulfate is a *Selenastrum capricornutum* EC_{50} of 11.5 ppm (MRID 433681-01).

Terrestrial Plant Toxicity

The vegetative vigor results demonstrated that the tomato was the most sensitive species. The tomato demonstrated an EC_{50} of 12 lb a.i./acre for fresh and dry weights. The most sensitive NOECs for these parameters were 1.2 and 4.7 lbs. a.i. /acre for tomato and radish respectively (MRID 433681-03). The seed germination and seedling emergence studies demonstrated that urea sulfate had insignificant toxic effects on the endpoint parameter measured in these studies (MRID 433755-02).

Urea Most Sensitive Endpoints

There are no urea endpoints for freshwater fish, freshwater invertebrates, or birds because urea is practically nontoxic to all these organisms (LC_{50} and EC_{50} values were higher than the highest values tested in any of the studies for these organisms).

Most Sensitive Endpoints for Sulfuric Acid

The Agency will use open literature data and information gleaned from studies with urea sulfate to assess the ecotoxicological effects of sulfuric acid.

CONCEPTUAL MODEL

In order for a chemical to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a pesticide moves in the environment from a source to an ecological receptor. For an ecological exposure pathway to be complete, it must have a source, a release mechanism,

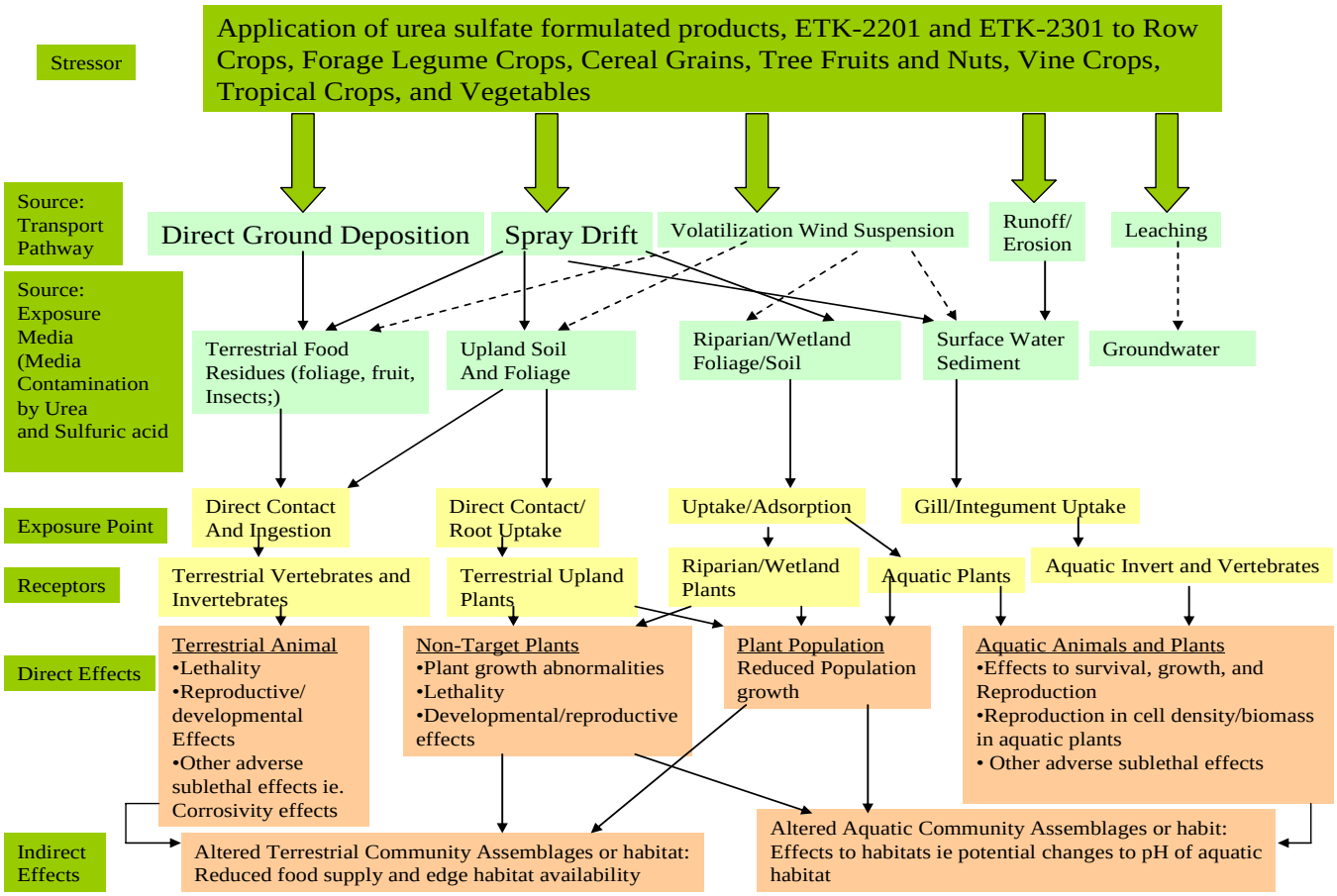
an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure.

The conceptual model (**Figure 1**) depicts the potential pathways for ecological risk associated with urea sulfate, urea and sulfuric acid. The conceptual model provides an overview of the expected exposure routes for organisms within the urea sulfate action area. For terrestrial organisms, the major route of exposure considered is the dietary route; consumption of food items such as plant leaves or insects that have urea sulfate residues as a result of spraying, drift, and volatilization. For aquatic animal species, the major routes of exposure are considered to be via the respiratory surface (gills) or the integument. Direct contact and/or root uptake is the major route of exposure for terrestrial and wetland (riparian) plants, while aquatic plants may be exposed via direct uptake and adsorption. Estimated exposure concentrations for all organisms are obtained through the use of several Agency exposure models.

RISK HYPOTHESIS

Based on an examination of the physical/chemical properties of urea sulfate, the fate and disposition in the environment, and mode of application, a conceptual model was developed that represents the possible relationships between the stressor, ecological receptors, and the assessment endpoints. EFED predicts that once urea sulfate enters the environment it will readily dissociate into urea and sulfuric acid. EFED also predicts that the sulfuric acid may pose at least two primary environmental threats. Firstly, sulfuric acid may contaminate surface waters in close proximity to the urea sulfate use sites by way of spray drift. Once the water bodies are contaminated with sulfuric acid, they could potentially, depending upon volume and concentration, be subject to changes in pH. The change in pH could potentially pose an adverse threat to the inhabitants of these water bodies. Secondly, EFED predicts terrestrial organisms that come in direct contact with the sulfuric acid may be at risk of experiencing the corrosive effects this chemical can have on tissue.

FIGURE 1. ECOLOGICAL CONCEPTUAL DIAGRAM FOR UREA SULFATE



ANALYSIS PLAN OPTIONS

In Registration Review, pesticide ecological risk assessments will follow the Agency's Guidelines for Ecological Risk Assessment and will be in compliance with the paper titled "Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency" ("Overview Document") (January 2004), and will address obligations under Section 7 of the Endangered Species Act.

A screening level ecological risk assessment has never been conducted for urea sulfate. The only type of ecological assessments that the Agency has conducted for the agricultural use of urea sulfate are "hazard assessments." These types of assessments were conducted prior to the Agency's policy implementing that "ecological risk assessments" be conducted to assess the potential ecological harm of pesticides. Hazard assessments evaluated the ecological effects of a pesticide by focusing only on the toxic effects of a pesticide to non-target organisms. The focus of an ecological risk assessment is on both the toxic effects of a pesticide to non-target organisms and the potential routes of the pesticide's exposure to non-target organisms. In addition to addressing a pesticide's toxic effects and potential routes of exposure, an ecological risk assessment addresses the uncertainties associated with a pesticide's risk to non-target organisms.

EFED will utilize the Agency's most recently conducted hazard assessments and all the data that support these assessments as a resource for conducting the ecological risk assessment for the registration review process. These hazard assessments include the following:

Ecological Effects Branch, February 21, 1989. Urea Sulfate - Review of Proposed Registration of New Crops and Expansion of Geographic Areas from Previous Label

U.S. EPA Ecological Effects Branch, September 1989. Risk Assessment for Terrestrial Organisms Exposed to Enquik

The conclusions of these documents were as follows:

- Urea Sulfate usage may pose a risk to terrestrial wildlife. This risk is primarily attributed to the corrosive nature of urea sulfate which can potentially cause damage to the terrestrial animal's exposed body parts.

- Urea Sulfate usage may introduce sulfuric acid to water bodies in close proximity to the use sites. The sulfuric acid could lower the pH of very small and shallow water bodies with low buffering capacity, and therefore may harm aquatic organisms.

Additionally, EFED notes there was a US Fish and Wildlife Service (USFWS) 1989 Biological Opinion regarding the nation wide use of urea sulfate on a variety of vegetables, fruit, and nut tree crops. While some of the information available in this

document may be useful, other portions could be outdated and no longer applicable due to changes in labels, use patterns, etc.

ANTICIPATED DATA NEEDS

Although the guideline ecotoxicity data set is not complete for urea sulfate and sulfuric acid, the Agency does not foresee requiring any additional ecological effects or environmental fate studies prior to conducting the planned assessments (see Table 5). The Agency will however conduct a search of the open literature to ensure that all best available science is utilized. The Agency uses the ECOTOX database as its mechanism for searching the open literature for ecological effects information. ECOTOX integrates three previously independent databases – AQUIRE, PHYTOTOX, and TERRETOX – into a system which includes toxicity data derived predominately from the peer-reviewed literature, for aquatic life, terrestrial plants, and terrestrial wildlife, respectively.

Table 5. Evaluation of the need for additional effects data on urea sulfate, urea, and sulfuric acid

Guideline study title	Chemical	Projected status of data gap	Basis for decision
Gdln. 72-2(a): Freshwater Aquatic Invertebrate Toxicity Study (TGAI)	Urea Sulfate	Study **not** requested at this time	The Agency presumes that urea sulfate will not pose a significant toxic concern to aquatic invertebrates based on the following rationale. The available registrant submitted toxicity data demonstrate that urea sulfate has low acute toxicity (only slightly to practically nontoxic) to birds, mammals, and fish. Since urea sulfate has demonstrated low toxicity to all animals tested, it is expected to also demonstrate low toxicity to aquatic invertebrates. In addition, urea sulfate degrades rapidly into urea and sulfuric acid, neither of which is expected to pose a significant risk to aquatic invertebrates because; 1) urea has been shown to be practically nontoxic to aquatic invertebrates, and 2) sulfuric acid is expected to readily dissociate into sulfate ions which are innately nontoxic and naturally and abundantly occur in the environment.
71-1(a): acute avian oral, (TGAI)	Sulfuric acid	Study **not** requested at this time	Because sulfuric acid is expected to readily dissociate into innately non-toxic sulfate ions, EFED does not expect sulfuric acid to pose a significant toxicological hazard to nontarget organisms. Additionally, available aquatic toxicity data based on a preliminary search of the EPA ECOTOX database indicates that sulfuric acid is only slightly acutely toxic to fish and aquatic invertebrates (Table 4). Furthermore, the available registrant submitted studies testing urea sulfate contained up to 49% sulfuric acid, and these studies showed no concerns for acute avian toxicity.

OTHER INFORMATION NEEDS

There is specific information that will assist the Agency in refining the ecological risk assessment, including any species-specific effects determinations. The Agency is very much interested in obtaining the following information:

1. confirmation on the following label information
    a. sites of application
    b. formulations
    c. application methods and equipment
    d. maximum application rates
    e. frequency of application, application intervals, and maximum number of applications per season
    f. geographic limitations on use
2. use or potential use distribution (e.g., acreage and geographical distribution of relevant crops)
3. use history
4. median and 90th percentile reported use rates (lbs. a.i./acre) from usage data – national, state, and county
5. application timing (date of first application and application intervals) by crop – national, state, and county
6. sub-county crop location data
7. usage/use information for non-agricultural uses (e.g., forestry, residential, rights-of-way)
8. directly acquired county-level usage data (not derived from state level data)
    a. maximum reported use rate (lbs. a.i./acre) from usage data – county
    b. percent crop treated – county
    c. median and 90th percentile number of applications – county
    d. total pounds per year – county
    e. the year the pesticide was last used in the county/sub-county area
    f. the years in which the pesticide was applied in the county/sub-county area
9. typical interval (days)
10. state or local use restrictions
11. ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency
12. monitoring data

The analysis plan will be revisited and potentially revised depending upon the data available in the open literature and the information submitted by the public in response to the opening of the Registration Review docket.

IV. HUMAN HEALTH EFFECTS SCOPING DOCUMENT

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

May 10, 2007

SUBJECT: Urea-sulfuric acid adduct: Registration Review Scoping Document for Human Health Assessments; PC Code 128961; DP Barcode D337871.

FROM: Ray Kent, Chief
Sue Hummel, Chemist
Reregistration Branch 4
Health Effects Division (7509P)

TO: Andrea Carone
Special Review Branch 1
Special Review and Reregistration Division (7508P)

Attached is the human health scoping/problem formulation document to support the registration review of the herbicide and desiccant, urea-sulfate adduct.

Introduction

The HED Urea Sulfate Registration Review Team has evaluated the status of the human health assessments for the herbicide, desiccant, and harvest aid, urea sulfate to determine the scope of work necessary to support registration review. The team looked at the hazard and exposure databases for urea sulfate and determined whether changes in science policy or deficiencies in the databases *materially* affected the overall risk picture

The Agency has determined that urea sulfate rapidly degrades to urea and sulfuric acid and/or sulfate ions in the human body and the environment. Urea is a natural product, which humans synthesize in large quantities during normal metabolism. Urea has been

designated by FDA as Generally Recognized as Safe (GRAS) (see 21 CFR 184.1923). Sulfuric acid produces sulfate salts in the environment, many of which are designated as GRAS, and sulfuric acid is designated as GRAS for some uses in low concentrations.

Urea-sulfuric acid adduct is currently registered (on the technical label) for use on numerous raw agricultural commodities, as an herbicide, desiccant, or harvest aid, as shown in Table 1. Urea-sulfuric acid adduct currently has an exemption from the requirement of a tolerance when used as an herbicide or desiccant in all raw agricultural commodities (40 CFR 180.1084). There are currently no residential uses for urea sulfate.

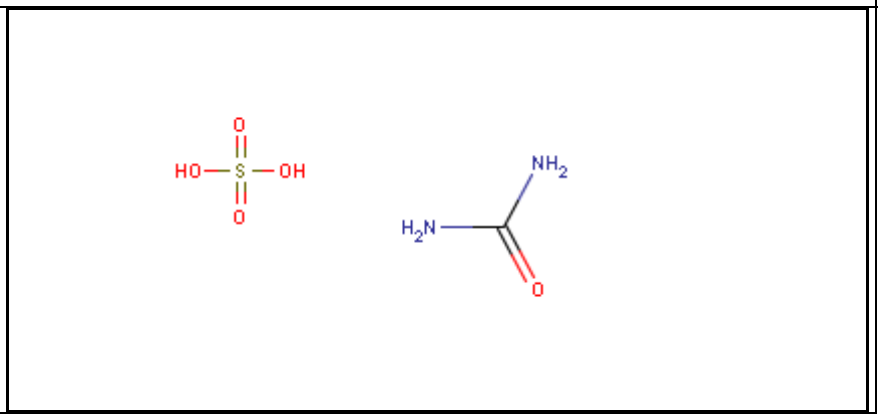
Table 1. **Urea Sulfate Use Pattern**

Row Crops:	Alfalfa, Clover, Corn (All), Cotton, Peanuts, Soybeans
Cereal Grains:	Barley, Millet, Oats, Rice, Rye, Triticale, Wheat (All)
Tree Fruits:	Apple, Apricot, Cherry, Nectarine, Olive, Peach, Pear, Plum, Plumcot, Prune
Tree Nuts:	Almond, Beechnut, Brazil Nut, Butternut, Cashew, Chesnut, Filbert (Hazelnut), Hickory Nut, Macadamia Nut, Pecan, Pistachio, Walnut
Citrus:	Calamondin, Chironja, Citron, Grapefruit, Kumquat, Lemon, Lime, Mandarin Orange, Orange (All), Pummelo, Tangelo, Tangerine, Tangors
Vegetables:	Asparagus, Beans (All), Broccoli (All), Brussels Sprouts, Cabbage (All), Cabbage (Chinese), Cantaloupe, Cauliflower, Casaba Melon, Celery, Chard (Swiss), Collards, Crenshaw Melon, Cucumber, Eggplant, Endive, Garlic, Gourds, Honeydew Melon, Honeyball Melon, Kale, Kohlrabi, Leek, Lettuce, Mango Melon, Melons (All), Muskmelon, Mustard Greens, Onion (All), Parsley, Peas (All), Pepper (All), Persian Melon, Potato, Pumpkin, Rape Greens, Rhubarb, Spinach (All), Squash (Summer and Winter), Sugarbeet, Tomatillo, Tomato, Watermelon
Vines:	Grapes
Tropical Fruits:	Avocado, Banana, Coffee, Dates, Figs, Guava, Papaya, Passion Fruit, Persimmon, Pineapple, Plantain
Berries:	Blackberry, Blueberry, Boysenberry, Cranberry, Elderberry, Huckleberry, Raspberry
Other Crops:	Grass Seed, Peppermint Spearmint
Noncrop Uses:	Farmstead Weed Control; Conservation Reserve Program (CRP); Forestry Site Preparation, Rights of Way; Ornamentals, Nursery Stock, Christmas Tree Plantings, Pastures, Fallow and Reduced Tillage Systems

The last comprehensive review of urea sulfate was the Tolerance Reassessment Eligibility Decision (TRED), completed June 2005. In the TRED, the existing exemption from the requirement for a tolerance for urea sulfate was reassessed per FQPA. 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.

Section 1. Chemical Identity

Table 1.1 Chemical Identity	
Common Name	Urea-sulfuric acid adduct Monocarbamide dihydrogen sulfate
IUPAC name	1 -aminomethanamide dihydrogen tetraoxosulfate
CAS name	Urea, sulfate (1:1)
PC Code	128961
CAS registry number	21351-39-3
Registration Review Case No.	7213
Chemical Structure	

Section 2. Toxicology

No toxicity studies have been received since the last human health risk assessment was completed for the TRED in 2005. A comprehensive search of the open literature was not done primarily because a screening Google search (Google Scholar) and a Science Direct search indicated little new information relevant to the human health risk assessment has been published on this herbicide that had not already been considered in previous assessments.

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.

The acute toxicity profile of urea sulfate is presented in Table 2.

Table 2. Acute Toxicity Profile for Urea 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	

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 (urea and sulfuric acid and its salts documents) for the 2005 TRED, 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 or 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, and can be reduced to 1x.

Section 3. Current Dietary Assessments

Based on the dissociation of urea sulfate in the human body to urea and sulfuric acid and/or sulfate ion, and the results of the REDs and TREDs for these constituent products, the Agency has determined that only a qualitative dietary assessment is needed. 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).

Section 4. Aggregate and Cumulative Exposure

There are no residential uses for urea sulfate. No aggregate exposure assessment is needed, given the lack of human health concerns associated with exposure to urea sulfate, as well as its constituent products (urea and sulfuric acid and/or sulfate ions).

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.

Section 5. Occupational Exposure

As mentioned above, the Agency has 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 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 would not present a human health hazard to occupational workers or the general public.

Section 6. Anticipated Data Needs

The Agency does not expect to require any additional data for urea sulfate. There are several unreviewed product chemistry studies which will be reviewed later in the process.

Section 7. Tolerances/Exemptions from the Requirement of a Tolerance

The following table lists the current U.S. exemptions from the requirement of ~~a~~ tolerance for urea sulfate (40 CFR 180.1084).

Table 7.1. Exemption from the Requirement for a Tolerance Being Reassessed for Urea Sulfate

Tolerance Exemption Expression	CAS No.	40 CFR	PC Code	Use Pattern
Active Ingredient				
"monocarbamide dihydrogen sulfate"	21351-39-3	180.1084	128961	as an herbicide or desiccant

Section 8. Overall Conclusions

The qualitative risk assessments for dietary and occupational exposure to urea sulfate are up to current standards.

Section 9. Reference Memoranda

Table 9.1. HED Memoranda Relevant to Registration Review			
Author	Barcode	Date	Title
SRRD	--	6/14/2005	Tolerance Reassessment Eligibility Decision: Urea Sulfate

V. GLOSSARY OF TERMS AND ABBREVIATIONS

ai	Active Ingredient
AR	Anticipated Residue
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison
EC	Emusifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GENEEC	Tier I Surface Water Computer Model
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Microgram Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking submitted studies.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Ambient Water Quality Assessment

NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agricultural Commodity
RED	Reregistration Eligibility Document
REI	Restricted Entry Interval
Rfd	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLN	Special Local Need (Registrations Under Section 24c) of FIFRA
TGAI	Technical Grade Active Ingredient
TRED	Tolerance Reassessment and Risk Management Decision
USDA	United States Department of Agriculture
UF	Uncertainty Factor
WPS	Worker Protection Standard