US Environmental Protection Agency
Office of Pesticide Programs

Dipotassium Phosphate
PC Code 176407

March 23, 2003
Dipotassium Phosphate
Biopesticides Registration Action Document

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
Dipotassium Phosphate
(PC Code 176407)
Table of Contents

I. Executive Summary
   A. IDENTITY
   B. USE/USAGE
   C. RISK ASSESSMENT
   D. DATA GAPS / LABELING RESTRICTIONS

II. Overview
   A. ACTIVE INGREDIENT OVERVIEW
   B. USE PROFILE
   C. ESTIMATED USAGE
   D. DATA REQUIREMENTS
   E. REGULATORY HISTORY
   F. CLASSIFICATION
   G. FOOD CLEARANCES/TOLERANCES

III. Science Assessment
   A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT
      1. Product Identity and Mode of Action
      2. Food Clearances/Tolerances
      3. Physical and Chemical Properties Assessment
   B. HUMAN HEALTH ASSESSMENT
      1. Toxicology Assessment
         a. Acute Toxicology
         b. Mutagenicity and Developmental Toxicity
         c. Subchronic Toxicity
         d. Chronic Exposure and Oncogenicity Assessment
         e. Effects on Immune and Endocrine Systems
      2. Dose Response Assessment
      3. Dietary Exposure and Risk Characterization
      4. Occupational, Residential, School and Day care Exposure and Risk Characterization
         a. Occupational Exposure and Risk Characterization
         b. Residential, School and Day Care Exposure and Risk Characterization
      5. Drinking Water Exposure and Risk Characterization
      6. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children
      7. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation
      8. Cumulative Effects
      9. Risk Characterization
C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment
2. Environmental Fate and Ground Water Data
3. Ecological Exposure and Risk Characterization

D. EFFICACY DATA

IV. Risk Management Decision

A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

B. REGULATORY POSITION

1. Conditional/Unconditional Registration
2. CODEX Harmonization
3. Nonfood Re/Registrations
4. Risk Mitigation
5. Endangered Species Statement

C. LABELING RATIONALE

1. Human Health Hazard
   a. Worker Protection Standard
   b. Non-Worker Protection Standard
   c. Precautionary Labeling
   d. Spray Drift Advisory
2. Environmental Hazards Labeling
   End-Use Product Environmental Hazards Labeling
3. Application Rate

D. LABELING

V. Actions Required by Registrants

VI. Appendix A
I. Executive Summary

A. IDENTITY

The Technical Grade Active Ingredient (TGAI) is an odorless white powder. The end-use product Lexx-A-Phos® Fungicide that contains 22.67% dipotassium phosphate and 20.40% dipotassium phosphonate (a registered active ingredient) is manufactured by an integrated process. The product chemistry data submitted by the registrant satisfies the requirement for product identity.

B. USE/USAGE

The TGAI will be used for incorporation into the end-use product Lexx-A-Phos® Fungicide, which is intended to control certain fungal diseases in woody ornamentals, turfgrasses and non-bearing fruits and nut tree crops. This use is classified as a terrestrial nonfood application.

C. RISK ASSESSMENT

No unreasonable adverse effects on humans and the environment are anticipated from aggregate exposure to dipotassium phosphate. This includes all anticipated exposures for which there is reliable information.

1. Human Health Risk Assessment

a. Toxicological Endpoints

No toxicological endpoints were identified. Mammalian toxicology data requirements have been submitted and adequately satisfy data requirements to support the registration. Submitted data for Lexx-A-Phos® indicate Toxicity Category IV for acute oral toxicity, dermal toxicity and acute inhalation toxicity. The primary eye irritation placed the active ingredient in Toxicity Category IV. Dermal exposure to Lexx-A-Phos® produced a very slight erythema in animal tests; as a result, dermal irritation was given a Toxicity Category IV.

b. Human Exposure

Human exposure is expected to be minimal because of the 24 hours re-entry interval required by the label. Moreover, the label’s mitigating language and user safety recommendations will limit worker exposure to Lexx-A-Phos®.

c. Risk Assessment
The Biopesticides and Pollution Prevention Division (BPPD) has not identified any subchronic, chronic, immune, endocrine, or nondietary exposure issues as they may affect children and the general U.S. population. Risk to applicators is mitigated as long as the product being registered at this time is used according to label directions. No toxicological endpoints have been identified, and there is limited exposure to this product when used according to label instructions. The Agency has considered dipotassium phosphate in light of the relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and has determined that there will be no unreasonable adverse effects from the use of this compound.

2. Ecological Risk Assessment

a. Ecological Toxicity Endpoints

No toxic endpoints were identified.

b. Ecological Exposure

Dipotassium phosphate is commonly used as a foliar fertilizer. There have been no adverse ecological effects noted from its usage as a fertilizer. As a result, the data requirements for nontarget organisms were waived.

c. Risk Assessment

According to the Mineral Acids Red (dated December, 1993), phosphoric acid (and its salts) generally dissociates and releases hydrogen ions in the environment. As a result, risk to nontarget organisms is expected to be minimal. BPPD believes that the use of dipotassium phosphate according to label use directions, should result in no significant adverse effects to wildlife.

D. DATA GAPS / LABELING RESTRICTIONS

There are no data gaps. Do not mix Lexx-A-Phos with any other fertilizer or pesticide.
I. Overview

A. ACTIVE INGREDIENT OVERVIEW

Common Name: Dipotassium Phosphate  
Dipotassium phosphate (dibasic)

Chemical Name: Dipotassium Phosphate  
Potassium Salts of Phosphoric Acid

Chemical Formula: HK₂PO₄

Chemical Family: Potassium Salts of Phosphoric Acid  
Mineral Acids

Trade and Other Names: LEXX-A-PHOS® Fungicide

CAS Registry Number: 7758-11-4

OPP Chemical Code: 176407

Basic Manufacturer: Foliar Nutrients, Inc.  
P.O. Box 474  
Cairo, GA 31728

B. USE PROFILE

The following is information on the proposed uses with an overview of use sites and application methods.

Type of Pesticide: Technical grade active ingredient. For use in the manufacturing of a fungicide

Use Sites: End-use product Lexx-A-Phos is intended for application on woody ornamentals, turfgrass, non-bearing fruit and nut trees, and grapes.

Target Pests: Broad spectrum of fungal diseases (powdery mildew, leaf spot, root rot, downy mildew, etc.).

Formulation Type: Powder
Method and Rates of Application: When incorporated into the end-use product Lexx-A-Phos® Fungicide (registrant: Foliar Nutrients, Inc.), the product is applied as a foliar spray or soil drench at a rate of 1 - 2% v/v.

Use Practice Limitations: Do not mix Lexx-A-Phos with any other fertilizer or pesticide.

Timing: Foliar application should be made at 3-4 week intervals during the growing season.

C. ESTIMATED USAGE

None used yet since this will be the first registered product.

D. DATA REQUIREMENTS

The data requirements for granting this registration under Section 3(c)(5) of FIFRA have been reviewed by BPPD. The mammalian toxicology and ecological effects data requirements for dipotassium phosphate have been fulfilled. Product analysis data requirements are adequately satisfied.

E. REGULATORY HISTORY

Mineral acids such as phosphoric acid are derived from inorganic rather than carbonized precursors. In water, these acids undergo extensive ionization forming positively charged ions (hydrogen cations) and negatively charged ions (dihydrogen phosphate anions). When the water is removed, the resulting product is a salt (potassium salt). Hence, potassium salts of phosphoric acid (also known as dipotassium phosphate) could be considered a mineral acid because it can ionize to produce hydrogen ions and anions. As a result, the findings in the Mineral Acid RED of December, 1993 could be applied to dipotassium phosphate.

On October 27, 1999, the Agency received an application from Foliar Nutrients, Inc. to register Lexx-A-Phos® containing 22.67% dipotassium phosphate and 20.4% dipotassium phosphonate (a registered active ingredient), as a fungicide.

A notice of receipt of the application for registration of dipotassium phosphate as a new active ingredient was published in the Federal Register on May 10, 2000 (65 FR 30112), with a 30-day comment period. No comments were received as a result of this publication.

F. CLASSIFICATION

On April 15, 1999, the Biochemical Classification Committee determined that although dipotassium phosphate has a toxic mode of action, it is eligible to be reviewed by BPPD because it is naturally occurring, and widely used (as a fertilizer) with no reported adverse effects.

G. FOOD CLEARANCES/TOLERANCES
A numeric tolerance or exemption from the requirement of a tolerance is not needed because there are no food uses associated with the registration of Lexx-A-Phos®.
III. Science Assessment

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for Lexx-A-Phos® are satisfied.

1. Product Identity and Mode of Action

   a. Product Identity:

   Lexx-A-Phos® is produced by an integrated system which involves the blending of almost equal amounts of dipotassium phosphate and dipotassium phosphonate. The TGAI is a solid, odorless powder. The product chemistry data submitted by the registrant satisfies the requirement for product identity.

   b. Mode of Action:

   Lexx-A-Phos® is a fungicide with a mode of action involving direct toxicity to fungi.

2. Food Clearances/Tolerances

There are no food uses associated with this action. As a result, a tolerance establishment or exemption is not required.

3. Physical And Chemical Properties Assessment

The data requirements for physical and chemical characteristics that support the registration are summarized in Table 1.

Table 1. Product chemistry data requirements

<table>
<thead>
<tr>
<th>GUIDELINE NO.</th>
<th>STUDY</th>
<th>RESULTS</th>
<th>MRID NO.</th>
</tr>
</thead>
<tbody>
<tr>
<td>151B-10</td>
<td>Product identity; Manufacturing process;</td>
<td>TGAI is a blend of dipotassium phosphate and</td>
<td>448150-01</td>
</tr>
<tr>
<td>151B-11</td>
<td>Discussion of formulation of unintentional</td>
<td>dipotassium phosphonate. EU contains 22.67%</td>
<td></td>
</tr>
<tr>
<td>151B-12</td>
<td>ingredients</td>
<td>dipotassium phosphate and dipotassium</td>
<td>448150-02</td>
</tr>
<tr>
<td></td>
<td></td>
<td>phosphonate.</td>
<td></td>
</tr>
<tr>
<td>GUIDELINE NO.</td>
<td>STUDY</td>
<td>RESULTS</td>
<td>MRID NO.</td>
</tr>
<tr>
<td>--------------</td>
<td>-------</td>
<td>---------</td>
<td>----------</td>
</tr>
<tr>
<td>151B-13</td>
<td>Analysis of samples CBI</td>
<td>Data submitted shows analysis by a titration method of both percent active ingredients dipotassium phosphonate (20.96%, 20.56%, 21.37%, 19.54%, and 19.56%) and dipotassium phosphates (23.45%, 19.50%, 22.04%, 24.76%, and 23.60%) with nominal concentration at 20.40% and 22.67% (respectively).</td>
<td>452244-01</td>
</tr>
<tr>
<td>151B-15</td>
<td>Certification of limits CBI</td>
<td>Nominal concentration of potassium phosphonate at 20.40% (upper limit 21.37 and lower limit 19.54) and potassium phosphate at 22.67% (upper limit 24.76 and lower limit 19.50)</td>
<td>452244-01</td>
</tr>
<tr>
<td>151B-17</td>
<td>PHYSICAL / CHEMICAL PROPERTIES OF DIPOTASSIUM PHOSPHATE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>151B-17(a)</td>
<td>Color</td>
<td>White</td>
<td>454499-01</td>
</tr>
<tr>
<td>151B-17(b)</td>
<td>Physical State</td>
<td>Crystal or powder</td>
<td>454499-01</td>
</tr>
<tr>
<td>151B-17©</td>
<td>Odor</td>
<td>No odor</td>
<td>454499-01</td>
</tr>
<tr>
<td>151B-17(d)</td>
<td>Melting point</td>
<td>&gt; 465 /°C</td>
<td>454499-01</td>
</tr>
<tr>
<td>151B-17(e)</td>
<td>Boiling point</td>
<td>Not applicable (solid)</td>
<td></td>
</tr>
<tr>
<td>151B-17(f)</td>
<td>Density/Specific gravity</td>
<td>0.519 g/ml at 22 /°C</td>
<td>454499-01</td>
</tr>
<tr>
<td>151B-17(g)</td>
<td>Solubility</td>
<td>150 g/100 g. cold water</td>
<td>454499-02</td>
</tr>
<tr>
<td>151B-17(h)</td>
<td>Vapor Pressure</td>
<td>0% Volatiles by volume at 21 /°C</td>
<td>454499-01</td>
</tr>
<tr>
<td>151B-17(l)</td>
<td>pH</td>
<td>9.0 ± 0.3</td>
<td>454499-01</td>
</tr>
<tr>
<td>151B-17(j)</td>
<td>Stability</td>
<td>Stable</td>
<td>454499-01</td>
</tr>
<tr>
<td>151B-17(k)</td>
<td>Flammability</td>
<td>Does not contain combustible liquid</td>
<td>448520-03</td>
</tr>
<tr>
<td>151B-17(l)</td>
<td>Storage stability</td>
<td>Stable</td>
<td>451477-01</td>
</tr>
</tbody>
</table>
### Table of Results

<table>
<thead>
<tr>
<th>GUIDELINE NO.</th>
<th>STUDY</th>
<th>RESULTS</th>
<th>MRID NO.</th>
</tr>
</thead>
<tbody>
<tr>
<td>151B-17(m)</td>
<td>Viscosity</td>
<td>Not applicable (Solid)</td>
<td></td>
</tr>
<tr>
<td>151B-17(n)</td>
<td>Miscibility</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>151B-17(o)</td>
<td>Corrosion characteristics</td>
<td>Non-corrosive</td>
<td>451477-01</td>
</tr>
<tr>
<td>151B-17(p)</td>
<td>Octanol/water partition coef.</td>
<td>Below limit of detection</td>
<td>454499-02</td>
</tr>
</tbody>
</table>

### B. HUMAN HEALTH ASSESSMENT

The information submitted in support of the application for registration of Lexx-A-Phos® adequately satisfies the requirements set forth in 40 CFR 158.690 (c) for biochemical pesticides for nonfood outdoor uses. With regards to the new active ingredient dipotassium phosphate, the applicant requested a waiver for acute toxicity data requirement. Following the review of the rationale (see next paragraph), the waiver request was approved. EPA concluded that the overall toxicological risk from human exposure to dipotassium phosphate is considered to be negligible.

1. **Toxicology Assessment**

The active ingredient dipotassium phosphate is a *Mineral Acid*, and is on the EPA inert ingredient list “4b”. This indicates that sufficient information is available to conclude that current uses of potassium salts of phosphoric acid in pesticide products will not adversely affect public health or the environment. In addition, dipotassium phosphate (potassium salts of phosphoric acid) is exempt from a tolerance of residues when used as an inert ingredient in pesticide formulations applied to growing crops (40 CFR 180.1001(d)).

Furthermore, acceptable data has been submitted to support the end-use product, which incorporates dipotassium phosphate. The Agency review indicates no acute mammalian toxicity for the end-use product Lexx-A-Phos® Fungicide containing 22.67% dipotassium phosphate by weight, in combination with 20.40% dipotassium phosphonate, at the limit dose levels for the following studies: acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation, primary dermal irritation, and dermal sensitization.

#### a. Acute Toxicology Studies
References for acute toxicity end-points for dipotassium phosphate are summarized in Table 2 below. Results of the acute toxicity studies on the end-use product are summarized in Table 3 below.

Table 2. **Acute Mammalian Toxicity: Tier I Dipotassium Phosphate**

<table>
<thead>
<tr>
<th>OPPTS Guideline Number</th>
<th>OPPTS Guideline Name</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>870.1100</td>
<td>Acute Oral Toxicity - Rat</td>
<td>Waived</td>
</tr>
<tr>
<td>870.1200</td>
<td>Acute Dermal Toxicity - Rabbit</td>
<td>Waived</td>
</tr>
<tr>
<td>870.1300</td>
<td>Acute Inhalation Toxicity - Rat</td>
<td>Waived</td>
</tr>
<tr>
<td>870.2400</td>
<td>Primary Eye Irritation - Rabbit</td>
<td>Waived</td>
</tr>
<tr>
<td>870.2500</td>
<td>Primary Dermal Irritation - Rabbit</td>
<td>Waived</td>
</tr>
<tr>
<td>870.2600</td>
<td>Dermal Sensitization - Guinea Pig</td>
<td>Waived</td>
</tr>
<tr>
<td>870.5000</td>
<td>Genotoxicity</td>
<td>Waived</td>
</tr>
<tr>
<td>870.2600</td>
<td>Immunotoxicity</td>
<td>Waived</td>
</tr>
</tbody>
</table>

Acceptable acute toxicity studies for the end-use product Lexx-A-Phos® were also submitted and reviewed. The test material was administered at a dose of 5050 mg/kg. All rats survived the treatment, which indicates that oral LD₅₀ in rats was >5050 mg/kg (Toxicity category IV). The acute dermal LD₅₀ in rabbits was >5050 mg/kg with no observable abnormalities (Toxicity category IV). The acute inhalation LC₅₀ in rats was > 2.97 mg/L; all animals survived and gained weight; (Toxicity category IV). The highest Ocular Indices observed on exposed animals for unwashed and washed eyes were 20.0 and 4.0 respectively. This classifies the test material as minimally irritating (Toxicity category IV). Dermal application did not result in irritation. This classifies the product as practically non-irritating (Toxicity category IV). The Buehler method used demonstrates that this product is not dermal contact sensitizer in guinea pigs.

Table 3. **Acute mammalian toxicity data for Lexx-A-Phos®**

<table>
<thead>
<tr>
<th>GUIDELINE NO.</th>
<th>STUDY</th>
<th>RESULTS</th>
<th>MRID NO.</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIER I</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>152-10</td>
<td>Acute oral toxicity</td>
<td>LD₅₀ &gt; 5050 mg/kg</td>
<td>448150-05</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Toxicity Category IV</td>
<td></td>
</tr>
<tr>
<td>152-11</td>
<td>Acute dermal toxicity</td>
<td>LD₅₀ &gt; 5050 mg/kg</td>
<td>44150-06</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Toxicity Category IV</td>
<td></td>
</tr>
</tbody>
</table>
### Dipotassium Phosphate  
**Biopesticides Registration Action Document**

<table>
<thead>
<tr>
<th>GUIDELINE NO.</th>
<th>STUDY</th>
<th>RESULTS</th>
<th>MRID NO.</th>
</tr>
</thead>
</table>
| 152-12        | Acute inhalation toxicity          | LC$_{50}$ > 2.97 mg/L  
Toxicity Category IV | 44150-07 |
| 152-13        | Primary eye irritation             | No corneal opacity, positive conjunctival  
irritation.  Tox. Cat. IV | 448150-08 |
| 152-14        | Primary dermal irritation          | Very slight erythema on 2/6 rabbits one hour after  
patch removal, with resolution by 24 hours. Tox. Cat. IV | 448150-09 |
| 152-15        | Dermal sensitization               | Not a sensitizer                             | 448150-10 |
| 152-16        | Hypersensitivity incidents         | Any incident must be reported if observed    | 448150-10 |
| 152-17        | Genotoxicity -  
*Salmonella typhimurium* gene  
mutation assay | Waived                                       |          |
| 152-18        | Cellular immune response           | Waived                                       |          |

**b. Mutagenicity and Developmental Toxicity**

Studies to detect genotoxicity are only conditionally required for terrestrial, non-food use biochemical pesticides. 40 CFR 158.690(c)(v) indicates that these studies are required if use is likely to result in significant human exposure, or if the active ingredient or its metabolites are structurally related to a known mutagen or belong to a class of chemical compounds which contains known mutagens. Human exposure to the active ingredient when used in accordance with label instructions on ornamental plants is anticipated to be very low due to the low application rate, re-entry restrictions, and protective wear requirements for applicators and workers. In addition, the active ingredient is not structurally related to a known mutagen, nor does it belong to a class of known mutagens. Furthermore, this product is a common foliar fertilizer which has been used and is presently being applied to the same sites for which it is intended under the proposed label. There have been no reports of adverse effects over many years of significant human exposure; as a result, these studies were waived.
Although immune response studies are required under 40 CFR 158.690(c), the test compound did not cause dermal sensitization in guinea pigs when tested by the Buehler method. The immunotoxicity study (cellular immune response study) was waived based on the minimal potential for human exposure, the low toxicity of this compound shown in the studies submitted, and the wide use of this product as a fertilizer with no reports of adverse effects in humans after many years of significant human exposure. Any incidents resulting from the use of this product must be reported to the Agency.

c. Subchronic Toxicity

A 90-day feeding study was not required because of the nonfood use of Lexx-A-Phos®. Moreover, the 90-day dermal and inhalation toxicity studies are not required because the proposed use pattern does not result in prolonged exposure at concentrations that are likely to be toxic.

d. Chronic Exposure and Oncogenicity Assessment

The Agency has granted waivers for chronic repeat-dose studies. The Agency did not require these studies as part of the Mineral Acid Red, based on the available information from literature sources to characterize the toxicity of Mineral Acids. Moreover, chronic exposure studies are conditionally required to support nonfood uses only if the potential for adverse chronic effects are indicated based on 1) the subchronic effect levels established in Tier I subchronic oral, inhalation, or dermal studies, 2) the pesticide use pattern, or 3) the frequency and the level of repeated human exposure that is expected. Oncogenicity studies are required to support nonfood uses only if the active ingredient or any of its metabolites, degradation products, or impurities produce in Tier I studies morphologic effects in any organ that potentially could lead to neoplastic changes. The triggers for chronic exposure and oncogenicity studies were not met.

e. Effects on the Endocrine Systems

Potassium Salts of Phosphoric Acid do not belong to a class of chemicals known or suspected to have adverse effects on the endocrine system and there is no evidence that dipotassium phosphate bio-accumulates in the environment.

2. Dose Response Assessment

No toxicological endpoints are identified.

3. Dietary Exposure and Risk Characterization

Dietary exposure is not anticipated because of the nonfood use of Lexx-A-Phos®. In the absence of any toxicological endpoints, risk from the consumption of residues is not expected for the general population including infants and children.
4. **Occupational, Residential, School and Day Care Exposure and Risk Characterization**

Significant human exposure to Lexx-A-Phos® is expected to be minimal in residential, school and day care areas.

a. **Occupational Exposure**

The possibility for dermal, eye and inhalation exposure to Lexx-A-Phos® is mitigated as long as the product is used according to label directions, which requires the use of protective equipment and restricted entry interval into treated areas to allow the product to dry before allowing human activity in the treated areas.

b. **Residential, School and Day Care Exposure and Risk Characterization**

No indoor residential, school, or day care uses currently appear on proposed labels. Human exposure to Lexx-A-Phos® should not occur in these areas.

5. **Drinking Water Exposure**

No significant exposure is expected from an accumulation of dipotassium phosphate in the aquatic environment when used according to the precautionary label language for the end-use product. Per the Mineral Acids RED and the tolerance exemption for Phosphorous Acid, the Agency stated that Mineral Acids are likely to be degraded in the terrestrial and aquatic environments to hydrogen and phosphite ions.

6. **Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children**

There are no food uses associated with the proposed use of the human exposure to Lexx-A-Phos®. Therefore, the acute dietary risks should be negligible based on the lack of exposure.

7. **Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation**

Aggregate exposure would primarily occur to the mixer/loader/applicator via the dermal and inhalation routes. Risks associated with dermal and inhalation aggregate exposure are measured via the acute toxicity studies submitted to support registration. Because the inhalation toxicity studies for human exposure to Lexx-A-Phos® showed no toxicity (Toxicity Category IV), the risks anticipated for this route of exposure are considered minimal. Results of the acute dermal study indicated low toxicity (Toxicity Category IV), and no significant dermal irritation was observed (Toxicity Category IV). Based on these results, the anticipated risks from dermal exposure are also considered minimal. Therefore, the risks from aggregate exposure via dermal and inhalation exposure are a compilation of two low risk exposure scenarios and are considered negligible.

8. **Cumulative Effects**
Due to the lack of toxicity and human exposure associated with the proposed use of Lexx-A-Phos®, no cumulative effects from common mechanisms of toxicity are expected.

9. **Risk Characterization**

The Agency has considered human exposure to dipotassium phosphate in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U. S. population in general, and to infants and children in particular, will result from the use of human exposure to Lexx-A-Phos® when label instructions are followed.

C. **ENVIRONMENTAL ASSESSMENT**

1. **Ecological Effects Hazard Assessment**

The registrant has requested waivers for avian oral toxicity, avian dietary toxicity, fish toxicity, aquatic invertebrate toxicity, nontarget plant toxicity, nontarget insect toxicity and honeybee toxicity data requirements. These data requirements were waived in the Mineral Acids RED (December 1993) in spite of information regarding the corrosive nature of Mineral Acids. The Agency has granted waivers of these data requirements provided that the registrant includes appropriate precautionary and mitigating language on the end-use product label to indicate that the product is toxic to birds, fish, aquatic invertebrates and nontarget insects (honey bees).

2. **Environmental Fate and Ground Water Data**

The need for environmental fate and groundwater data (Tier II, (40 CFR Section 158.690(d)(2)(vii through xv)) was not triggered because of practically non-toxic results indicated in Tier I studies. Risk to nontarget species is minimal due to the lack of toxicity, use pattern, and application methods.

3. **Ecological Exposure and Risk Characterization**

A potential for exposure exists to nontarget wildlife with terrestrial spray applications. However, the extensive use of this product as a foliar fertilizer has not resulted in reports of adverse ecological effects. BPPD also believes that low toxicity, and mitigating label language present minimal to nonexistent risk to wildlife.

D. **EFFICACY DATA**

No efficacy data are required, because no public health uses are involved.
IV. Risk Management Decision

A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

To satisfy criteria “A” above, dipotassium phosphate is similar in composition to other registered Mineral Acids active ingredients. Mineral Acids are suitable alternatives to other more toxic synthetic chemical pest control products. Criteria “B” is satisfied by the current label and by the data presented in this document. It is believed that Potassium Salts of Phosphoric Acid will not cause any unreasonable adverse effects, is an effective biochemical fungicide for plant diseases, and does provide protection as claimed to satisfy criteria “C.” Criteria “D” is satisfied in that the toxicological properties of this active ingredient are less toxic than other products currently in use, and the active ingredient is similar to other presently registered Mineral Acid active ingredients. Therefore, dipotassium phosphate is eligible for registration.

B. REGULATORY POSITION

1. Conditional/Unconditional Registration

Based on eligible data submitted, the Agency recommends that dipotassium phosphate is eligible for registration under Section 3(c)(5) of FIFRA. The Agency foresees no adverse effects to human health or the environment from the use of this active ingredient.

2. CODEX Harmonization

There are no Codex harmonization considerations since there is no food use associated with this registration.

3. Nonfood Re/Registrations

There are no nonfood issues at this time. The nonfood uses are listed in Appendix A, Table 4.

4. Risk Mitigation
There are no significant risk issue, and as such mitigation measures for dietary risk, occupational and residential risk or ground and surface water contamination are not required. Risk to nontarget organisms will be mitigated by appropriate label precautions.

5. Endangered Species Statement

Currently, the Agency is developing a program (The Endangered Species Protection Program) to identify all pesticides whose use may cause potential adverse impacts on endangered and threatened species and their habitats. To aid in the identification of threatened and endangered species and their habitats, several companies have formed an Endangered Species Task Force (EST) under the direction of the American Crop Protection Association (ACPA). Moreover, the EST will assist in providing species location information at the subcounty level, and particularly if an endangered species occurs in areas where pesticides would be used. This information will be useful once the Endangered Species Protection Program has been implemented.

The Agency has no evidence to believe that any endangered or threatened species will be adversely affected by products containing dipotassium phosphate, when used as labeled. In this regard labeling specific for endangered or threatened species is not imposed at this time for such products.

C. LABELING RATIONALE

It is the Agency’s position that the labeling for Lexx-A-Phos® complies with the current pesticide labeling requirements.

1. Human Health Hazard

a. Worker Protection Standard

Any product whose labeling reasonably permits its use in an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, “Labeling Revisions required by the Worker Protection Standard (WPS),” and PR Notice 93-11 “Supplemental Guidance for PR Notice 93-7,” which reflect the requirements of EPA’s labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in PR Notices 93-7 and 93-11. Unless otherwise specifically directed, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those Notices. After October 23, 1995, except as provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person. The labels and labeling of all products must comply with EPA’s current regulations and requirements as specified in 40 CFR 156.10 and other applicable notices. Labeling must also conform to Worker Protection Safety standards concerning reentry into sprayed fields.
Dipotassium Phosphate
Biopesticides Registration Action Document

End-use products containing dipotassium phosphate must comply with WPS, and as such have the appropriate language as required by the standard.

b. Non-Worker Protection Standard

There are no non-WPS human health hazard issues.

c. Precautionary Labeling

The Agency has examined the toxicological database for dipotassium phosphate and concluded that the proposed precautionary labeling (i.e. Signal Word, First Aid Statement and other label statements) adequately mitigates the risks associated with the proposed uses. Precautionary labeling for end-use products containing this active ingredient are:

"CAUTION. Harmful if inhaled or absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling."

d. Spray Drift Advisory

An advisory statement is contained in the DIRECTIONS FOR USE statement: "Do not apply this product in a way that will contact workers or other persons, either directly or through drift."

2. Environmental Hazards Labeling

The precautionary labeling for end-use products containing dipotassium phosphate is:

"This pesticide is toxic to birds, fish, aquatic invertebrates and honey bees. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not apply where runoff is likely to occur. Do not apply where weather conditions favor drift from areas treated. Do not contaminate water when disposing of rinsate or equipment washwaters."

3. Application Rate

When incorporated into the end-use product Lexx-A-Phos® Fungicide (registrant: Foliar Nutrients, Inc.), the product is applied as a foliar spray or soil drench at a rate of 1 - 2% v/v.
D. LABELING

(1) Product name: **Lexx-A-Phos® Fungicide**

Active Ingredient:
- Dipotassium Phosphate .................................................. 22.67%
- Dipotassium Phosphonate ............................................. 20.4%
- Other Ingredients .......................................................... 56.93%

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>100.00%</td>
</tr>
</tbody>
</table>

Signal word is "CAUTION". Eye irritation warning is appropriate.

The product shall contain the following information:
- Product Name
- Ingredient Statement
- Registration Number
- "Keep Out of Reach of Children"
- Signal Word (CAUTION)
V. **Actions Required by Registrants**

Reports of incidences of adverse effects to humans or domestic animals under FIFRA, Section 6(a)2 and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16. There are no data requirements, label changes and other responses necessary for the reregistration of the end-use product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. There are also no existing stocks provisions at this time.
vi. Appendix A

Table 4 lists the use sites for the product. The label for the product is also attached.

Table 4. Non-food Use Site Registration/Reregistration

<table>
<thead>
<tr>
<th>Lexx-A-Phos® Fungicide</th>
<th>Official date registered:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-food use sites</td>
<td></td>
</tr>
<tr>
<td>Turf, ornamentals, non-bearing fruit and nut tree crops to control plant diseases.</td>
<td></td>
</tr>
</tbody>
</table>