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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM **DATE: 08/24/2011**

SUBJECT: Non-target Organism and Endangered Species Screening Risk Assessment for the Methyl Anthranilate (Benzoic Acid, 2-Amino, Methyl Ester) Registration Review Preliminary Work Plan

Chemical Class:	Biochemical
PC Code:	128725
CAS Number:	134-20-3
Tolerance Exemptions:	40 CFR 180.

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EXECUTIVE SUMMARY

The bird repellent, Methyl Anthranilate, in a naturally occurring flavoring substance in grapes. The repellent action arises from the stimulation of the trigemimal nerve in the head of a bird resulting in a pain response (Kirifides et. al., 2004).

Based on the available data and information, the Agency does not foresee the need for new data or for new risk assessments for this active ingredient. Non-target organism hazard and exposure information as well as Agency risk assessments on Methyl Anthranilate were evaluated against current safety standards established by the Agency's scientific policies and regulations and it was determined that there is no need to conduct additional risk assessments. The active ingredient is a naturally occurring substance, has a non-toxic mode of action, and is of low toxicity. There is reasonable certainty of no harm to non-target organisms when Methyl Anthranilate is applied in accordance with EPA-approved product

labeling. A screening level assessment was conducted to evaluate the existing non-target organism data base.

Toxic endpoints have not been identified for non-target mammals and non-target birds on an acute and dietary basis in laboratory testing (respective non-definitive endpoints of >5000 mg/kg and >500 mg/kg/day). The active ingredient is moderately toxic to slightly toxic to freshwater fish on a acute basis (9.12 ppm to 42.56 ppm), and practically non-toxic on a dietary basis (>1000 mg/kg in diet) in laboratory testing. It is slightly toxic to aquatic invertebrates (17.0 to 29.1 ppm). Toxic endpoints have not been established for non-target insects (honey bees). Non-target terrestrial plants can tolerate >40,000 ppm of Methyl Anthranilate before exhibiting any observable foliar desiccation or necrosis (MRID 42740204). Based on the highest respective application rates for terrestrial and aquatic use sites, calculated Risk Quotients (RQs) are all <0.05 for all taxa.

Based on the fact that Methyl Anthranilate is relatively non-toxic to non-target organisms and on its use pattern and use instructions, EPA has determined that Methyl Anthranilate will have **"No Effect"** on any currently listed threatened or endangered species or any designated critical habitat.

1. Description of the Active Ingredient

Common Name:	Methyl Anthranilate
Chemical Name:	Benzoic Acid, 2-Amino, Methyl Ester
Synonyms:	Anthranilic Acid, methyl ester
	Methyl-2-amonobenzoate
	Methyl o-aminobenzoate
	o-Carbomethoxyaniline
	Neroli Oil
	Nevoli Oil
CAS Number:	134-20-3
Empirical Formula:	$C_8H_9NO_2$

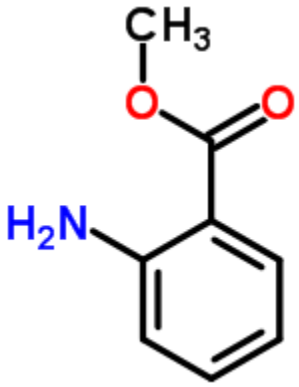

Figure 1. Structure of Methyl Anthranilate

Methyl Anthranilate is a repellent used to repel pest birds from food use and non-food use sites. The active ingredient is employed in pesticide products used on landfills, tailing ponds, commercial/industrial water impoundments, temporary pools, decorative fountains, non-fish bearing waters, electrical substations, farmsteads, agricultural sites, structures, buildings, airports & other open areas; ornamental trees & shrubs; turf; lakes, ponds, harbors, boat docks, aquatic production sites (non-fish bearing waters such as hatcheries and culture ponds), pome fruits, stone fruits, cereal grains, blueberries, sunflowers, table grapes, and turf.

Methyl Anthranilate was classified as a Biochemical Pesticide Active Ingredient by the OPP Biotechnology Work Group August 24, 1992 (EPA, 1992).

2. Registered End-Use Products and Maximum Use Rates

There are 7 currently registered End-Use Products (EPs) containing Methyl Anthranilate as their active ingredient (see Appendix Table 1).

3. Ecological Hazards

Adequate non-target toxicology data/information are available to support registration of Methyl Anthranilate. All non-target organism toxicology data requirements for Methyl Anthranilate have been satisfied. No additional data are required.

There are no concerns for any non-target organisms when Methyl Anthranilate is applied in accordance with EPA-approved label use directions. Toxic endpoints have not been identified for non-target mammals and non-target birds on an acute and dietary basis in laboratory testing. The active ingredient is moderately toxic to slightly toxic to freshwater fish on a acute basis, and practically non-toxic on a dietary basis in laboratory testing. It is slightly toxic to aquatic invertebrates. Toxic endpoints have not been established for non-target insects (honey bees). Non-target terrestrial plants can tolerate >40,000 ppm of Methyl Anthranilate before exhibiting any observable foliar desiccation or necrosis (MRID 42740204).

A review of the ECOTOX database did not reveal any additional non-target toxicity data or endpoints that were lower than those previously evaluated by the Agency.

4. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data was not triggered because results of the acute toxicity assessment did not trigger any additional Tier I studies. Some data, however, are available from studies submitted in support of a Tolerance Exemption and from external technical sources. Residues of Methyl Anthranilate (MA) applied to food crops are expected to dissipate to background levels before they are distributed for consumption.

Methyl anthranilate is extremely volatile (vapor pressure of 2.7 x 10-2 mm Hg at 25^{o}C) and will rapidly dissipate into the surrounding atmosphere from foliar surfaces to which it has been applied, and is expected to have an atmospheric half-life of 11 hours (HSDB, 2004). Based on its vapor pressure and low water solubility, MA is also expected to volatilize rapidly from water surfaces (HSDB, 2004) in as little as 16 days.

Data obtained from the technical literature suggest a range of degradation rates depending upon environmental conditions. Aronov and Clark (1996) report that MA is not subject to hydrolysis under laboratory conditions between pH 5 to pH 9 in aqueous phosphate buffers, but is susceptible to degradation by UV light (up to 42% after 27 days of illuminance at 1.25 mW cm^{-2}, equivalent to natural sunlight at noon at 40^{o} north latitude). Microbial activity was observed to be a significant degradation pathway with 22% loss after nine days and 100% loss after 20 days at optimal conditions of light and temperature (a 12:12 hr light:dark cycle and 23^{o}C). Laboratory studies (Askham, 1992) with MA on glass slides demonstrated that MA was extremely photolabile with 50% loss after two days of exposure to full sunlight and was undetectable after four days exposure.

Avery et. al. (1995) reported residues on rice as 11.7 ppm immediately following an application of ReJex-It AG-36 (14.5% a.i.) at 6.2 lb a.i./A, which rapidly declined over the next 14 days with a half-life of 7 days (interpolated by reviewer based on study author data). The application rate used in this study is equivalent to the maximum approved label application rate for food crops (see Appendix Table 1).

Based on data from empirical studies, MA residues will be low immediately following application and will rapidly dissipate in terrestrial environments under the combined influences of UV light and microbial degradation (Aronov & Clark, 1996; Askham, 1992) . Low solubility in water coupled with rapid volatilization and microbial degradation will result in minimal residues in aquatic habitats.

5. Ecological Exposure and Risk Characterization

Methyl Anthranilate is a naturally-occurring substance in plants such as corn, sunflowers, grapes (33 ppm) and cherries (35 ppm), as well as cocoa and black tea (EPA, 1994). Honey made from citrus floral sources has been reported to contain from 3.60 to 5.04 mg/kg of MA (Ferreres et. a., 1994; White & Bryant, 1996, unpublished study). It is extremely volatile and degrades rapidly into non-toxic components such as anthranilic acid. Numerous studies are available evaluating residues on crops and aquatic environments following application of Methyl Anthranilate at maximum label use rates for the respective use sites.

Terrestrial Residues: Data from magnitude of the residue studies on apples, corn (sweet), and sunflower, submitted in support of an Experimental Use Permit in 2000 (66550-EUP-001; EPA, 2000) confirm the rapid dissipation of MA. Residues on whole apples treated with a single foliar application of MA at 2.29 lbs a.i./A declined from 1.79 ppm at 1-hour posttreatment to <0.055 ppm (non-detectable) by 14 days posttreatment (MRID 45065105). Residues on sweet corn treated with a single foliar application of MA at 0.573 lbs a.i./A were

1.65 ppm at 1-hour posttreatment. Following a second treatment after a five-day application interval, residues were 0.374 ppm 10-days after the second application (MRID 45065103). Residues on sunflowers treated with a single foliar application of MA at 0.573 lbs a.i./A were 0.011 ppm at 1-hour posttreatment. Following a second treatment after a five-day application interval, residues were 0.233 ppm 10-days after the second application (MRID 45065104).

Avery et. al. (1995) reported residues on rice as 11.7 ppm immediately following an application of ReJex-It AG-36 (14.5% a.i.) at 6.2 lb a.i./A, which rapidly declined over the next 14 days with a half-life of 7 days (interpolated by reviewer based on study author data). The application rate used in this study is equivalent to the maximum approved label application rate for food crops (see Appendix Table 1).

The residue value reported by Avery et. al. (1995) was used to calculate Risk Quotients (RQs) for mammals and birds following terrestrial applications of methyl Anthranilate at the maximum label used rate.

Aquatic Residues: Magnitude of the residue studies have been conducted for both direct application and fogging applications of Methyl Anthranilate products to aquatic sites.

In a catfish toxicity study (Dorr et. al. 1998), a 40% liquid MA end-use product (ReJex-iT AG 40; EPA Reg. No. 58035-7; not currently registered) was applied directly to the surface of an aquaculture pond at an exaggerated rate of 80 lb a.i./A water surface (10X the maximum label rate for currently registered products). The maximum concentration of MA was 4.44 ppm at a depth of 24 inches following seven applications over a two week period. If mathematically adjusted to a 1X rate, the calculated residues are estimated to be approximately **0.444 ppm**.

A magnitude of the residue study (MRIDs 45210201, 45210202, & 45229701) was conducted to determine the maximum amount of MA residues that would occur in a pond following fogging applications using two different types of foggers (thermal and ultra low volume) and a product that is no longer registered for use (ReJex-iT TP-40; EPA Reg. No. 58035-7; 40% a.i.). The samples were not replicated which precluded statistical analysis and an assessment of sample variability, and there were five anomalously high MA residue measurements (5.97 ppm to 60.47 ppm) that were well outside the range of the majority of samples (total = 26), which were in the range of <0.016 ppm to 1.6 ppm. In addition, the unusually high values were well outside the values reported by Dorr et. al. (1998), following direct spray application to pond. Therefore, these data are considered unreliable for purposes of non-target organism risk assessment. It was observed, however, that MA content of water samples generally decreased with distance from the foggers.

Fog application rates are an order of magnitude below that of direct spray applications (0.21 lb a.i/A vs. 8.0 lb a.i./A). The Tier I Rice Model equation (EPA, 2007) was used to estimate environmental concentrations in water following a fog application at maximum label use rates (0.21 lbs a.i./A or 0.24 kg a.i./ HA) and assuming a K_{oc} of 250 for MA (HSDB, 2004):

$C_w = m_{ai}/(0.00105 + (0.00013 * K_d))$

Where: C_w = water concentration [µg/L]
m_{ai}' = mass applied per unit area [kg/ha]
K_d = water-sediment partitioning coefficient [L/kg] (and $K_d = 0.01K_{oc}$)
K_{oc} = organic carbon partitioning coefficient [L/kg]

Then: $Cw = 0.24/(0.00105 + (0.00013 * 2.5)) =$ **0.175 ppm**

This value is less that the calculated EEC of 0.444 ppm (estimated using data from Dorr et. al., 1998). The conservative **EEC of 0.444 ppm** will be used to evaluate risk to non-target aquatic organisms when Methyl Anthranilate is applied at the maximum label use rates.

6. Threatened and Endangered Species Assessment

A qualitative risk assessment can be conducted with acute and dietary mammal and avian toxicity data; aquatic organism LC_{50} and EC_{50} data; and terrestrial plant and insect (honey bee) data from obtained from guideline studies, non-guideline studies, and the open technical literature (Appendix Table 2), in conjunction with the label use information for Methyl Anthranilate from the product labels (Appendix Table 1). Although none of the labels specified any limitation on the number of applications, there is sufficient information to conduct a qualitative endangered species risk assessment due to the minimal toxicity of Methyl Anthranilate to non-target species and its rapid biodegradation in the environment. Toxic endpoints were not found for mammals, birds, and terrestrial insects in laboratory testing (Appendix Table 2). Field testing on cherries, blueberries, grapes, and sweet corn demonstrated that >40000 ppm of methyl anthranilate was required to induce slight necrosis and desiccation of foliage (MRID 42740204). The product is considered slightly toxic for five of six fish species tested (LD_{50} range: 16.23 to 42.56 ppm) and moderately toxic (LD_{50} = 9.12 ppm) to one fish species (Appendix Table 2).

Mammals: Mammalian (rat) acute oral toxicity is >5000 mg/kg (Toxicity Category IV; Appendix Table 2). The subchronic (90-day) dietary No Observable Effects Level (NOEL) was >500 ppm (Appendix Table 2). The non-definitive endpoints are respectively approximately 430X and 43X greater than the observed maximum environmental concentrations of 11.7 ppm for MA residues (Avery et. al., 1995) on terrestrial foliage. Based on the data and the *Guidance for Using Non-Definitive Endpoints in Evaluating Risks to Listed and Non-listed Animal Species* (EPA, 2010), there are no concerns for non-target mammals.

Birds: Avian acute oral toxicity >2250 mg/kg (Practically Non-toxic; Appendix Table 2). avian dietary toxicity was >5620 ppm (Practically Non-toxic; Appendix Table 2). The non-definitive endpoints are respectively approximately 192X and 480X greater than the observed maximum environmental concentrations of 11.7 ppm for MA residues (Avery et.

al., 1995) on terrestrial foliage. Based on the data and the *Guidance for Using Non-Definitive Endpoints in Evaluating Risks to Listed and Non-listed Animal Species* (EPA, 2010), there are no concerns for non-target birds.

Fish: Freshwater fish 96-hr LC_{50}s ranged from 9.12 ppm to 42.56 ppm across five fish species, which are categorized as moderately toxic to slightly toxic (Appendix Table 2). Using the most conservative endpoint for fish in laboratory testing (Bluegill sunfish; 9.12 ppm) and the measured calculated maximum EEC of MA in water (0.44 ppm), the Risk Quotient (RQ) was calculated as:

$$RQ = \frac{0.44 \text{ ppm}}{9.12 \text{ ppm}} = 0.019$$

The RQ is well below any Level of Concern (LOC) for non-target fish, including threatened and endangered species.

Aquatic Invertebrates: Aquatic Invertebrate EC_{50}s for daphnids ranged from 17.0 to 29.1 ppm which is categorized as moderately to slightly toxic (Appendix Table 2). Using the most conservative endpoint for aquatic invertebrates (17.0 ppm) in laboratory testing and the maximum estimated environmental concentration (EEC) of MA in water following a direct spray application to water (0.44 ppm), the RQ was calculated as:

$$RQ = \frac{0.44 \text{ ppm}}{17.0 \text{ ppm}} = 0.048$$

The RQ is below any LOC for non-target aquatic invertebrates, including threatened and endangered species.

Plants: Methyl anthranilate is a naturally-occurring substance found in many plant species such as corn, sunflowers, grapes (33 ppm) and cherries (35 ppm). It is extremely volatile and degrades rapidly into non-toxic components such as anthranilic acid. MA has no known toxic effects when applied exogenously to plants at the proposed rates of application. Reports of leaf desiccation in some studies were later attributed to the presence of certain surfactants in the end-use products and were not caused by MA (Askham, 1992; MRID 42740204). In a field study using leaves of blueberries, cherries, and grapes, it was demonstrated that non-target terrestrial plants can tolerate >40,000 ppm of Methyl Anthranilate before exhibiting any observable, but minor foliar desiccation or necrosis (MRID 42740204). Minor foliar desiccation or necrosis was observed at 80000 ppm, but no plant mortality was reported (Askham, 1992; MRID 42740204). .

Using the most conservative non-definitive endpoint for plants (40000 ppm) and the maximum observable residues on plants following a foliar spray application at the maximum label use rate (11.7 ppm; Avery et. al., 1995), the RQ was calculated as:

$$RQ = \frac{11.7 \text{ ppm}}{40000 \text{ ppm}} = 0.002$$

The RQ is well below any LOC for non-target plants, including threatened and endangered species.

Insects: Non-target insect contact toxicity LD_{50} for insects (honey bee) was >25 ug/bee (see Appendix Table 2), which is categorized as practically non-toxic. No toxic effects were observed at the highest rate used in laboratory testing. Methyl anthranilate is a naturally-occurring substance found in many plant species such as corn, sunflowers, grapes (33 ppm) and cherries (35 ppm) to which pollinators and other insects are exposed on a regular basis (EPA, 1994). Endogneous levels of MA reported for grapes and cherries are higher than residues measured on foliage (11.7 ppm) following a single application of MA at maximum label use rates (Avery et. al., 1995). Honey made from citrus floral sources has been reported to contain from 3.60 to 5.04 mg/kg of MA (Ferreres et. a., 1994; White & Bryant, 1996, unpublished study) indicating regualr dietary and contact exposure to naturally-occurring MA by pollinators. Based on these data, the Agency has no concerns to non-target insects.

CONCLUSIONS: There are no concerns for any non-target organism when Methyl Anthranilate is applied in accordance with EPA-approved product labeling.

Based on the fact that Methyl Anthranilate has minimal toxicity to non-target organisms and on its use pattern and use instructions, EPA has determined that Methyl Anthranilate will have "No Effect" on any currently listed threatened or endangered species or any designated critical habitat.

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APPENDIX

Appendix Table 1. Currently registered products and maximum label use rates for each product label. Highest use rates are boldfaced.

Product	EPA Reg. No.	Methyl Anthranilate Percentage	Maximum Use Rate per Acre per Application	Application Intervals
Avian Control™	33162-1	20.00%	**Ground: 8 lb a.i./A surface water [1]**	1 - 4 days
			Fog: 0.21 lbs a.i./A [2]	1 - 4 days
ReJex-It Fog Force™	58037-7	40.00%	**Ground: 8 lb a.i./A surface water [1]**	1 - 4 days
			Outdoor Fog: 0.21 lbs a.i./A [2, 3]	1 - 4 days
ReJex-It AG-36™	58035-9	14.50%	**Ground: 6.18 lb a.i./A [4]**	Not specified
			Aerial: 6.18 lb a.i./A [5]	Not specified
			Aerial: 6.18 lb a.i./A [6]	22 days
			Ground: 0.07 lb a.i./A [7]	4 days
ReJex-It Fog Force AR-20™	58035-15	20.00%	Outdoor Fog: 0.21 lb a.i./A [2, 7]	1 - 4 days
Bird Shield Repellent	66550-1	20.00%	**Ground/aerial: 0.28 – 5.73 lb a.i./A [8]**	Not specified
			Aerial: 0.28 lb a.i./A [9]	Not specified
			Ground: 2.29 lb a.i./A [10]	Not specified
			Ground: 4.58 lb a.i./A [7]	7 – 14 days
			Ground: 0.07 lb a.i./gal	Spot spray
			Ground: 0.12 lbs a.i./gal [1]	Added to pool
Liquid Fence Goose Repellent	72041-2	20.72%	Ground: 0.5 gal/40K sq ft [7]	Not specified
Avex	83359-4	26.40%	Ground/aerial: 5.73 lb a.i./A [8]	Not specified
			Aerial: 0.28 lb a.i./A [9]	Not specified
			Ground: 2.29 lb a.i./A [10]	Not specified
			Ground: 2.29 – 4.58 lb a.i./A [7]	7 – 14 days
			Ground: 0.07 lb a.i./gal	Spot spray
			Ground: 0.12 lbs a.i./gal [1]	Added to pool

1 Ground application to landfills, tailing ponds, commercial/industrial water impoundments, temporary pools, decorative fountains, non-fish bearing waters.
2 Electrical substations, farmsteads, agricultural sites, structures, buildings, airports & other open areas; ornamental trees & shrubs; turf; lakes, ponds, harbors, boat docks, aquatic production sites (non-fish bearing waters such as hatcheries and culture ponds)
3 Tree fruits & cereal grains
4 Apples, stonefruits, blueberries, & grapes
5 Cereal Grains
6 Sunflowers
7 Turf
8 Pome fruit, stone fruit
9 Sunflower, blueberries
10 Table grapes

Appendix Table 2. Summary of Non-Target Organism Data

Study Type/OCSPP Guideline	$LD_{50}/LC_{50}/EC_{50}$ Results	Toxicity Category	MRID
Acute Oral Toxicity /OCSPP 870.1100	>5000 mg/kg (rat)	Tox Category IV	42608702
90-day Feeding (rat) /OCSPP 870.	>500 mg/kg/day	No effects on growth or survival	42151904
Avian Acute Oral Toxicity /OCSPP 850.2100	>2036 ppm (Bobwhite quail)	Practically non-toxic	42966902
	>2250 ppm (Bobwhite quail)	Practically non-toxic	43610701
Avian Dietary Toxicity /OCSPP 850.	>5620 ppm (Mallard duck)	Practically non-toxic	42608808
	>2200 (White crowned sparrow)	Practically non-toxic	42966903
	>5259 ppm (Mallard duck)	Practically non-toxic	44741501
Freshwater Fish Acute Toxicity, 96 hr /OCSPP 850.1075	9.12 ppm [1, 2] (Bluegill sunfish)	Moderately toxic	42718202
	42.56 ppm NOEC = 33.6 ppm (bluegill)	Slightly toxic	43610702
	22.91 ppm [1] (Rainbow trout)	Slightly toxic	42966901
	25.40 ppm [2] (Rainbow trout)	Slightly toxic	43610703
	16.23 ppm [1] (Channel catfish)	Slightly toxic	42699803
	32.25 ppm [1] (Atlantic salmon)	Slightly toxic	42995101
Freshwater Fish Dietary Toxicity, 12-hr /Non-Guideline	>1000 mg/kg (striped bass & African cichlid)	No effects on growth or survival	Harpaz & Clark, 2006
Aquatic Freshwater Invertebrate Toxicity, 48-hr /OCSPP 850.1010	17.0 mg/L	Slightly toxic	41895207
	29.1 mg/L	Slightly toxic	42718203
Non-target Plants	>40000 ppm on blueberries, cherries, grapes, and raspberries[3]	Practically non-toxic	42740204
Non-target Insects (Honey Bee Contact Toxicity,	>25 ng/bee	Practically non-toxic	41623704

Study Type/OCSPP Guideline	$LD_{50}/LC_{50}/EC_{50}$ Results	Toxicity Category	MRID
48-hr)/OCSPP 850.3020			

[1] Static conditions
[2] Flow-through conditions
[3] Based on visual observations of foliar necrosis/desiccation

Appendix Table 3. Maximum N-6-BA residues following a single application, or two consecutive applications at the maximum label use rates. [1]

Environmental Matrix	Residues (ppm) following single application at 0.039lb a.i./A [2]	Residues (ppm) following two applications at 0.041 lb a.i./A with a 3-day interval [3]	Residues (ppm) following two applications at 0.165 lb a.i./A with a 7-day interval [3]
Short Grass			
Tall Grass			
Broadleaf Plants/Small Insects			
Fruits/Pods/Seedlings/Large insects			

[1] Dietary-based Estimated Environmental Concentration (EEC) calculated using T-REX model (EPA, 2005).
[2] Promalin Plant Growth Regulator (EPA Reg. No. 73049-1)
[3] Riteway (EPA Reg. No. 71368-60)

Appendix Table 4. Maximum N-6-BA residues in aquatic environments following a single application, or two consecutive airblast applications at the maximum label use rates (airblast/orchard application method). [1]

Environmental Matrix	Residues (ppb) following single application at 0.039lb a.i./A [2]	Residues (ppb) following two applications at 0.041 lb a.i./A with a 3-day interval [3]	Residues (ppb) following two applications at 0.165 lb a.i./A with a 7-day interval [3]
Peak GEEC			
Maximum 4-Day Avg. GEEC			
Maximum 21-Day Avg. GEEC			
Maximum 60-Day Avg. GEEC			
Maximum 90-Day Avg. GEEC			

[1] Estimated Environmental Concentration (EEC) calculated using GENEEC2 model (EPA, 2001).
[2] Promalin Plant Growth Regulator (EPA Reg. No. 73049-1)
[3] Riteway (EPA Reg. No. 71368-60)