



Rec. 9/27

September 24, 2010

Program Manager, USDA/AMS/TM/NOP
Room 4008-So, Ag Stop 0268
1400 Independence Ave., SW
Washington, DC 20250
202-720-3252

RE: Petition to include gibberellic acid on the NOP National List §205.605

Dear Sir/Madam:

Valent BioSciences Corporation located at 870 Technology Way, Libertyville, IL 60048, is submitting the present petition for evaluation of gibberellic acid (GA₃) to amend the National List of Allowed and Prohibited Substances (National List) by including GA₃ in the NOP National List §205.605 Non-agricultural (non-organic) substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)). Gibberellic acid is a non-synthetic substance manufactured through the fermentation process of the fungus *Gibberella fujikuroi* and is classified by US EPA as a bio-pesticide, plant growth regulator and it is naturally occurring in plants.

The information for the petition requested through Federal Register Vol. 72, No. 11 is listed below.

The official contact for this petition is:

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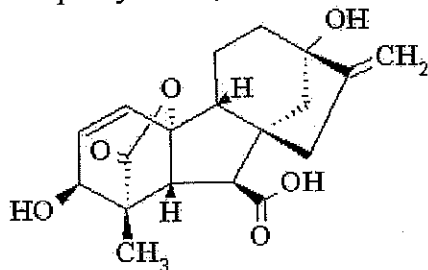
Item A

The present petition is for including gibberellic acid (GA₃) on the NOP National List as non-agricultural (non-organic) substances allowed in or on processed products labeled as “organic” or “made with organic (specified ingredients),” § 205.605.

Item B

1. The substance petitioned for inclusion in the National List is gibberellic acid (GA₃) having chemical name and structure presented below:

(3S,3aR,4S,4aS,7S,9aR,9bR,12S)-7,12-dihydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenoazuleno[1,2-b]-furan-4-carboxylic acid.



2. Gibberellic acid is manufactured for:

Valent BioSciences Corporation
870 Technology Way,
Libertyville, IL 60048.

3. Gibberellic acid is used as the active ingredient in formulating of several end use products registered for use in US and around the world as plant growth regulator for a variety of crops both pre- and post-harvest. These crops are: grapes, citrus, blueberry, banana/plantain, pineapple, sour and sweet cherries, pecan, celery, lettuce for seed, artichoke, carrot, cucumber, pepper, rhubarb, spinach, mustard greens, collard greens, turnip, strawberry, watercress and the stonefruit group. Also there are uses on rice, hops, dry bean, wheat and cotton.

Attached it is the US EPA approved label for ProGibb 40% EPA Reg. No. 73049-1 containing 40% active ingredient gibberellic acid (GA₃) including all the mentioned uses.

4. ProGibb 40% intended use for which this application is submitted is post-harvest on banana to prevent early ripeness.
5. The gibberellic acid technical is manufactured for Valent BioSciences Corporation. Attached is the manufacturing process as CBI.

6. OMRI has certified a number of end use products containing the active ingredient gibberellic acid for use in organic production, Class: Crop Pest, Weed, and Disease Control. Also certifications for use in organic production for the end use products were obtained in Australia, New Zealand and Latin America. (Attachments).
7. Gibberellic acid is approved by FDA for use as an additive in the beer making (extract of Code of Federal Regulations, Title 21, Volume 3, Revised as of April 1, 2009 is attached).

Gibberellic Acid Technical Powder containing 90% active ingredient is registered by US EPA with the registration number 73049-4. Also it is registered in Canada by PMRA with PCP Reg. No. 28509 and it was included in EU Annex I (Directive 2008/127/EC).
8. Chemical Abstract Service (CAS) # 77-06-5
9. Summaries of the physical properties, toxicity to the environment, environmental impact and effects on human health are presented below.

Natural occurrence of GA3

GA3 is a member of a family of naturally occurring plant hormones called gibberellins (GAs) which are widespread in plants and fungi. GAs are thought to be ubiquitous in higher plants and are usually most abundant in growing tissues, where they are present at concentrations in the range $10^{-5} - 10^{-2}$ mg/kg fresh weight, depending on the tissue, species and nature of the GA. Roots also produce GAs, which are normally present at lower concentrations than in shoots. Reproductive tissues generally have a higher GA content than vegetative organs, with particularly large amounts in anthers and pollen, and in developing seeds. Concentrations greater than 10 mg/kg fresh weight have been found in the endosperm and /or immature cotyledons of some species of plants (Hedden, P.) and developing seeds often contain more structurally diverse GAs than are found in other tissues. The most widespread active GA is GA1, and although at one time thought to be only a fungal product, GA3 is now also known to be produced by plants, although is usually a minor component.

GAs are a group of diterpenoid acids that function as plant growth regulators influencing a range of developmental processes in higher plants including stem elongation, germination, dormancy, flowering, enzyme induction and leaf and fruit senescence. Gibberellins fall into two groups; C₁₉-GAs and C₂₀-GAs. The C₁₉-GAs generally form a lactone bridge between the C-19 and C-10 carbon atoms and are generally the most active (although the C₂₀-GAs may act as precursors). Gibberellic Acid (GA3) is a member of the C₁₉-GAs.

Synthesis of GAs occurs to the greatest extent in growing tissues of plants. The bioactive GAs are always accompanied by their biosynthetic precursors and catabolites, which maybe present at higher concentrations than the active form.

Gibberellins are produced commercially by fermentation using the fungus *Gibberella fujikuroi*, the most important and widely-used product being GA3.

Pesticidal use

GA3 is used in agriculture as a plant regulator to stimulate both cell division and cell elongation that affect leaves as well as stems (eventually affecting fruit development and fruit set). Applications of GA3 can also hasten plant maturation and seed germination.

Because they are naturally occurring compounds and have a nontoxic mode of action in target plants, GA3 has been classified as a biochemical pesticide by the US EPA. GA3 is applied to growing crops (field crops, small fruits, vines and tree fruits), ornamental and shade trees, and ornamental plants, shrubs and vines.

The biggest use of GA3 world-wide is on seedless grapes varieties in order to increase berry size and modify their shape. Applications at full bloom cause the berries to elongate, while an additional pre-bloom application of GA₃ increases the length of the rachis, producing a looser cluster that is less susceptible to fungal infection, and decreases pollen viability and ovule fertility so reducing fruit numbers and increasing the weight of remaining fruit.

Physical and chemical properties of the substance

Study	Year	Purity of AI used	Guideline No. / Method used	GLP	Result	Reference*
Melting point, freezing point, or solidification point	1988	97.8%	USP method, equivalent to OECD 102	Y	223 - 226°C	Schilling, 1988
Boiling point	2009	99.1%	EEC Method A2 OECD Method 103	Y	The boiling point was not determined since the product started to decompose at 217°C	Comb, A 2009
Bulk density	1988	97.8%	OECD 109	Y	0.60 g/ml at 23°C	Schilling, 1988
Colour/physical state	1988	97.8%	Visual inspection	Y	White, fine powder at 23°C	Schilling, 1988
Odour	1988	97.8%	USPXXI,	Y	Odourless	Schilling, 1988
Water solubility	2003	91.1%	EEC A.8, flask method	Y	4.28 g/L 20°C	Parsons, 2003
Solvent solubility	1988	97.8%	USP procedure identical to OECD 105	Y	Isopropanol: 26 g/L at 25°C	Schilling, 1988
	1988	97.8%	USP procedure identical to OECD 105	Y	Chloroform, 0.028g/L at 25°C	Schilling, 1988
Stability in air	2005	N/A	Atkinson calculation, performed using EPIWIN (Aopwin v 1.91)	N/A	Photochemical reaction with OH radicals and ozone: half life 0.98 hrs and 12.1 hrs, respectively (12 hr day; 1.5×10^6 OH/cm ³ & 7×10^{11} mol/cm ³ ozone)	Calculation using AOPWIN v 1.91 (US EPA, 2000)
Flammability	2004	91.1%	EEC method A10	Y	GA3 was found to be not highly flammable	Young, 2004
Auto-flammability	2004	91.1%	EEC method A16	Y	No exothermic reaction; indicating it does not self-ignite below 400°C	Young, 2004
Flash point					Not flammable	

Study	Year	Purity of AI used	Guideline No. / Method used	GLP	Result	Reference*
Explosive properties	2004	91.1%	EEC method A 14	Y	Thermal and mechanical sensitivity (shock and friction): Not explosive	Young, 2004
Oxidizing Properties	2004	91.1%	EEC method A 17	Y	Not oxidizing	Young, 2004

Ecotoxicology

Three acute oral toxicity studies with Gibberellic Acid (GA3) are available for birds. These are summarized in the table below. All the studies show that GA3 has low acute toxicity to birds. The report using Mallard Duck has been identified as the critical study for the risk assessment and is summarized below.

Acute avian toxicity data for GA3

Report: Hakin, B. Johnson, A.J. Anderson, A. and Suzanne Dawe, I. (1991) Gibberellic Acid Acute Oral Toxicity (LD₅₀) to Mallard Duck. Valent Biosciences Report

Summary: Groups of 5 male and 5 female birds were given a single oral dose, by intubation, of either 500, 1000 or 2000 mg GA3/kg bodyweight. A similar sized control group was given the vehicle (corn oil) alone. Birds were observed for 14 days following dosing. There were no mortalities following dosing and no clinical signs of toxicity were observed in any bird. Bodyweight and food consumption remained unaffected by treatment with GA3. At necropsy, no treatment-related abnormalities were observed. The LD₅₀ value must lie in excess of 2000 mg/kg and the NOEC is 2000 mg/kg.

Results:

Mortality: A single bird in group 2 was found dead on Day -1 and was replaced by a spare bird. There were no mortalities following dosing.

Clinical Signs: No clinical signs of toxicity were observed in any bird.

Conclusion: No treatment related mortalities occurred during the study therefore the acute oral LD₅₀ value for Gibberellic Acid (GA3) to Mallard Duck is in excess of 2000 mg/kg bw. There were no treatment related effects on any of the measured parameters. Therefore, 2000 mg/kg bw is considered to be the no-effect level. It is therefore considered that GA3 is of low acute toxicity to birds.

Avian dietary toxicity (5 – day)

Five short-term dietary toxicity studies with Gibberellic Acid (GA3) are available for birds. All the studies show that GA3 has low dietary toxicity to birds. The 1991 report using Mallard Duck has been identified as the critical study for the risk assessment and is summarized below.

Hakin, B. Johnson, A.J. Anderson, A. Suzanne Dawe, I. (1991) Gibberellic Acid Subacute Dietary Toxicity (LC₅₀) to Mallard Duck, Valent Biosciences report.

Summary: Groups of 10 young Mallard ducklings were offered diet containing 163, 325, 650, 1300, 2600 and 5200 mg/kg Gibberellic Acid. Two similar sized control groups were offered basal diet only. There were no mortalities and all birds remained in good health throughout the study. Bodyweight and food consumption were unaffected by treatment with Gibberellic Acid. No abnormalities were detected in any bird *post-mortem*. The subacute dietary LC₅₀ of Gibberellic Acid to Mallard Duck was found to be greater than 5200 mg/kg diet (1509 mg/kg bw/day). No treatment related effects were observed at any

dose level. Therefore, 5200 mg/kg diet is considered to be the no-effect level in this study.

Results:

Mortality: There were no mortalities

Clinical Signs: No clinical signs of toxicity were observed in any bird. The excreta of all groups remained normal in appearance throughout the study

Conclusion: No mortalities occurred during the study therefore the subacute dietary LC₅₀ value for Gibberellic Acid (GA3) to Mallard Duck is in excess of 5200 mg/kg diet. There were no treatment related effects at any dose level, therefore, 5200 mg/kg is considered to be the no-effect level. It is therefore considered that GA3 is of low dietary toxicity to birds.

Daily dose (mg/kg bw/d) = concentration in food (mg/kg) multiplied by daily food consumption (g per bird per day) divided by body weight (g). At the 5200 dose rate the mean food consumption over the 5 day exposure period was 55 g per bird per day and the mean body weight was 189.5 g (mean of day 0 and day 5 weights). Therefore the LC₅₀ for Gibberellic Acid is greater than a daily dose of 1509 mg/kg bw/d.

Acute toxicity (24 and 48 hr) for a representative species of aquatic crustacean

The proposed uses of Gibberellic Acid (GA3) do not include any direct use on surface waters therefore data on the acute toxicity to a representative species of aquatic crustacean (other than *Daphnia*) are not required. However, data on the crustaceans *Penaeus duorarum* (Pink shrimp) and *Neopanope texana* (Mud Crab) are available (Hasbrouck Sleight, B 1973a). These data show that the 96 hour LC₅₀ for Pink Shrimp was >750 <870 mg/L and that for Mud Crab was > 1000 mg/L. The NOECs for both species was 750 mg/L. These additional data show extremely low toxicity of Gibberellic Acid (GA3) to aquatic crustacean species. The data show that the toxicity data for *Daphnia magna* (EC₅₀ values for 24 and 48 hours, based on nominal concentration of gibberellic acid, are 785 and 488 mg/L, respectively. The 48 hour no-observed-effect-level was 360 mg/L) provides a conservative end-point for the risk assessment to aquatic crustacean invertebrate species.

Acute toxicity (24 and 48 hr) for a representative species of aquatic gastropod molluscs

The proposed uses of Gibberellic Acid (GA3) do not include any direct use on surface waters therefore data on the acute toxicity to a representative species of aquatic gastropod mollusc are not required. However, data on the aquatic gastropod mollusc *Crassostrea virginica* (Atlantic Oyster) are available (Hasbrouk Sleight, B. 1973b). These data show that the 48 hour TL₅₀ (inhibiting 50% of developing oyster larvae) is 242 mg/L with 95% confidence interval of 185-316 mg/L GA3. No effect on normal embryonic development was observed among oyster larvae exposed to GA3 at 180 mg/L for 48 hours. These data again illustrate that the *Daphnia* end-point (EC₅₀ of 76 mg/L) to be used in the risk assessment is conservative and will adequately cover the risk to aquatic invertebrates.

Effects on biological methods for sewage treatment

Summary: Samples of activated sludge (suspended solids 1.6 g/L), fed with synthetic sewage, were exposed to the test substance at nominal concentrations of 1, 10, and 100 mg active substance (a.s./L) for three hours. Their rates of oxygen consumption were determined and compared to controls containing activated sludge and synthetic sewage alone. A positive control with the reference inhibitor 3,5-dichlorophenol was also performed.

The result for the controls and positive control showed the test to be valid and that the sample of activated sludge employed was sensitive to inhibition. Gibberellic Acid (GA3) was considered to have had no biologically significant inhibitory effect on the respiration rate of activated sludge at any of the concentrations tested. The EC₂₀, EC₅₀ and EC₈₀ are all considered to be greater than 100 mg a.s./L, the highest dose tested.

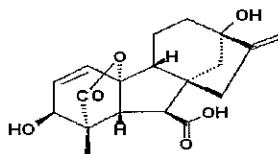
Conclusion: Gibberellic acid (GA3) (technical grade) was considered to have no biologically significant inhibitory effect on the respiration of activated sludge at concentrations up to 100 mg a.s./L. The EC₂₀, EC₅₀ and EC₈₀ for GA3 are concluded to be greater than 100 mg a.s./L.

Environmental Fate Data Summary

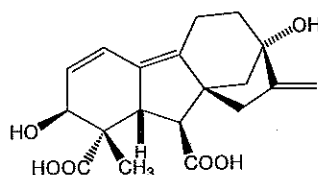
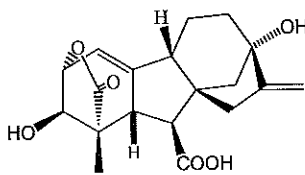
Gibberellins are widely found in the tissues of plants and also in various fungi. They are diterpenoid acids having an ent-gibberellane skeleton and fall into two groups; C₁₉-GAs and C₂₀-GAs. The C₁₉-GAs generally form a lactone bridge between the C-19 and C-10 carbon atoms and are generally the most active (although the C₂₀-GAs may act as precursors). Gibberellic Acid (GA3) is a member of the C₁₉-GAs and is produced commercially by fermentation using the fungus *Gibberella fujikuroi*.

It is clear that gibberellins, including GA3, are ubiquitous in the wider environment, being found in plant tissues and fungi (especially those associated with plants). Information on the presence of gibberellins in soils is sparse due to the difficulties of extraction and analytical detection. However it is considered overall that gibberellins probably exist endogenously in soils, particularly the rhizosphere. Biological metabolism of gibberellins appears to progress via; (1) conversion to other gibberellins, (2) conjugation or (3) catabolism. (Phytohormones in Soil: microbial production and function; Frankenberger, W.T. and Arshad, M. 1995. Chapter 3. Gibberellins).

Gibberellic Acid (GA3) has a number of acronyms including Gibberellin A3 and Gibberellic acid A3. For the purposes of this dossier the compound is summarized as GA3 throughout, irrespective of the name used in the original reports. The chemical structure of GA3 is shown below.

Summary of behavior in water

The hydrolytic degradation of GA3 was rapid with calculated first order DT_{50} values of 46.2 hours at pH 9 to 216 hours at pH 4.0 at 30°C. In a separate experiment first order DT_{50} values of 249-271 hours at 25°C in pH 5 buffer or sterile natural water were obtained. Gibberellenic acid and isogibberellic acid were identified as the major hydrolytic metabolites in acid/neutral conditions (Gibberellenic acid is not considered to be a gibberellin due to the presence of the double bond in the 5-membered ring). Photolytic degradation was not significant in comparison to hydrolytic degradation.

**Gibberellenic acid****Isogibberellic acid**

GA3 is one of the most active gibberellins (Phytohormones in Soil: microbial production and function; Frankenberger, W.T. and Arshad, M. 1995. Chapter 3. Gibberellins) and hence it is strongly probable that any metabolism of the GA3 would result in compounds of lower activity regarding the gibberellin mode of action. In addition, the structural complexity of the naturally occurring gibberellin structure makes it extremely unlikely that metabolism of this compound would lead to other highly active compounds with a totally different mode of action. No experimental data are available on the degradation of GA3 in natural water/sediment systems. However based on the hydrolysis data and ready biodegradability data the following can be deduced; (1) Rapid hydrolysis of GA3 will occur, (2) complete mineralization to CO_2 is not significant as there was <1% CO_2 production after 29 days of the ready biodegradation test and (3) partitioning of GA3 to the sediment will be insignificant due to the very low K_{oc} values.

Fate of Pesticide in Soil

The degradation of GA3 in soils has been studied with non-radiolabelled compound only, and for this reason there is no available information regarding the possible metabolites of GA3. However, gibberellins are widely present in higher plants and fungi and biological metabolism of these organisms in the soil can be expected to result in similar metabolites to those derived from exogenously applied GA3 (i.e. as a plant protection product). In this case it is anticipated that natural levels of gibberellin catabolites are more significant than those occurring from the very limited uses of GA3 in plant protection products. GA3 is one of the most active gibberellins

(Phytohormones in Soil: microbial production and function; Frankenberger, W.T. and Arshad, M. 1995. Chapter 3. Gibberellins) and hence it is strongly probable that any metabolism of the GA3 would result in compounds of lower activity regarding the gibberellin mode of action. In addition, the structural complexity of the naturally occurring gibberellin structure makes it extremely unlikely that metabolism of this compound would lead to other highly active compounds with a totally different mode of action. Soil metabolites of GA3 are thus considered not to require further consideration.

The degradation rate of GA3 in the soil is very rapid with DT_{50} values of *ca* 1.4- 3.3 days under laboratory conditions at 25°C in two Japanese soils with a range of textural characteristics (%OC 1.4 – 4.79, pH 5.9 – 7.01). DT_{90} values were *ca* 4.3 – 5 days in these experiments. The rapid dissipation was confirmed in two field studies in the same soils in Japan (application was in January). At one site concentrations of GA3 were never present above the limit of determination whilst at the other site DT_{50} and DT_{90} values of *ca* 4.5 and *ca* 9.6 days, respectively were obtained. Studies on the batch sorption of GA3 also demonstrated that rapid degradation occurred.

The sorption of GA3 was investigated in 5 soils with a range of characteristics (pH 4.5 to 7.4, %OC 1.0 – 6.6). GA3 is an acid and hence it can be expected that sorption would be affected by pH. However, based on the data for K_{ow} it is expected that above pH 5 (i.e. at realistic soil pHs) the compound will be entirely dissociated. A Freundlich adsorption coefficient value for GA3 on Speyer 2.2 soil was not calculable as no apparent adsorption to soil was observed. K_{Foc} values of 0.875 – 29.7 (1/n 0.51-0.98) were calculated for the remaining four soils but the variability in the data indicates the practical experimental difficulty in determining quantitative values for a compound with very low affinity for soil. Therefore at relevant soil pHs GA3 has potential mobility, although due to the rapid degradation it is unlikely to be expressed in the environment

Human Health Effects

Acute toxicity

Acute oral toxicity

Acute Oral Toxicity Study in Rats with Gibberellic Acid Technical Material.
Ricerca, Inc.

Single maximum dose by gastric intubation. Gibberellic Acid Technical Material administered to 5 male and 5 female Sprague-Dawley rats at a dose of 5000 mg/kg.

All animals survived through the 14 day observation period. With the exception of anogenital staining and soft feces in several rats on the day of dosing, the treated rats all appeared normal throughout the 14-day observation period. $LD_{50} > 5000$ mg/kg

Acute percutaneous toxicity

Acute Dermal Toxicity Study in Albino Rabbit with Gibberellic Acid Technical Material.
Ricerca, Inc.

Single dose, topical application of Gibberellic Acid Technical Material on the skin of a group of 5 male and 5 female New Zealand White rabbits at a dose of 2000 mg/kg.

All animals survived through the 14 day observation period. With the exception of very slight erythema at the site of application and soft feces, no abnormal clinical findings and no effect on body weight were noted in any of the animals. $LD_{50} > 2000$ mg/kg.

Acute inhalation toxicity

Acute Inhalation Toxicity Study with Gibberellic Acid (GA3) in the Rat.
Hazleton Laboratories America, Inc.

Five male and five female Crl:CDBR rats were exposed whole body during four-hours to an acute concentration of 1.74 ± 0.227 mg/L Gibberellic Acid. The exposure level was considered the maximum attainable concentration and was determined gravimetrically.

All animals survived to termination. Signs related to treatment were observed only on the day of exposure and included: compound on fur, piloerection, lacrimation and rhinorrhea. Based on this study the LC_{50} for a four-hour exposure of the rat with Gibberellic Acid is > 1.74 mg/L.

Primary Dermal Irritation:

Primary Dermal Irritation Study of Gibberellic Acid (GA3) in Rabbits.
Hazleton Laboratories America, Inc.

The test material, Gibberellic Acid (GA3) at a dose of 0.5g was evaluated for its primary skin irritation potential on the intact skin of 4 male and two female New Zealand White rabbits. The test material produced no dermal irritation during the study.

Primary Eye Irritation:

Primary Eye Irritation Study of Gibberellic Acid (GA3) in Rabbits.
Hazleton Laboratories America, Inc.

The test material, Gibberellic Acid (GA3) was evaluated for its primary eye irritation in rabbits. Each rabbit received 0.06 g (0.1 ml weight equivalent) of the test material into the inverted lower lid of one eye. Observations were made at 1, 24, 48, 72 and 96 hours at 7 days after treatment. The test material produced iridal involvement and moderate to severe conjunctival irritation. Irritation in all animals had cleared by Day 7.

Skin sensitisation

Gibberellic Acid A3: Skin Sensitization To The Guinea Pig.
ICI Central Toxicology Laboratory

Tested first by intradermal injection and secondly by topical application.
Thirty female guinea pigs are used (20 test and 10 controls).

Two main procedures were used:

- a) the induction of the immune response
- b) a challenge of that response

Gibberellic Acid A3 was not a skin sensitizer under the conditions of the test. Challenge of previously induced guinea pigs with 75% or a 30% w/v preparation of the test sample in corn oil did not elicit a skin sensitization response.

90-day feeding studies:

A 14-week gavage study in Fisher 344 rats and B6C3F₁ mice was conducted with the plant growth hormone Gibberellic Acid. Weight depression in excess of 10% was seen only in mice - males at the 5% dose level and females at 0.62%, 2.5% and 5.0% dose levels. Weight gain in comparison to controls exceeded 10% in male mice at 0.31% gibberellic acid. Fourteen weeks of feeding with gibberellic acid produced no apparent effect in rats. It is recommended that the chronic study in rats be run at the maximum allowable dose level of 5.0% and 2.5%. Mice fed 5.0% gibberellic acid for 14 weeks developed inflammation of the stomach mucosa. Several females at that dose level also had mild liver lesions. Inflammation of the stomach was also seen in male and female mice in the 2.5% dose group. No related lesions were seen in mice fed 1.25% gibberellic acid. Recommended doses for the chronic study in male and female mice are 1.25% and 0.62% of the diet.

Long term toxicity (chronic and carcinogenicity)

Short-term and subchronic toxicity studies show that gibberellic acid has a low order of toxicity, which doesn't appear to increase with duration of exposure. Since it is a naturally occurring plant hormone that is ubiquitous in higher plants, and therefore has continuous exposure in the human diet, long-term chronic and carcinogenicity studies in the rat are not necessary.

Teratogenicity

The embryo-lethal and teratogenic potentials of gibberellic acid following daily oral administration to pregnant rats during the period of major organogenesis were evaluated. Crl:CD (SD)BR rats were used. Mated rats were given oral (by gavage) dosages of 10, 100 and 1000 mg/kg/day of gibberellic acid. Gibberellic Acid (GA3) was devoid of maternal or embryonic effects and was not teratogenic when administered to pregnant rats at dosages as great as 1000 mg/kg/day during pregnancy.





Species	Doses Tested Mg/kg bw	NOEL mg/kg bw	LOEL Mg/kg bw	Toxicity seen at LOEL
Rat	0, 10, 100, 1000	1000	>1000	No maternal, foetal, or developmental toxicity seen
Rabbit	0, 100, 300, 1000	1000	>1000	No maternal, foetal, or developmental toxicity seen

Reproduction (2generations)

Short-term and subchronic toxicity and rat and rabbit developmental studies show that gibberellic acid has a low order of toxicity, which doesn't appear to increase with duration of exposure.

Since it is a naturally occurring plant hormone that is ubiquitous in higher plants, and therefore has continuous exposure in the human diet, a two-generation reproduction study in rats does not need to be completed.

Mutagenicity

The mutagenic potential of Gibberellic acid (GA₃) was evaluated in five strains of *Salmonella typhimurium*. The compound was tested in both non-activated and rat-liver-microsome-activated test systems. Mutagenicity test results for Gibberellic acid were negative at concentrations up to 10,000 micrograms in both activated and non-activated test systems for all five *Salmonella typhimurium* strains tested.

Gibberellic Acid A3 has been evaluated in the bacterial mutagenicity assay of Maron and Ames using five strains of *Salmonella typhimurium* (TA-1535, TA-1537, TA-1538, TA-98, TA-100). In two separate experiments the compound did not induce any significant reproducible increase in the observed numbers of revertant colonies in any of the tester strains used, either in the presence or absence of an auxiliary metabolizing system (S9). Under the conditions of this assay, Gibberellic Acid A3 therefore gave a negative, (i.e. non-mutagenic) response in *S. typhimurium* strains TA-1535, TA-1537, TA-1538, TA-98, and TA-100 in both the presence and absence of S9.

The *in vitro* assay of gibberellin A3 to induce sister chromatid exchange (SCE) in Chinese hamster ovary cells (CHO) under treatment conditions with and without activation was evaluated. No *in vitro* cellular toxicity was detected even at a concentration of 2.7 mg/ml, the maximum concentration tested as limited by solubility. No increase in SCE was detected at concentrations of 90 µg/ml through 2.7 mg/ml. Gibberellin (GA3) is considered negative for inducing sister chromatid exchange in Chinese hamster ovary cells under the conditions of metabolic activation and non-activation.

An evaluation of the clastogenic potential of Gibberellic Acid (GA3) was made in Human lymphocytes from two donors, treated *in vitro* with a range of concentrations of test material both in the presence and absence of rat liver-derived auxiliary metabolic activation system (S9-

mix). No statistical or biological significant increase in percentage of aberrant cells, compared to the solvent control values, were seen at any of the gibberellic acid GA3 concentrations tested, in either donor, either in the presence or absence of S9-mix. It is therefore concluded that, under the conditions of this assay gibberellic acid GA3 is not clastogenic to cultured human lymphocytes in vitro.

The mutagenic potential of Gibberellic acid GA3 to mammalian cells was tested. L5178Y lymphoma cells were treated in vivo with various concentrations of the test sample up to 2500 µg/ml, (limited by pH effects), both in the presences and absence of an auxiliary metabolizing system (S9), in 3 independent experiments. Mutant frequencies were assessed by cell growth in the presence of trifluorothymidine after a 48-hour expression time. All experiments gave negative results with no reproducible increase in mutant frequencies being observed. Under the conditions of this assay, gibberellic acid GA3 is non-mutagenic to L5178Y cells both in the presence and absence of an auxiliary metabolizing system (S9) when tested to a concentration 2500 µg/ml, (limited by pH effects).

Gibberellic Acid GA3 has been evaluated for its ability to induce micronucleated polychromatic erythrocytes in the bone marrow of C57BL/6JfBL10/Alph mice. No statistically or biologically significant increase in the incidence of micronucleated polychromatic erythrocytes, over vehicle control values were seen at either dose level in males at any of the sampling times investigated. A small but statistically significant increase in the incidence of micronucleated polychromatic erythrocytes, compared to the vehicle control values, was noted in the female 24 hours after being dosed with gibberellic acid GA3 at 5000 mg/kg. This increase was considered not to be biologically significant and this was confirmed by extended analysis of a further 2000 polychromatic erythrocytes from, the female vehicle and the 5000 mg/kg groups at the 24 hour time point. No statistically or biologically significant increases were observed in the extended counts or when the data from the original and extended counts were pooled prior to statistical analysis.

In the in vitro Primary Rat Hepatocyte Unscheduled DNA Synthesis (UDS) assay, gibberellin GA3 did not induce significant increase in UDS. Low to non-detectable toxicities were induced and higher concentrations could not be analyzed because of the presence of a precipitate. None of the criteria used to indicate UDS were approached by the treatments, and no dose-related response was observed. Therefore, the test material was considered inactive in the Primary Rat Hepatocyte UDS Assay.

Gibberellic Acid A3 was tested for the ability to induce unscheduled DNA synthesis (UDS) in an in vivo rat hepatocyte assay incorporating an autoradiographic technique. The highest test treatment, 2000 mg/kg, was the limit dose for this assay. Two independent experiments were carried out at each time point, validated by concurrent control treatments of rats with HPMC, (the vehicle for gibberellic acid GA3), and with the carcinogen 6-p-dimethylaminophenyl azobenzthiazole (6BT) or N-nitrosodimethylamine (NDMA). Examination of the mean net nuclear grain count and percentage of cells in repair showed that gibberellic acid GA3 did not induce UDS at either dose level or time point. When tested up to a limit dose of 2000 mg/kg, the test sample of gibberellic acid GA3 did not induce DNA repair in hepatocytes of rats exposed in vivo.

10. Material Safety Data Sheet is attached. The substance report from National Institute of Environmental Health is not available.
11. No formal efficacy data for the post-harvest on banana is available. The request is based on the field experience from the banana exporters to USA.

List of references included in present petition:

Author	Year	Study Title	Performing Laboratory
Young, S	2004	GA3 - Physicochemical Properties	Huntingdon Life Sciences,
Schilling, J	1988	Gibberellic Acid A3 – Physical and Chemical Properties	Abbott Laboratories
Comb, A	2009	GA3 – Boiling Point	Huntingdon Life Sciences,
Hakin, B. & al.	1991	Gibberellic Acid Acute Oral Toxicity (LD ₅₀) to Mallard Duck	Huntingdon Research Center
Hakin, B. & al.	1991	Gibberellic Acid Subacute Dietary Toxicity (LC ₅₀) to Mallard Duck	Huntingdon Research Center
Barnes, S.P & al	2004	Gibberellic Acid, GA3 (Technical Grade) Activated Sludge – Respiration Inhibition	Huntingdon Life Sciences
Hakin, B. & al.	1991	Gibberellic Acid Subacute Dietary Toxicity (LC ₅₀) to Mallard Duck	Huntingdon Research Center
Shults, S.K. Brock, A.W. Killeen, J.C.	1991	Acute oral toxicity study in rats with Gibberellic acid technical material.	Ricerca, Inc.
Shults, S.K.	1991	Acute dermal toxicity study in Albino Rabbit with Gibberellic Acid Technical Material.	Ricerca, Inc.
Terrill, J.B.	1988	Acute inhalation toxicity study with Gibberellic Acid (GA3) in the rat.	Hazleton Laboratories America, Inc
Glaza, S.M.	1988(a)	Primary dermal irritation study of Gibberellic acid (GA3) in rabbits.	Hazleton Laboratories America, Inc
Glaza, S.M	1988(b)	Primary eye irritation study of Gibberellic acid (GA3) in rabbits.	Hazleton Laboratories America, Inc
Brammer, A. Robinson, P.	1991(d)	Gibberellic acid A3: Skin Sensitisation to the Guinea Pig.	ICI Central Toxicology Laboratory
Auletta, C.S.	1990	A subchronic (3 month) oral toxicity study in the Rat with gibberellic acid (GA 3) via dietary admixture.	Bio/dynamics Inc
Callander, R.D.	1991	Gibberellic acid A3 – An evaluation of mutagenic potential using <i>S. typhimurium</i> .	ICI Central Toxicology Laboratory
Diehl, M.S.	1987	Salmonella/mammalian microsome mutagenicity test (Ames test) of gibberellic acid.	Abbott Laboratories
Jones, K. Mackay, J.M.	1991	Gibberellic acid A3: An evaluation in the <i>In vitro</i> cytogenic assay in human lymphocytes.	ICI Central Toxicology Laboratory
Kennelly, J.C. Lane, M.P.	1991	Gibberellic acid A3: Assessment for the induction of unscheduled DNA synthesis in rat hepatocytes <i>In vivo</i> .	ICI Central Toxicology Laboratory
Cifone, M.A., Myhr, B.C	1986	Evaluation of Gibberellin A3 (acid gibberellic) in the rat primary hepatocytes unscheduled DNA synthesis assay.	Hazleton Biotechnologies

Ivett, J.L.	1986	Mutagenic evaluation of Gibberellin A3 Lot #84-526-CD list code 33690 in an <i>In vitro</i> cytogenic assay measuring sister chromatid exchange in Chinese hamster ovary (CHO) cells.	Hazleton Biotechnologies
Callander R.D. Clay, P.	1991	Gibberellic acid A3: Assessment of mutagenic potential using L5178Y mouse lymphoma cells..	ICI Central Toxicology Laboratory
Howard, C.A. Mackay, J.M.	1991	Gibberellic acid A3: An evaluation in the mouse micronucleus test.	ICI Central Toxicology Laboratory
Lehrer, S.B.	1986	Evaluation of the effects of orally administered gibberellic acid on the embryonic and fetal development of the rat (segment II, TFR)..	Abbott Laboratories

12. Petition Justification.

Gibberellic acid is naturally occurring plant hormone that act as plant regulator, promoting cell division and cell elongation leading to increased fruit set and crop yields.

Why is the substance necessary for use in organic handling?

Facts:

- The main organic banana producing countries for the US market are Peru, Ecuador and Colombia.
- Bananas are a perishable crop. Once banana are harvested they have a limited shelf life.
- Shipping time from the Tropics to the U.S. market could take from 15 to 21 days depending on the logistics.
- Some fungus diseases have an effect over the banana's natural ripening process. One of those fungus diseases is *Mycosphaerella fijiensis*, known as Black Sigatoka, the main disease on banana cultivation.
- Black Sigatoka appears during the rainy season, when wet and hot conditions take place in the Tropics where bananas are grown.
- Rainy season in the Tropics could last from 3 to 6 months or even longer.
- One of the major banana quality problems is when the fruit arrives ripe to the destination. If that happen, the fruit is rejected and dumped.
- In order to prevent the ripeness, the banana producers reduces the harvesting age of the fruit and the number of banana fingers per stem (reducing the weight of the stem and the yield of the plantation and thus his income)
- Quality Claims due to ripeness can be found all year around.
- Gibberellic Acid (GA₃), a plant growth regulator found in plants, is commonly used in conventional banana production to prevent early ripeness problems. GA₃ is applied to the cluster's crowns, to influences fruit senescence and increases the shelf life of the product. The bananas applied with GA₃ last green for longer (at least 5 or 6 days more) and thus resist the shipping time without ripening.
- Gibberellic Acid is a natural by-product of a fungus, *Gibberella fujikuroi*.

The use of Gibberellic Acid (GA₃) in Organic Banana processing is necessary to prevent one of its major quality problems, early ripeness. Without the use of this substance, the producer's income is strongly affected by a reduction in the plantation's yield and the quality claims. The whole industry is affected by a reduction in the offer, the quality claims and the increase in the production costs.

Describe non-synthetic or synthetic substances on the National List or alternate cultural methods that could be used in place of the petitioned substance.

No other non-synthetic or synthetic substance has proved similar effectiveness as the GA₃ increasing the shelf life of fruits. A cultural but unaffordable practice would be the shipping of the organic bananas in vacuum pack, but as the bananas need to be ripened by entering in contact with ethylene gas, every banana box should be manually opened before entering the ripening facility and it is simply not feasible.

13 Confidential Business Information Statement

The manufacturing process for Gibberellic Acid is considered "trade secret" and it is claimed Confidential Business Information. Valent BioSciences Corporation manufacturing process is proprietary and the loss of CBI will be damaging to our business.

Attached to this petition are the manufacturing process containing the CBI and the manufacturing process with the CBI deleted.

For any additional information or questions please contact me at 847-968-4724 or by e-mail at doina.bujor@valentbiosciences.com.

Doina Bujor
Regulatory Manager
Valent BioSciences Corporation

[Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2009]
[CITE: 21CFR172.725]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED)

PART 172 -- FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

Subpart H--Other Specific Usage Additives

Sec. 172.725 Gibberellic acid and its potassium salt.

The food additives gibberellic acid and its potassium salt may be used in the malting of barley in accordance with the following prescribed conditions:

(a) The additives meet the following specifications:

- (1) The gibberellic acid is produced by deep-culture fermentation of a suitable nutrient medium by a strain of *Fusarium moniliforme* or a selection of this culture.
- (2) The gibberellic acid produced is of 80 percent purity or better.
- (3) The empirical formula of gibberellic acid is represented by C₁₉H₂₂O₆.
- (4) Potassium gibberellate is the potassium salt of the specified gibberellic acid.
- (5) The potassium gibberellate is of 80 percent purity or better.
- (6) The gibberellic acid or potassium gibberellate may be diluted with substances generally recognized as safe in foods or with salts of fatty acids conforming to 172.863.

(b) They are used or intended for use in the malting of barley under conditions whereby the amount of either or both additives present in the malt is not in excess of 2 parts per million expressed as gibberellic acid, and the treated malt is to be used in the production of fermented malt beverages or distilled spirits only, whereby the finished distilled spirits contain none

and the finished malt beverage contains not more than 0.5 part per million of gibberellic acid.

(c) To insure the safe use of the food additives the label of the package shall bear, in addition to the other information required by the Act:

(1) The name of the additive, "gibberellic acid" or "potassium gibberellate", whichever is appropriate.

(2) An accurate statement of the concentration of the additive contained in the package.

(3) Adequate use directions to provide not more than 2 parts per million of gibberellic acid in the finished malt.

(4) Adequate labeling directions to provide that the final malt is properly labeled as described in paragraph (d) of this section.

(d) To insure the safe use of the additive the label of the treated malt shall bear, in addition to the other information required by the Act, the statements:

(1) "Contains not more than 2 parts per million ___", the blank being filled in with the words "gibberellic acid" or "potassium gibberellate", whichever is appropriate; and

(2) "Brewer's malt--To be used in the production of fermented malt beverages only" or "Distiller's malt--To be used in the production of distilled spirits only", whichever is appropriate.

Registered Product

CERTIFICATE
REGISTERED OPERATION

Valent Bio-Sciences

PO Box 60 Epping NSW 1710 Australia

REGISTERED LOGO



SCOPE OF REGISTRATION

FACILITIES

Suite 402, Building B 242 Becroft Road Epping NSW 2121 in Australia

PRODUCTS


DIPEL DF BIOLOGICAL INSECTICIDE, PROGIBB SG PLANT
GROWTH REGULATOR, RETAIN PLANT GROWTH REGULATOR,
VECTOBAC WG BIOLOGICAL LARVICIDE, XENTARI WG BTA
BIOLOGICAL INSECTICIDE

The above named operator has been assessed by Australian Certified Organic on behalf of Biological Farmers of Australia Cooperative Ltd and is licensed to supply or direct the application of the BFA trademark. This certificate is not a legal or commercial document and may not be used as such. This certificate remains the property of Biological Farmers of Australia Co-op Ltd and remains valid until the expiry date or until surrendered, suspended or revoked.

Valid Until 30th November 2011



Authorised by:
Akiko Nicholls
ACO Managing Director



**BIOLOGICAL
FARMERS OF
AUSTRALIA**



Place & Date of Issue:
Brisbane, Australia
9 December 2009

Biological Farmers of Australia Co-op Ltd
ABN 75 699 664 781
766 Gympie Rd (PO Box 530) CHERMSIDE QLD 4032
Ph: +61 (0)7 3350 5716 Fax: +61 (0)7 3350 5996
Email: info@bfa.com.au Internet: www.bfa.com.au

Valent BioSciences Corporation
Attn. Sra: María Pilar Herrero
870 Technology Way,
Suite 100 Libertyville,
Illinois 60048,
USA

BCS Öko-Garantie GmbH
Control System Peter Grosch
Cimbernstraße 21
90402 Nuremberg
Alemania

Tel: +49 911 42439-0
Fax:
Dept Internac. +49 911 42439-71
Dept Nacional +49 911 492239
E-Mail: info@bcs-oeko.de
Internet: www.bcs-oeko.com

Fecha:
22 de julio de 2009

Confirmación para el uso de insumos en la agricultura orgánica

Estimada señora Herrero:

Con gusto le enviamos en anexo la Confirmación de Compatibilidad en inglés y español para sus insumos:

- RYZUP 4 SL / PROGIBB 4%

Les rogamos comedidamente verificar inmediatamente los datos indicados en este documento para evitar errores eventuales antes del envío de los originales. En caso de que no recibamos respuesta de la parte de Ustedes durante las próximas 2 semanas, les mandaremos los originales de aquellos.

Le agradecemos mucho su confianza y su cooperación y le saludamos

Atentamente

BCS Öko-Garantie GMBH



por
Peter Grosch
Gerente General
Nuremberg, Alemania

Copia

CONFIRMATION OF COMPATIBILITY

for the use of inputs in organic agriculture

issued to:

VALENT BIOSCIENCES CORPORATION
870 Technology Way,
Suite 100 Libertyville,
Illinois 60048,
USA

Document No.

VALENT-7950/07.09/0000-US

This document is to confirm that the commercial products

RYZUP 4 SL

PROGIBB 4%

produced and distributed by the company mentioned above came to the following result

The final products are considered as products allowed in organic agriculture, according to the requirements of

- (CE) n° 889/2008, Annex II (European Union)
- USDA/NOP-Final rule (USA) 205.206 (d) (2), 205.601 (m)

Anyhow, it has to be underlined that - due to the absence of a uniform interpretation of the term "equivalency" - every state authority in the EU has got the right to apply its own criteria in this respect, although BCS confirms the conformity of the products with the requirements of EU Regulation (CE) n° 834/2007.

The inspection and evaluation of the procedure of production was carried out by BCS Öko-Garantie GmbH, Nuremberg, Germany. BCS is an EU-accredited inspection and certification body, controlled by 16 German state supervising authorities. In addition BCS is accredited by the US authority USDA to certify according to the NOP-final Rule and as an Registered Foreign Certification Company by the Japanese Ministry for Agriculture, Fishery and Forestry to certify according to the Japanese Agricultural Standard for Organic Agricultural Products.

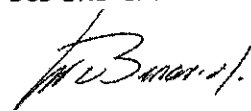
This confirmation does not constitute any guarantee of product quality. It only confirms that the use of these products can be considered as equivalent to the requirements in the above mentioned regulations.

It has to be taken into consideration that the official registration in every country where the products are to be sold is not covered by this confirmation. It remains the obligation of the distributing company to carry out the respective legal steps for the official registration of these products.

Nuremberg, July 22nd, 2009

Validity of document, until July 31st, 2010

BCS ÖKO-GARANTIE GMBH



for
Peter GROSCH
General Manager
Nuremberg, Germany

Copy

BCS Öko-Garantie GmbH



Cimbernstr. 21, 90402 Nuremberg, Germany Phone: +49 (0)911 42 43 9-0, Fax: +49 (0)911 42 43 9 71
EU-Code-No.: DE-001-Öko-Kontrollstelle

CONFIRMACION DE COMPATIBILIDAD

para el uso de insumos en la agricultura ecológica

extendido para

VALENT BIOSCIENCES CORPORATION
870 Technology Way,
Suite 100 Libertyville,
Illinois 60048,
USA

No. del documento:

VALENT-7950/07.09/0000-US

Este documento confirma que los productos comerciales

RYZUP 4 SL

PROGIBB 4%

producidos y comercializados por la empresa mencionada arriba ha llegado al siguiente resultado:

Los productos finales son considerados como permitidos para el uso en la producción agrícola orgánica, según los requerimientos de los reglamentos

- (CE) n° 889/2008, Anexo II (Unión Europea)
- USDA/NOP-Final rule (EEUU) 205.206 (d) (2), 205.601 (m)

Cabe destacar que - aunque BCS está atestando la conformidad del producto con los requerimientos del reglamento (CE) n° 834/2007 - por falta de definiciones uniformes del termino "equivalencia", cada autoridad estatal en la UE tiene el derecho de aplicar su propio criterio a este respecto.

Los procedimientos de producción fueron revisados y evaluados por BCS OEKO-Garantie, Nuremberg, Alemania. BCS OEKO-GARANTIE es una certificadora independiente de productos ecológicos con sede principal en Alemania, acreditada por la Unión Europea y supervisada por 16 autoridades alemanas. Adicionalmente BCS es acreditada por la autoridad USDA para certificar según el reglamento NOP-final Rule y como "Registered Foreign Certification Company" por la autoridad japonesa MAFF, Ministry for Agriculture, Fishery and Forestry, para certificar según el reglamento "Japanese Agricultural Standard for Organic Agricultural Products".

La presente confirmación no es una garantía para la calidad de los productos. Solamente confirma que pueden ser considerados como equivalentes a los requerimientos de los reglamentos arriba mencionados.

Se debe tomar en consideración que este atestado no reemplaza el registro de los productos ante las autoridades de los países donde se los van a comercializar. Es obligación de la empresa responsable para la venta de los productos efectuar los respectivos trámites legales para el registro oficial de los mismos.

Nuremberg, 22 de Julio de 2009

Validez del Documento: 31 de Julio de 2010

BCS OEKO-GARANTIE GMBH



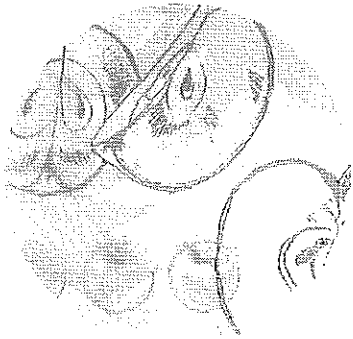
por
Peter GROSCH
Gerente General
Nuremberg, Alemania

Copia

BCS Öko-Garantie GmbH



Cimbernstr. 21, 90402 Nuremberg, Alemania, Tel.: +49 (0)911 42 43 9-0, Fax: +49 (0)911 42 43 9 71
EU-Code-No.: DE-001-Öko-Kontrollstelle



OMRI Listed®

The following product is OMRI Listed. It may be used in certified organic production or food processing and handling according to the USDA National Organic Program Rule.

Product

ProGibb® 4%

Company

Valent BioSciences® Corp.

Doina Bujor
870 Technology Way
Libertyville, IL 60048

Status

Allowed with Restrictions

Category

Gibberellic Acid

Issue date

01-Jul-02

Product number

abb-9794

Class

Crop Pest, Weed, and Disease Control

Expiration date

01-Mar-2011

Restrictions

May be used as a pesticide if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

Executive Director

Product review is conducted according to the policies in the current *OMRI Policy Manual* and based on the standards in the current *OMRI Standards Manual*. To verify the current status of this or any OMRI Listed product, view the most current version of the *OMRI Products List* at www.omri.org. OMRI listing is not equivalent to organic certification and is not a product endorsement. It cannot be construed as such. Final decisions on the acceptability of a product for use in a certified organic system are the responsibility of a USDA accredited certification agent. It is the operator's responsibility to properly use the product, including following any restrictions.

OMRI[®]
L i s t e d

Organic Materials Review Institute
P.O. Box 11558, Eugene, OR 97440-3758, USA
541.343.7600 • fax 541.343.8971 • info@omri.org • www.omri.org



OMRI Listed®

The following product is OMRI Listed. It may be used in certified organic production or food processing and handling according to the USDA National Organic Program Rule.

Product

ProGibb® 40%

Company

Valent BioSciences® Corp.

Doina Bujor
870 Technology Way
Libertyville, IL 60048

Status

Allowed with Restrictions

Category

Gibberellic Acid

Issue date

04-Oct-02

Product number

abb-9526

Class

Crop Pest, Weed, and Disease Control

Expiration date

01-Mar-2011

Restrictions

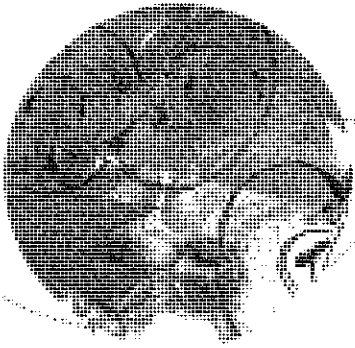
May be used as a pesticide if the requirements of 205.206(e) are met, which requires the use of preventative, mechanical, physical, and other pest, weed, and disease management practices.

Executive Director

Product review is conducted according to the policies in the current *OMRI Policy Manual* and based on the standards in the current *OMRI Standards Manual*. To verify the current status of this or any OMRI Listed product, view the most current version of the *OMRI Products List* at www.omri.org. OMRI listing is not equivalent to organic certification and is not a product endorsement. It cannot be construed as such. Final decisions on the acceptability of a product for use in a certified organic system are the responsibility of a USDA accredited certification agent. It is the operator's responsibility to properly use the product, including following any restrictions.



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OMRI Listed®

The following product is OMRI Listed. It may be used in certified organic production or food processing and handling according to the USDA National Organic Program Rule.

Product

ProGibb® T&O

Company

Valent BioSciences® Corp.

Doina Bujor
870 Technology Way
Libertyville, IL 60048

Status

Allowed

Category

Gibberellic Acid

Issue date

11-Jul-03

Product number

abb-3138

Class

Crop Pest, Weed, and Disease Control

Expiration date

01-Mar-2011

Restrictions

Not Applicable.

Executive Director

Product review is conducted according to the policies in the current *OMRI Policy Manual* and based on the standards in the current *OMRI Standards Manual*. To verify the current status of this or any OMRI Listed product, view the most current version of the *OMRI Products List* at www.omri.org. OMRI listing is not equivalent to organic certification and is not a product endorsement. It cannot be construed as such. Final decisions on the acceptability of a product for use in a certified organic system are the responsibility of a USDA accredited certification agent. It is the operator's responsibility to properly use the product, including following any restrictions.

OMRI
Listed

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541.343.7600 • fax 541.343.8971 • info@omri.org • www.omri.org



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

Ms. Maria Herrero
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

JUL 08 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: Valent BioSciences Corporation; ProGibb 40%
EPA Registration No. 73049-1
Amendment to Add Crops and Pasture
D#408757, Application Dated 4/15/9

Dear Ms. Herrero:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(A), is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit two (2) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(b). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions contact Chris Pfeifer at 703-308-0031 or by email at pfeifer.chris@epa.gov. A stamped copy of the label is enclosed for your records.

Sincerely,

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure

MASTER LABEL

Primary Product name: ProGibb 40% Plant Growth Regulator, Water Soluble Granule.

Sublabel I: ProGibb 40%, Plant Growth Regulator, Water Soluble Granule;
For agricultural use on grapes, citrus, blueberry, banana/plantain, pineapple, sour and sweet cherries, pecan, celery, lettuce for seed, artichoke, carrot, cucumber, pepper, rhubarb, spinach, mustard greens, collard greens, turnip, strawberry, watercress and the stonefruit group. Also rice, hops, dry bean, wheat and cotton.

Sublabel II: RyzUp Smartgrass, Plant Growth Regulator;
For agricultural use on Pastures and commercial use on Sod and Turf.

For Organic Production

Active Ingredient	
Gibberellin A ₃	40.0% w/w
Other Ingredients.....	60.0% w/w
Total.....	100.0% w/w

Contains a total of 128 g of Gibberellic Acid in 320 g of product.

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Registration No. 73049-1
EPA Establishment No.

Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, IL 60048

Net Contents: 2.5g satchets, 80 or 320 g bottles
This container will treat ___ acre at the maximum use rate, as directed for use on _____.

ACCEPTED

JUL 08 2009

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No.

73049-1

SUB-LABEL I

ProGibb® 40% Plant Growth Regulator

Water Soluble Granule

For agricultural use on grapes, citrus, blueberry, banana/plantain, pineapple, sour and sweet cherries, pecan, celery, lettuce for seed, artichoke, carrot, cucumber, pepper, rhubarb, spinach, mustard greens, collard greens, turnip, strawberry, watercress and the stonefruit group. Also rice, hops, dry bean, wheat and cotton.

PROGIBB® 40%
Plant Growth Regulator
Water Soluble Granule

For Organic Production

Active Ingredient	
Gibberellin A ₃	40.0% w/w
Other Ingredients.....	60.0% w/w
Total.....	100.0% w/w

Contains a total of 128 g of Gibberellic Acid in 320 g of product.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See inside booklet for Precautionary Statements.

EPA Registration No. 73049-1
 EPA Establishment No.

Valent BioSciences Corporation
 870 Technology Way, Suite 100
 Libertyville, IL 60048
 1-847-968-4700

Net Contents: 2.5g, 80 g and 320 g
 This container will treat ___acre at the maximum use rate, as directed for use on _____.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also call toll-free 1-800-892-0099 (24 hours) for emergency medical treatment and/or transport emergency information. For all other information, call 1-800-6-Valent.	

PROGIBB® 40%
Plant Growth Regulator
Water Soluble Granule

For Organic Production

Active Ingredient	40.0% w/w
Gibberellin A ₃	60.0% w/w
Other Ingredients.....	100.0% w/w
Total.....	

Contains a total of 128 g of Gibberellic Acid in 320 g of product.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See inside booklet for Precautionary Statements.

EPA Registration No. 73049-1
EPA Establishment No.

Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, IL 60048
1-847-968-4700

Net Contents: 2.5 g

Please see Box or Pamphlet for Precautionary Statements and Directions For Use

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Caution: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants.
- Waterproof gloves.
- Shoes plus socks.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning or disposing of equipment washwaters or rinsate.

Do not use treated seed for food, feed, or oil purposes. Exposed treated seed may be hazardous to birds and other wildlife. Treat only those seeds needed for immediate use and planting. Do not store excess treated seed beyond planting time. Dispose of all excess treated seed and seed packaging by burial away from bodies of water.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribe agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours *unless wearing appropriate PPE*.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls.
- Waterproof gloves.
- Shoes plus socks.

GENERAL DIRECTIONS FOR USE

Use only as directed. Read the label thoroughly and make sure it is understood before making applications. Keep out of reach of children.

Application Instructions:

- ProGibb 40% water soluble granule contains gibberellic acid which is an extremely potent plant growth regulator; when applying plant growth regulators, deviations from the label directions in the rates, timings, water volumes, or the adoption of untested spray mixes, results in undesirable effects. Always consult the local Valent representative in your area for the spray regimen best suited to your conditions.
- Do not apply to plants under pest, nutritional, or water stress.
- When a range of rates is indicated, use the concentration and spray volume indicated by the local Valent representative.
- For optimum effectiveness, thorough spray coverage of the target area must be achieved. Prepare solution concentrations by mixing the required amount of product with water in a clean, empty spray tank. Discard any unused spray material at the end of each day following local, state or federal law.
- For most efficacious results, the water pH is best at 7.0, and always below 8.5.
- Applications made under slow drying conditions (cool to warm temperatures, medium to high relative humidity, and no wind) will increase absorption of the active ingredient by the plant, thus optimizing effectiveness. Night-time applications are encouraged when day-time conditions are not conducive to slow drying conditions.
- Product persistence: Re-apply if significant rain occurs within 2 hours of application.
- Compatibility: When considering tank mixing with other products, use the following compatibility jar test before mixing a whole tank.

Start with a clear glass or plastic quart jar. Add water from the same water source that will be used for the larger tank mix. Add the pesticides in correct proportions. Mix thoroughly and let stand for a minimum 15 minutes. Heat, separation, gelling, are all signs of incompatibility. Before using any mixes that pass the jar tests for compatibility, it is imperative to test the mixture on a designated area as it may result either in phytotoxicity or ineffectiveness. For further information, consult your local Valent representative.

- For aerial applications spray volumes must be greater than 2 gallons per acre (10 gallons per acre for tree crops).
- No preharvest interval is required for this product.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage

Keep containers tightly closed when not in use.

Pesticide Disposal

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Disposal: (80 or 320 g bottles)

Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or mix tank. Fill container $\frac{1}{4}$ full with water and recap. Shake 10 seconds. Pour rinsate into application equipment or mix tank or store rinsate for later use or disposal. Drain for 10 seconds after flow begins to drip. Repeat this procedure two more times. Then offer for recycling or dispose of in a sanitary landfill, or incineration, if allowed by state and local authorities by burning. If burned, stay out of smoke.

(2.5 g sachets)

Nonrefillable container. Do not reuse or refill this container. Offer for reconditioning if appropriate or dispose of in a sanitary landfill, or incineration, if allowed by state and local authorities by burning. If burned, stay out of smoke.

SPRAY GUIDELINES FOR GRAPE

For all grapes, application by ground sprayer gives the most efficacious coverage. Apply as a concentrate or dilute spray in sufficient water volume to ensure complete coverage of all flower clusters or berries. For cultivar specific spray rates and timings, see accompanying tables.

SEEDLESS TABLE GRAPE

CLUSTER STRETCH SPRAYS – SEEDLESS TABLE GRAPE			
OBJECTIVE/BENEFIT	APPLICATION TIMING		
For cluster elongation and looser cluster forms. To reduce costs of thinning, allow better air circulation to aid in the control of bunch rot, and increase light penetration to aid in sugar development.	Make one to three applications before bloom when flower clusters are 2 to 7 inches long.		
CROP/ CULTIVAR	GRAMS A.I./Acre	Grams Product/Acre	Ounces Product/Acre
Perlette Seedless	8 - 24	20 - 60	0.7 – 2.2 oz
Flame Seedless	8 - 24	20 - 60	0.7 – 2.2 oz
Thompson Seedless	8 - 24	20 - 60	0.7 – 2.2 oz
Raisin	8 - 24	20 - 60	0.7 – 2.2 oz
Other Seedless Grapes	No indications are available at this time.		

BERRY THINNING SPRAYS - SEEDLESS TABLE GRAPE			
OBJECTIVE/BENEFIT	APPLICATION TIMING		
For decreased berry set, reduced hand-thinning costs, and hastened maturity.	Make one to four applications during bloom. Make only 1-2 applications for “Other Seedless Grapes.” When the bloom period is extended, subsequent sprays are to be made 1 to 7 days after the first application.		
CROP/ CULTIVAR	GRAMS A.I./Acre	Grams Product/Acre	Ounces Product/Acre
Flame Seedless	3 - 16	7.5 – 40	0.3 - 1.4 oz
Thompson Seedless	8 - 20	20 – 50	0.7 – 1.8 oz
Raisin	3 - 12	7.5 – 30	0.3 - 1.1 oz
Other Seedless Grapes	0.5 - 12	1.3 – 30	0.1 - 1.1 oz
NOTE: At the high end of the prescribed range of rates and number of applications, expect significantly more thinning in young vines or vines with high vigor. For “Other Seedless Grapes” use caution as some of the new cultivars are very responsive and over-thin easily. Consult the Valent representative or local specialist before thinning cultivars with which there is no familiarity.			

BUMP SPRAY – SEEDLESS TABLE GRAPE			
OBJECTIVE/BENEFIT	APPLICATION TIMING		
To help initiate the beginning of the berry growth period.	Make one application during the period between the last thinning spray and the first sizing spray.		
CROP/ CULTIVAR	GRAMS A.I./Acre	Grams Product/Acre	Ounces Product/Acre
Thompson Seedless	16 - 24	40 - 60	1.4 – 2.2 oz

BERRY SIZING SPRAYS - SEEDLESS TABLE GRAPE				
OBJECTIVE/BENEFIT		APPLICATION TIMING		
For larger berries and larger clusters when used in conjunction with established girdling and thinning practices.		Make one to four applications beginning when the average berry size reaches “target” diameter (See below). Timing of the subsequent sprays will be dictated by experience in the vineyard and temperatures occurring between sprays. Sprays made after 15-20 days from the first sizing spray are less effective.		
CROP/ CULTIVAR	TARGET BERRY DIAMETER*	GRAMS A.I./Acre	Grams Product/Acre	Ounces Product/Acre
Perlette Seedless	4-5 mm	32 - 128	80 – 320	2.9 – 11.5 oz
Flame Seedless	6-9 mm	20 - 128	50 – 320	1.8 – 11.5 oz
Thompson Seedless	3-5 mm	32 - 128	80 – 320	2.8 – 11.5 oz
Raisin	3-5 mm	4 - 20	10 - 50	0.4 – 1.8 oz
Other Seedless Grapes	3-14 mm	8 - 60	20 - 150	0.7 – 5.4 oz
*Target average berry diameter for the first application.				
NOTE: In some growing regions and for some cultivars, the higher amounts of gibberellic acid indicated will reduce fruitfulness (cluster counts) the following year. At the high end of the prescribed range of rates and number of applications, a delay in berry skin color development, sugar accumulation and overall maturation has been observed. Consult the Valent representative or local specialist before sizing cultivars with which there is no familiarity.				

BERRY SIZING CLUSTER DIP - SEEDLESS TABLE GRAPE			
OBJECTIVE/BENEFIT	APPLICATION TIMING		
To increase berry size.	Apply 20 - 50 ppm GA3 solution as a dip or direct spray to the cluster when berries reach 12-15 mm.		
CROP/ CULTIVAR	Rate Per 5 Gallons Treatment Solution		
	PPM AI	Grams Product	Ounces Product
Seedless Grapes	20 - 50	1 - 2.5	0.1 - 0.25
Note: To prepare dip solution, add 1 - 2.5 gram ProGibb 40% for every 5 gallons of solution needed. Consult the Valent representative or local specialist before sizing cultivars with which there is no familiarity.			

BERRY SIZING SPRAYS – SEEDED TABLE GRAPE				
OBJECTIVE/BENEFIT		APPLICATION TIMING		
To increase berry size in listed cultivars; and also to reduce berry shrivel in Emperor.		Make one application during the indicted berry diameter range to the entire vine.		
CROP/ CULTIVAR	BERRY DIAMETER (mm)*	Rate		
		GRAMS A.I./Acre	Grams Product / Acre	Ounces Product / Acre
Emperor	12-16	20	50	1.8
Red Globe	12-18			
Calmeria	12-16			
Christmas Rose	12-16			
Rogue	12-16			
Queens	12-15			
*Predominant average berry diameter for this application.				
NOTE: Whole vine applications have been known to reduce fruitfulness (cluster counts) the following year. Consult the Valent representative or local specialist before sizing cultivars with which there is no familiarity.				

BERRY SIZING CLUSTER DIPS – SEEDED TABLE GRAPE				
OBJECTIVE/BENEFIT		APPLICATION TIMING		
To increase berry size in listed cultivars; and also to reduce berry shrivel in Emperor.		Make one 20 - 50 ppm application during the indicted berry diameter range. Make the application as a direct spray or dip to the cluster.		
CROP/ CULTIVAR	BERRY DIAMETER (mm)*	Rate Per 5 Gallons Treatment Solution		
		PPM AI	Grams Product	Ounces Product
Emperor	12 - 16	20 - 50	1 - 2.5	0.1 - 0.25
Red Globe	12 - 18			
Calmeria	12 - 16			
Christmas Rose	12 - 16			
Rogue	12 - 16			
Queens	12 - 15			
Other Seeded Grapes	2-3 weeks after bloom or when shatter is completed			
*Predominant average berry diameter for this application.				
NOTE: To prepare a 50 ppm GA3 solution, add 1 gram A.I. for every 5 gallons of dip solution needed. Consult the Valent representative or local specialist before sizing cultivars with which there is no familiarity.				

BERRY SIZING SPRAYS – BLACK CORINTH			
OBJECTIVE/BENEFIT	APPLICATION TIMING		
To increase berry size.	Make one application 3-5 days after full bloom, but before shatter begins.		
CROP/ CULTIVAR	GRAMS A.I./Acre	Grams Product / Acre	Ounces Product / Acre
Black Corinth (Zante Currant)	1 - 12	2.5 - 30	0.1 - 1.1

SPRAY GUIDELINES FOR CITRUS

For citrus, apply in sprays of sufficient water volume to ensure thorough fruit wetting. In most cases, this application will cause some drop of oldest (most mature) leaves; this drop of older leaves is inconsequential. However, application to trees of low vigor or under stress (pest, nutritional, or water, etc) causes severe leaf and/or fruit drop. Do not apply in white wash sprays in which lime or other caustic material has produced a high pH in the spray tank. Applications of copper fungicides and/or oils within three weeks (before or after) the ProGibb 40% application often results in significant leaf drop and fruit drop.

CITRUS: FIELD APPLICATIONS

CITRUS – INCREASE FRUIT SET			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE / ACRE	APPLICATION TIMING
Navel and Ambersweet Orange	To enhance fruit set and yield.	15 – 25 GRAMS A.I 37.5 – 62.5 grams product 1.4 – 2.3 ounces product	Make a single dilute spray between mid December and late January using sufficient spray volume for adequate coverage of tree canopy
<p>NOTE: Many blocks of Ambersweet and Navel orange in Florida tend to flower very heavily, yet set poor crops. In these blocks, it appears that tree resources are wasted by heavy flowering, compromising the trees' ability to set fruit, support early fruit growth, and carry fruit to harvest. Productivity of heavily blooming blocks is often increased by reducing flower formation.</p>			
Clementine Mandarin	To increase fruit set and yield	1 – 40 GRAMS A.I 2.5 – 150 grams product 0.9 – 3.6 ounces product	Make one to two applications from early bloom up to 4 weeks after petal fall. Use a dilute spray with sufficient spray volume for adequate coverage of tree canopy. Typically 1 – 8 grams a.i. is diluted per 100 gallons spray solution. Allow a minimum of three days between sprays.

<p>Tangerines and Mandarin Hybrids</p> <p>(Orlando, Robinson, Minneola, Sunburst, and others)</p> <p>(Not for use in California)</p>	<p>To increase fruit set and yield.</p>	<p>8 - 30 GRAMS A.I</p> <p>20 - 75 grams product</p> <p>0.7 - 2.7 ounces product</p>	<p>Make one to two applications during the bloom period. Apply as a dilute spray.</p>
<p>Grapefruit</p> <p>(Not for use in California)</p>	<p>To enhance fruit set, size and yield</p>	<p>8 - 30 GRAMS A.I</p> <p>20 - 75 grams product</p> <p>0.7 - 2.7 ounces product</p>	<p>Make a single application in December - January. Apply in 125-175 gallons of water per acre.</p>

NOTE: The rate and number of applications depends upon amount of desired fruit set. Generally, more fruit will be set by 2 applications, earlier applications, higher rates, and climactic conditions more favorable to set. Differential responses to the PGR across citrus cultivars also interact with the above factors to affect the degree of fruit set achieved. Reductions in final fruit size are known to occur as a result of excessive fruit set. Increases in mature leaf drop occur in trees under stress.

CITRUS - REDUCE FRUIT DROP			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE / ACRE	APPLICATION TIMING
<p>Star Ruby Grapefruit</p> <p>(Not for use in California)</p>	<p>To reduce early-season small fruit drop of Star Ruby Variety thereby increasing yields.</p>	<p>25 - 35 GRAMS A.I</p> <p>62.5 - 87.5 grams product</p> <p>2.3 - 3.2 ounces product</p>	<p>Make a single dilute application during the bloom period.</p>
<p>NOTE: Results vary from season to season depending on environmental conditions. Maintain a well-balanced fertilization and watering program.</p>			

CITRUS – DELAY RIND AGING			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE / ACRE	APPLICATION TIMING
Navel and other orange cultivars (except Valencia)	To delay rind aging, reduce physiological disorders (e.g., rind staining, water spotting, sticky or tacky surface, oleocellosis), and produce a more orderly harvesting pattern	16 - 48 GRAMS A.I 40 – 120 grams product 1.4 – 4.3 ounces product	Make one or two applications as a concentrate or dilute spray. Early application: spray approximately 2 weeks prior to color break (typically AUG. – NOV.). This timing causes the greatest delay in rind aging and produces the firmest rind possible. AND/OR Late application: one application after marketable color (typically OCT. – DEC.). This late spray has been known to cause re-greening.
Valencia Orange	To reduce rind creasing and to delay rind aging and softening	40 - 80 GRAMS A.I 100 – 300 grams product 3.6 – 7.2 ounces product	Make a single application as a concentrate or dilute spray in August to October to target crop of young fruit.
NOTE: <ul style="list-style-type: none"> Do not apply the early spray to groves that will be harvested early, as fruit coloring will be delayed. Do not apply from January through July, as production is often reduced the following year. Slower color development is to be expected in the target crop. Increased re-greening of mature fruit has been known to occur. After marketable color is achieved, treatment effects are reduced the longer treated fruit remain on the tree. 			

Tangerine Hybrids (Orlando, Robinson, Minneola, Sunburst, and others)	To delay disorders associated with rind aging, puffiness, and softening, and to increase peel strength, of tangerine hybrids	20 - 40 GRAMS A.I 50 - 100 grams product 1.8 - 3.6 ounces product	Make one spray application two weeks prior to color break. Apply as a dilute spray.
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NOTE: Do not apply if early harvest is planned. Do not apply after coloring as pre-harvest rind staining and re-greening has been known to occur. Application during coloring sometimes causes variation in rind color development.

Grapefruit (Not for use in California)	To delay disorders associated with rind aging (e.g., puffiness, softening, and orange coloration), prevent preharvest drop of mature fruit, increase peel strength, reduce water loss during storage, and produce a more orderly harvesting pattern.	16 - 48 GRAMS A.I 40 - 120 grams product 1.4 - 4.3 ounces product	Make one or two dilute spray applications in sufficient volume to ensure coverage. Do not exceed 20 ppm a.i. (8 grams a.i. /100 gallons) in spray solution. EARLY: Make application two weeks prior to color break. Apply as a dilute spray (AUG. - SEPT). AND/OR LATE: Make application after marketable color has developed (OCT - DEC).
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NOTE: Do not spray groves that will be harvested early, as fruit coloring will be delayed. Treated fruit will re-green if allowed to remain on the tree for extended periods. Do not use concentrate sprays. Results vary from season to season depending on environmental conditions. For maximum effect on rind firmest and delay in rind aging, make applications before color change.

Lemon/ Lime	To decrease rind aging, yellowing, and the amount of small ripe fruit, and to produce a more desirable production pattern relative to market demand.	10 - 32 GRAMS A.I 25 – 80 grams product 0.9 – 2.9 ounces product	Make a single application when target crop is 1/2 to full size, but still green.
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NOTE: When applied two years in a row, an even larger difference in harvest pattern and maturity have been known to occur.

CITRUS – INCREASE JUICE YIELD			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE / ACRE	APPLICATION TIMING
Processing oranges	To increase juice extraction yield in late-harvested processing oranges.	20 GRAMS A.I 50 grams product 1.8 ounces product	Make a single application at fruit color break in sufficient volume to ensure complete coverage of the fruits.

CITRUS: POST-HARVEST APPLICATIONS

CITRUS – DELAY SENESCENCE			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE	APPLICATION METHOD
Lemon	To delay fruit senescence and prolong storage life. The delay in senescence has been shown to reduce the incidence of infection by sour rot (<i>Geotrichum candidum</i>).	50-1000 PPM	Dilute 2 to 40 grams a.i. per 10 gallons of final post-harvest application solution. Apply post-harvest application solution to the entire fruit as a spray or drench.
Yellow lemons and other mature citrus fruit	To delay aspects of rind senescence and color changes	50-1000 PPM	Dilute 2 to 40 grams a.i. per 10 gallons of final post-harvest application solution. Apply post-harvest application solution to the entire fruit as a spray or drench.

SPRAY GUIDELINES FOR TEMPERATE FRUIT CROPS

For temperate fruit crops, apply in sprays of sufficient water volumes to ensure thorough fruit wetting. Application to plants or trees of low vigor or under stress (pest, nutritional, or water, etc) causes severe leaf and/or fruit drop. Applications of copper fungicides and/or oils within three weeks (before or after) the ProGibb 40% application often results in significant leaf drop and fruit drop.

TEMPERATE FRUIT CROPS: FIELD APPLICATIONS

TEMPERATE FRUIT CROPS – FRUITSET			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE/ ACRE	APPLICATION TIMING
Highbush Blueberry : Coville, Jersey, Stanley, Earliblue, Weymouth, Walcott, Berkeley, Blueray, Bluecrop, 1316A, Concord, and others (Not for use in California)	To improve fruit set.	40 – 80 GRAMS AI 100 – 200 grams product 3.6 – 7.2 ounces product	Make a single application of 80 grams a.i. per acre in 40 to 100 gallons of water. The application should be made at full bloom (when 75% of the flowers are fully open). OR Make two applications of 40 grams a.i. per acre in 40 to 100 gallons of water. Make the first application at full bloom, and the second application within 10-14 days of the first spray. For Weymouth, application can be delayed up to two weeks after bloom to increase size of “shot” berries.

<p>Rabbiteye Blueberry:</p> <p>Aliceblue, Beckyblue, Bonita, Brightwell, Climax, Delite, Tiftblue, Woodward and others.</p> <p>(Not for use in California)</p>	<p>To improve fruit set.</p>	<p>40 – 80 GRAMS A.I</p> <p>100 – 200 grams product</p> <p>3.6 – 7.2 ounces product</p>	<p>Make a single application of 40 to 80 grams a.i. in 40 -to- 100 gallons of water per acre when most of the flowers are elongated but not yet open (Bloom Stage 5).</p> <p>OR</p> <p>Make two to four applications 10-to-14 days apart starting at bloom Stage 5. Spray 20 to 40 grams in 40 to 100 gallons of water per acre per application.</p>
<p>Melon</p> <p>(Not for use in California)</p>	<p>To stimulate fruit set during periods of cool temperatures</p>	<p>1 - 4 GRAMS A.I</p> <p>2.5 – 10 grams product</p> <p>0.1 – 0.4 ounces product</p>	<p>Make application just prior to bloom. For cantaloupes and watermelons two additional applications should be made at intervals of 10-to-14 days.</p>

NOTE:

• For maximum benefits, vines must be in good condition, except for reduced rate of growth due to cool temperatures.

TEMPERATE FRUIT CROPS – SPUR FORMATION			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE/ ACRE	APPLICATION TIMING
Sour Cherry (Not for use in California)	To maintain and extend high fruiting capacity of sour cherry trees by promoting spur formation and reducing the occurrence of "blind" nodes. Spur formation is apparent the year after application. Therefore, changes in shoot, spur, and flower production will not be evident until two or three years after program initiation.	4 - 18 GRAMS A.I 10 – 45 grams product 0.4 – 1.6 ounces product	Apply one spray 14-to-28 days after bloom. Optimum timing is defined as that stage when 3-to-5 terminal leaves have fully expanded, or, at least 1-to-3 inches of terminal shoot extension has occurred. Use 4 – 18 grams a.i. per acre, depending on tree age and vigor (See Table below). Apply as a dilute spray in sufficient water to ensure thorough wetting, or as a concentrate spray ensuring uniform coverage.

NOTE:

- Applications must be applied annually to ensure spur development and subsequent yield improvement year after year.
- Rates are based on expected normal tree vigor at various ages. Adjust rate according to tree vigor. If trees are vigorous, use lowest recommended rates. Lowest rates should also be used on trees that have been heavily pruned or hedged. Use higher rates for trees low in vigor and weak in shoot and spur production. Excessive application rates will increase vegetative growth at the expense of fruit production the following year.
- Applications will not improve growth of trees under stress conditions, such as nutritional, moisture, or pest. Best results will be obtained when combined with good cultural practices.

TREE AGE (YEARS)	GRAMS A.I./ACRE	GRAMS PRODUCT/ ACRE	OUNCES PRODUCT/ ACRE
6-10	4 - 6	10 – 15	0.4 – 0.5
11-15	8 - 10	20 – 25	0.7 – 0.9
16-20	10 - 14	25 – 35	0.9 – 1.3
20 + years	14 - 18	35 – 45	1.3 – 1.6

APPLICATION RATES FOR SOUR CHERRY TREES BY AGE

TEMPERATE FRUIT CROPS – FRUIT QUALITY			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE/ ACRE	APPLICATION TIMING
Sweet Cherry	To produce larger, brighter colored, firmer fruit.	16 – 48 GRAMS A.I 40 – 120 grams product 1.4 – 4.3 ounces product	Apply a single spray when the fruit is translucent green to straw colored. Use sufficient water volume to ensure thorough wetting.
Sweet Cherry in cultivars with uneven maturity (Not for use in California)	To produce larger, brighter colored, firmer fruit	16 – 48 GRAMS A.I 40 – 120 grams product 1.4 – 4.3 ounces product	Make 2 applications. Apply 1/3 to 1/2 of the total desired amount when the majority of the fruit is translucent green, Apply the remaining material 3-7 days later, when the majority of the fruit is straw colored.
NOTE:			
<ul style="list-style-type: none"> • Color development and harvest date is often slightly delayed. • Use higher rates with heavier crop loads. 			
Stone Fruit Group	To increase fruit firmness and improve fruit quality in the season of application	16 - 32 GRAMS A.I 40 – 80 grams product 1.4 – 2.9 ounces product	Apply as a single spray one to 4 weeks prior to the beginning of the harvest period. Use sufficient water to achieve complete coverage of fruits and foliage.
NOTE:			
<ul style="list-style-type: none"> • This application has been known to cause reduction in flower counts the year following the application, particularly if it is made during the months of May through July. 			

<p>Stone Fruit: Italian Prune</p> <p>(Not for use in California)</p>	<p>To reduce internal browning, improve quality, and increase size.</p>	<p>16 - 48 GRAMS A.I</p> <p>40 - 120 grams product</p> <p>1.4 - 4.3 ounces product</p>	<p>Make a single application four to five weeks before expected harvest. Apply in sufficient water volume to ensure thorough wetting.</p>
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NOTE:

- Color development and harvest may be slightly delayed. May reduce bloom the following season.

TEMPERATE FRUIT CROPS - NON BEARING USES

CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE/ ACRE	APPLICATION TIMING
<p>Pecan</p>	<p>To extend leaf retention and enhanced the canopy during late season in pecan; maintaining green foliage later in the season will improve return bloom and fruit set in next season's crop.</p>	<p>10 GRAMS A.I</p> <p>25 g rams product</p>	<p>Make four applications at two week intervals beginning in late August and continuing until mid-October. Apply in 50-100 gals. total volume per acre.</p>

TEMPERATE FRUIT CROPS – NON BEARING USES			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE/ ACRE	APPLICATION TIMING
Non Bearing Stone Fruit (Not for use in California)	To reduce flowering and fruiting in young stone fruit trees in order to minimize the competitive effect of early fruiting on tree development.	20 – 80 GRAMS A.I 50 – 200 grams product 1.8 – 7.2 ounces product	Make a single application during the period of flower bud initiation for the following year. Use sufficient water to achieve good coverage of the canopy.
Non Bearing Blueberry (Not for use in California)	To reduce flowering and fruiting in young blueberry plants in order to minimize the competitive effect of early fruiting on plant development.	20 – 80 GRAMS A.I 50 – 200 grams product 1.8 – 7.2 ounces product	Make one to four applications during the period of flower bud initiation for the following year. Use sufficient water to achieve good coverage of the canopy.
NOTE: Do not spray plants/trees in their first year. Treat in the second season for reduction of flowering in the third season, and again in the third season if flower reduction and fruiting is desired in the fourth season. Treat only plants/trees that are in good physiological condition. Discontinue treatment the year before desired harvest. Consult with the Valent representative or local horticulturist for timings and rates for specific cultivars in your area.			
Strawberry (Not for use in California)	To increase runner production of mother plants.	15 - 25 GRAMS A.I 37.5 – 62.5 grams product 1.4 – 2.3 ounces product	Make a single application to mother plants 10 – 30 days after planting. Plants should have 1-6 leaves at spraying. Apply 100 gallons spray/acre to point of run-off.
NOTE: Not for use on fruiting plants. Treatments have not always been effective on plantings set out after mid-May. Response varies with cultivar and location. Consult your Valent representative or local horticulturist for specific recommendations.			

SPRAY GUIDELINES FOR TROPICAL FRUIT CROPS

TROPICAL FRUIT CROPS – FIELD USES			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE / ACRE	APPLICATION TIMING
Pineapple	To improve fruit size.	125-250 GRAMS A.I. 312.5 – 625 grams product 11.3 – 22.5 ounces product	Apply after flowering. Make 2 applications at 3-5 weeks intervals. Direct sprays to the fruit. Use sufficient water to achieve adequate coverage.

TROPICAL FRUIT CROPS – POST-HARVEST USES			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE	APPLICATION TIMING
Banana / Plantains	Extend fruit green life	750 to 1500 ppm	Spray or brush treatment solution directly to the crown after washing the fruit and before packing.

SPRAY GUIDELINES FOR VEGETABLE CROPS

For vegetable crops, apply in sprays of sufficient water volumes to ensure thorough fruit wetting. Foliage of treated plants occasionally and temporarily appears lighter green in color due to accelerated growth rates following application. Application to plants of low vigor or under stress (pest, nutritional, or water, etc) causes severe leaf yellowing, poor performance and/ or undesirable effects. Tank-mixing with surfactants, fertilizers, and/or other pesticides should not be done unless compatibility and phytotoxicity testing is done first using appropriate methods.

VEGETABLE CROPS			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE/ ACRE	APPLICATION TIMING
Artichoke	To accelerate maturity and shift harvest to an earlier date	10 -20 GRAMS A.I 25 – 50 grams product 0.9 – 1.8 ounces product	For perennials: apply one to three applications at bud initiation stage. For annuals: apply one to four applications at 2-week intervals, beginning at the fourth true leaf. Use sufficient water volume to ensure thorough wetting of the entire plant (leaves, stems and buds).
Carrots Fresh and Processing	To delay leaf senescence. Maintaining vigorous foliage has been shown to help reduce the incidence of infection by <i>Alternaria dauci</i> .	1 - 6 GRAMS A.I 2.5 – 15 grams product 0.1 – 0.5 ounces product	Make the first application 4 –6 weeks after emergence using commercial ground or aerial equipment with spray concentrations of 20-30 ppm. In severe disease situations or cool weather a second spray 14 days later is sometimes required to achieve the desired amount of foliar recovery. Do not apply more than twice per crop.
NOTE: • Dilutions of greater concentration can increase the risk of excessive top growth, particularly with a second application.			

Celery	To increase plant height and yield and to overcome stress due to cold weather conditions or saline soils, and obtain earlier maturity.	2.5 - 10 GRAMS A.I 6.3 - 25 grams product 0.2 - 0.9 ounces product	Make a single application one to four weeks prior to harvest. Use 25-to-50 gallons of water per acre by ground application or 5-to-10 gallons of water per acre for aerial application (except in California). Use lower concentrations if applying 3-to-4 weeks before harvest and higher concentrations within 1-to-2 weeks before harvest.
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NOTE: Do not apply by air in California. Do not apply earlier than 4 weeks before harvest as bolting has been known to occur.

Cucumber (Not for use in California)	To stimulate fruit set during periods of cool temperatures.	1 - 4 GRAMS A.I 2.5 - 10 grams product 0.1 - 0.4 ounces product	Make one application prior to bloom followed by two additional applications at intervals of 10-to-14 days. It is acceptable to use up to four applications. Use sufficient water volume for thorough coverage of exposed foliage.
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NOTE: For maximum benefits, vines must be in good condition, except for reduced rate of growth due to cool temperatures.

Lettuce for Seed	To obtain uniform bolting and increase seed production	1 - 4 GRAMS A.I 2.5 - 10 grams product 0.1 - 0.4 ounces product	Apply one to four applications at two-week intervals, beginning at the fourth true leaf. Use sufficient water volume to ensure thorough wetting.
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Pepper (Not for use in California)	To increase fruit set and promote early season fruit growth	1 - 3 GRAMS A.I 2.5 - 7.5 grams product 0.1 - 0.27 ounces product	Apply one to two sprays of 25 to 50 gallons per acre at weekly intervals during the flowering period.
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NOTE: This use is best for areas with short growing seasons, or when low temperatures slow plant growth. The high rate is most efficacious for areas and/or varieties with pollination and/or fruit set problems.

Pepper (Not for use in California)	To increase fruit size and yield	1 - 3 GRAMS A.I 2.5 - 7.5 grams product 0.1 - 0.27 ounces product	Apply in 25-to-50 gallons of water per acre at the beginning of the picking period.
NOTE: The high rate is best for plants with heavy fruit loads.			
Rhubarb	To break dormancy on plants receiving insufficient chilling and to increase marketable yield of forced rhubarb.	10 - 20 GRAMS A.I 25 - 50 grams product 0.9 - 1.8 ounces product	1) When the rest period is not completely broken, make a single application of 2 fluid ounces (60 ml) of a solution containing 20 grams a.i. in 10 gallons of water to each cleaned crown. 2) When the rest period is broken by cold weather, apply 2 fluid ounces (60 ml) of a solution containing 10 grams a.i. in 10 gallons of water to each cleaned crown.
NOTE: • Keep forcing house temperatures at 40 - 50F for 24 hours after application. If house is warmer than 50F, cover crowns with plastic. Temperatures above 50F lower yields and cause poor stalk color.			
Spinach, Mustard greens, Collard greens and Turnip greens. (Not for use in California)	To facilitate harvest, increase yield and improve quality of fall and over-winter crops.	4 - 10 GRAMS A.I 10 - 25 grams product 0.4 - 0.9 ounces product	Apply a single spray 10-to-18 days before each anticipated harvest on fall or over-winter crops, ideally when daytime temperatures are 40° F-to-70° F and during early morning hours when dew is present on crop. When applied to promote growth of second cutting, wait until some regrowth has started before spraying. Maximum benefit is obtained when below normal

			temperatures prevail following application and growth would be otherwise slowed in untreated crops.
NOTE: • Since the promotion of bolting has been known to occur, do not apply after the mid-winter period or if temperatures are expected to exceed 75 F within several days of application. Do not apply on spring plantings.			

TEMPERATE FIELD CROPS – SEED TREATMENT			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE / 100 LB SEED	APPLICATION TIMING
Rice (semi-dwarf and tall varieties)	To promote germination, emergence and stand uniformity.	0.5 – 2.1 GRAMS A.I 1.25 – 5.25 grams product 0.05 – 0.2 ounces product	For every 100 lbs rice seed to be treated, mix the desired amount of product into 8 – 20 fl ounces of water to form treatment solution.
Note: <ul style="list-style-type: none"> • Do not apply product prior to a 24 hour presoak or to water used for the presoak. • Do not exceed 2.1 grams a.i./100 lbs of seed 			

TEMPERATE FIELD CROPS – FIELD USES			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE/ ACRE	APPLICATION TIMING
Rice	To promote early season plant vigor and more uniform seedling growth prior to permanent flood establishment.	1 – 3 GRAMS A.I 2.5 – 7.5 grams product 0.1 – 0.3 ounces product	Make one to two applications at the 1-2 and/or 4-5 leaf stages of growth.
NOTE: <ul style="list-style-type: none"> • Early flooding reduces the additional flushing costs associated with a delay in establishing the permanent flood, reduce weed infestations and the number of herbicide applications, and/or promote earlier and more uniform grain maturity. • Do not apply prior to the 2-to-3 leaf stage if gibberellin seed treatment is used. • Timing and dosage are to be based upon environmental conditions, tank mix combinations with herbicides, and preferred permanent flood practice in relation to rice leaf stage. • Do not apply when rice is subjected to drought stress conditions. 			
Rice	To promote main culm and tiller panicle extension resulting in improved	3 - 8 GRAMS A.I 7.5 – 20 grams product	Make a single application between split-boot and 100% panicle heading. Heading applications to the

	pollination and seed yield.	0.3 – 0.7 ounces product	first crop also has been observed to accelerate re-growth of second crop rice.
Rice (Hybrid Seed Production)	To promote main culm and tiller panicle extension resulting in improved pollination and seed yield.	20-100 GRAMS A.I 50 – 250 grams product 1.8 – 9.0 ounces product	Make 1-5 applications at regular intervals during the heading period to promote main culm and tiller panicle extension.
Cotton	Promote early season growth and increase seedling vigor.	1 - 6 GRAMS A.I 2.5 – 15 grams product 0.1 – 0.5 ounces products	Apply 1 – 2 applications as a foliar broadcast spray during the 3 to 7 leaf/node stage. If applying as a banded spray reduce rates accordingly. Complete coverage of leaf tissue is essential. Use higher rates when temperatures will likely average 75°F or less during the 14 days following application(s).
Dry Bean	Promotes early season growth, increased seedling vigor, and increased plant height allowing for improved harvesting efficiency.	1 - 6 GRAMS A.I 2.5 – 15 grams product 0.1 – 0.5 ounces products	Apply 1 – 2 applications as a foliar broadcast spray during the 3 to 7 leaf/node stage. If applying as a banded spray reduce rates accordingly. Complete coverage of leaf tissue is essential. Use higher rates when temperatures will likely average 75°F or less during the 14 days following application(s).

NOTE:

- Do not apply plants that are under drought stress. If plants are under continuous stress, delay the application until the stress is alleviated and the plants are beginning to recover.
- Applying more often than necessary to achieve the desired height results in excessive vegetative growth.
- Avoid drift or accidental application to other crops.

Hops Seeded and seedless Fuggle hops and similar varieties adapted to the North-western states.	To increase fruit set and yield.	4 - 6 GRAMS A.I 10 - 15 grams product 0.4 - 0.5 ounces product	Make a single application in 100-150 gallons of water per acre when vine growth is 5-8 feet in length.
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Wheat seed treatment (Not for Use in California)	To promote germination, emergence, and plant establishment, particularly for seed with dormancy problems that are planted under cool soil conditions.	0.1 -0.27 oz product in 8-20 fl oz water / 100 lb seed. (1.0 to 3.0 grams a.i. or 2.5-7.5 grams product in 237-591 ml / 45 kg seed.	Do not exceed 0.27 oz. Product / 100 lb seed.
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SPRAY GUIDELINES FOR WATERCRESS:

DIRECTIONS FOR CHEMIGATION

Fill the supply tank with the desired amount of water. Then add the amount of ProGibb 40% required in order to achieve the final solution rate recommended for the specific crop to be treated. Agitate the mixture of ProGibb 4% frequently during the chemigation period to assure a uniform distribution throughout the system. Apply ProGibb 4% continuously for the duration of the water application but do not exceed recommended rates and volumes as outlined on the product label.

CHEMIGATION PRECAUTIONS

Apply this product only through the following systems: Overhead sprinklers such as impact, micro-sprinklers, or booms. Do not apply this product through any other type of irrigation system. Crop injury or lack of effectiveness can result from nonuniform distribution of treated water. If you have any questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts. Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label prescribed safety devices for public water systems are in place. A person knowledgeable of the chemigation system and responsible for its operation or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise. Prior to application ensure that the chemigation system meets the following requirements:

- The system must contain a functional check valve, vacuum relief valve, and low-pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
- The pesticide injection pipeline must contain a functional, automatic, quick closing check valve to prevent the flow of fluid back toward the injection pump.
- The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- The irrigation line or water pump must include a functional pressure switch, which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.

- Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

In addition to the above use rates and recommendations, the following precautions must be observed when using this product in any type of irrigation system.

CHEMIGATION SYSTEMS CONNECTED TO PUBLIC WATER SYSTEMS

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days of the year. Chemigation systems connected to public water systems must contain a functional, reduced pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water systems should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe. The pesticide injection pipeline must contain a functional, automatic, quick closing check valve to prevent the flow of fluid back toward the injection pump. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where the pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Watercress			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE/ ACRE	APPLICATION TIMING
Watercress	1) To enhance growth in adverse weather conditions; 2) To help plants resume growth after insect and	15 - 25 GRAMS A.I 37.5 – 62.5 grams product 1.4 – 2.3 ounces product	Make one or two applications per acre per crop 3 to 7 days before harvest. Use 50-100 gallons of water per acre.

	disease attacks; 3) To increase root free stem length during low light/short day conditions.		
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PROGIBB 40% CONVERSIONS

ProGibb 40% contains 1.0 gram of active ingredient per 2.5 grams (0.09 oz) of product.

To convert from Grams AI to Grams Product – Multiply grams AI x 2.5
 (i.e. 32 g a.i. x 2.5 = 80g ProGibb 40%)

To convert from Grams AI to Dry Ounces Product – Multiply grams AI x 0.09
 (i.e. 32 g a.i. x 0.09 = 2.9 oz ProGibb 40%)

CONVERSION TABLE (for the 320 g size)

Grams of Active Ingredient	Grams of ProGibb 40%	Ounces of ProGibb 40%
2	5	0.2
4	10	0.4
5	12.5	0.5
6	15	0.6
8	20	0.7
10	25	0.9
15	37.5	1.4
20	50	1.8
30	75	2.7
40	100	3.6
50	125	4.5
60	150	5.4
80	200	7.2
100	250	9.0
128	320	11.5

Grams of ProGibb 40% WSG for given ppm's of Gibberellic Acid at Different Water Volumes.

Gallons of Water	Desired parts per million (ppm) gibberellic acid									
	4	5	6	8	10	15	20	30	40	50
75	1.5	3	4.5	6	7.5	11	14	21	28	35
100	2	4	6	8	10	14	19	28	38	47
125	2.5	5	7.5	9	12	18	24	35	47	59
150	3	6	9	11	14	21	28	43	57	71
200	4	8	11	15	19	28	38	57	76	95
250	5	10	14	19	24	35	47	71	95	118
300	5.5	11	17	23	28	43	57	85	113	142
400	7.5	15	23	30	38	57	76	113	151	189
500	9.5	19	28	38	47	71	95	142	189	236
600	11	23	34	45	57	85	113	170	227	284
750	14	28	43	57	71	106	142	213	284	

Note: The numbers inside the table are the grams of ProGibb 40% WSG needed to obtain the desired ppm's for each gallonage.

Example:

To make 250 gallons of a 40 ppm gibberellic acid solution, dissolve 95 grams of ProGibb 40% WSG in 250 gallons of water (see shaded area).

CONVERSION TABLE (for the 80 g size)

ProGibb 40% contains approximately 10 grams of active ingredient per 25 grams of product.

Grams of Active Ingredient	Grams of ProGibb 40%	Ounces of ProGibb 40%
2	5	0.2
4	10	0.4
5	12.5	0.5
6	15	0.6
8	20	0.7
10	25	0.9
15	37.5	1.4
20	50	1.8
30	75	2.7
40	100	3.6
50	125	4.5
60	150	5.4
80	200	7.2

(Alternate for 80 g packaging)

Gallons of Water	parts per million (ppm) gibberellic acid									
	4	5	6	8	10	15	20	30	40	50
75	3.0	3.8	4.5	6.0	7.5	11.3	15.0	22.5	30.0	38
100	4.0	5.0	6.0	8.0	10.0	15.0	20.0	30.0	40.0	50
125	5.0	6.3	7.5	10.0	12.5	18.8	25.0	37.5	50.0	63
150	6.0	7.5	9.0	12.0	15.0	22.5	30.0	45.0	60.0	75
200	8.0	10.0	12.0	16.0	20.0	30.0	40.0	60.0	80.0	

Note: The numbers inside the table are the grams of ProGibb 40% WSG needed to obtain the desired ppm's for each gallonage.

Example:

To make 200 gallons of a 40 ppm gibberellic acid solution, dissolve 80 grams of ProGibb 40% WSG in 200 gallons of water (see shaded area).

Warranty and Disclaimer Statement:

To the fullest extent permitted by law, seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning use of this product other than as indicated on the label. User assumes all risks of use, storage or handling not in strict accordance with accompanying directions.

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SUB-LABEL II

RyzUp Smartgrass™
PLANT GROWTH REGULATOR
Water Soluble Granule

For agricultural use on Pastures and commercial use on Sod and Turf.

**RyzUp Smartgrass™
Plant Growth Regulator
Water Soluble Granule**

For Organic Production

Active Ingredient	40.0% w/w
Gibberellin A ₃	60.0% w/w
Other Ingredients.....	100.0% w/w
Total.....	

Contains a total of 128 g of Gibberellic Acid in 320 g of product.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See inside booklet for Precautionary Statements.

EPA Registration No. 73049-1
EPA Establishment No.

Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, IL 60048
1-847-968-4700

Net Contents: 320 g
This container will treat ___ acre at the maximum use rate, as directed for use on _____.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also call toll-free 1-800-892-0099 (24 hours) for emergency medical treatment and/or transport emergency information. For all other information, call 1-800-6-Valent.</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

Caution: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants.
- Waterproof gloves.
- Shoes plus socks.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning or disposing of equipment washwaters or rinsate.

Do not use treated seed for food, feed, or oil purposes. Exposed treated seed may be hazardous to birds and other wildlife. Treat only those seeds needed for immediate use and planting. Do not store excess treated seed beyond planting time. Dispose of all excess treated seed and seed packaging by burial away from bodies of water.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribe agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours *unless wearing appropriate PPE*.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls.
- Waterproof gloves.
- Shoes plus socks.

GENERAL DIRECTIONS FOR USE

Use only as directed. Read the label thoroughly and make sure it is understood before making applications. Keep out of reach of children.

Application Instructions:

- Ryzup Smartgrass water soluble granule contains gibberellic acid which is an extremely potent plant growth regulator; when applying plant growth regulators, deviations from the label directions in the rates, timings, water volumes, or the adoption of untested spray mixes, results in undesirable effects. Always consult the local Valent representative in your area for the spray regimen best suited to your conditions.
- Do not apply to plants under pest, nutritional, or water stress.
- When a range of rates is indicated, use the concentration and spray volume indicated locally by the local Valent representative.
- For optimum effectiveness, thorough spray coverage of the target area must be achieved. Prepare solution concentrations by mixing the required amount of product with water in a clean, empty spray tank. Discard any unused spray material at the end of each day following local, state or federal law.
- For most efficacious results, the water pH is best at 7.0, and always below 8.5.
- Applications made under slow drying conditions (cool to warm temperatures, medium to high relative humidity, and no wind) will increase absorption of the active ingredient by the plant, thus optimizing effectiveness. Night-time applications are encouraged when day-time conditions are not conducive to slow drying conditions.
- Product persistence: Re-apply if significant rain occurs within 2 hours of application.
- Compatibility: When considering tank mixing with other products, use the following compatibility jar test before mixing a whole tank.

Start with a clear glass or plastic quart jar. Add water from the same water source that will be used for the larger tank mix. Add the pesticides in correct proportions. Mix thoroughly and let stand for a minimum 15 minutes. Heat, separation, gelling, are all signs of incompatibility. Before using any mixes that pass the jar tests for compatibility, it is imperative to test the mixture on a designated area as it may result either in phytotoxicity or ineffectiveness. For further information, consult your local Valent representative.

- For aerial applications spray volumes must be greater than 2 gallons per acre (10 gallons per acre for tree crops).

- No preharvest interval is required for this product.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage

Keep containers tightly closed when not in use.

Pesticide Disposal

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Disposal

Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or mix tank. Fill container $\frac{1}{4}$ full with water and recap. Shake 10 seconds. Pour rinsate into application equipment or mix tank or store rinsate for later use or disposal. Drain for 10 seconds after flow begins to drip. Repeat this procedure two more times. Then offer for recycling or dispose of in a sanitary landfill, or incineration, if allowed by state and local authorities by burning. If burned, stay out of smoke.

SPRAY GUIDELINES

Apply in sprays of sufficient water volumes to ensure thorough wetting. Foliage of treated plants occasionally and temporarily appears lighter green in color due to accelerated growth rates following application. Application to plants of low vigor or under stress (pest, nutritional, or water, etc) causes severe leaf yellowing, poor performance and/ or undesirable effects. Tank-mixing with surfactants, fertilizers, and/or other pesticides should not be done unless compatibility and phytotoxicity testing is done first using appropriate methods.

DIRECTIONS FOR CHEMIGATION

Fill the supply tank with the desired amount of water. Then add the amount of Ryzup Smartgrass required in order to achieve the final solution rate recommended for the specific crop to be treated. Agitate the mixture of Ryzup Smartgrass frequently during the chemigation period to assure a uniform distribution throughout the system. Apply of Ryzup Smartgrass continuously for the duration of the water application but do not exceed recommended rates and volumes as outlined on the product label.

CHEMIGATION PRECAUTIONS

Apply this product only through the following systems: Overhead sprinklers such as impact, micro-sprinklers, or booms. Do not apply this product through any other type of irrigation system. Crop injury or lack of effectiveness can result from nonuniform distribution of treated water. If you have any questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts. Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label prescribed safety devices for public water systems are in place. A person knowledgeable of the chemigation system and responsible for its operation or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise. Prior to application ensure that the chemigation system meets the following requirements:

- The system must contain a functional check valve, vacuum relief valve, and low-pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
- The pesticide injection pipeline must contain a functional, automatic, quick closing check valve to prevent the flow of fluid back toward the injection pump.
- The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- The irrigation line or water pump must include a functional pressure switch, which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

In addition to the above use rates and recommendations, the following precautions must be observed when using this product in any type of irrigation system.

CHEMIGATION SYSTEMS CONNECTED TO PUBLIC WATER SYSTEMS

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days of the year. Chemigation systems connected to public water systems must contain a functional, reduced pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water systems should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe. The pesticide injection pipeline must contain a functional, automatic, quick closing check valve to prevent the flow of fluid back toward the injection pump. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where the pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

PASTURES – FIELD USES			
CROP/ VARIETY	OBJECTIVE/ BENEFIT	USE RATE/ ACRE	APPLICATION TIMING
Pasture Grass	To stimulate dry matter production when cool season soil conditions limit natural pasture growth rates.	3 - 11 GRAMS A.I 7.5 – 27.5 grams product 0.3 – 1.0 ounces product	Apply 1 to 6 applications every 3 to 4 weeks from late autumn to early spring. Allow at least 1 – 5 days after grazing before treating. Moisture levels and fertility must be adequate for grass growth prior to application.
NOTE: <ul style="list-style-type: none"> • Do not apply to pastures that are not at least 1 year old.. • When natural pasture grass growth is very rapid, grass may not respond with additional growth. • Do not apply when pasture grass is subjected to drought stress conditions. • Foliage occasionally and temporarily appears lighter green in color due to accelerated growth rates following application. 			
Bermudagrass (Tifdwarf, Tifgreen, and other cultivars)	To initiate or maintain growth and prevent color change during periods of cold stress and light frosts.	10-25 GRAMS A.I 25 – 62.5 grams product 0.9 – 2.3 ounce product	Under cool conditions, apply 10 grams a.i./acre weekly or 25 grams a.i./acre biweekly in 25-to-100 gallons of water/acre.
Bermudagrass Tifdwarf, Tifgreen	To maintain or enhance regrowth Bermudagrass during summer months.	1-3 GRAMS A.I 2.5 – 7.5 grams product 0.1 – 0.3 ounces product	Under hot conditions, apply 1-to-3 grams a.i./acre weekly in 25-to-100 gallons of water/acre.
NOTE: <ul style="list-style-type: none"> • Maintain adequate moisture and proper fertilization programs as required for the local area. • Keep applications of the high rate at least two weeks apart. • Do not use on dormant grass • Discontinue treatments if thinning is observed. • More frequent mowing is occasionally necessary. 			

CONVERSION TABLE (for the 320 g size)

Ryzup Smartgrass contains approximately 10 grams of active ingredient per 25 grams of product.

Grams of Active Ingredient	Grams of ProGibb 40%	Ounces of ProGibb 40%
2	5	0.2
4	10	0.4
5	12.5	0.5
6	15	0.6
8	20	0.7
10	25	0.9
15	37.5	1.4
20	50	1.8
30	75	2.7
40	100	3.6
50	125	4.5
60	150	5.4
80	200	7.2
100	250	9.0
128	320	11.5

Grams of ProGibb 40% WSG for given ppm's of Gibberellic Acid at Different Water Volumes.

Gallons of Water	Desired parts per million (ppm) gibberellic acid									
	4	5	6	8	10	15	20	30	40	50
75	1.5	3	4.5	6	7.5	11	14	21	28	35
100	2	4	6	8	10	14	19	28	38	47
125	2.5	5	7.5	9	12	18	24	35	47	59
150	3	6	9	11	14	21	28	43	57	71
200	4	8	11	15	19	28	38	57	76	95
250	5	10	14	19	24	35	47	71	95	118
300	5.5	11	17	23	28	43	57	85	113	142
400	7.5	15	23	30	38	57	76	113	151	189
500	9.5	19	28	38	47	71	95	142	189	236
600	11	23	34	45	57	85	113	170	227	284
750	14	28	43	57	71	106	142	213	284	

Note: The numbers inside the table are the grams of RyzUp Smartgrass™ WSG needed to obtain the desired ppm's for each gallonage.

Example:

To make 250 gallons of a 40 ppm gibberellic acid solution, dissolve 95 grams of RyzUp Smartgrass™ WSG in 250 gallons of water (see shaded area).

CONVERSION TABLE (for the 80 g size)

ProGibb 40% contains approximately 10 grams of active ingredient per 25 grams of product.

Grams of Active Ingredient	Grams of ProGibb 40%	Ounces of ProGibb 40%
2	5	0.2
4	10	0.4
5	12.5	0.5
6	15	0.6
8	20	0.7
10	25	0.9
15	37.5	1.4
20	50	1.8
30	75	2.7
40	100	3.6
50	125	4.5
60	150	5.4
80	200	7.2

(Alternate for 80 g packaging)

Gallons of Water	parts per million (ppm) gibberellic acid									
	4	5	6	8	10	15	20	30	40	50
75	3.0	3.8	4.5	6.0	7.5	11.3	15.0	22.5	30.0	38
100	4.0	5.0	6.0	8.0	10.0	15.0	20.0	30.0	40.0	50
125	5.0	6.3	7.5	10.0	12.5	18.8	25.0	37.5	50.0	63
150	6.0	7.5	9.0	12.0	15.0	22.5	30.0	45.0	60.0	75
200	8.0	10.0	12.0	16.0	20.0	30.0	40.0	60.0	80.0	

Note: The numbers inside the table are the grams of RyzUp Smartgrass™ WSG needed to obtain the desired ppm's for each gallonage.

Example:

To make 200 gallons of a 40 ppm gibberellic acid solution, dissolve 80 grams of RyzUp Smartgrass™ WSG in 200 gallons of water (see shaded area).

WARRANTY AND DISCLAIMER STATEMENT

To the fullest extent permitted by law, seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning use of this product other than as indicated on the label. User assumes all risks of use, storage or handling not in strict accordance with accompanying directions.

Ryzup Smartgrass is a registered trademark of Valent BioSciences Corporation.
Products That Work, From People Who Care is a trademark of Valent U.S.A.
Corporation.

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Registered by:

Valent BioSciences Corporation

870 Technology Way, Suite 100

Libertyville, IL 60048

04-XXXX/RX

Distributed by Valent U.S. A. Corporation.

ProGibb® Technical Powder
MSDS# BIO-0068 Rev. 2

ISSUED 02/23/10

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MATERIAL NAME: ProGibb® Technical Powder
EPA Reg.No.: 73049-4
Code Number: 52705
List Number: 5158

SYNONYMS: Gibberellic Acid Technical Powder

MANUFACTURER: Valent BioSciences Corporation
870 Technology Way, Suite 100
Libertyville, Illinois 60048

EMERGENCY TELEPHONE NUMBERS

Emergency Health or Spill:

Outside the United States: 651-632-6184
Within the United States: 877-315-9819

2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT NAME: Gibberellic Acid (GA3)
CONCENTRATION: 90.00%
CAS NUMBER: 77-06-5
OSHA-PEL 8HR TWA: N/L
STEL: N/L
CEILING: N/L
ACGIH-TLV 8HR TWA: N/L
STEL: N/L
CEILING: N/L
OTHER 8HR TWA: N/A
LIMITS STEL: N/A
CEILING: N/A

INGREDIENT NAME: Proprietary Ingredients
CONCENTRATION: 10.00%
CAS NUMBER: NA
OSHA-PEL 8HR TWA: N/L
STEL: N/L
CEILING: N/L
ACGIH-TLV 8HR TWA: N/L
STEL: N/L
CEILING: N/L
OTHER 8HR TWA: N/A
LIMITS STEL: N/A
CEILING: N/A

ProGibb® Technical Powder
MSDS# BIO-0068 Rev. 2

ISSUED 02/23/10

3. HAZARDS INFORMATION

EMERGENCY OVERVIEW: This material is non-toxic by ingestion, skin contact, or inhalation. This material is a moderate eye irritant.

ROUTE(S) OF ENTRY: Skin: No
 Inhalation: Possible, but unlikely
 Ingestion: No

SKIN CONTACT: Non-irritant

SKIN SENSITIZATION: Non-sensitizer

EYE CONTACT: Moderate irritant

TARGET ORGANS: Eyes (Irritation)

CARCINOGENICITY RATING: NTP: N/L IARC: N/L OSHA: N/L ACGIH: N/L
None

SIGNS AND SYMPTOMS: Direct contact and/or overexposure to the dust may cause mechanical irritation which may result in coughing, sneezing, and eye and skin irritation.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: None that are known.

4. FIRST AID MEASURES

EYES: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

SKIN: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

INGESTION: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

INHALATION: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

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5. FIRE FIGHTING PROCEDURES

FLASH POINT: N/A
FLASH POINT METHOD: N/A
LOWER EXPLOSIVE LIMIT(%): N/A
UPPER EXPLOSIVE LIMIT(%): N/A
AUTOIGNITION TEMPERATURE: N/D

FIRE & EXPLOSION HAZARDS: Non-flammable and no explosive properties.

EXTINGUISHING MEDIA: Use appropriate medium for underlying cause of fire.

FIRE FIGHTING INSTRUCTIONS: Wear protective clothing and self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

SPILL OR RELEASE PROCEDURES: Recover product, place into appropriate container for disposal. Avoid dust. Ventilate and wash spill area.

7. HANDLING AND STORAGE

HANDLING: The usual precautions for handling chemicals should be observed.

STORAGE: Avoid excessive temperatures and direct sunlight. Store in dry area, keep material dry and container tightly closed.

SPECIAL PRECAUTIONS: Wash thoroughly with soap and water after handling.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: Use local exhaust.

RESPIRATORY PROTECTION: Not usually required. If necessary, use a MSHA/NIOSH approved (or equivalent) respirator with high efficiency filter.

SKIN PROTECTION: Impervious gloves, clothing to minimize skin contact.

EYE PROTECTION: Safety glasses or goggles.

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9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: White, fine powder
ODOR: Odorless
BOILING POINT: N/A
MELTING/FREEZING POINT: 223.0 - 226.0° C
VAPOR PRESSURE (mm Hg): N/A
VAPOR DENSITY (Air=1): N/A
EVAPORATION RATE: N/A
BULK DENSITY: 0.60 g/ml
SPECIFIC GRAVITY: N/D
SOLUBILITY: Soluble in water and alcohols.
pH: 2.7 (1% aqueous solution)
VISCOSITY: N/A

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable under normal conditions of use.
INCOMPATIBILITIES: None that are known.
HAZARDOUS DECOMPOSITION PRODUCTS: N/D.
HAZARDOUS POLYMERIZATION: Will not occur.

11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

ORAL LD50: > 5,000 mg/kg (rat)
DERMAL LD50: > 2,000 mg/kg (rabbit)
INHALATION LC50: > 1.44 mg/l (rat) No lethality resulted at the highest attainable concentration for this 4-hour, nose-only exposure.
CORROSIVENESS: N/D. Not expected to have any corrosive properties.
DERMAL IRRITATION: Produced slight to well-defined redness at site of application in several animals. Not classified as a skin irritant.
OCULAR IRRITATION: Conjunctival irritation was observed in test animals immediately after application. Effects were temporary. Classified as a mild to moderate irritant.

ProGibb® Technical Powder
MSDS# BIO-0068 Rev. 2

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11. TOXICOLOGICAL INFORMATION, continued

DERMAL SENSITIZATION: Product did not produce evidence of skin sensitization in test animals. Not classified as a sensitizer.

SPECIAL TARGET ORGAN EFFECTS: In reproduction studies in rats, no maternal or fetal toxicity, or other adverse effects to the fetus were noted following large dosages (1000 mg/kg/day) of gibberellic acid.

CARCINOGENICITY INFORMATION: N/D. None of the components are classified as carcinogens.

12. ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: N/D

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHODS: Dispose of product in accordance with federal, state, and local regulations.

14. TRANSPORTATION INFORMATION

DOT STATUS: Not Regulated
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
UN NUMBER: N/A
PACKING GROUP: N/A
REPORTABLE QUANTITY: N/A

IATA/ICAO STATUS: Not Regulated
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
UN NUMBER: N/A
PACKING GROUP: N/A
REPORTABLE QUANTITY: N/A

IMO STATUS: Not Regulated
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
UN NUMBER: N/A
PACKING GROUP: N/A
REPORTABLE QUANTITY: N/A
FLASH POINT: N/A

ProGibb® Technical Powder
MSDS# BIO-0068 Rev. 2

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15. REGULATORY INFORMATION

TSCA STATUS: Exempt

RCRA STATUS: N/D

CERCLA STATUS: N/D

PROP 65 (CA): N/D

SARA STATUS: N/D

16. OTHER INFORMATION

REASON FOR ISSUE	Reviewed and reissued with current date.
APPROVAL DATE	02/23/10
SUPERSEDES DATE	08/08/03
MSDS NUMBER	BIO-0068, replaces MSDS #BIO-0176 Rev. 0

LEGEND: N/A = Not Applicable

N/D = Not Determined

N/L = Not Listed

L = Listed

C = Ceiling

S = Short-term

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VALENT BIOSCIENCES.
CORPORATION

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Libertyville, IL 60048 - 800-323-9597

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Study Title
PRODUCT IDENTITY
MANUFACTURING PROCESS
FORMATION OF UNINTENTIONAL INGREDIENTS
Gibberellic Acid (GA3)

Data Requirements

151-10/OPPTS 880.1100 Product Identity and Disclosure of Ingredients
151-11/OPPTS 880.1200 Manufacturing Process / Formulation Process
151-12/OPPTS 880.1400 Discussion on the Formation of Unintentional Ingredients

Authors

Thomas Bade Ph.D.

Date

July 19, 2007

Author Address

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Project ID

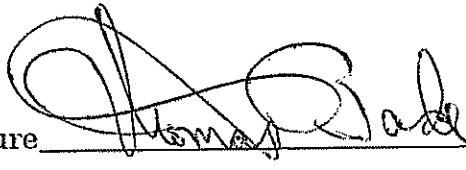
VBC-(GA3); 07-1

Statement of Data Confidentiality Claims

Information claimed confidential on the basis of its falling within the scope of FIFRA 10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

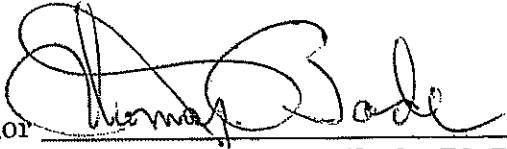
Company: Valent BioSciences Corp


Company Agent: Thomas Bade, Ph.D.
Regulatory Manger
Regulatory Affairs

Signature  Date 7/19/07

GLP COMPLIANCE STATEMENT

The information contained in this document does not meet the requirements of GLP (40 CFR 160) because it is descriptive in nature, and not a study.

Author  Date 7/19/07
Thomas Bade, Ph.D.
Valent BioSciences Corp.

Sponsor  Date 7/19/07
Thomas Bade, Ph.D.
Regulatory Manager, Regulatory Affairs
Valent BioSciences Corp.

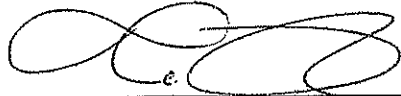
Submitter  Date 7-19-07
Maria Pilar Herrero
Regulatory Manager, Regulatory Affairs
Valent BioSciences Corp.

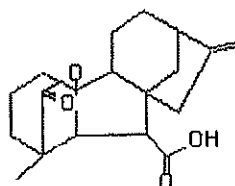
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PRODUCT IDENTITY

Gibberellic acid (GA3) is a plant growth regulator.

Common Name:	Gibberellic Acid, (GA3)
ISO Name:	None
Chemical Abstracts Name:	(1 α ,2 β ,4 α ,4 β ,10 β)-2,4a,7-trihydroxy-1-methyl-8-methylenegibb-3-ene-1,10-dicarboxylic acid 1,4a-lactone
IUPAC Name:	(3S,3aS,4S,4aS,7S,9aR,9bR,12S)-7,12-dihydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenoazuleno[1,2-b]furan-4-carboxylic acid
CAS Number:	77-06-5
Molecular Formula:	C ₁₉ H ₂₂ O ₆
Molecular weight:	346.4 g/mole
Structure:	



Color:	White
Physical State:	Fine Powder
Odor:	Odorless
Boiling Point:	NA
Melting Point:	223 - 224° C
Bulk Density:	0.60 gm/ml
pH:	2.7 (in a 1% slurry)
Solubility:	
Water	0.46 gm/100 ml
Organic Solvents	2.6 gm/100 ml (isopropanol, 25° C)
	0.0028 gm/100 ml (chloroform, 25° C)

880.1100 Product Identity and Disclosure of Ingredients

And

Certification of Limits

PLACE HOLDER PAGE

Composition of Technical Grade Active Ingredient.

The contents of this section have been removed to Confidential Cross-Reference 1.

880.1200 Manufacturing Process

Description of the Basic Manufacturing Process and Beginning Materials

PLACE HOLDER PAGE

The contents of this section have been removed to Confidential Cross-Reference 2.

880.1200 Manufacturing Process (continued)

B. Toxic or sensitizing substances

None of the materials that are present in gibberellic acid technical grade active ingredient are considered to be toxic or sensitizing.

151-12/OPPTS 880.1400 Discussion on the Formation of Unintentional Ingredients

PLACE HOLDER PAGE

The contents of this section have been removed to Confidential Cross-Reference 3.

CONFIDENTIAL APPENDIX
CROSS-REFERENCE 1

Study Title

PRODUCT IDENTITY
MANUFACTURING PROCESS
FORMATION OF UNINTENTIONAL INGREDIENTS
Gibberellic Acid (GA3)

Data Requirements

OPPTS 880.1100 Product Identity and Disclosure of Ingredients
OPPTS 880.1200 Description of starting materials, production and
formulation process
OPPTS 880.1400 Discussion on formation of unintentional ingredients

Authors

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CONFIDENTIAL APPENDIX

Cross-Reference 1: This cross-reference number noted on place-holder page 7 is used in place of the following whole pages at the indicated volume and page reference.

Deleted Pages: Attached immediately behind this page

<u>Page Reference</u>	<u>Line</u>	<u>Reason for deletion</u>	<u>FIFRA</u>
6	All	Certification of Limits	10(d)(1)(C)

CERTIFICATION OF LIMITS

Comment [c1]:
CBI deleted Confidential Statement of Formula

Current Approved CSF (70349-4)

	Nominal %w/w	Maximum %w/w	Minimum %w/w	
Gibberellic Acid (GA3) CAS No. 65733-16-6	90.0	94.0	85.0	Active Ingredient
[REDACTED]	■	■	■	■
[REDACTED]	■	■	■	■
[REDACTED]	■	■	■	■
[REDACTED]	■	■	■	■
[REDACTED]	■	■	■	■

CONFIDENTIAL APPENDIX

Cross-Reference 2: This cross-reference number noted on place-holder page 7 is used in place of the following whole pages at the indicated volume and page reference.

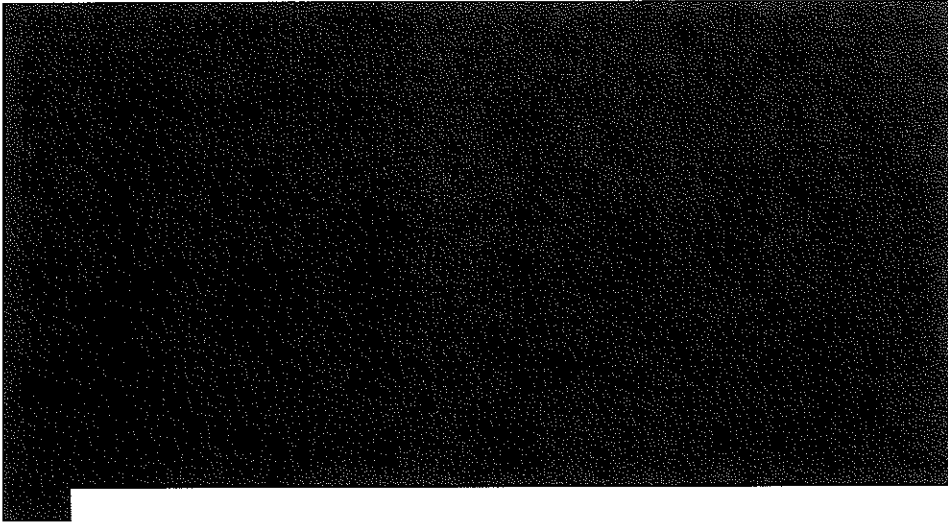
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<u>Page Reference</u>	<u>Line</u>	<u>Reason for deletion</u>	<u>FIFRA</u>
7	All	Disclosure of Ingredients	10(d)(1)(C)

TABLE OF CONTENT

[Material Safety Data Sheets for Beginning Materials]

Comment [c4]:
CBI Deleted



CBI-deleted
Pages 9 to 100

Confidential manufacturing information

Comment [c5]:
CBI Deleted
Pages 9 to 100 Confidential
Manufacturing Information

CONFIDENTIAL APPENDIX

Cross-Reference 3: This cross-reference number noted on place-holder page 8 is used in place of the following whole pages at the indicated volume and page reference.

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<u>Page Reference</u>	<u>Line</u>	<u>Reason for deletion</u>	<u>FIFRA</u>
8	All	Manufacturing process	10(d)(1)(A)

MANUFACTURING PROCESS

I. Strain Maintenance and Seed Preparation

A. Organism Identification

Family: *Hypocreaceae*
Genus: *Gibberella*
Species: *fujikuroi*

B. Frozen Vials and Slants

Comment [c6]:
CBI Deleted

[Redacted]
[Redacted]
[Redacted]
[Redacted]

A purity evaluation is performed to assure culture integrity.

C. Inoculum Flasks

Comment [c7]:
CBI Deleted

[Redacted]
[Redacted]
[Redacted]
[Redacted]

A purity evaluation is performed to assure culture integrity.

D. Seed Tanks

Comment [c8]:
CBI Deleted

The entire content of the QC approved flask inoculum is used to inoculate seed tanks.

[REDACTED]

For each set of new working slants, shake flasks are run to evaluate the performance of the slants before they are used in production.

II. Gibberellin Fermentation Process

A. Medium and Raw Material Specifications

Several formulations of raw materials have been used to successfully manufacture gibberellin products. The raw materials and are listed in the following table:

B. Fermentation Operation

Comment [c10]:
CBI Deleted

During fermentation process, the fermentation parameters are controlled according to a pre-established protocol. [REDACTED]

[REDACTED]

[REDACTED]

These parameters are monitored and recorded [REDACTED]

[REDACTED]

[REDACTED]

At the end of the fermentation, the fermentation broth is harvested and transferred [REDACTED]

[REDACTED]

III. Gibberellin Purification Process

Comment [c11]:
CBI Deleted

A. Step 1. Filtration of Fermentation Broth

[REDACTED]

[REDACTED] filtration system. The filtrate is [REDACTED]

[REDACTED]

C、 Step 3. Concentration

Concentrate the filtrate 10 – 12 folds using [REDACTED]

D、 Step 4. - Extraction

In extraction tank, adjust gibberellin solution to [REDACTED]

E、 Step 5. Concentration and Crystallization

[REDACTED]

F、 Step 6. Drying

[REDACTED]

IV. Quality Control

[REDACTED]

Comment [c12]:
CBI Deleted

Comment [c13]:
CBI Deleted

A. Raw Materials

Raw material suppliers are selected based on, amongst other factors, the quality of raw materials, background checks, and audit results of the suppliers. [REDACTED]

[REDACTED]

B. In Process Quality Control

[REDACTED]

[REDACTED] Through quality control checks at each stage of our production process, we ensure that our intermediate products meet our stage release requirements prior to proceeding with the next process stage.

C. Finished products quality control

Our finished products are subject to a last round of quality tests prior to packaging in order to ensure that only products that pass our quality control specifications are released and delivered to our customers.

Comment [c14]:
CBI Deleted

[REDACTED]

D. Storage quality control

To ensure the quality of our finished products during storage, we store our finished products in a product warehouse [REDACTED]

[REDACTED]

E. Pre-sales quality control

Prior to delivering our products to customers, our quality control staff will check the product again [REDACTED]

[REDACTED]

CONFIDENTIAL APPENDIX

Cross-Reference 4: This cross-reference number noted on place-holder page 9 is used in place of the following whole pages at the indicated volume and page reference.

Deleted Pages: Attached immediately behind this page

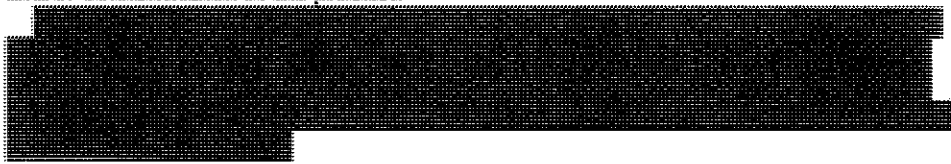
<u>Page Reference</u>	<u>Line</u>	<u>Reason for deletion</u>	<u>FIFRA</u>
9	All	Discussion on the Formation of Unintentional Ingredients	10(d)(1)(A)

DISCUSSION ON THE FORMATION OF UNINTENTIONAL INGREDIENTS

Comment [c15]:
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To prevent the formation of unintentional ingredients during the manufacturing of Gibberellic Acid (GA3) Technical Grade Active Ingredient (TGAI), "Good Lab Practices" are followed in product preparations. Strict quality assurance specifications and compliance procedures are in place to assure that all raw materials used in the preparation of Gibberellic Acid (GA3) meet identity and purity requirements necessary to control product quality and stability.

All the equipments used in the preparation of Gibberellic Acid (GA3) are cleaned according to the guidelines described, to avoid the formation of unintentional ingredients ~~and/or contamination of the product.~~



Based on the 95% purity of Gibberellic Acid (GA3) Technical Grade Active Ingredient, no impurities of toxicological significant are considered to be present.

References

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Hedden, P., J. MacMillan and B.O. Phinney, 1978. The metabolism of the gibberellins. *Ann. Reev. Plant Physiol.*, 29:149-192.