

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 14, 2016

Georgia Anastasiou Agent Plant Cell Technology, Inc. c/o Lewis & Harrison, LLC 122 C Street, N.W. Suite 505 Washington, DC 20001

Subject: Label and CSF Amendment – Updating CSF and Revising Ingredient Statement

Product Name: PPM

EPA Registration Number: 71806-1

Application Date: 12/06/16 Decision Number: 524244

Dear Ms. Anastasiou:

The amended label and CSF referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Please note that the record for this product currently contains the following CSF:

Basic CSF dated 11/18/16

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false

Label and CSF Acceptable v.20150821

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or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at heffernan.aline@epa.gov.

Sincerely,

John Hebert, Chief

Regulatory Management Branch I Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure Stamped Label

Precautionary Statements Hazards to Humans and Domestic Animals **CAUTION**

Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Use rubber gloves when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

FIRST AID

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

IF IN EYES: 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. Call a poison control center or doctor for treatment advice.

IF ON SKIN: 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.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

PPM is a broad-spectrum preservative and biocide. PPM is an excellent preservative agent that can be used in research and commercial laboratories to inhibit the growth of, or kill bacteria and fungi in plant tissue culture growth media. It targets fundamental enzymes in the Krebs cycle and in the Electron Transport Chain. Depending on the dose level, PPM is both biocidal (>2ml/L of media) and biostatic (<2ml/L of media). When diluted with plant growth media (5-20 ml/L) PPM/liter growth media is effective as a microbiocide against non-human health pathogenic organisms.

- 1. Media containing *PPM* may be dispensed outside the laminar flow hood (LFH) exposed to the ambient air. The plates should be covered soon after agar solidification. In the event a pump dispenses the media, we recommend passing autoclaved hot water through the hoses before and after dispensing media.
- 2. Heat sensitive or heat stable liquid media containing PPM does not need to be filter sterilized or autoclaved provided that it will be stored in sterile containers and that the stock solutions are not contaminated. In rich media containing 200 mg/liter or more of amino acids or proteins, it is recommended to filter the media with the PPM

PPM

Preservative for Plant Tissue Culture Media **ACTIVE INGREDIENTS:**

5-Chloro-2-methyl-3(2H)-isothiazolone...... 0.1305% 2-methyl-3(2H)-isothiazolone..... 0.0459% INERT INGRDIENTS...... 99.8236%

KEEP OUT OF REACH OF CHILDREN **CAUTION**

EPA REG. NO. 71806-1 EPA EST NO.

- 3. Working in the LFH the utensils (forceps or scalpels) do not need to be flamed. They may be periodically dipped in 70% alcohol. The LFH does not need to be certified and the work can also be done outside the LFH on a clean surface for a period not exceeding 2 - 3 hours.
- 4. PPM comes in an acidic liquid solution (pH 3.8) and should be stored at 4°C. The recommended dose is 0.5 - 2.0 ml of *PPM* per liter of medium. Higher doses are required to treat endogenous contamination or to obtain Agrobacteria free plant material.
- 5. *PPM* is less effective when exposed to high density of bacteria or fundi spores found regularly on a seed's coat. For in vitro germination, seeds should be conventionally surface sterilized with EPA registered bleach. Therefore, in the presence of PPM (in the germination medium), the seeds can be rinsed under tap water in a non-sterile strainer and left to dry preferably in the LFH. Protoplast isolation solution should be sterilized mechanically through Millipore filters with the PPM. If the utensil ends have touched active bacteria, fundi culture or otherwise suspected of being contaminated, they should be sterilized by autoclave or by use of an electric heating element.
- 6. Endogenous Contamination: Plant tissue culture media containing PPM at doses of 5-20 ml/l can be used to eliminate endogenous contamination in seeds and plant-explants. In such cases, the seeds or the explants should be treated with an EPA registered plant disinfectant. After rinsing with DD water, explants or buds should be embedded or placed in autoclaved semisolid or liquid medium respectively. The proper media such as callus proliferation or regeneration can be used with only 1/4 strength of the inorganic salts, supplemented with 5-20 ml/l PPM/media mixture. After 2-5 days the explants can be transferred without rinsing into a similar media (full strength inorganic salts) supplemented with at least 0.5 ml/l *PPM* at 20-24 degrees centigrade. Seeds can be transferred to germination medium (full strength of inorganic salts) supplemented with 0.5 ml/l PPM after 5-10 days.

It is up to the researchers to determine the optimal combination of *PPM* doses and time exposure. Different plant types and different explant sources are highly varied in their response to *PPM*.

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal. Storage: Ideal storage temperature is 39°F (4°C). Do not store at temperatures in excess of 70°F (21°C).

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

NET CONTENTS:

PLANT CELL TECHNOLOGY, INC. 1823 Jefferson Place, NW WASHINGTON, DC 20036

Patent No. 5,750,402

[See insert for additional (precautionary statements and) directions for use.1

ACCEPTED

Dec 14, 2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 71806-1