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



Plant Cell Technology, Inc. 1823 Jefferson Place NW Washington, DC 20036

SEP 2 3 2010

Attention: Christina M. Swick

Subject: Plant Cell Technology, Inc. EPA Registration No: 71806-1 Amendment Dated, June 30, 2010

This will acknowledge receipt of your Amendment to update the container handling statement per PR Notice 2007-4 and make other minor changes to the product label, submitted under the provision of FIFRA section 3 (c) (9).

# **Proposed Amendment**

-Revise label in the **"Container Disposal"** in accordance with PR Notice 2007-4 -Revise label and additional minor changes to the **"First Aid"** in accordance with per PR Notice 2001-1

# **General Comments:**

Based on a review of the submitted material, the following comments apply:

The Amendment dated June 30, 2010 is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Zebora Johnson at (703) 308-7080.

Sincerely

Marshall Swindell

Marshall Swindéll<sup>6</sup> Product Manger (33) Regulatory Management Branch I Antimicrobial's Division (7501P)

### 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* do not need to be sterilized by Millipore filters or autoclaved provided that it will be stored in sterile containers and that the proteins, it is recommended to filter the media with the *PPM*.

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

# PPM

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

5-Chloro-2-methyl-3(2H)-isothiazolone	0.135%
2-methyl-3(2H)-isothiazolone	0.0412%
INERT INGRDIENTS	99.8238%

## KEEP OUT OF REACH OF CHILDREN CAUTION EPA REG. NO. 71806-1 EPA EST NO.

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 fungi 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, fungi 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 ¼ 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

Storage: Ideal storage temperature is 39°F (4° C). Do not store at temperatures in excess of 70°F (21°C).

Pesticide Disposal: Do not contaminate water, food, or feed by storage and disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility

Container Disposal: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

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.]

## ACCEPTED With COMMENTS In EPA Letter Dated: SEP 2 3 2010 Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

71806-1