



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 4, 2017

Jacob S. Moore
Regulatory Consultant
Stockton (Israel) Ltd.
c/o Technology Sciences Group Inc.
712 Fifth Street, Suite A
Davis, CA 95616

Subject: EPA Response to E-mail received from Stockton, November 7, 2016.

Dear Mr. Moore:

The U.S. Environmental Protection Agency (EPA or the Agency) has received and reviewed your e-mail correspondence dated November 7, 2016, written on behalf of Stockton (Israel) Ltd. (formerly Biomor Israel Ltd.), which contained a request for the Agency to provide clarity as to why the non-food determination for the active ingredient Tea Tree Oil was not published at 40 CFR 180.2020.

As you know, Tea Tree Oil is currently registered as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use as a bactericide and fungicide on leafy vegetables, fruiting vegetables, cucurbit vegetables, berries, tree nuts, cereal grains, avocado, banana, mango, papaya, passion fruit, plantain, and peanuts. As stated in the Agency's 2014 Biopesticide Registration Action Document (BRAD), when applied at maximum application rate of 1.54 lbs a.i./acre and a pre-harvest interval (PHI) of 48 hours is observed, EPA does not believe use on these listed crops is likely to result in residues on those crops.

Once the determination was made by the Agency that these uses, with the stated limitations, will not result in residues on the stated crops, there is no further obligation for rulemaking under the Federal Food, Drug and Cosmetic Act (FFDCA). EPA considers such uses to be non-food uses (40 CFR 180.2003(b)); section 180.2020 of EPA's regulations reflects several, although not all, of EPA's non-food determinations. The general principle behind such codification is to provide greater transparency regarding those determinations and ensure consistent treatment of chemicals and the uses for which such determinations have been made; however, there is no legal requirement to populate that section with all non-food use determinations.

The Agency acknowledges the concerns/confusion of growers regarding the lack of publication of the Tea Tree Oil decision. At this point, the Agency has not proposed to update section 180.2020. That may be something that can be done in the future. If more certainty is desired, we suggest referencing the BRAD's determination that residues are not likely to be present on certain crops when the pesticide is applied in accordance with the labeled application rates.

If you have any questions, please contact Gina Burnett of my branch by phone at (703) 605-0513 or via email at burnett.gina@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Linda Hollis".

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs