



## Bio-Insek / Bio-Neem

Agro-Organics

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### Snuitkewers, Witluis, Blaaspootjie

Dankie vir hierdie korrespondensie en dat ons dit mag aanstuur. Baie dankie!

“Hallo kollega,

Ek het die afgelope somer meer gebruik gemaak van Bio Insek en Bioneem. Die snuitkewers/kalenders gee soms probleme 2 tot 4 weke na blomval in appels en soms in Forelle pere in Jan. Ek spuit Bio Insek teen 1 lt per ha saam met Bioneem 5 lt per ha mengbaar met normale kodlingmot en fusie program. Na 3 dae sien ek geen kalender aktiwiteit nie. Ek het ook by een klient wat baie witluis vorige jaar in Pink Ladys gehad het 3 spuite opgesit Des/Jan/Feb en geen witluis gehad nie. Forelle of appels wat erg besmet was het ek dadelik na oes gespuit die afgelope seisoen want die witluis was nog op die lote. Onthou dus dat die kalender spuit ook witluis beheer sal gee, so twee plae word beheer. Neil het genoem dat Fruitways nie Bioneem toelaat op uitvoer vrugte nie, maar ek sal ingaan daarop en met Dr Ferreira vra wat die storie is rakende kankervorming van die Neem olie, en terug rapporteer aan my.

Louwrens

082 570 6594”

Vir meer besonderhede kan Dr Ferreira per e-pos gekontak word: [strauss@agroorganics.co.za](mailto:strauss@agroorganics.co.za)

**Bio-Insek: Registrasie L8466**

**Bio-Neem: Registrasie L7052**

#### EPA (Environmental Protection Agency of the United States of America): Extracts from the BIOPESTICIDES REGISTRATION ACTION DOCUMENT

##### Executive Summary

Based on the data available to the Agency, it has been determined that no unreasonable adverse effects to the U.S. population and the environment will result from the use of the active ingredient when label instructions are followed and good agricultural practices are employed. Laboratory studies indicate that the active ingredient is not toxic following oral, inhalation or dermal exposure. Cold Pressed Neem Oil and neem extracts are widely used in cosmetics (soap, hair products, hand creams, etc.), traditional folk medicine (acne, fevers, rheumatism, diuretics, inflammations, etc.), as an insect repellent, insecticide, nematicide, fungicide, and as a fertilizer.

There are no reports of adverse effects following human exposure to Neem Oil. Moreover, the pesticidal usage of this biochemical will not have any harmful environmental effects. Studies indicate that Cold Pressed Neem Oil will not cause adverse effects to mammals, birds, fish and aquatic invertebrates, other non-target insects, or plants.

##### Toxicity and Mutagenicity

Pressed Neem Oil, it seems that developmental toxicity may occur in test animals when exposed to Cold Pressed Neem Oil by intravaginal, intrauterine, subcutaneous injection, or by direct exposure to mammalian sperm and eggs in *in vitro* laboratory studies. The three generation study in rats fed Cold Pressed Neem Oil in the diet, however, demonstrates that chronic oral ingestion of food commodities containing Cold Pressed Neem Oil residues does not result in any mammalian developmental toxicity. Taken together, these data demonstrate that no developmental toxicity is expected to occur from the use of Cold Pressed Neem Oil as a pesticide.

Furthermore, Cold Pressed Neem Oil and its components are not structurally related to known mutagens, nor do they belong to any chemical class of compounds containing known mutagens. Humans are regularly exposed to this substance via oral exposure (as a traditional folk medicinal product) and dermal exposure (when used on skin and hair) at levels that are significantly greater than that which would be expected from the product as a pesticide under conditions of use. In addition, an extensive literature search of several scientific databases (i.e. ChemIDPlus, HSDB, Toxline, CCCRIS, DART, GENETOX, IRIS, ITER, LactMed, Multi-Database, TRI, HazMap, Household Products, TOXMAP and TOXNET) for the period 1980 to 2008 failed to locate any other data / information regarding mutagenicity or genotoxicity of Cold Pressed Neem Oil. As a result, EPA concludes that Cold Pressed Neem Oil is not mutagenic or genotoxic.

##### Dietary Exposure and Risk Characterization

Moreover, humans are regularly exposed to this compound via consumption of Cold Pressed Neem Oil medicinal products, and at levels that are significantly greater than what would be expected from pesticide applications. EPA has determined that dietary exposure is not a concern because of the low toxicity of this active ingredient and the history of its use without any reports of adverse effects.

##### Food Clearances/Tolerances

The applicant filed a petition (PP 7F7249) proposing to establish an exemption from the requirement of a tolerance for residues of Cold Pressed Neem Oil in or on all food commodities.

A notice of filing was published on November 2, 2007 (72 FR 62237). On October 13, 2009, EPA promulgated a final rule exempting residues of the biochemical pesticide Cold Pressed Neem Oil, from the requirement for tolerance in or on all food commodities.