

Type	insecticide and fungicide
Controls	Insects (white flies, aphids, scales, mealy bugs, spider mites, locusts, thrips, and beetles), controls powdery mildew and has other fungicidal uses (Reference 1).
Mode of Action	Insect growth inhibitor, antifeedant, and repellent. Reduces the ability of fungal spores to adhere and penetrate the leaf cuticle.

**Thurston County Review Summary:**

This review is for neem oil, which includes cold pressed neem oil and clarified hydrophobic extract of neem oil because the EPA has registered both forms of neem oil with the same Chemical Abstract System number (CAS#) 8002-65-1. Cold pressed neem oil is the oil directly squeezed out of the seeds of the neem tree (azadirachta indica). Clarified hydrophobic extract of neem oil is pressed out of neem seeds and then separated from other chemicals, like azadirachtin, with the use of alcohol. Since the active ingredient azadirachtin has been reviewed by Thurston County and it is considered low in hazard, its presence in cold pressed neem oil will not affect the outcome of this review.

## MOBILITY

Property	Value	Reference	Rating
Water Solubility (mg/L)	52.3	3	Moderate
Soil Sorption (Kd=mL/g)	Not found		
Organic Sorption (Koc=mL/g)	Not found		

**Mobility Summary:**

Neem oil is moderately water soluble, but no information could be found pertaining to its ability to bind to soil. The octanol/water partition coefficient (log Kow 6.26) indicates that it has a strong affinity to bind to organics, but this value is not typically used to determine pesticide mobility in soil. Without more chemical information about the binding potential of neem oil to soil, the mobility hazard will be considered a data gap - but does not cause the pesticide review to "fail".

## PERSISTENCE

Property	Value	Reference	Rating
Vapor Pressure (mm Hg)	0.00000025	3	Moderate
Biotic or Aerobic Half-life (days)	19.8	3	Moderate
Abiotic Half-life (days)	31.5	3	Moderate
Terrestrial Field Test Half-life (days)	3 to 6	3	Low
Hydrolysis Half-life (days)	Not found		
Anaerobic Half-life (days)	Not found		
Aquatic Field Test Half-life (days)	8 to 13	3	Moderate

**Persistence Summary:**

Comparing laboratory half-lives to field half-lives indicates that microbial activity is the major source of neem oil degradation in the environment. The persistence hazard of neem oil is rated moderate (likely to degrade to half of the applied concentration between 8 and 60 days).

## BIOACCUMULATION

Property	Value	Reference	Rating
Bioaccumulation Factor	Not found		
Bioconcentration Factor	Not found		
Octanol/Water Partition Coefficient	Log Kow =6.26	3	High

**Bioaccumulation Summary:**

Neem oil has a strong affinity to bind to organic matter and may accumulate in fish or animal tissue, however, it is considered very low in toxicity potential. Neem oil consists of long-chain fatty acids and glycerides that are readily synthesized by most forms of life and are common constituents of human, avian, and other mammalian diets. So, even though neem oil may have the potential to bioaccumulate, the hazard of toxicity due to accumulation is considered low.

# ACUTE TOXICITY HAZARD - ECOTOXICITY

Test Subject	Value	Reference	Rating
Mammalian (LD50)	>5,000 mg/kg	2	Low
Avian (LD50)	>2,150 mg /kg bw	3	Low
Honey bee or insect (LD50)	>45 ug/bee	3	Low
Annelida -worms (LC50)	Not found		
Fish (LC50)	70.6 to 84.3 ppm	3	Moderate
Crustacean (LC50)	57.5 - 63.9 ppm	3	Moderate
Mollusk (LC50)	Not found		
Amphibian (LD50 or LC50)	Not found		

## Acute Toxicity Testing and Ecotoxicity Summary:

The EPA concluded that there is no reason to believe that any nontarget organisms, including honeybees and other beneficial insects, would be adversely affected by the use of Cold Pressed Neem Oil (Reference 1). Concerning aquatic toxicity potential, the EPA stated; "Although Cold Pressed Neem Oil is slightly toxic to aquatic organisms in laboratory testing, as a result of the rapid biodegradation of Neem Oil under approved conditions of use, calculated Risk Quotients (RQs) for fish and aquatic invertebrates are well below any Levels of Concern (LOCs) for threatened and endangered species." (Reference 3)

Concerning toxicity, the EPA stated: "When used as directed on product labels, neither clarified hydrophobic extract of neem oil nor azadirachtin are expected to harm non-target organisms." The EPA also stated that these products should not be directly applied to water bodies or when honeybees are actively foraging.

## ACUTE TOXICITY - Risk Assessment

Subject and Scenario	Route	Dose of Concern	Exposure	Margin of Safety	Reference	Rating
Short term exposures were not evaluated						
Short term exposures were not evaluated						
Short term exposures were not evaluated						
Short term exposures were not evaluated						

## Acute Toxicity Risk Assessment Summary:

Neem oil is used in medicinal lotions, toothpaste, creme, shampoo, etc. Toxicity testing with neem oil did not produce toxic effects and exposures from pesticidal use are expected to be minimal in comparison to other neem oil uses.

Neem oil is registered for use on greenhouse crops and outside agricultural food and ornamental crops. On October 13, 2009, EPA adopted a rule exempting residues of the biochemical pesticide Cold Pressed Neem Oil, from the requirement for tolerance in or on all food commodities. The EPA also made the following statement concerning toxicity; "Adverse effects are not expected to humans, wildlife, or the environment when products containing these active ingredients [Azadirachtin and Clarified Hydrophobic Extract of Neem Oil] are used according to label directions." Reference 1

# CHRONIC TOXICITY HAZARDS

Property	Value	Adverse Effect	Reference	Rating
Carcinogenicity			4	Low
Mutagenicity	--	"not mutagenic"	1 and 5	Low
Neurotoxicity - (NOAEL)	Not found			
Endocrine Disruption	--	No known effects	1	Low
Developmental Toxicity (NOAEL)	See summary	Varies with application	1	*Low
Reproductive Toxicity (NOAEL)	10% of diet	None	1	*Low
Chronic Toxicity (NOAEL)	5,000 mg/kg bw	None	1	Low

## Chronic Toxicity Hazard Summary:

\* "Reproductive/developmental effects occur only in in vitro studies on sperm or eggs, subcutaneous exposure; contraceptive effects with intrauterine/intravaginal exposure." (Reference 3) Use of neem oil as a pesticide would result in small skin and oral exposures, therefore, Thurston County does not think the positive reproductive or developmental toxicity tests are relevant for the neem oil pesticide review and will use the EPA's determination that "...no developmental toxicity is expected to occur from the use of cold pressed neem oil as a pesticide." (Reference1). Neem oil is not considered a mutagen, there are no known effects on the endocrine system, and neem oil is not listed by ACGIH; IARC; NIOSH; NTP; or the EPA as a known or suspected carcinogen.

# CHRONIC TOXICITY - Risk Assessment

Subject and Scenario	Route	Dose of Concern	Exposure	Margin of Safety	Reference	Rating
Long term exposures were not evaluated						
Long term exposures were not evaluated						
Long term exposures were not evaluated						
Long term exposures were not evaluated						

## Chronic Toxicity Risk Assessment Summary:

EPA waived the requirements for risk assessments for long-term exposures to neem oil from pesticidal use. The EPA stated: "No risk to human health is expected from the use of Cold Pressed Neem Oil because of its low toxicity via all routes of exposure." Reference 1

## Metabolites and Degradation Products:

Neem oil is a mixture of terpenoids, steroids, fatty acids, glycerides, and essential oils . Neem oil is metabolized and becomes the components of carbohydrates, lipids, or amino acids (References 1 and 3).

## Comments:

Cold pressed neem oil is not an eye or skin irritant, and it is not a dermal sensitizer (Reference 3).

## References

1. USEPA. Cold Pressed Neem Oil; Exemption from the Requirement of a Tolerance. [EPA-HQ-OPP-2007-1025; FRL-8434-5].
2. USEPA. Biopesticides and Pollution Prevention Division. Company Notice of Filing for Pesticide Petitions Published in the Federal Register (1/1/2007).
3. USEPA. Office of Pesticide Programs Biopesticides and Pollution Prevention Division. Cold Pressed Neem Oil (PC Code 025006). Last updated October 14, 2009.
4. International Agency for Research on Cancer. Agents Classified by the IARC Monographs, Volumes 1,100. (Accessed 4/14/2011). <http://monographs.iarc.fr>
5. California Department of Pesticide Registration. Memorandum. To: Bob Rollins, Program Supervisor. Subject: Registration Request for NeemGard BOTANICAL. December 5, 1995.