



# Pesticide Fact Sheet

Name of Chemical: Naled  
Reason for Issuance:  
Date Issued: June 30, 1983  
Fact Sheet Number:

4

## 1. Description of Chemical

Generic name: 1,2-dibromo-2,2-dichloroethyl dimethyl phosphate  
Common name: Naled  
Trade name: Dibrom®  
EPA Shaughnessy code: 034401  
Chemical abstracts service (CAS) number: 300-76-5  
Year of initial registration: 1959  
Pesticide type: insecticide - acaricide  
Chemical family: organophosphate  
U.S. and foreign producers: Chevron Chemical Co.

## 2. Use patterns and formulations

Application sites: field, vegetable, and orchard crops; livestock and poultry, and their surroundings; greenhouses; forest and wasteland; agricultural, domestic, medical, and commercial establishments; and urban and rural outdoor areas (mosquito control).

Types of formulations: dusts, impregnated materials, emulsifiable concentrates, soluble concentrates, liquid and ready-to-use liquids.

Types and methods of application: aerial and ground as a spray or dust; fogging; ultra low volume (ULV)

Application rates: varies from .01 to 10 lbs/acre

Usual carriers: Confidential Business Information

## 3. Science Findings

Summary science statement:

Available acute oral and dermal LD<sub>50</sub> data place naled in toxicity category II and toxicity category I based on primary eye irritation data.

Naled is characterized as very highly toxic to bees and aquatic invertebrates. It is moderately to highly toxic to fish and slightly toxic to upland game birds and waterfowl.

Naled has numerous data gaps in areas of product chemistry, residue chemistry, toxicity, environmental fate and ecological effects. The Agency cannot conduct a full risk assessment until the data required in the Naled Standard are submitted and evaluated.

#### Chemical characteristics:

Manufacturing-use naled is a light, straw-colored, oily liquid with a slightly pungent odor. The pure compound is a white, low melting point solid. The boiling point for pure naled is 120°C at 0.5 mm Hg and the vapor pressure is  $2 \times 10^{-4}$  mm. Hg at 20°C. The empirical formula is  $C_4H_7O_4PBr_2Cl_2$  and the molecular weight is 381. Naled has limited solubility in aliphatic solvents; is highly soluble in oxygenated solvents such ketones and alcohols; and a low solubility in water.

#### Toxicological characteristics:

Current available toxicology studies on naled are as follows:

- Acute oral LD<sub>50</sub>: rat, 222-389 mg/kg; mouse, 160 mg/kg (Tox category II)
- Acute dermal LD<sub>50</sub>: rabbit, 390-1100 mg/kg; rat, 800 mg/kg (Tox category II)
- Primary eye irritation: corneal opacities 7 days+ (Tox category I)
- Primary dermal irritation: rabbit, PIS 5.8 - 5.92; human volunteers, severe irritation
- Subchronic feeding: cholinesterase NOEL in dog, 0.25 mg/kg/day

Additional data are needed to fully assess the toxicity of naled.

Major routes of exposure: application by fog and mist sprayers, and aircraft increases the potential for exposure of humans and non-target organisms to naled. Human exposure to naled during mixing, handling, application, and reentry operations would be minimized by the use of approved respirators and other protective clothing. However, data are not available to fully assess such exposures. PR Notice 83-2 sets forth current Agency policy on required label changes for reentry and farmworker safety. A reentry level of 24 hours for the use of naled on crops is required.

#### Physiological and Biochemical Behavioral Characteristics:

Mechanism of pesticidal action: stomach and/or contact poison

Metabolism and persistence in plants and animals: no naled or DDVP was detected in tissues or milk of two goats dosed with naled at 107 ppm in three equal daily portions and sacrificed on day -4. The limits of detection were 0.05 ppm for tissues and 0.005 ppm for milk. The dose is estimated to be about twenty times that which would normally occur in the goats diet.

Residues were non-detectable ( $<0.01$  ppm) in milk from Holstein cows subject to body and premise sprays for 14 days with the 7.2 lb/gal EC formulation.

#### Environmental Characteristics:

Naled degrades fairly rapidly with half-lives of  $\leq 8$  hours in soils and  $\leq 25$  hours in aqueous solutions. Dichlorvos (DDVP), a metabolite of naled is also rapidly degraded in soil with half-lives of 2.3 - 8.0 hours. Naled exhibits low to intermediate mobility in soils, whereas dichlorvos is intermediately mobile to mobile.

Limited data indicate that the rapid dissipation and relatively low mobility of naled and intermediate mobility of dichlorvos in soil will mitigate contamination of ground water.

Naled did not accumulate in whole body tissues of kill-fish exposed to naled in static bioassay tests. Naled was not detected ( $<0.02$  ppm) in any fish tissue samples taken over the 7-day test period. The degradate dichlorvos was found at a maximum concentration of 0.04 ppm, approximately twice the concentration in corresponding water samples, 1 hour after treatment, but was not found ( $<0.01$  ppm) in tissue samples taken after 24 hours. Naled half-life in water samples was  $<24$  hours. Dichlorvos was found in all water samples, at a maximum concentration of 0.02 ppm after 24 hours, but  $<0.01$  ppm was found in samples taken at the end of the test period.

In summary naled and its degradate dichlorvos dissipate rapidly in aerobic soils. Naled exhibits low to intermediate mobility in soils, whereas, dichlorvos is intermediately mobile to mobile. Mobility appears to be related to soil organic matter content. Naled degrades rapidly in aqueous solution, with rates increasing at higher temperatures and pHs. Naled also rapidly degrades in sewage water to dichlorvos and dichloroacetaldehyde. Neither naled nor dichlorvos accumulate in fish tissues. In conclusion, naled does not appear to represent an environmental hazard based on the aforementioned data which indicate very rapid degradation and extremely low bioaccumulation potential.

However, available data are insufficient to fully assess the environmental fate of naled.

### Ecological Characteristics:

Currently available ecological effects studies on naled are as follows:

- Avian oral LD<sub>50</sub>; 37-65 mg/kg
- Avian dietary LC<sub>50</sub>; 2117-2724 ppm
- Freshwater fish LC<sub>50</sub>; 160-900 ppb
- Acute LC<sub>50</sub> freshwater invertebrates; 0.3 ppb

Based on studies available to assess hazards to wildlife and aquatic organisms, naled is characterized as very highly toxic to bees and aquatic invertebrates. It is moderately to highly toxic to fish and slightly toxic to upland game birds and waterfowl. Insufficient data are available to assess the toxicity of naled to estuarine and marine organisms.

Label precautionary statements required by the Standard should reduce the hazard to fish and other wildlife. After data gaps are filled, the potential hazards to terrestrial and aquatic species will be better defined and additional labeling requirements may be imposed.

Efficacy review results: none conducted.

### Tolerance Assessment:

The following tolerances are established for combined residues of naled and 2,2-dichlorovinyl dimethyl phosphate (DDVP), expressed as naled, in or on raw agricultural commodities resulting from the application of naled formulations to growing crops livestock, and poultry (40 CFR 180.125).

<u>Commodity</u>	<u>Tolerance (ppm)</u>
Almonds (hulls, nuts)	0.5
Beans (dry, succulent)	0.5
Broccoli	1.0
Brussels sprouts	1.0
Cabbage	1.0
Cattle (fat, meat, meat by-products)	0.05
Cauliflower	1.0
Celery	3.0
Citrus fruits (grapefruit, lemons, oranges, tangerines)	3.0
Collards	3.0
Cottonseed	0.5
Cucumbers	0.5
Eggplant	0.5
Eggs	0.05

Goats (fat, meat, meat by-products)	0.05
Grapes	0.5
Grasses, forage	10.0
Hogs (fat, meat, meat by-products)	0.05
Hops	0.5
Horses (fat, meat, meat by-products)	0.05
Kale	3.0
Legumes, forage	10.0
Lettuce	1.0
Melons	0.5
Milk	0.05
Mushrooms	0.5
Peaches	0.5
Peas (succulent only)	
Peppers	0.5
Poultry (fat, meat, meat by-products)	0.05
Pumpkins	0.5
Rice	0.5
Safflower seed	0.5
Sheep (fat, meat, meat by-products)	0.05
Spinach	3.0
Squash (summer, winter)	0.5
Strawberries	1.0
Sugar beets (roots, tops)	0.5
Swiss chard	3.0
Tomatoes	0.5
Turnips (tops)	3.0
Walnuts	0.5
All other raw agricultural commodities except those listed. (To account for area pest [fly and mosquito] control.)	0.5

The components of the residue metabolism in plants which are of concern are naled and DDVP, and to a lesser extent, organic bromide. Tolerances exist for combined residues of naled and DDVP (expressed as naled) and should continue to reflect the concern for these two components.

The components of the residue from the metabolism in animals which are of concern are the same as those in or on plants. However, data on the metabolism or naled in poultry are missing and this constitutes a data gap.

The Theoretical Maximum Residue Contribution (TMRC) is 1.1021 mg/day as naled, assuming a 1.5 kg diet, based on the tolerances and food factors for all of the commodities for which U.S. tolerances are established. No Acceptable Daily Intake (ADI) or Maximum Permissible Intake (MPI) figures have been established, due to the absence of

acceptable toxicological data for naled. Reassessment of the established naled tolerances must await receipt and evaluation of the required data.

Although the Agency is unable to complete a tolerance reassessment for naled because of a number of residue chemistry and toxicology data gaps, the Agency has concluded, based on available data, that no changes in present tolerances are necessary at this time. The Agency has also considered the residues of inorganic bromide, resulting from the use of naled on crops and in meat, milk, poultry and eggs, and does not anticipate these residues to be of toxicological concern, and no additional residue data on inorganic bromides are needed.

However, the Agency is concerned about organic brominated metabolites of naled and its impurities. Accordingly, additional data on this organic bromide in plants and animals are being requested.

#### 4. Summary of Regulatory Position and Rationale:

Use classification: not classified

Use restrictions: None

Unique warning statements required on labels:

The following environmental hazard statement must appear on the manufacturing-use product labels:

"This product is toxic to fish, aquatic invertebrates, and wildlife. Do not discharge into lakes, streams, ponds or public water unless in accordance with NPDES permit. For guidance contact your regional office of the Environmental Protection Agency."

Labeling changes to end-use products are not required by the Standard, however, based on data reviewed by the Agency the following statements will be required for end-use products under the Agency's Label Improvement Program:

"This product is toxic to fish, aquatic invertebrates, and wildlife. Do not apply directly to water or wetlands. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes."

"This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area."

The following "General Warnings and Limitations" statements must appear on end-use product labels which bear directions for aquatic use on food or feed crops:

"Do not use with highly alkaline materials such as lime or bordeaux mixture. Shrimp and crabs may also be killed at application rates recommended. Do not apply to tidal or marsh waters which are important shrimp producing areas."

A reentry interval of 24 hours for the use of naled on crops is required on end-use product labels containing directions for use on crops.

The absence of reported fatalities from the Pesticide Incidence Monitoring System (PIMS) report, taken in conjunction with the apparent adequacy of medical and/or emergency room treatment suggests an acceptably low level of risk associated with incidental or accidental exposure to naled products.

#### Summary of risk/benefit review:

Dichlorvos (DDVP), a metabolite of naled was originally referred to the Rebuttable Presumption Against Registration (RPAR) process because scientific studies indicated that dichlorvos was mutagenic, might cause cancer, nerve damage and birth defects in laboratory animals. The RPAR Decision Document on Dichlorvos, was issued September 30, 1982. It was concluded that the existing evidence does not support the issuance of an RPAR for dichlorvos and consequently, that an RPAR for naled as a precursor of dichlorvos is also not warranted.

However, the Decision Document concluded that additional data on carcinogenicity and mutagenicity are needed to complete the risk assessment for dichlorvos. Because the data base was incomplete, dichlorvos was removed from the RPAR process and returned to the registration process. A Data Call-in Notice under FIFRA Section 3(c)(2)(B) was issued March 23, 1983, requesting data on potential mutagenic effects of dichlorvos be submitted by March 23, 1985. Additionally, the Agency will wait until the ongoing National Cancer Institute dichlorvos bioassay on carcinogenicity is completed (currently scheduled for completion in 1984) and evaluated prior to determining if additional data on the carcinogenicity of dichlorvos will be required. Since dichlorvos is a metabolite of naled, evaluation of these studies will be necessary for the completion of the naled risk assessment.

No other human toxicological hazards of concern to the Agency have been identified in studies reviewed for the Standard.

## 5. Summary of Major Data Gaps:

**Product chemistry:** data on the discussion of formation of ingredients; preliminary analysis; certification of limits; and analytical methods for enforcement of limits are the major product chemistry data gaps.

**Residue chemistry:** additional data are required to support the tolerances for beans (dry and succulent), broccoli, Brussels sprouts, cabbage, cauliflower, celery, collards, cottonseed, cucumbers, eggplant, eggs, grapefruit, hops, kale, lemons, melons, mushrooms, oranges, pea forage, peaches, peas, peppers, poultry (fat, meat, meat by-products), pumpkins, soybean forage, spinach, strawberries, Swiss chard, tangerines, turnip tops, and winter squash.

Data are required on residues in the processed products of citrus (any member fruit), cottonseed, grapes, hops, rice, and tomatoes. Data are also needed for turnip roots. A tolerances must be established for this commodity.

**Toxicology:** inhalation LC<sub>50</sub>, rat; 21-day dermal, rabbit; 90-day inhalation, rat; chronic toxicity, 2 species; oncogenicity, 2 species; teratogenicity, 2 species; reproduction, 2-generation rat; gene mutation; chromosomal aberration.

**Reentry protection:** foliar dissipation.

**Wildlife and aquatic organisms:** freshwater fish LC<sub>50</sub> (on typical end-use product); acute LC<sub>50</sub>, freshwater invertebrates (on technical grade of active ingredient, and on typical end-use product); acute LC<sub>50</sub>, estuarine and marine organisms).

All data must be submitted by June, 1986.

## 6. Contact person at EPA:

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