



R.E.D. FACTS

Pesticide Reregistration

Tetrachlorvinphos

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0321, tetrachlorvinphos.

Use Profile

Tetrachlorvinphos is an organophosphate insecticide. It is currently used as a dermal and feed-through (oral) larvicide in cattle, hogs, goats and horses; in cattle ear tags to control flies in cattle feedlots; in poultry dust boxes to control poultry mites. Tetrachlorvinphos is also used in pet sleeping areas and pet flea collars. It is used to control nuisance and public health pests (flies) in and around refuse sites, recreational areas, and for general outdoor treatment. Formulations include wettable powders, dusts, granules, mineral blocks for livestock, impregnated materials (pet collars, cattle ear tags), ready-to-use liquids, pressurized liquids, and emulsifiable concentrates. Products containing tetrachlorvinphos are applied by hand, pressurized aerosol, hand and power sprayers and dusters, and as free-choice mineral blocks, livestock feed supplements, poultry dust boxes, pet collars, and cattle ear tags.

Regulatory History

Tetrachlorvinphos (commonly referred to by the trade names Rabon[®] and Gardona[®]) was initially registered for use in the United States in 1966 by the U.S. Department of Agriculture. Tetrachlorvinphos was originally registered for use on various food crops, livestock, pet animals, and in or

around buildings. The crop uses were voluntarily canceled from product registrations in 1987.

In October 1988, EPA issued a Registration Standard. In the Standard the Agency summarized its assessment of the supporting scientific data available at that time, and identified and required the submission of additional data to support the continued registration of tetrachlorvinphos products.

Human Health Assessment

Toxicity

In studies using laboratory animals, tetrachlorvinphos has been shown to be practically non-toxic to slightly toxic in acute toxicity studies.

Tetrachlorvinphos did not cause delayed neurotoxicity in hens in two neurotoxicity studies. In an acute neurotoxicity study, rats exhibited signs consistent with cholinesterase inhibition but there was no indication of any permanent behavioral changes or of any adverse neuropathological effects.

Cholinesterase inhibition was also observed at higher doses in two subchronic studies (one dermal, one oral) conducted on rats.

Decreased plasma cholinesterase activity and increased kidney and liver weights were noted in several chronic toxicity studies conducted on dogs and rats.

Tetrachlorvinphos produced effects in three carcinogenicity studies involving rats and mice as test animals. Effects included increased incidences of adrenal cortical adenomas and thyroid C-cell adenomas, high incidences of thyroid C-cell hyperplasia, hepatocellular carcinoma, hepatocellular adenomas, and granulomatous lesions of the liver.

No indications of developmental toxicity were seen at the highest dose tested in two developmental toxicity studies conducted on pregnant rats. However, some clinical signs were noted in the mothers. A similar developmental toxicity study conducted on rabbits noted developmental toxicity at the mid-dose level. The signs of developmental toxicity included abortions, red vaginal fluid, and reduced weight gain.

Two reproductive toxicity studies conducted using rats were submitted. The two-generation reproductive toxicity study resulted in reduced weight gains and increases in adrenal gland weights. The no observed effects level (NOEL) was the highest dose tested. The three-generation reproductive toxicity study produced an increase in liver weights in the third generation rats. The livers and other organs exhibited no effects when examined microscopically, however.

While two mutagenicity studies returned negative results, a third study returned a positive result in the absence of metabolic activation and negative result in the presence of metabolic activation.

Very little unmetabolized tetrachlorvinphos was found 48 hours after dosing in a metabolism study conducted on rats. Metabolites found (mostly

in urine and feces) included trichlorophenylethandiol and trichloromandelic acid.

After 10 hours duration (longest test period), 84% of the total applied tetrachlorvinphos remained unabsorbed in a dermal absorption study in rats. The percent absorption increased with the duration of the exposure and generally decreased with increasing dose. The actual quantity of tetrachlorvinphos absorbed increased with increasing dose.

Tetrachlorvinphos has been classified as a group C (possible human) carcinogen by the Carcinogenicity Peer Review Committee of EPA's Office of Pesticide Programs based on the results of 3 studies using rats and mice in which liver tumors were observed.

Dietary Exposure

Although no food or feed crop uses currently are registered, the livestock uses of tetrachlorvinphos result in human dietary exposure. Since people may be exposed to residues of tetrachlorvinphos through the diet., a tolerance reassessment was conducted.

Tolerances or maximum residue limits have been established for alfalfa, apples, cattle, cherries, corn, cranberries, eggs, goats, hogs, horses, milk, peaches, pears, poultry, sheep, and tomatoes (please see 40 CFR 180.252). EPA has reassessed the fenthion tolerances and found that for use on cattle, eggs, goats, hogs, milk, and poultry the tolerances must be reassessed after additional data has been submitted to the Agency. The tolerance for use on horses has been proposed for revocation due to the label requirement precluding use on horses destined for slaughter.

While there are established tolerances for tetrachlorvinphos on certain crops (as listed above), no currently registered tetrachlorvinphos end-use product is labeled for use on any plant commodity. The Agency has proposed revocation of the associated tolerances.

EPA has assessed the dietary risk posed by tetrachlorvinphos. The Anticipated Residue Concentration (ARC) for the overall U.S. population represents 1 % of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The most highly exposed subgroup, children (1-6 years), has an ARC which represents 3 % of the RfD. This low fraction of the allowable RfD is considered to be an acceptable dietary exposure risk.

For the U.S. population, the upperbound carcinogenic risk was calculated using anticipated residues for meat, milk, poultry, and eggs, and was refined using percent livestock treated estimates. The carcinogenic risk for all published and supported uses was 4.3×10^{-5} . This assumes that 100% of the fruit and vegetable commodities consumed are imported and contain tetrachlorvinphos at tolerance levels. However, only meat, milk, poultry, and eggs are supported for reregistration. When only these commodities are considered, the dietary cancer risk is 1×10^{-6} , a degree of risk considered acceptable.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to tetrachlorvinphos during and after normal use. Increased cancer risks to tetrachlorvinphos handlers wearing full protective clothing range from 5.7×10^{-8} to 1.3×10^{-5} , which the Agency considers to be acceptable.

Risk estimates for occupational/residential uses of tetrachlorvinphos were calculated using the upper bound carcinogenic risk for mixers/loaders/applicators from ten different use scenarios. The highest calculated risk (1.3×10^{-5}) is for the low pressure handwand scenario. This risk is less than the Agency's 10^{-4} level of concern for worker exposure. Since risks to workers under this worst-case scenario do not exceed the Agency's level of concern, it is not likely that exposures resulting from applications of dusts, pellets, or impregnating materials will exceed the Agency's level of concern.

To minimize worker exposure and reduce the risk to handlers, baseline PPE are set through the RED document, including: long-sleeved shirt, long pants, socks and shoes, and chemical-resistant gloves. The Agency expects that this PPE will adequately protect workers from exposures to tetrachlorvinphos. The use of chemical-resistant gloves by applicators using low pressure handwands should further reduce the potential carcinogenic risk.

Although there is the potential for homeowner exposure to tetrachlorvinphos, it is unlikely that homeowners would experience significant exposure resulting from typical household uses.

Human Risk Assessment

Tetrachlorvinphos has been shown to be practically non-toxic to slightly toxic in all acute toxicity studies but causes reduced weight gain and increased organ weights in certain studies.

Tetrachlorvinphos has been classified as a group C (possible human) carcinogen by the Carcinogenicity Peer Review Committee of the EPA's Office of Pesticide Programs.

Both chronic systemic and carcinogenic dietary risks were calculated. These risks appear to be minimal when only uses supported for reregistration are included in the assessment.

When dietary risk from chronic systemic effects was assessed, the calculated exposure for the U.S. population was 59% of the RfD. However, when only the anticipated residues from supported uses were included, the estimated exposure for the U.S. population was only 1% of the RfD.

In addition to revoking the food crop tolerances for tetrachlorvinphos, the Agency is also proceeding to revoke the feed additive tolerances, as required by the Delaney clause. When these tolerances are revoked and the

uses are removed from labeling, the dietary risk will change. It is not possible to estimate the amount that the risk will be reduced or increased, however, since it is possible that some users of tetrachlorvinphos would switch from a feed-through application to a dermal application.

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to tetrachlorvinphos during and after normal use. Increased cancer risks to tetrachlorvinphos handlers wearing full protective clothing range from 5.7×10^{-8} to 1.3×10^{-5} , which the Agency considers to be acceptable. Although there is the potential for homeowner exposures to tetrachlorvinphos, it is unlikely that homeowners would experience significant exposure resulting from such uses.

Environmental Assessment

Environmental Fate

In the environment, tetrachlorvinphos is not persistent but its mobility increases as soil texture becomes coarse and the organic matter content decreases. The primary route of dissipation is through biotic degradation. Under alkaline conditions, abiotic processes (e.g., hydrolysis) are somewhat effective. Parent tetrachlorvinphos is not available from the manure of treated animals and is therefore not available to the environment from the feed-through (oral) larvicide uses. Based on current product labeling, it is unlikely that serious detrimental impacts to ground or surface water will occur from the use of tetrachlorvinphos. Confirmatory data describing the hydrolysis of tetrachlorvinphos have been submitted and are in review. The results of this review are not likely to change the environmental assessment for this pesticide.

Ecological Effects

Tetrachlorvinphos is practically non-toxic to birds, and moderately to very highly toxic to freshwater and estuarine/marine organisms.

Ecological Effects Risk Assessment

Under the use patterns described in the RED document, tetrachlorvinphos poses little acute or chronic risk to wildlife. Exposure to the environment is expected to be minimal, especially exposures to aquatic species because of the use patterns. Although the acute levels of concern are exceeded for fresh water invertebrates and endangered fish and invertebrates, significant risk is unlikely due to low exposure. Chronic exposures and risks are unlikely because of the use patterns.

Risk Mitigation

To lessen the potential human health risks posed by tetrachlorvinphos, EPA is requiring the following risk mitigation measures:

- Personal Protection Equipment (PPE) Requirements for Handlers
- Entry Restrictions
- Product Specific Labeling Changes

Additional Data Required	<p>Because of the feed additive tolerance issue associated with the Delaney clause, the requirement for livestock residue data for the feed-through use is deferred. Data are required to upgrade the existing Mixer/Loader/Applicator exposure study.</p>
Product Labeling Changes Required	<p>All tetrachlorvinphos end-use products must comply with EPA's current pesticide product labeling requirements and with the following.</p> <ul style="list-style-type: none"> ■ All Products <p>Because tetrachlorvinphos is classified as a skin sensitizer, the Agency requires that the following statement appear on all tetrachlorvinphos labels in the "Hazards to Humans (and Domestic Animals)" section of the Precautionary Statements:</p> <p style="padding-left: 40px;">"This product may cause skin sensitization reactions in certain individuals."</p> ■ Products Intended Primarily for Occupational Use <p>The Agency is requiring the following labeling statements to be located on all end-use products containing tetrachlorvinphos that are intended primarily for occupational use:</p> <ul style="list-style-type: none"> ◆ Application Restrictions: <p>"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."</p> ◆ User Safety Requirements: <p>"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."</p> ◆ User Safety Recommendations: <ul style="list-style-type: none"> ● "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." ● "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." ● "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing." ■ Occupational Products Used in Recreational Areas <p>The following entry restriction must be added to the labels of all products used occupationally in recreational areas:</p> <p style="padding-left: 40px;">"For Liquid Application:</p> <p style="padding-left: 80px;">Do not enter or allow others to enter the treated area until sprays have dried."</p>

■ Products with Feed-Through Uses

All products labeled for use on horses must have the following restriction:

"This product is not to be used on horses destined for slaughter."

Labels of all products with directions for use as a feed-through for livestock must be clarified so that weights of pesticide to be added to feed refer to weights of active ingredient and not weights of product.

For a comprehensive list of labeling requirements, please see the Tetrachlorvinphos RED document.

Regulatory Conclusion

The Agency has determined that all uses of tetrachlorvinphos, with the exception of oral feed-through larvicide treatment to livestock intended for food use, will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration. The Agency has determined that the dermal application to livestock, non-food animal, general outdoor treatment, and pet uses of tetrachlorvinphos, specified in the RED document, will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration. However, the Agency cannot make a determination regarding the reregistration eligibility of the feed-through (oral) livestock use at this time.

Tetrachlorvinphos products will be reregistered once the required product-specific data, generic data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for tetrachlorvinphos during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the Tetrachlorvinphos RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the Tetrachlorvinphos RED, or reregistration of individual products containing tetrachlorvinphos, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.