

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



OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM**

**Date:** February 14, 2012

**SUBJECT:** Prallethrin: Review of Human Incidents

**PC Code:** 128722  
**Decision No.:** 458525  
**Petition No.:** NA  
**Risk Assessment Type:** NA  
**TXR No.:** NA  
**MRID No.:** NA

**DP Barcode:** D398043  
**Registration No.:** NA  
**Regulatory Action:** NA  
**Case No.:** NA  
**CAS No.:** 23031-36-9  
**40 CFR:** NA

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**THROUGH:** David Miller, Acting Branch Chief  
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**TO:** Douglas Dotson, Risk Assessor  
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and  
Wilhelmena Livingston, Chemical Review Manager  
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**I. CONCLUSION**

In general, a relatively high frequency of incidents has been reported involving prallethrin. Although most of these incidents were of low severity, it appears exposures to prallethrin have the potential to result in high severity outcomes. Consequently, based on the frequency of exposures and the potential for exposures to result in high severity outcomes, these incident data may warrant further analysis in the preliminary risk assessment phase of Registration Review.

## II. ACTION REQUESTED

This review is intended to fulfill our requirement to docket summaries of incident data that were reported to the Agency, as well as to ensure human incident data and the Agricultural Health Study (AHS) are part of the problem formulation phase of registration review. Reports of adverse health effects allegedly due to a specific pesticide exposure (*i.e.*, an “incident”) are largely self-reported and therefore, generally speaking, neither exposure to a pesticide or reported symptom (or the connection between the two) is validated or otherwise confirmed. Typically, causation cannot be determined based on incident data. However, incident information can be an important source of feedback to the Agency: incidents of severe outcome, or a suggested pattern or trend among less severe incidents, can signal the Agency to further investigate a particular chemical or product. Observational epidemiology studies relate the risk of disease, *e.g.*, cancer, and exposure to an agent such as a pesticide product in the general population or specific sub-groups like pesticide applicators.

## III. BACKGROUND

For this evaluation, the OPP Incident Data System (IDS) was utilized to retrieve pesticide incident data on the active ingredient prallethrin (PC Code 128722). Prallethrin is an insecticide in the synthetic pyrethroid class of compounds registered for use inside households, in outdoor yards and patios, and on pets. The purpose of the database search is to identify potential patterns in the frequency and severity of the health effects attributed to prallethrin exposure. The IDS includes reports of alleged human health incidents from various sources, including mandatory Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 6(a)(2) reports from registrants, other federal and state health and environmental agencies, and individual consumers. Since 1992, OPP has compiled these reports in IDS. IDS contains reports from across the U.S. and most incidents have all relevant product information recorded. Reports submitted to the IDS represent anecdotal reports or allegations only, unless otherwise stated in the report.

The AHS is a high quality, prospective epidemiology study evaluating the link between pesticide use and various health outcomes including cancer. The AHS includes private and commercial pesticide applicators and their spouses. If there are AHS findings relevant to a particular pesticide going through registration review, the Agency will ensure they are considered in the problem formulation/scoping phase of the process and, if appropriate, fully reviewed in the risk assessment phase of the process. The AHS includes information on use of 50 different pesticide active ingredients commonly used in agriculture.

## IV. RESULTS/DISCUSSION

IDS records incidents resulting in higher severity outcomes in more detail, in a module called the Main IDS module. This system stores incident data for death, major and moderate incidents, and it includes more details about the location, date and nature of the incident. Main IDS incidents involving only one pesticide are considered to provide more certain information about the potential effects of exposure from the pesticide. The less severe human incidents (minor, unknown, or no effects outcomes) are reported by registrants as counts called aggregate summaries and are recorded in a separate module called Aggregate IDS.

In Aggregate IDS, from January 1, 2006 to December 14, 2011, there were 1887 reported incidents involving prallethrin resulting in low severity outcomes. There are relatively few details provided on the incidents in the Aggregate IDS module and these incidents are low severity; regardless, the relatively high frequency of exposures (relative to other pesticides in IDS) reported involving prallethrin may indicate a high potential for exposure.

For the Main IDS, from January 1, 2006 to December 14, 2011, there was 1 incident reported for the single chemical only in the database and an additional 169 incidents reported that involved more than one chemical. During the scoping phase of Registration Review, the higher severity exposures (those resulting in fatal or major outcomes) are considered in more detail. Additionally, as described above, incidents involving one pesticide are typically focused on because they are considered to provide more certain information about the potential effects of the particular pesticide. However, because prallethrin is always co-formulated with other active ingredients, it is important to review the incidents involving multiple chemicals in this case. Six incidents were classified as having major severity outcomes and these incidents, that involve prallethrin and other chemicals, are described in Table 1. Similar to the Aggregate IDS module, the relatively high frequency of exposures may indicate a high potential for exposure.

Prallethrin is not included in the AHS, and therefore this study does not provide information for this report.

In general, both the Aggregate and Main IDS modules result in relatively high frequency of prallethrin exposures. Although most of these exposures resulted in low severity outcomes, high severity outcomes did occur. Subsequently, based on the frequency of exposures and the potential for exposures to result in high severity outcomes, these incident data may warrant further analysis in the preliminary risk assessment phase of Registration Review.

**Table 1: Main IDS high severity incidents involving prallethrin and other substances**

Human Incidents		Chemical: Prallethrin			PC Code: 128722	
Incident Number	Incident Date	Location	Registration Number	Product Name	Exposure Severity*	Incident Description
018089 - 00016	10/8/2006	SULLIVAN, MO	000239-02679	ROACH, ANT AND SPIDER KILLER (AEROSOL)	HB	Unknown age (18 - 64 year old) adult female sprayed product. Two to three days later she developed a bladder infection and kidney failure.
018089 - 00028	10/22/2006	WOODLAND HILLS, CA	000239-02679	ROACH, ANT AND SPIDER KILLER (AEROSOL)	HB	A 79 year old male sprayed the product in the garage for 30 minutes. The next day he developed a fever and shortness of breath. Had low O2 stats and was admitted to the ICU. He had a chest x-ray and CT scan of his chest. The MDs concluded that the cause of the symptoms is due to the use of pesticides.
018357 - 00005	11/1/2006	BARTOW, FL	009688-00190-008845	HOT SHOT WASP & HORNET KILLER 3	HB	A 74 year old female sprayed the product overhead which resulted in exposure to her right arm and upper body. She developed sores on her forehead, back of neck and nose that are raised and red in color.
018799 - 00008	7/4/2007	BATTLE CREEK, MI	009688-00190	NO PEST WASP & HORNET KILLER 3	HB	A 47 year old male used almost a full container of product outside on a windy day. The product blew back on his face, hands, and arms during use. He did not shower after use of the product. Seven hours later he developed a headache and vomiting and a fever. In morning his fiancé could not wake him and he was admitted to a critical care unit. He experienced visual changes, changes in urine color and slurred speech. An MRI found a lesion on his brain.
022293 - 00009	8/19/2010	LAS VEGAS, NV	009688-00253-008845	HOT SHOT SPIDER KILLER 3	HB	An 80 year old female sprayed the product in her bedroom. Four day later she experienced delusions, memory loss, slurred speech, and was unconscious. She was taken to the hospital and the MD's evaluation was inconclusive.
022960 - 00001	3/5/2011	VENICE, FL	001021-01855-079529	BLACK FLAG ANT, AND SPIDER KILLER	HB	A 30 year old female applied product 2 to 3 months prior to having a miscarriage. Says other pesticides are used around the home and suspects malicious intent.

\* Severity Categories

H-A	Human Fatality	Death (if the person died)
H-B	Human Major	Major (if the person alleged or exhibited symptoms which may have been life-threatening, or resulted in adverse reproductive effects or in residual disability)
H-C	Human Moderate	Moderate (if the person alleged or exhibited symptoms more pronounced, more prolonged or of a more systemic nature than minor symptoms; and involved some form of treatment, even though symptoms were not life threatening and the person returned to his/her pre-exposure state of health with no additional residual disability)
H-D	Human Minor	Minor (if the person alleged or exhibited some symptoms, but they were minimally traumatic; the symptoms

		resolved rapidly and usually involve skin, eye or respiratory irritation)
H-E	Human Unspecified	Unspecified (if symptoms are unknown, unspecified or are alleged to be of a delayed or chronic nature that may appear in the future)
H	Human	Undetermined (an undetermined severity)

from 40 CFR § 159.184