

**ADDENDUM TO ACEPHATE RISK CHARACTERIZATION DOCUMENT**

**HS-1890**

By

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## ABSTRACT

Acephate (O,S-dimethyl acetylphosphoramidothioate) is currently registered in California as a systemic insecticide/miticide in agricultural and non-agricultural settings. There were 46 illness/injury cases associated with exposure to acephate, alone and in combination with other pesticides, in California from 2000 through 2009. The dermal absorption of acephate in humans was determined to be 7.6%.

An Exposure Assessment Document (EAD) and a Risk Characterization Document for acephate, identifying several scenarios with health concerns, were finalized in 2009 (Gammon, 2009). To provide current information for the risk mitigation effort, this Addendum to the Risk Characterization Document (RCD Addendum) was prepared; it considers exposure scenarios associated with current uses that were covered by the EAD and RCD and addresses new uses and new exposure and use data.

Exposure scenarios were identified from the uses listed on current product labels. These were sorted into relatively high and low priorities, by risk estimated as Margin of Exposure (MOE), which is calculated by dividing the acute (human) no observed effect level of 1.0 mg/kg/day by estimated exposure. As the NOEL is from a human study, a MOE of > 10 is generally considered adequate to protect human health. High-priority scenarios are defined as those in which the MOE is less than or equal to 10. Scenarios with MOE above 10 are considered low priority. Exposure and risk estimates are given in this Addendum for 18 high-priority scenarios. Two highest priority scenarios, with MOE < 1, involve mixer/loader for Aerial use and mixer/loader for Hopper Box applications.

Seventeen of twenty six occupational scenarios are high-priority, as listed below.

- Mixer/loader (M/L) handling soluble powder for aerial application on agricultural crops (MOE: <1)
- M/L handling soluble powder for groundboom on Golf Course (MOE: 7)
- M/L handling soluble powder for airblast on non-bearing citrus (MOE: 8)
- M/L handling soluble powder for handgun on turf (MOE: 8)
- M/L handling soluble powder for Slurry seed treatment on cotton seed (MOE: 9)
- M/L handling soluble powder for Hopper Box treatment on cotton seed (MOE: <1)
- M/L handling soluble powder for chemigation on cranberries (MOE: 9)
- Applicator handling soluble powder for aerial spraying on agricultural crops (MOE: 1)
- Applicator handling soluble powder for airblast on trees/shrubs (MOE: 6)
- Applicator handling soluble powder for handgun on turf (MOE: 1)
- Mixer/Loader/Applicator handling soluble powder for using Hopper Box on trees, cotton seed (MOE: 2)
- Mixer/Loader/Applicator handling soluble powder for using backpack sprayer on trees, shrubs, outdoor floral (MOE: 9)
- Mixer/Loader/Applicator handling soluble powder for using high pressure handwand on trees, shrubs, outdoor floral (MOE: 2)

- Mixer/Loader/Applicator handling granules for using belly grinder on trees and shrubs (MOE: 1)
- Mixer/Loader/Applicator handling granules for using shaker can and hand tool on trees and shrubs (MOE: 7)
- Mixer/Loader/Applicator handling granules by hand for fire ants (MOE: 2)
- Flagger involved with application on agricultural crops (MOE: 5)

One of fourteen representative occupational reentry scenarios is a high-priority scenario:

- Tying & pruning grapes (MOE: 6)

## INTRODUCTION

Acephate (O,S-dimethyl acetylphosphoramidothioate) is an organophosphate pesticide that is applied as a systemic insecticide/miticide in agricultural and non-agricultural settings. This RCD Addendum was prepared to provide current information for the risk mitigation effort. Among 31 products currently registered in California, 20 were registered since the original RCD was completed in 2009. Also, several uses discussed in the 2009 RCD have since been discontinued, and the affected exposure scenarios are not included in this RCD Addendum

## REGULATORY STATUS AND RISK ASSESSMENTS

### U.S. EPA

The United States Environmental Protection Agency (U.S. EPA) classifies the acute oral and dermal toxicity of acephate as Category III, and the acute inhalation toxicity as Category II/III. In available animal studies, acephate was not a dermal irritant or sensitizer, and it was classified as a minimal dermal irritant (Category IV). Acephate is classified as a Group C, possible human carcinogen by U.S. EPA. However, it was concluded that no quantitative risk assessment is needed based on the occurrence of hepatocellular carcinomas in only one sex (female) of one species (mouse), and only at the highest dose; and the lack of mutagenicity seen in *in vivo* mutagenicity studies (Davis, *et al.*, 2009).

Acephate was first registered with the U.S. EPA in 1973, and a registration standard was published in 1987. The most recent risk assessment was completed in 1999 (Fort, 1999), and the most recent Reregistration Eligibility Decision was issued on 2006 (U.S. EPA, 2006). In both documents, NOEL values used by U.S. EPA for risk assessment were: 12 mg/kg/day from a 21-day rat dermal toxicity study for short and intermediate-term dermal exposure risks in occupational and residential settings; 0.14 mg.kg/day from a 4-week rat inhalation toxicity study for assessing risks of similar duration from inhalation exposure (Fort, 1999). Table 1 summarizes scenarios reaching U.S. EPA's level of concern (i.e., scenarios with Margins of Exposure (MOEs) below the target MOE).

**Table 1. Scenarios Meeting U.S. Environmental Protection Agency Level of Concern for Acephate**

Scenario <sup>a</sup>	Use Site	Use Rate (lb ai/A)	Short- and Intermediate-Term (MOE) <sup>b</sup>
Mixer/Loader			
<u>SP, Aerial</u>	Agricultural crops	1	6.5
	Turf	1	2.2
SP, Groundboom	Agricultural crops	1	19
	Turf	4	10
SP, Slurry Seed Treatment	Cotton Seed (/100 lb seed)	0.04	49
Mixer/Loader/Applicator			
SP, Low Pressure Handwand	Trees, shrubs, outdoor floral (/100 gal)	1	73
G, Belly Grinder	Trees/shrubs (1000 ft <sup>2</sup> )	0.1125	31
G, Shaker Can	Trees.shrubs (1000 ft <sup>2</sup> )	0.1125	35
G, By Hand	Trees.shrubs (1000 ft <sup>2</sup> )	0.1125	35
Flagger			
Flagging Aerial Spray	Turf	5	82

<sup>a</sup> From U.S. EPA (2006a). SP = Soluble Powder; G = Granule.

<sup>b</sup> Margins of Exposure (MOEs) listed here are less than 100 and were assessed considering personal protective equipment (PPE) according product labels. MOEs were calculated using a No-Observed-Effect-Level of 12 mg/kg/day from a rat dermal toxicity study.

U.S. EPA published acephate product cancellations and use deletions for all residential indoor and outdoor uses, that were requested to reduce certain residential risks, including risks to children, which exceeded the Agency's level of concern. The principal registrant, Valent, also requested the cancellation of one acephate product registered under Section 3 (of FIFRA) and 8 products under Section 24(c), special local needs. The effective date of the cancellations is December 31, 2002 (U.S. EPA, 2001a). Numerous combined dermal and inhalation MOEs for occupational mixer/loader scenarios are less than 100 when assessed considering baseline personal protective equipment (PPE). However, most of these risks can be mitigated with additional levels of protection. For dermal exposures, U.S. EPA assumed 100% absorption for dermal.

### California

The California Department of Pesticide Regulation (DPR) finalized its exposure assessment for acephate in 2009 (Zhao, 2009). Dermal absorption was estimated at 7.6%. The default inhalation absorption rate is 100%.

The Risk Characterization Document (RCD) for acephate, identifying several scenarios with health concerns, was finalized in 2009 (Gammon, 2009). The NOEL for calculating acute MOE values was 1.0 mg/kg/day based on the inhibition of plasma and RBC ChE in a human oral capsule study. As the NOEL was from a human study, the target MOE considered protective of human health was 10. Seasonal and annual MOEs were calculated with NOELs from animal studies (see footnotes in Table 2), and seasonal and annual target MOEs were 100.

Table 2 summarizes high-priority scenarios assessed by DPR in 2009. These are defined as scenarios having MOEs below the target MOE.

**Table 2. Scenarios Meeting California Department of Pesticide Regulation Level of Concern for Acephate in 2009 Risk Characterization Document**

Scenario <sup>a</sup>	Use Site	Use Rate (lb ai/A)	Acute MOE <sup>b</sup>	Seasonal MOE <sup>c</sup>	Annual MOE <sup>d</sup>
Mixer/Loader					
<u>WP, Aerial</u>	Cotton <sup>e</sup>	1.0	19	12	22
<u>SP, Aerial</u>	Agricultural crops	1.0	0.1	0.1	0.1
	Turf	5.0	0.1	-	-
	Pasture	0.125	4	0.2	4
<u>L, Aerial</u>	Pasture/forest	0.75	1	0.3	0.5
	Forest	0.75	0.31	0.1	0.1
SP, Groundboom	Agricultural crops	1.0	0.8	0.4	0.5
SP, Airblast	Citrus, non-bear	0.5	8	4	6
	Tress/shrubs	1.0	16	9	11
SP, Handgun	Trees/shrubs/floral	1.0/100 gal	16	9	11
SP, Slurry Seed Treatment	Cotton Seed	0.04/100 lb seed	2	1	1
DF, Slurry Seed Treatment	Cotton Seed	0.04/100 lb seed	16	8	10
SP, Chemigation	Cranberry	1.0	9	3	4
Mixer/Loader/Applicator					
SP, Hopper box	Cotton seed <sup>e</sup>	0.225	1.8	1	1
SP, Low Pressure Handwand	Trees, shrubs, outdoor floral (/100 gal)	1.0	17	11	13
SP, Backpack Sprayer	Trees/shrubs/floral	1.0 (100 gal)	19	11	14
SP, High press sprayer	Trees/shrubs/floral	1.0 (100 gal)	2	0.6	0.8
G, Belly Grinder	Trees/shrubs (1000 ft <sup>2</sup> )	0.1125/1000 sf <sup>2</sup>	0.9	0.4	0.5
G, Shaker Can	Trees.shrubs (1000 ft <sup>2</sup> )	0.1125/1000 sf <sup>2</sup>	7	4	5
G, By Hand	Trees.shrubs (1000 ft <sup>2</sup> )	0.1125/1000 sf <sup>2</sup>	16	10	12
Applicator					
L, Aerial	Agricultural crops	1.0	0.8	0.3	0.5
SP, Grounboom	Agricultural crops	1.0	28	13	17
SP, Airblast	Citrus	0.5	11	6	7
	Tress/shrubs	1.0	10	5	6
SP, Handgun	Trees/shrubs/floral	1.0	2	0.6	0.8
Flagger					
Flagging Aerial Spray	Agricultural crops	1.0	5	3	5

<sup>a</sup> From Risk Characterization Document (Gammon, 2009). WP = water soluble pellet; SP = Soluble Powder; G = Granule; DF = dry flowable; L = liquid.

<sup>b</sup> Acute MOE = ratio of critical acute (human) NOEL of 1 mg/kg/day to ADD. Target MOE = 10.

<sup>c</sup> Seasonal MOE = ratio of subchronic (rat) NOEL of 0.12 mg/kg/day to SADD. Target MOE = 100.

<sup>d</sup> Annual MOE = ratio of critical chronic (dog) NOEL of 0.09 mg/kg/day to AADD. Target MOE = 100.

<sup>e</sup> Calculated from a field monitoring study, otherwise using PHED.

To provide current information for the risk mitigation effort, this RCD Addendum was prepared; it considers exposure scenarios associated with these uses and addresses new uses and new data.

## PHYSICOCHEMICAL PROPERTIES

Physicochemical properties of acephate were summarized in the RCD and EAD (Gammon, 2009; Zhao, 2009).

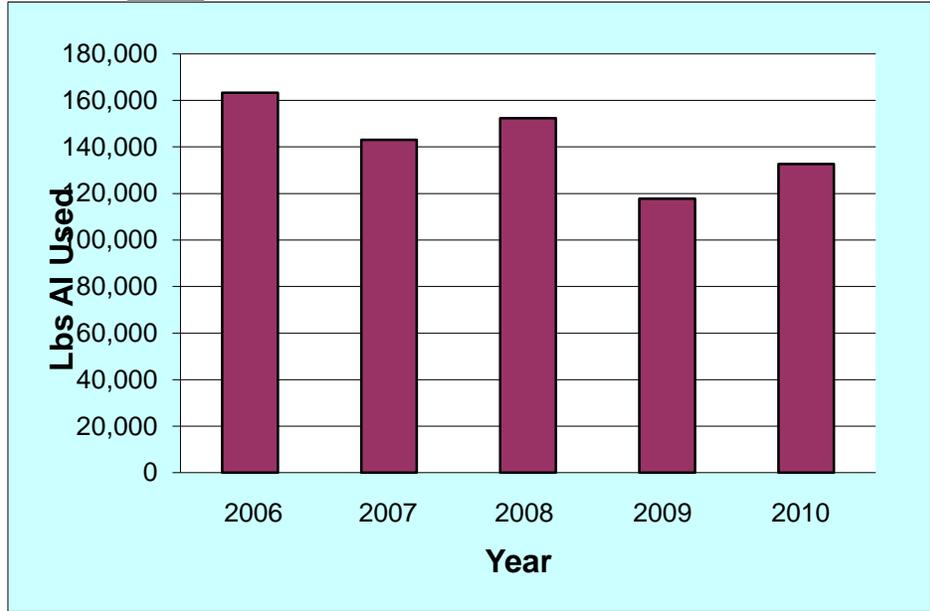
## FORMULATIONS AND USES

As of June 2013, there were 31 acephate-containing products registered in California. Among them, 24 products are registered for agriculture uses, 13 products registered primarily for ornamental, landscape maintenance, and trees uses, 2 products for industrial and institutional use and one product is for outdoor use around building. Some of the end uses overlap in different categories. Acephate formulations include: granular/flake (4, 90, 97, 97.4, 98.5% active ingredient [AI]), soluble powder or wettable powder (75, 90, 97, 97.4, 98.9% AI), pressurized liquid/sprays/foggers (0.25, 1 and 12% AI), pelleted (97.4% AI), dry flowable (90, 97% AI), aqueous concentrate (9.4% AI), and dust/powder (50, 97% AI).

### Pesticide Use in California

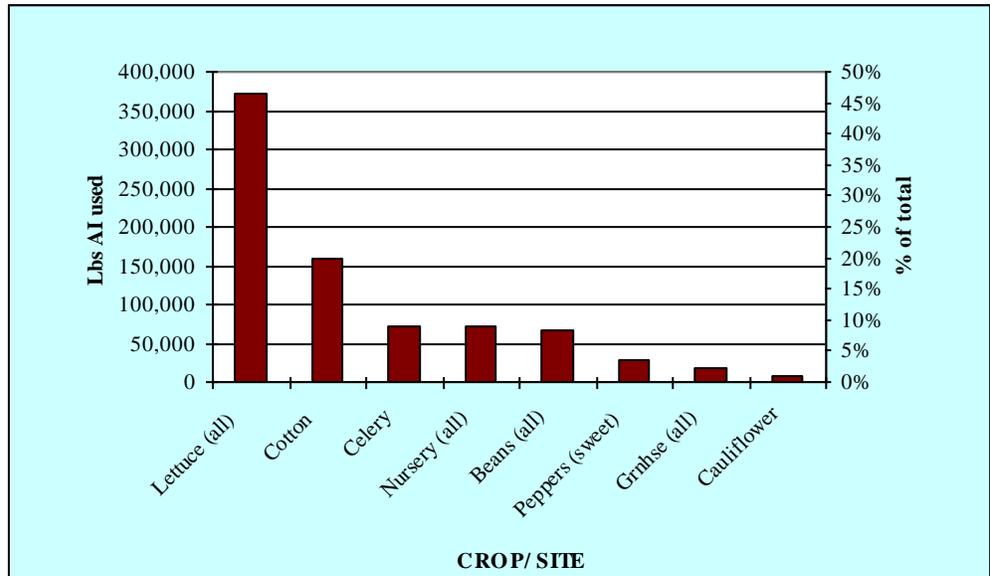
Based upon the data provided by the annual pesticide use reports (DPR, 2012a), the total annual usage of acephate in California was approximately 100,000 to 170,000 pounds AI per year during 2006 to 2010. The pounds AI used have gradually decreased in recent years (Figure 1). The uses above 1% of total amount of acephate used in California, as reported by the 2006 to 2010 pesticide use reports (PUR), are shown in Figure 2. The major uses of acephate include: lettuce (44%), cotton (17%), beans (13%), celery (12%), nursery crops (7%), peppers (3%), greenhouse crops (2%), cauliflower (1%) and other sites. The amount and relative percentage of seasonal use are shown in Figure 3. The top usage months (over 190,000 pounds AI and above 10% of total annual usage) are June, July and August.

**Figure 1. Total Pounds Acephate (AI) Used per Year in California During 2006 – 2010<sup>a</sup>.**



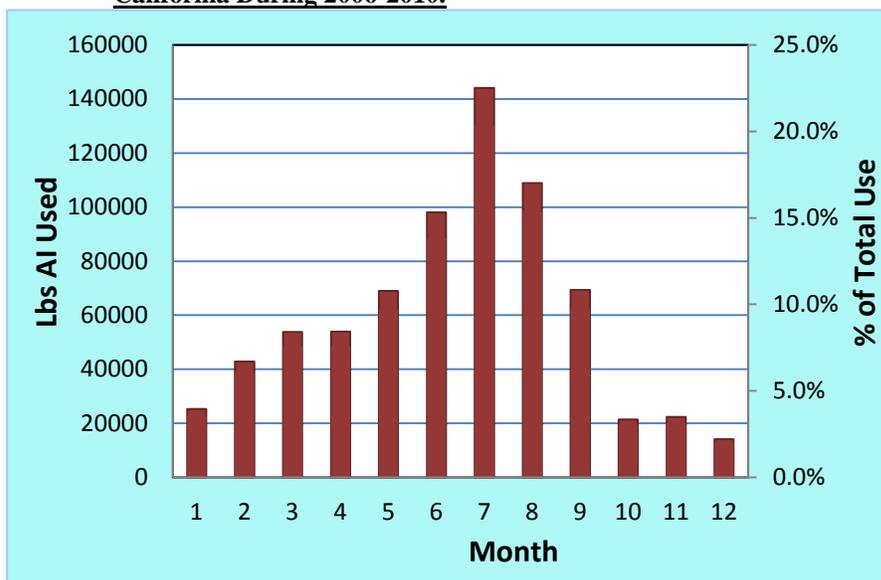
a Data from California pesticide use summaries (DPR, 2012a).

**Figure 2. Pounds Acephate and Relative Percentage of Uses for the Top Crops/Sites in California During 2006-2010<sup>a</sup>.**



a Data from California Pesticide Use Summaries Database (DPR, 2012a).

**Figure 3. Pounds and Relative Percentage of Seasonal Uses of Acephate in California During 2006-2010.**



a Pounds applied by all methods to all crops in Tulare County (DPR 2012a, queried on July 31, 2012).

The application methods for acephate include ground application, aerial application, hand application and seed treatment. Table 3 summarizes application rates for various uses, as stated on current product labels.

**Table 3. Maximum Application Rates for Acephate <sup>a</sup>.**

Site/Crop	Label Rates (lbs AI/acre) <sup>b</sup>
Food Crops	1.1
Commercial Turf	4.3
Fruit Trees	0.75
Cotton	1.1
Cotton Seed Treatment	0.4 (per 100 lbs)
Non Crop Areas	0.25
Evergreens in Large Stands	1.1
Commercial Ornamentals	1.1

a Data from product labels and U.S. EPA (U.S. EPA, 2006a).

b lb = pound; AI = active ingredient.

## PHARMACOKINETICS AND TOXICITY

### Dermal Absorption

The dermal absorption rate was calculated as 7.6 % based on a percutaneous absorption study of acephate conducted by Chevron Chemical Company (Zhao, 2009).

### **Inhalation Absorption**

No inhalation absorption studies are available. In the absence of these data, the current default inhalation absorption value of 100% is used for calculations of doses absorbed via inhalation.

### **Toxicity**

Based on the currently available data, DPR has concluded that the principal toxicological effect of acephate is an inhibition of ChE (plasma, RBC, brain). The lowest acute NOEL from an animal study is 0.5 mg/kg/day, for inhibition of brain AChE at the LOEL (2.5 mg/kg/day) in a rat neurotoxicity single oral gavage study. Plasma and RBC ChE inhibition had LOEL/NOEL values of 5 and 2.5 mg/kg/day, respectively. However, for the purposes of risk assessment, a human, oral capsule study is available. The NOEL for inhibition of plasma and RBC ChE in this study was 1.0 mg/kg/day. This NOEL was used for calculating acute MOE values in DPR's RCD for acephate. Following longer duration exposure, NOEL values of 0.12 mg/kg/day (rat) and 0.09 mg/kg/day (estimated, dog) were obtained, for the inhibition of brain AChE, in dietary studies lasting for 13-wks and 1-yr., respectively. These NOELs were used for the determination of seasonal and annual MOE values, respectively (Gammon, 2009).

Based on available studies, DPR concluded that although acephate is weakly genotoxic in isolated systems, its potential for causing genotoxicity in humans, *in vivo*, is limited.

## **ENVIRONMENTAL CONCENTRATIONS**

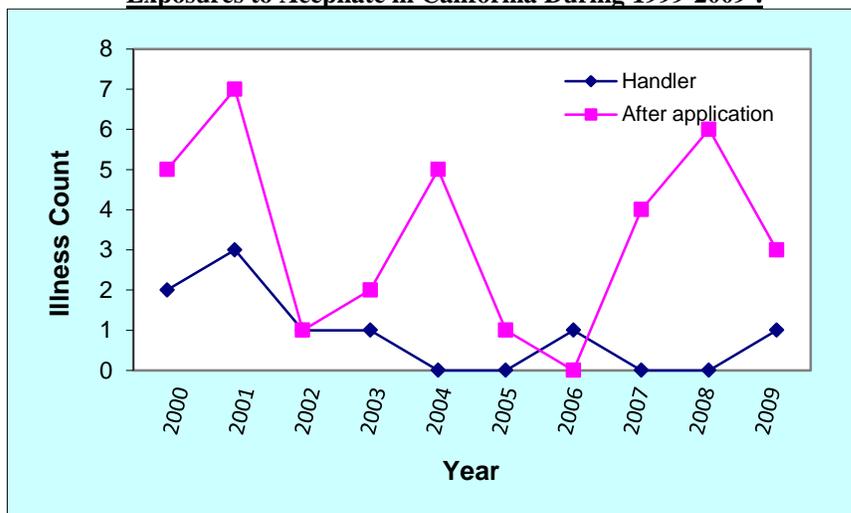
Dislodgeable foliar residues of acephate in various crops and air monitoring study were summarized in the acephate EAD (Zhao, 2009).

## **REPORTED ILLNESSES**

When both Poison Control Center and California illness data were considered, acephate was generally considered less hazardous than other organophosphates and carbamates. Outdoor agricultural use was associated with lower risks of illness and poisoning than most other organophosphate and carbamate insecticides (U.S. EPA, 2006).

The California Pesticide Illness Surveillance Program database maintained by the Worker Health and Safety Branch (WHS) indicated that from 2000 through 2009, there were 46 illnesses/injuries associated with exposure to acephate (DPR, 2012b). Among these 46 cases, 10 involved acephate exposure alone, while the remaining 36 were exposures to acephate in combination with other pesticides. No deaths occurred, but two of the exposed were hospitalized for one and three days respectively. Generally, there were more illness cases involving bystander and post-application exposures (residue and drift) than illness cases involving handlers (Figure 4).

**Figure 4: Reported Illnesses Related to Handler and Non-Handler Exposures to Acephate in California During 1999-2009<sup>a</sup>.**



a Data from the illness report (DPR, 2012b).

## LABEL PRECAUTIONS AND CALIFORNIA REQUIREMENTS

### Label Precautions

Among 31 acephate products registered in California (as of June 21, 2013), 4 products are classified as toxicity category II (with the signal word WARNING), and 27 products are classified as toxicity category III/IV (with the signal word CAUTION).

Product labels state that acephate can be harmful if swallowed and that it may cause eye irritation. Hazards of and treatments for ingestion, inhalation, and dermal or eye contact have been indicated on the product labels. Applicators and other handlers must wear the following protective clothing and equipment:

- For toxicity category II (Warning) products:
  - Agriculture use: Wear goggles, face shield or safety glasses. Applicators and other handlers must wear a long-sleeved shirt and long pants, chemical-resistant gloves, shoes plus socks, protective eyewear, and a respirator with either an organic vapor-removing cartridge with a prefilter approved for pesticides (U.S. Mine Safety and Health Administration (MSHA)/National Institute of Occupational Safety and Health (NIOSH) approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G). Chemical-resistant headgear is required for overhead exposure.
  - Residential/home & garden use: Handlers must wear chemical-resistant gloves, long pants, and a long-sleeved shirt. When using outdoors, spray with the wind to your back and do not use when wind speeds are 10 mph or more.

- For toxicity category III/IV products:
  - Agriculture use: Applicators and other handlers must wear chemical-resistant headgear for overhead exposure, long pants, long-sleeved shirt, and shoes plus socks. Mixers and loaders must also wear waterproof gloves. Early entry field workers must wear coveralls, waterproof gloves, shoes plus socks, and chemical-resistant headgear for overhead exposure.

These PPE and clothing requirements are based on labels of some products that contain acephate at a concentration of 75% or lower. However, applicators and other handlers are required to wear waterproof gloves when they use products containing acephate at a concentration of 80% or greater, or some other products containing a lower percentage of acephate such as Pinpoint 15 Granular (15% AI) or Acephate 75SP AG (75% AI). Therefore, exposures were estimated for applicators and other handlers with and without the use of waterproof gloves (see Exposure Assessment section).

- Industrial/commercial use: Handlers must wear chemical-resistant gloves, long-legged pants, a long-sleeved shirt, and shoes plus socks.

### **Restricted Entry Intervals**

For most field crops, vegetables, tree crops, greenhouse and nursery ornamentals, pasture, grassland, forests, rangeland, parks, paths, greens, golf-courses, cemeteries and abatement districts, and quarantine areas the restricted entry interval (REI) is 24 hours. For some residential, institutional and industrial uses, the REI is when sprays have dried or dust has settled. The preharvest intervals (PHI) are various, depending on different uses (see exposure section).

### **California Requirements**

Under California regulations, employees must wear protective eyewear when required by pesticide product labeling or when employees are engaged in mixing or loading, maintaining or cleaning application equipment, application with hand-held equipment, application with some ground equipment and flagging (except when using an enclosed cab) (Title 3 California Code of Regulations [3 CCR] 6738(b)(1)). Also, employees must wear gloves when required by the pesticide product labeling or when employees are engaged in mixing or loading, maintaining or cleaning application equipment and application with hand-held equipment (3 CCR 6738(c)(1)).

## **EXPOSURE SCENARIOS**

This RCD Addendum is intended to address all exposure scenarios, with exposure estimates provided for the highest-priority scenarios having the highest exposure

potential. Scenarios are prioritized according to risk as estimated by the MOE, which is calculated by dividing the no observed effect level of 1.0 mg/kg/day by exposure. High-priority scenarios are defined as those in which  $MOE \leq 10$ . Scenarios with MOE above 10 are considered low priority. Of 31 occupational and recreational scenarios, 19 were high-priority.

### **Occupational Handler**

26 occupational handler exposure scenarios for acephate were identified in this document. 23 of these exposure scenarios were identified in the U.S. EPA Reregistration Eligibility Decision (RED) for Acephate (U.S. EPA, 2006). The scenarios identified by DPR include agricultural, institutional and recreational area uses, and they serve as the basis for quantitative exposure assessments. The occupational handler exposure scenarios are listed in Table 4. Of the 26 scenarios listed, 17 are high-priority.

**Table 4: Occupational Handler Exposure Scenarios for Acephate<sup>a</sup>.**

Activity <sup>b</sup>	Formulation	Application Method	Scenario Priority <sup>c</sup>
M/L	Soluble Powder	Aerial	<b>H</b>
M/L	Water-soluble pellet	Aerial <sup>d</sup>	L
M/L	Soluble Powder	Groundboom	<b>H</b>
M/L	Soluble Powder	Airblast	<b>H</b>
M/L	Soluble Powder	Handgun (hydraulic sprayer)	<b>H</b>
M/L	Soluble Powder	Slurry Seed Treatment	<b>H</b>
L/T	Soluble Powder	Hopper Box	<b>H</b>
M/L	Soluble Powder	Chemigation	<b>H</b>
M/L	Dry Flowable	Slurry Seed Treatment	L
L	Granular	Tractor-Drawn Drop-Type Spreader	L
A	Soluble Powder	Fixed-Wing Aircraft	<b>H</b>
A	Soluble Powder	Groundboom Sprayer	L
A	Soluble Powder	Airblast Sprayer	<b>H</b>
A	Soluble Powder	Handgun Sprayer	<b>H</b>
A	Granular	Tractor-Drawn Drop-Type Spreader	L
A	Water-Soluble Pellet	Paintbrush <sup>d</sup>	L
M/L/A	Granular	Shaker Can	<b>H</b>
M/L/A	Soluble Powder	Low-Pressure Hand Wand	L
M/L/A	Soluble Powder & Wettable Powder	Backpack Sprayer	<b>H</b>
M/L/A	Soluble Powder	High-Pressure Sprayer	<b>H</b>
M/L/A	Soluble Powder	Sprinkler Can	L
L/T/P	Soluble Powder	Hopper Box	<b>H</b>
L/A	Granular	Belly Grinder	<b>H</b>
L/A	Granular	Hand	<b>H</b>
Flagging	Liquid, Soluble Powder	Aerial Spray	<b>H</b>

a The occupational handler exposure scenarios are identified based upon the product labels and U.S. EPA (U.S. EPA, 2006).

b M/L = mixer/loader; L = loader; A = applicator; M/L/A = mixer/loader/applicator; L/A = loader/applicator; L/T = loader/treater; L/T/P = loader/treater/planters.

c Scenario priority identified as follows: H = high. M = moderate. L = low. See text for definition of priorities. High-priority scenarios are bolded. .

d These scenarios were not covered by U.S. EPA, they were added by DPR based on the product labels.

### Occupational Post-Application

All of the identified agricultural reentry scenarios are shown in Appendix A. These reentry scenarios represent activities allowed by acephate product labels registered for use in the state of California. Table 5 summarized representative and represented occupational reentry scenarios for acephate. One of eleven scenarios, combining canopy management activities of tying and pruning in grapes, is high-priority.

**Table 5: Representative and Represented Post-Application Agricultural, Residential, and Recreational Area Activities with Potential Exposure to Acephate<sup>a</sup>.**

Site	Activity	Crops/Activities Represented	Priority <sup>b</sup>
<b>Agricultural Post-Application</b>			
Cotton <sup>c</sup>	Scouting	Tobacco	L
Cauliflower <sup>c</sup>	Harvesting	Lettuce, Celery, Peppers, Brussels Sprouts, Mint	L
Succulent Beans <sup>c</sup>	Harvesting	Dry Beans, Potatoes, Peanuts, Onions, Tomatoes	L
Greenhouse Roses <sup>c</sup>	Pruning & Harvesting	Greenhouse Crops	L
Nursery Ornamentals	Pruning & Harvesting	Nursery Crops	L
Citrus <sup>c,d</sup>	Pruning & Thinning	Oranges <sup>e</sup> , Grapefruit <sup>e</sup> , Lemons <sup>e</sup> , Almonds <sup>e</sup> , Walnuts <sup>e</sup> , Pistachio <sup>e</sup>	L
Grapes <sup>c</sup>	Scouting, Tying & Pruning, Harvesting (hand)	Cranberries, Kiwi Fruit	<b>H</b>
Turf <sup>c</sup>	Harvesting	Mowing	L
<b>Recreational Areas Post-Application</b>			
Golf Course Mower <sup>c</sup>	Mowing turfgrass of golf course	Park Turf Mower	L
Golfers <sup>c</sup>	Playing on golf course	Tennis Player	L
Maintenance Worker <sup>c</sup>	Cleaning holes, etc.	Tennis Court Maintenance Worker, Park Maintenance Worker	L

a The post-application agricultural activities exposure scenarios are identified based upon the product labels, U.S. EPA (U.S. EPA, 2006) and WHS guidance. As mentioned before, although U.S. EPA published acephate product cancellations and use deletions for home and garden uses in 2002, these products are still actively registered in California. Therefore, potential exposures for these uses were assessed in this document.

b Scenario priority of acute MOE was identified as follows: H = high. M = moderate. L = low. See text for definition of priorities. High-priority scenarios are bolded.

c The scenarios with enough information/data to estimate the exposure.

d The applications are for non-bearing citrus, or as the product labels indicate: "Do not harvest citrus for one year after treatment." Therefore, the exposures to harvesters are not anticipated.

e The product labels indicate that acephate applications are limited to non-bearing fruit trees, nut trees or orchards. Therefore, the exposures to harvesters are not anticipated.

### Residential Handler and Post-application

U.S. EPA published acephate product cancellation and use deletions for all residential indoor and outdoor uses.

### Recreational Areas

Acephate is applied to recreational areas, including golf courses, tennis courts, and parks. The major site is golf course turf. Table 6 summarizes 5 scenarios. One of them is high-priority.

**Table 6: Golf Course Exposure Scenarios for Acephatea.**

	Activity <sup>b</sup>	Formulation	Application Method	Scenario Priority <sup>c</sup>
Handler	M/L	Soluble Powder	Groondboom	<b>H</b>
	Appl	Soluble Powder	Groondboom	L
Post-application	Mowers			L
	Maintainers			L
	Golfers			L

## EXPOSURE AND RISK ASSESSMENT

This RCD Addendum provides short-term exposure estimates for high-priority scenarios. For short-term exposures, WHS estimates the highest exposure an individual may realistically experience in association with legal uses. In order to estimate this “upper bound” of daily exposure, WHS generally uses the estimated population 95<sup>th</sup> percentile of daily exposure (Frank, 2009).

### Occupational Handler Exposure and Risk

Available exposure monitoring studies were used to estimate exposure of handlers. Detailed estimates were summarized in the acephate RCD (Gammon, 2009; Zhao, 2009). When such studies were unavailable, exposure estimates were based on the Pesticide Handler Exposure Database (PHED, 1995). PHED was developed by the U.S. EPA, Health Canada and the American Crop Protection Association to provide non-chemical-specific (generic) pesticide handler exposure estimates for specific handler scenarios. It combines exposure data from multiple field monitoring studies using several different AIs. All exposure rates and assumptions used to estimate exposures for the high-priority scenarios based on PHED (Beauvais *et al.*, 2007). Some exposure estimates are different from those estimated in the EAD (Zhao, 2009) due to changes in product labels.

Table 7 summarizes exposure rates and short-term exposure estimates and MOE for high-priority occupational handler exposure scenarios.

**Table 7. Updated Acephate Exposure and Risk Estimates for High-Priority Occupational Handler Exposure Scenarios.**

Scenario (Formulation) & Application Rate <sup>a</sup>	Exposure Rate <sup>b</sup> (µg/lb AI handled)		Total STADD <sup>c</sup> (µg/kg/day)	Scenario Number <sup>d</sup>	MOE <sup>e</sup>
	Dermal	Inhalation			
Aerial, M/L (SP)					
Ag=1.0	635	50	7577	1	<1
Groundboom, M/L (SP)					
Golf Course Turf <sup>f</sup> =4.0	54	0.2	153	-	7
Airblast, M/L (SP)					
Non-bearing citrus=0.5	635	50	126	1	8
Handgun M/L (SP)					
Turf=4.0	635	50	126	1	8
Slurry seed treatment, M/L (SP)					
Cotton seed =0.04 lb/100 lb seed	635	50	114	1	9
Hopper Box <sup>f</sup> , M/L (SP)					
Cotton Seed = 0.225	-	-	7490	-	<1
Chemigation, M/L (SP)					
Cranberries=1.0	635	50	115	9	9
Aerial, Applicator					
Ag=1.0	149	0.6	1215	5	1
Airblast, Applicator (SP)					
Trees/Shrubs=1.0 lb/100 gal	1560	5.4	170	7	6
Handgun, Applicator (SP)					
Turf=4.0	6600	151	936	11	1
Hopper Box <sup>f</sup> , M/L/A (SP)					
Cotton Seed = 0.225	-	-	542	-	2
Backpack Sprayer, M/L/A (SP, WP)					
Trees, Shrubs, Ground Cover, Floral Crops=1.0 lb/100 gal	22310	18	59	9	9
High Pressure Sprayer, M/L/A (SP)					
Trees, Shrubs, Ground Cover, Floral Crops=1.0 lb/100 gal	6600	151	468	11	2
Belly Grinder, L/A (G)					
Trees/Shrubs/Ornamentals =0.1125 lb/1000 sq ft	26334	81	1170	15	1
Shaker Can/Handtool (G)					
Trees/Shrubs/Ornamentals =0.1125 lb/1000 sq ft	26334	81	134	15	7
By Hand (G)					
0.00099 lb per pot up to 12 in diameter.	96660	350	546	12	2
Flagging					
Ag=1.0	33	0.2	185	16	5

a The exposure scenarios are based on RED (U.S. EPA, 2006) and U.S. EPA guidance (2001b). Formulation types are given in parentheses: SP = Soluble powder; DF = Dry flowable; G = Granular. Maximum application rates are values found on currently registered labels.

b The exposure rates are from PHED (PHED, 1995). Dermal values are sum of dermal (non-hand) and hand (Beauvais *et al.*, 2007). Appropriate protection factors were applied depending on label precaution.

c Short-Term Absorbed Daily Dosage (STADD) = [(short-term exposure) x (absorption) x (acres treated/day) x (application rate)]/(70 kg body weight). Calculation assumptions include:

- Dermal absorption rate = 7.6 % (see Dermal Absorption section of EAD by Zhao, 2009);
- Inhalation absorption is assumed to be 100% (Frank, 2008);
- Inhalation rate 16.7 liters/min (Andrews and Patterson, 2000).

- Body weight = 70 kg (Thongsinthusak et al., 1993).
- d Scenario numbers from Beauvais *et al.* (2007).
- e Margin of Exposure (MOE) calculated by dividing the critical acute (human) no observed effect level of 1 mg/kg/day by total STADD.
- f Indicates the estimates are based on a monitoring study.

### Occupational Post-Application Exposure and Risk

Representative exposure scenarios for reentry workers were selected from Table 5. Table 9 summarizes the exposure and risk estimates of acute exposure to acephate for field workers from an exposure monitoring study with a surrogate chemical, and from extrapolating from a dermal transfer factor which is defined as the ratio of hourly dermal exposure in  $\mu\text{g/hr}$  to foliar residue (DFR) in  $\mu\text{g/cm}^2$ .

**Table 9. Updated Representative Occupational Reentry Exposure and Risk Estimates for High-Priority Scenario for Acephate.**

Task	REI/PHI <sup>a</sup> (day)	Daily Exposure <sup>b</sup> ( $\mu\text{g/person/day}$ )	TF <sup>c</sup> ( $\text{cm}^2/\text{hr}$ )	STADD <sup>d</sup> ( $\mu\text{g/kg/day}$ )	Acute MOE <sup>e</sup>
<b>Grapes<sup>f</sup></b>					
Tying & Training	1	166318	10100	181	<b>6</b>

a REI (restricted entry interval) and PHI (pre-harvest interval) were taken from the product labels.

b Daily exposure ( $\mu\text{g/kg/day}$ ) = daily exposure \* 7.6% dermal absorption / 70 kg body weight (Thongsinthusak et al., 1993).

c TF (transfer factor) values are taken from Agricultural Default Transfer Coefficients (U.S. EPA, 2012).

d Short-term Absorbed Daily Dosage (STADD) = daily exposure (DFR x dermal transfer factor x work hours/day) x 7.6% dermal absorption rate / 70 kg body weight.

e Acute MOE = ratio of critical acute (human) NOEL of 1 mg/kg/day to STADD.

f Since acephate was very seldom applied on grape in California during a recent five-year interval (DPR, 2012a), only acute average daily dosage was estimated in this document.

### Residential and Institutional Uses

U.S. EPA published acephate product cancellation and use deletions for all residential indoor and outdoor uses. Therefore, residential exposure was not considered in this document.

For institutional use, although there is still one product used for indoor pest control, its formulation is pellet/tablet/cake/briquet, the exposure associated with these formulation types is very low. Therefore, the handler exposure indoors was considered to be minimal.

Current active products used for turf are limited to golf courses and sod farms. Therefore, post-application dermal exposure from residues on turf for children is not considered.

There are some products used for ornamental plants, floral crops, and outdoor spray. However, based on the pesticide use report, acephate was very seldom applied on nursery ornamentals, stone fruit, grape, and turf in California during a recent five-year interval

(DPR, 2012a), only acute exposure for agriculture handlers was estimated in this document.

### Recreational Areas

Acephate is applied to recreational areas, including golf courses, tennis courts, and parks.

A monitoring study performed by Chevron Chemical Company was evaluated and used as a golf course application exposure estimate (Zhao, 2009). Among mixer/loader, applicator, mower, golfers, and maintainers, only the mixer/loader scenario with a high priority acute MOE as shown in Table 10.

**Table 10. Estimated Short-Term Exposure and Risk with High Priority MOE of Handlers, Mowers and Golfers to Acephate from the Application to Golf Courses.**

Scenario <sup>a</sup>	TC <sup>b</sup>	TE <sup>c</sup> (hour)	Acute ADD <sup>d</sup> (µg/kg/day)	Acute MOE <sup>e</sup>
M/L <sup>f</sup>	-		153	7

a M/L = Mixer/loader.

b TC (Transfer Coefficient) value for mowers workers are taken from U.S. EPA (2000); TC value for golfers are based on the RED (U.S. EPA, 2006); TC value for maintainers using TC value for golf course turf maintenance, which are taken from U.S. EPA (2012).

c TE (Exposure duration): Exposure hours for mowers was assumed to be 8 hours per day; Exposure hours for golfers were assumed to be 4 hours (golfing 18 holes); Exposure hours for maintainers (cleaning holes) were assumed to be 4 hours.

d Acute ADD for handler is an upper-bound estimate (95th percentile estimate, Frank, 2009), based on the arithmetic mean (AM) and standard deviation (SD) of the log-transformed ADD, then calculating: 95<sup>th</sup> percentile = Antilog (AM + 1.645 x SD). The values were adjusted by use rate (4.0 lbs based on current label instead of use rate of 5.0 lbs based on old label in the study).

e Acute MOE = ratio of critical acute (human) NOEL of 1 mg/kg/day to Acute ADD.

f Handlers' exposure estimates were based on a monitoring study performed by Chevron Chemical Company (Zhao, 2009). These scenarios are the same ones listed in Table 7.

Other recreational areas (tennis courts and parks) handlers and players and maintainers' exposures and risk estimates are covered by golf course scenarios.

## EXPOSURE AND RISK APPRAISAL

Uncertainties are associated with all estimates of exposure and risk. The uncertainties affecting the hazard identification and calculations of risk estimates were appraised by Gammon and Zhao (2009). These uncertainties include PHED data as surrogate to estimate handler dermal and inhalation exposure; estimating the annual exposure frequency based on PUR data; estimating the field worker exposure based on DFR data; estimating the dermal absorption rate based on an animal study; using surrogate DFR data for some crops; selecting reasonable cauliflower DFR data; selecting reasonable grape DFR data; missing data for hopper box monitoring study; and comparing DPR and U.S. EPA estimates.

In DPR's RCD, Gammon (2009) used a NOEL of 1.0 mg/kg/day to calculate acute MOE

and to estimate risk associated with acephate exposure; the value was based the NOEL for inhibition of human plasma and RBC ChE in a human oral capsule study. In this RCD Addendum, this NOEL of 1.0 mg/kg/day is still used. DPR believes this NOEL is appropriate, rather than the NOEL of 12 mg/kg/day used by U.S. EPA, which is based on a 21-day rat dermal toxicity study, because the human study better predicts human response to acephate than rats. However, use of the NOEL of 1.0 mg/kg/day rather than the NOEL of 12 mg/kg/day might result in an overestimate of risk for reasons explained by Gammon (2009), including that female controls exhibited high variability in ChE activity levels, and that no clinical signs or symptoms related to acephate exposure were reported in the human study. However, because DPR assigned a target MOE of 10 for the acute NOEL of 1.0 mg/kg/day, and U.S. EPA assigned a target MOE of 100 for the acute NOEL of 12 mg/kg/day, the toxicity portion of the risk calculation did not differ substantially between the two agencies.

## CONCLUSIONS

This RCD Addendum identifies exposure scenarios according to current acephate product labels; these labels differ from ones used to prepare the acephate RCD finalized in 2009 (Gammon, 2009). The product label changes resulted in new scenarios and use limitations, which led to changes in exposure estimates. Risks were calculated by dividing the appropriate NOEL by exposure. When the NOEL for an adverse effect is derived from a human study, a calculated MOE of 10 is generally considered adequate for protection against the potential toxicity of a chemical. This benchmark of 10 includes an uncertainty factor of 10 for intraspecies variability. For acephate, several MOEs are below the benchmark of 10. Exposure and risk estimates are given for the 18 high-priority scenarios having MOEs less than 10. There are 2 highest priority scenarios, with  $MOE < 1$ , both of which involve agricultural mixer/loader tasks: M/L handling soluble powder in support of aerial applications, and M/L supporting Hopper Box treatment of cotton seed. These scenarios were also among the ten that exceeded U.S. EPA's level of concern (see Table 1). Several scenarios assessed in this RCD Addendum have MOEs that exceed the level of concern, suggesting that mitigation should be considered.

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**APPENDIX A**  
**Agricultural Reentry Scenarios for Acephate Uses in California**

The following table was prepared by reviewing acephate product labels. Reentry activities were listed for each use site, and assigned to tiers based on anticipated exposure. Tier I: Most of the body (approximately > 50 % of the body surface) is in contact with residues. Tier II: Some of the body (approximately 25 - 50 % of the body surface) is in contact with residues (e.g., hands, arms and face; or hands, forearms, feet, and lower legs). Tier III: Very little of the body (approximately < 25 % of the body surface) is in contact with residues (e.g., hands only; or hands and feet only).

Within Tier I and Tier II, suggested representative activities are shown in bold. These are activities that generally should be addressed specifically in an exposure assessment. Tier III activities are considered to be covered by Tier I and Tier II activities. For an activity designated "None" means a representative activity was not assigned or chosen for that Tier activity.

Site Cat <sup>a</sup>	Use Sites <sup>b</sup>	REI <sup>c</sup> (day)	PHI <sup>d</sup> (day)	Tier I Activities (High)	Tier II Activities (Medium)	Tier III Activities (Low)
FC	Cotton	1	21	<b>Scouting</b>	Irrigating <sup>e</sup> , Weeding, Harvesting (Mech.)	None
FC	Tobacco	1	3	<b>Harvesting</b> (Hand)	<b>Scouting</b>	Irrigating <sup>e</sup> , Weeding, Harvesting (Mech.), Thinning, Topping, Reset
FN	Citrus	1	365	None <sup>g</sup>	<b>Pruning</b> (Hand)	Scouting, Weeding (Hand, Mech.), Irrigating <sup>e</sup> , Transplant/Propagate <sup>f</sup>
FN	Cranberries	1	90	None	Pruning, Weeding (Hand), Scouting, Thinning <sup>g</sup>	Irrigating <sup>e</sup> , Weeding, Harvesting (Mech.), Sanding beds, Scouting, Transplant/Propagate
FN	Stone Fruits (Apricot, Cherry, Plum, Prune)	1	356	Thinning	<b>Pruning</b> (Nondormant)	Scouting, Irrigating <sup>e</sup> , Weeding (Mech.), Pruning (Dormant), Propping, Transplanting/ Propagating <sup>f</sup>
FN	Pome Fruits (Apple, Pear)	1	356	Thinning	<b>Pruning</b> (Nondormant)	Scouting, Irrigating <sup>e</sup> , Weeding (Mech.), Pruning (Dormant), Propping, Transplanting/ Propagating <sup>f</sup>
FN	Kiwi	1	356	Thinning <sup>g</sup>	<b>Pruning</b> (Nondormant)	Scouting, Irrigating <sup>e</sup> , Weeding (Mech.), Pruning (Dormant), Propping, Transplanting/ Propagating <sup>f</sup>
FN	Nut (Almond, Walnut, Pistachio)	1	356	None	None <sup>g</sup>	Weeding (Mech.), Irrigating <sup>e</sup> , Scouting, Transplant/Propagate <sup>f</sup> , Pruning (Dormant)

Site Cat <sup>a</sup>	Use Sites <sup>b</sup>	REI <sup>c</sup> (day)	PHI <sup>d</sup> (day)	Tier I Activities (High)	Tier II Activities (Medium)	Tier III Activities (Low)
FN	Grape	1	356	Cane Turning	Thinning, Scouting, Tying/Training/ Trellising, Cane Cutting <sup>g</sup>	Weeding (Hand), Irrigating <sup>e</sup> , Transplant/Propagate <sup>f</sup> , Suckering
M	Turf, Golf Course	0.5	0.5	None	None	Aerating, Pruning, Scouting, Irrigating <sup>e</sup> , Golfing, Weeding, Mowing
M	Lawns	0.5	-	None	<b>Contact with treated turf, ingest treated soil</b>	Aerating, irrigating <sup>e</sup> , weeding, mowing, scouting
M	Non-Crop Areas (Field borders, Fencerows, Roadsides, Ditchbanks, Borrow pits, Wasteland)	1	-	None	None	Scouting, Weeding
OT	Nursery Ornamentals (Tree/Shrubs, Flowering, Crape Myrtle)	1	-	None	<b>Pruning</b>	Scouting, Irrigating <sup>e</sup> , Thinning, Weeding, Transplanting <sup>f</sup>
OT	Nursery Plants in Containers	1	1	None	<b>Harvesting (Hand)</b>	Irrigating <sup>e</sup> , Scouting, Thinning, Turning, Tying, Weeding, Transplanting <sup>f</sup>
OT	Outdoor Floral crops and Ground Covers	1	-	None	<b>Harvesting (Hand)</b>	Irrigating <sup>e</sup> , Scouting, Thinning, Turning, Tying, Weeding, Transplanting <sup>f</sup>
OT	Greenhouse (Cut Flowers or Greens)	1	1	None	<b>Harvesting (Hand)</b>	Irrigating <sup>e</sup> , Scouting, Thinning, Turning, Tying, Weeding, Bud Pinching (flowers), Transplanting <sup>f</sup>
OT	Mint	1	14	None	None	Irrigating <sup>e</sup> , Scouting, Harvesting
V	Beans (Succulent and Dried)	1	14	<b>Harvesting (Hand)</b>	Irrigating <sup>e</sup> , <b>Scouting</b>	Weeding, Harvesting (Mech.)
V	Brussels Sprouts	1	14	Irrigating <sup>e</sup> , Topping, <b>Harvesting (Hand)</b>	<b>Scouting</b>	Weeding, Thinning, Transplanting <sup>f</sup> , Harvesting (Mech.)
V	Cauliflower	1	14	Tying, Irrigating <sup>e</sup> , Banding, <b>Harvesting (Hand)</b>	Scouting	Weeding, Transplanting <sup>f</sup> , Harvesting (Mech.)
V	Celery	1	21	<b>Harvesting (Hand)</b>	Irrigating <sup>e</sup> , <b>Scouting</b>	Weeding, Transplanting <sup>f</sup>

Site Cat <sup>a</sup>	Use Sites <sup>b</sup>	REI <sup>c</sup> (day)	PHI <sup>d</sup> (day)	Tier I Activities (High)	Tier II Activities (Medium)	Tier III Activities (Low)
V	Head Lettuce	1	21	Head Breaking, <b>Harvesting</b> (Hand)	Irrigating <sup>e</sup> , <b>Scouting</b>	Weeding, Thinning, Transplanting <sup>f</sup>
V	Onion	1	14	None	<b>Harvesting</b> (Hand)	Scouting, Irrigating <sup>e</sup> , Weeding, Transplanting <sup>f</sup> , Thinning
V	Peanut	1	14	None	Irrigating <sup>e</sup> , <b>Scouting</b>	Weeding, Harvesting (Mech.)
V	Pepper (Bell and Non- Bell types)	1	7	Thinning, <b>Harvesting</b> (Hand)	Irrigating <sup>e</sup> , <b>Scouting</b>	Weeding, Transplanting <sup>f</sup>
V	Potato	1	N/A	None	Irrigating <sup>e</sup> , <b>Scouting</b>	Weeding, Transplanting <sup>g</sup> , Harvesting (Mech.)
V	Tomato (Fresh Market, Processing/ Canning)	1		Tying, Training, Staking, <b>Harvesting</b> (Hand)	Irrigating <sup>e</sup> , <b>Scouting</b>	Weeding, Thinning, Transplanting <sup>f</sup>

<sup>a</sup> Use site categories: FC = Field crops; FN = Fruits and nuts; M = Miscellaneous; OT = Ornamentals, herbs, trees, nursery/greenhouse; V = Vegetables.

<sup>b</sup> Use Sites were listed based on the product labels.

<sup>c</sup> REI = Minimum restricted entry interval listed for crop in California on any product label.

<sup>d</sup> PHI = Minimum preharvest interval listed for crop in California on any product label.

<sup>e</sup> Irrigator exposure is dependent upon the method of irrigation used for the crop, which are (1) drip irrigation is Tier III (low), (2) flood or furrow irrigation of crops less than 18 inches high is Tier III (low), (3) flood or furrow irrigation of crops 18 inches or taller is Tier II (moderate), (4) sprinkler irrigation of crops less than 18 inches high is Tier II (moderate), and (5) sprinkler irrigation of crops 18 inches or taller is Tier I (high).

<sup>f</sup> Transplant/propagate activity has little potential for exposure in the field, but may present a potential for exposure during the propagation stage in the nursery or greenhouse setting. Refer to greenhouse/nursery scenario.

<sup>g</sup> Based on the product labels, acephate is limited to application to non-bearing fruit trees, nut trees and vines in nursery fields or non-bearing orchards. Therefore, harvest activities on fruits were not assessed in this document.

<sup>h</sup> Mechanical (Mech.) harvesting by shaking and sweeping to drop and collect fruits/nuts, respectively, may generate dust and debris (falling leaves, branches, produce) sufficient to expose harvester to pesticide residues by dermal contact or via inhalation of debris/dust.