US EPA ARCHIVE DOCUMENT

United States Environmental Protection Agency
Prevention, Pesticides and Toxic Substance (7508C)
EPA 738-R-04-07016
May 2004

Reregistration Eligibility Decision (RED)

Naphthaleneacetic Acid, Its Salts, Ester, and Acetamide

REREGISTRATION ELIGIBILITY DECISION (RED)
for
Naphthaleneacetic Acid, Its Salts, Ester, and Acetamide

CASE 0379

Includes chemicals:

056001 1-Naphthaleneacetamide
056002 1-Naphthalene acetic acid,
056003 Potassium 1-naphthaleneacetate
056004 Ammonium 1-naphthaleneacetate
056007 Sodium 1-naphthaleneacetate
056008 Ethyl 1-naphthaleneacetate

Approved by: _____
Debra Edwards, Ph. D.
Director
Special Review and Reregistration Division

Date: _____
May 26, 2004

Naphthalene Acetates Team

Office of Pesticide Programs:

Health Effects Risk Assessment
Becky Daiss
Gary Otakie
Abdallah Khasawinah

Environmental Fate Risk Assessment
Jose Melendez
Dirk Young
Allen Vaughn

Biological and Economics Division
Julie Heflin
Nicole Zinn

Registration Division Support
John Bazuin

Risk Management
Mark T. Howard
Neil Anderson

I. Determination of Reregistration Eligibility for the Naphthalene Acetates

Section 4(g)(2)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) calls for the Environmental Protection Agency (EPA or the Agency) to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration, which is set forth in the reregistration eligibility decision (RED). The Agency has previously identified and required the submission of the generic (i.e., an active ingredient specific) data required to support reregistration of products containing naphthalene acetate active ingredients.

The Agency has completed its assessment of the dietary, residential, occupational, and ecological risks associated with the use of currently registered pesticide products containing naphthalene acetate active ingredients. Based on a review of these data and registrant comments on the Agency's assessments for the naphthalene acetate active ingredients, EPA has sufficient information on the human health and ecological effects of the naphthalene acetates to make decisions as part of the tolerance reassessment process under the Federal Food, Drug and Cosmetic Act (FFDCA) and reregistration under FIFRA, as amended by the Food Quality Protection Act (FQPA). The Agency has determined that the naphthalene acetates are eligible for reregistration provided that: (i) current data gaps and additional data needs are addressed and (ii) the label changes outlined in this document are adopted. Accordingly, should a registrant fail to implement any of the label change or other measures identified in this document, the Agency may take further regulatory action for the naphthalene acetates.

II. Chemical Overview

A. Regulatory History

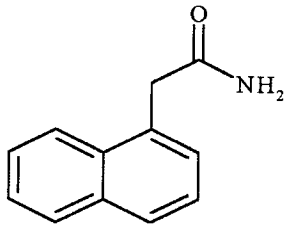
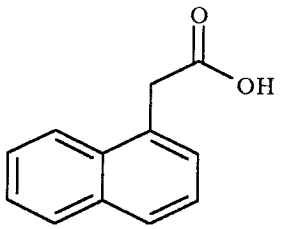
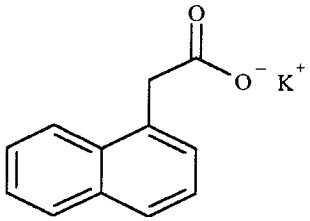
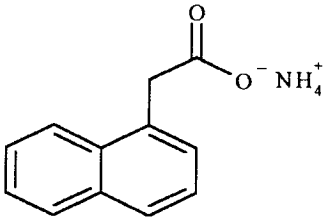
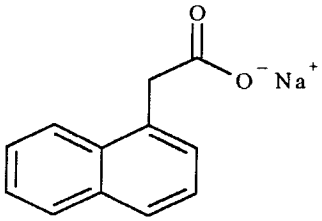
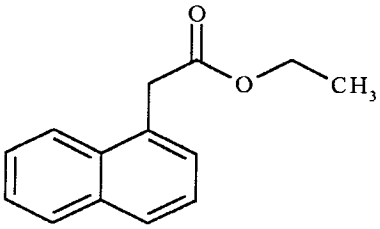
The first naphthalene acetate end-use product (with the naphthalene acetimide as the active ingredient), Rootone Brand Rooting Hormone with Fungicide, was registered in 1952. Its labeled use was to stimulate root growth of cuttings of a number of ornamental plants, vines, and shrubs, deciduous trees, and evergreens. Seven more naphthalene acetates, including naphthalene acetic acid (NAA), were registered in the early to mid-1960s. There are six active ingredients currently registered as part of the naphthaleneacetates case.

In August 1981, EPA published a Registration Standard for "Naphthaleneacetic Acid its, Salts, Ester, and Acetamide." This document described the uses and established the data requirements to reregister the naphthalene acetates. Tolerances were established for NAA in/on apples, pears, quinces, olives, and pineapples (as the sodium salt); for the ethyl ester of NAA in/on apples, pears, and olives; and for naphthaleneacetamide in/on apples and pears. Data Call-ins (DCIs) were issued in October and November 1990, and October 1995. The 1990 DCIs mainly restated data requirements of the Registration Standard and the 1995 DCI required data to discern post-application (reentry) occupational and residential exposure.

B. Chemical Identification

- Common Family: Naphthalene acetates
- Case number: 0379
- Basic manufacturer: Amvac Chemical Company

Table 1. Naphthalene Acetates Nomenclature

Common name	NAA acetamide (NAAm)	NAA
Chemical structure		
Molecular Formula	$C_{12}H_{11}NO$	$C_{12}H_{10}O_2$
Molecular Weight	185.23	186.20
CAS name	1-naphthaleneacetamide	1-naphthaleneacetic acid
CAS #	86-86-2	86-87-3
PC Code	056001	056002
Common name	**NAA potassium salt**	**NAA ammonium salt**
Chemical structure		
Molecular Formula	$C_{12}H_{10}O_2K$	$C_{12}H_{13}NO_2$
Molecular Weight	225.31	203.24
CAS name	1-naphthalene acetic acid, potassium salt	1-naphthaleneacetic acid, ammonium salt
CAS #	15165-79-4	25545-89-5
PC Code	056003	056004
Common name	**NAA sodium salt**	**NAA ethyl ester (NAA-OEt)**
Chemical structure		

Molecular Formula	$C_{12}H_{10}O_2Na$	$C_{14}H_{14}O_2$
Molecular Weight	209.2	214.26
CAS name	1-Naphthaleneacetic acid, sodium salt	1-Naphthaleneacetic acid, ethyl ester
CAS #	61-31-4	2122-70-5
PC Code	056007	056008

C. Use Profile and Estimated Use of Pesticide

1-Naphthaleneacetic acid (NAA), its salts, ester, and acetamide are plant growth regulators (PGR) which are collectively referred to as naphthalene acetates. The PGR activity of NAA is due to its structural similarity to the natural plant hormone indole acetic acid (IAA). They are currently registered for use on various orchard and fruit crops including apple, cherry, olive, orange, pear, tangelo, and tangerine. As plant growth regulators, they may be used on the above-listed crops to prevent preharvest drop of fruits, thin fruit trees, and delay flower induction. They can also stimulate growth and delay leaf drop on ornamentals.

Approximately 20,000 lbs of the naphthalene acetate active ingredients are applied annually in the U.S. The registered formulation classes of naphthalene acetates, which may be used on food/feed crops, include wettable powder, dust, flowable concentrate, soluble concentrate, and liquid ready-to-use. These formulations may be applied using broadcast ground or aerial equipment, hand-held sprayers, paint brush, dip treatment or soil drench. The naphthalene acetates are typically applied as a dilute (1-2%) spray solution, and the timing of treatment would vary depending on the purpose of treatments. The ethyl ester and acetamide of NAA are used early in the season to control sprout formation and fruit set (thinning), respectively. NAA or its ammonium, potassium, or sodium salts can be used either early in the season for fruit thinning or later in the season for control of fruit drop.

III. Summary of Human Health and Environmental Risk Assessments

The Agency's human health and environmental risk findings for the naphthalene acetate pesticides are summarized in the *Overview of Naphthaleneacetic Acid Its Salts, Ester, and Acetamide Risk Assessments*, dated May 25, 2004, which is located in Section VI of this document. The findings contained in the *Overview* document are hereby incorporated in this RED. A complete list of supporting documents detailing EPA's human health and ecological risk findings and conclusions for the naphthalene acetates are provided in Appendix C. These technical support documents for the naphthalene acetates are available on the Internet at http://www.epa.gov/e-dockets and in the Office of Pesticide Program's (OPP) public docket for viewing. The OPP docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, and is open Monday through Friday, excluding legal holidays, from 8:30 AM to 4:00 PM.

A. Human Health Risk Assessment

For the purpose of the human health risk assessment, all forms of the naphthalene acetates are combined (1-Naphthaleneacetic acid (NAA), its salts, ester, and acetamide) because they are structurally related and are metabolized to the acid form and eliminated from the body as glycine and glucuronic acid conjugates within 48 hours after exposure. The Agency conducted a screening-level risk assessment for the naphthalene acetates in which high-end assumptions were used for most key parameters. Analyses of dietary (food), drinking water, residential and occupational exposure pathways were evaluated in the naphthalene acetates risk assessment. An aggregate assessment of risk from the combined food and drinking water pathways was also conducted.

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is essentially complete to support a reregistration eligibility determination for all currently registered uses of the naphthalene acetates. The naphthalene acetates show low acute toxicity, are not mutagenic, and are not expected to be carcinogenic. The most common effect from high exposure to the naphthalene acetates is vomiting and reduced body weight gain. They also affect the stomach and liver. The Agency has not identified any metabolites (break down substances) of toxicological concern. A summary of the toxicological endpoints selected and other factors used in the human health risk assessment are provided in Table 2.

Table 2. Summary of Toxicological Endpoints and Other Factors Used in the Risk Assessment of the Naphthalene Acetates

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study	Uncertainty Factor	FQPA Safety Factor	PAD - (mg/kg/day)
Dietary Risk Assessment						
Acute Dietary all populations	NOAEL = 50 LOAEL = 250	Decreased body weight gain during gestation period.	Rat Developmental	100	1X	0.5
Chronic Dietary all populations	NOAEL = 15 LOAEL = 75	vomiting, stomach and liver effects	Chronic Dog	100	1X	0.15
Occupational and Residential Risk Assessment						
Dermal Short-Term (1 - 30 days)	NOAEL = 300 LOAEL = 1000	reduced body weight gain and food efficiency	21-day Dermal Rat	100	1X	N/A

Inhalation Short-Term (1 - 30 days)	NOAEL = 50* LOAEL = 150	decreased body weight gain during gestation period.	Oral DevelopmentalRat	100	N/A	N/A

NOAEL = No Observable Adverse Effects Level LOAEL - Lowest Observable Adverse Effects Level
PAD = Population Adjusted Dose
No intermediate-term (1 - 6 Months) or long-term (> 6 Months) dermal or inhalation exposure scenarios were identified - therefore, toxicity endpoints were not selected.
* Inhalation NOAEL is based on an oral study with route adjustment (adjust from oral/ingestion to inhalation route)

The Food Quality Protection Act Safety Factor (FQPA SF) was removed (reduced to 1x) for all population subgroups. The Agency determined that this safety factor is adequate to protect infants and children because there are no residual uncertainties in the exposure databases, the toxicology database is complete, and the endpoint and NOAELs/LOAEL for risk assessment were well defined. In the toxicology database, there was no quantitative or qualitative evidence of increased susceptibility in rat or rabbit fetuses following *in utero* exposure to naphthalene acetates or to pre- and post-natal exposure in rat reproduction studies.

1. Dietary Risk From Food

Acute (one day) and chronic (lifetime) dietary naphthalene acetates exposure and risk estimates resulting from food intake were determined for the general U.S. population and various population subgroups using conservative assumptions and two different computer models (DEEM-FCID™ and Lifeline) that use surveys of U.S. dietary consumption patterns. Based on analyses of estimated dietary risks for the general U.S. population and various population subgroups, the acute and chronic dietary exposure estimates for naphthalene acetates are significantly below EPA's level of concern for all supported commodities and not a risk of concern; therefore, no measures are necessary to mitigate dietary risk from food. No cancer dietary exposure assessment was performed because carcinogenicity studies do not indicate a carcinogenic concern.

2. Dietary Risk from Water

Dietary exposures from drinking water contaminated with concentrations of the naphthalene acetates can potentially occur from sources of ground water and surface water in areas where these pesticides are used. EPA calculated estimated drinking water concentrations (EDWCs) for the naphthalene acetates using screening-level computer models that provide high-end estimates of pesticide concentrations for surface water and ground water sources. Based on these models, all EDWCs are low and not of risk concern; therefore, no measures are necessary to mitigate dietary risk from drinking water.

3. Residential Risks

Residential uses are limited to application of naphthalene acetates to stimulate root growth (root dips and soil drench) and application of the ethyl ester of naphthalene acetates to control sprouts and sucker growth on fruit and ornamental trees. Both uses are considered short-term (1 - 30 days) exposure scenarios. Estimated dermal and inhalation margins of exposure (MOEs) for the most highly exposed scenario of residential exposure to the naphthalene acetates are well above the target MOE of 100 and are not of risk concern; therefore, no measures are necessary to mitigate risk from residential uses.

4. Aggregate Risk

The aggregate risk assessment integrates the assessments conducted for food and drinking water, and residential exposure where appropriate. Since there is potential for concurrent exposure via the food, drinking water and short-term residential exposure pathways, the combined exposures are estimated and compared with modeling-based estimates of drinking water contamination. The acute and chronic aggregate risk assessment for naphthalene acetates include exposure from food and drinking water only. Both acute and chronic aggregate risks are not of concern; therefore, no measures are necessary to mitigate risk from the aggregation of dietary (food and drinking water) exposures. Short-term aggregate risk cannot be estimated for dietary and residential exposures, because the toxicity endpoints selected for the dietary routes of exposure and those selected for residential exposures of the naphthalene acetates are not based on common effects.

5. Occupational Handler and Post-Application Risks

Based on actively registered labels for the naphthalene acetates, EPA assessed 12 scenarios for the naphthalene acetates RED. All handler scenarios evaluated indicate that risks are not of concern. Both dermal and inhalation MOEs for the occupational handler exposure scenarios are above the target MOE of 100 using baseline personal protective equipment (PPE), which includes long-sleeved shirt, long pants, shoes, and socks.

For individuals who can be exposed to pesticides after entering areas previously treated with pesticides and performing certain activities (also often referred to as reentry exposure), two occupational post-application scenarios were assessed for the naphthalene acetates. Post-application exposures are based on dermal routes only, inhalation exposure is not expected. The MOEs for the two post-application exposure scenarios are well above the target MOE of 100 on the day of application and, therefore, not of risk concern. As a result no measures are necessary to mitigate risk from occupational exposures.

B. Environmental Risk Assessment

1. Risk to Non-Target Species

Based on the limited data set available, EPA believes that the naphthalene acetates risks are not of concern to nontarget organisms, including mammals, birds, aquatic organisms, and nontarget plants. Risks to terrestrial insects cannot be quantified, but the available data do not suggest a substantial potential for adverse effects. Therefore, no measures are needed to mitigate risk to non-target species.

2. Endangered Species Assessment

For endangered species, the Agency adopts lower levels of concern (LOCs) for risks to some groups – i.e., 0.1 for mammals and birds and 0.05 for aquatic animals – relative to levels of concern for acute risks in non-endangered species – i.e., 0.5 for mammals and birds as well as aquatic animals. Based on the environmental risk assessment, the Agency's levels of concern for endangered and threatened species for mammals, birds, aquatic animals and plants are not exceeded for the naphthalene acetates. Hence, the Agency concludes that the use of NAA will have no effect on any endangered or threatened species or their critical habitat, from the uses currently registered.

C. Cumulative Risk

The estimated risks summarized in this document are those that result only from the use of the naphthalene acetates. FQPA requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for the naphthalene acetates. They do not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of the risk assessments, EPA has not assumed that the naphthalene acetates have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

D. Endocrine Disrupter Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such

endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, the naphthalene acetates may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

E. Tolerance Summary

The Agency has determined that the terminal residues of concern in plants, resulting from currently registered food/feed uses, are the parent compounds, NAA and its conjugates. There are several tolerance expressions for naphthalene acetates resulting from applications of NAA, its salts, ester, and acetamide. Currently, the tolerances listed under 40 CFR §180.155 (a) are for residues of 1-naphthaleneacetic acid. The tolerances listed under 40 CFR §180.155 (b) are for residues of the ethyl ester of 1-naphthaleneacetic acid. The tolerances listed under 40 CFR §180.309 are for residues of α-naphthaleneacetamide and its metabolite α-naphthaleneacetic acid (calculated as α-naphthaleneacetic acid). According to 40 CFR §180.3(d)(7), for commodities having both NAA and NAA metabolite tolerances, the total amount of residues, calculated as NAA, shall not exceed the higher of the two tolerances.

EPA is now recommending that various NAA tolerance expressions under 40 CFR §180 be combined in §180.155(a). In 40 CFR §180.155, the Agency is recodifying paragraph (b) and the table under it from (b) to (a). Also, to conform to current Agency practice, paragraphs (b), (c), and (d) should be established and reserved as follows:

(b) Section 18 emergency exemptions. [Reserved]
(c) Tolerances with regional registrations. [Reserved]
(d) Indirect or inadvertent residues. [Reserved]

Consequently, 40 CFR §180.309 will be removed because that specific tolerance expression is no longer needed since it is included in the recodified paragraph (a).

Available olive residue data using application rates representative of the use pattern in a region where the naphthalene acetate products are commonly used, show residues of NAA which range (0.306 to 0.604 ppm) above the current tolerance level of 0.1 ppm. Therefore, the Agency is recommending that the tolerance on olive for combined residues of 1-naphthaleneacetic acid, its ammonium, sodium, and potassium salts, ethyl ester, and acetamide should be increased to 0.7 ppm in 40 CFR §180.155(a).

At this time, the Agency has tentatively determined that NAA is a Category 3 pesticide (i.e., no reasonable expectations of finite residues of concern in meat and milk). This tentative conclusion is reserved pending submission of the required citrus processing study and a determination of the residues in the processed commodities of citrus fruits. When the requested processing data are submitted, the Agency will re-evaluate NAA's Category 3 determination and, if necessary, recalculate the estimated dietary burden for ruminants. There are no poultry feed items associated with the currently registered food/feed uses of naphthalene acetates.

The reassessed tolerance for sweet cherry is contingent upon revising existing labels to specify a 30-day pre-harvest interval. EPA is also recommending that the naphthalene acetate tolerances currently established for apple, pear and quince be reassigned to fruit, pome; and the tolerance level be lowered to 0.1 ppm because residue levels from field trial data never exceeded 0.06 ppm. A summary of the tolerance reassessments and the changes to occur under 40 CFR §180.155 for the naphthalene acetates is presented in Table 3.

Table 3. Tolerance Reassessment Summary for Naphthalene Acetates.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.155 (a)			
Apple	1	Reassign 0.1	Crop group tolerance is being established at 0.1 ppm based on field trial data that indicate a range of <0.02 (nondetectable) to 0.06 ppm residues for NAA-OEt, NAAm, and NAA-potassium salt. *[fruit, pome, group 11]*
Cherry, sweet	0.1	0.1	Residues of NAA in/on whole cherries were each nondetectable (<0.04 ppm) in/on treated samples collected at 2 hours, 15 days, and 30 days post-treatment.
Olive	0.1 (N)	0.7	Residues of NAA ranged from 0.306 to 0.610 ppm in/on olives harvested 102-112 days following the last of two sequential treatments consisting of: (i) a single spot treatment of the 1.15% RTU formulation (NAA ethyl ester) applied to runoff at a rate of 0.14-1.00 lb ai/A to control suckers and sprouting early in the growing season; and (ii) a single broadcast thinning application of the 24.2% SC formulation (NAA-potassium salt) at 0.871-1.13 lb ai/A.
Oranges, sweet	0.1	0.1	The maximum expected residue of NAA resulting from registered uses on oranges is 0.05 ppm. [*Orange*]
Pear	1	Reassign 0.1	Crop group tolerance is being established at 0.1 ppm based on field trial data that indicate a range of <0.02 (nondetectable) to 0.06 ppm residues for NAA-OEt, NAAm, and NAA-potassium salt. *[fruit, pome, group 11]*

Table 3. Tolerance Reassessment Summary for Naphthalene Acetates.			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Pineapple (from the application of the sodium salt to the growing crop)	0.05	0.05	Registrant is supporting tolerance for importation purposes only.
Quince	1	Reassign 0.1	Crop group tolerance is being established at 0.1 ppm based on field trial data that indicate a range of <0.02 (nondetectable) to 0.06 ppm residues for NAA-OEt, NAAm, and NAA-potassium salt. *[fruit, pome, group 11]*
Tangerine	0.1	0.1	The residue data that were submitted by IR-4 for tangerine and in combination with orange, through PP#7E1956, are adequate to support reregistration requirements.
Tolerances Currently Listed Under 40 CFR §180.155 (b) ** all tolerances in this section are to be reassigned to 40 CFR §180.155 (a) **			
Apple	1	Reassign 0.1	See Comments for apple above under 40 CFR §180.155 (a). *[fruit, pome, group 11]*
Pear	1	Reassign 0.1	See Comments for pear above under 40 CFR §180.155 (a). *[fruit, pome, group 11]*
Olive	0.1	Reassign 0.7	See Comments for olive above under 40 CFR §180.155 (a).
Tolerances Currently Listed Under 40 CFR §180.309 ** all tolerances in this section are to be reassigned to 40 CFR §180.155 (a) **			
Apple	0.1	Reassign 0.1	See Comments for apple and pear above under 40 CFR §180.155 (a). *[fruit, pome, group 11]*
Pear	0.1	Reassign 0.1	

Codex/International Harmonization

No maximum residue limits (MRLs) have been established in the Codex alimentarius, the food code established by the UN's World Health Organization and the Food and Agriculture Organization for NAA, its salts, ester, and acetamide; therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist. Moreover, no Canadian or Mexican MRLs have been established for naphthalene acetates. For more information on Codex see http://www.codexalimentarius.net/standard_list.asp.

IV. Confirmatory Generic Data Requirements

The generic database supporting the reregistration of the naphthalene acetates is substantially complete, except for the following additional required confirmatory data:

- UV/visible Absorption (OPPTS 830.7050)
- Storage stability data on the processed commodities of apples (or citrus fruits) and olives. (OPPTS 860.1380)
- Data depicting residues of NAA and its conjugates in the processed commodities of citrus (dried pulp, oil, and juice). (OPPTS 860.1520)
- The replenishment of analytical reference standards for all registered NAA acid salts, ester, and acetamide as requested by the Repository. (OPPTS 860.1650)

V. Label Changes:

In order to be eligible for reregistration, all product labels are to be amended to incorporate measures outlined in this RED document. Furthermore, many of the existing labels for the naphthalene acetates need to be revised to provide clear use directions. EPA, through discussions with the registrant, user groups, and USDA, determined the following maximum use pattern information which is to be clearly stated on naphthalene acetates product labels. Table 4 describes how language on the labels should be amended.

- Maximum single application rate:	0.11 lb ai/acre
- Maximum application rate per year or crop cycle:	0.33 lb ai/acre/year or crop cycle
- Minimum re-treatment interval between applications:	5 days
- Restricted Entry Interval (REI):	48 hours for NAA; NAA Potassium Salt; NAA Ammonium Salt; NAA Sodium Salt; and NAA Acetamide 12 hours for NAA Ethyl Ester

Table 4: Summary of Labeling Changes for Naphthalene Acetates		
Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
For all Manufacturing Use Products	"Only for formulation into plant growth regulators for the following use(s) [*fill blank only with those uses that are being supported by MP registrant*]."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements
End Use Products Intended for Occupational Use		
PPE Requirements Established by the RED[1] for All Formulations	"Personal Protective Equipment (PPE)" "All mixers, loaders, applicators, flaggers, and other handlers must wear: Long-sleeved shirt and long pants, Shoes plus socks."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Table 4: Summary of Labeling Changes for Naphthalene Acetates		
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	"For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."	Precautionary Statements immediately following the User Safety Recommendations

Table 4: Summary of Labeling Changes for Naphthalene Acetates		
Restricted-Entry Interval for Products Formulated with any of the Following Active Ingredients: NAA NAA Potassium Salt NAA Ammonium Salt NAA Sodium Salt NAA Acetamide	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours."	Directions for Use, Under Agricultural Use Requirements Box
Early Entry Personal Protective Equipment established by the RED for the Following Active Ingredients: NAA NAA Potassium Salt NAA Ammonium Salt NAA Sodium Salt NAA Acetamide.	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: * coveralls, * shoes plus socks, * chemical-resistant gloves made of any waterproof material, * protective eyewear"	Direction for Use Agricultural Use Requirements box
Restricted-Entry Interval for Products Formulated with NAA Ethyl Ester	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours." (Products containing NAA Ethyl Ester may be eligible for a 4 hour REI. Registrants are required to submit the required certification statement to the Agency and formally request the 4-hour REI as specified in PR Notice 95-3.)	Directions for Use, Under Agricultural Use Requirements Box

Table 4: Summary of Labeling Changes for Naphthalene Acetates		
Early Entry Personal Protective Equipment established by the RED for NAA Ethyl Ester	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: * coveralls, * shoes plus socks * chemical-resistant gloves made of any waterproof material"	
General Application Restrictions	"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."	Place in the Direction for Use directly above the Agricultural Use Box.
Other Application Restrictions (Risk Mitigation)	"For broadcast use, the maximum application rate is 0.11 pounds active ingredient per acre of NAA equivalent for all uses. [*Registrant: state the maximum use rate as a maximum rate of pounds or gallons of formulation per acre equivalent to 0.11 pounds active ingredient per acre or less*]" "The maximum application rate per year or crop cycle is not to exceed 0.33 pounds active ingredient per acre of NAA equivalent. [*Registrant: state the maximum rate per year or crop cycle as a maximum rate of pounds or gallons of formulation per acre equivalent to 0.33 pounds active ingredient per year or crop cycle or less*]" "The minimum interval between applications is to be no less than 5 days."	Directions for Use
Spray Drift	"Avoiding spray drift is the responsibility of the applicator. The interaction of many equipment and weather-related factors determine the potential for spray drift. The applicator is responsible for considering all these factors when making decisions."	Directions for Use

Table 4: Summary of Labeling Changes for Naphthalene Acetates		
End Use Products Intended for Residential Use		
Application Restrictions	"Do not apply this product in a way that will contact any person, pet, either directly or through drift. Keep people and pets out of the area during application."	Directions for Use under General Precautions and Restrictions
Entry Restrictions	Liquid: "Do not allow people or pets to enter the treated area until sprays have dried."	Directions for use under General Precautions and Restrictions
Environmental Hazards	"Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate."	

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

VI. Overview Document

The following *Overview of Naphthaleneacetic Acid Its Salts, Ester, and Acetamide Risk Assessments* document provides further details on the human health and environmental risk assessments and conclusions.

Overview of Naphthaleneacetic Acid Its Salts, Ester, and Acetamide Risk Assessments

May 26, 2004

Introduction

This document summarizes the Environmental Protection Agency's (EPA or the Agency) human health risk and environmental assessments and conclusions for the chemicals collectively referred to as the naphthalene acetates[1]. The naphthalene acetates are plant growth regulators currently registered for use on various orchard and fruit crops and on ornamental trees. Naphthalene acetates are used to stimulate growth, delay flower induction and leaf drop, prevent preharvest fruit drop, thin fruit, and control sprout formation.

The purpose of this overview is to assist the reader by identifying the key features and findings of the risk assessments, and to allow the reader to better understand the conclusions reached in the assessments and in the Reregistration Eligibility Decision (RED). The Agency developed this overview format in response to comments and requests from the public which indicated that the risk assessments were difficult to understand, that they were too lengthy, and that it was not easy to compare the assessments for different chemicals due to differing formats.

The Agency now has adequate information to make eligibility decisions for all of the naphthalene acetate products. EPA has reviewed the data provided by the naphthalene acetates registrant and data available in the public literature. Using this information, EPA has conducted assessments of the human health and environmental risks for the labeled use of the naphthalene acetate products. These assessments and all their supporting technical documents are posted on the Internet (http:www.epa.gov/edockets) under docket number OPP-2004-0144.

The estimated risks summarized in this document are those that result only from the use of the naphthalene acetates. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as

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[1] Naphthalene acetates include: 1-Naphthaleneacetamide, 1-Naphthalene acetic acid, Potassium 1-naphthaleneacetate, Ammonium 1-naphthaleneacetate, Sodium 1-naphthaleneacetate, Ethyl 1-naphthaleneacetate

would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for the naphthalene acetates. They do not appear to produce a toxic metabolite produced by other substances. For the purposes of the risk assessments, therefore, EPA has not assumed that the naphthalene acetates have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

Use Profile

The naphthalene acetates are plant growth regulators. The plant growth regulating activity of the naphthalene acetates is due to their structural similarity to the most common, naturally occurring plant growth hormone (auxin), which is chemically known as indole acetic acid (IAA). Auxins promote growth in excised plant organs, induces adventitious roots, inhibits axillary bud growth, and regulates gravitropism. Naphthalene acetates are used to stimulate growth, delay flower induction and leaf drop, prevent preharvest fruit drop, thin fruit, and control sprout formation and sucker growth.

Technical Registrant: AMVAC Chemical Company

Use Sites and Use Related Information:

- Approximately 20,000 lbs of the naphthalene acetate active ingredients are applied annually in the U.S.

- The naphthalene acetates are registered for use on apples, pears, citrus, olives, cherries, some non-bearing fruit and nut trees, ornamental plants (herbaceous, non-flowering trees, woody shrubs and vines) and shade trees. They also have residential uses to stimulate root growth (root dips and soil drench) and to control sprouts and sucker growth on fruit and ornamental trees.

- Apples and pears represent approximately 95% of the total active ingredient used annually with all other registered use sites accounting for the remaining use.

Formulations:

- Forty active products are currently registered for the naphthalene acetates with 12 Special Local Need registrations (FIFRA §24(c)) in California, Oregon and Washington.

- Registered products include the following formulations: dust (0.2% active ingredient or a.i.), emulsifiable concentrate (6.25-15.1% a.i.), wettable powder (7.1-8.4% a.i.), soluble concentrate/liquid (0.1-24.2% a.i.), ready-to-use (0.08-1.15% a.i.), flowable concentrate (0.45-1.2% a.i.), and pressurized liquid (1% a.i.).

Application Methods and Equipment:

- Thinning and stop drop formulations - ground spray or aerial equipment.
- Sprout/sucker formation control - hand held sprayer and paint brush.
- Root growth stimulant - dilute root dip or soil drench.

Human Health Risk Assessment

Dietary Risk from Food

Acute and chronic dietary exposure assessments were conducted for all supported naphthalene acetates food uses using both Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 1.3) and Lifeline Model (Version 2) software. The acute and chronic dietary (food) risk analyses were conducted using tolerance values and assuming 100% crop treated (Tier 1). The acute and chronic dietary exposure and risk estimates resulting from intake of food with residues of the naphthalene acetates was determined for the general U.S. population and various population subgroups. No cancer dietary exposure assessment was performed because carcinogenicity studies do not indicate a carcinogenic concern.

The assessment concludes that, for all supported commodities, the acute and chronic dietary exposure estimates are well below EPA's level of concern. Naphthalene acetate risks from food consumption are summarized in Table 1 below for the general U.S. population and the various population subgroups. Risks less than 100% of the Population Adjusted Dose (PAD), either acute (aPAD) or chronic (cPAD), are not of concern to the Agency. The aPAD is the dose at which a person could be exposed on any given day and no adverse health effects would be expected. The cPAD is the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected.

Table 1. Estimated Acute and Chronic Dietary Exposures and Risks for the Naphthalene Acetates

Population Subgroup	Acute (95th %-ile)			Chronic (average exposure)		
	aPAD (mg/kg/day)	Exposure (mg/kg/day)	% aPAD	cPAD (mg/kg/day)	Exposure (mg/kg/day)	% cPAD
U.S. Population	0.5	0.007763	2	0.15	0.001689	1
All Infants (< 1 yr old)	0.5	0.039407	8	0.15	0.008784	6
Children (1-2 yrs)	0.5	0.048857	10	0.15	0.012100	8

Acute Dietary Risk from Food

For acute dietary exposure and risk assessments, individual one-day food consumption data are used on an individual-by-individual basis.

- The acute dietary exposure/risk analysis for all supported naphthalene acetates food uses were conducted using Tier 1 conservative exposure assessments. Tier 1 analyses assume tolerance level residues for all registered uses, 100% crop treated for all commodities with existing tolerances, and default processing factors. Acute dietary risk was then calculated by comparing dietary exposure to the aPAD.

- As shown in Table 1, risk estimates for all commodities are less than 100% of the aPAD for all subpopulations when considering the 95th percentile of exposure. The highest exposed subpopulation (children 1-2 years) is at 10% of the aPAD, and the general population is at 2% of the aPAD.

- EPA calculated the aPAD and acute dietary risk levels for the naphthalene acetates using the following data:

  - The toxicity endpoint selected for acute dietary food exposure is based on a developmental study in rats with a No Observed Adverse Effect Level (NOAEL) of 50 mg/kg/day. Decreased body weight gain with no increase in resorptions during the gestation period was observed at a Lowest Observed Adverse Effect Level (LOAEL) of 250 mg/kg/day.

  - The uncertainty factor (UF) is 100 for acute dietary risk, based on a 10x for standard uncertainties in applying animal studies to humans (interspecies extrapolation) and a 10x for varying effects among individuals (intraspecies variability).

- The acute reference dose (acute RfD) is 0.5 mg/kg/day, calculated by dividing the NOAEL (50 mg/kg/day) by the UF (100).

- The Food Quality Protection Act Safety Factor (FQPA SF) was removed (reduced to 1x) for all population subgroups. The Agency determined that this safety factor is adequate to protect infants and children because there are no residual uncertainties in the exposure databases, the toxicology database is complete, and the endpoint and NOAELs/LOAEL for risk assessment were well defined. In the toxicology database, there was no quantitative or qualitative evidence of increased susceptibility in rat or rabbit fetuses following *in utero* exposure to naphthalene acetates or to pre- and post-natal exposure in rat reproduction studies.

- The aPAD is 0.5 mg/kg/day, and is calculated by dividing the acute RfD (0.5 mg/kg/day) by the FQPA SF. Since the FQPA SF is 1x, the aPAD and the acute RfD are identical.

- The acute dietary exposure analysis is based on the DEEM-FCID™, which uses exposure and consumption data to calculate risk as a percentage of the PAD. The DEEM-FCID™ analysis evaluated individual food consumption as reported by respondents in the USDA 1994-1996 and 1998 Continuing Surveys of Food Intake by Individuals (CSFII). For acute dietary risk assessments, the entire distribution of consumption events for individuals is multiplied by a randomly selected distribution of residues (probabilistic analysis, referred to as "Monte Carlo") to obtain a distribution of exposures.

- Acute dietary (food) risk was also estimated using the Lifeline model (Version 2.0). The Lifeline model estimated acute exposure based on the acute 1-day dietary dose drawn randomly from an age-specific seasonal profile of 1000 individuals. Results of the acute dietary (food) Lifeline analysis are fully consistent with the DEEM-FCID results.

Chronic Dietary Risk from Food

Chronic dietary risk from food is calculated by using the average consumption value for foods and average residue values on those foods over a 70-year lifetime. As previously shown in Table 1, chronic dietary exposure for the naphthalene acetates in all populations subgroups is equal to or less than 8% of the cPAD, and therefore not of concern to the Agency.

- The chronic dietary exposure/risk analysis for all supported naphthalene acetates food uses were conducted using Tier 1 conservative exposure assessments: assuming tolerance level residues for all registered uses, 100% crop treated for all commodities, and default processing factors. Chronic dietary risk was then calculated by comparing dietary exposure to the cPAD.

- EPA calculated the cPAD and dietary risk levels for the naphthalene acetates using the following data:

  - The toxicity endpoint selected for chronic dietary food exposure is based on a one-year oral feeding study in dogs. The NOAEL was 15 mg/kg/day and a LOAEL of 75 mg/kg/day was based on stomach lesions and slight sinusoidal histiocytosis in the livers of males.

  - The uncertainty factor (UF) is 100, based on a 10x for standard uncertainties in applying animal studies to humans (interspecies extrapolation) and a 10x for varying effects among individuals (intraspecies variability).

  - The chronic reference dose (chronic RfD) is 0.15 mg/kg/day, calculated by dividing the NOAEL (15 mg/kg/day) by the UF (100).

  - The FQPA SF was removed (reduced to 1x) for all population subgroups, as discussed in the acute dietary section.

  - The cPAD is 0.15 mg/kg/day, and is calculated by dividing the chronic RfD (0.15 mg/kg/day) by the FQPA SF. Because the FQPA SF is 1x, the cPAD and the chronic RfD are identical.

  - The chronic dietary exposure analysis is also based on the DEEM-FCID™, as discussed in the acute dietary section. For chronic dietary risk assessments, a 3-day average consumption for each subpopulation is combined with average residues in commodities to determine average exposures.

Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through surface and ground water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available and of sufficient quality, to estimate those risks. However, for the naphthalene acetates water monitoring data are not available.

This section describes the Estimated Drinking Water Concentrations (EDWCs) of the naphthalene acetates in drinking water. Output values from computer modeling (FIRST and SCIGROW) are based on use of 1-naphthalenacetic acid on apples, which represents the highest use rate scenario and results in the highest potential environmental loading. Risks from exposure to these concentrations are discussed later in the section titled "Aggregate Exposure and Risk."

- In the environment, the sodium, potassium, and ammonium salts, amide, and ester of NAA are expected to rapidly degrade to the acid in the environment. Therefore, 1-naphthalenacetic acid is the only residue of concern in drinking water.

- The Agency calculated screening-level EDWCs (high-end estimates) for the naphthalene acetates using computer modeling for both surface (FIRST) and ground water (SCIGROW) sources. Both models provide estimates suitable for screening purposes. Table 2 presents the modeled concentrations for 1-naphthalenacetic acid.

- For the purpose of estimating risks from surface water sources, EPA uses the 1 in 10 year annual peak concentration of 1-naphthalenacetic acid generated by FIRST for acute exposures. For evaluating reasonable worst case chronic concerns, the estimated 1 in 10 year annual mean concentration of 1-naphthalenacetic acid in drinking water is used.

- For estimating drinking water risks from ground water sources, both acute and chronic, EPA uses a single EDWC because ground water is generally more stable than surface water and less likely to exhibit different concentrations over time.

Table 2. Modeled 1-naphthalenacetic acid EDWCs from Surface and Ground Water Sources.

Drinking Water Source	Acute Peak (ppb)	Chronic Annual Average (ppb)
Surface Water (FIRST)	12.9	0.712
Ground Water (SCIGROW)	0.0008	N/A

Residential Exposure and Risk

Residential uses of the naphthalene acetates are limited to applications to stimulate root growth (dips and soil drench) of ornamentals, and spray applications to control sprouts and sucker growth on fruit and ornamental trees. Only the spray application of naphthalene acetates to control sprout and sucker growth was evaluated for the residential exposure assessment. Residential exposures from root dip applications are expected to be significantly less than spray applications for sucker growth because of the low concentration of NAA in root dip and soil drench products, and the very short exposure duration and limited area of exposure associated with use of these products. Further, only short-term exposures (<30 days) are expected for residential applications of the naphthalene acetates. Post-application exposure to homeowners reentering and children playing in treated areas is expected to be negligible based on the use patterns and were, therefore, not assessed.

To estimate residential risks, the Agency calculates a margin of exposure (MOE), which is the ratio of the NOAEL selected for risk assessment to the exposure. This MOE is compared to a level of concern which is the same value as the uncertainty factor (UF) applied to a particular toxicity study.

The standard UF is 100x (10x to account for interspecies extrapolation and 10x for intraspecies variation), plus any additional safety factor retained due to concerns unique to the protection of infants and children under FQPA. A MOE less than the target MOE, or level of concern (LOC), is generally a risk concern to the Agency.

Residential handlers can be exposed to the naphthalene acetates by mixing, loading, or applying products containing this active ingredient. Exposure assumptions for residential handler included maximum label application rate for an aerosol spray application, application of the entire contents (one quart) of the sprout inhibitor formulation available for residential use, and no protective clothing. Estimated dermal and inhalation margins of exposure (MOEs) for this residential exposure scenario to the naphthalene acetates are 3,800 and 58,000, respectively. The combined MOE is 3,600. These MOEs are well above the target MOE of 100 and not of risk concern.

Toxicity Summary

- Short-term dermal risk assessments for the naphthalene acetates are based on a 21-day dermal toxicity study with a systemic NOAEL of 300 mg/kg/day, based on reduced body weight gain and food efficiency at the LOAEL of 1000 mg/kg/day.

- Short-term inhalation risk assessments for the naphthalene acetates are based on an oral route development study with a NOAEL of 50 mg/kg/day, based on decreased body weight gain during gestation at the LOAEL of 150 mg/kg/day.

- Intermediate and long-term dermal and inhalation exposures from the use of naphthalene acetates are not expected, since they are used only during growing seasons.

- The FQPA SF has been reduced to 1x for the reasons explained above in the dietary section. Therefore, the target MOE from dermal and inhalation exposures is 100.

Table 3. Acute Toxicity Data of NAA

Guideline No.	Test Chemical	MRID #(S).	Results	Toxicity Category
870.1100 Acute Oral	NAA	00103128	LD_{50} = 2520 mg/kg	III
	NAA acetamide	43495901	LD_{50} = >5000 mg/kg	IV
	NAA Na Salt	00108829	LD_{50} = 933-1350 mg/kg	III
	NAA Ethyl Ester	43494101	LD_{50} = 2186 mg/kg	III
870.1200 Acute Dermal	NAA	00103129	LD_{50} = > 2000 mg/kg	III
	NAA acetamide	43495902	LD_{50} = > 2000 mg/kg	III
	NAA Na Salt	00108829	LD_{50} = > 2000 mg/kg	III
	NAA Ethyl Ester	43494102	LD_{50} = > 2000 mg/kg	III

870.1300 Acute Inhalation	NAA	–	–	–
	NAA acetamide	43495903	LC_{50} = > 2.17 mg/L	IV
	NAA Na Salt	–	–	–
	NAA Ethyl Ester	43494103	LC_{50} = > 2.13 mg/L	IV
870.2400 Primary Eye Irritation	NAA	00103127	corrosive	I
	NAA acetamide	00103051	corrosive	I
	NAA acetamide	43495904	minimally irritating	IV
	NAA Na Salt	00108829	corrosive	I
	NAA Ethyl Ester	43494104	minimally irritating	IV
870.2500 Primary Skin Irritation	NAA	00103127	not a skin irritant	IV
	NAA acetamide	–	–	–
	NAA Na Salt	00108829	not a skin irritant	IV
	NAA Ethyl Ester	00103053	not a skin irritant	IV
870.2600 Dermal Sensitization	NAA	00153217	not a skin sensitizer	NA
	NAA acetamide	43495905	not a skin sensitizer	NA
	NAA Na Salt	–	–	–
	NAA Ethyl Ester	43494105	not a skin sensitizer	NA

Aggregate Exposure and Risk

An aggregate risk assessment evaluates the combined risk from dietary exposure to residues in food and drinking water and, if applicable, residential exposure to homeowners. For aggregate risk, EPA typically considers combined exposures from food and residential sources and calculates a drinking water level of comparison (DWLOC), which represents the maximum allowable exposure through drinking water after considering food and residential exposures. If the estimated drinking water concentrations (EDWCs) in water are less than the DWLOCs, EPA does not have concern for aggregate exposure. If EDWCs are greater than DWLOCs, EPA will conduct further analysis to characterize the potential for aggregate risk of concern.

While there is potential for concurrent naphthalene acetate exposure via the food, water, and short-term residential exposure pathways, short-term aggregate risk cannot be estimated for naphthalene acetates because the toxicity endpoints selected for the different exposure pathways are not based on common effects. The toxicity endpoint for chronic dietary and the drinking water routes of exposure are based on systemic effects, while those selected for residential exposures (inhalation and dermal) are based on decreased body weight gain. Therefore, the aggregate exposure assessment for the naphthalene acetates considers only food and drinking water exposures.

Acute and chronic DWLOCs were calculated based on the dietary exposure estimates, default body weights and water consumption figures, and are shown in Table 4. Peak (acute) and average

(chronic) modeled EDWCs for both surface water and groundwater are significantly below the acute and chronic DWLOCs for all population subgroups. Hence, aggregate exposure to naphthalene acetates in food and water do not present risks of concern.

Table 4. Naphthalene Acetates Drinking Water Levels of Comparison (DWLOC) and Estimated Drinking Water Concentrations (EDWC)s

	Population Subgroup	DWLOC (ppb)	Surface Water Conc. (ppb)	Ground Water Conc. (ppb)
Acute Risk	All	≥3000	12.9	0.0008
Chronic Risk	All	≥1400	0.7	0.0008

Occupational Risk

Workers can be exposed by mixing, loading, or applying (handlers) naphthalene acetates or by entering a previously treated site (post-application). Worker risk is also measured as a MOE, which determines how closely the occupational exposure comes to a NOAEL. For the naphthalene acetates, all occupational scenarios assessed (handler and post-application) had MOEs greater than 100, and therefore are not of risk concern.

Only short-term exposures (<30 days) are expected and assessed for occupational exposure scenarios because exposures for more than 30 days is unlikely to occur based on use patterns. Occupational toxicity endpoints and uncertainty factors are the same as those described in the residential risk assessment above. However, the FQPA SF is not applied in occupational risk assessments. No chemical-specific handler or post-application exposure data have been submitted by the registrant. Therefore, an exposure assessment for each handler scenario was developed using PHED Version 1.1 and EPA Standard Operating Procedures for agricultural exposure. The mixer/loader/handler/applicator exposure scenarios were assessed utilizing liquid formulations for the risk assessment because those products had the highest percentage of active ingredients and highest usage patterns when compared to the dry formulations (wettable powder and dust).

Handler Exposure Assessment

- The term "handler" refers to individuals who mix, load, and apply the pesticide product. Based on actively registered labels, EPA assessed 12 handler scenarios for the naphthalene acetates. Mixing and loading for aerial sprayers resulted in the highest level of exposure.

- A target MOE of 100 for the dermal and inhalation routes is considered adequate for the occupational handler risk assessment. Using baseline personal protective equipment (PPE), combined dermal and inhalation MOEs are $\geq$ 130 for all handler scenarios and not of risk concern. Baseline PPE include long pants, long sleeved shirts, shoes, socks, and no respirator.

Post-Application Exposure Assessment

- "Post-application" is the term used to describe individuals who can be exposed to pesticides after entering areas previously treated with pesticides and performing certain activities (also often referred to as reentry exposure). Occupational post-application activities were assessed for the naphthalene acetates uses expected to result in the highest exposures. Based on their use on apples and pears, EPA assessed the following post-application activities: irrigation, scouting, and weeding, and harvesting, pruning, propping, training, and thinning for the naphthalene acetates.

- For post-application exposures, EPA calculates the minimum length of time required following an application before residues have dissipated to the level where the calculated MOE reaches the target MOE. EPA uses this information to determine restricted entry intervals (REIs), the time period after which workers are allowed to reenter a treated area.

- A target MOE of 100 for the dermal exposure route is considered adequate for the occupational post-application risk assessment. No post-application inhalation exposure is expected. The MOEs for the two post-application exposure scenarios are $\geq$ 3500, and significantly greater than the target MOE of 100, and not of risk concern on the day of application.

- A minimum 48-hour REI is required for 1-naphthaleneacetamide, 1-naphthalene acetic acid, potassium 1-naphthaleneacetate, ammonium 1-naphthaleneacetate, and sodium 1-naphthaleneacetate because they are classified as Toxicity Category I for eye irritation.

- A 12-hour REI is required for ethyl 1-naphthaleneacetate because it is classified as Toxicity Category III or IV for all acute toxicity endpoints. However, products containing ethyl 1-naphthaleneacetate may be eligible for a 4 hour REI. Registrants are required to submit the required certification statement to the Agency and formally request the 4-hour REI as specified in PR Notice 95-3.

Occupational Incident Reports

The Agency has conducted a review and consulted the following databases of reported poisoning incidents associated with human exposure from occupational uses of naphthalene acetates:

Office of Pesticide Programs (OPP) Incident Data System; Poison Control Center Data, 1993 through 1998; California Data, 1982 through 1998; and the National Pesticide Information Center.

No incidents were reported from the use of naphthalene acetates in the Incident Data System, Poison Control Center Data, and the National Pesticide Information Center. Detailed descriptions of six cases submitted to the California Pesticide Illness Surveillance Program (1982-1998) were reviewed. Workers were exposed either through accidental spraying in the face from broken equipment during treatment or from post-application contact with treated foliage or fruit. These exposures resulted in eye or sinus irritation, chemical conjunctivitis, dermatitis, and a rash. None of the incidents resulted in hospitalization

Ecological Risk

To estimate potential ecological risk, EPA integrates the results of the exposure and ecotoxicity data to evaluate the potential for adverse ecological effects. The method divides exposure estimates, which are based on maximum application rates (worst case), by ecotoxicity data to derive risk quotients (RQs) for acute and chronic effects. These RQ values are then compared to the Agency's levels of concern (LOCs), which indicate whether a chemical, when used as directed, has the potential to cause adverse effects on nontarget organisms. When the RQ exceeds the LOC for a particular category, the Agency presumes a potential risk of concern to that category.

Based on the data available and through the use of Structure Activity Relationships (SAR), EPA believes that the naphthalene acetates present little or no potential for risks to nontarget organisms, including mammals, birds, aquatic organisms, nontarget plants, and threatened and endangered species. In other words, all RQs are below the Agency's LOC, and therefore are not of risk concern. All RQs (acute and chronic) for birds, mammals and aquatic organisms are ≤ 0.02. RQ's for nontarget plants, including endangered, are all ≤ 0.9. Risks to terrestrial insects cannot be quantified but the available data do not suggest a substantial potential for adverse effects. Moreover, no ecological incidences have been reported for the naphthalene acetates.

Generally speaking, risks from the use of plant growth regulators (PGRs) are not adequately addressed using data from current plant studies that deal with growth endpoints. Currently, there are no validated tests which address reproductive effects on plants. EPA recognizes that reproductive plant studies would be useful to characterize potential reproductive risks to non-target plants, from herbicides as well as PGRs.

Environmental Fate

Environmental fate of all naphthalene acetates is expected to be similar. A detailed discussion of the environmental fate, transport, and physical-chemical properties and chemical structures of naphthaleneacetic acid, naphthaleneacetamide, and ethyl 1-naphthaleneacetate are given in the *Amended Environmental Fate and Effects Risk Assessment for the Reregistration of 1-Naphthaleneacetic acid (NAA) and Related Compounds as a Low Toxicity Substance*, dated May 13, 2004 (see particularly Tables 2 and 3, pages 9 & 10). In the environment, the sodium, potassium, and ammonium salts of NAA rapidly degrade to the acid. Physical and chemical properties suggest moderate to low soil mobility. The major routes of dissipation appear to be volatilization (on plants) and photolysis (on plants in water), and perhaps some through biodegradation.

Data Needs

Outstanding data needs include:

- UV/visible Absorption (OPPTS 830.7050)
- Storage stability data on the processed commodities of apples (or citrus fruits) and olives. (OPPTS 860.1380)
- Data depicting residues of NAA and its conjugates in the processed commodities of citrus (dried pulp, oil, and juice). (OPPTS 860.1520)
- The replenishment of analytical reference standards for all registered NAA acid salts, ester, and acetamide as requested by the Repository. (OPPTS 860.1650)