Reregistration Eligibility Decision (RED) for Benzyl Benzoate (Benzoic Acid case 4013)

June 26, 2007

Reregistration Eligibility Decision

For

Benzyl Benzoate

List [D]

Case No. 4013

Reregistration Eligibility Decision (RED) Document for Benzyl Benzoate

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Date: 6/26/07

Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter

MOE	Margin of Exposure
MRID	Master Record Identification (number)
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

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I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all data submitted to the Environmental Protection Agency (hereafter referred to as EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of a pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

This document, consisting of five sections, presents the EPA decision regarding the reregistration eligibility of the registered uses of benzyl benzoate. Section I contains the regulatory framework for reregistration; Section II provides an overview of the chemical and a profile of its use and usage; Section III gives an overview of the human health risk assessment; and Section IV presents the Agency's decision on reregistration eligibility and risk management. Finally, Section V contains the Appendices which list related information, supporting documents, and studies evaluated for the reregistration decision. The risk assessments for benzyl benzoate and other supporting documents are available in the Office of Pesticide Program (OPP) public docket (http://www.regulations.gov) under docket number EPA-HQ-OPP-2007-0470.

As a result of this review, the Environmental Protection Agency has determined that all currently registered products containing the active ingredient benzyl benzoate are eligible for reregistration, with the exception of the two products S.C. Johnson has requested to cancel.

II. Chemical Overview

Benzyl benzoate is part of the Benzoic Acid (Case # 4013). The active ingredients in the case are listed in Table 1 below. Of the 4 active ingredients in the case, benzyl benzoate is the only one with registered products. The other 3 active ingredients are not being supported for reregistration. These active ingredients would be evaluated only if new registration applications were submitted for new products.

Benzyl benzoate, a member of the benzyl derivative family, is an insecticide/miticide used to control dust mites in carpets, mattresses, upholstery, and on furniture, as well as for control of mites on dogs. Benzyl benzoate can occur naturally in many types of foods, and is also regulated by the FDA as a flavoring agent.

Table 1. Active Ingredients in Case 4013

Active Ingredient Name	PC Code	CAS	Status
Benzyl Benzoate	009501	120-51-4	Active
Benzoic Acid	009101	65-85-0	No Active Products
Benzyl Alcohol	009502	100-51-6	No Active Products
Sodium Benzoate	009103	532-32-1	No Active Products

Table 2. Benzyl Benzoate Uses			
Use Sites	**Maximum Appl. Rate (Reg. #)**	**Maximum Number of Applications**	**Application Methods**
Residential Handler			
Carpets, Upholstery, Furniture, and Carpets	0.05 lb ai/Can (59820-4) (4822-433) (777-87) (6297-6) (6297-7) (4822-480)	Not Specified	Shaker Can
		Not Specified	Aerosol Spray
Pets (Dogs)	0.02 lb ai/Can (1910-1) (2781-51)	Not Specified	Aerosol Spray
Occupational Handler			
Pets (Dogs)	0.014 lb ai/Can (1910-1) (2781-51)	Not Specified	Aerosol Spray

Use Profile

Type of Pesticide: Insecticide/miticide

Summary of Use: Applied as a powder or as a liquid on carpets, mattresses, upholstery, and on furniture, as well as on dogs.

Formulation Type: Benzyl benzoate is available as a ready-to-use (RTU) powder and an aerosol (spray).

Application Methods: Applied via shaker can (powder) or aerosol spray (liquid)

Use Rates: There is no limit to the maximum number of applications or re-treatment intervals

Common Trade Names: Tulsa, LeGear, Bissell, Raid

Basic Manufacturer(s): Reckitt Benckiser, Allergopharma Joachim, Vetellus Performance Materials

Other non-pesticidal uses: FDA approved flavoring agent

III. Summary of Benzyl Benzoate Risk Assessment

The following is a summary of EPA's human health risk findings and conclusions for benzyl benzoate, as presented fully in the document: "Benzyl Benzoate: Risk assessment-Preliminary (Phase 1) HED Chapter of the Re-registration Eligibility Decision Document (RED)" (2/28/2007). While the full risk assessments and related supporting documents are not included in this document, they are available in the public docket at www.regulations.gov (docket number EPA-HQ-OPP-2007-0470) and on the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

A. Human Health Risk Assessment

EPA has conducted a human health risk assessment for benzyl benzoate for the purpose of making a reregistration eligibility decision. The Agency evaluated the toxicology, the product chemistry, and the occupational and residential exposure studies submitted for benzyl benzoate and determined that the data are adequate to support a reregistration decision.

1. Toxicology

The available submitted toxicity data and published literature on benzyl benzoate are adequate to assess the chemical's hazard potential. The toxicology database is limited to acute toxicity studies, a developmental study in rats, a subchronic dermal study, and mutagenicity tests; however, there is adequate information on benzyl benzoate's metabolites (benzyl alcohol, benzoic acid, the benzoates, and benzaldehyde) to supplement benzyl benzoate data and assert the safe use of the chemical. Table 3 presents the acute toxicity profile for benzyl benzoate:

Table 3. Acute Toxicity Profile on Benzyl Benzoate

Guideline	Study Type	MRID	Results	Toxicity Category
870.1100	Acute oral toxicity - rat	43896601	LD_{50} = 3650 mg/kg in males LD_{50} = 2,804 mg/kg in females	III
870.1200	Acute dermal toxicity - rat	43896602	LD_{50} > 5,000 mg/kg	IV
870.1300	Acute inhalation toxicity - rat	41881701 41881801	$LC_{50} \geq 5.02$ mg/L	IV
870.2400	Primary eye irritation - rabbit	43896603	Slight irritant	III
870.2500	Primary dermal irritation - rabbit	43896604	Minimal irritant	IV
870.2600	Dermal sensitization	43896605	Slight to moderate dermal sensitizer	

Benzyl benzoate is one of 37 benzyl derivative flavoring agents that were evaluated by the Joint FAO/WHO Joint Expert Committee on Food Additives (JECFA). JECFA confirmed a group acceptable daily intake (ADI) for benzyl benzoate at 0-5 mg/kg bw. The estimated daily intake per person in Europe and the United States is 1900 µg (1.9 mg) and 4200 µg (4.2 mg) for benzyl benzoate, respectively (Benzyl Derivatives -JECFA Food Additives Series 48). The JECFA committee concluded that benzyl benzoate and the other benzyl derivatives would not present safety concerns when used as a flavoring agent.

In terms of the chemical's toxicological profile, benzyl benzoate did not cause maternal toxicity in rats at the highest dose tested, 1000 mg/kg/day. It did, however, induce developmental toxicity at 850 mg/kg/day, but not at 625 mg/kg/day. Benzyl benzoate was tested for mutagenicity and found to be negative in inducing unscheduled glycol nucleic acid (GNA) syntheses in rat liver cells. The chemical did not cause damage to hormones nor did it cause mammalian cell gene mutations *in vitro*. Benzyl benzoate was not tested for carcinogenicity, but the metabolite benzyl alcohol was tested in rats and mice. No evidence of carcinogenic activity was found in benzyl alcohol, and therefore benzyl benzoate is not expected to be carcinogenic. See Table 4 for additional toxicological information and endpoint selection.

Table 4. Summary of Toxicological Doses and Endpoints for Benzyl Benzoate

Exposure Scenario	Dose Used in Risk Assessment	Level of Concern for Risk Assessment	Study and Toxicological Effects
Dietary: Acute and Chronic (All Populations)	There is no dietary exposure from the miticidal uses of benzyl benzoate.		
Incidental Oral Short-Term (1-30 days)	NOAEL= 1000 mg ai/kg/day 70% dermal absorption	**Residential MOE** = 100 **Occupational MOE** = 100	**MRID: 43025501** **Developmental toxicity study** No maternal toxicity occurred at 1000 mg/kg/day.
Incidental Oral Intermediate-Term (1-6 months)	NOAEL= 400 mg ai/kg/day	**Residential** MOE = 100 **Occupational** MOE = 100	**NTP 1989** **Benzyl alcohol 13-week study in rats.** Decreased body weight gain and mortality at 800 mg/kg/day. Neurotoxicity signs such as staggering, respiratory difficulty, and lethargy. Hemorrhages around the mouth and nose, and histologic lesions in the brain, thymus, skeletal muscle, and kidney.
Dermal and Inhalation **Short-Term** (1-30 days)	**For all adults** Oral NOAEL= 625 mg ai/kg/day 70% dermal absorption	**Residential MOE** = 100 **Occupational MOE** = 100	**MRID: 43025501:** **Developmental toxicity study** Decreased fetal body weight at 850 mg/kg/day, manifested as ossification anomalies and increased fetal and litter incidence of wavy ribs.

Table 4. Summary of Toxicological Doses and Endpoints for Benzyl Benzoate			
Exposure Scenario	**Dose Used in Risk Assessment**	**Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
	For children (all ages): Oral NOAEL= 1000 mg ai/kg/day. 70% dermal absorption		**MRID: 43025501:** **Developmental toxicity study** See above
Dermal and Inhalation **Intermediate-Term** (1-6 months)	NOAEL = 400 mg ai/kg/day 70 % dermal absorption 100% inhalation absorption	**Residential MOE** = 100 **Occupational MOE** = 100	**NTP 1989** **Benzyl alcohol 13-week study in rats.** See above
Cancer (Oral, dermal, inhalation)	Benzyl benzoate is not expected to be carcinogenic.		

MOE = margin of exposure
NOAEL= no observed adverse effect level

2. Dietary Exposure and Risk from Food and Drinking Water

Because there are no food uses for benzyl benzoate pesticidal uses, a quantitative dietary (food and water) risk assessment is not necessary and was not conducted. Additionally, food additive uses have been evaluated by JEFCA as discussed in Section A.1., and the food additive uses are not considered by JEFCA to result in risks of concern.

3. Residential Exposure and Risk

There is a potential for exposure in residential settings during the application process for homeowners who use products containing benzyl benzoate. Adults and children could be exposed to benzyl benzoate after entering treated areas. Risk assessments have been completed for both residential handlers and postapplication scenarios. For detailed information about the residential risk assessment, please see "Benzyl Benzoate: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document" (11/6/2006).

Non-cancer risk estimates (such as residential estimates) are expressed as a margin of exposure (MOE), the ratio of the dose from a toxicological study selected for a risk assessment (typically a NOAEL) to the predicted exposure. Estimated MOEs are compared to a level of concern which reflects the dose selected for the risk assessment and uncertainty factors (UF) applied to that dose. The standard UF is 100x, which includes 10x for interspecies extrapolation (to account for differences between laboratory animals and humans) and 10x for intraspecies variation (to account for differences within a species of laboratory animal). In the case of benzyl

benzoate, EPA's level of concern for residential exposure is an MOE of 100 for short and intermediate term residential risk for both dermal and inhalation routes of exposure.

a. Residential Handler Exposure and Risk

The handler exposure data were taken from the Pesticide Handler Exposure Database (PHED), as well as a carbaryl hand held pump study (MRID 444598-01). EPA uses the term "handler" to describe individuals who are involved in the pesticide application process. As a result, a risk assessment has been completed for residential handler scenarios. Residential handler risks were calculated using the assumption that homeowners complete all elements of an application without use of any protective equipment. The quantitative exposure/risk assessment developed for residential handlers is based on applying powder via a shaker can and applying a liquid via an aerosol spray. Short-term risks for residential handlers are presented in Table 5. For all exposure scenarios, risks are below the Agency's level of concern assuming handlers are wearing a short-sleeved shirt, short pants, shoes, and socks.

Table 5. Summary of Residential Handler Exposure Estimates

Application. Equip.	Exposure scenario	Max Appl. Rate	Daily Area Treated	Handler Scenario	Short-Term MOE
		lb ai/can	Cans/day		Dermal + Inhalation Baseline
Shaker Can	Carpets, upholstery, and furniture	0.05	2	Powder	4,100
Aerosol Spray	Carpets, upholstery, and furniture	0.02	2	Liquid	7,000
Aerosol Spray	Pets (Dogs)	0.014	0.5	Liquid	39,000

b. Residential Postapplication Exposure and Risk

Postapplication exposure scenarios were developed for each residential setting where benzyl benzoate can be used. The major routes of exposure are dermal for adults and dermal and incident oral for children. Assessments were conducted for "pre-vacuum" and "post-vacuum" scenarios. Label-specific directions state that vacuuming after application of benzyl benzoate products is required; however, entrance into a treated area before vacuuming is possible. While people can be exposed to benzyl benzoate pre-vacuum, MOEs were calculated for an 8 hour exposure scenario. The Agency does not believe a person would be exposed for 8 hours in an un-vacuumed environment, and therefore MOEs reflecting the post-vacuum scenario are more realistic.

Using the assumptions from EPA's screening level linear model, short-term residential postapplication risks exceed the Agency's level of concern (MOEs below 100) on the day of application with pre- vacuum MOEs ranging from 11 to 44 for children and adults. In order to

refine the assessment for toddlers, an equilibrium adherence model was conducted. The screening level model assumes that unlimited amounts of active ingredient can be absorbed and that the application never reaches equilibrium, whereas the equilibrium adherence model is more realistic of actual exposure and assumes that at equilibrium, the mass/area of exposed skin equals the mass/area of the treated area. For benzyl benzoate, the treated area refers to carpet and upholstery. The equilibrium model was not used to assess adult exposure because adult post-vacuum MOEs were above the Agency's level of concern.

Using the equilibrium adherence refinement model, only one scenario exceeded EPA's level of concern for postapplication exposure:

For **pre-vacuum:**

- Child: Short-Term Postapplication Combined (Dermal + Incidental oral) via shaker can-carpets, upholstery and furniture "Pre-Vacuum"- MOE = 80

Based on the conservative assessment, the Agency believes that the pre-vacuum MOE is protective of children exposed to benzyl benzoate. This MOE represents a scenario for a toddler spending eight hours in a treated, un-vacuumed area; this scenario was included for characterization. Since the labels instruct the user to vacuum treated areas, the Agency is regulating on the post-vacuum scenarios only.

A summary of risk estimates for residential postapplication risks for adults and children is provided in Table 6 and Table 7, respectively. Additionally, when toxicological effects are the same for all routes of exposure and it is likely they can occur simultaneously based on the use pattern and the behavior associated with the exposed population, EPA combines risk values resulting from separate postapplication exposure scenarios. In the case of benzyl benzoate, dermal and incidental oral effects for children are the same, and therefore the scenarios were combined.

Table 6. Adult Residential Risk Estimates for Post-application Exposure to Benzyl Benzoate- Linear Model

Exposure Scenario		TC cm^2/hr	Route Of Exposure	App. Rate (lb ai/sq ft) Pre-Vacuum	App. Rate (lb ai/sq ft) Post-Vacuum	S-Term Pre-vacuum MOE	S-Term Post-vacuum MOE
Indoors : Residential carpets, furniture and upholstery							
Gen. Activities	Shaker Can	16,700	Dermal	0.0008	0.00008	12	120
	Aerosol Spray			0.0004	0.00004	50	500
Indoors : Residential Pets (Dogs)							
Exposure Scenario		DAT Can/day	Route of Exposure		Application Rate (lb ai/can)	S-Term Adult MOE	S-Term Child MOE

Gen. Activities (petting, touching)	Aerosol Spray	0.5	Dermal	0.02	166,000	57,000

Table 7. Child Residential Risk Estimates for Post-application Exposure to Benzyl Benzoate-Equilibrium Model							
Exposure Scenario		TC cm^2/hr	Route of Exposure	App. Rate (lb ai/sq ft) Pre-Vacuum	App. Rate (lb ai/sq ft) Post-Vacuum	S-Term Pre-vacuum MOE	S-Term Post-vacuum MOE
Indoors : Residential carpets, furniture and upholstery (Equilibrium Adherence Model)							
Gen .Activities	Shaker Can	6000	Dermal	0.0008	0.00008	120	1200
	Aerosol Spray			0.0004	0.00004	N/A	N/A
Indoors : Combined Dermal and Incidental Oral (Equilibrium Adherence Model)							
Shaker Can	Please see Appendix B of the Benzyl Benzoate Occupational and Residential Exposure Assessment (Miller, 11/6/2006)					78	760
Aerosol Spray						N/A	N/A

Note:

TC = Transfer Coefficient

Level of Concern: MOE = 100

N/A = Powder formulation is protective of Aerosol Spray

4. Aggregate Exposure and Risk

An aggregate exposure assessment considers the different pathways (food, water, occupational, and residential) through which exposures to benzyl benzoate may occur. Because there are no registered pesticide food uses for benzyl benzoate, no food exposure from pesticide use is expected. Also, because registered residential uses are indoor uses, exposure from residues in drinking water is not expected. The aggregate risk assessment includes residential exposure only.

a. Risk Characterization

The assessed residential postapplication risks are mainly from dermal exposures. The toxicity profile of benzyl benzoate indicated that toxic effects only occur at high doses (90-day rat oral, 90-day mouse oral, and 16-day rat and mice oral), including a developmental study, in which only minor developmental effects occurred at 850 mg/kg/day. There was no systemic dermal toxicity at the limit dose of 1000 mg/kg/day in the 90-day rat dermal study. The calculated dermal MOEs (adults), combined dermal and incidental oral MOEs (children) are below the Agency's level of concern.

5. Occupational Exposure and Risk

There is the potential for exposure to benzyl benzoate in occupational scenarios from handling benzyl benzoate during the application process. EPA uses the term "handler" to

describe individuals who are involved in the pesticide application process. As a result, a risk assessment has been completed for occupational handler scenarios. Like residential risk, worker risk is also measured by MOEs. For handlers, the Agency initially assesses risk at "baseline" which considers an individual's normal work clothing (e.g., long sleeve shirt and long pants), no gloves, and no respirator.

a. Occupational Handler Risk

The only benzyl benzoate formulations applied by professional handlers are the shaker and aerosol spray cans uses. No chemical specific information was available for benzyl benzoate handler exposure assessments; all analyses were completed using acceptable surrogate data. Information from the current labels, use and usage information, toxicology data, and exposure data were all key components in developing the exposure scenarios. The dermal and inhalation unit exposures were also based on surrogate data from the Pesticide Handlers Exposure Database (PHED). It is assumed that the number of cans used per day is 10 cans. All non-cancer occupational handler MOEs are above 100 on the day of treatment, and therefore risks are not of concern. The application rate was calculated as described in Table 8 below:

Table 8. Summary of Short- and Intermediate-Term Benzyl Benzoate Occupational Handler Non-cancer Risks.

Exposure Scenario	Application Scenario	Appl. Rate (lb ai/can)	DAT (cans/day)	Short-Term MOE (Dermal+Inhalation)	Intermediate-Term MOE (Dermal+Inhalation)
				Baseline	Baseline
Applicator: Aerosol Spray					
Aerosol Spray	Pets (Dogs)	0.014	10	2,300	1,200

Day of Application=Baseline PPE = (long sleeve shirt, long pants, no gloves, and no respirator)
MOE = NOAEL/Daily Dose where the NOAEL for both dermal and inhalation is 625 mg/kg/day for Short-term and 400 mg/kg/day for Intermediate-term exposures.

b. Occupational Postapplication Risk

EPA uses the term "postapplication" to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. After reviewing label specific information on application rate and exposure scenario practices, the Agency believes that no occupational postapplication scenarios exist for the registered benzyl benzoate uses. All products supported for reregistration are applied via shaker cans or aerosol sprays. An assessment for this type of application is not applicable. EPA believes that occupational settings involving pet care operators are unique. Typically, once the pet is treated, it leaves the treatment facility shortly after. Based on the application scenario described concerning treatment of dogs for mites via an aerosol spray, the Agency believes that there will be little or no postapplication exposure for an occupational handler, and risks are below the Agency's level of concern.

6. Incidents reports

On January 13, 2000, S.C. Johnson and Son, Inc issued an immediate voluntary recall of AllerCare Dust Mite Powder (Raid Product 319) and AllerCare Dust Mite Allergen Spray for Carpet and Upholstery (Raid Product 420). The recall was prompted by numerous reports of adverse health reactions in humans and pets exposed to the products. Over 400 complaints were received, the majority being allergy and asthma sufferers negatively affected by the products. Symptoms included severe coughing, asthma attacks and rashes. Several individuals were hospitalized, though no deaths were reported in conjuncture with use of the products.

No AllerCare Dust Mite Products have been marketed since January 2000. All incidents reported to the Agency involving benzyl benzoate as an active ingredient pertained to these two products including all incidents reported after the recall. No other benzyl benzoate incidents have been reported; therefore, it is reasonable to conclude that incidents seen with Allercare are due to the formulation of the products, and not the active ingredient benzyl benzoate. In addition, S.C. Johnson has requested the voluntary cancellation of both products involved in the recall. For a complete analysis of the benzyl benzoate incidents that have occurred since the product recall, please refer to "Review of Benzyl Benzoate Incident Reports" (5/11/07).

B. Environmental Risk Assessment

Use patterns for benzyl benzoate are limited to indoor and dog uses. There is a low likelihood of outdoor or water exposure, and risks to non-target species are not anticipated from the indoor carpet and upholstery uses. For the pet uses, while dogs are generally treated indoors, they may move outdoors which could allow for environmental exposures. EPA has concluded that based on benzyl benzoate's very low toxicity to mammals and aquatic arthropods and the application rate to dogs, risks to non-target species are also not anticipated from the pet uses. Therefore, EPA has determined that no effect on federally listed endangered and threatened species is anticipated from the pesticidal uses of benzyl benzoate discussed in this RED. For more detailed information, refer to "No Effect Determination for Registered Active Uses of Benzyl Benzoate" (6/22/07)

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support the reregistration of products containing benzyl benzoate as an active ingredient.

The Agency has completed its review of submitted data and its assessment of the residential and occupational risks associated with the use of pesticide products containing the active ingredient benzyl benzoate. Based on these data, the Agency has sufficient information on

the human health effects of benzyl benzoate to make its decision as part of the reregistration process under FIFRA. Appendix A is a detailed table listing all benzyl benzoate uses that are eligible for reregistration. Appendix B identifies generic data requirements that the Agency reviewed as part of its determination of the reregistration eligibility of benzyl benzoate, and lists the submitted studies the Agency found acceptable.

B. Public Comments and Responses

Because the risks associated with the use of benzyl benzoate were minimal and did not require mitigation, a Phase 3 public comment period on the benzyl benzoate risk assessments was not conducted. A 60-day public comment period will be conducted after the RED is issued, and will be announced in the Federal Register. Comments may be submitted under Docket Number EPA-HQ-OPP-2007-0470 at http://www.regulations.gov. In addition, the benzyl benzoate RED document may be accessed through Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

C. Regulatory Position

1. Regulatory Rationale

S.C. Johnson and Son, Inc, the registrant for AllerCare products Raid Product 319 and Raid Product 420, has asked for the voluntary cancellation of both products. The Agency has determined that all other remaining benzyl benzoate products are eligible for reregistration. The following is a summary of the rationale for managing risks associated with the use of benzyl benzoate.

a. Human Health Risk Management

As discussed in Chapter 3, risk refers to the combined risk from food and residential exposures. There are no pesticidal uses of benzyl benzoate on food, and the residential risks are below the Agency's level of concern. No mitigation is necessary for human health exposure.

b. Occupational Risk

All handler and postapplication occupational risks for benzyl benzoate are below the Agency's level of concern, and therefore no mitigation is necessary.

c. Ecological Risk Management

Based on the indoor use pattern of benzyl benzoate and the low likelihood of outdoor or water exposures, no risk to non-target species or federally recognized species are anticipated.

d. Other Risk Management

S.C. Johnson and Son, Inc has requested the cancellation of the registrations of their two products, Raid Product 319 and Raid Product 320. These products were the subject of a recall by

S.C. Johnson and have not been marketed since the recall in January 2000. The cancellation will include no existing stocks provisions. EPA will publish a 6(f) Notice of Receipt of Request for Cancellation that will be available for public comment in the near future.

2. Endocrine Disruptor Effects

EPA is developing 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 recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis 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 pesticides, 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).

In the available toxicity studies on benzyl benzoate, there was no evidence of endocrine disruption effects. When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, benzyl benzoate may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

V. What Registrants Need to Do

The Agency has determined that benzyl benzoate is eligible for reregistration. In the near future, the Agency intends to issue a Data Call-In Notice (DCI) requiring product specific data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product specific data, the registrant will have 8 months to submit data and amended labels.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of benzyl benzoate has been reviewed and determined to be complete. No additional data are required.

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements.

2. Labeling for End-Use Products

Based on the review of the active ingredient, there are no currently required labeling changes for benzyl benzoate.

VI. Appendices

Appendix A. Use Patterns Subject to Reregistration for Benzyl Benzoate (Case 4013).

Benzyl Benzoate Uses*				
Use Sites	**Maximum Appl. Rate**	**Reg. #**	**Maximum Number of Applications**	**Application Methods**
Residential Handler				
Upholstery, Furniture, and Carpets	0.05 lb ai/Can	6297-6	Not Specified	Shaker Can
		59820-4 777-87 6297-7	Not Specified	Aerosol Spray
Pets (Dogs)	0.02 lb ai/Can	1910-1 2781-51	Not Specified	Aerosol Spray
Occupational Handler				
Pets (Dogs)	0.014 lb ai/Can	1910-1 2781-51	Not Specified	Aerosol Spray

* There are three technical products: 777-88, 51147-5, and 59820-5

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Benzyl Benzoate

GUIDE TO APPENDIX B

Appendix B contains a listing of data requirements which support the reregistration for active ingredients within the case Napropamide covered by this RED. In contains generic data requirements that apply benzyl benzoate in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data requirement. The data requirements are listed in the order in which they appear in 40 CFR 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which is available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. (703) 487-4650.

2. Use Pattern. This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

   A. Terrestrial food
   B. Terrestrial feed
   C. Terrestrial non-food
   D. Aquatic food
   E. Aquatic non-food outdoor
   F. Aquatic non-food industrial
   G. Aquatic non-food residential
   H. Greenhouse food
   I. Greenhouse non-food
   J. Forestry
   K. Residential
   L. Indoor food
   M. Indoor non-food
   N. Indoor medical
   O. Indoor residential

3. Bibliographic Citation. If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number is no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Benzyl Benzoate

New Guideline Number	Old Guideline Number	Description	Use Pattern	Citation
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Disclosure of Ingredients (Composition) (Chemical Identity)	M	44552401
870.1100	81-1	Acute Oral Toxicity - Rat	M	43896601
870.1200	81-2	Acute Dermal Toxicity – Rabbit/Rat	M	43896602
870.1300	81-3	Acute Inhalation Toxicity – Rat	M	41881701 41881801
870.2400	81-4	Primary Eye Irritation - Rabbit	M	43896603
870.2500	81-5	Primary Skin Irritation	M	43896604
870.2600	81-6	Dermal (Skin) Sensitization	M	43896605
870.3250	82-3	90-day dermal-rodent	M	43566901
870.5100	84-2	Bacterial Reverse Gene Mutation	M	42023101 42023102 43025501* 43413302

* Duplicate Study: 43031801

Appendix C. Citations Considered to be Part of the Data Base Supporting the Reregistration Eligibility Decision (Bibliography)

MRID	Citation
41881701	Duchosal, F.; Vogel, O.; Chevalier, H.; et al. (1990) 4-Hour, Acute Inhalation Toxicity Study With Benzyl Benzoate in Rats: Lab Project Number: 282508. Unpublished study prepared by Research and Consulting Company AG. 69 p.
41881801	Duchosal, F.; Vogel, O.; Chevalier, H.; et al. (1990) 4-Hour, Acute Inhalation Toxicity Study with Benzyl Benzoate in Rats: Lab Project Number: 282508. Unpublished study prepared by Research and Consulting Company AG. 69 p.
42023101	Heidemann, A. (1990) Gene Mutation Assay in Chinese Hamster Ovary (CHO) Cells in Vitro With Benzyl Benzoate: Lab Project Number: 203422. Unpublished study prepared by Cytotest Cell Research GmbH & Co. KG. 47 p.
42023102	Heidemann, A. (1991) Chromosome Aberration Assay in Human Lymphocytes in Vitro with Benzyl Benzoate: Lab Project Number: 203411. Unpublished study prepared by Cytotest Cell Research GmbH & Co. 61 p.
43025501	Becker, H. (1991) Embryotoxicity Study (Including Teratogenicity) with Benzyl Benzoate in the Rat: Lab Project Number: 294952. Unpublished study prepared by RCC, Research and Consulting Co. AG. 371 p.
43413302	Fautz, R. (1994) Unscheduled DNA Synthesis in Primary Hepatocytes of Male Rats In vitro with Benzyl Benzoate: Lab Project Numbers: CCR 444100: 357570: 444100. Unpublished study prepared by RCC Research & Consulting Co., Ltd.; RCC Umweltchemie AG; and BRL Biological Research Labs, Ltd. 34 p.
43566901	Schmid, H.; Biedermann, K.; Weber, K. et al. (1994) Subchronic 90-day Repeated Dose Dermal Toxicity Study with Benzyl Benzoate: Interim Report: Lab Project Number: 323504. Unpublished study prepared by RCC, Research & Consulting Co., Ltd in cooperation with Biological Research Labs, Ltd. 384 p.
43896601	Glaza, S. (1995) Acute Oral Toxicity Study of Benzyl Benzoate in Rats: Final Report: Lab Project Number: CHW 50902210. Unpublished study prepared by Corning Hazleton Inc. 27 p.
43896602	Glaza, S. (1995) Acute Dermal Toxicity Study of Benzyl Benzoate in Rabbits: Final Report: Lab Project Number: CHW 50902211. Unpublished study prepared by Corning Hazleton Inc. 20 p.
43896603	Glaza, S. (1995) Primary Eye Irritation Study of Benzyl Benzoate in Rabbits: Final Report: Lab Project Number: CHW 50902213. Unpublished study prepared by Corning Hazleton Inc. 16 p.
43896604	Glaza, S. (1995) Primary Dermal Irritation Study of Benzyl Benzoate in Rabbits: Final Report: Lab Project Number: CHW 50902212. Unpublished study prepared by Corning Hazleton Inc. 14 p.
43896605	Glaza, S. (1995) Dermal Sensitization Study of Benzyl Benzoate in Guinea Pigs--Closed Patch Technique: Final Report: Lab Project Number: CHW 50902214. Unpublished study prepared by Corning Hazleton Inc. 19 p.

44459801 Merricks, D. (1997) Carbaryl Mixer/Loader/Applicator Exposure Study During Application of RP-2 Liquid (21%), Sevin Ready to Use Insect Spray or Sevin 10 Dust to Home Garden Vegetables: Lab Project Number: 1519: 10564: ML97-0676-RHP. Unpublished study prepared by Agrisearch Inc., Rhone-Poulenc Ag Co. and Morse Labs., Inc. 358 p.

44552401 Scarpa, N. (1998) Group A Product Chemistry Information, Product Identity, Composition, and Analysis: Benzyl Benzoate. Unpublished study prepared by Haarman & Reimer T/A H&R Florasynth. 69 p. {830.1000}

44552501 Hanavan, P. (1998) Product Chemistry Studies: Lab Project Number: 98.0041. Unpublished study prepared by Reckitt & Colman, Inc. 49 p. {OPPTS 830.6302, 830.6303, 830.6304, 830.6313, 830.6315, 830.6316, 830.6319, 830.7050, 830.7100, 830.7200, 830.7220, 830.7300, 830.7550, 830.7840, 830.7950}

Appendix D. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room s-4400, Potomac Yard One, 2777 South Crystal Drive, Arlington Va. It is open Monday through Friday, excluding legal holidays, from 8:30 AM to 4:30 PM.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following website:

http://www.epa.gov/pesticides/reregistration/status.htm.

These documents include:

— *Benzyl Benzoate: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document.* November 6, 2006. Miller.

— *Benzyl Benzoate: Risk assessment – Preliminary (Phase 1) HED Chapter of the RE-registration Eligibility Decision Document (RED). PC Code: 009501.* Reregistration Case No. 4013. DP Barcode D327110.

— *No Effect Determination for Registered Active Uses of Benzyl Benzoate.* June 22, 2007. Arthur-Jean Williams.