



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Review of AllerCare (benzyl benzoate) Incident Reports
Chemical #009501, DP Barcode 262276

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BACKGROUND

S.C. Johnson is the manufacturer of AllerCare Dust Mite Carpet Powder (EPA Registration number 4822-433) and AllerCare Dust Mite Allergen Spray for Carpet & Upholstery (not registered with EPA). The AllerCare Dust Mite Carpet Powder (henceforth referred to as AllerCare Powder) contains 4.6% benzyl benzoate as an active ingredient. The AllerCare Dust Mite Allergen Spray for Carpet & Upholstery (henceforth referred to as AllerCare Spray) is reported to contain 18% benzyl benzoate. The incident data for this product will be covered in a separate review. The AllerCare Powder registered with EPA states on the label that it "kills dust mites", whereas the AllerCare Spray, which is not registered, states "controls dust mite allergens."

Both the AllerCare Powder and Spray were initially marketed starting on August 4, 1999. At the same time, two other AllerCare products a pillow case cover and a mattress cover, impervious to dust mites but not containing any insecticide were sold as part of the AllerCare line of products. The product line was intended for asthmatics and persons with allergies that were sensitive to dust mites. The date of the first reported incident related to use of either the powder or spray was on August 30, 1999. The purpose of this review is to summarize the incidents reported since that date, covering primarily the two-month period September and October 1999.

This incident review reports on two principle sources of data:

- 1) OPP Incident Data System (IDS) - reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992. For this review, the overwhelming majority of reports (greater than 90%) came from the registrant. Reports submitted to the Incident Data System represent anecdotal reports or allegations only, unless otherwise stated. Typically no conclusions can be drawn implicating the pesticide as a cause of any of the reported health effects. Nevertheless, sometimes with enough cases and/or enough documentation, conclusions can be drawn about the likelihood that the pesticide was responsible for the adverse effects and risk mitigation measures may be suggested.

- 2) National Pesticide Telecommunications Network (NPTN) - NPTN is a toll-free information service supported by OPP. Telephone contacts are recorded and may include human incidents, animal incidents, calls for information, and others. Note that some of the cases reported may duplicate those reported to IDS.

Normally an incident review would also include data reported by the American Association of Poison Control Centers and the California Pesticide Illness Surveillance Program. However, the most recent data available from these two data bases is from 1996 before the AllerCare products were marketed. Some individual reports have been obtained by states and direct contact from the public. All of these cases have been added to and will be reported under the Incident Data System.

The following potential sources of data were also asked specifically to report on AllerCare cases that came to their attention over the past few months:

- 1) NIOSH funded SENSOR (Sentinel Event Notification System for Occupational Risks) States which include health departments in Florida, New York, Oregon, California, and Texas were asked to report on any case seen in the past 2-3 months. Only one report was received from Florida which was added to the Incident Data System.
- 2) The Association of Occupational and Environmental Clinics canvassed their membership for any cases found in the past couple of months. There were no reports.
- 3) The Asthma and Allergy Foundation of America was asked to send a request to their centers asking for any reports of adverse effects from use of AllerCare products. Reports were sent directly from the individuals to EPA, so the exact number of incidents generated by this source is unknown. However, at least one report was received from this source and included in the Incident Data System.

ALLERCARE REVIEW

I. Incident Data System

Please note that cases submitted to the IDS do not have documentation confirming exposure or health effects unless otherwise stated. Cases involving the AllerCare Dust Mite Allergen Spray for Carpet & Upholstery are not covered in the current review.

A total of 133 incidents were reported due to AllerCare Dust Mite Carpet Powder from September 1 through November 30, 1999. Two additional cases were reported just before or after this time period for a total of 135 cases. Table 1 below shows the breakdown of these cases by age class and sex. Note that this table includes only those cases with moderate (typically requiring professional medical care) or major (life-threatening) medical outcome. Four of the 135 cases were classified as major and the rest moderate medical outcome.

Table 1. Number of cases of AllerCare Dust Mite Carpet Powder by age class and sex with percent female and male in each age class. Only cases with moderate or major medical outcome reported.

Age class	Females		Males		Total
	Number	Percent	Number	Percent	Number
Adult (20+ years)	79	83%	16	17%	95
Children (19 years)	13	33%	26	67%	39*
Total	92	69%	42	31%	134

* The sex of one child was unknown and not included in this table.

The excess prevalence of male children and female adults is consistent with their prevalence in asthma epidemiology data. Both mortality and hospitalization data report more male children than female children treated for asthma and more female adults than male adults.

Of the 135 moderate and major cases, at least 66 or about half were seen in a health care facility. A number of additional cases contacted their physician by phone and/or took additional medication for their asthma. Just over half of the cases had a history of asthma. However, a number of additional cases may have been missed because the history of asthma was not specifically requested or recorded. The majority of cases, specifically mentioned a problem with the odor of the product.

The number of AllerCare Dust Mite Carpet Powder incidents reported almost entirely in the three month period, September through November 1999, were 4 major cases and 131 moderate cases. If the 135(4+131) major and moderate cases due to the powder in three months were extrapolated to a year (4 x 135), there would be 540 such cases. And if all of these cases were reported to Poison Control Centers, they would account for 24% of the total major and moderate cases reported on average per year from 1993 through 1996 from residential use of all pesticides. In short, the AllerCare Dust Mite Powder almost certainly would account for more serious cases (moderate and major medical outcome) than any other single pesticide product in the residential market.

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For moderate and major cases, 70% of the victims are adults and 30% are children. Over half of the cases were asthmatics who experienced an asthmatic reaction from using the product. In most cases the asthmatic reaction started within 15 to 30 minutes of using the product, ruling out the possibility that the reactions were simply coincidental with use. Most of the remainder of the cases were other types of allergic or irritant type reactions (e.g., hives, rash, swelling, coughing).

At least 7 cases had to move completely out of their homes for a period of days or weeks (one family was out of their home for 7 weeks) and at least another 4 had to stop using their own bedroom because a residual odor remained. Cleaning to remove the odor was often difficult, had to be performed multiple times, and in some cases carpeting had to be removed. For example, one lady vacuumed her home 16 times and had to triple her medication. In a few severe cases walls, ceiling and floor were covered with several coats of primer and paint to seal out remaining odor.

II. National Pesticide Telecommunications Network (NPTN)

Most of the cases reported to the NPTN appear to be duplicate reports of the cases reported to IDS and are excluded here. Only three cases were reported to the NPTN which appear to be independent reports not part of IDS and involve AllerCare Dust Mite Carpet Powder. There were also three cases involving the AllerCare Dust Mite Allergen Spray for Carpet & Upholstery, but they are not included in this review. Cases reported to the NPTN do not have documentation confirming exposure or health effects unless otherwise stated.

Case log# 18346

Caller reported using both AllerCare powder and spray. Her son had an allergic reaction to the product. This case may be a duplicate of one of the Incident Data System cases.

Case log# 19116

Female adult caller report using AllerCare powder which smells really bad and reports trouble breathing.

Case log# 19666

Adult male (45-64 years old) used AllerCare powder according to

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directions. He had nausea, bad taste in mouth, headaches and the soles of his feet were sore. He said a cleaning company came and they reported many similar cases. He did not think the product was clearly labeled as a pesticide product.

Poison Control Center data on benzyl benzoate

Although AllerCare has not been captured in the nation's Poison Control Center data base until this past month, other products containing benzyl benzoate have been reported. From 1993 through 1996 there were 18 unintentional exposures to such products. None of these exposures resulted in a moderate or major outcome, although one case that was not followed, was considered to be potentially a moderate or major case. The most common symptoms reported included coughing and difficulty breathing. Both products intended for dog mange and products similar to AllerCare (e.g., Acarosan which is also a 5% powder used against dust mites) were among the 18 reported cases. It is very unlikely that a random sample of AllerCare cases would not include at least one or more cases with a moderate or major medical outcome.

The number of Acarosan cases may be lower than those due to AllerCare partly because Acarosan is made available through physicians and does not have a telephone number on the product label for contacting the registrant about adverse effects. Therefore, the registrant would not be reporting cases they did not know about through the Incident Data System. This does not preclude users from contacting Poison Control Centers. However, even these cases might contact their treating physician who may or may not contact the Poison Control Center for advice on anticipated adverse effects and recommended treatment. There is scientific literature on benzyl benzoate which bears on its potential to cause adverse effects. This information is reviewed below.

III. Literature Review

The literature reviewed below is not exhaustive but is representative of the literature on adverse effects of benzyl benzoate. This review attempts to capture both positive and negative reports which examined adverse effects of benzyl benzoate either from use against scabies or head lice or for use against dust mites.

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Benzyl benzoate used against scabies or head lice

Rajan (1975) reported on a test of pyrethrum and benzyl benzoate on 150 children each for use against head lice. Both products were 90% effective, but 31% of benzyl benzoate users reported reactions compared to 18% of pyrethrum users. Reactions were reported to be mostly minor, like smarting or burning sensations and itchiness.

Gurevitch (1985) reported that 20-35% benzyl benzoate used for scabies could irritate the skin and eyes.

Haustein and Hlawa (1989) reported testing 10% benzyl benzoate on 31 children and 20% benzyl benzoate on 31 adults. Burning (6 cases), redness (6 cases), or drying (2 cases) was reported in 22% of all cases.

Glaziou et al. (1993) reported on 21 patients treated with 10% benzyl benzoate for scabies. Five patients reported mild and transient symptoms, principally itching.

Stransky et al. (1996) reported on a 25 year old man treated with 30% benzyl benzoate who developed a red rash and blisters that were widely and evenly distributed.

Direct use of benzyl benzoate on the skin can result in adverse effects. However, the majority of the effects are minor and transitory (Rajan 1975 - 46 minor cases, Haustein and Hlawa 1989 - 12 minor cases, and Glaziou et al. 1993 - 5 minor cases).

Benzyl benzoate used as a powder against dust mites

Bronswijk et al. (1990) reports that benzyl benzoate has been used as a scabicide for over 100 years. Initially it was used as a Peruvian tree resin and then as an active ingredient since 1912. Bronswijk et al. reported that "No toxic effects on the human, canine, or feline inhabitants of dwellings in which Acarosol is used can be expected. Only a theoretical risk of dermatitis exists for person already sensitized. . . . No toxic effects or sensitization have been reported for any of the 20,000 persons exposed to Acarosol in 1987 to 1988 in West Germany [based on a personal communication with the manufacturer]".

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Wolf et al. (1992) reported on a severe reaction from the use of Acaroson:

After application of the Acaroson powder, following directions supplied with the powder, a severe, almost suffocating odor was noted. This was present not only in the bedroom but also throughout the house. This odor was associated with a flare of asthma. . . . The strong 'noxious' odor persisted for at least 48 hours. The family insisted that even up to 5 weeks after this episode, the odor was detectable.

The Fisons Corporation steam cleaned the carpet, but when this was not effective, paid to have the carpet removed. The company analyzed the carpet and concluded that "water or an active cleaning substance used 8 months prior on the textile base, in conjunction with the normal accumulation of dirt, combined with Acaroson, may have been responsible." The company paid to have tile installed in the bedroom.

Kniest et al. (1992) reported on a test of Acaroson in 10 homes and reported no evidence of side-effects after short- or long-term contact with the remaining concentrations of benzyl benzoate.

Ridout et al. (1993) reported on 61 homes treated with Acaroson in the United Kingdom and noted that four mothers complained of the smell and one mother had hay-fever like symptoms.

Kroidl et al. (1998) reported on use of Acaroson in 78 homes. None of the asthmatics who used the product at the initiation of the study or at the six months application reported significant side effects, although three patients reported a strange smell.

Only a few studies were located that evaluated adverse effects from the use of Acaroson. Most of these reports found no side effects (Bronswijk et al. 1990, Kniest et al. 1992) or only a small number complaining of the smell or minor effects (Ridout et al. 1993, Kroidl et al. 1998).

Conclusions

AllerCare Dust Mite Carpet Powder has been associated with 135 reports of adverse reactions categorized as moderate or major medical outcome. Most of the effects reported are of a respiratory or dermal nature related to an asthmatic or allergic type of reaction. Some of the reactions have been severe enough to require moving out of the home or at least the area where AllerCare was applied to, avoid any further exposure. In some cases, this has resulted in removal of carpeting and other furnishings that became impregnated with the odor.

It appears likely that the fragrance in the product was a likely cause of most of the reported reactions. This is partly because odor was overwhelmingly referred to by most of those who became sick and re-exposure to odor often brought on the same symptoms. Also, adverse effects reported from other benzyl benzoate cases (used for head lice, scabies, and dust mites) are almost always minor which supports the likelihood that moderate and major cases associated with AllerCare are related to one of the other ingredients in the product besides the benzyl benzoate.

Most of those who became sick from exposure to AllerCare experienced symptoms within a few minutes of their exposure which supports the finding that most cases were probably due to exposure to the chemicals in AllerCare rather than coincidental with its use. It is also possible that a small number of cases developed asthma or reacted from the physical activity (which itself can bring on an asthmatic reaction) of vacuuming which may have momentarily increased exposure to dust mite proteins. However, this would be relatively uncommon and would not apply in cases who developed repeated attacks of asthma or other allergic reaction upon re-exposure to the odor.

Among the factors evaluated to determine whether the weight-of-evidence supports causation between chemical exposure and an adverse effects are temporal relationship, strength of association, dose-response relationship, consistency of the association, replication of findings, specificity of the association and biological plausibility. In the case of the AllerCare reports there is strong evidence of a temporal relationship. Most cases occurred within minutes of exposure. Some cases (exact number unknown) reported that their reaction from applying the product was

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quite strong. For example, at least a couple of cases reported asthma attacks that were more severe than they had experienced in several months or even years. There is insufficient evidence to judge strength of association because of the inability to compare with other products. Dose-response information is typically not available for incident data and the findings related to AllerCare have not been replicated in another case series. For example, it is not possible to say whether major cases experienced higher doses than moderate cases. However, there is evidence from use of Acarosan (where the majority of effects are almost always minor and infrequently reported) that would suggest the rate and severity should be lower if benzyl benzoate, itself were responsible for most of the adverse effects reported from AllerCare. Therefore, it appears likely that many, if not most of the moderate and major (severe) reactions to AllerCare Dust Mite Carpet Powder are due to the added fragrance.

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cc: Correspondence

Benzyl benzoate file (chemical no.009501)

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