Bactol Alcohol Gel

Macadamia Oil Safety Profile

Background

Peanut and tree nut allergy is most common in infants, but may appear for the first time in adults. Peanut allergy causes more problems than other food allergies because it is common (1 in 50 infants), exposure is hard to avoid and in some cases even trace amounts can trigger symptoms. Around 20 % of cases resolve, and while severity may occasionally lessen with age, around 20% of cases can become worse with time[1].

Peanut allergy can be characterized by more severe symptoms, such as gastrointestinal, skin and respiratory symptoms, than other food allergies and by a high rate of symptoms on minimal contact[2,3].

Severe sufferers also may experience potentially life-threatening anaphylactic shock in response to ingestion of peanuts. Anaphylactic shock is an allergic reaction in which the release of histamine causes swelling, difficulty in breathing, heart failure, circulatory collapse, and sometimes death. As many as one-third of peanut-sensitive patients may have severe reactions, such as fatal, and near-fatal, anaphylaxis[4].

Probably due to the fact peanut induced anaphylaxis typically will occur to children, and its onset may be rapid and life-threatening, peanut (and tree nut) allergy tends to attract a disproportionate level of interest, often resulting in responses that represent a gross over-reaction to the magnitude of the threat[5]. This may be exemplified by the fact that in the United States, there are approximately 3.3 million Americans who are allergic to nuts. However, all told, serious allergic reactions to any food cause just 2000 hospitalisations a year (out of more than 30 million hospitalisations nationwide), with 150 people (children and adults) die each year from all food allergies combined. This may be compared to the 100 killed in the US by lightning strikes[5].

The causative agent (allergen) for nearly all food related allergic reactions are proteins[6]. Typically, most whole nuts will contain between 7-22 % protein[7]. In order for an allergic reaction to be elicited, the allergen has to enter the body, and typically this will be via ingestion.

Direct skin contact with the allergen, even with highly sensitive patients, may also elicit a mild, highly localised reaction (typically weals and erythema), particularly if the epidermis is compromised (this is the basis of the diagnostic skin prick test)[8].

1 For general information on food allergies see the website of the Australasian Society of Clinical Immunology and Allergy (http://www.allergy.org.au/)
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Nut oils

Oils expressed from nuts have been shown to contain significantly lower levels of protein than the parent nut, and as a consequence will tend to be less allergenic than the parent nut.

Refining of the oil (degumming, winterisation and decolourisation) will also lower the level of protein still further (with each refining step contributing to the lowering of the protein level), and hence a highly refined oil will be significantly less allergenic than a virgin (unrefined) oil. The typical protein content of several common nut oils, along with their allergenicity rating is shown in table 1.

Table 1:

Comparison of protein levels for various gourmet oils and their immunoassay relative reactivity (data ex Teuber et al[9]).

Oil type (and manufacturer)	Protein content (ppm)	Immunoassay relative reactivity
Peanut		
Flora	62.2 ± 2.2	+/-
Hain	2.2 ± 0.7	-/+
Spectrum	16.7 ± 0.8	-/+
Gourmet Int.	12.7 ± 2.8	++
Nut extract	5300	++++
Macadamia		
Oil of Aloha	21.3 ± 0.9	-/+
Loriva	81.1 ± 0.8	+
Nut extract	3000	++

Key:

Relative reactivity was based on a subjective visual scale with ++++ assigned to the most reactive oil tested (peanut oil)
-/+ indicates a band in the immunoassay was barely visible
+/- indicates a very light band in the immunoassay was visible

9 S. S. Teuber, R. L. Brown, L. A. D. Haapanen, J Allergy Clin. Immunol, 99, 502-507 (1997)

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Macadamia nut allergy

As can be seen in table 1, macadamia oil can potentially give rise to allergic reactions, as evidenced by the mild responses shown in the immunoassay relative reactivity scores. It is also notable that crude extracts of macadamia nut are significantly less reactive than crude peanut extracts.

Whilst much less common, there have been several reports of allergy to macadamia nuts with reactions typically being triggered by consumption of the nut kernels[10]. There are also reports of contact dermatitis amongst macadamia pickers, although it has been shown that the outer husk is significantly more allergenic than the edible kernel[11].

Even rarer are reports of anaphylaxis due to macadamia, and again these are limited to patients who have consumed the nut[12]. These patients were also found to be allergic to several other nut types.

In one case, a patient who had suffered anaphylaxis after consuming an orange flourless cake slice made from macadamia meal also demonstrated a marked skin reaction after being rubbed with a cut macadamia nut kernel. The same patient showed no reaction when pure macadamia oil was rubbed onto her skin[9].

Macadamia oil

According to the Approved Criteria for the Classifying Hazardous Substances[13], and the UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS)[14], any substance for which there is evidence that the individual substance can cause sensitisation by skin contact in a substantial number of humans, or where there are positive results from an appropriate animal model will be classified as a skin sensitiser. However, any product containing less than 1% of such a substance will NOT be classifiable as a skin sensitiser.

Given the slight reactivity in the immunoassay reported in table 1, a cosmetic grade macadamia oil was tested for potential delayed hypersensitivity. Neat macadamia oil was shown to be a ***potential*** skin sensitiser, and it was further shown that the concentration at which the oil meets the test criterion for being classifiable as a potential sensitiser (the EC3 value) was 25.11%, which further classifies neat macadamia oil as a weak sensitiser. Any formulation containing less than *ca* 25% macadamia oil would therefore probably not be classifiable as a potential sensitiser.

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12 M. F. Sutherland, R. E. O'Hehir, C. Suphioglu, "Macadamia nut anaphylaxis: Demonstration of specific IgE reactivity and partial cross-reactivity with hazelnut" J. Allergy Clin Immunol, 104, 889-890 (1999)
13 Approved Criteria For Classifying Hazardous Substances [NOHSC:1008(2004)]
14 Globally Harmonized System of Classification and Labelling of Chemicals (GHS) 1st revised Edition, United Nations, New York and Geneva, 2005

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Bactol alcohol gel has been formulated with a macadamia oil emollient. The macadamia oil used in Bactol Alcohol Gel is a highly refined cosmetic grade oil, and therefore can be expected to be low in allergenic protein.

The actual concentration of macadamia oil in Bactol Alcohol Gel is 0.25%, which is substantially below the 1% concentration cut-off specified by both the Approved Criteria and GHS for classification as a skin sensitiser. The concentration of macadamia oil is also 2 orders of magnitude less than that which may be expected to elicit a sensitisation reaction in the hypersensitivity test.

Conclusion

The risk of allergic reaction from the use of Bactol Alcohol Gel is extremely low. In the rare event that a highly sensitive individual does experience an adverse reaction, it is highly likely that any reaction will be localised and present as an irritation, or in severe cases wheals and/or erythema).

Whiteley Medical makes every effort to ensure that its products are always safe to use, however products can effect individuals differently and the company cannot predict individual responses. Therefore, if irritation does occur when using this product or any other cleaning/disinfecting solution then the individual should be removed from direct contact with the solution until a satisfactory safe working environment for that individual is determined. Medical advice should then be sought and the product use not recommence by that individual until after suitable medical clearance is independently provided.

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