

ESSENTIA MATTRESS: LATEX ALLERGY TEST RESULTS



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Essentia Natural Memory Foam Rubber (*Hevea brasiliensis*) Latex Mattress
Use by Hevea Latex Allergic Individuals

Background:

Natural rubber that is used in the manufacturing of Essentia foam material is produced by the *Hevea brasiliensis* rubber tree. In its raw state from the tree, it contains polymeric hydrocarbon 1,4 cis-polyisoprene, water, and cytoplasmic organelles composed of enzymes and structural proteins that are involved in the biosynthesis of polyisoprene, coagulation of latex and plant defense against microbes.(1) Of the 250 latex polypeptides (proteins) that have been identified in unprocessed Hevea sap, 60 have been shown to be potentially allergenic by their ability to bind IgE antibodies and 15 have been deemed as principal allergens by the International Union of Immunology Societies (2). By definition, an allergen is an immunogen (protein, carbohydrate or lipid molecule) that when introduced into a host (e.g. human by ingestion, injection or inhalation) elicits the formation of IgE antibodies. IgE is an immunoglobulin (blood protein) which binds to high affinity receptors expressed on mast cells and basophils and low affinity receptors on other cells. The IgE antibodies mediate the release of vasoactive mediators such as histamine following the binding of allergen which can lead to an allergic reaction. An allergy can be defined as a heightened sensitivity to a foreign substance (called an allergen) that causes an individual's body's defense system (the immune system) to overreact when defending itself. Classic symptoms experienced by latex allergic individuals can include rhinitis (runny nose), asthma, hives, and in severe cases, systemic anaphylaxis.

Scope of Report:

An individual who is sensitized (IgE antibody positive) to natural rubber *Hevea* latex allergens and has allergic reactions following exposure to the principal *Hevea* allergens may have concerns about potential latex exposure from the use of an Essentia latex memory foam mattress that is manufactured with natural rubber from the *Hevea brasiliensis* tree. This brief opinion addresses two related questions: (a) whether the use of an Essentia memory foam latex mattress poses an allergen risk for exposure and allergic symptoms by a known natural rubber *Hevea* latex allergic individual and (b) whether the use of an Essentia memory foam latex mattress for one or many nights poses a risk of becoming sensitized (IgE anti-latex positive) to natural rubber allergens by a non-latex allergic individual and possibly developing a latex allergy.

Essentia Mattress Composition:

The Essentia mattress is manufactured using an ammoniated natural rubber *Hevea* latex that has a number of essential oils from grapefruit seed cone flower and jasmine essence which have added to enhance the quality of the finished mattress. Importantly, the highly sensitizing accelerator chemicals that are commonly present in natural rubber latex gloves and dental dams (e.g thiurams, carbamates, thiazoles) and that cause a type IV (delayed-type) hypersensitivity with resultant contact dermatitis are not present in Essentia mattresses. A foaming machine distributes two forms of *Hevea* rubber latex into a mold: a layer of natural latex (Dunlop process) and a natural memory foam layer are placed in the mold together. Then the machine pours high density natural memory foam, covering the top and sides “like icing on a cake”. Once the mold is fully baked, this new latex mattress assembly is cured on a rack for 7 days and then tested for firmness, stiffness and load bearing capacity. Importantly, no latex gloves are used in the manufacturing process. The cured latex foam mattress core is then encased in a Kevlar fire barrier knit and this whole unit is encased in a 3 layer knit 100% certified organic cotton cover.

Latex Allergy Related Issues: The construction of the latex foam mattress with the Kevlar and cotton encasings precludes any direct contact of skin with the latex mattress core and precludes any potential release of any latex allergic protein that might be residual on the surface of the mattress core into the user’s airspace. To empirically examine the latex foam mattress for the presence of releasable latex proteins, samples of the latex memory foam support layer and comfort layer were separately extracted and analyzed using the American Society for Testing Materials (ASTM) D6499-12 ELISA inhibition assay.(3) The ELISA inhibition assay detects latex antigenic protein that may be residual in the latex foam core of the mattress. Following the ASTM procedure, 2-2.5 gram quantities of the mattress core specimens were cut into cubes, weighed and extracted with a phosphate buffered saline for 2 hours with agitation. The ASTM defined extraction ratio that was used to prepare the test specimens was 5 milliliters of buffer for each gram of mattress latex foam. The final assay results as provided by the LEAP Testing Service of the Guthrie Laboratory report #9777 (10/31/14) were negative (<0.2 micrograms of latex antigen per gram of memory foam), which indicated no detectable latex antigenic proteins were extractable from the latex memory foam support or comfort layers. (Guthrie Laboratory report attached).

Conclusions:

There are multiple reasons to conclude that the Essentia latex memory foam latex mattress poses no risk to a latex allergic person in terms of potential exposure to latex allergens and no risk to a non-sensitized individual of become sensitized to latex proteins by sleeping on the Essentia mattress for one or more nights. First, there are 2 types of natural rubber latex products, those that are dipped and molded. Dipped rubber

products are exemplified by medical latex gloves, latex dental dams and latex toy balloons. These are known to release high levels latex allergens, especially when they are powdered. Repetitive exposure to these dipped latex rubber products can induce IgE antibody, lead to sensitization (IgE anti-latex positivity) and possible development of latex allergy. Molded rubber products are exemplified by hard septa in pharmaceutical vials. A 100% natural rubber latex molded product does not release detectable levels of allergen except through direct surface contact.(4) The Essentia memory foam latex mattress is a molded foam rubber product which would not be expected to release allergen since protein is embedded in the solid matrix of the foam mattress. This is confirmed by the non-detectable latex antigen levels as measured by Guthrie Laboratory (<0.2 microgram/gram) using a well-documented and validated ASTM procedure.(3) Second, the Dunlop process used in the latex processing reduces the level of protein that may be found in the final latex product by involving washing steps. Third, the Kevlar and cotton encasements preclude any direct contact between human skin and the latex foam core of the mattress and minimize the risk of airborne latex exposure.

From an epidemiological point of view, wide spread Hevea latex avoidance programs at hospitals and dental clinics through the use of synthetic examination and surgeon gloves has fostered a major reduction in the number of new cases of latex allergic individuals in developed countries.(5) Historically, two populations were highly sensitized to natural rubber latex allergens; healthcare workers who repetitively use latex gloves to prevent infection transmission and children with spina bifida who received multiple surgical exposures to powdered latex gloves. Powder free and synthetic gloves used in healthcare facilities has led to a reduction in the incidence of new cases of latex allergy.(5) Moreover, sensitization requires multiple exposures to high levels of allergen, most likely airborne and attached to cornstarch donning powder to induce sensitization (IgE antibody positivity). From all accounts, the Essentia natural memory foam rubber latex mattress can be safely used by latex allergic and non-allergic individuals.

References:

1. Jacob JL, d'Auzac J, Prevôt JC. The composition of natural latex from Hevea brasiliensis. Clin Rev Allergy 1993; 11:325.
2. Raulf M. Latex allergy: allergen, diagnosis and management. In Handbook of Molecular Allergy, European Academy of Allergy, Asthma and Clinical Immunology, Chapter 20: Occupational Allergy, 2015.
3. ASTM D6499-12, Standard Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products, ASTM International, West Conshohocken, PA, 2012, www.astm.org

4. Hamilton RG, Brown RH, Veltri MA, Feroli ER, Primeau MN, Schauble JF, Adkinson NF Jr. Administering pharmaceuticals to latex-allergic patients from vials containing natural rubber latex closures. Am J Health Syst Pharm. 2005;62:1822-7.
5. Hamilton RG. Latex allergy: Epidemiology, clinical manifestations and diagnosis. www.UpToDate.com, 2015

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**LEAP Testing Service**

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Date: October 31, 2014**Report Number:** 9777

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We have completed testing the two foam samples which were received on 10/30/2014.

Note: *Results relate only to the items tested. This report can not be reproduced except in full, without the written consent of the LEAP Testing Service.*

Sample preparation and extraction: The samples were cut, weighed and allowed buffer contact with all surfaces. The extraction was performed for 2 hours with constant agitation at 25±5°C in 100 mM phosphate buffered saline pH 7.4 (PBS). The extraction ratio used (mls buffer/gram sample) was 5:1. The extract was centrifuged to remove particulates and then assayed. Since the physical nature of the foam is porous, the surface area cannot be accurately determined and is considered "n/a" not applicable.

ELISA Inhibition Assay (ASTM D6499-12): The samples are assayed using seven 2-fold serial dilutions in duplicate. The resulting data is calculated by using latex protein extracted from non-compounded ammoniated latex as the reference standard. The data is expressed as antigenic latex protein in micrograms/gram of sample and micrograms/dm².

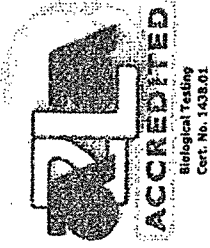
As always, be assured that the data we obtained with your samples will be held in strict confidence. Should you have any questions or require any further analysis please do not hesitate to call.

Sincerely,

Katrina Teeter, B.S.
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10/31/2014

ASTM D6499-12 Inhibition ELISA

Report Number: 9777

Sample #	LTS#	Sample Identification	Sample Weight (g)	Extract Volume (ml PBS)	Inhibition Assay Conc. (µg/ml)	Surface Area dm ²	Antigenic Protein Concentration	
							(µg/g)	(µg/dm ²)
1	40121	Latex Memory Foam "Support" Layer	2.0	10.0	b.d.	n/a	< 0.2	< n/a
2	40122	Latex Memory Foam "Comfort" Layer	2.5	12.5	b.d.	n/a	< 0.2	< n/a

<ul style="list-style-type: none"> Inhibition values are determined in µg/ml using duplicate values of at least 2 serial dilutions. Reporting limit of the assay = 0.03 µg/ml. "<" Indicates values (in µg/g or µg/dm²) are below the calculated reporting of the assay b.d. = below detection (reporting limit). n/a = not applicable 	LEAP Testing Service Donald Guthrie Foundation 1 Guthrie Square, Sayre, PA, USA 18840 570.887.4645 Email: its@guthrie.org www.guthrie.org/LEAP	 Reported by: Katrina Teeter, B.S. Research Technician Approved by: Kelly M. Horton, B.S. Laboratory Director
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