



## No evidence of allergenic reactions to soy lecithin phospholipids used in Membrane Lipid Replacement studies

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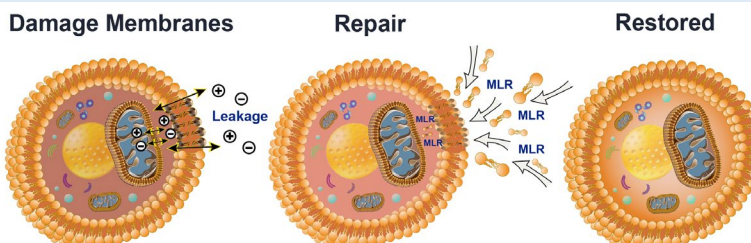
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### ABSTRACT

Membrane Lipid Replacement (MLR) is the functional use of dietary supplements containing cell membrane glycerolphospholipids and antioxidants to safely replace and remove damaged membrane phospholipids that accumulate during



**MLR repairs and replaces damaged cell and mitochondrial membranes with unoxidized glycerolphospholipids, restoring normal functioning.**

various chronic and acute illnesses and during aging. Some products used in MLR are obtained from soy lecithin extracts that contain cell membrane glycerolphospholipids. Thus the soybean source has been questioned because of concerns related to genetic engineering (GMO) and the potential presence of hormone-like components and soy allergens. There is a complete absence of proteins, glycoproteins or carbohydrates in soy lecithins and MLR supplements that could be allergenic. One lecithin ingredient that contains purified membrane phospholipids (NTFactor Lipids<sup>®</sup>) has been shown to produce significant positive health benefits in clinical trials. NTFactor Lipids<sup>®</sup> are fractionated and purified from non-GMO soy lecithin, but this formulation does not contain detectable amounts of protein or glycoprotein allergens or other components that could elicit allergic or non-allergic adverse reactions. In addition, allergenic and non-allergenic reactions have not been found in multiple clinical trials and studies that have utilized this dietary supplement. NTFactor Lipids<sup>®</sup> are manufactured in certified Good Manufacturing Practices (cGMP) facilities using established allergen-control strategies to minimize any cross-

contact with food allergens.

**Keywords:** Phospholipids, Clinical trials, Allergies, Cellular membranes

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## INTRODUCTION

Membrane glycerolphospholipids form the matrix of all biological membranes [1]. When they are damaged by free radical oxidants during aging and disease [2-4], they must be repaired or replaced to retain normal cellular functions [5, 6]. The replacement process has been termed Membrane Lipid Replacement (MLR), and this has been achieved using natural plant dietary membrane phospholipid supplements that repair cellular membranes by replacement and sequester the damaged glycerolphospholipids for their natural removal in order to maintain a variety of cellular and tissue functions and to improve general health [5-8]. Multiple studies have shown the health benefits of taking oral MLR glycerolphospholipids, and these studies have not found adverse allergenic reactions among trial participants (reviewed in [5, 6, 8]). Here we discuss the consequences that MLR supplements like NTFactor Lipids® do not contain allergenic components.

### ***Soy Lecithins and MLR–Absence of Soy Allergens:***

Dietary MLR products like NTFactor Lipids® are obtained from selected natural soybeans that are not contaminated (non-GMO) with genetically-modified soybeans. The fractionated soy lecithins do not contain measureable amounts of soy proteins, glycoproteins or carbohydrates (the composition of NTFactor Lipids® can be found in [5]). NTFactor Lipids® are manufactured in certified Good Manufacturing Practices (cGMP) facilities following established allergen-control strategies to minimize

any cross-contact with food allergens. This manufacturing process also complies with National Sanitation Foundation (NSF) requirements to provide the highest quality phospholipid products that conforms to the Food Chemicals Codex.

Soy lecithins have been used as additives in thousands of foods and food supplements without any problems associated with soy allergies [9-12]. When these soy lecithins were studied in more detail, they were found to be allergen-free. For example, Müller et al. [12] examined commercial soy lecithins for residual allergenicity and compared them with extracts from untreated or heat-treated soybeans. They concluded that commercial soy lecithins do not contain soy proteins, do not cause soy allergic reactions and are safe for soy-allergic consumers. Similarly, Awazuhara et al. [11] studied the antigenicity of the small amounts of residual proteins that are found in some soy lecithins and soybean oils. They found vanishingly small or no antigenicity or allergenicity in these residual proteins, as measured by the binding of IgE and other immunoglobulins to residual lecithin proteins and by allergic challenge to the residual lecithin proteins. Thus there is no evidence indicating that soy lecithins, the starting ingredient for manufacturing MLR supplements like NTFactor Lipids®, contain any soy allergens that could cause reactions in soy-allergic individuals [11].

***MLR Use in Clinical Studies–No Evidence of Allergic Reactions:*** Membrane lipids are

commonly used in dietary supplements for support of general health [12, 13], and they have also been used to improve the clinical status of chronic illness patients (reviewed in [5, 6, 8]). The most common therapeutic use of MLR products is to treat fatigue that is caused by loss of mitochondrial function [5, 6, 8]. Fatigue is the most common complaint of patients seeking general medical care, and it is associated with aging and most if not all chronic medical conditions [14]. Fatigue develops in older individuals and in chronic diseases due to different possible causes, most notably the loss of mitochondrial function and reductions in the synthesis of ATP [15]. Using MLR NTFactor® or NTFactor Lipids® fatigue has been successfully and significantly reduced in hundreds of patients with chronic fatigue (fatigue lasting more than 6 months), chronic fatigue syndrome (CFS/ME), fibromyalgia, Gulf War illnesses and other fatiguing illnesses without any evidence of allergenic soy reactions (reviewed in [5, 6, 8]).

In addition to fatigue, MLR supplements have been used to improve mental clarity, focus and memory loss. For example, volunteers were given NTFactor Lipids® dissolved in a drink, and fatigue and mental focus were examined after 3 hours. A majority of the participants responded within 1 hour, and by 3 hours perceived improvements in cognition, mental clarity and focus and fatigue reductions were found [16].

Widespread pain is another symptom treated with MLR supplements, such as NTFactor Lipids® [17, 18]. Pain is a complex symptom that involves nerve cell channelopathies, microcirculation, autoimmune responses and other factors [19, 20]. In fibromyalgia patients NTFactor Lipids® significantly reduced pain,

fatigue, gastrointestinal symptoms and improved Quality of Life assessments without evidence of adverse reactions [17]. In patients with widespread musculoskeletal and peripheral pain, chronic fatigue and many other signs and symptoms there were dramatic improvements while taking oral NTFactor Lipids® [18].

In the multiple clinical studies cited above and in various publications cited in reviews on the subject none of the patients reported any allergenic reactions to NTFactor® or NTFactor Lipids® contained in various natural supplements (reviewed in [5, 6, 8]).

## CONCLUSIONS

There is no evidence that indicates that taking oral MLR supplements made from soy lecithins results in allergenic or other adverse reactions. Thus these natural food supplements are safe. The FDA has determined that lecithins are GRAS (Generally Regarded As Safe) and safe to use, even in soy-allergic individuals [21, 22].

**List of Abbreviations:** CFS/ME: Chronic fatigue syndrome/myalgic encephalomyelitis, cGMP: Certified Good Manufacturing Practices, GMO: genetically modified organisms, GRAS: Generally Regarded As Safe, IgE: immunoglobulin E, MLR: Membran Lipid Replacement, NSF: National Science Foundation

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