

Expert Opinion of Therapeutx™ *Maori Miracle*® Joint Health Companion;

Submitted to Health Canada By John Croft.

B) Qualifications.

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D) Summary of Relevant Information.

Taking the ingredients of the product in the order on the proposed label:

- 1) **Glycomarine™**: This is an extract derived from the New Zealand Green-Lipped Mussel (*Perna canaliculus*) and produced as a freeze dried powder that has been shown in in vitro, in vivo and clinical studies in human and animal subjects to have properties valuable for the relief of the symptoms associated with arthritic disorders. In particular, specific anti-inflammatory and gastroprotective activity has been documented as has clinical evidence of benefit for sufferers of osteo arthrosis. Several mechanisms of action of the product have been studied and papers published on these.

Toxicity and teratogenic studies have been conducted by the Department of Medicine, University of Auckland and the product has now been in widespread use for over 30 years.

References: A collection of the papers reporting on both laboratory and clinical studies together with the toxicity and teratogenic study reports on Glycomarine are attached. It should be noted that the studies will refer to Green-Lipped Mussel Extract or, in some cases Seatone. However, Glycomarine is the identical Green – Lipped Mussel Extract to that referred to in the studies.

- 2) **Myristin®** : This is the registered trade name for cetyl myristoleate a fatty acid ester. In nature it could be derived from the oil of the sperm whale but is normally derived from palm oil or coconut oil. As an aid in the relief of the symptoms associated with arthritic disorders Cetyl myristoleate functions as an immunomodulatory agent and anti-inflammatory reported to inhibit aberrant T-cell activity.

In two clinical studies an absence of toxic effects has been reported with adverse side effects being limited to mild gastric discomfort and possible reflux in some subjects.

References:

Cochran CL, Dent R. Cetyl myristoleate-A unique natural compound valuable in arthritis conditions. *Townsend Journal for Doctors and Patients*, 168: 70-74, 1997.

Siemandi et al. The effect of cis-9-cetyl myristoleate and adjunctive therapy on the course of arthritic episodes in patients with various auto-immune diseases characterized by the common terminology, "arthritis and psoriasis". *Townsend letter for Doctors and Patients*, 169: 58-63, 1997.

- 3) **Kolla2®**: This is the registered trade name for 100% Type II collagen that has been derived from unhydrolyzed chicken sternum cartilage. Several clinical studies have been conducted with human subjects and have indicated various levels of benefit for relief of the classical symptoms of both rheumatoid arthritis and osteo arthrosis. The mechanisms by which type II collagen appears to mediate these symptoms is by a combination of oral tolerization (T-cell and cytokine mediation) with angiogenesis inhibition and potential chondroprotective functions due to the natural content of glycosaminoglycans in the product.

The clinical studies did not report any significant adverse side effects resulting from the use of type II collagen.

Kolla2® ; Hyaluronic acid is a natural component of type II collagen derived from chicken sternum. It is widely distributed in the body and has a major role in the maintenance of joint health. Therapeutically it is mainly used as an injectable in cosmetic surgery but is contained in many natural substances that are consumed orally. Most of the documented studies relate to its use as an injectable with the adverse effects being mainly injection related as opposed to

substance related. None of the adverse effects are particularly serious or of lasting duration. Orally there would not appear to be any significant adverse effects with naturally derived hyaluronic acid at low dosage levels. As hyaluronic acid is normally consumed as a minor component of another natural substance the dosage level would tend to be low.

References:

Barnet M et al. Treatment of rheumatoid arthritis with oral type II collagen. Results of a multicentre, double blind, placebo controlled trial. *Arthritis and Rheumatism*, 41(2): 290-297, 1998.

Trentham DE, Dynesius-Trentham RA et al. Effects of oral administration of type II collagen on rheumatoid arthritis. *Science*, 261: 1727-1730, 1993.

Vedamurthy M. Soft tissue augmentation. Use of hyaluronic acid as dermal filler. *Indian J Dermatol Venereal Leprol*, 70: 383-387, 2004.

Conclusion:

The ingredients comprising the product Maori Miracle, Joint Health Companion have pharmacological functions which are complimentary in terms of their application for the relief of symptoms of arthritic disorders. Individually, each of the components is non toxic and does not cause significant adverse side effects.* The caution statement on the label for the product covers allergy, pregnancy and lactation risks which are a factor for many food and pharmaceutical products.

Each of the components has been shown to have beneficial properties for the relief of the symptoms associated with arthritic disorders. However, the product formulation has been designed to achieve a significantly enhanced effect from the complimentary functions of these over that of any of the individual components.

I have no reason to believe that the combined effect of the components in the product will lead to an increased risk of adverse events as a result of synergistic reactions.

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