

BACKGROUND

What's special about Théra Wise® product ingredients?

Ninety nine percent of Théra Wise® ingredients have natural healing properties. Olive oil derivatives are used as a base in all Théra Wise® products because olive oil's fatty acids are the closest natural substance to the lipid (fat) composition of human sebum. Olive oil provides an extra layer of protection and enhancement to skin while still allowing it to breathe. It's also good for the environment because it is 100% biodegradable.

Several other unique Théra Wise® healing ingredients are:

- **Barley Beta Glucan concentrate** – comes from the Barley grain, which activates macrophage cells, responsible for the skin's immunological system, that promote skin renewal and repair from damage caused by environmental elements.
- **Argan Oil** – comes from the nuts of the Argan tree. It contains beneficial fatty acids, rare phytosterols, high levels of tocopherols (vitamin E) and saponins to help suppress inflammation and restore the skin's water lipid layer.
- **Tea Tree oil** and **Honeysuckle extract** – natural antimicrobial agents, helps to ensure product safety and reliability
- **Alpha Glucan Oligosaccharide** – obtained from natural sugars, this ingredient helps encourage “good” (ecoflora) and assist in the elimination of “bad” bacteria (pathogens).

Plant vs. Petroleum based ingredients. Why is this important?

Petroleum is not an optimal ingredient to use in contact with skin because:

1. Petrochemical ingredients can be absorbed into the bloodstream. Petroleum and its derivatives have been implicated in various health concerns.
2. It strips the hydro-lipid layer of the skin, further compromising the very tissue that the ointment is meant to treat.
3. It does not allow the skin to breathe, skin respiration is one the most important factors in skin healing and repair.
4. Petroleum and its derivatives are not ecologically compatible or biodegradable. Pollution from personal care products causing ground water contamination is a major ecological issue.

Over The Counter (OTC) pharmacy sales. Why is this important?

Natural health products are not commonly found on pharmacy shelves because previously there were no standards for safety and efficacy for natural health products, and legislation prohibited Natural Health Products from making science-based health claims.

In 2004 new Health Canada Natural Health Product Regulations came into effect that helped paved the way for science-based natural health products to be

offered in conjunction with conventional OTC medicines. The move to legislate natural health products was due to increasing consumer demand and a need to ensure safety and responsible health claims. However, it has taken several years for natural product companies to conduct testing and pass licensing requirements to reach pharmacy shelves. Théra Wise® products are one of the first to receive this essential licensing.

DEFINITIONS:

What is a “Bioactive” ingredient?

A bioactive ingredient is one that has a capacity to interact with a living tissue or human cells. Théra Wise® licensed products are composed of plant/natural bioactive ingredients that effect optimal healing on a cellular level.

What constitutes a “Natural” personal care product?

The term “natural” has become a dubious word in the personal care industry as many companies fall short of a realistic claim for being “natural”. Théra Wise® however defines “natural” for its products as using a minimum of 99.5% of all ingredients from plant origin. These ingredients are transformed with low-impact environmentally friendly processes without the use of hydrocarbon extraction methods.

What constitutes an “Organic” personal care product?

Organic ingredients are made according to certain production standards, meaning they are grown without the use of conventional pesticides and artificial fertilizers. They are free from contamination by human or industrial waste, and processed without irradiation or additives. Organic ingredients in most countries may not be genetically modified.

Théra Wise® licensed products guarantee a minimum of 35% of the total ingredients from organic agricultural sources. A minimum of 10% of Théra Wise® ingredients have *Ecocert certification.

* **ECOCERT** is an organic certification organization, founded in France in 1991. It is based in Europe but conducts inspections in over 80 countries, making it one of the largest organic certification organizations in the world. ECOCERT primarily certifies food and food products, but also certifies cosmetics, detergents, perfumes, and textiles. The company inspects about 70% of the organic food industry in France and about 30% worldwide.

What constitutes a “Vegan” personal care product?

Vegans are people who choose to avoid using or consuming animal products. This includes dairy and eggs, as well as fur, leather, wool, down, and any cosmetics or chemical products containing animal or insect ingredients. A Vegan will also avoid personal care/cosmetic products tested on animals.

Théra Wise® products are vegan friendly and do not use any materials or by-products from animals or insects. Théra Wise® has also joined PETA's cruelty free company program. PETA does not support companies involved in animal testing.

NATURAL HEALTH PRODUCT REGULATIONS AND LICENSING

CANADA:

In Canada, natural health products (NHPs), also referred to as complementary medicines or traditional remedies, are subject to the Natural Health Products Regulations of the Food and Drugs Act, which came into effect on January 1, 2004.

Health Canada's approval is important because it means Théra Wise® products have met stringent government standards of safety, manufacturing, quality/consistency and effectiveness of which only *33% of natural product applicants receive licenses.

Health Canada's licensing system requires that all licensed products display a product identification number preceded by the prefix NPN on their labels. This system assists Health Canada in ensuring that quality natural health products are sold to the public, and that quick and effective product recalls can be undertaken if ever required.

*NHPD quarterly report. <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfbdqpsa/nhpd-dpsn/index-eng.php>

UNITED STATES:

The Federal Drug Administration (FDA) requires a registration number for any product (pharmaceutical or OTC medication) sold in the US that makes a health claim.

Many natural health products sold in the US are regulated as "dietary or cosmetic supplements," a category that does not require pre-market review or proof of safety by the manufacturer before marketing.

INTERNATIONAL:

Internationally, the regulation of these types of products varies significantly. European Union countries and Japan have a long history of offering both natural and conventional over the counter (OTC) personal care products on pharmacy shelves. Generally in Europe, these personal care products are separated into sections based on the healing system, (homeopathic, phytopathic or other traditional natural remedies) and regulated as drugs.

Australia has recently classified many of these products as "complementary medicines" and made legislative and regulatory changes to regulate these products as a subclass of "therapeutic goods".

MARKET/PRODUCT STATISTICS:

- North American retail sales of Natural Personal Care products exceeded \$9 billion in 2008 with an annual growth rate of 15%.
- A notable 71% of Canadians use some form of natural health products.
<http://www.hc-sc.gc.ca/dhp-mpps/prodnatur/index-eng.php>
- The outlook for natural personal care remains healthy throughout 2013. Double-digit growth is expected to continue at a rate of 13.2% on average annually, pushing the market to \$11.7 billion U.S. in retail sales for both natural-inspired and truly natural products.
- Growth for the natural products segment outpaced the general personal care market by a landslide in 2007. The general U.S. personal care market grew by 3% in sharp contrast to the naturals' market growth of 13%.

(**Source:** Kline Group Report, *Natural Personal Care, 2008: Competitive Brand Assessment and Ingredient Analysis*)

Hemorrhoidal Ointments

- Statistics show more than 50% of the population in North America will develop symptomatic hemorrhoids at some point in their lives. It is also estimated that one in three women will experience hemorrhoids during pregnancy or after the birth. Hemorrhoids are among the most commonly reported disorders. (Levy, 2004).

Skin Healing / First Aid Ointments

- Statistics show 20 -30 million people in the North America have some form of eczema.
- About 15 to 25 percent of all infants worldwide have eczema/atopic dermatitis characterized by a chronic relapsing itchy rash.

- OTC topical wound care sales in Canada is estimated at \$46.2 million.

Decongestant Rub / Cold Remedies

- Cough and cold remedies, a category comprising cold remedies, cough syrup, throat lozenges and nasal preparations, rang up \$259.5 million in 2003 for a 4% annual increase.
- In the USA Vicks Vaporub chest rubs did \$39,861,864 in sales in 2003 (Levy, 2004).

Acne Ointments

- Approximately 20 million people in North America suffer from acne, making it the most common skin disorder.
- 20% of all adults have active acne approximately equaling 60 million North Americans.