



PHYTOR Ltd.
15, YA'AKOV EVEN CHEN ST.
JERUSALEM 9313062 ISRAEL

TEL: + 972 2 6711911
FAX: +972 1532 6711911
phytor1@gmail.com



Consulting in Human Health, Toxicology & Regulatory Affairs

Phytor Ltd.

*Consultant: **Dr. Yehoshua Maor** (Ph.D, M.Sc.,B.Pharm.)*

15, Ya'akov Even Chen St.

9313062 Jerusalem – ISRAEL

Phone: +972-2-6711-911

Fax: +972-153-2-6711-911

e-mail: phytor1@gmail.com

Jerusalem, Israel

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Expert opinion on the toxicological aspects and risk assessment of the products H.FORMULA CAP, a nutritional supplement from Dr. K company.

Dr. Yehoshua Maor

Expert in pharmacology, toxicology and regulation of medicines and nutritional supplements.

This initial review relates only to the toxicological aspects and risk assessment of the inactive substances used in the formulation of H.Formula Cap, a nutritional supplement from Dr. K company.

This independent opinion has been done on the request of Dr. K. as represented by Mrs. Linoy Hoffman.

About my training:

- Bachelor's degree in Pharmacy (B.Pharm , Brazil)
- Medicinal Chemistry degree (M.Sc. , Hebrew University)
- PhD in Medicinal Chemistry and Molecular Biology (PhD, Hebrew University)
- Post - Doctoral School of Medicine and Harvard University , Boston , USA, on Pharmacology of cardiovascular
- Currently** , coordinator of the Center of Excellence for Research in Agriculture and Environmental Health of the Hebrew University of Jerusalem (HU CEAEH) in the Rehovot campus and lecturer of Toxicology at the Faculty of Medicine in the Ein Kerem campus - Jerusalem.
- Senior consultant at Phytor Ltd. Engaged in consulting in pharmacology, toxicology and regulatory aspects of new drugs and chemical substances of medicinal plants.



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Product Name: H.FORMULA CAP

Manufacturer: E.M.B. YARDEN AGRICULTURAL FARM LTD. 1, Haoman Beit Shemesh – 99061 - ISRAEL

Product description: Capsules containing dried herbs, vitamins and minerals weighing 614.2 mg (net weight)

Directions for use: 2 capsules a day with a glass of water

Components of the formula

COMPONENT NAME	% in Formula	Amount in the capsule (mg)	Safety Code
Serenoa repens	49	300	✓
Stephania tetranda	13	100	✓
Tocopherol(Vitamin E)	8.1	30	✓
Taurine	5	30	✓
Pyridoxine(Vitamin B6)	5	30	✓
Bambusa	4	25	✓
Zinc picolinate	3.5	22	✓
Cysteine	3.2	20	✓
(Vitamin B1) Thiamine	3.2	20	✓
(Vitamin B5) Pantothenic acid	3.2	20	✓
Riboflavin (Vitamin B2)	2.44	15	✓
Copper	0.24	1.5	✓
(Vitamin B12) Cobalamin	0.05	0.3	✓
Biotine (Vitamin H)	0.05	0.3	✓
Selenium	0.02	0.1	✓
Capsule	0	120	
	100%	734.2	

**Warning: Pregnant women, lactating women, people taking prescription drugs, children, consult your doctor.
Keep out of reach of children.**

After thoroughly reviewing the scientific literature and professional, this document will refer only to the following issues relating to H.Formula Cap product components:

1. The amount of active substance in the plant before and after extraction
2. Reaction between components
3. Usual doses and toxicity of formula or component
4. Warnings (if any) about the product
5. Level of safety

1. Active substances in the plant before and after extraction

The amount of active ingredient in the plant before the extraction can vary with the harvest season, cultivation location, and other factors.

As for herbal medicines, the active ingredient is sometimes known and sometimes requires co - factors (other materials in the plant that are active together synergistically) to achieve therapeutic goals. This leads to complications in tagging the active ingredient. One way manufacturers have found to solve the problem of labeling is selecting the marker element (the most active component in the plant) and perform standardization of the cursor element.

However, official standardization by government agencies such as the Ministry of Health, has not been achieved yet, and therefore not required by the health of natural herbal products manufacturers in Israel or in Europe. Consequently, various companies use different markers, or different levels of the same markers, or different methods of testing marker compounds.

Both the Israeli Ministry of Health and EMEA/EFSA do not publish a list of active substances in plants. Instead, they provide a list of plants approved for use.

In order to compare the amount of active ingredient in the plant before and after extraction, we find that in the British Herbal Pharmacopoeia and - British Herbal Compendium doses comparing different forms of plants, such as root dry compared to the extraction liquid tincture.

Therefore, one can prepare a tincture on the basis of literature data. Typically use 45% ethanol. Which is the case regarding the specific formula, which we discuss in this document, the following value of the component may vary in a formula according to the British Pharmacopoeia.

2. Reaction between components

Plants contain a plethora of molecules with biological activity. However, there are no spontaneous interactions among the components of the plants after the completion of their biogenesis.

In alcoholic extracts all the chemical properties are maintained and there is no indication in the literature that there is an interaction between the components of plants – that is said of the components of one plant and even if it is a herbal mixture formula. Such formulas represent a very acceptable alternative form of medicine because according to this method, the plants work synergistically to achieve the goal of treatment.

Since some plants possess certain compounds with strong pharmacological activity, there is a possibility of interaction between the components of the plants and pharmaceutical drugs. These interactions are based on enzymatic reactions in the liver of a patient taking both herbal medicines and conventional drugs. Extreme care should be taken and monitoring of relevant biochemical values in the patient should be applied in order to guarantee the safety of herbal medicines taken concomitantly with conventional drugs.

In the component table above:

*we have marked with a sign (✓) all the components for which there is no fear of reactions between conventional drugs component, as well as between the component and other components in the formula.

It is noteworthy that these reactions in principle, may mainly occur in chronic patients or those taking conventional drugs intended for chronic diseases such as diabetes, blood thinners and blood pressure controlling and cholesterol lowering medications.

As an aid for our interaction investigation we made use of the accredited website WebMD

<http://reference.medscape.com/drug-interactionchecker>

For all the combinations of the formula, we got the answer:

No Interactions Found

Other accredited online tools were also searched like the site of the American Botanical Council:

-Commission E Monographs from the American Botanical Council.

<http://abc.herbalgram.org/site/PageServer?pagename=Monographs>

and the following additional sites:

www.mskcc.org (Memorial Sloan- Kettering)

www.drugdigest.org (Drug Digest)

www.naturalstandard.com (Natural Standard)

All components in the formula found in normal use in humans by the British and American Pharmacopoeia.

There is no fear of a chemical reaction during the average shelf life of this product.

Also, there is no fear of a chemical reaction between vitamins and this herbal formula.

3. Usual doses and toxicity of formula or component

The recommended daily dose of the product allows the use of reasonable and absolutely safe margin of toxicity. The product can be safely administered up to 5 capsules/day for an adult, without any fear of side effects or toxicity.

To the best of my knowledge and according to the literature, from the toxicological standpoint, there is no fear of toxicity or poisoning from taking this product.

4. Warnings (if any) about the product

There are no warnings concerning this product.

5. Level of safety

Based on a critical evaluation of available public data sources listed in the bibliographic sources and above, as an expert in toxicology I have reached the conclusion that the active ingredients used in the formulation of H.Formula Cap, and consequently the final product, is safe for human use especially when followed the instructions for use from the producer. The formulation possesses a wide safety margin concerning its risk of toxicity.



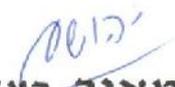
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In addition, all components are included in the EAFUS (Everything Added to Food in the United States) list and the GRAS (Generally Regarded as Safe) of the FDA, indicating the safety of the product.

In conclusion, since these substances have been certified by the Ministry of Health and possess a long history of safe use for humans, the review of the substances and the product allows me to state that the product has a high safety level, once it is administered in accordance with the use and guidance of the Ministry of Health.

Sincerely,


פיטאור בע"מ
514486240 .פ.ח
PHYTOR LTD.

Yehoshua Maor
Ph.D., M.Sc., B.Pharm.

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