

BEE PRODUCTS – between physiological and pharmacological effects

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IBA - SNPMAPS

*** President APIMONDIA Scientific Commission on Apitherapy**

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Definitions

Food Supplements

- **Food supplements** are concentrated sources of nutrients (i.e. mineral and vitamins) or other substances with a nutritional or physiological effect.
- They are marketed in “dose” form (e.g. pills, tablets, capsules, liquids in measured doses).
- They are intended **TO CORRECT NUTRITIONAL DEFICIENCIES**, maintain an adequate intake of certain nutrients, or **TO SUPPORT SPECIFIC PHYSIOLOGICAL FUNCTIONS**.
- They **ARE NOT MEDICINAL PRODUCTS** and as such ***cannot exert a pharmacological, immunological or metabolic action.*** Therefore their use is **NOT** intended to treat or prevent diseases in humans or to modify physiological functions.

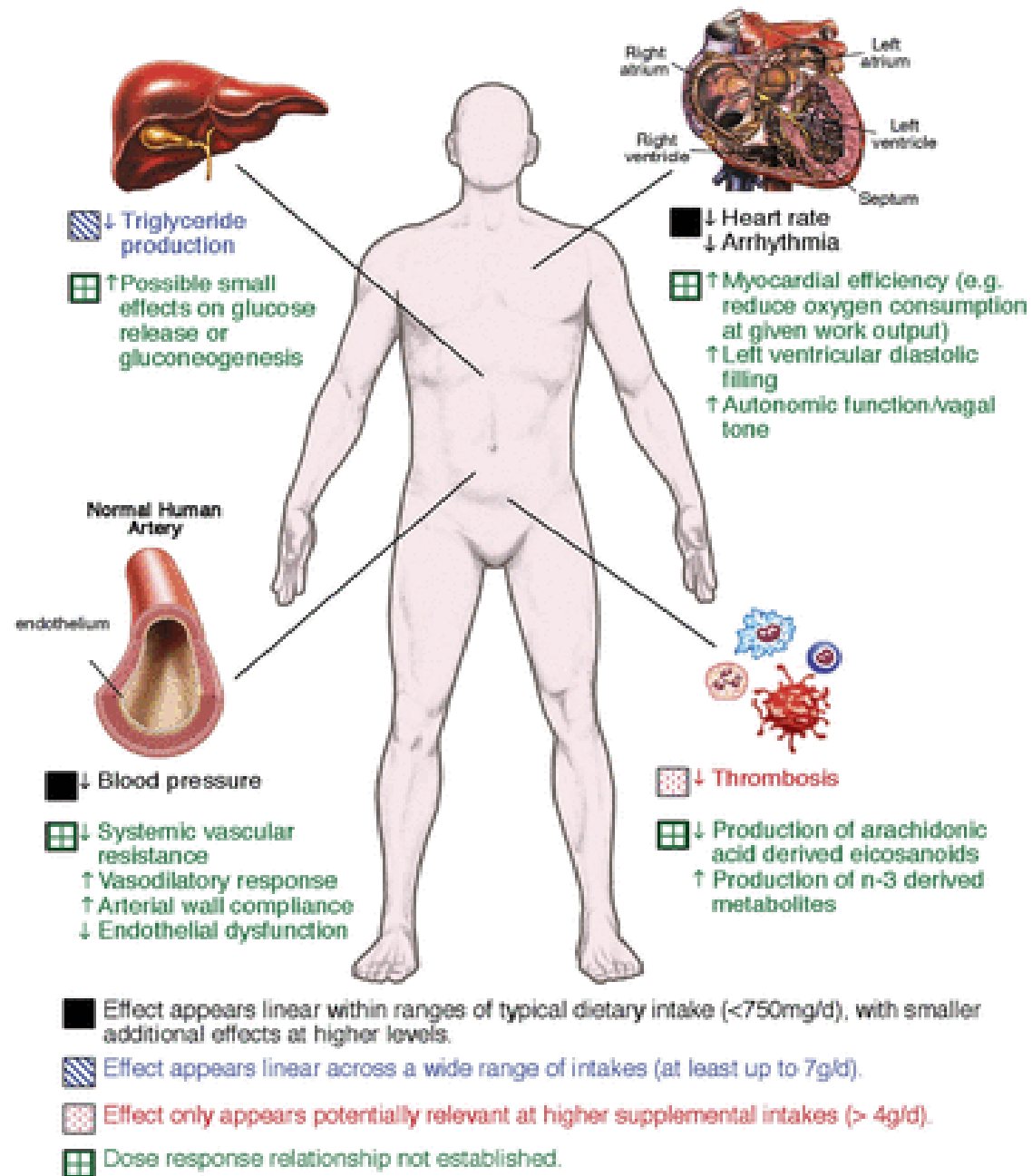


Physiological effects

Physiological effects are:

- those resulting from some imbalance to the overall human system, or some specific part of it. The word “effect” means that the change can be seen or measured in some way.
- the alterations or changes which the body does on its own to maintain a constant inner state called ‘*Homeostasis*’, including circulation, respiratory rhythm, temperature, biochemicals like pH, pO₂, pCO₂ etc.

Ex. Physiological effects of PUFA



Medicinal (Pharmaceutical) Product

a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings;

b) used to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action

c) to make a medical diagnosis.



Medicinal (Pharmaceutical) Product

Observation: The definition of a medicinal product includes 2 main elements: **the presentation of the product** (the therapeutic effect or prevention is addressing a disease and **its function**).

If the health claim related to the physiological effect does not refer to a disease (i.e., decrease of cholesterol level), the product is not considered a medicinal product, but a food supplement.

Substances used in food supplements for which a maximum limit is specified

- Bioflavonoide* (complex)-1000 mg
- Phytosterols – 3 g – (sterols, stanols)
- Inositol – **2 g** (4 g) – sugar alcohol (royal jelly)
- Isoflavones – 80 mg
- Lycopene – 2,5 mg - 15 mg (carotene)
- Luteine – 2 mg (10 mg) (xantophylle)

Some common flavonoids usually found in some bee products (honey, bee pollen and propolis

- *Quercetin - 200 mg (found in Brazilian green propolis, poplar propolis...
- *Quercitrin - 300 mg (a glycoside formed from the flavonoid quercetin and rhamnose, a deoxy sugar).
- *Rutin - 300 mg – found mostly in bee pollen (rutoside or quercetin-3-O-rutinoside or sophoroside)
- *Hesperidin - 600 mg, (Hesperetin's 7-O-glycoside)
- *Hesperetin - 300 mg,
- *Diosmin - 300 mg

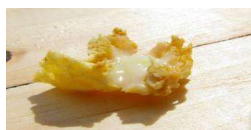


BEE PRODUCTS
Food,
Food supplements,
Traditional medicinal products,
Cosmetics,
others?



Bee products

nutritional and/or therapeutic value



Bee Product	Nutritional value	Therapeutic value
HONEY	FOOD	<i>Medicinal / vehicle</i> <i>External applications</i>
BEE POLLEN BEE BREAD	FOOD	Medicinal
PROPOLIS	- Physiologic effects	MEDICINAL
ROYAL JELLY	<i>Food</i>	Medicinal
BEE VENOM	-	Medicinal



Regulation On Bee Products As Food Supplements

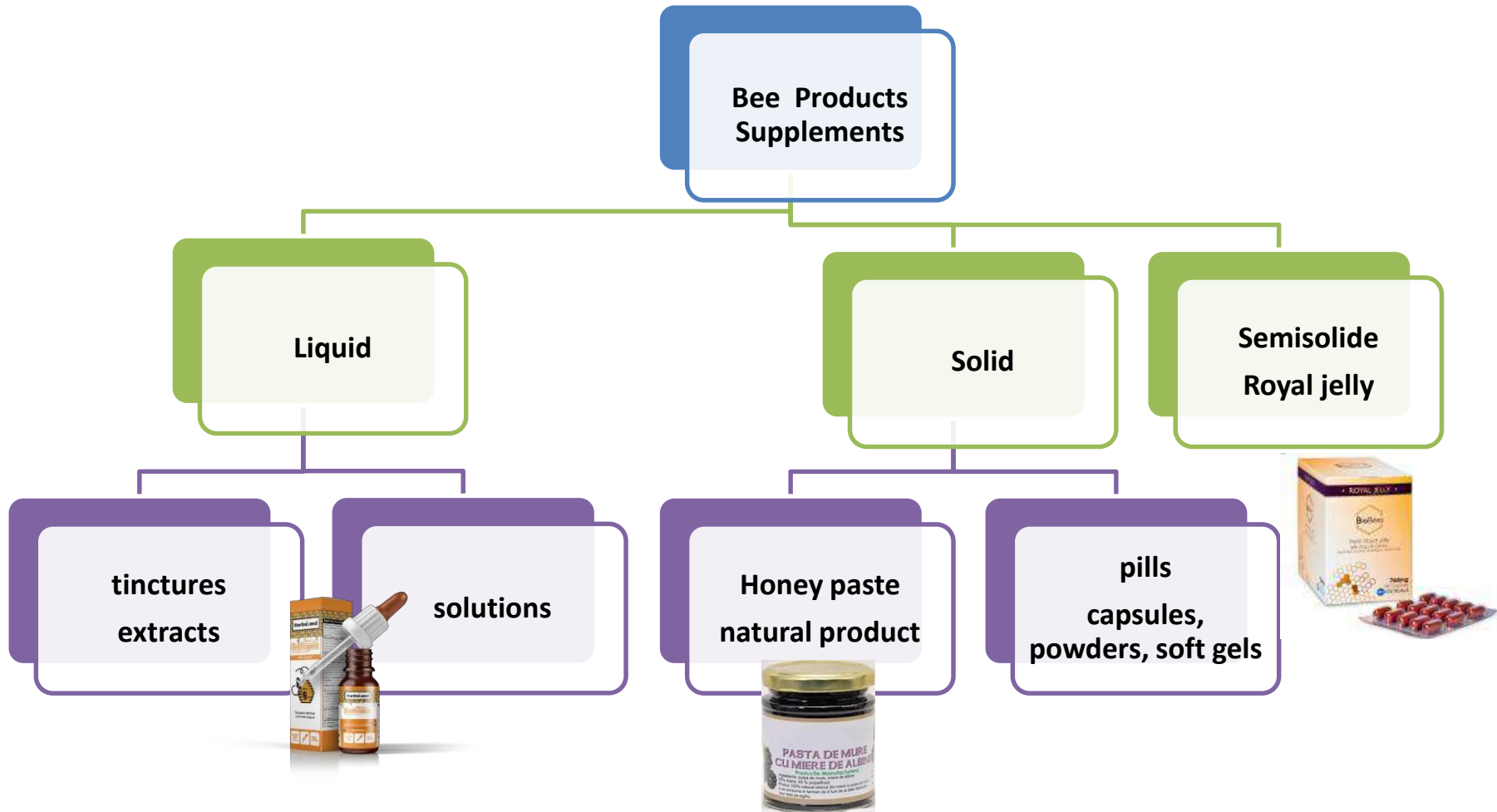
In Romania, **BEE PRODUCTS** are subject to Order no. **1228/2005** (norms of application) – related to food supplements based on medicinal plants, aromatic herbs and bee products.

Art.2 lit.c.

- c) **BEE PRODUCTS**: pollen, bee bread, royal jelly, propolis, bee/drone larval triturations, other bee products and mixtures of bee products or mixtures of bee products with herbal extracts, or animal products, essential oils, vitamins, minerals and other nutrients;



Food Supplements With Bee Products



Nutritional And Health Claims For Bee Products

Unfortunately, EFSA has already published many **unfavorable opinions** on bee products or the food (dietary) supplements containing bee products (as ingredients) and most opinions were related to the **poor quality** of the information provided to EFSA

Lack of information: what does it mean: **??????**

- **Incapacity to identify specific substances** on which the respective claim is made;
- **Lack of evidence** to substantiate the respective claim (i.e. propolis is beneficial for the maintenance and improvement of the body functions) or
- **Lack of accuracy** related to the respective health claim.



HONEY

HONEY



HONEY

HONEY - FOOD

- conventional honey
- **Organic honey – the product itself is NOT certified**
- Energetic FOOD, prebiotic effects, etc.



Honey in dietary (food) supplements (vehicle)

- Other bee products, essential oils, herbal extracts, aromatic herb extracts



Scientific Opinion on the substantiation of health claims related to honey and “respiratory health through presence of antioxidant phytochemicals” (ID 1161), “the unique composition and ratio of effective substances adds energy to the human body” (ID 3188), and “it stimulates the whole metabolism and the immune system” (ID 3189) pursuant to Article 13(1) of Regulation (EC) No 1924/2006



(ID 1159, 1160, 1318, 4678, 4679)

NO such claim has been authorized....



HONEY NUTRITION FACTS

Serving size 100 g



CALORIES		304
Calories from fat		0
		% Daily Values
TOTAL FAT		0%
Saturated fat 0 g		
Polyunsaturated fat 0g		
Monounsaturated fat 0g		
Cholesterol 0 mg		0%
Sodium 4 mg		0%
Potassium 52 mg		
TOTAL CARBOHYDRATE 82.4 G		27%
Dietary fiber 0.2 g		1%
Sugars 82.12 g		
PROTEIN 0.3 G		
VITAMIN A 0%	VITAMIN C 1%	
Calcium 1%	Iron 2%	

Calories
304

Fat
0

Carbohydrates
82,4 g

Protein
0.3 g

15% of RDI
(304 calories)

HONEY – HEALTH CLAIMS

Health Relationship

ID 4679 - Honey - Energy metabolism (**what are then the direct assimilable sugars and glucose in honey?**)

ID 4678 - Honey - Helps heart health and to maintain a balanced level of cholesterol and lipids in the body (**could we speak about polyphenols, could we speak about miocard...**)

ID 3189 - Honey comb - It stimulates the whole metabolism and the immune system.

3188 - Honey comb - The unique composition and ratio of effective substances adds energy to the human body (**again energy?**)

1321 - Honey - Antioxidant properties Target Group : For children and adults older than three years old
Excluded Group : Nobody (only person who are allergic)

1318 - Honey - Antibacterial and antifungal properties Target Group : For children and adults older than three years old
Excluded Group : Nobody (only person who are allergic)

1161 - Honey, including the antioxidants in honey - Respiratory Health through presence of antioxidant phytochemicals.

1160 - Honey - Digestive health through presence of fructo-oligosaccharides and antioxidant phytochemicals.



Honey – Physiological Effects

Example of physiological effect

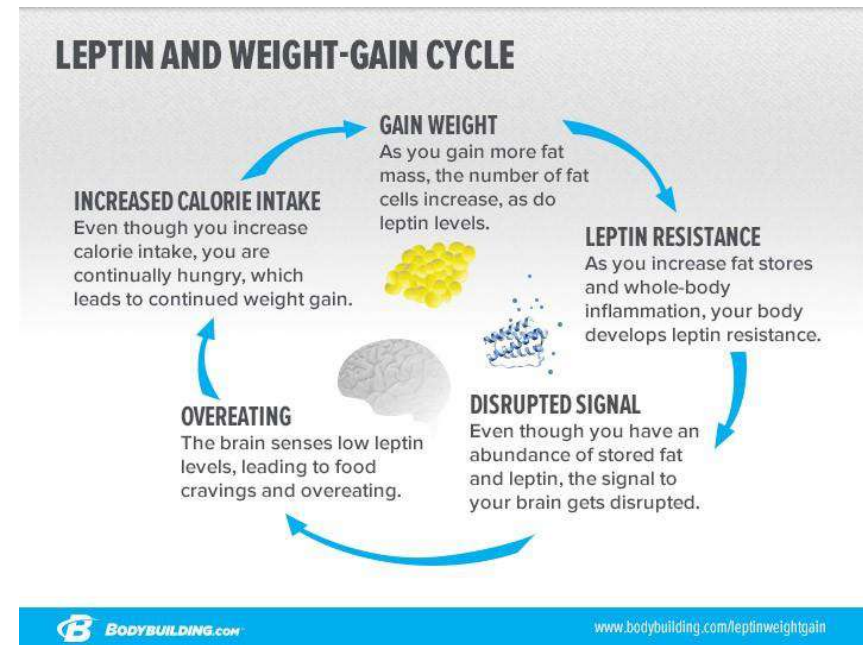
- Honey – **weight control** through polyphenols and FOS – mechanism
- One of the first reported effects of honey on human health is **regulation of body weight**. Animal experiments have shown that honey-based diets **can reduce body weight in mature animals** or **body weight gain in growing animals when compared to sucrose-based diet**.
- Moreover, the antioxidant properties of honey can reduce **lipid peroxidation and contribute to increased cardiovascular health**. For example, honey-based diets reduced hyper-triglyceridemia effect that is normally associated with high-fructose diet.
- But unfortunately, the law says it should not be given to children!



Honey and weight control (loss)

Reduced weight gain in growing animals was traced to reduction in food intake, which was attributed to altered production and increased sensitivity to leptin (appetite-suppressing hormone).

Sucrose-fed rats have high levels of circulating *leptin* but develop *leptin resistance*, which promotes excessive food consumption that leads to increased /undesirable weight gain.



Other physiological effects of honey

EFSA Journal 2011;9(6):2243

Scientific Opinion ... HONEY (ID 1159, 1160, 1318, 4678, 4679)

The following effects are object to the above mentioned claims:

- Protection of cells and molecules against oxidative damage,
- Defense against pathogens
- Maintenance of normal blood cholesterol level
- The Panel considers that the food, honey, **has not been sufficiently characterized** in relation to the claimed effects;
- On the basis of the data presented, the Panel concludes **that a cause and effect relationship has not been established** between the consumption of honey and the claimed effects.

However, SOME SCIENTIFIC STUDIES SHOW...



Antioxidant Activity Of Honey

Beretta G., Granata P., Ferrero M., Orioli M., Facino R.M. *Chimica Acta* 533, pp. 185-191 (2005)

Wilczynska A. *Polish Journal of Food and Nutrition Sciences*, vol.60, n°4, pp. 309-313 (2010)

Aazza S., Lyoussi B., Antunes D. and Graça Miguel M. *Journal of Food Science* 78, n°8, pp. C1159-C1165 (2013)



Honey	Polyphenols contents (mg gallic acid 100g)	ORAC value (μ mole TE/g)
Heather honey (<i>Calluna vulgaris</i>)	154,4 \pm 40,9	22,58 \pm 0,61
Buckwheat honey (<i>Fagopirum aesculentum</i>)	125,9 \pm 48,3	11,60 \pm 0,70
Honeydew honey	65,5 \pm 5,7	6,30 \pm 0,22
Dandelion honey (<i>Taraxacum</i>)	54,2 \pm 12,4	7,59 \pm 0,60
Acacia honey (<i>Robinia pseudoacacia</i>)	37,7 \pm 4,5	2,12 \pm 0,01

J. Agric. Food Chem. **2003** Feb 26; 51(5):1500-5.

Physiological effect

Buckwheat honey increases serum antioxidant capacity in humans. *Gheldof N., Wang XH, Engeseth NJ*



Honey and Health: A Review of Recent Clinical Research

[Pharmacognosy Res.](#) 2017 Apr-Jun; 9(2)

[Saeed Samarghandian](#), [Tahereh Farkhondeh](#),¹ and [Fariborz Samini](#)²

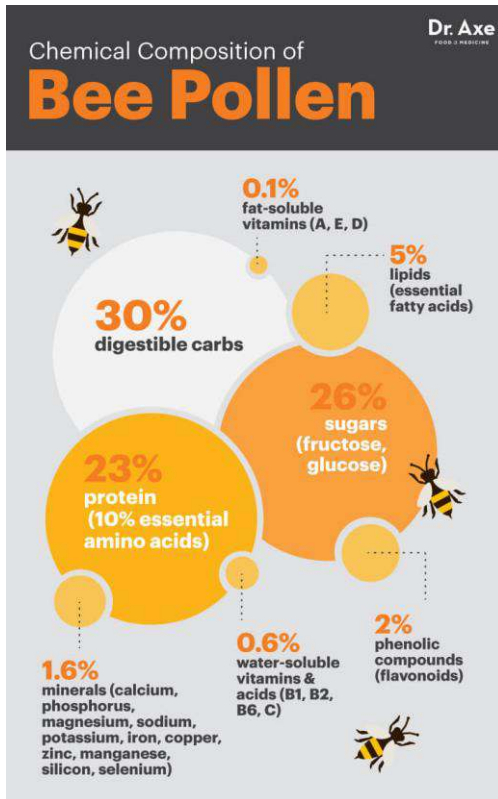
Nutrients and non-nutritional compounds in honey

Aprox. 300 recognized types (varieties) of honey.

These varieties are related to various types of nectar collected by honeybees (bees).

Pure honey contains ***flavonoids***, ***polyphenols***, reducing compounds, alkaloids, glycosides, cardiac glycosides, anthraquinones and volatile compounds.

Bee Collected Pollen



Bee Collected Pollen



COMPOSITION

Major chemical compounds
Aminoacids, Proteins, Enzymes,
Polyphenols
Carotenoids
Sugars
Vitamins
Macro and oligoelements

BENEFITS (HEALTH EFFECTS)

Antioxidant activity
Immunomodulatory effects*
Liver Protection*
Sustains the heart good functioning and a
balanced level of blood lipids*
Contributes to the well-being of
gastrointestinal tract*
Health of urinary bladder and prostate in
men over the age of 40th *
Menopause*

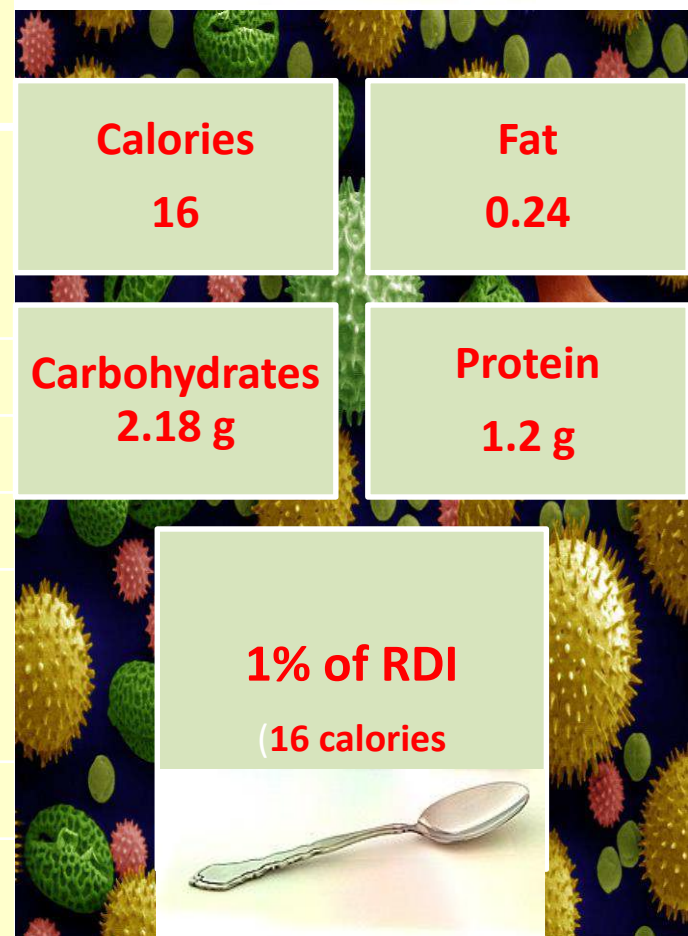


Bee Pollen Nutrition Facts

Serving size 1 Tablespoon

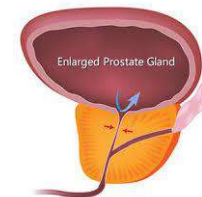
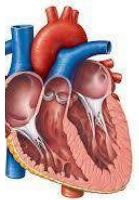
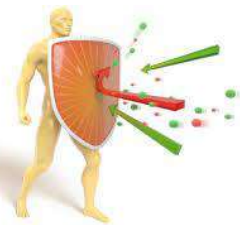


CALORIES	16
Calories from fat	0.24
	% Daily Values
TOTAL FAT 0.24 g	1%
Saturated fat 0.173 g	
Polyunsaturated fat 0.027 g	
Monounsaturated fat 0.025g	
Cholesterol 0 mg	0%
Sodium 0 mg	0%
Potassium 11 mg	
TOTAL CARBOHYDRATE 2.18 g	1%
Dietary fiber 0.4 g	2%
Sugars 1.79 g	
PROTEIN 1.2 G	
VITAMIN A 0% VITAMIN C 4%	
Calcium 0 % Iron 2%	

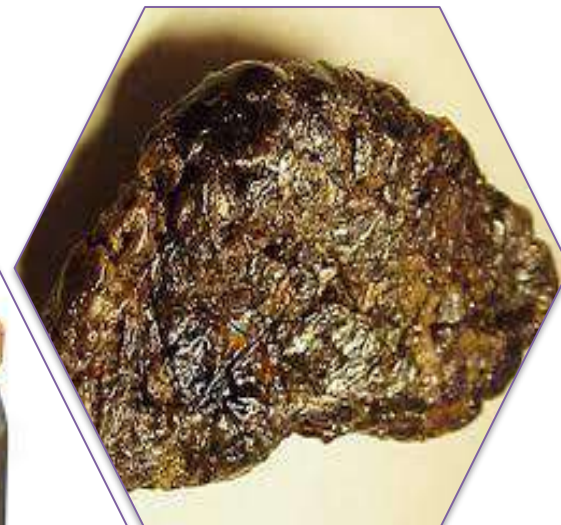


Bee Pollen Health Claims (Pending)

- 4695 - Pollen-Bee pollen - Immunomodulating agent due to enzymes and vitamins content/ **Stimulates an immune response.**
- 4658 - Bee pollen - Helps heart health and to maintain a balanced level of cholesterol and lipids in the body/ **Promotes a good heart functioning and a balanced level of blood lipids. / Supports a good heart functioning and the health of the blood vessels.**
- 4323 - Pollen (from multi-flowers) - is effective in the management of gastrointestinal disorders/ **Contributes to the gastrointestinal well-being**
- 3136 - Bee pollen - helps to improve immunity/ **helps to improve immunity**
- 3135 - Bee pollen - **enhances appetite**
- 1956 - Pollen – Menopause /**Contributes to comfort during menopause. Contributes to well-being during menopause. Helps to reduce discomfort during menopause. Helps to decrease hot flushes.**
- 1955 - Pollen - Resistance/ tonus/ **Helps in case of fatigue/tiredness. Helps to support body's vitality and body's resistance. Helps to make you feel more energetic. Enhancement of vitality/energy.**
- 1836 - Pollen - Mental state and performance /**Pollen contains a lot of vitality substances. Increases vigour, vitality and alertness.**
- 852 – Rye Pollen (*Secale Cereale* L) – maintenance of urinary bladder and prostate health
- 1650 - Rye Pollen (*Secale Cereale* L) – Maintenance of normal urinary function



PROPOLIS



Propolis Products



MEDICINE



**FOOD
SUPPLEMENTS**

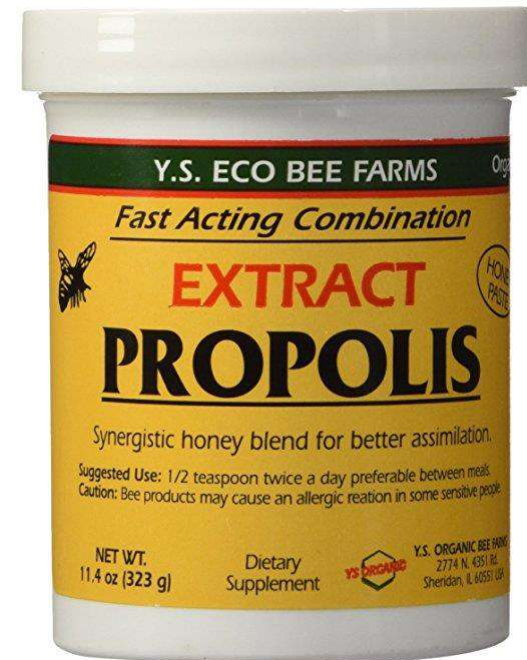


COSMETICS



Propolis Supplement Facts

Supplement Facts		
Serving Size 1/2 tsp (5g)		
Servings Per Container 65		
Amount Per Serving	% D.V.	
Calories	15	
Carbohydrates	4 g	2%†
Sugar	4 g	
Bee Propolis extract (2x) 200 mg* (equivalent to 400 mg raw Propolis)		
†% Daily Value based on 2,000 Calorie diet		
*Daily Value not established		

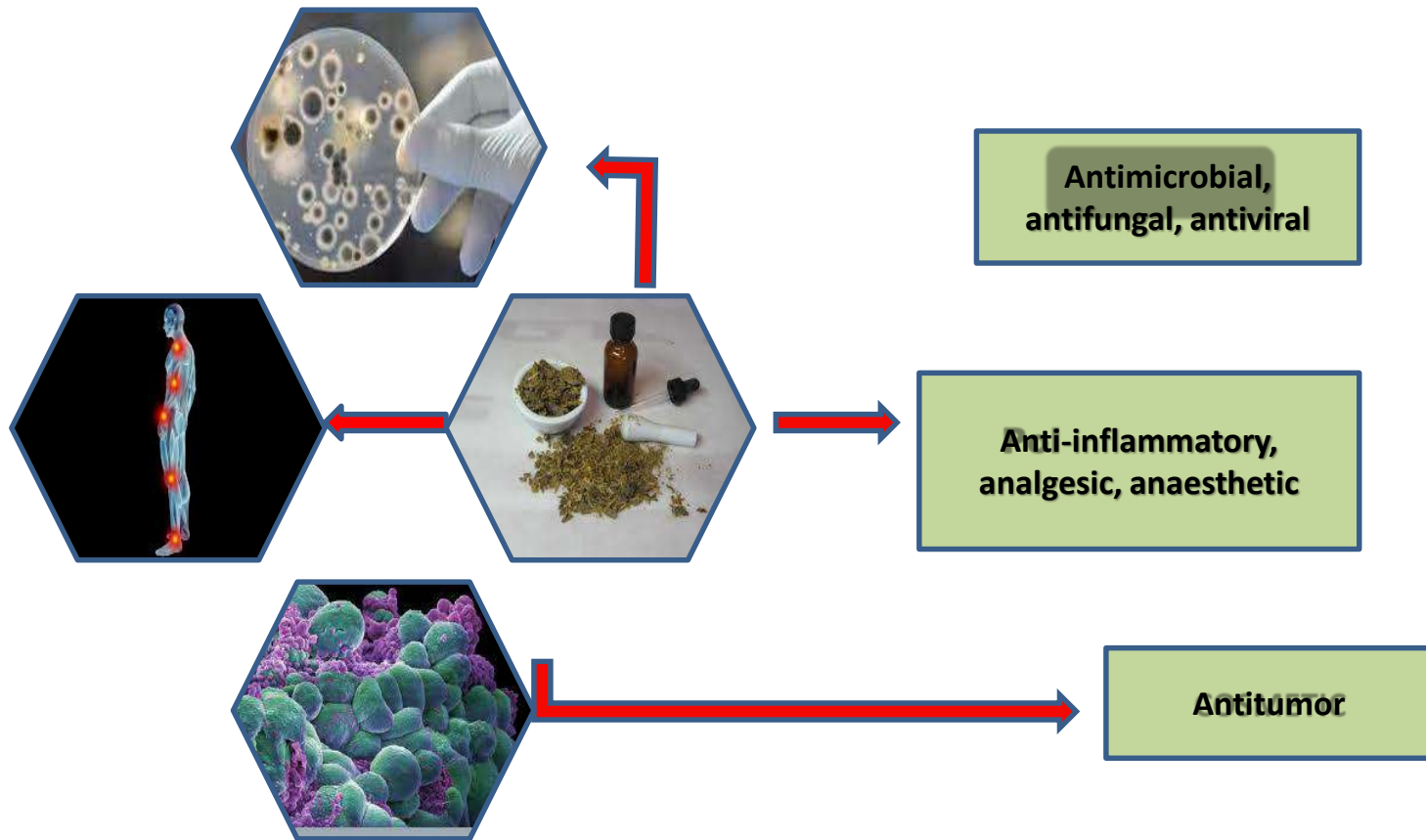


PROPOLIS

Nutritional value / physiological effects

- Proteins: max 1 g/100 g;
- Carbohydrates: max 1 g/100 g;
- Fat: max: 1 g/100 g
- *Considering the low suggested intake of 200 mg per day, propolis has an **insignificant** contribution to the daily requirements regarding the basic nutrients.*
- *Propolis has **no nutritional value** but due to its composition has important **physiological effects***

Biological Activity Of Propolis



Conditions of use – according to the data provided by the EU member states

- Food supplement with **24-72 mg** of propolis the daily dose / Soothes the stomach and gut.
- Propolis **2 x 200mg/day** - help in controlling colds, help the natural defense, support the natural defense system
- Helps to maintain the integrity of the body thanks to its antimicrobial effects/Propolis has a natural antimicrobial action / Conditions of use: propolis soft extract / -contributes to ease throat discomfort - helps to soften the throat

Support for a normal level of blood lipids and cholesterol

- A study demonstrated that propolis **1% is safe** and quiet enough to induce beneficial hypolipidemic and hypocholesterolemic effects in serum of rats fed high cholesterol diet.
- The hypolipidemic and hypocholesterolemic effects of propolis could be investigated in birds and animals.
- In addition, future studies are recommended to investigate the mechanisms of action of propolis as hypolipidemic and hypocholesterolemic agent at molecular levels.



European Food Safety Authority

EFSA Journal 2010;8(10):1810

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to propolis (ID 1242, 1245, 1246, 1247, 1248, 3184) and flavonoids in propolis (ID 1244, 1644, 1645, 3526, 3527, 3798, 3799) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to propolis and flavonoids in propolis. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

EFSA Opinion on PROPOLIS

- The food(s)/food constituent(s) that are the subject of the health claims are **propolis or flavonoids in propolis** related to the following claimed effects: “respiratory health”, “antibacterial and antifungal activities”, “throat comfort”, “gut health”, “supports immune defences”, “maintenance of oral health”, “helps to maintain a normal blood circulation” and “hepatoprotective”.
- The references provided reported on **differences in biological activity between propolis preparations from different sources.**
- Levels of what are assumed to be biologically active constituents in some propolis preparations are low or undetectable in other propolis preparations.
- Further, the papers provided for the scientific substantiation of the claims reported on **a wide range of different propolis preparations, extracts and isolated components, and it is not clear for which type of propolis preparation/constituent the claims are made.**

Propolis standardization might be based on the concentration of biologically (or pharmacologically) active chemical compounds in various parts of the world



Products With Various Types Of Propolis



Brazilian Red propolis



Poplar propolis



Brazilian green propolis



<https://healthywithhoney.com/composition-of-propolis/>



Propolis as Medicine in Herbal Medicine

RECOMMENDED USE OR PURPOSE:

Source of antioxidants for the maintenance of good health. Used in **Herbal Medicine** to help relieve sore throat and other mouth and throat infections. Used in Herbal Medicine to help relieve mucous membrane inflammations of the mouth and throat.

MEDICINAL INGREDIENT –

Each 1 ml (approximately 25 DROPS) contains:
Bee Propolis.....**167 mg**
[Bee hive of the honey bee (*Apis mellifera* L.)]

NON-MEDICINAL INGREDIENTS:

Glycerin, Purified Water.

RECOMMENDED DOSE – (ORAL) ADULTS ONLY:

1 ml (approximately 25 drops) 3 times per day.

DURATION OF USE: a health care practitioner should be consulted for use beyond 1 month.



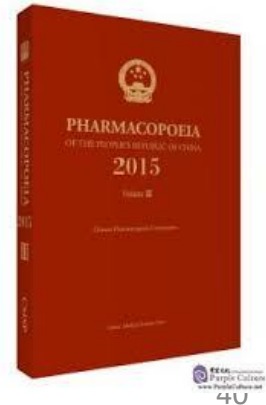
Propolis in the Pharmacopoeias

Pharmacological effects

- **Provisions of the Chinese Pharmacopoeia 2015** (2015 version (Pharmacopoeia Committee of P. R. China, 2015), the 10th Pharmacopoeia in China

Quality conditions

- Chrysin no less than 2.0%,
 - Galangin no less than 1.0%,
 - Caffeic acid phenethyl ester(CAPE) no less than 0.50%,
 - Pinocembrin no less than 1.0%
-
- **Drug safety control in TCMs in 2015 version**
 - Heavy metals $Pb \leq 8 \text{ mg/kg}$ Propolis
 - $Cu \leq 20 \text{ mg/kg}$ All CMM





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Ingredient Search

Search For:

Role:

Date Database Last Changed: 2018-08-29

Search Results

Your search found 3 Ingredients:

Result Page: 1

List of Returned Ingredients

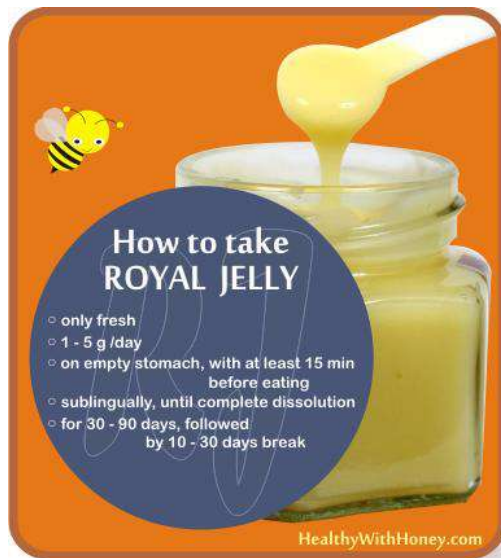
Ingredient	Proper Name(s)	Common Name(s)
Propolis (Defined Organism Substance) Pre-cleared Information: <ul style="list-style-type: none"> Propolis - Topical Propolis - Oral Traditional Chinese Medicine 	Propolis	<ul style="list-style-type: none"> Bee propolis Feng jiao Propolis Propolis balsam Propolis resin Propolis wax

Propolis toxicity

- Burdock reviews many toxicological studies in animals. He concluded that at an intake of **4000 mg/kg** per day there are no measurable effects and established a **No Effect Level (NOEL)** at **1400 mg/kg per day**.
- Generally a safety margin of 100 is assumed for drug and food additives.
- This means that a maximum of **14 mg/kg per os or 980 mg per day for a human of 70 kg** can be the daily acceptable intake.

Origin	Anti-bacterial	Anti-inflammatory	Antitumor	Hepato-protective	Antioxidant	Allergenic
EUROPE (Poplar)	Flavonones, flavones, phenolic acids, phenolic acids esters	Flavonones, flavones, phenolic acids, phenolic acids esters	Caffeic acid phenethyl ester (CAPE) quercetine,	Caffeic acid, ferulic acid, Caffeic acid phenethyl ester CAPE	Flavonoids, phenolic acids, phenolic acid esters	3,3-dimethyl caffeate
BRAZIL (<i>Baccharis</i>)	Prenylated p-coumaric acids, labdanic diterpenes	Non-identified	Prenylated p-coumaric acids, clerodane diterpenoids benzofurans	Prenylated p-coumaric acids, lignans, flavonoids, caffeoyl-quinic acids	Prenylated p-coumaric acids, flavonoids	Non – examined yet
CUBA	Prenylated benzophenones	Non examined	Prenylated benzophenones	Non examined	Prenylated benzophenones	Non examined
TAIWAN	Non examined	Examined flavonones	Prenylated flavonones	Examined flavonones	Prenylated flavonones	Examined flavonones

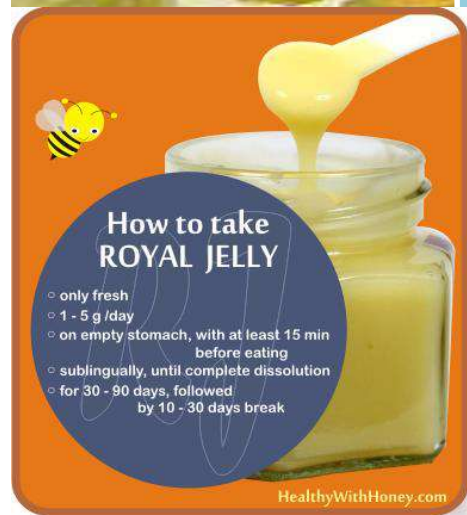
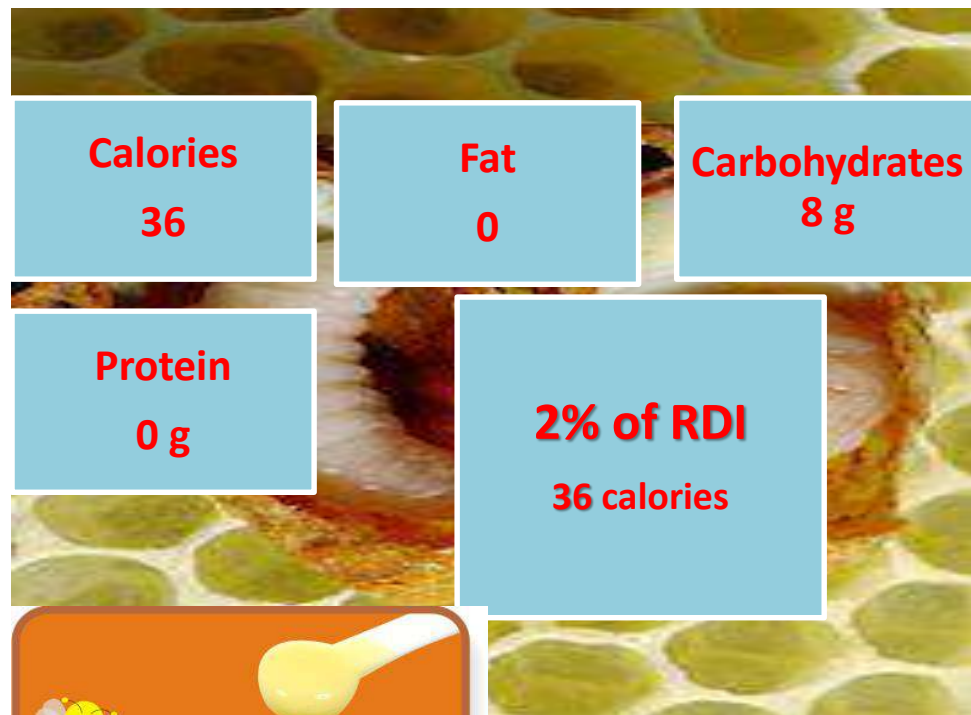
ROYAL JELLY



Royal Jelly Nutrition Facts

Serving size 1 tsp (10g)

CALORIES	36
Calories from fat	0
	% Daily Values
TOTAL FAT 0 g	
Saturated fat -	
Cholesterol -	
Sodium -	
TOTAL CARBOHYDRATE 8 g	
Dietary fiber -	3 %
Sugars 6g	2%
PROTEIN 0 g	
VITAMIN A -	VITAMIN C -
Calcium -	Iron -



Royal Jelly Health Claims/ physiological effects

Royal jelly related to the following claimed effects:

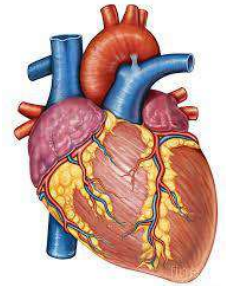
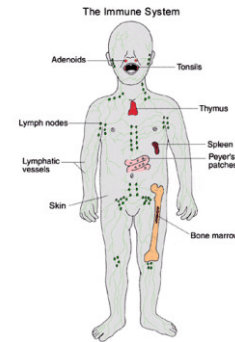
— natural defence/immune system
— metabolism, — vasodilation, — endocrine glands function, — skin health, — tonus/vitality, — muscle tone, immunostimulant, — ménopause, effet oestrogénique, — hypolipémiante, — vitalité physique et intellectuelle, — heart health and to maintain a balanced cholesterol and lipids in the body (ID 1225, 1226, 1227, 1228, 1230, 1231, 1326, 1328, 1329, 1982, 4696, 4697)

In the human studies provided which addressed outcomes related to the claimed effects the origin and composition of the royal jelly used was not specified.

The Panel notes that from the references **PROVIDED IT WAS NOT POSSIBLE TO CHARACTERIZE ROYAL JELLY IN GENERAL, NOR THE SPECIFIC COMPONENTS OF ROYAL JELLY** mediating the functions for which the claims were made.

The Panel considers that royal jelly, which is the subject of the claims, is not sufficiently characterized in relation to the claimed effects considered in this section.

The Panel concludes that **A CAUSE AND EFFECT RELATIONSHIP CANNOT BE ESTABLISHED BETWEEN THE CONSUMPTION OF ROYAL JELLY AND THE CLAIMED EFFECTS** considered in this section.



General concerns related to natural products

- **Doses may be based** on those most commonly used in available trials, or on historical practice.
- However, with natural products it is often not clear what the optimal doses are to balance efficacy and safety.
- Preparation of products may vary from manufacturer to manufacturer, and from batch to batch within one manufacturer.
- Because it is often not clear what the active component(s) of a product is, **standardization may not be possible**, and the clinical effects of different brands may not be comparable.

Are the medicinal products containing propolis eligible for traditional use registration?

Acc. To Directive 2001/83/EC

The Committee on Herbal Medicinal Products (HMPC) considers that **propolis** does not meet the legal definition of herbal substances or herbal preparations laid down in Directive 2001/83/EC.

The literature classifies **propolis as a natural substance of animal origin**. As a result of the action of the bees in the course of collection, it is not possible to precisely define the plant part and botanical binomial name as required by the legislation.

In addition, **it is not clear how the substances collected by the bees are modified.**

Therefore, products containing propolis **ARE NOT ELIGIBLE** for traditional use registration.



Could It Be A Future Way For Some Bee Products to be Registered As Medicines?



Propolis

Will it Help Fight Diabetes?



CONCLUSION

Attention should be paid to **the possible extension** of the scope of the traditional use registration procedure to “products other than herbal substances with a long tradition of **safe** use’ including ‘substances of animal, mineral or metallic origin and micro-organisms’ (such as **‘honey, royal jelly, propolis,** fish oils, minerals, micro-organisms and other substances”).

References

- <https://www.insectstings.co.uk/immunotherapy/>
- <http://bonspomeditistory.com/category>
- <http://www.deepbluehealth.com/product/f6ff36c2-dda2-4a74-a4b7-49ec372c6621.aspx>
- <http://anxiety symptoms in children.blogspot.ro/2011/01/what-do-you-know-about-propolis.html>
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**THANK YOU FOR YOUR
ATTENTION!**

MULȚUMESC PENTRU ATENȚIE!

