SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to OPC Plus and reducing the risk of chronic venous insufficiency by increasing microcirculation pursuant to Article 14 of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from GP International Holding B.V. submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to OPC Plus and reducing the risk of chronic venous insufficiency by increasing microcirculation. The scope of the application was proposed to fall under a health claim referring to disease risk reduction. The food that is the subject of the health claim is OPC Plus, which contains 40 mg oligomeric procyanidins (OPC) and 40 mg berry-blend per capsule. The Panel considers that OPC Plus is sufficiently characterised with respect to OPC extracted from grape (*Vitis vinifera* L.) seeds. The claimed effect is "OPC improves venous microcirculation and increases capillary resistance and therefore may reduce the risk of chronic venous insufficiency (CVI)". The target population is males and females over 30 years of age. The Panel considers that the evidence provided does not establish that improving the "alterations in the venous microcirculation" is a beneficial physiological effect by reducing the risk of chronic venous insufficiency. No human intervention studies using OPC extracted from grape seeds have been provided. The Panel concludes that a cause and effect relationship has not been established between the consumption of OPC Plus and reducing the risk of chronic venous insufficiency by increasing microcirculation.

KEY WORDS

OPC Plus, oligomeric procyanidins, berries, microcirculation, risk reduction, health claims.

[1] On request from GP International Holding B.V., Question No EFSA-Q-2009-00751, adopted on 9 July 2010.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

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SUMMARY

Following an application from GP International Holding B.V. submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to OPC Plus and reducing the risk of chronic venous insufficiency by increasing microcirculation.

The scope of the application was proposed to fall under a health claim referring to disease risk reduction.

The food that is the subject of the health claim is OPC Plus, which contains 40 mg oligomeric procyanidins (OPC) and 40 mg berry-blend per capsule. The capsule also contains inulin (338 mg). The manufacturing process has been described. The Panel notes that no information has been provided regarding the berry-blend in the OPC Plus capsules. The Panel considers that the food, OPC Plus, which is the subject of the health claim, is sufficiently characterised with respect to OPC extracted from grape (*Vitis vinifera* L.) seeds.

The claimed effect is "OPC improves venous microcirculation and increases capillary resistance and therefore may reduce the risk of chronic venous insufficiency (CVI)". The target population is males and females over 30 years of age. The Panel notes that "alterations" in the venous microcirculation (i.e., venous microangiopathy) is a consequence rather than a cause of (or a risk factor for) CVI. The Panel considers that the evidence provided does not establish that improving the "alterations in the venous microcirculation" is a beneficial physiological effect by reducing the risk of chronic venous insufficiency.

The Panel notes that no human intervention studies using OPC extracted from grape (*Vitis vinifera* L.) seeds have been provided.

The Panel concludes that a cause and effect relationship has not been established between the consumption of OPC Plus and reducing the risk of chronic venous insufficiency by increasing microcirculation.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1924/2006[4] harmonises the provisions that relate to nutrition and health claims and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of that Regulation and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Articles 14 to 17 of that Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to Article 15 of that Regulation, an application for authorisation shall be submitted by the applicant to the national competent authority of a Member State, who will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

Steps taken by EFSA:

- The application was received on 11/08/2009.
- The scope of the application was proposed to fall under a health claim referring to disease risk reduction.
- The scientific evaluation procedure started on 15/03/2010.
- During the meeting on 09/07/2010, the NDA Panel, after having evaluated the overall data submitted, adopted an opinion on the scientific substantiation of a health claim related to OPC Plus and reducing the risk of chronic venous insufficiency by increasing microcirculation.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: OPC Plus and reducing the risk of chronic venous insufficiency by increasing microcirculation.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of OPC Plus, a positive assessment of its safety, nor a decision on whether OPC Plus is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 17 of Regulation (EC) No 1924/2006.

[4] European Parliament and Council (2006). Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: GP International Holding B.V., Am Roda-Ring 39, NL-6460 HA Kerkrade, The Netherlands.

Food/constituent as stated by the applicant

Each OPC Plus capsule contains: 40 mg OPC, 40 mg Berry–blend.

Health relationship as claimed by the applicant

Alterations in the venous microcirculation are the main risk factors in chronic venous insufficiency (CVI). The beneficial effects of OPC improve the venous microcirculation and increase the capillary resistance and therefore may reduce the risk of CVI.

Wording of the health claim as proposed by the applicant

"OPC has been shown to increase the microcirculation and may therefore reduce the risk of chronic venous insufficiency (CVI)".

Specific conditions of use as proposed by the applicant

Two capsules per day orally for at least two months.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is OPC Plus, which contains 40 mg oligomeric procyanidins (OPC) and 40 mg berry-blend per capsule. The capsule also contains inulin (338 mg) and magnesium stearate (2 mg). The manufacturing process has been described.

According to the applicant, the active constituent of the product is OPC. OPC is extracted from grape (*Vitis vinifera* L.) seeds. According to the specifications, OPC (Vitaflavan®) contains a minimum of 75 % of procyanidins (gel permeation chromatography method) or 65 % of procyanidins (Porter test), and typical values are 22 % for monomers, 19-21 % for dimers, and 56 % for trimers and tetramers. OPC also contains other phenolics including epicatechin-3-O-gallate and phenolic acids. The composition of OPC has been assessed in batch to batch analyses (n=6). Analytical data on residual solvents, sulphuric ashes, heavy metals, pesticides, and microbial count are given. No data are available regarding stability or bioavailability of OPC. The manufacturer states that there is no significant modification in the product quality when it is retained in its original closed packaging for up to a period of two years.

No information has been provided regarding the berry-blend in the OPC Plus capsules. The OPC Plus capsules also contain inulin (Frutafit® IQ).

The Panel considers that the food, OPC Plus, which is the subject of the health claim, is sufficiently characterised with respect to the constituent OPC extracted from grape (*Vitis vinifera* L.) seeds.

2. Relevance of the claimed effect to human health

The claimed effect after clarification from the applicant is "alterations in the venous microcirculation are the main risk factors in chronic venous insufficiency (CVI). The beneficial effects of OPC improve the microcirculation and increase the capillary resistance and therefore may reduce the risk of CVI". The target population is males and females over 30 years of age.

CVI develops as a consequence of venous hypertension and results in the development of venous microangiopathy, which can contribute to symptoms such as varicose veins, calf tenderness or

heaviness, ankle or leg oedema, pigmentation of the skin, and ulceration (Eberhardt et al., 2005; Gschwandtner et al., 2001; Ibrahim et al., 1996).

The Panel notes that "alterations" in the venous microcirculation (i.e., venous microangiopathy) is a consequence rather than a cause of (or a risk factor for) CVI.

The Panel considers that the evidence provided does not establish that improving the "alterations in the venous microcirculation" is a beneficial physiological effect by reducing the risk of chronic venous insufficiency.

3. Scientific substantiation of the claimed effect

The applicant has identified a total of 20 references as being pertinent to the claimed effect. No details concerning the search strategy have been provided.

The Panel notes that no human intervention studies using the constituent OPC extracted from grape (*Vitis vinifera* L.) seeds have been provided.

The Panel concludes that a cause and effect relationship has not been established between the consumption of OPC Plus and reducing the risk of chronic venous insufficiency by increasing microcirculation.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food, OPC Plus, which is the subject of the health claim, is sufficiently characterised with respect to OPC extracted from grape (*Vitis vinifera* L.).
- The claimed effect is "OPC has been shown to increase the microcirculation and may therefore reduce the risk of chronic venous insufficiency (CVI)". The target population is males and females over 30 years of age. The Panel considers that the evidence provided did not establish that improving the "alterations in the venous microcirculation" is a beneficial physiological effect by reducing the risk of chronic venous insufficiency.
- A cause and effect relationship has not been established between the consumption of OPC Plus and reducing the risk of chronic venous insufficiency by increasing microcirculation.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on ready to eat breakfast cereals and reduction of body weight pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0258_DE). March 2010. Submitted by GP International Holding B.V.

REFERENCES

Eberhardt RT, Raffetto JD, 2005. Chronic venous insufficiency. Circulation, 111, 2398-2409.

Gschwandtner ME, Ehringer H, 2001. Microcirculation in chronic venous insufficiency. Vascular Medicine, 6, 169-179.

Ibrahim S, MacPherson DR, Goldhaber SZ, 1996. Chronic venous insufficiency: mechanisms and management. American Heart Journal, 132, 856-860.

GLOSSARY / ABBREVIATIONS

CVI	Chronic venous insufficiency
OPC	Oligomeric procyanidins