



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to OXY 280 and reduction of body weight pursuant to Article 13(5) of Regulation (EC) No 1924/2006.

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to OXY 280 and reduction of body weight pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

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

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Actina, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to OXY 280 and reduction of body weight. The food constituent that is the subject of the health claim, OXY 280, which is a powder composed of kidney bean, olive and rosemary extracts, is sufficiently characterised. The claimed effect, reduction of body weight, is a beneficial physiological effect for overweight subjects. One unpublished human intervention study was provided by the applicant as pertinent to the health claim. This randomised, double-blind, placebo-controlled study investigated the effect of OXY 280 vs placebo on body weight, BMI, and waist, hip and thigh circumferences in 60 overweight subjects. The Panel notes that the results of between-group comparisons with respect to changes in the outcome variables assessed in this study were not provided. The Panel considers that the data as analysed do not allow the evaluation of the effect of the food constituent on changes in body weight relative to the placebo, and that no conclusions can be drawn from this study for the scientific substantiation of the claim. The Panel notes that no studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant. The Panel concludes that a cause and effect relationship has not been established between the consumption of OXY 280 and a reduction in body weight.

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KEY WORDS

OXY 280, kidney bean, olive, rosemary, body weight, health claims

¹ On request from the Competent Authority of Belgium following an application by Actina, Question No EFSA-Q-2012-00572, adopted on 28 November 2012.

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SUMMARY

Following an application from Actina, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to OXY 280 and reduction of body weight.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and including a request for the protection of proprietary data.

The food constituent that is the subject of the health claim is OXY 280, a powder composed of kidney bean extract (410 mg), olive extract (45 mg) and rosemary extract (45 mg). The Panel considers that OXY 280 is sufficiently characterised.

The claimed effect proposed by the applicant is “helps to lose weight”. The target population proposed by the applicant is overweight and obese healthy adults in the general population. The Panel considers that reduction of body weight is a beneficial physiological effect for overweight subjects.

The applicant provided one unpublished human intervention study as pertinent to the health claim. In this double-blind, placebo-controlled study, 60 overweight men and women with stable body weight for the past two months were randomised to consume 500 mg of OXY 280 (n=30) or placebo (microcrystalline cellulose; n=30) daily for 60 days. The Panel notes that no information (in the application or upon EFSA’s specific request to the applicant) was provided on the usual diet of participants at baseline or during the study. The primary outcomes of the study were changes in body weight, BMI, and waist, hip and thigh circumferences. No power calculations were performed. The Panel notes that the results of between-group comparisons with respect to changes in the outcome variables assessed in the study were not provided in the application or upon EFSA’s request. The Panel considers that the data as analysed do not allow the evaluation of the effect of the food constituent on changes in body weight relative to the placebo, and that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant.

The Panel concludes that a cause and effect relationship has not been established between the consumption of OXY 280 and a reduction in body weight.

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BACKGROUND

Regulation (EC) No 1924/2006⁴ 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 this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which 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 04/05/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and including a request for the protection of proprietary data.
- On 01/06/2012, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 29/06/2012, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 11/07/2012.
- On 12/09/2012, the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application. The clock was stopped on 23/09/2012 and restarted on 08/10/2012, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 17/10/2012, EFSA received the requested information (which was made available to EFSA in electronic format on 11/10/2012).
- During its meeting on 28/11/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to OXY 280 and reduction of body weight.

TERMS OF REFERENCE

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: OXY 280 and reduction of body weight.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of OXY 280, a positive assessment of its safety, nor a decision on whether OXY 280 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.

⁴ 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. OJ L 404, 30.12.2006, p. 9–25.

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 18(4) of Regulation (EC) No 1924/2006.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Actina, PO BOX 16764, DUBAI, United Arab Emirates.

The application includes a request for the protection of proprietary data for the unpublished study report by Tanaka et al. (2006) in accordance with Article 21 of Regulation (EC) No 1924/2006.

Food/constituent as stated by the applicant

According to the applicant, the food constituent that is the subject of the health claim is OXY 280, a combination of kidney bean extract (phaseolamins), olive extract (oleuropein) and rosemary extract (carnosic acid) as active ingredients.

Health relationship as claimed by the applicant

According to the applicant, the health claim is “helps to lose weight”. The applicant claims that the effect of OXY 280 on weight loss is due to the synergic action of its three active ingredients. Carnosic acid is proposed to reduce lipid absorption and phaseolamins are proposed to inhibit pancreatic α -amylase, a pancreatic enzyme which is responsible for starch hydrolysis.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “OXY 280 helps to lose weight”.

Alternative wordings: “OXY 280 is used to facilitate the weight loss” and “OXY 280 contributes to lose weight”.

Specific conditions of use as proposed by the applicant

The applicant has proposed an intake of 250 mg before lunch and 250 mg before dinner or 500 mg before lunch or dinner during at least four consecutive weeks. OXY 280 is commercialised under tablets, soft gel capsules, capsules or sachets to be diluted in water. According to the applicant, OXY 280 is intended for overweight and obese healthy adults in the general population.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is OXY 280.

OXY 280 is a powder composed of kidney bean extract (410 mg), olive extract (45 mg) and rosemary extract (45 mg). OXY 280 is proposed to be used in the form of tablets, soft gel capsules, capsules or sachets to be diluted in water.

The kidney bean extract, which is obtained from kidney beans (*Phaseolus vulgaris* L.) by water extraction, is standardised to its *in vitro* α -amylase inhibitory activity (at least 4000 units) by an enzymatic α -amylase inhibitor assay. The olive extract, which is obtained from the fruits of *Olea europaea* L. by methanol/water (50/50 v/v) extraction, is standardised to its oleuropein content (at least 20 %). The rosemary extract, which is obtained from the leaves of *Rosmarinus officinalis* L. by methanol/water (90/10 v/v) extraction, is standardised to its total diterpene content (at least 3 %) as carnosic acid, carnosol and 12-O-methylcarnosic acid.

The constituents which are used to standardise the kidney bean, olive and rosemary extracts can be analysed in foods by established methods.

Information pertaining to the control specifications of the extracts and the OXY 280 powder, the manufacturing process, batch-to-batch variability and stability data has been provided by the applicant.

The Panel considers that the food constituent, OXY 280, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is “helps to lose weight”. The target population proposed by the applicant is overweight and obese healthy adults in the general population.

Weight loss can be interpreted as the achievement of a normal body weight in previously overweight subjects. Even a moderate weight loss without achieving a normal body weight in this population subgroup is considered a beneficial physiological effect.

The Panel considers that reduction of body weight is a beneficial physiological effect for overweight subjects.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed/Medline, Science Direct, Google Scholar, IBIDS, Scopus, Scirus and Google using the key words [(“OXY280”) AND (“weight loss” OR “weight management” OR “slimming”)] in order to identify human intervention studies on the effects of OXY280 on body weight. No information has been provided on the time period considered and no exclusion criteria were applied. No publications were identified by the applicant as being pertinent to the health claim. The Panel notes the limitations of the literature search performed.

The applicant provided one unpublished human intervention study (Tanaka et al., 2006, claimed as proprietary by the applicant) as being pertinent to the health claim.

In the randomised, double-blind, placebo-controlled study by Tanaka et al. (2006, unpublished), 60 overweight men and women (age 24-65 years; BMI >25 kg/m² and <30 kg/m²), with stable body weight for the past two months, and who were not under pharmacological treatment, were randomised to consume 500 mg of OXY 280 (n=30) or placebo (microcrystalline cellulose; n=30) daily for 60 days. The intervention and placebo tablets were administered as 2x125 mg twice a day before meals. All participants were advised to follow their usual dietary habits and to avoid changes in their lifestyle during the study. The Panel notes that no information (in the application or upon EFSA’s specific request to the applicant) was provided on the usual diet of participants at baseline or during the study. Body weight and waist, hip and thigh circumferences were measured at baseline and on days 30 and 60 of the study. Upon EFSA’s request for clarification, the applicant indicated that the primary outcomes of the study were changes in body weight, BMI, and waist, hip and thigh circumferences, and that no power calculations were performed. The Panel notes the multiplicity of primary outcomes. Following EFSA’s request for clarification on the statistical methods, which were used for the data analysis and which were poorly described in the application, the applicant claimed that “repeated measures pair-wise t-tests followed by repeated measures ANOVA” were used for the data analysis. However, the Panel notes that the results of between-group comparisons with respect to changes in the outcome variables assessed in the study were not provided in the application or upon EFSA’s request. The Panel considers that the data as analysed do not allow the evaluation of the effect of the food constituent on changes in body weight relative to the placebo, and that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant.

The Panel concludes that a cause and effect relationship has not been established between the consumption of OXY 280 and a reduction in body weight.

CONCLUSIONS

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

- The food constituent, OXY 280, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is “helps to lose weight”. The target population proposed by the applicant is overweight and obese healthy adults in the general population. Reduction of body weight is a beneficial physiological effect for overweight subjects.
- A cause and effect relationship has not been established between the consumption of OXY 280 and a reduction in body weight.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on OXY 280 and reduction of body weight pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0348_BE). May 2012. Submitted by Actina.

REFERENCES

Tanaka M, Kanemoto H and Fujiwara A, 2006 (unpublished, claimed as proprietary by the applicant). Dietary supplement OXY 280 derived from white kidney bean, olive and rosemary extracts, on weight loss of overweight human subjects.