

The examination is being carried out on the **following application documents**

Description, Pages

1-13 as originally filed

Claims, Numbers

1-15 as originally filed

Drawings, Figures

1-9 as originally filed

Basis of opinion

Claims 1-15 as submitted upon entry into the European phase (s. supra).

Claim 1 **use of an opioid receptor stimulating compound** for the preparation of a composition to **treat or prevent food allergy**

d2 cf claim 1, wherein the opioid receptor stimulating compound is selected from the group consisting of **μ - receptor stimulating compounds, κ - receptor stimulating compounds, δ - receptor stimulating compounds** or combinations thereof

d3 cf preceding claims, wherein the opioid receptor stimulating compound is **thymoquinone (2 - Isopropyl - 5 - methyl - 1,4 - benzoquinone) and/or a thymoquinone containing extract**

d4 cf preceding claims, wherein the opioid receptor stimulating **compound is provided as a component of a plant or a plant extract, for example from Nigella sativa, Eupatorium ayapana, Satureja montana, Thymus** or a combination thereof

d5 cf preceding claims, wherein the **food allergy is** selected from the group consisting of **dairy allergy, egg allergy, peanut allergy, tree nut allergy, sesame allergy, corn allergy, rice allergy, buckwheat allergy, parsley allergy, seafood allergy, shellfish allergy, soy allergy, wheat allergy** or combinations thereof

d6 cf preceding claims, to **treat or prevent the symptoms of food allergy**, for example **symptoms selected from the group consisting of tissue swelling; itching of the mouth, throat, eyes and/or skin; nausea; vomiting; diarrhea; stomach cramps and/or abdominal pain; nasal congestion; wheezing; scratchy throat; shortness of breath; difficulty swallowing**; or combinations thereof

d7 of preceding claims, wherein the composition is to be administered to a subject selected from the group consisting of a **human or a pet animal**

d8 of preceding claims, wherein the composition is selected from the group consisting of **food compositions, food products, drinks, nutritional formulas, infant feeding formulas, nutraceuticals, food additives, medicaments**

d9 of preceding claims, wherein the composition is to be **administered orally, enterally and/or parenterally**

d10 of preceding claims wherein the **opioid receptor stimulating compound** is to be **administered in a daily dose in the range of 0, 1 mg/ kg body weight - 90 mg/ kg body weight**, preferably 1 mg/kg body weight - 20 mg/kg body weight of the subject to be treated and/or wherein the opioid receptor stimulating compound is to be **provided as Nigella sativa** in a daily dose in the range of 1 mg Nigella sativa plant material /kg body weight - 50 g Nigella sativa plant material /kg body weight, preferably 2 g Nigella sativa plant material /kg body weight - 20 g Nigella sativa plant material /kg body weight of the subject to be treated and/or wherein the opioid receptor stimulating compound is to be provided as an extract of Nigella sativa in a daily dose in the range of 1 mg Nigella sativa plant extract /kg body weight - 160 mg Nigella sativa plant extract /kg body weight, preferably 6 mg Nigella sativa plant extract /kg body weight - 80 mg Nigella sativa plant extract/kg body weight of the subject to be treated

d11 of preceding claims wherein the composition further comprises a **protein source in an amount of 1.6 - 7.5 g/100kcal of the composition**

d12 of claim 11, wherein the **protein source is hydrolyzed with a degree of hydrolysis (DH)** in the range of between 2 and 20%

d13 of claims 11 or 12, wherein the **protein source is milk protein or a milk protein fraction**, for example **sweet whey, acid whey, a -lactalbumin, p - lactoglobulin, bovine serum albumin, acid casein, caseinates, a - casein, α - casein, γ - casein**

d14 of the preceding claims wherein the composition **further comprises a carbohydrate source** in an amount of 9 - 18 g/100kcal of the composition

d15 of claims wherein the composition **further comprises a lipid source** in an amount of 1.5 - 7 g/100kcal of the composition

Having regard to the above, it is noted that a European Search Opinion has already been drawn up for the present application in accordance with the EPC.

In particular as the claims have remained unamended, the deficiencies mentioned in that report should be addressed in the Applicant's response.

Note in particular

I. Third Party Observation Article 115 EPC

A Third Party Observation has been filed in view of this application referring to 7 documents from the TKDL (Traditional Knowledge Digital Library).

Those documents appear to be of relevance, i.e. novelty destroying in view of claim 6 which claims the prevention and treatment of the symptoms of food allergy.

II. Amendments Article 123(2) EPC

When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims. Care should be taken during revision, especially of the introductory portion and any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).

In order to facilitate the examination, the Applicant should clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (GL E-II, 1). Preferably, these indications should be submitted in handwritten form on a copy of the relevant parts of the application as filed.