European Food Safety Authority

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SCIENTIFIC OPINION

Inability to assess the safety of sodium hyaluronate added for nutritional purposes as a source of sodium in food supplements and the bioavailability of sodium from this source, based on the supporting dossier [1]

Scientific Statement of the Panel on Food Additives and Nutrient Sources added to Food

(Question No EFSA-Q-2006-190)

Adopted on 4 June 2009

PANEL MEMBERS

F. Aguilar, U.R. Charrondiere, B. Dusemund, P. Galtier, J. Gilbert, D.M. Gott, S. Grilli, R. Guertler, G.E.N. Kass, J. Koenig, C. Lambré, J-C. Larsen, J-C. Leblanc, A. Mortensen, D. Parent-Massin, I. Pratt, I.M.C.M. Rietjens, I. Stankovic, P. Tobback, T. Verguieva, R.A. Woutersen.

[1] For citation purposes: Scientific Statement of the Panel on Food Additives and Nutrient Sources added to Food on the inability to assess the safety of sodium hyaluronate added for nutritional purposes as a source of sodium in food supplements and the bioavailability of sodium from this source, based on the supporting dossier following a request from the European Commission. *The EFSA Journal* (2009) 1117, 1-6.

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

The European Community legislation lists nutritional substances that may be used for nutritional purposes in certain categories of foods as sources of certain nutrients.

The Commission has received a request for the evaluation of sodium hyaluronate added for nutritional purposes to food supplements. The relevant Community legislative measure is:

- Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements[2].

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to provide a scientific opinion, based on its consideration of the safety and bioavailability of sodium hyaluronate added for nutritional purposes in food supplements.

[2] OJ L 183, 12.7.2002, p. 51.

STATEMENT

1. Introduction

Following a request from the European Commission to the European Food Safety Authority (EFSA), the Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to provide a scientific opinion on the safety of sodium hyaluronate added for nutritional purposes as a source of sodium in food supplements and on the bioavailability of sodium from this source.

2. Summary of the information provided

Sodium hyaluronate (CAS Registry Number 9067-32-7) is the sodium salt of hyaluronic acid, a linear polysaccharide composed of D-glucuronic acid and D-N-acetyl glucosamide linked by β-(1-3) glycoside bonds.

The petitioner describes three forms of sodium hyaluronate with molecular weights of <90000 Da, <200000 Da and >1000000 Da which are proposed to be used as a source of sodium in food supplements. A low molecular weight form of sodium hyaluronate with molecular weight of < 20000 Da is mentioned in the dossier but not further described.

Sodium hyaluronate is produced by means of fermentation of a vegetable-origin derived substrate by a selected strain (non-GMO) of *Streptococcus zooepidermicus*. The product of the fermentation is subsequently pasteurised and separated by filtration.

The product is described as a white powder, containing more than 95% hyaluronic acid; the sodium content is not explicitly stated. Limited chemical and microbiological specifications are provided. No methods of analysis of sodium hyaluronate in food are provided by the petitioner.

The petitioner intends to use sodium hyaluronate as an ingredient in capsules, however the proposed levels of use are not stated.

The petitioner provides limited information on toxicity (only cytotoxicity and acute toxicity data). No data are provided on the bioavailability of sodium from sodium hyaluronate. Other data provided by the petitioner are eye and skin irritation studies.

3. Assessment

The Panel notes that:

- The petitioner has not provided adequate information on the chemical characterisation of sodium hyaluronate.
- The petitioner has not provided any data on the bioavailability of sodium from sodium hyaluronate nor on the toxicity of sodium hyaluronate, apart from cytotoxicity, acute oral and dermal toxicity and eye and skin irritation studies.

The Panel is aware that there are reports that hyaluronic acid can interfere with medications and of allergic reactions to hyaluronic acid products (University of Maryland).

CONCLUSIONS

The Panel concludes that due to the lack of an adequate dossier supporting the use of sodium hyaluronate in food supplements, the safety of sodium hyaluronate and the bioavailability of sodium from this substance cannot be assessed.

Key words:

Food supplements, sodium hyaluronate, hyaluronic acid.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier on sodium hyaluronate proposed for addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements. Submitted by Soliance (France).

REFERENCES

University of Maryland Medical Center, 2009. http://www.umm.edu/altmed/drugs/hyaluronate-and-061805.htm

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GLOSSARY / ABBREVIATIONS

ANS	Panel on Food Additives and Nutrient Sources added to Food
CAS	Chemical Abstracts Service
EC	European Commission
EFSA	European Food Safety Authority
GMO	Genetically Modified Organisms