

## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to glucosamine alone or in combination with chondroitin sulphate and maintenance of joints (ID 1561, 1562, 1563, 1564, 1565) and reduction of inflammation (ID 1869) pursuant to Article 13(1) of Regulation (EC) No 1924/2006<sup>1</sup>**

**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2</sup>**

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 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to glucosamine, either as glucosamine hydrochloride or as glucosamine sulphate, either alone or in various combinations with chondroitin sulphate and the following claimed effects: maintenance of joints and reduction of inflammation. 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.

The food constituent that is the subject of the health claims is glucosamine, either as glucosamine hydrochloride or as glucosamine sulphate, either alone or in various combinations with chondroitin sulphate. The Panel considers that glucosamine, either as glucosamine hydrochloride or as glucosamine sulphate, either alone or in various combinations with chondroitin sulphate, is sufficiently characterised.

#### **Maintenance of joints**

The claimed effect is “joints health”. The Panel assumes that the target population is the general population. The Panel considers that the maintenance of normal joints is beneficial to human health.

In weighing the evidence, the Panel took into account that the evidence provided does not establish that patients with osteoarthritis are representative of the general population with respect to the status of joint tissues, or that results obtained in studies on subjects with osteoarthritis can be extrapolated to

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1 On request from the European Commission, Question No EFSA-Q-2008-2298, EFSA-Q-2008-2299, EFSA-Q-2008-2300, EFSA-Q-2008-2301, EFSA-Q-2008-2302, EFSA-Q-2008-2602 adopted on 02 July 2009.

2 Panel members: Jean-Louis Bresson, Albert Flynn, Marina Heinonen, Karin Hulshof, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Hildegard Przyrembel, Seppo Salminen, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Henk van den Berg, Hendrik van Loveren and Hans Verhagen.  
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the maintenance of normal joints in the general population. The Panel also took into account that the evidence provided in the animal and *in vitro* studies submitted does not predict the occurrence of an effect of glucosamine intake, either as glucosamine hydrochloride or as glucosamine sulphate, either alone or in various combinations with chondroitin sulphate, on the maintenance of normal joints in humans.

On the basis of the data available, the Panel concludes that a cause and effect relationship has not been established between the consumption of glucosamine, either as glucosamine hydrochloride or as glucosamine sulphate, either alone or in combination with chondroitin sulphate and maintenance of normal joints in the general population.

### **Reduction of inflammation**

The claimed effect is “immune system”. The Panel assumes that the target population is the general population. In the context of the proposed wordings, the Panel notes that the claimed effect relates to the reduction of inflammation. The Panel considers that under certain circumstances the reduction of inflammation might be beneficial to human health.

In weighing the evidence, the Panel took into account that the evidence provided does not establish that patients with osteoarthritis are representative of the general population with regard to the inflammatory status of the joint tissues, and that the evidence provided in the animal studies does not establish the occurrence of an effect of glucosamine sulphate intake on inflammation in humans

On the basis of the data available, the Panel concludes that cause and effect relationship has not been established between the dietary intake of glucosamine sulphate and reduction of inflammation in the general population.

### **KEY WORDS**

Glucosamine, chondroitin sulphate, joints, inflammation, health claims.

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## **BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION**

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## **TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION**

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## **EFSA DISCLAIMER**

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## **ACKNOWLEDGEMENTS**

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The members of the Working Group on Claims: Jean-Louis Bresson, Albert Flynn, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Sean (J.J.) Strain, Inge Tetens, Henk van den Berg, Hendrik van Loveren and Hans Verhagen.

The members of the Claims Sub-Working Group on Bone/Teeth/Connective Tissue: Rikke Andersen, Olivier Bruyère, Albert Flynn, Ingegerd Johansson, Jukka Meurman and Hildegard Przyrembel.

## INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006<sup>3</sup> submitted by Member States contains main entry claims with corresponding conditions of use and literature from similar health claims. The information provided in the consolidated list for the health claims subject to this opinion is tabulated in Appendix C.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is glucosamine, either as glucosamine hydrochloride or as glucosamine sulphate, either alone or in various combinations with chondroitin sulphate.

Glucosamine is an amino monosaccharide where a hydroxyl group (-OH) is replaced with an amino group (-NH<sub>2</sub>) (2-amino-2-deoxy-D-glucose). The raw material is derived from chitin, a biopolymer present in the exoskeleton of marine invertebrate animals (Foot and Mulholland, 2005). Glucosamine is usually formulated as the hydrochloride salt or as glucosamine sulphate. Glucosamine sulphate is most often the glucosamine-6-sulphate. There are large differences between the hydrochloride and the sulphate compounds regarding biological activity (Foot and Mulholland, 2005).

Chondroitins are glycosaminoglycans consisting of an alternating sequence of D-glucuronate and N-acetyl-D-galactosamine-4/6-sulphate residues linked through alternating bonds. The disaccharide units are joined to one another by a  $\beta$ 1-4 linkage. The residues are joined by a  $\beta$ 1-3 linkage. Chondroitin is a mixture of different forms. The most common ones are chondroitin-4-sulphate, also known as chondroitin sulphate A, chondroitin-6-sulphate also known as chondroitin sulphate C, and dermatan sulphate, also known as chondroitin sulphate B (Foot and Mulholland, 2005; Šimánek et al., 2005; Lamari and Karamanos, 2006).

The Panel considers that the food constituent, glucosamine, either as glucosamine hydrochloride or as glucosamine sulphate, either alone or in various combinations with chondroitin sulphate, which is the subject of the health claims, is sufficiently characterised.

### 2. Relevance of the claimed effect to human health

#### 2.1. Maintenance of joints (ID 1561, 1562, 1563, 1564, 1565)

The claimed effect is “joints health”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that these claimed effects relate to the maintenance of normal joints.

The Panel considers that the maintenance of normal joints is beneficial to human health.

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<sup>3</sup> 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.

## **2.2. Reduction of inflammation (ID 1869)**

The claimed effect is “immune system”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that this claimed effect relates to the reduction of inflammation.

The Panel considers that under certain circumstances the reduction of inflammation might be beneficial to human health.

## **3. Scientific substantiation of the claimed effect**

### **3.1. Maintenance of joints (ID 1561, 1562, 1563, 1564, 1565)**

A total of 11 human intervention studies (plus one sub-analysis of one of the interventions and one combination of two of the studies), three meta-analyses including most of the individual studies, 21 reviews and background papers, 2 animal studies, one *in vitro* study, one short report, and one case report were provided for the substantiation of the claimed effect.

Glycosaminoglycans are the major polymers of the ground substance of connective tissue. Glucosamine is a structural component of several glycosaminoglycans other than chondroitin sulphate which is an important structural component of joint cartilage and in part responsible for its resistance to compression. Both glucosamine and chondroitin sulphate are formed in the body. No dietary requirement for the maintenance of the structure (e.g. of cartilage or other connective tissues) or function (e.g. maintenance of flexibility or mobility of the joints) of the joints in healthy humans has been demonstrated by the evidence provided.

All the human studies presented on the effects of glucosamine (either as glucosamine hydrochloride or as glucosamine sulphate), either alone or in combination with chondroitin sulphate, on joint health (e.g. joint pain, joint structure/function) have been conducted in patients with clinical diagnosis of (primarily knee) osteoarthritis (OA). OA is the most common joint disease worldwide (Issa and Sharma, 2006; Corti and Rigon, 2003; Arden and Nevitt, 2006) and a major cause of disability (Hunter et al., 2008; Pollard and Johnston, 2006; Sarzi-Puttini et al., 2005; Ethgen et al., 2004).

The Panel considers that the evidence provided does not establish that patients with OA are representative of the general population with regard to the status of joint tissues, or that results obtained in studies on subjects with OA relating to the treatment of symptoms of this disease (e.g. erosion of articular cartilage, reduced mobility of joints) can be extrapolated to the maintenance of normal joints in the general population.

The Panel also considers that the evidence provided in the animal and *in vitro* studies submitted does not predict the occurrence of an effect of glucosamine intake, either alone or in combination with chondroitin, on the maintenance of normal joints in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of glucosamine (either as glucosamine hydrochloride or as glucosamine sulphate), either alone or in combination with chondroitin sulphate, and the maintenance of normal joints.

### **3.2. Reduction of inflammation (ID 1869)**

Three review papers on the role of glucosamine sulphate in the treatment of osteoarthritis, one review on the general functions of glucosamine in the body, one review on the effects of glucosamine on markers of inflammation in animal models of acute chemical toxicity, and one animal study on the

anti-inflammatory activity of glucosamine in carrageenan- and cotton pellet-induced acute and sub-acute inflammation in rats were provided to substantiate the claimed effect.

The Panel considers that the evidence provided does not establish that patients with OA are representative of the general population with regard to the inflammatory status of the joint tissues, and that the evidence provided in the animal studies does not establish the occurrence of an effect of glucosamine sulphate intake on inflammation in humans.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of glucosamine sulphate and the reduction of inflammation.

## CONCLUSIONS

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

- The food constituent, glucosamine either as glucosamine hydrochloride or glucosamine sulphate, either alone or in combination with chondroitin sulphate, which is the subject of the health claims is sufficiently characterised.

### **Maintenance of joints (ID 1561, 1562, 1563, 1564, 1565)**

- The claimed effect is “joint health”. The target population is assumed to be the general population. The maintenance of normal joints is beneficial to human health.
- A cause and effect relationship has not been established between the consumption of glucosamine, either as glucosamine hydrochloride or as glucosamine sulphate, either alone or in combination with chondroitin sulphate and the maintenance of normal joints.

### **Reduction of inflammation (ID 1869)**

- The claimed effect is “immune system”. The target population is assumed to be the general population. Under certain circumstances the reduction of inflammation might be beneficial to human health.
- A cause and effect relationship has not been established between the dietary intake of glucosamine sulphate and reduction of inflammation in the general population.

## DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2298, EFSA-Q-2008-2299, EFSA-Q-2008-2300, EFSA-Q-2008-2301, EFSA-Q-2008-2302, EFSA-Q-2008-2602). 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.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>

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## APPENDICES

### APPENDIX A

#### BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods<sup>4</sup> (hereinafter "the Regulation") entered into force on 19<sup>th</sup> January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

#### ISSUES THAT NEED TO BE CONSIDERED

##### IMPORTANCE AND PERTINENCE OF THE FOOD<sup>5</sup>

Foods are commonly involved in many different functions<sup>6</sup> of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

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<sup>4</sup> OJ L12, 18/01/2007

<sup>5</sup> The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

<sup>6</sup> The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

#### **SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE**

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

#### **WORDING OF HEALTH CLAIMS**

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

## **TERMS OF REFERENCE**

### **HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH**

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.

- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

## **APPENDIX B**

### **EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. 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 wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to glucosamine alone or in combination with chondroitin sulphate, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1561	Glucosamine	Joints health	<p>-Glucosamine alone or in combination with chondroitin sulphate contributes to the maintenance of flexibility and mobility of the joints</p> <p>-helps to maintain healthy joint</p> <p>-supports mobility</p> <p>-helps to keep joints supple and flexible -necessary for the structure of cartilage and other connective tissues -is produced naturally by the body where it plays a role in the smooth working of the joints</p> <p>-is produced naturally by the body where it helps maintain connective tissues -helps maintain healthy joints, bones, ligaments and tendons</p> <p>-occurs naturally in the joints and muscles where it plays a role in the smooth working of connective tissue</p> <p>-helps maintain joint health</p> <p>-helps keep joints in good condition/</p> <p>--helps maintain cartilage",</p> <p>-"helps rebuilding cartilage" and</p> <p>"lays down the foundation for everyday rebuilding of connective tissues around the joints, including tendons, ligaments and cartilage</p>
<p><b>Conditions of use</b></p> <p>Dose journalière recommandée : 1500 mg A utiliser pendant 1 mois Destiné aux adultes, plus particulièrement aux seniors A déconseiller aux femmes enceintes et allaitantes Ne doit pas être consommé par des personnes allergiques à l'iode ou aux fruits de mer</p> <p>250 mg täglich Nahrungsergänzung–</p> <p>250 mg/d (Kombination mit Sojaisoflavon)</p> <p>1.000mg/d–Erwachsene</p> <p>250 mg pro Tag</p> <p>Max 500 mg per day</p> <p>180 mg per day (15% of the lower therapeutic dose 1200 mg).</p> <p>The equivalent of 1200-1500 mg/day as glucosaminesulphate Up to equivalent of 1500mg glucosamine sulphate/day 1500 mg/day</p>			

1562	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Glucosamine	Joints health, especially knees	-Glucosamine (and chondroitin) may help to maintain healthy joints -Glucosamine (and chondroitin) helps support healthy knees
<b>Conditions of use</b>			
In the forms glucosamine sulphate, hydrochloride or hydroiodide, with the majority of research having been conducted on the sulphate form. Typical adult dosage: 500 mg three times daily or 1500 mg in a single dosage. May be delivered on its own, or in conjunction with chondroitin and/or other ingredients			
1563	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Glucosamine (Glucosamine HCl or Glucosamine sulphate)	Joints health	-Helps maintain joint health. -Helps maintain healthy and flexible joints.
<b>Conditions of use</b>			
Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC 1500 mg glucosamine daily for at least 4 - 8 weeks. Tagesdosis Glucosaminsulfat: 1500 mg–Ein längerfristiger Verzehr wird empfohlen.– Erwachsene			
1564	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Glucosamine (Glucosamine HCl or Glucosamine sulphate) and Chondroitin sulphate	Joints health	-Helps maintain joint health. -Helps maintain healthy and flexible joints.
<b>Conditions of use</b>			
Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC Glucosamine 1000-1500 mg and chondroitin sulphate 800-1200 mg daily for at least 4 - 8 weeks. Number of nutrients/other substances that are essential to claimed effect: 2 Names of nutrient/other substances and Quantity in Average daily serving: 1400mg glucosamine sulphate, 1100mg chondroitin sulphate Weight of average daily food serving: 1400 miligram(s) Daily amount to be consumed to produce claimed effect: 1500 miligram(s) Number of food portions this equates to in everyday food portions: 4 Are there factors that could interfere with bioavailability: Yes Please give reason: do not store above 25 degrees C Length of time after consumption for claimed effect to become apparent: 4-6 weeks Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Don't Know			
1565	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Glucosamine hydrochloride	Joints health	-Glucosamine helps to maintain strong joints and connective tissues. -Naturally required by the body as building blocks for connective tissues which are optimal for joint health and mobility. Connective tissues include cartilage which coats and cushions the bones in the joint.

			Synovial fluid bathes and lubricates the joints.
	<p><b>Conditions of use</b></p> <p>Product must contain at least 1500 mg of glucosamine hydrochloride per serving 1500mg/day</p> <p>Administration: For at least 2 to 3 months, repeat twice a year</p>		
1869	<b>Food or Food constituent</b>	<b>Health Relationship</b>	<b>Proposed wording</b>
	Glucosamine sulfate	Immune system	<ul style="list-style-type: none"> <li>-Glucosamine sulfate possesses antiinflammatory activity</li> <li>-Helps the bodys antiinflammatory defenses</li> <li>-Reverses pro-inflammatory effects</li> <li>-Is a useful anti-inflammatory</li> <li>-Is a potent anti-inflammatory</li> <li>-Down-regulates the catabolic effects of pro-inflammatory molecules</li> </ul>
	<p><b>Conditions of use</b></p> <p>Quantity in Average daily serving: 1500 mg Glucosamine sulphate. Weight of average daily food serving: 1500 miligram(s)Daily amount to be consumed to produce claimed effect: 1500 miligram(s). Duration of consumption for claimed effect to become apparent: up to 12 weeks. This product should be avoided by pregnant and lactating women, and children.</p>		



## **GLOSSARY / ABBREVIATIONS**

OA                    Osteoarthritis