

SUBSTANTIAL EQUIVALENCE OPINION

Glucosamine HCl, KCl & NaCl

The Food Safety Authority of Ireland (FSAI) received an application in May of 2017 from TSI (China) Co. Ltd. of China for an opinion on the substantial equivalence of its three glucosamine salts (Glucosamine-HCl, Glucosamine sulphate KCl, Glucosamine sulphate NaCl). The novel ingredient is compared with similar ingredients derived from shellfish that have been on the EU market since before 1997. Though stability tests are ongoing, the applicant has determined that the glucosamine salts are stable for at least three years when stored away from sunlight in sealed containers at <30°C. Each of the glucosamine salts is freely soluble in water, slightly soluble in methanol and largely insoluble in acetone. The glucosamine salts are obtained by initial hydrolysis of the precursor (N-acetyl-D-glucosamine), a fermentation product of a GM strain of *Escherichia coli* K-12 with glucose as the sole substrate. The GM *E. coli* secretes the precursor into the growth medium from where it is collected, purified and processed into the final glucosamine salts. Therefore, the GMM is considered a processing aid and not subject to the GM authorisation and labelling requirements as set out in the relevant EU legislation. The bacterial production strain (*Escherichia coli* K-12) has been deposited at the China General Microbiological Culture Collection Centre under the description CGMCC 12411. The applicant intends to market the glucosamine salts exclusively in food supplements with glucosamine concentrations similar to those for the comparator shellfish glucosamine products already on the EU market.

The applicant considers the novel ingredients to be novel and fall within the category of “*food and food ingredients consisting of or isolated from microorganisms, fungi or algae*” as set out in *Article 1.2(d)* of the novel food Regulation EC No. 258/97.

Composition

The novel glucosamine salts appear as white or almost white crystalline powders and the applicant has provided information demonstrating the chemical and structural similarity to the shellfish counterparts. Hydrolysis of the precursor N-Acetyl-D-glucosamine yields glucosamine HCl, from which glucosamine KCl and glucosamine NaCl are derived by further processing.

Parameter	Shellfish Comparator	Glucosamine HCl	Glucosamine SO ₂ KCl	Glucosamine SO ₂ NaCl
Appearance	White crystalline powder	White crystalline powder	White crystalline powder	White crystalline powder
Glucosamine salt	100%	98-101%	98-101%	98-101%
Molecular formula	-	C ₆ H ₁₃ NO ₅ -HCl	(C ₆ H ₁₄ NO ₅) ₂ SO ₄ -2KCl	(C ₆ H ₁₄ NO ₅) ₂ SO ₄ -2NaCl
Relative Molecular Mass	-	215.6 g/mole	605.5 g/mole	573.3 g/mole
Specific Rotation	-	+70° to +74°	+47° to +53°	+50° to +55°

Nutritional Value and Metabolism

The novel glucosamine salts have little or no nutritional value other than being a source of carbohydrate and therefore the nutritional value and metabolism is the same as the existing comparator.

Intended Use

The applicant intends to use the novel glucosamine salts in food supplements, in accordance with Directive 2002/46/EC and at the same levels as the existing shellfish counterparts.

Levels of Undesirable Substances

The fermenting GM *E. coli* used to produce the precursor is a non-virulent bacterium and is not detected in the final product. The production process is relatively harsh and should serve to denature any residual proteins, which are present at minimal levels and so there is no significant allergenicity risk. The applicant provides analytical results for heavy metals including arsenic, cadmium, iron, lead and mercury, and demonstrates the absence of bacteria such as *E. coli* and *Salmonella*.

Conclusions

The FSAI is satisfied from the information provided by the applicant that glucosamine HCl, glucosamine sulphate KCl and glucosamine sulphate NaCl to be marketed in food supplements by TSI (China) Co. Ltd. are substantially equivalent to the comparators derived from shellfish in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances.