

## FACT SHEET

### Steviol glycosides (INS 960)

#### What are steviol glycosides?

Steviol glycosides are natural constituents of the plant *Stevia rebaudiana* Bertoni, which belongs to the Compositae family. Steviol glycosides are of interest due to their sweetening properties, and stevioside and rebaudioside are the principle components of them. The product is obtained from the leaves of *Stevia rebaudiana* Bertoni. The leaves are processed with hot water and the aqueous extract is further concentrated and purified. The final product may be spray-dried. Steviol glycosides preparations are white or slightly yellowish white crystalline odourless or having a slight characteristic odour, water soluble powders, which are 200 to 300 times sweeter than sucrose.

Stevia extracts generally contain a high percentage of the glycosides stevioside (CAS no. 57817-89-7) and rebaudioside A (CAS no. 58543-16-1), and smaller amounts of other steviol glycosides i.e rebaudioside C, dulcoside A, rubusoside, steviolbioside, and rebaudioside B. The composition of the extracts depends on the composition of the leaves, influenced by soil and climate, and on the extraction and purification processes used. The impurities occurring in extracts of the Stevia leaves are typical plant materials, such as pigments and saccharides.

#### Chemical names

*Stevioside*: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy] kaur-16-en-18-oic acid, β-D-glucopyranosyl ester

*Rebaudioside A*: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-8-oic acid, β-D-glucopyranosyl ester

*Rebaudioside B*: 13-[(2-O-α-L-rhamnopyranosyl-3-O-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester

*Dulcoside A*: 13-[2-O-α-L-rhamnopyranosyl-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester

The commercially available products under various names (Stevioside, Stevia extracts, Purified Stevia Extract etc.) vary in composition from one manufacture to another with respect to the relative ratios of the steviol glycosides and other constituents.

Data from countries in different parts of the world suggest that the main components of the commercially available extracts of stevia contain as the main components stevioside and rebaudioside A in various amounts ranging from about 10-70% stevioside and 20-70% rebaudioside A.

#### The plant

*Stevia* is a genus of about 240 species of herbs and shrubs in the sunflower family (Compositae) native to subtropical and tropical South America and Central America. The species *Stevia rebaudiana* Bertoni, commonly known as sweetleaf, sweet leaf, sugarleaf, or simply stevia, is widely grown for its sweet leaves.

Stevia species are found in the wild in semi-arid habitats ranging from grassland to mountain terrain. Today, stevia is cultivated in many countries around the world, including Latin America and Asian countries. China is the world's largest exporter of steviol glycosides.

One of the advantages of stevia is that it can be grown almost anywhere. Its native conditions are sub-tropical, but it is cultivated in both temperate and in tropical areas.

#### How are steviol glycosides used?

Steviol glycoside extracts have broad applications as sweetener in the manufacture of fruit and milk drinks, desserts, yoghurt, delicacies, confectioneries, fruit products, processed seafood products, pickles, table-top sweeteners and dietary supplements. The extracts are suitable for cooking purposes as they are heat stable, unlike some artificial sweeteners such as aspartame. However, they are unsuitable for certain confectionary

such as fudge or icing as they lack bulking property. Water extracts of the crushed leaves of the stevia plant have been used for many years as a sweetener in some countries in South America and Asia. It is also known that stevia leaves are used to prepare a sweetened tea in a number of countries throughout the world.

### **Safety of steviol glycosides**

The steviol glycosides have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at its 51<sup>st</sup> (stevioside only, no ADI allocated due to lack of data), 63<sup>rd</sup>, 68<sup>th</sup> and 69<sup>th</sup> meeting, with the goal to establish an acceptable daily intake, (ADI). The ADI is the amount of a food additive that can safely be ingested on a daily basis over life-time. These evaluations were performed on request of the former Codex Committee on Food Additives and Contaminants (CCFAC).

At the 63<sup>rd</sup> meeting a temporary ADI of 0-2 mg/kg bodyweight and day, expressed as steviol, was established based on a No-Observed-Effect-Level (NOEL) in a long-term experimental study in rats and applying safety factor of 200, based on the standard safety factor of 100 times an extra factor of 2. The ADI was made temporary and the additional safety factor applied due to lack of data on pharmacological effects of steviol glycosides in humans. JECFA noted that stevioside is being investigated as a potential treatment for hypertension and diabetes, with some evidence of pharmacological effects at higher doses. There was inadequate data to assess whether these pharmacological effects would also occur at lower levels of dietary exposure, which could lead to adverse effects in some individuals. Hence the 63<sup>rd</sup> JECFA requested additional human studies to address effects in diabetic, as well as normotensive and hypotensive individuals.

The results of specific human studies to address these concerns were evaluated by JECFA at its 68<sup>th</sup> and 69<sup>th</sup> meeting (2008). JECFA concluded that the new data were sufficient to allow the additional safety factor of 2 and the temporary designation to be removed. An ADI for steviol glycosides of 0–4 mg/kg bw was established, expressed as steviol. Steviol glycosides are a mixture of compounds with different molecular weights. Since the actual active ingredient is the steviol part of the different molecules, the 0-4 mg refers only to the molecular weight of total steviol in the mixture.

JECFA noted that some estimates of high-percentile dietary exposure to steviol glycosides exceeded the ADI, particularly when assuming complete replacement of caloric sweeteners with steviol glycosides, but recognized that these estimates were highly conservative and that actual intakes were likely to be within the ADI. A more refined intake assessment can only be performed if actual use levels of this sweetener in a wide variety of foods are known.

Specifications for steviol glycosides have been established by JECFA. At the 63<sup>rd</sup> meeting, only tentative specifications for the identity and purity of steviol glycosides were prepared, pending receipt of additional technical information. At the 68<sup>th</sup> meeting, full specifications were prepared. The minimum assay value, i.e. the purity of the food additive, is 95% of the seven named steviol glycosides (including stevioside and rebaudioside A), allowing for considerable flexibility in the use of different varieties of stevia in the production of the food additive steviol glycosides in compliance with the JECFA specifications. At the 69<sup>th</sup> meeting, the specifications monograph was slightly modified with respect to the solubility and limit for the solvent ethanol.

### **Codex and steviol glycosides**

#### INS no.

An INS (international numbering system) no. 960 was assigned to glycosides in 1990, at the request of the 30<sup>th</sup> Session of the former Codex Committee on Food Additives and Contaminants. The name of INS 960 was changed to steviol glycosides at the request of the 37<sup>th</sup> Session of the Committee in 2005.

#### Specification of identity and purity

Codex specifications for identity and purity for steviol glycosides, prepared by the 68<sup>th</sup> JECFA (see above), were adopted by the Commission in 2008, at the request of the 40<sup>th</sup> Codex Committee on Food Additives.

#### Provisions for their use

Currently there are no provisions (i.e. maximum levels) for the use of steviol glycosides in Codex commodity standards and in the General Standard for Food Additives (CODEX STAN 192-1995).

The results and recommendation of 69<sup>th</sup> JECFA meeting, including the revised specifications, will be considered by the 41<sup>st</sup> Session of the Codex Committee on Food Additives, to be held in China in March 2009.

### **Steviol glycosides/ stevia extracts in national regulations**

Currently stevia extracts have been approved in some countries either as food supplement or food additives. In other countries, the use of stevia extracts in foods have not been approved and are either not allowed by default or forbidden for use as food additive/food supplement.

### **References**

WHO (2000). *Evaluation of certain food additives* (Fifty-first report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 891. [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_891.pdf](http://whqlibdoc.who.int/trs/WHO_TRS_891.pdf)

WHO (2005). *Evaluation of certain food additives* (Sixty-third report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 928 [http://whqlibdoc.who.int/trs/WHO\\_TRS\\_928.pdf](http://whqlibdoc.who.int/trs/WHO_TRS_928.pdf)

WHO (2005) *Safety evaluation of certain food additives*. WHO Food Additives Series, No 54, 2005. [http://whqlibdoc.who.int/publications/2006/9241660546\\_eng.pdf](http://whqlibdoc.who.int/publications/2006/9241660546_eng.pdf)

WHO (2008) *Evaluation of certain food additives and contaminants* (Sixty-eighth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 947. [http://whqlibdoc.who.int/publications/2007/9789241209472\\_eng.pdf](http://whqlibdoc.who.int/publications/2007/9789241209472_eng.pdf)

WHO (2008). *Safety evaluation of certain food additives and contaminants*. WHO Food Additives Series, No. 59. [http://whqlibdoc.who.int/publications/2008/9789241660594\\_eng.pdf](http://whqlibdoc.who.int/publications/2008/9789241660594_eng.pdf)

WHO. *Evaluation of certain food additives* (Sixty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series (in preparation).

WHO. *Safety evaluation of certain food additives*. WHO Food Additives Series, No. 60 (in preparation).

FAO (2004). Compendium of Food Additive Specifications. FAO Food and Nutrition Paper 52, Addendum 12, p. 47. Food and Agriculture Organization, Rome, Italy.

FAO (2007). Compendium of Food Additive Specification. FAO JECFA Monographs 4, p. 61. Food and Agriculture Organization, Rome, Italy.

FAO (2008). Compendium of Food Additive Specification. FAO JECFA Monographs 5. Food and Agriculture Organization, Rome, Italy. (in preparation)

FAO/WHO (2008). Summary and Conclusions of the 69<sup>th</sup> meeting of the Joint FAO/WHO Expert Committee on Food Additives, 17-26 June 2008, Rome, Italy. ([http://www.fao.org/ag/agn/agns/files/jecfa69\\_final.pdf](http://www.fao.org/ag/agn/agns/files/jecfa69_final.pdf) , accessed 1 September 2008).

ALINORM 95/12A: Report of the 27<sup>th</sup> Session of the Codex Committee on Food Additives and Contaminants <http://www.codexalimentarius.net/download/report/21/al9512ae.pdf>

ALINORM 97/12 App. XI Report of the 28<sup>th</sup> Session of the Codex Committee on Food Additives and Contaminants <http://www.fao.org/docrep/meeting/005/w1362e/w1362e00.htm>

ALINORM 99/12 Report of the 30<sup>th</sup> Session of the Codex Committee on Food Additives and Contaminants [http://www.codexalimentarius.net/download/report/24/A199\\_12e.pdf](http://www.codexalimentarius.net/download/report/24/A199_12e.pdf)

ALINORM 03/12A Report of the 35<sup>th</sup> Session of the Codex Committee on Food Additives and Contaminants <http://www.codexalimentarius.net/download/report/47/A10312ae.pdf>

ALINORM 05/28/12: Report of the 37<sup>th</sup> Session of the Codex Committee on Food Additives [http://www.codexalimentarius.net/download/report/639/al28\\_12e.pdf](http://www.codexalimentarius.net/download/report/639/al28_12e.pdf)

ALINORM 08/31/12: Report of the 40<sup>th</sup> Session of the Codex Committee on Food Additives [http://www.codexalimentarius.net/download/report/702/al31\\_12e.pdf](http://www.codexalimentarius.net/download/report/702/al31_12e.pdf)

- Codex Class Names and International Numbering System (CAC/GL 36-1989)  
[http://www.codexalimentarius.net/download/standards/7/CXG\\_036e.pdf](http://www.codexalimentarius.net/download/standards/7/CXG_036e.pdf)
- Codex Specifications for Food Additives (CAC/MISC 6)  
[http://www.codexalimentarius.net/download/standards/9/CXA\\_006e.pdf](http://www.codexalimentarius.net/download/standards/9/CXA_006e.pdf)
- Codex General Standard for Food Additives (CODEX STAN 192-1995)  
[http://www.codexalimentarius.net/download/standards/4/CXS\\_192en.pdf](http://www.codexalimentarius.net/download/standards/4/CXS_192en.pdf)