

Therapeutic Goods Administration Compositional Guideline for Steviol glycosides

Name of the ingredient

Steviol glycoside (AAN)

CAS No.: 471-80-7

Definition of the ingredient

Steviol glycosides consist of a mixture of compounds containing a steviol backbone conjugated to any number or combination of the principal sugar moieties (glucose, rhamnose, xylose, fructose, arabinose, galactose, and deoxyglucose) in any of the orientations occurring in the leaves of *Stevia rebaudiana Bertoni*. The ingredient can be produced by hot water extraction from the leaves of *Stevia rebaudiana Bertoni*, by fermentation of non-toxigenic non-pathogenic strains of *Yarrowia lipolytica* and *Saccharomyces cerevisiae* that have been genetically modified with heterologous genes from multiple donor organisms to overexpress steviol glycosides, or through enzymatic treatment of purified steviol glycosides extracted from the leaves of *Stevia rebaudiana Bertoni*.

Ingredient specific requirements

Except for the incidental constituents given below, requirements are the same as in the specification monograph of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for Steviol glycosides prepared at the 96th JECFA (2023), published in FAO JECFA Monographs 31 (2023)*.

Table 1. Ingredient specific requirements

Test	Method reference	Accentance criteria
Description		
Characteristics	Please refer to the FAO/WHO JECFA Monographs 31 (2023)*	
	*https://openknowledge.fao.org/server/	
Identification	api/core/ bitstreams/2e773d19-5b25-4b2e-9811- a5dc3406ee79/content	
Assay		
	mbined Compendium of Food Additive Specifications" availal	•

Table 2.Incidental constituents

Test	Method reference	Acceptance criteria
Incidental metals and non-metals		
Total heavy metals	BP (Appendix VII); Ph Eur method 2.4.8	≤20 ppm
Pesticide residues and environmental contaminants: (including agricultural and veterinary substances)	BP (Appendix XI L); Ph Eur method 2.8.13	Complies

Key to abbreviations:

BP = British Pharmacopoeia Ph Eur = European Pharmacopoeia