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Revised Guidelines for the Use of Stevia in Natural Health Products

2009-09-18

Based on a review of the international regulation of *Stevia rebaudiana* and the clinical evidence for safety and efficacy, the Natural Health Products Directorate has adopted the following guidelines for the use of *Stevia* and steviol glycosides in Natural Health Products (NHPs). The revised recommendation for the maximum limit for steviol glycosides in NHPs is in accordance with the full ADI (acceptable daily intake) of 4 mg steviol/kg body weight established by the Joint Expert Committee on Food Additives (JECFA) of the Food and Agriculture Organization and the World Health Organization in June, 2008 (JECFA 2008).

As a Medicinal Ingredient:

The maximum daily limit without cautionary labelling and additional safety evidence is set at 4 mg/kg bw/day expressed as steviol content. This limit is equivalent to 10 mg/kg bw/day (i.e. ~ 710 mg/day for an adult) for stevioside or mixed steviol glycosides, 12 mg/kg bw/day (i.e. ~ 850 mg/day for an adult) for rebaudioside A, or 50 mg/kg bw/day (i.e. ~ 3550 mg/day for an adult) of stevia leaf. Product Licence Applications for products containing *Stevia* leaf, mixed steviol glycosides, stevioside or rebaudioside A as a medicinal ingredient in excess of this level will require evidence of safety and efficacy under the proposed conditions of use (e.g. dose, frequency, duration, indication, etc.). In the absence of new evidence to the contrary, products exceeding the maximum limit will require the following cautionary labelling: “Consult a health care practitioner prior to use if you have high blood pressure or diabetes” and “Consult a health care practitioner prior to use if you are pregnant or breastfeeding”.

As a Non-medicinal Ingredient:

As a sweetener or flavour enhancer, the quantity used should be according to conditions of Good Manufacturing Practice, i.e. the amount added to a natural health product in manufacturing and processing should not exceed the amount required to accomplish the purpose for which that non-medicinal ingredient is permitted to be added. As a non-medicinal ingredient, it should not exceed 4 mg/kg bw/day expressed as steviol content.

In accordance with the above, entries for *Stevia* leaf, stevioside/mixed steviol glycosides and rebaudioside A in the Natural Health Products Ingredients Database have been updated and may be found at:

<http://webprod.hc-sc.gc.ca/nhp-id-bdipsn/search-rechercheReq.do>

Reference

JECFA 2008: Joint FAO/WHO Expert Committee on Food Additives. Sixty-ninth meeting. Rome (IT), 17-26 June 2008. Summary and Conclusions. Available from: http://www.fao.org/ag/agn/agns/files/jecfa69_final.pdf [Accessed 2008-07-31].