Letter dated:
31 March 2010

From:
Ministry of Health, Welfare and Sport
Postbus 20350
2500 EJ The Hague
Netherlands

To:
Cargill Research and Development Centre Europe
Attn Mr Y. Le Bail-Collet
Director, Scientific and Regulatory Affairs
Havenstraat 84
1800 Vilvoorde
Belgium

Subject: Sucromalt

Our ref.: VGP/VC 2997088

Dear Mr Le Bail-Collet,

In your letter of 16 March 2006, you submitted to me a request as referred to in Article 4(1) of Regulation (EC) 258/97 (hereinafter: "the Regulation"). This request concerns the initial placing on the market of Sucromalt. In this connection, I would like to inform you of the following:

Your request has been assessed using the procedure described in Article 6 of the Regulation. The initial assessment was carried out by the Novel Foods Unit (*Bureau Nieuwe Voedingsmiddelen*) of the Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen*). During this procedure, it emerged that no additional assessment as referred to in Article 6(3) of the Regulation was required. Furthermore, no reasoned objection as referred to in Article 6(4) of the Regulation has been presented by any Member State. There are thus no objections to the introduction of Sucromalt onto the market.

In view of this, I have decided that Sucromalt may be placed on the market. I enclose a copy of my decision to this effect. This will be published in the Netherlands Government Gazette (*Nederlandse Staatscourant*) and notified to the European Commission.

In this connection, I assume that when you are trading in Sucromalt it will be mentioned – as set out in your own proposal – that the product is a source of glucose and fructose. This information is, after all, crucially important for certain groups of consumers.

For the record, I would draw your attention to the obligation to comply with all relevant legal provisions when trading in Sucromalt.

These provisions include, among other things, the labelling requirements under the Commodities Act (Labelling of Foods) Decree (*Warenwetbesluit etikettering van levensmiddelen*) and Article 8 of the Regulation.

I hope that the above will be sufficient to meet your requirements.

Yours sincerely,

The Minister for Health, Welfare and Sport

pp. (signature)
Mr A.M.P. van Bolhuis
Director, Food, Health Protection and Prevention

Ministry of Health, Welfare and Sport

Ref. VGP/VC 2997089

Decision of the Minister for Health, Welfare and Sport of 31 March 2010, VGP/VC 2997089 allowing the introduction onto the market of Sucromalt

Date: 31 March 2010

The Minister for Health, Welfare and Sport,

having considered the application of 16 March 2006 from Cargill Inc., MN, USA c/o Cargill Research and Development Centre Europe in Vilvoorde, Belgium;

having considered the initial assessment report of 17 September 2009 (ref. 2009-05 BNV), as referred to in Article 6(3) of Regulation (EC) 258/97 (OJEC L 43), which was prepared by the Novel Foods Unit (*Bureau Nieuwe Voedingsmiddelen*) of the Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen*);

having regard to Article 4(2) of Regulation (EC) 258/97 and Article 3, first paragraph, of the Commodities Act (Novel Foods) Decree,

HAS DECIDED AS FOLLOWS.

Article 1

In this Decision, *Sucromalt* shall be understood to mean the sweetened and concentrated aqueous solution of saccharides, as referred to in the Annex hereto.

Article 2

Cargill Inc., MN, USA c/o Cargill Research and Development Centre Europe in Vilvoorde, Belgium, is permitted to introduce Sucromalt onto the market as a food ingredient.

Article 3

This Decision shall enter into effect on 1 April 2010.

ANNEX

Definition

Sucromalt is a complex mixture of saccharides which is produced from sucrose and a starch hydrolysate by means of an enzymatic reaction. In this process, glucose units are attached to saccharides from the starch hydrolysate by means of an enzyme produced by the bacterium *Leuconostoc citreum* or by means of a recombinant strain of the production organism *Bacillus licheniformis.* The resulting oligosaccharides are characterised by the presence of α-(1→6) and α-(l→3) glycosidic compounds.

The overall product is a syrup which, in addition to these oligosaccharides, contains mainly fructose but also the disaccharide leucrose and other disaccharides.

Specifications

Total solids	75-80%
Moisture	20-25%
Sulphatase	max. 0.05%
pH	3.5-6.0
Conductivity	<200 (30%)
Nitrogen	<10ppm
Fructose	35-45% d.w.
Leucrose	7-15% d.w.
Other disaccharides	max. 3%
Higher saccharides	40-60% d.w.

Use of Sucromalt

Sucromalt may be used as a sucrose substitute in a wide range of foodstuffs.

This decision will be published in the Government Gazette (*Staatscourant*)[1].

The Minister for Health, Welfare and Sport

pp. (signature)
Mr A.M.P. van Bolhuis
Director, Food, Health Protection and Prevention

*An interested party may appeal against this Decision pursuant to Article 7 paragraph 1 of the General Administrative Regulations Act (*Algemene wet bestuursrecht*) by submitting a written complaint to: Ministerie van Volksgezondheid, Welzijn en Sport, Directie Wetgeving en Juridische Zaken, Postbus 20350, 2500 EJ The Hague.*

The period allowed for lodging a complaint is six weeks. This period shall begin to run on the day following the date of the Decision.

The complaint must be signed by the complainant and specify:

- *the name and address of the complainant;*
- *the date;*

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[1] Decision of the Minister for Health, Welfare and Sport of 31 March 2010, VGP/VC 2997089, authorising the placing on the market of Sucromalt, *Staatscourant* (NL) No 53021, 6 April 2010.

- *the decision being contested, for example by reference to the case number, the date or reference number of the notification, or by enclosing a copy of the decision;*
- *the reasons for the complaint.*