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OPINION
ON A MALTITOL SYRUP NOT COVERED BY THE CURRENT SPECIFICATIONS

(expressed on 2 December 1999)

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SCIENTIFIC COMMITTEE ON FOOD

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Opinion on a maltitol syrup not covered by the current specifications
(expressed on 1 December 1999)

Terms of reference
To evaluate the safety in use of a maltitol syrup not covered by current specifications.

Background
Maltitol syrups (synonyms: hydrogenated high maltose-glucose syrup, hydrogenated glucose syrup) previously considered by this Committee are mixtures of mainly maltitol with sorbitol and hydrogenated oligo- and polysaccharides. They are manufactured by the catalytic hydrogenation of high maltose-content glucose syrup. The articles of commerce are supplied both as a syrup and as a solid product [(1)]. Maltitol syrups are used as bulk sweeteners.

Maltitol and maltitol-based products (hydrogenated glucose syrups) were reviewed by SCF in 1984 [(2)]. The commercial products varied from liquid syrups to crystalline solids, containing about 50% maltitol and hydrogenated tri- to heptasaccharides and higher polysaccharides. The Committee reviewed and found adequate several studies with a product containing about 55% maltitol. These comprised acute toxicity, subchronic toxicity in two species, a large number of mutagenicity tests, metabolic studies and several clinical tolerance studies. Additionally, the Committee reviewed several studies with a product containing 60-95% maltitol. Many of these studies were found inadequate in terms of modern toxicological requirements. Furthermore, the Committee reviewed the studies on metabolism of radiolabelled pure maltitol in rat and man. Based on the reviewed data (also for sorbitol which along with glucose is a metabolic product of maltitol in rat and man) the Committee considered the continued use of maltitol-based products acceptable provided limitation due to their laxative action were kept in mind.

In 1987 and 1988 the Committee re-evaluated certain sweeteners [(3)]. No changes were made to the previous evaluation of maltitol and maltitol-based products.

Furthermore, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) reviewed maltitol syrup on several occasions. A temporary ADI allocated on 27th meeting[(4)] was replaced by ADI "not specified" on 29th meeting[(5)], which was confirmed on 33rd meeting[(6)] and 41st meeting[(7)]. Recently on its 49th meeting JECFA reviewed maltitol syrup with new specifications and ADI "not specified" was extended also to cover the new product[(8)].

Specifications
The present specifications for maltitol syrup [1] are as follows:

- Maltitol	not less than 50%
- Sorbitol	not more than 8%
- Maltotriitol	not more than 25%
- Hydrogenated polysaccharides containing more than three glucose units	not more than 30%.

According to the producer the new maltitol syrup is composed of 50%-55% maltitol and up to50% hydrogenated polysaccharide fraction (obtained by hydrogenation of a food dextrin) [9].

Compared to maltitol syrup described in [1] (see above) the new maltitol syrup has:

- Sorbitol <2% instead of not more than 8%
- Hydrogenated polysaccharides containing more than three glucose units or glucitol units 40-50% instead of not more than 30%

Furthermore, maltotriitol is not defined instead of not more than 25%.

Thus, the new maltitol syrup contains a broader range of high molecular weight hydrogenated polysaccharides than currently permitted.

Toxicological studies
The SCF found earlier maltitol and maltitol-based products acceptable based on the studies with products with 55% maltitol, some studies with products up to 95% maltitol and metabolic studies with pure maltitol in rat and man [2,3]. Sorbitol was also found acceptable [2,3]. Therefore, the current toxicological evaluation of new maltitol syrup concentrates on the consequences of higher content of the higher-order hydrogenated saccharides in the product.

<u>Review of results of metabolic studies with higher-order polyols of hydrogenated starch hydrolysates (HSH)[10]</u>

The results of metabolic studies in rats and humans indicated that higher-order polyols component of HSH of different composition was efficiently hydrolysed in the gastrointestinal tract to glucose and a small amount of maltitol. Maltitol was hydrolysed less readily by endogenous enzymes. Metabolism of maltitol was primarily through fermentation by the intestinal flora. Some absorption of maltitol occurred but it was quickly excreted unchanged in the urine.

Test materials with a content of higher-order polyols of 78% or 33% were less glycaemic than glucose when given to non diabetic, non-insulin dependent diabetic (NIDDM), and insulin-dependent (IDDM) subjects due to the slower release of glucose from HSH compared to directly ingested glucose, rapidly absorbed in the small intestine.

Tolerance studies with HSH[10]

Tolerance studies showed that the human digestive system responded to higher levels of ingested HSH by enhancing microbial enzymatic activity leading to laxation and flatulence. However, materials containing 7% sorbitol, 25% maltitol and 65% higher-order polyols at doses 45 and 90 g per day were generally well tolerated by human volunteers and there were no effects on clinical chemistry or haematological parameters, including glycaemia in either diabetic or nondiabetic subjects.

Mutagenicity studies of hydrogenated dextrin

Hydrogenated dextrin (concentration 50-5000 µg/plate) was not mutagenic in either *Salmonella typhimurium* or *Escherichia coli* strains in the absence or presence of rat S9 microsomal fraction[11].

Subchronic toxicity

Subchronic toxicity (13 weeks) by the oral route of hydrogenated polysaccharide fraction in rats[12].

A subchronic toxicity (13 weeks) study on hydrogenated polysaccharide fraction of the new maltitol syrup preparation in the rat was performed according to OECD Guideline for testing chemicals 408 (subchronic oral toxicity - rodent: 90-day study, 1981). Dietary levels of 0, 1.25, 2.5 or 5% of hydrogenated polysaccharide fraction were used. No treatment related effects were observed on clinical appearance, body weight gain and feed consumption. The calculated mean product intake was 1.0, 2.0 or 4.0 g/kg body weight per day in males and 1.4, 2.8 or 5.2 g/kg per day for females in low- mid- and high-dose groups respectively. No eye abnormalities were detected. No treatment related mortalities occurred during the study. No abnormalities were seen at necropsy. There were no treatment related differences in organ weights. Some statistically significant differences were seen in several haematological parameters (red blood count, mean cell volume, mean cell haemoglobin and mean cell haemoglobin concentration) and blood biochemistry parameters (uric acid, ASAD, ALAT, glucose, urea, LDH, Mg, P). Except for increased glucose the differences were only observed either at one time point or in one sex and were not dose related. Therefore they were considered of no toxicological significance. It was concluded that the hydrogenated polysaccharide fraction was not toxic in rats up to 5% in the diet (the highest dose tested).

Conclusions

In relation to existing maltitol syrup studies which already have been evaluated by the Committee, the data from the animal feeding study with hydrogenated polysaccharide fraction in the rat, mutagenicity tests in bacteria with hydrogenated dextrin, as well as review of available metabolism data and tolerance studies of hydrogenated starch hydrolysates, indicate that hydrogenated starch hydrolysates do not exhibit toxicological effects. Based on the above the Committee considered that the use of this new material does not raise any additional safety concerns in relation to existing maltitol syrups. Its laxative potential is considered to be similar to, or less than, that of existing maltitol syrups. Its use is therefore considered acceptable.

References

1. Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs. Official Journal of the EU N° L 178, 28.07.1995.
2. Reports of the SCF, 16th series, Cat. N° EUR 10210, Office of Official Publications of the European Communities, 1985.
3. Reports of the SCF, 21st series, Cat. N° EUR 11617, Office of Official Publications of the European Communities,1989.
4. Evaluation of certain food additives and contaminants. Twenty-seventh report of the Joint FAO/WHO Expert Committee on food additives. WHO Technical Report Series, No 696, 1983 and corrigenda.
5. Evaluation of certain food additives and contaminants. Twenty-ninth report of the Joint FAO/WHO Expert Committee on food additives. WHO Technical Report Series, No 733, 1986.
6. Evaluation of certain food additives and contaminants. Thirty-third report of the Joint FAO/WHO Expert Committee on food additives. WHO Technical Report Series, No 776, 1989.
7. Evaluation of certain food additives and contaminants. Forty-first report of the Joint FAO/WHO Expert Committee on food additives. WHO Technical Report Series, No 837, 1993.
8. Evaluation of certain food additives and contaminants. Forty-ninth report of the Joint FAO/WHO Expert Committee on food additives. WHO Technical Report Series, No 884, 1999.
9. Dossier on LYCASIN ® HBC submitted to SCF by petitioner, (SCF/CS/ADD/EDUL/180, 30/06/99).
10. Modderman JP (1993): Safety assessment of hydrogenated starch hydrolysates. Regulatory Toxicology and Pharmacology, **18**:80-114.
11. Study report. Mutagenicity test on bacteria (*Salmonella typhimurium* his^- and *Escherichia coli* trp^-) using B.N. Ames's technique with hydrogenated dextrin. IPL-R 950305/Hydrogenated dextrin/ Roquette, 1995.
12. Study report. Subchronic toxicity (13 weeks) by the oral route of LAB 2204 in rats. Biology & Toxicology Dpt. Roquette Freres, Report N° 95041, 1995.