**SCIENTIFIC OPINION**

# Scientific Opinion on the use of Polyglycitol Syrup as a food additive[1]

**EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)**[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

## ABSTRACT

Following a request from the European Commission (EC), the Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to deliver a scientific opinion on the safety of polyglycitol syrup when used as a food additive. Polyglycitol syrup belongs to the hydrogenated starch hydrolysate syrups composed of maltitol, sorbitol and higher molecular weight polyols. In contrast to maltitol syrup EU specifications, the polyglycitol syrup has a defined concentration of sorbitol, a lower concentration of maltitol and a defined concentration of higher molecular weight polyols. Consequently, it is not covered by specifications for maltitol syrup which is an EU authorised food additive. In humans, the main reported adverse effect specifically associated with polyglycitol syrup exposure was gastric disturbance. The Panel considers that conservative estimates of the exposure to polyglycitol syrup, for consumer-only and the general population, arising from the proposed uses and use-levels, are close to, and for children even higher than, doses associated with gastric disturbances when administered as bolus doses in human trials and as reported in recent case reports. However, the Panel notes that these estimates are based on the assumption that polyglycitol syrup will be present in all food for which its use is proposed. When potential exposures from all foods are combined, this scenario becomes less likely and exposure from all sources at maximum usage levels becomes less probable. However, for individual food categories this might be a realistic scenario since consumer loyalty and individual preferences might cause consumers to always choose particular brands, which may contain this particular food additive. The Panel considers that the chemical and toxicological data available on polyglycitol syrup are insufficient to establish an ADI, but based on the available data concludes that there are no indications of a safety concern for the proposed uses and use levels.

1 On request from the European Commission, Question No EFSA-Q-2007-072, adopted on 24 November 2009.

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**KEY WORDS**

Food additive, Polyglycitol Syrup, CAS Registry Number 68425-17-2.

## SUMMARY

Following a request from the European Commission, the Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to deliver a scientific opinion on the safety of polyglycitol syrup when used as a food additive.

Polyglycitol syrup belongs to the hydrogenated starch hydrolysate syrups composed of maltitol, sorbitol and higher molecular weight polyols. In contrast to maltitol syrup specifications, the polyglycitol syrup has a defined concentration of sorbitol, a lower concentration of maltitol and a defined concentration of higher molecular weight polyols. Consequently, it is not covered by the specifications for maltitol syrup which is already authorised in the EU as a food additive.

Higher-order polyols of hydrogenated starch hydrolysates can be hydrolysed in the gastrointestinal tract in mammals to glucose and maltitol. Maltitol is mainly digested in the small intestine, being fermented by the intestinal flora to glucose and sorbitol, the latter being absorbed and converted to fructose and partially to glucose.

In a 13-week feeding study conducted in male and female Charles River CD rats, upon exposure to polyglycitol syrup in the diet, the following effects were observed: a decrease in the average testis to body weight ratio of male rats, which upon microscopic examination of both testes (including epididymides) did not reveal any treatment-related effect; an increase in the empty caecum to body weight ratio in both sexes; an increase in urinary excretion of calcium in the absence of elevated serum calcium in both sexes (observed in the 4700 and 9700 mg/kg bw/day male groups and in the 2400 and 5000 mg/kg bw/day female groups); and an increase in blood glucose concentration in male animals only (observed in the 4700 and 9700 mg/kg bw/day groups). NOAELs of approximately 15 400 mg/kg bw/day in males and 7600 mg/kg bw/day in females, the highest doses levels tested, were identified by the Panel for this study. The Panel considered these effects as non–adverse, being commonly observed also with other authorised indigestible polysaccharides.

No further toxicity data were provided on polyglycitol syrup, however in light of the absence of reported carcinogenicity potential of authorised higher-order polyols such as the maltitol syrups, and taking into consideration that the metabolism of polyglycitol syrup leads to the production of normal dietary constituents such as glucose, the Panel considers that no further toxicity testing is needed.

In a human study, the principal reported adverse effect specifically associated with polyglycitol syrup exposure was gastric disturbance which occurred at bolus doses equivalent to 1 g polyglycitol syrup/kg bw administered during 3 days.

The Panel noted that the highest daily exposure to polyglycitol syrup from all proposed food-uses was estimated on a per body weight basis, to be for pre-school children (1.5–4.5 years old) 3.67 g/kg bw/day at the 95$^{th}$ percentile and children (4 – 10 years old) 2.79 g/kg bw/day at the 95$^{th}$ percentile. The adult population group consumed the lowest amount of polyglycitol syrup on a per body weight basis with mean and 95$^{th}$ percentile all-user intakes around 0.35 and 0.85 g/kg bw/day, respectively.

Breakfast cereals, biscuits, cakes and pastries, were found to be the most important potential sources of polyglycitol syrup (>10%) in all age groups.

The Panel notes that the highest dietary exposure to polyglycitol syrup arising from the proposed use levels (3.67 g/kg bw/day) does not exceed the NOAELs identified by the Panel in the 13-week rat study, which were the highest doses tested (7.6 g polyglycitol syrup/kg bw/day in females and 15.4 g polyglycitol syrup/kg bw/day in males).

The Panel noted that these exposure estimates are based on the assumption that polyglycitol syrup

would be present in all food for which its use is proposed. For individual food categories this might be realistic since consumer loyalty and individual preferences might cause a person to always choose particular brands containing this particular food additive. The Panel therefore considers that exposure to polyglycitol syrup from the proposed food uses and use-levels is close to the doses associated with gastric disturbances when administered as bolus doses in human trials and as reported in case reports. Therefore, laxative effects should be taken into account as with other polyols authorised as food additives.

The Panel considers that the toxicological data available on polyglycitol syrup are insufficient to establish an Acceptable Daily Intake (ADI), but based on the available data concludes that there is no indication of a safety concern for the proposed uses of polyglycitol syrup.

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## BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

A manufacturer has requested the authorisation of polyglycitol syrup under Directive 94/35/EC of the European Parliament and the Council on sweeteners for use in foodstuffs and under Directive 95/2/EC of the European Parliament and the Council Directive on food additives other than colours and sweeteners. This additive is proposed to be used in the first case for sweetening purposes in a range of foodstuffs, e.g. cereals and cereal products, fruits and nuts, preserves and confectionery and in the second case as humectants, bulking agents and carriers in a range of foodstuffs in line with the uses already permitted for other polyols.

Polyglycitol syrups are made from starch hydrolysates by catalytic hydrogenation. The hydrogenated starch hydrolysates are mixtures of polyglycitols such as sorbitol, maltitol, and higher order sugar alcohols. Also referred to as polyhydric alcohols or sugar alcohols, they are used mainly as bulk sweeteners but also as humectants, texturisers, viscosity or bodying agents, stabilisers, crystallisation modifiers, rehydration aids and carriers for food ingredients such as enzymes, colours, flavours and food premixes.

In 1998 JECFA evaluated the safety of polyglycitols and assigned a group ADI of 'not specified'. Other polyols which have similarities with polyglycitol syrup, e.g. maltitol syrup, have been assessed by the SCF and EFSA and approved to be used as food additives. In one of its related opinions adopted in 1999, the Scientific Committee on Food, (http://ec.europa.eu/food/fs/sc/scf/out48_en.pdf) concluded that hydrogenated starch hydrolysates do not exhibit toxicological effects.

## TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to provide a scientific opinion, on the safety of polyglycitol syrup as a food additive for use in the food categories specified in the dossier.

## ASSESSMENT

## 1. Introduction

The present opinion deals with the safety of polyglycitol syrup when used as a food additive.

## 2. Technical data

### 2.1. Identity of the substance

Polyglycitol syrup is described as a mixture consisting mainly of maltitol and sorbitol and lesser amounts of hydrogenated oligo- and polysaccharides and maltrotriitol (JECFA, 1998). Synonyms include hydrogenated starch hydrolysate, hydrogenated glucose syrup and polyglucitol. The Panel notes that the CAS Registry Number 68425-17-2 proposed by the petitioner is for syrups, hydrolysed starch, hydrogenated.

### 2.2. Specifications

Polyglycitol syrup is described by the petitioner as a colourless and odourless, clear viscous liquid. It is very soluble in water and slightly soluble in ethanol. It contains not more than 31% water and not more than 0.1% sulphated ash. In the anhydrous state, polyglycitol syrup contains not less than 99% total hydrogenated saccharides of which not more than 50% is maltitol and 20% is sorbitol as a white crystalline solid (Table 1). It is described as containing not more than 50 mg/kg chlorides, not more than 100 mg/kg sulphates, not more than 2 mg/kg nickel, not more than 1 mg/kg lead and not more than 0.3% reducing sugars. The Panel notes that chlorides and sulphates mentioned in the specifications provided by the petitioner may need to be specifically described.

Chemically, polyglycitol syrup differs from the food additive maltitol syrup [E 965 (ii)] in its quantitative composition (EC, 1995), as shown in Table 1. According to the petitioner this different composition is obtained by using a more standardised raw material in terms of maltose and glucose contents. Compared to maltitol syrup specifications, the polyglycitol syrup has a defined concentration of sorbitol, a lower concentration of maltitol and a defined concentration of higher molecular weight polyols (not chemically identified).

**Table 1.** Specifications for polyglycitol syrup from JECFA (1998), for maltitol from the EU (1995) and for polyglycitol syrup as proposed by the petitioner

| | Polyglycitol syrup (JECFA, 1998) | Maltitol syrup [E 965(ii)] (EC, 1995) | Polyglycitol syrup (proposed) |
|---|---|---|---|
| Sorbitol content (%) | < 20 | not specified | < 20 |
| Maltitol content (%) | < 50 | > 50 | < 50 |
| Higher molecular weight polyols | not specified | not specified | > 50 |

## 2.3. Manufacturing process

Polyglycitol syrup is manufactured by the catalytic hydrogenation of a mixture of starch hydrolysates consisting of glucose, maltose and higher glucose polymers, similar to the catalytic hydrogenation process used for the manufacture of maltitol syrup. The resulting syrup is desalted by ion exchange and concentrated to the desired level.

## 2.4. Methods of analysis in foods

Information on specific analysis for polyglycitol syrup in food was not provided.

## 2.5. Stability, reaction and fate in food

No specific information on the reaction and fate of polyglycitol syrup in foods was provided. The petitioner claims that polyglycitol syrup is stable and does not react with food components such as proteins and amino acids. Upon request from the Panel, the petitioner further stated that the terminal reducing groups of polyglycitol syrup are hydrogenated; thereby all functional groups are reduced to alcohol groups that do not interact in Maillard browning reactions or with other reactive groups.

However, the Panel notes that amylolytic enzymes present in foods may partially hydrolyse hydrogenated starch hydrolysate syrups giving rise to e.g. glucose (SCF, 1999). Thus the formation of Maillard reaction products under the conditions of some of the uses as proposed by the petitioner cannot be excluded.

## 2.6. Case of need and proposed uses

The petitioner proposes to use polyglycitol syrup as a bulk sweetener to modulate the sweetness of foods and also to act as a bulking agent, carrier and moisture control agent (humectant), with its main use being in "sugar free" food. The petitioner proposed the following food uses and use levels for polyglycitol syrup (Table 2).

**Table 2.** Food uses and use levels for polyglycitol syrup proposed by the petitioner

| Food category | Proposed food uses | Polyglycitol syrup use levels in the finished product (g/kg) |
|---|---|---|
| Cereals and cereal products | Biscuits | 300 |
| | Breakfast cereals | 200 |
| | Cakes and pastries | 300 |
| | Cereal based desserts | 200 |
| | Water based desserts | 300 |
| Fruits and nuts | Fruit based desserts (caked, stewed, canned with sugar or syrup) | 300 |
| Milk and milk products | Dairy based desserts | 300 |

| | | |
|---|---|---|
| Sugars, preserves[4], and confectionary | Chewing gum | 200 |
| | Chewy candy | 800 |
| | Chocolate confectionery | 200 |
| | Edible ices | 200 |
| | Hard candy | 990 |
| | Jams, jellies, marmalades | 500 |
| | Starch based candy | 600 |
| Vegetable, potatoes and savory snacks | Vegetable based desserts | 300 |

## 2.7. Information on existing authorisations and evaluations

In 1984, the Scientific Committee on Food (SCF) reviewed maltitol and maltitol-based products, composed essentially of maltitol, sorbitol and glucose, and concluded that although the establishment of an Acceptable Daily Intake (ADI) was considered inappropriate, a limited use was acceptable provided that their laxative action was taken into account (SCF, 1985).

In 1999, the SCF evaluated a maltitol syrup composed of 50-55% maltitol, < 2% sorbitol and < 30% hydrogenated polysaccharides, and concluded that its use does not raise any additional safety concerns in relation to existing maltitol syrups, and was thus considered acceptable for use as other authorised polyols (SCF, 1999).

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated maltitol syrup and allocated an ADI "not specified" to materials meeting the revised specifications (WHO, 1998).

JECFA evaluated polyglycitol syrup containing 8% maltitol, 14% sorbitol and 78% higher-order polyols and allocated an ADI "not specified" to materials conforming to the JECFA specifications for polyglycitol syrup and maltitol syrup (WHO, 1999).

The former EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) issued an opinion on maltitol syrup from a new production process and considered that provided that the composition was in accordance with the existing EU specifications, the previous evaluation by the SCF will also cover this product (EFSA, 2006).

In the European Community maltitol syrup [E 965 (ii)], defined as mainly maltitol, sorbitol and hydrogenated oligo- and polysaccharides, is an authorised sweetener (EC 1994, 1995).

JECFA established an ADI "not-specified" for sorbitol (JECFA, 1982).

Sorbitol is a food substance affirmed in the United States as Generally Recognized As Safe (GRAS); it can be used as an ingredient in certain foods with no limitation other than levels should not exceed good manufacturing practices (CFR, 2001).

[4] jams, jellies, marmalades

## 2.8. Exposure

The petitioner provided estimates of daily exposures to polyglycitol syrup based on the proposed use levels (Table 2) and on raw data from individual food consumption surveys collected as part of the UK National Diet and Nutrition Survey (NDNS) (Table 3). These were 4-day dietary records for pre-school children (Gregory *et al.*, 1995) and 7-day dietary records for young people (Gregory *et al.*, 2000) and adults (Gregory *et al.*, 1990). To facilitate comparison with the adult and youth survey data, dietary data from the pre-school children's survey were weighted to 7 days. The exposure estimates were performed for pre-school children aged 1.5-4.5 years, young people aged 4–10 years, female and male teenagers aged 11–18 years, and male and female adults aged 16–64 years (Table 3). The NDNS data were comprised of records of more than 2000 different food items declared to be consumed in these individual food consumption surveys. NDNS individual food codes were matched to the proposed food uses reported in Table 2, and then each individual potential exposure was calculated based on the assumption that polyglycitol syrup was present at the proposed use levels in all proposed food uses. Individual body weights were available in all population groups to calculate individual's exposures per kg bw/day. Estimated total exposure to polyglycitol syrup from all combined proposed food uses (in g/day and g/kg bw/day) for the mean and high-level (95$^{th}$ percentile), all-persons (including non-users), consumers-only, and percentages of consumers were provided.

As shown in Table 3 the percentage of users of those food products in which polyglycitol syrup is proposed for use was high (varying from 90.5% in female adults to 99.6% in young people aged 4-10 years). As large user percentages within a population group typically lead to comparable results for the all-persons and consumers-only, the Panel decided to present exposure estimates from consumers-only.

**Table 3.** Summary of the potential dietary exposure to polyglycitol syrup from all proposed food uses in the UK for the consumers-only population group (NDNS Data)

| Population group | Age group (years) | n | Users (%) | Consumers-only (g/day) | | Consumers-only (g/kg bw/day) | |
|---|---|---|---|---|---|---|---|
| | | | | Mean | 95$^{th}$ percentile | Mean | 95$^{th}$ percentile |
| Pre-school children | 1.5 - 4.5 | 1624 | 98.5 | 26.1 | 52.5 | 1.83 | 3.67 |
| Young children | 4 - 10 | 834 | 99.6 | 39.4 | 71.0 | 1.55 | 2.79 |
| Female teenagers | 11 - 18 | 433 | 97.1 | 29.3 | 69.8 | 0.58 | 1.47 |
| Male teenagers | 11 - 18 | 409 | 98.3 | 39.9 | 83.0 | 0.77 | 1.80 |
| Female adults | 16 - 64 | 867 | 90.5 | 24.7 | 57.1 | 0.37 | 0.85 |
| Male adults | 16 - 64 | 694 | 90.6 | 29.1 | 70.3 | 0.35 | 0.83 |

The exposure to polyglycitol syrup from all proposed food-uses was estimated to be highest for male teenagers and young people aged 4 to 10 years. Whereas female adults had the lowest mean intakes (approximately 25 g/day), and pre-school children had the lowest 95$^{th}$ percentile of consumers-only (approximately 53 g/day).

Table 3 shows that the pre-school children consumed the greatest amount of polyglycitol syrup on a per body weight basis with the highest mean and 95$^{th}$ percentile all-user intakes of 1.83 and 3.67 g/kg bw/day, respectively. The adult population group consumed the lowest amount of polyglycitol syrup on a per body weight basis with mean and 95$^{th}$ percentile all-users intakes ranged around 0.35 and 0.85 g/kg bw/day, respectively.

Table 4 shows the percentage of the main contributors to the mean total potential exposure to polyglycitol syrup for all population groups, from individual proposed food uses. Breakfast cereals, biscuits, cakes and pastries were found to be the most important potential sources of polyglycitol syrup (>10%) for all age groups. For each of these food groups and also for chocolate confectionary and cereal-based desserts, the lowest and highest polyglycitol potentially exposed age-groups are given below. Biscuits contributed approximately 14% (female teenagers) to 17% (pre-school children) of the mean total potential exposure to polyglycitol syrup. Breakfast cereals contributed approximately 14% (young people) to 22% (adult males), and cakes and pastries approximately 11% (pre-school children) to 22% (male adults) of the mean total potential exposure to polyglycitol syrup. Chocolate confectionery provided 6% (adults) to 13% (female teenagers) of the mean total potential exposure to polyglycitol syrup, whereas cereal-based desserts contributed 7% (male teenagers) to 11% (pre-school children) of the mean total potential exposure to polyglycitol syrup. Other individual food uses were found to contribute less than 10% for all age groups.

The Panel agrees with the view of the petitioner that the potential dietary exposures to polyglycitol syrup can be considered as conservative estimates since it was assumed that polyglycitol syrup would be present in all individual foods for which it is proposed for use (i.e. that it would achieve a 100% share of the market). However, for individual food uses this might be realistic since consumer loyalty and individual preferences might cause a person to always choose particular brands, which may contain this particular additive.

**Table 4.** Summary of the percentage of the main contributors to the total mean potential dietary exposure to polyglycitol syrup from all proposed food uses in the UK by population groups (NDNS Data)

| Food uses | Exposure (g/kg bw/day, all populations) | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Pre-school children | | | Young children | | | Female teenagers | | | Male teenagers | | | Female adult | | | Male adult | | |
| | Mean | 95th | %[a] | Mean | 95th | % | Mean | 95th | % | Mean | 95th | % | Mean | 95th | % | Mean | 95th | % |
| **Cereals and Cereals products** | | | | | | | | | | | | | | | | | | |
| Biscuits | 0.31 | 0.82 | 17.2 | 0.24 | 0.63 | 15.6 | 0.08 | 0.26 | 14.3 | 0.11 | 0.34 | 14.5 | 0.05 | 0.18 | 15.2 | 0.05 | 0.2 | 15.6 |
| Breakfast Cereals | 0.26 | 0.68 | 14.4 | 0.22 | 0.52 | 14.3 | 0.08 | 0.27 | 14.3 | 0.13 | 0.38 | 17.1 | 0.07 | 0.26 | 21.2 | 0.07 | 0.26 | 21.9 |
| Cakes and Pastries | 0.19 | 0.76 | 10.6 | 0.26 | 0.75 | 16.9 | 0.11 | 0.41 | 19.6 | 0.13 | 0.38 | 17.2 | 0.07 | 0.28 | 21.2 | 0.07 | 0.3 | 21.9 |
| Cereal Based Desserts | 0.19 | 0.99 | 10.6 | 0.16 | 0.58 | 10.4 | 0.05 | 0.21 | 8.9 | 0.05 | 0.24* | 6.6 | 0.03 | 0.16 | 9.1 | 0.03 | 0.16 | 9.4 |
| Water Based Desserts | 0.01 | na | 0.56 | 0.01 | na | 0.69 | 0.01 | na | 1.8 | 0.01 | na | 1.3 | 0.01 | na | 3.0 | 0.01 | na | 3.2 |
| **Fruits and Nuts** | | | | | | | | | | | | | | | | | | |
| Fruit Based Desserts | 0.04 | 0.25 * | 2.2 | 0.03 | 0.21* | 1.9 | 0.01 | 0.02 | 1.8 | 0.01 | 0.05* | 1.3 | 0.01 | 0.08* | 3.0 | 0.01 | 0.06* | 3.1 |
| **Milk and Milk Products** | | | | | | | | | | | | | | | | | | |
| Dairy Based Desserts | 0.16 | 0.88 | 8.9 | 0.13 | 0.49 | 8.4 | 0.04 | 0.21* | 7.1 | 0.06 | 0.28 | 7.9 | 0.02 | 0.14 | 6.1 | 0.02 | 0.12 | 6.3 |
| **Sugars, Preserves, and Confectionery** | | | | | | | | | | | | | | | | | | |
| Chewing Gum | 0.01 | na | 0.56 | 0.01 | 0.01* | 0.65 | 0.01 | 0.01* | 1.8 | 0.01 | 0.01* | 1.3 | 0.01 | na | 3.0 | 0.01 | na | 3.1 |
| Chewy Candy | 0.12 | 0.79 | 6.7 | 0.11 | 0.55 | 7.1 | 0.04 | 0.22* | 7.1 | 0.05 | 0.34* | 6.6 | 0.01 | 0.05* | 3.0 | 0.01 | na | 3.1 |
| Chocolate Confection | 0.15 | 0.48 | 8.3 | 0.12 | 0.35 | 7.8 | 0.07 | 0.25 | 12.5 | 0.09 | 0.29 | 11.8 | 0.03 | 0.11 | 9.1 | 0.02 | 0.1 | 6.3 |
| Edible Ices | 0.1 | 0.52 | 5.6 | 0.1 | 0.37 | 6.5 | 0.03 | 0.14* | 5.4 | 0.04 | 0.20* | 5.3 | 0.01 | 0.04* | 3.0 | 0.01 | 0.03* | 3.1 |
| Hard Candy | 0.11 | 0.7 | 6.1 | 0.08 | 0.41 | 5.2 | 0.03 | 0.15* | 5.4 | 0.04 | 0.24* | 5.3 | 0.01 | 0.04* | 3.0 | 0.01 | 0.01* | 3.1 |
| Jams, Jellies, Marmalades | 0.05 | 0.25 | 2.8 | 0.04 | 0.22 | 2.6 | 0.01 | 0.07* | 1.8 | 0.02 | 0.13* | 2.6 | 0.02 | 0.11 | 6.1 | 0.02 | 0.11 | 6.3 |
| Starch Based Desserts | 0.11 | 0.72 | 6.1 | 0.06 | 0.37 | 3.9 | 0.02 | 0.12* | 3.6 | 0.03 | 0.21* | 3.9 | 0.01 | 0.01* | 3.0 | 0.01 | na | 3.1 |
| **Vegetables, Potatoes & Savoury Snacks** | | | | | | | | | | | | | | | | | | |
| Vegetable Based Dress | 0.01 | na | 0.56 | 0.01 | na | 0.65 | 0.01 | na | 1.8 | 0.01 | na | 1.3 | 0.01 | na | 3.0 | 0.01 | na | 3.1 |
| **Total** | **1.8** | **3.66** | | **1.54** | **2.79** | | **0.56** | **1.47** | | **0.76** | **1.8** | | **0.33** | **0.84** | | **0.32** | **0.81** | |

* Indicates an intake estimate that may not be statistically reliable, as the sample size does not meet the minimum reporting requirements;
na indicates that % of consumers is below 5%; [a] percentage of the main contributors to the total mean potential dietary exposure

# 3. Biological and toxicological data

## 3.1. Absorption, distribution, metabolism and excretion

An *in vitro* digestibility study of polyglycitol syrup using an immobilised digestive enzyme assay system composed of porcine pancreas alpha-amylase, isomaltase and maltase from bakers yeast, showed that polyglycitol syrup was partially digested (approximately 20% digestion based on combined mean change in maltitol, sorbitol and glucose concentrations) by this combination of enzymes, resulting in the production of glucose as the main hydrolysis product.

*In vitro*, digestibility studies with human salivary and hog pancreatic α-amylases, and artificial gastric juices have shown that hydrogenated oligosaccharides are generally resistant to digestion (Tsunehiro *et al.*, 1999). However, when tested in a rat small intestinal mucosal enzymes assay, partial hydrolysis (17 and 23% hydrolysis ratio after 2 and 4 h of incubation, respectively) of hydrogenated oligosaccharides was observed, leading to the production of sorbitol, glucose and other disaccharides (Tsunehiro *et al.,* 1999).

Higher-order polyols of hydrogenated starch hydrolysates can be hydrolysed in the gastrointestinal tract of mammals to glucose and maltitol (SCF, 1999; WHO, 1998; Livesey, 2003). It has been considered that digestion and absorption of higher-order polyols is similar to that of maltitol in humans, being mainly digested in the small intestine (Beaugerie *et al.,* 1990; Livesey, 2003). Maltitol and polymerised sugar alcohols can be slowly but almost completely degraded to glucose and sorbitol, primarily in the jejunum, ileum and duodenum mainly through fermentation by the intestinal flora, although it has also been reported that they can also be absorbed in the small intestine and excreted unchanged in the urine (WHO, 1998; Lian-Loh *et al.,* 1982; Beaugerie *et al.,* 1990). In humans, absorbed sorbitol is rapidly metabolised to $CO_2$ in the liver through conversion into fructose, a proportion of which can in turn be converted to glucose (Adcock and Gray, 1957).

## 3.2. Toxicological data

### 3.2.1. Acute oral toxicity

No data were available on polyglycitol syrup.

### 3.2.2. Short-term and subchronic toxicity

A 13-week feeding study was conducted in 4 groups (10 males and 10 females) of Charles River CD rats fed a semi-purified diet supplemented with polyglycitol syrup composed of approximately 14% (w/w) sorbitol, 8% maltitol and 78% higher molecular weight polyols. It was stated that the study was done in accordance with Organisation for Economic Co-operation and Development (OECD) Guidelines for the Testing of Chemicals No. 408, the OECD Principles of Good Laboratory Practice (GLP) and the US Food and Drug Administration (FDA) GLP Regulations. Groups of animals were fed polyglycitol syrup at concentrations of 0, 6.7, 13.3 and 20% in the diet, which according to reported mean body weights and food consumption would be equivalent to approximately 4700, 9700 and 15 400 mg/kg bw/day in males respectively, and 2400, 5000 and 7600 mg/kg bw/day in females respectively. The study also included groups of animals fed 20% maltitol, 20% maltitol syrup or 20% of a mixture of sorbitol/glucose (46/54%), defined as the metabolic control and an untreated control. All mixtures were shown to be stable in the diets for the duration of the study.

Parameters evaluated included in-life records of body weight and food consumption, gross and microscopic examinations, clinical pathology and ophthalmology examinations and *post-mortem* gross and microscopic evaluations. Calcium urinalysis, gross examination of the caecum and full microscopic examinations, especially of the adrenal gland and kidneys, were performed in detail.

During the study, weekly observations revealed no polyglycitol syrup treatment-related effects on clinical appearance. Induction of diarrhoea was not reported in the exposed animals.

A statistically significant increase in weekly food consumption was observed in all 20% fed groups. No statistically significant differences in body weight, body weight change and feed efficiency were reported amongst the groups. In males, compared to respective controls the increase in food consumption was observed at weeks 1, 3, 4, 10 and 13 and, in females, at weeks 1 and 8. However, this increase in food consumption was not accompanied by a significant effect on body weight values compared to control animals.

No treatment-related effects for polyglycitol syrup were seen in ophthalmologic examinations. The scattered observed pathologies (conjunctivitis, keratitis) were those expected for these animals considering their age, sex and strain.

Haematological parameters (red blood cell, leukocyte, neutrophils and platelet counts, haemoglobin and haematocrit levels, mean corpuscular volume, mean corpuscular haemoglobin concentration) in males and females did not show significant effects related to polyglycitol syrup exposure as compared to untreated controls.

Serum biochemical parameters in males showed significantly increased glucose mean levels in the 13.3 and 20% polyglycitol syrup dose groups as compared to untreated controls. These levels did not differ from those measured in 3 other equivalent treated groups of animals tested with either maltitol, or maltitol syrup, or sorbitol/glucose, and the effects were not observed in females of those groups compared to the untreated controls. No treatment related effects were observed on blood electrolytes (sodium, potassium, chloride), calcium and phosphorus levels, alkaline phosphatase, total bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), creatine phosphokinase (CPK), urea nitrogen, creatinine, total protein, albumin/globulin (A/G) ratio or in cholesterol levels of animals exposed to all doses of polyglycitol syrup.

Urinalysis showed treatment-related increases in urine calcium concentration (24 hours) and in the ratio of urinary calcium/creatinine excretion following exposure to polyglycitol syrup. Mean values of the urinary calcium excretion increased statistically significantly among males exposed to the 13.3 and 20% polyglycitol syrup doses (1.4 mg at 24 hours and 2.7 mg at 24 hours, respectively), compared to controls (0.7 mg at 24 hours), whereas in females it was statistically significant in the 6.7 and 20% polyglycitol syrup exposed groups (2 and 4 mg at 24 hours, respectively) compared to controls. A statistically significant higher mean calcium to creatinine ratio was observed in males exposed to the highest polyglycitol syrup dose (20%) as compared to untreated controls. The same effects were observed in the equivalent dose of maltitol syrup dosage group but ratios were higher than those in the maltitol and the sorbitol/glucose mixture groups. In females, these increases were observed already at the lowest polyglycitol syrup dose tested (6.7%) but became statistically significant only at the 13.3 and 20% doses. Equivalent mean levels of calcium to creatinine ratios were found in the corresponding maltitol syrup, maltitol and the sorbitol/glucose mixture groups in females.

No differences in the body weight data and in most organ and organ weight/body weight ratios were reported in either sex of rats supplemented with polyglycitol syrup. However, the average empty caecum/body weight ratio of male rats exposed to the highest dose of polyglycitol syrup (20%) was statistically significantly increased compared to untreated animals. In females, the same statistically significant pattern of increase in the empty caecum/body weight ratio was observed. In males and females from the equivalent maltitol syrup, maltitol and sorbitol/glucose mixture dosage groups the average empty caecum/body weight ratios were even higher than those in the polyglycitol syrup group.

A slight decrease in the average kidney to body weight ratio was observed in females exposed to 13.3

and 20% polyglycitol syrup although it only became statistically significant in the latter group as compared to untreated animals. This decrease was not observed in males.

The average testis to body weight ratio of male rats showed a statistically significant decrease in animals exposed to the highest dose of polyglycitol syrup (20%) as compared to untreated animals. This ratio remained slightly lower than that in the equivalent maltitol syrup, maltitol and sorbitol/glucose mixture dosage groups.

Upon macroscopic or microscopic examinations, no treatment-related effects were reported in all groups. Microscopic examinations were carried out in most tissues of animals from the 20% polyglycitol syrup exposed group, whereas they were restricted to the adrenal gland (cortex and medulla) and the kidney in the 6.7 and 13.3% polyglycitol syrup exposed groups. Particularly for the kidneys and adrenal glands, which previous studies had identified as target organs for some polyol materials, histopathological examinations were also performed on animals from the 6.7 and the 13.3% polyglycitol syrup groups. Histopathological examinations of more than 40 organs and tissues, including the large intestine (caecum, colon, rectum), testis and the kidneys and adrenal glands from animals in the 20% polyglycitol syrup groups were reported to be within normal limits in all groups of animals exposed.

From this study, the Panel identified No-Observed-Adverse-Effect Levels (NOAELs) of approximately 15 400 mg/kg bw/day for males and 7600 mg/kg bw/day for females, which were the highest dose levels tested.

No additional *in vivo* or *in vitro* toxicology studies on polyglycitol syrup were available.

### 3.2.3. Genotoxicity

No data were available on polyglycitol syrup.

### 3.2.4. Chronic toxicity and carcinogenicity

No data were available on polyglycitol syrup.

### 3.2.5. Reproductive and developmental toxicity

No data were available on polyglycitol syrup.

### 3.2.6. Human observations

A randomised double-blind crossover study was performed in 18 subjects (31-69 years of age), consisting of 6 non-diabetic individuals, 6 patients with non-insulin-dependent *diabetes mellitus* (NIDDM) and six individuals with insulin-dependent *diabetes mellitus* (IDDM) (3 men and 3 women in each group), challenged with 50 g of polyglycitol syrup per 1.73 $m^2$ of body surface area

(equivalent to approximately 1 g polyglycitol/kg bw)[5], with 50 g of glucose or with 50 g of sorbitol/maltitol mixture (7 %/60 %, w/w) for 3 consecutive days (Wheeler *et al.,* 1990). The plasma glycaemic response (area under 5-hour curve) to polyglycitol syrup was between those for the glucose and the sorbitol/maltitol mixture (Table 5). Results of breath exhaled hydrogen measurements indicated increased degradation of carbohydrates by colonic bacteria.

In this study gastric disturbances were reported to occur in the subjects consuming the polyglycitol syrup (approximately 1 g polyglycitol syrup/kg bw).

**Table 5.** Area under 5- hour curve responses (mM glucose/h) after oral challenges with either 50 g of glucose, polyglycitol or sorbitol/maltitol mixture [a]

| | **Non-diabetic** | **NIDDM** | **IDDM** |
|---|---|---|---|
| Glucose | 30.2 ±2.4 | 60.1 ±7.6 | 62.5 ±15.2 |
| Polyglycitol | 28.6 ±3.5 | 47.6 ±5.2 | 46.6 ±10.5 |
| Sorbitol/maltitol mixture | 27.9 ±2.0 | 37.4 ±5.3 | 43.6 ±14.5 |

[a] values are means ± SD ($n$ = 6 subjects per group; group $P < 0.001$)

Two human case-reports mentioned severe functional bowel disorder symptoms associated with ingestion of sorbitol from food products (Bauditz *et al*., 2008). A 21 year old woman suffering diarrhoea and abdominal pain for several months, showing important weight loss (11 kg), hypoalbuminaemia and high levels of electrolytes in stools, was found to consume a daily dose of 18-20 g of sorbitol, arising from chewing large amounts of sugar-free gum. Laboratory analyses and clinical examinations (e.g. antigastrin antibodies, stool cultures, histology, duodenal biopsy) were within normal ranges. The second case report was a 46 year old man showing also important weight loss (22 kg), diarrhoea, abdominal gas and bloating and high levels of electrolytes in stools. As in the previous case report, laboratory analysis and clinical examinations showed no abnormal changes. It was reported that this patient chewed 20 sticks of sugar-free gum per day and ate up to 200 g of sweets daily, accounting, according to (Bauditz *et al*., 2008), to about 30 g sorbitol/day. In both cases symptoms stopped after cessation of consumption of these foodstuffs. Both patients reported to have replaced the gum sticks frequently and the observed symptoms were attributed, by the authors, to a habitual ingestion of sorbitol. Except for a statement indicating that one stick contained about 1.25 g sorbitol, there were no indications of the actual sorbitol concentrations in the other foodstuffs.

## 4. Discussion

Polyglycitol syrup belongs to the hydrogenated starch hydrolysate syrups composed of maltitol, sorbitol and higher molecular weight polyols, such as the food additive maltitol syrup [E 965 (ii)]. In contrast to maltitol syrup EU specifications, the polyglycitol syrup has a defined concentration of sorbitol, a lower concentration of maltitol and a defined concentration of higher molecular weight polyols. Consequently, it is not covered by the specifications of the maltitol syrup already authorised in the EU as a food additive.

In a 13-week feeding study conducted in Charles River CD rats, upon exposure to up to 20%

[5] body mass indexes (kg/m$^2$) reported in this study were 24.4 ±3.5 for non-diabetic, 31.7 ±2.2 for non-insulin-dependent *diabetes mellitus,* and 23.2 ± 2.7 for insulin-dependent *diabetes mellitus* subjects.

polyglycitol syrup in the diet (equivalent to approximately 15 400 mg/kg bw/day in males and 7600 mg/kg bw/day in females) the following effects were observed: a decrease in the average testis to body weight ratio of male rats, which upon microscopic examination of both testes (including epididymides) did not reveal any treatment-related effect; an increase in the empty caecum to body weight ratio in both sexes; an increase in urinary excretion of calcium in the absence of elevated serum calcium in both sexes (observed in the 4700 and 9700 mg/kg bw/day male groups and in the 2400 and 5000 mg/kg bw/day female groups) and an increase in blood glucose concentration in male animals only (also observed in the 4700 and 9700 mg/kg bw/day groups). NOAELs of approximately 15 400 mg/kg bw/day in males and 7600 mg/kg bw/day in females, the highest doses levels tested, were identified by the Panel for this study.

Increased caecum weight in rats has been observed in animals fed carbohydrates other than polyglycitol syrup (Licht *et al.,* 2006). Rats fed diets containing potato starch, inulin or oligofructose, had significantly higher caecum weights and lower pH values than the cornstarch-fed reference animal group. An increased caecum weight in animals fed these types of carbohydrates is considered a physiological response to increased fermentation, due to a carbohydrate-induced modification on the composition of the intestinal microbiota (Licht *et al.,* 2006).

Sugar alcohols and other polysaccharides are known to increase calcium absorption in rats (Brommage *et al*., 1993). Stimulation of the intestinal absorption of calcium in animals, fed diets containing high doses (> 5%, w/w) of lactulose, xylitol, lactobionate, L- or D-arabinose, raffinose, pyroglutamic acid, sorbitol, gluconate and raftilose, was statistically significantly higher than in animals fed control diets and did not differ amongst the various compounds tested. Absorbed calcium would then be rapidly excreted in the urine. It has been suggested that the mechanistic action of stimulated calcium absorption by resistant sugars is passive, involving an increase in perfused fluid within the lumen to maintain isotonicity and consequently an increase in permeability of the intracellular junctions between enterocytes (Brommage *et al.,* 1993). Alternatively, *in vitro* sugar-induced changes in the transepithelial permeability of the intestinal epithelium *via* the activation of tight junctions have also been suggested (Mineo *et al*., 2001).

Polyglycitol syrup and its metabolites can produce glucose as their main end-product and it is thus not unexpected that serum glucose concentration can be increased after exposure to high concentrations of polyglycitol syrup. The same disturbances were observed in rats exposed to high levels of maltitol, maltitol syrup or a sorbitol/glucose mixture. Generally, hydrogenated starch hydrolysate syrups are considered less glycaemic than glucose in diabetic and non-diabetic individuals (SCF, 1999; WHO, 1999). Polyglycitol has been reported to induce glycaemic and insulineamic indexes (39 and 23, respectively) similar to those of maltitol and maltitol syrup (high-polymer), lower than those induced by regular maltitol syrup and higher than those of other polyols (e.g. sorbitol, xylitol) (Livesey, 2003). The Panel therefore considered these effects as non-adverse, being commonly observed also with other authorised indigestible polysaccharides.

No further toxicity studies were provided on polyglycitol syrup, however in light of the absence of reported carcinogenicity potential of authorised higher-order polyols such as the maltitol syrups, and taking into consideration that the metabolism of polyglycitol syrup leads to the production of normal dietary constituents such as glucose, the Panel considers that no further toxicity testing is needed.

In humans, the main reported adverse effect specifically associated with polyglycitol syrup exposure was gastric disturbance, observed at bolus doses equivalent to approximately 1 g/kg bw/day in adults. Gastric disturbance is a known effect of exposure to polyols following oral administration. The Panel noted that this study design (bolus administration of the liquid) would maximise the potential induction of gastric disturbances. The SCF (1989) described the laxation caused by osmotic pressure as "osmotic diarrhoea", in order to differentiate it from the term "diarrhoea" which is commonly used to describe a gastro-enteric sickness. Maltitol and lactitol have been described as inducing transitory osmotic diarrhoea in humans by the hyperosmotic retention of fluids in the small and large intestines at doses down to 15 g (Nakamura *et al*., 2007). Upon regular consumption of maltitol and other polyols (daily for two 9-day periods), the occurrence of an intestinal adaptation to maltitols laxative

effect at doses of up to 30 g has been reported in some individuals (Brommage *et al*., 1993; Ruskoné-Fourmestraux *et al.,* 2003).

The Panel noted that the highest daily exposure to polyglycitol syrup from all proposed food-uses was estimated on a per body weight basis, to be for pre-school children (1.5–4.5 years old) 1.83 g/kg bw/day at the mean and 3.67 g/kg bw/day at the 95$^{th}$ percentile and for children (4 – 10 years old) to be 1.55 g/kg bw/day at the mean and 2.79 g/kg bw/day at the 95$^{th}$ percentile. The adult population group consumed the lowest amount of polyglycitol syrup on a per body weight basis with mean and 95$^{th}$ percentile intakes ranged around 0.35 and 0.85 g/kg bw/day, respectively.

Breakfast cereals, biscuits, cakes and pastries, were found to be the most important potential sources of polyglycitol syrup (>10%) in all age groups

The Panel notes that the highest dietary exposure to polyglycitol syrup arising from the proposed use levels (3.67 g/kg bw/day) does not exceed the NOAELs identified by the Panel in the 13-week rat study, which were the highest doses tested (7.6 g polyglycitol syrup/kg bw/day in females and 15.4 g polyglycitol syrup/kg bw/day in males).

However, the Panel notes that these exposure estimates at the highest percentile will result in exposure levels matching those associated with gastric disturbances, when administered as bolus doses in human trials. The Panel also notes that these estimates are based on the assumption that polyglycitol syrup will be present in all food for which its use is proposed. When potential exposures from all foods are combined, this scenario becomes less likely and exposure from all sources at the maximum usage level becomes less probable. However, for individual food categories this might be a realistic scenario since consumer loyalty and individual preferences might cause a person to always choose particular brands, which may contain this particular food additive.

## CONCLUSIONS

The Panel considers that the chemical and toxicological data available on polyglycitol syrup are insufficient to establish an ADI, but based on the available data concludes that there is no indication of a safety concern for the proposed uses and use levels of polyglycitol syrup.

The Panel considers that conservative estimates of the exposure to polyglycitol syrup, for consumer-only and the general population, arising from the proposed uses and use-levels, are close to, and for children even higher than, doses associated with gastric disturbances when administered as bolus doses in human trials and as reported in recent case reports.

## DOCUMENTATION PROVIDED TO EFSA

1. Application for the approval of polyglycitol syrup under the directive 94/35/EC of 20 June 1994 on sweeteners for use in foodstuffs and Directive 95/2/EC on food additives other than colours and sweeteners. February 2007. Submitted by SPI Polyols, Inc., USA
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## GLOSSARY AND ABBREVIATIONS

| | |
|---|---|
| ADI | Acceptable Daily Intake |
| AFC | Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food |
| ANS | Scientific Panel on Food Additives and Nutrient Sources added to Food |
| A/G | albumin/globulin |
| ALT | alanine aminotransferase |
| ANS | Scientific Panel on Food Additives and Nutrient Sources added to Foods |
| AST | aspartate aminotransferase |
| bw | body weight |
| CAS | Chemical Abstracts Service |
| CPK | creatine phosphokinase |
| EC | European Commission |
| EFSA | European Food Safety Authority |
| EU | European Union |
| FDA | Food and Drug Administration |
| GLP | Good Laboratory Practice |
| GRAS | Generally Recognized As Safe |
| IDDM | insulin-dependent *diabetes mellitus* |
| JECFA | Joint FAO/WHO Expert Committee on Food Additives |
| NIDDM | non-insulin-dependent *diabetes mellitus* |
| NDNS | National Diet and Nutrition Survey |
| NOAEL | No-Observed-Adverse-Effect Level |
| OECD | Organisation for Economic Co-operation and Development |
| SCF | Scientific Committee on Food |
| WHO | World Health Organization |