

## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to intense sweeteners and contribution to the maintenance or achievement of a normal body weight (ID 1136, 1444, 4299), reduction of post-prandial glycaemic responses (ID 4298), maintenance of normal blood glucose concentrations (ID 1221, 4298), and maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 1134, 1167, 1283) pursuant to Article 13(1) of Regulation (EC) No 1924/2006<sup>1</sup>**

**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>**

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to intense sweeteners and contribution to the maintenance or achievement of a normal body weight, reduction of post-prandial glycaemic responses, maintenance of normal blood glucose concentrations, and maintenance of tooth mineralisation by decreasing tooth demineralisation. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituents that are the subject of the health claims are intense sweeteners, which should replace sugars in foods and beverages in order to obtain the claimed effects. The Panel considers that intense sweeteners are sufficiently characterised in relation to the claimed effects.

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-1873, EFSA-Q-2008-1875, EFSA-Q-2008-1906, EFSA-Q-2008-1959, EFSA-Q-2008-2021, EFSA-Q-2008-2181, EFSA-Q-2010-00251, EFSA-Q-2010-00252, adopted on 08 April 2011.

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### **Contribution to the maintenance or achievement of a normal body weight**

The claimed effects are “weight management”, “weight control including weight loss”, and “intense sweeteners help to maintain a healthy body weight; intense sweeteners help to control calorie intake”. The target population is assumed to be the general population. The Panel considers that contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that data from both intervention and observational studies comparing high intakes of sugars (mainly as added sugars) to high intakes of starch with respect to weight gain are inconsistent, that epidemiological studies do not show a positive association between total sugar intake and obesity, and that three human intervention studies did not show an effect on body weight of replacing sugars by intense sweeteners in foods and beverages.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between total sugar intake and body weight gain, and that a cause and effect relationship has not been established between the consumption of foods and beverages in which sugars have been replaced by intense sweeteners and contribution to the maintenance or achievement of a normal body weight.

### **Reduction of post-prandial glycaemic responses**

The claimed effect is “intense sweeteners have no effect on carbohydrate metabolism or short or long term blood glucose”. The target population is assumed to be individuals who wish to reduce their post-prandial glycaemic responses. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the reduction of post-prandial glycaemic responses. The Panel considers that the reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

A claim on the sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose and reduction of post-prandial blood glucose responses has already been assessed with a favourable outcome. The Panel considers that the scientific substantiation and proposed conditions of use also apply to intense sweeteners.

### **Maintenance of normal blood glucose concentrations**

The claimed effects are “blood glucose control” and “intense sweeteners have no effect on carbohydrate metabolism or short or long term blood glucose”. The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal blood glucose concentrations. The Panel considers that maintenance of normal blood glucose concentrations is a beneficial physiological effect.

No human intervention studies on the effects on long-term blood glucose control of replacing sucrose by intense sweeteners in a food, meal or diet, have been provided in the consolidated list.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of foods and beverages in which sugars have been replaced by intense sweeteners and maintenance of normal blood glucose concentrations.

### **Maintenance of tooth mineralisation by decreasing tooth demineralisation**

The claimed effects are “dental health/sweeteners can not be fermented by oral bacteria, they are non-cariogenic”, “foods which under typical conditions of use are neither cariogenic nor erosive, help maintain healthy teeth and are, therefore, toothfriendly”, and “dental health”. The target population is assumed to be the general population. In the context of the proposed wordings, conditions of use, and

references provided, the Panel assumes that the claimed effects refer to the maintenance of tooth mineralisation by decreasing tooth demineralisation. The Panel considers that maintaining tooth mineralisation by reducing tooth demineralisation resulting from acid production in plaque caused by the fermentation of carbohydrates is a beneficial physiological effect, provided that it is not accompanied by tooth demineralisation resulting from erosive properties of a food.

A claim on the sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose and maintenance of tooth mineralisation by decreasing tooth demineralisation has already been assessed with a favourable outcome. The Panel considers that the scientific substantiation and proposed conditions of use also apply to intense sweeteners.

#### **KEY WORDS**

Intense sweeteners, body weight, post-prandial glycaemic responses, blood glucose, tooth, mineralisation, health claims.

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**BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION**

See Appendix A

**TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION**

See Appendix A

**EFSA DISCLAIMER**

See Appendix B

## INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006<sup>4</sup> submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out<sup>5</sup>. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The food constituents that are the subject of the health claims are “table top sweeteners and foods beverages containing intense sweeteners”, “foods in general, in particular confectionery, soft beverages, water-ice, chocolate-type products, table-top sweeteners and certain foods for a particular nutritional use”, “foods in general, particularly sugar-free chewing gum, candies, chocolate-type products and other confectionery; soft beverages and sports beverages, flavored water and table top sweeteners”, “aspartame sucrose substitute”, and “low calorie sweetener / table-top sweetener (granular & tablets - sucralose based)”.

In the context of the proposed wordings and conditions of use, the Panel assumes that the food constituent that is the subject of the health claims is intense sweeteners, which should replace sugars in foods and beverages in order to obtain the claimed effects.

Intense sweeteners are substances with an intense sweet taste and with no energy value that are used to replace sugars in foods. Intense sweeteners (e.g. acesulfame K; aspartame; cyclamic acid and its sodium and calcium salts; saccharin and its sodium, potassium and calcium salts; sucralose; neohesperidine DC and thaumatin) vary in their chemical composition. This evaluation applies to the intense sweeteners authorised for addition to foods (Annex of Directive 94/35/EC<sup>6</sup>), according to Regulation (EC) No 1333/2008<sup>7</sup>. Intense sweeteners can be measured in foods by established methods.

The Panel considers that the food constituents, intense sweeteners, which are the subject of the health claims, are sufficiently characterised in relation to the claimed effects.

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<sup>4</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

<sup>5</sup> EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

<sup>6</sup> Directive 94/35/EC of the European Parliament and Council of 30 June 1994 on sweeteners for use in foodstuffs. OJ L 237, 10.9.1994, p. 3-12.

<sup>7</sup> Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16-33.

## **2. Relevance of the claimed effect to human health**

### **2.1. Contribution to the maintenance or achievement of a normal body weight (ID 1136, 1444, 4299)**

The claimed effects are “weight management”, “weight control including weight loss”, and “intense sweeteners help to maintain a healthy body weight; intense sweeteners help to control calorie intake”. The Panel assumes that the target population is the general population.

Weight management can be interpreted as the contribution to maintenance of a normal body weight. In this context, weight loss in overweight individuals without achieving a normal body weight is considered to be a beneficial physiological effect.

The Panel considers that contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.

### **2.2. Reduction of post-prandial glycaemic responses (ID 4298)**

The claimed effect is “intense sweeteners have no effect on carbohydrate metabolism or short or long term blood glucose”. The Panel assumes that the target population is individuals who wish to reduce their post-prandial glycaemic responses.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the reduction of post-prandial glycaemic responses.

Post-prandial glycaemia is interpreted as the elevation of blood glucose concentrations after consumption of a food and/or meal. This elevation is a normal physiological response that varies in magnitude and duration, and which may be influenced by the chemical and physical nature of the food or meal consumed, as well as by individual factors (Venn and Green, 2007). Reducing post-prandial glycaemic responses may be beneficial to subjects with, for example, impaired glucose tolerance as long as post-prandial insulinaemic responses are not disproportionately increased. Impaired glucose tolerance is common in the general adult population.

The Panel considers that the reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionately increased) may be a beneficial physiological effect.

### **2.3. Maintenance of normal blood glucose concentrations (ID 1221, 4298)**

The claimed effects are “blood glucose control” and “intense sweeteners have no effect on carbohydrate metabolism or short or long term blood glucose”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal blood glucose concentrations.

The Panel considers that maintenance of normal blood glucose concentrations is a beneficial physiological effect.

### **2.4. Maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 1134, 1167, 1283)**

The claimed effects are “dental health/sweeteners can not be fermented by oral bacteria, they are non-cariogenic”, “foods which under typical conditions of use are neither cariogenic nor erosive, help

maintain healthy teeth and are, therefore, toothfriendly”, and “dental health”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, conditions of use, and references provided, the Panel assumes that the claimed effects refer to the maintenance of tooth mineralisation by decreasing tooth demineralisation.

Demineralisation of tooth tissues can occur following acid production caused by the fermentation of carbohydrates by acid-producing bacteria in dental biofilms. The effect may be balanced by remineralisation when pH is neutralised and a state of calcium and phosphate supersaturation is achieved. If demineralisation is not balanced by remineralisation then net demineralisation of tooth tissues results which, if sustained, can lead to dental caries. Demineralisation of tooth tissues can also occur as a result of consumption of dietary acids in foods or beverages, and frequent consumption can lead to dental erosion. Dental caries and dental erosion are diseases with a high prevalence in the EU.

The Panel considers that maintaining tooth mineralisation by reducing tooth demineralisation resulting from acid production in plaque caused by the fermentation of carbohydrates is a beneficial physiological effect, provided that it is not accompanied by tooth demineralisation resulting from erosive properties of a food.

### **3. Scientific substantiation of the claimed effect**

#### **3.1. Contribution to the maintenance or achievement of a normal body weight (ID 1136, 1444, 4299)**

The evidence provided by consensus opinions/reports from authoritative bodies and by reviews shows that data from both intervention and observational studies comparing high intakes of sugars (mainly as added sugars) to high intakes of starch with respect to weight gain is inconsistent (IoM, 2005; van Dam and Seidell, 2007), and that epidemiological studies do not show a positive association between total sugar intake and obesity (IoM, 2005).

The references provided for the scientific substantiation of the claim included five narrative reviews on the effects of intense sweeteners as sugar replacers on satiety, food intake, body weight and safety aspects which did not provide original data for the scientific substantiation of the claim (Bellisle and Drewnowski, 2007; Benton, 2005; Gougeon et al., 2004; Renwick, 1994; Vermunt et al., 2003).

One systematic review and meta-analysis of 16 intervention studies on the effects of intense sweeteners (i.e. mainly aspartame) as sugar replacers on satiety, energy intake and body weight (de la Hunty et al., 2006) was provided. These references contained all of the human intervention studies submitted individually in the consolidated list.

The meta-analysis by de la Hunty et al. (2006) included a total of 16 studies, of which only 10 had body weight changes as an outcome (Blackburn et al., 1997; Gatenby et al., 1997; Kanders et al., 1988; 1990; Naismith and Rhodes, 1995; Porikos et al., 1977; 1982; Raben et al., 2002; Reid and Hammersley, 1998; Tordoff and Alleva, 1990). These studies evaluated the effects of replacing sucrose with aspartame or other artificial sweeteners (Gatenby et al., 1997; Raben et al., 2002) in solid foods and/or beverages on body weight changes in the context of hypocaloric diets or of no energy restrictions. The Panel notes that in four of the studies (Naismith and Rhodes, 1995; Porikos et al., 1977; 1982; Reid and Hammersley, 1998) the study duration was between 7 and 12 days, which is too short to assess the effects of the intervention on sustained changes in body weight. In addition, some human intervention studies investigated the effect of replacing sugars with artificial sweeteners in beverages only. The Panel considers that no conclusions can be drawn from these studies, and therefore from the meta-analysis, for the scientific substantiation of the claim.



Three human intervention studies examined the effects of replacing sugars with artificial sweeteners in foods and beverages for 10 weeks or longer on body weight in overweight or obese subjects (Gatenby et al., (1997); Kanders et al., (1988) Blackburn et al., (1997)).

In the study by Gatenby et al. (1997), overweight male and female subjects not using reduced-fat (RF) or reduced-sugar (RS) food products were assigned to consume their usual diet (n=18), a diet where full-fat foods were replaced by reduced-fat foods (RF, n=22), or a diet where conventional sucrose-containing foods were replaced by reduced-sucrose (artificially sweetened) foods (RS, n=25), for 10 weeks after a two-week run-in period. Data analysis was based on the population of completers for which appropriate dietary intake data were available (13, 17 and 19 for control, RF and RS groups, respectively). *Post-hoc* power calculations led to a power of 90 % to observe a between-group difference in body weight changes of 0.4 kg. Subjects in the RF group significantly reduced fat intake compared to the RS and control groups (p=0.017), whereas subjects in the RS group significantly reduced sucrose intake compared to the RF and control groups (p=0.049). No differences between groups were observed with respect to energy intake or changes in body weight. Whether reduced sucrose items replaced solid foods, beverages, or both, and to what extent, was not reported. The Panel notes that this study does not show a differential effect on body weight of sucrose-sweetened foods and beverages *vs.* reduced (artificially sweetened) sucrose foods and beverages.

The study by Kanders et al. (1988) was designed to assess the effects of adding aspartame-sweetened foods and beverages to a low fat, hypocaloric diet for 12 weeks on compliance and weight loss. A total of 59 obese subjects (10 men) were randomised to consume aspartame-sweetened foods (e.g. puddings) and beverages (milkshakes, diet beverages), or to abstain from them, during 12 weeks in the context of a low-energy diet for weight loss. Changes in body weight did not differ significantly between groups for either males or females (results for the whole study sample combined were not provided). The Panel notes that this study does not show a differential effect on body weight of sucrose-sweetened foods and beverages *vs.* reduced (artificially sweetened) sucrose foods and beverages. In an abstract published two years later, Kanders et al. (1990) reported on the 46 subjects who participated in a 12-month weight maintenance period after the 12-week intervention. The Panel notes that this weight maintenance phase was not controlled for aspartame intake, that comparisons between intervention and control groups were not reported, that body weight changes were not reported, and that details on the statistical analysis used were not provided. The Panel considers that no conclusions can be drawn from the weight maintenance phase of this study for the scientific substantiation of the claim.

In a study by Blackburn et al. (1997), 163 obese women were randomised to either consume or abstain (control) from aspartame-sweetened foods and beverages during 16 weeks of a 19-week multidisciplinary weight loss program, a one-year maintenance program, and a two-year follow-up period. The no aspartame group was asked to use up to 50 g of sugar or honey as daily sweetener. No differences in body weight loss were observed between the aspartame and control groups during the active weight loss phase (-9.9±6.1 kg *vs.* -9.8±6.5, corresponding to about -10 % of initial body weight in both groups). During the weight maintenance phase, the aspartame group regained less weight than the control group (2.6 % *vs.* 5.4 % of initial body weight). Although a direct statistical comparison between groups is not reported in this paper, the meta-analysis by de la Hunty et al. (2006) reported no statistically significant differences between groups (p=0.143). When all study participants were considered together, a greater percentage of weight loss from baseline was predicted by randomisation to the aspartame group (p=0.05), but percentage weight loss was positively correlated with physical exercise (r=0.32, p=0.005) and self-reported eating control (r=0.37, p=0.0001), rather than with aspartame intake (r=0.19, p=0.07). As reported physical exercise and energy intake was not different between groups, the differences observed in body weight changes are difficult to explain. However, the Panel notes that dietary records in overweight subjects are not reliable to assess energy intake as they tend to closely report prescribed energy intakes. The Panel notes that the later phase (i.e after follow-up) of the study was uncontrolled. During the study, no

differences were found between groups with respect to desire for sweets or hunger. Whether aspartame consumption replaced sugar predominantly in foods or in beverages, and to what extent, is not reported. The Panel notes that this study does not support a differential effect on body weight of sucrose-sweetened foods and beverages *vs.* reduced (artificially sweetened) sucrose foods and beverages.

The Panel notes that three human intervention studies did not show an effect of replacing sugars by artificial sweeteners in foods and beverages on body weight in overweight and obese subjects, and that no studies which addressed the effects of replacing sugars by artificial sweeteners in foods and beverages on body weight in normal weight subjects were provided.

There is some evidence from epidemiological and intervention studies that high intake of sugars in the form of sugar-sweetened beverages might contribute to body weight gain (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010). However, the Panel notes that the effect on body weight of replacing sugars by intense sweeteners in beverages only is not the subject of the health claim evaluated in this opinion.

In weighing the evidence, the Panel took into account that data from both intervention and observational studies comparing high intakes of sugars (mainly as added sugars) to high intakes of starch with respect to weight gain is inconsistent, that epidemiological studies do not show a positive association between total sugar intake and obesity, and that three human intervention studies did not show an effect on body weight of replacing sugars by intense sweeteners in foods and beverages.

The Panel concludes that a cause and effect relationship has not been established between total sugar intake and body weight gain, and that a cause and effect relationship has not been established between the consumption of foods and beverages in which sugars have been replaced by intense sweeteners and contribution to the maintenance or achievement of a normal body weight.

### **3.2. Reduction of post-prandial blood glucose responses (ID 4298)**

A claim on the sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose and reduction of post-prandial blood glucose responses has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011).

The Panel considers that the scientific substantiation and proposed conditions of use also apply to intense sweeteners.

### **3.3. Maintenance of normal blood glucose concentrations (ID 1221, 4298)**

Some of the references provided for the scientific substantiation of the claim reported on human intervention studies which were unrelated to the claimed effect, (i.e. assessed the effects of sucralose on post-prandial blood glucose responses). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

One human study investigated the effect of a modified diet containing both a fat replacer (beta-glucan derived from oats) and the intense sweetener sucralose compared to a diet containing fructose on blood glucose concentrations (Reyna et al., 2003). The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of a claim on intense sweeteners alone.

In the study by Cooper et al. (1988), the effects of a usual diet for blood glucose control supplemented with either 28 g sucrose (sucrose diet) or with 30 g starch and saccharin (saccharin diet) for six weeks each on fasting blood glucose and insulin concentrations were assessed in 17 non-insulin dependent

diabetic patients following a randomised, cross-over design. The Panel notes that fasting blood glucose and insulin concentrations are not appropriate outcome measures of long-term blood glucose control. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

In the study by Grotz et al. (2003), 128 subjects with type 2 diabetes were randomly assigned to receive either placebo (cellulose) capsules (n=69) or 667 mg encapsulated sucralose (n=67) daily for 13 weeks. Glycated haemoglobin (HbA1c), fasting plasma glucose and fasting serum C-peptide were measured approximately every two weeks to evaluate blood glucose homeostasis. The Panel notes that in this study sucralose was compared to cellulose, and that such comparison does not allow drawing conclusions on the effect of replacing sugar (sucrose) with sucralose on the maintenance of normal blood glucose concentrations.

The evidence provided by consensus opinions/reports from authoritative bodies and by reviews shows that consumption of intense sweeteners in the diet in replacement of sucrose at the amounts likely to be consumed in a meal or day is unlikely to have an impact on blood glucose control in diabetic subjects (American Diabetes Association, 2002; Gougeon et al., 2004).

No human intervention studies on the effects on long-term blood glucose control of replacing sucrose with intense sweeteners in a food, meal or diet have been provided in the consolidated list.

The Panel concludes that a cause and effect relationship has not been established between the consumption of foods and beverages in which sugars have been replaced by intense sweeteners and maintenance of normal blood glucose concentrations.

### **3.4. Maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 1134, 1167, 1283)**

A claim on the sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose and maintenance of tooth mineralisation by decreasing tooth demineralisation has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011).

The Panel considers that the scientific substantiation and proposed conditions of use also apply to intense sweeteners.

## **CONCLUSIONS**

On the basis of the data presented, the Panel concludes that:

- The food constituents that are the subject of the health claims are intense sweeteners, which should replace sugars in foods and beverages in order to obtain the claimed effects. Intense sweeteners are sufficiently characterised in relation to the claimed effects.

### **Contribution to the maintenance or achievement of a normal body weight (ID 1136, 1444, 4299)**

- The claimed effects are “weight management”, “weight control including weight loss”, and “intense sweeteners help to maintain a healthy body weight; intense sweeteners help to control calorie intake”. The target population is assumed to be the general population. Contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.

- A cause and effect relationship has not been established between total sugar intake and body weight gain, and a cause and effect relationship has not been established between the consumption of foods and beverages in which sugars have been replaced by intense sweeteners and contribution to the maintenance or achievement of a normal body weight.

#### **Reduction of post-prandial glycaemic responses (ID 4298)**

- The claimed effect is “intense sweeteners have no effect on carbohydrate metabolism or short or long term blood glucose”. The target population is assumed to be individuals who wish to reduce their post-prandial glycaemic responses. In the context of the proposed wordings, it is assumed that the claimed effect refers to the reduction of post-prandial glycaemic responses. Reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionately increased) may be a beneficial physiological effect.
- A claim on the sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose and reduction of post-prandial glycaemic responses has already been assessed with a favourable outcome. The scientific substantiation and proposed conditions of use also apply to intense sweeteners.

#### **Maintenance of normal blood glucose concentrations (ID 1221, 4298)**

- The claimed effects are “blood glucose control” and “intense sweeteners have no effect on carbohydrate metabolism or short or long term blood glucose”. The target population is assumed to be the general population. Maintenance of normal blood glucose concentrations is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of foods and beverages in which sugars have been replaced by intense sweeteners and maintenance of normal blood glucose concentrations.

#### **Maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 1134, 1167, 1283)**

- The claimed effects are “dental health/sweeteners can not be fermented by oral bacteria, they are non-cariogenic”, “foods which under typical conditions of use are neither cariogenic nor erosive, help maintain healthy teeth and are, therefore, toothfriendly”, and “dental health”. The target population is assumed to be the general population. Maintaining tooth mineralisation by reducing tooth demineralisation resulting from acid production in plaque caused by the fermentation of carbohydrates is a beneficial physiological effect, provided that it is not accompanied by tooth demineralisation resulting from erosive properties of a food.
- A claim on the sugar replacers xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose and maintenance of tooth mineralisation by decreasing tooth demineralisation has already been assessed with a favourable outcome. The scientific substantiation and proposed conditions of use also apply to intense sweeteners.

#### **DOCUMENTATION PROVIDED TO EFSA**

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1873, EFSA-Q-2008-1875, EFSA-Q-2008-1906, EFSA-Q-2008-1959, EFSA-Q-2008-2021, EFSA-Q-2008-2181, EFSA-Q-2010-00251, EFSA-Q-2010-00252). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

## REFERENCES

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## APPENDICES

### APPENDIX A

#### BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods<sup>8</sup> (hereinafter "the Regulation") entered into force on 19<sup>th</sup> January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

#### ISSUES THAT NEED TO BE CONSIDERED

##### IMPORTANCE AND PERTINENCE OF THE FOOD<sup>9</sup>

Foods are commonly involved in many different functions<sup>10</sup> of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

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<sup>8</sup> OJ L12, 18/01/2007

<sup>9</sup> The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

<sup>10</sup> The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

#### **SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE**

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

#### **WORDING OF HEALTH CLAIMS**

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to



describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

## **TERMS OF REFERENCE**

### **HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH**

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity

consumed.

- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

## **APPENDIX B**

### **EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to intense sweeteners, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1134	<p>Table top sweeteners and foods, beverages containing intense sweeteners</p> <p><u>Clarification provided</u></p> <p>Table top sweeteners (as defined in Regulation 1333/2008*) and foods and beverages containing intense sweeteners**</p> <p>*Article 3.2(g) of Regulation (EC) 1333/2008 on food additives: "Table-top sweeteners shall mean preparations of permitted sweeteners, which may contain other food additives and/or food ingredients and which are intended for sale to the final consumer as a substitute for sugars."</p> <p>** Intense sweeteners as permitted for use in foodstuffs according to Directive 94/35/EC. These include Acesulfame K, Aspartame, Cyclamic acid and its Na and Ca Salts, Saccharin and its Na, K and Ca salts, Sucralose</p> <p>OR</p> <p>Table top sweeteners and foods, beverages containing intense sweeteners:</p> <p>Food or beverage shall not lower plaque pH below 5,7 by bacterial fermentation during, and up to 30 min after consumption, as determined by plaque pH telemetry (US 21CFR§101.80) or other comparable methods</p>	<p>Dental health/ sweeteners can not be fermented by oral bacteria, they are non-cariogenic.</p>	<p>Intense sweeteners are non-cariogenic; intense sweeteners do not promote tooth decay; this table top sweetener is safe for teeth.</p>
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Food or beverage shall not lower plaque pH below 5,7 by bacterial fermentation during, and up to 30 min after consumption, as determined by plaque pH telemetry (US 21CFR§101.80) or other comparable methods.</li> </ul>			

ID	Food or Food constituent	Health Relationship	Proposed wording
1136	<p>Table top sweeteners and foods beverages containing intense sweeteners</p> <p><u>Clarifications provided</u></p> <p>Table top sweeteners (as defined in Regulation 1333/2008*) and foods and beverages containing intense sweeteners**</p> <p>*Article 3.2(g) of Regulation (EC) 1333/2008 on food additives: "Table-top sweeteners shall mean preparations of permitted sweeteners, which may contain other food additives and/or food ingredients and which are intended for sale to the final consumer as a substitute for sugars."</p> <p>** Intense sweeteners as permitted for use in foodstuffs according to Directive 94/35/EC. These include Acesulfame K, Aspartame, Cyclamic acid and its Na and Ca Salts, Saccharin and its Na, K and Ca salts, Sucralose</p> <p>OR</p> <p>Table top sweeteners and foods, beverages containing intense sweeteners:</p> <p>Food or beverage shall not lower plaque pH below 5,7 by bacterial fermentation during, and up to 30 min after consumption, as determined by plaque pH telemetry (US 21CFR§101.80) or other comparable methods</p>	Weight management	<p>-intense sweeteners help to maintain a healthy body weight;</p> <p>-intense sweeteners help to control calorie intake.</p>
<p><b>Conditions of use</b></p> <p>- In an energy restricted diet</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
1167	Foods in general, in particular confectionery, soft beverages, water-ice, chocolate-type products, table-top sweeteners	Foods which under typical conditions of use are neither cariogenic nor erosive, help maintain healthy teeth and	Toothfriendly [pictorial claim]

<p>and certain foods for a particular nutritional use.</p> <p><u>Clarification provided</u></p> <p>"The toothfriendly trademark and the accompanying claim "toothfriendly" signifies that the respective food is not causing harm to the teeth. The claim is thus truthful for each consumed food that complies with the stated criteria, i.e. the claim is not tied to a specific ingredient of the food. Hence, there is no minimum amount of food required to achieve the claimed benefit and there is no dose-response relationship.</p>	<p>are, therefore, toothfriendly.</p>	
<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- "(a) Foods which, under usual conditions of consumption, do not lower the pH of the dental plaque below 5.7, are non-cariogenic (pH measurement in vivo in the interproximal space by means of an indwelling electrode) " "(b) Foods which, under usual conditions of consumption, do not expose the plaque-free tooth surface to more than 40 µmol H+ x min are non-erosive on the tooth surface (measurement in vivo with plaque-free electrode in the oral fluid)</li> </ul> <p>Only foods which comply with the criteria (a) and (b) are ""toothfriendly"".</p> <p>Sugarfree foods are not always and necessarily toothfriendly, because they may contain non-sugar, fermentable carbohydrates or excessive amounts of food acids with an erosive effect. The claim ""toothfriendly"" (or similar expressions) can, therefore, not simply be tied to the absence of sugar or the presence of sugar substitutes (polyols). The toothfriendly property depends upon the food's overall composition and some other characteristics. Therefore, it is best tested for each food applying the standardized tests mentioned under (a) and (b) above.</p> <p>The toothfriendly property of a food is an inherent characteristic that does not depend upon the amount of food consumed."</p> <ul style="list-style-type: none"> <li>- The Happy Tooth symbol can be used in the packaging descriptions of products that do not cause cavities or damage tooth enamel.</li> </ul> <p>The symbol is often used by tooth-friendly products, but juices, sorbets and sweeteners can also meet the criteria. The symbol is only granted to products that</p> <ul style="list-style-type: none"> <li>a) do not lower the pH level of plaque below 5.7 in conjunction with normal use (pH is measured in vivo from the area between two teeth using an electrode attached to the tooth surface.</li> <li>b) do not expose the tooth enamel to more than 40 µmol H+ x min in conjunction with normal use (this is measured in vivo from the saliva using an electrode attached to the tooth surface).</li> </ul> <p>Only products that meet criteria a) and b) are tooth-friendly.</p> <p>Use of the symbol is not tied to a specific raw material in the products, such as xylitol. In theory, a product with added xylitol can be harmful to the teeth.</p> <p>Unsweetened products are not always and automatically tooth-friendly, because they can contain sugar-like carbohydrates that cause cavities. Similarly, foods can include large amounts of (lemon, etc.) acids, which have a wearing effect on tooth enamel.</p>		

	<p>The health claim “tooth-friendly” (or a similar claim) can not directly refer to the sugar-free nature of the product or to the presence of certain sweeteners added to the product, such as xylitol. The tooth-friendliness of foods is based on the product’s complete recipe and other properties (for example, size).</p> <p>- A standardised test based on criterion a) or b) and which is used by the faculties of dentistry at several European universities must be used to determine the tooth-friendliness of the product.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1221	<p>Table top sweeteners and foods beverages containing intense sweeteners</p> <p><u>Clarification provided</u></p> <p>Table top sweeteners (as defined in Regulation 1333/2008*) and foods and beverages containing intense sweeteners**</p> <p>*Article 3.2(g) of Regulation (EC) 1333/2008 on food additives: "Table-top sweeteners shall mean preparations of permitted sweeteners, which may contain other food additives and/or food ingredients and which are intended for sale to the final consumer as a substitute for sugars."</p> <p>** Intense sweeteners as permitted for use in foodstuffs according to Directive 94/35/EC. These include Acesulfame K, Aspartame, Cyclamic acid and its Na and Ca Salts, Saccharin and its Na, K and Ca salts, Sucralose</p>	Blood glucose control	<p>-intense sweeteners have no effect on carbohydrate metabolism, short or long-term blood glucose control or insulin secretion;</p> <p>-product [x] assists in blood glucose control.</p>
	<p><b>Conditions of use</b></p> <p>- Food has no significant impact on blood glucose or insulin.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1283	<p>Foods in general, particularly sugar-free chewing gum, candies, chocolate-type products and other confectionery; soft beverages and sports beverages, flavored water and table top sweeteners.</p> <p><u>Clarification provided</u></p> <p>Foods in general, particularly chewing gum, candies,</p>	Dental health	<p>Tooth friendly</p> <p>Tooth friendly logo</p>

	chocolate-type products and other confectionery; soft beverages and sports beverages, flavored water and table top sweeteners. The food shall, under usual conditions of consumption (a) not lower the pH of the dental plaque below 5.7 (pH measurement in vivo in the interproximal space by means of an indwelling electrode) and (b) not expose the plaque-free tooth surface to more than 40 $\mu\text{mol H}^+$ x min (measurement in vivo with plaque-free electrode in the oral fluid).		
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- The food shall, under usual conditions of consumption (a) not lower the pH of the dental plaque below 5.7 (pH measurement in vivo in the interproximal space by means of an indwelling electrode) and (b) not expose the plaque-free tooth surface to more than 40 <math>\mu\text{mol H}^+</math> x min (measurement in vivo with plaque-free electrode in the oral fluid).</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1444	Aspartame sucrose substitute	Weight control, including weight loss	Weight control /management is helped by using foods and beverages sweetened with Aspartame in place of foods and beverages sweetened with sugar.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Should be consumed as part of a calorie controlled diet.</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
4298	<p>Name of Food product: Low Calorie Sweetener / Table-top Sweetener (Granular &amp; tablets - sucralose based)</p> <p>Description of food in terms of food legislation categories: food not covered by specific food legislation</p> <p>Was food on Irish market before 1st July 2007: Yes</p>	<p>Health benefits of food: intense sweeteners have no effect on carbohydrate metabolism or short or long term blood glucose</p> <p>Do benefits relate to a disease risk factor: No</p> <p>Target group: All of the general population including children and adults</p>	<p>Exact wording of claim as it appears on product: Suitable for people with diabetes within their healthy dietary plan / as part of a healthy diet and lifestyle.</p> <p>Examples of any alternative wording that may be used in relation to claim: Splenda has no effect on carbohydrate metabolism or short or long term blood glucose</p> <p>Splenda low calorie sweetener has no effect on short or long term blood glucose or insulin secretion</p> <p>Splenda can assist in blood glucose control</p>



			Is claim a picture: No
<p><b>Conditions of use</b></p> <p>- Number of nutrients/other substances that are essential to claimed effect: 1. Names of nutrient/other substances and Quantity in Average daily serving: 0.1 grams Sucralose. Weight of average daily food serving: 1 gram. Daily amount to be consumed to produce claimed effect: 1 gram. Number of food portions this equates to in everyday food portions: 2. Are there factors that could interfere with bioavailability: No. Length of time after consumption for claimed effect to become apparent: benefits on use. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Yes. State the maximum limit in mg/kg body weight/day: 15.00. Potential adverse health effects: N/A It is extremely unlikely that consumer would exceed the ADI. see FSAI report on intake). Describe subgroups this limit applies to: all sub groups. Where applicable outline nutritional composition (g per 100g) of food: Total Fat: .00, Saturated Fat: .00, Trans Fat: .00, Sugar: 6.90, Salt: .00, Sodium: .00. Other conditions for use: Food has no significant effect on blood glucose or insulin</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
4299	<p>Name of Food product: Low Calorie Sweetener / Table-top Sweetener (Granular &amp; tablets - sucralose based)</p> <p>Description of food in terms of food legislation categories: food not covered by specific food legislation</p> <p>Was food on Irish market before 1st July 2007: Yes</p>	<p>Health benefits of food: intense sweeteners help to maintain a healthy body weight; intense sweeteners help to control calorie intake</p> <p>Do benefits relate to a disease risk factor: No</p> <p>Target group: All of the general population including children and adults</p>	<p>Exact wording of claim as it appears on product: Splenda can help with slimming as part of a calorie controlled diet.</p> <p>Splenda is also suitable for those following a low carbohydrate diet. In France, 'peut contribuer a une reduction de l'apport calorique quotidien'</p> <p>Examples of any alternative wording that may be used in relation to claim: Splenda low calorie sweetener can help to maintain a healthy body weight as part of a calorie-controlled diet. Splenda low calorie sweetener helps to control calorie intake as part of a calorie controlled diet.</p> <p>Is claim a picture: No</p>
<p><b>Conditions of use</b></p> <p>- Number of nutrients/other substances that are essential to claimed effect: 1. Names of nutrient/other substances and Quantity in Average daily serving: 0.1 gram sucralose. Weight of average daily food serving: 1 gram. Daily amount to be consumed to produce claimed effect: 1 gram. Number of food portions this equates to in everyday food portions: 2. Are there factors that could interfere with bioavailability: No. Length of time after consumption for claimed effect to become apparent: Benefits on use. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Yes. State the maximum limit in mg/kg body weight/day: 15.00. Potential adverse health effects: N/A It is extremely unlikely that a consumer would exceed the ADI (see FSAI report on intake). Describe subgroups this limit applies to: all sub groups. Where applicable outline nutritional composition (g per 100g) of food: Total Fat: .00, Saturated Fat: .00, Trans Fat: .00, Sugar: 6.90, Salt: .00, Sodium: .00. Other conditions for use: requires a calorie controlled diet</p>			

## GLOSSARY AND ABBREVIATIONS

HbA1c	Glycated haemoglobin
RF	Reduced-fat
RS	Reduced-sugar