Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to L-Carnitine-L-tartrate for use in foods for particular nutritional uses

(adopted on 3 November 2003 by written procedure)

SUMMARY

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) has been asked to evaluate L-carnitine-L-tartrate as a source of L-carnitine for use in the manufacture of foods for particular nutritional uses. L-carnitine and L-carnitine hydrochloride are already permitted for use in foods for particular nutritional uses, including infant formulae, follow-on formulae, processed cereal-based foods and baby foods for infants and young children.

The evaluation was conducted in the context of proposed uses in foods for particular nutritional uses that might result in intakes of L-carnitine-L-tartrate of 1.5 - 3g/day in adults. L-carnitine-L-tartrate readily dissociates into L-carnitine and L-tartaric acid in the gastrointestinal tract. A human study has confirmed that the bioavailability of L-carnitine from L-carnitine-L-tartrate is similar to L-carnitine given as the free base. The upper value of 3g for intake of L-carnitine-L-tartrate would yield 1g of tartaric acid. This is equivalent to an intake of 16 mg tartaric acid/kg bodyweight/day for a 60kg adult, which is around half the Acceptable Daily Intake for tartaric acid of 0 – 30 mg/kg bodyweight. Human tolerance of L-carnitine-L-tartrate up to 5g/day has been established in adults with respect to gastrointestinal symptoms, haematology and clinical chemistry, including markers of liver and kidney function; this is equivalent to 2g/day L-carnitine. Further assurance that this amount would be unlikely to cause gastrointestinal distress is available from human tolerance studies on L-carnitine given as the free base, in which gastrointestinal distress has only been reported after consumption of 4 - 6g/day.

The petitioners’ proposed use levels of L-carnitine-L-tartrate in soy-based infant formulae (1.2 mg L-carnitine/100kcal) would give daily intakes of 7.2 mg L-carnitine and 3.6 mg tartaric acid for 3-month-old infants. This intake of tartaric acid from infant formula would be equivalent to 0.6 mg/kg bodyweight/day.

Based on the proposed levels of use and the dissociation of L-carnitine-L-tartrate into L-carnitine and L-tartaric acid, the Panel concluded that L-carnitine-L-tartrate is not of concern from the safety point of view as a source of L-carnitine for use in foods for particular nutritional uses, provided the Acceptable Daily Intake for tartaric acid from all sources in the diet is not regularly exceeded.

KEY WORDS

L-carnitine-L-tartrate, L-carnitine, tartaric acid, foods for particular nutritional uses, infant formula

http://www.efsa.eu.int/p_foodadd_en.html
BACKGROUND

The Scientific Committee on Food (SCF) was asked in November 2001 to consider the safety of a number of substances as sources of nutrients for foods for particular nutritional uses (FPNUs). Due to deficiencies in the original dossiers submitted, the evaluations could not be completed under the SCF mandate and continuation of this work now falls to the EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food. L-carnitine-L-tartrate as a source of L-carnitine was one of the substances.

L-carnitine and its hydrochloride were previously approved by the SCF as a nutrient for inclusion in infant formulae and follow-on formulae and in processed cereal-based foods and baby foods for infants and young children (SCF, 1989, 1991a). Accordingly they are listed in the relevant Commission Directives, 91/321/EEC and 96/5/EC (EC, 1991,1996). A detailed rationale for the nutritional requirement for L-carnitine in the pre-weaning infant can be found in the SCF opinion of 1989. In its opinion of 2003, the SCF reiterated its approval of the addition of L-carnitine to infant formula based on soy protein isolate and hydrolysed protein, but did not consider it necessary to add L-carnitine to cows’ milk-based formula or to follow-on formula (SCF, 2003). L-carnitine and its hydrochloride are also included in Commission Directive 2001/15/EC as substances that may be added to FPNUs (EC, 2001). The present paper therefore concerns only the safety of an alternative requested source of L-carnitine, that is, L-carnitine-L-tartrate.

A request for the use of L-carnitine-L-tartrate for use in infant formula only was first submitted to the European Commission some years ago (Lonza AG, 1994). The data submitted comprised an acute oral toxicity study in rats, an Ames test for mutagenicity, and a skin irritation test in rabbits. The request was considered by the SCF, but in its 1999 PARNUTS opinion it was stated that “No biological information has been submitted concerning L-carnitine-L-tartrate. No evaluation is therefore possible of the acceptability of its use in FPNUs.” (SCF, 1999). A further request for use of L-carnitine-L-tartrate was submitted by another petitioner, containing a new study on absorption of L-carnitine-L-tartrate in humans, but with no indication of proposed uses (IDACE, 2001). A further submission has now been received on behalf of the manufacturer Lonza AG (Bioresco, 2003a). The submission conforms to the SCF guidance on submissions for safety evaluation of sources of nutrients (SCF, 2001b). For completeness, not just the new information but all the relevant information and studies now available from petitioners are reviewed below.

L-carnitine was also considered by the SCF as a foodstuff for particular nutritional uses intended to meet the expenditure of intense muscular effort and especially for sportsmen (SCF, 2001a). The SCF concluded that the available information, including controlled studies in humans during exercise, did not support commercial claims that carnitine supplementation helps weight loss and improves physical performance.

TERMS OF REFERENCE

The Commission asks the European Food Safety Authority to provide a scientific opinion, based on its consideration of the safety and bioavailability of the nutrient source, L-carnitine-L-tartrate, when used in the manufacture of foods for particular nutritional uses.
ASSESSMENT

Chemistry

L-carnitine-L-tartrate is the salt of L-carnitine base with tartaric acid with the formula (C\(_7\)H\(_{16}\)NO\(_3\))\(_2\).C\(_4\)H\(_4\)O\(_6\). It is a crystalline powder, with a melting point of 169-175°C, consisting of approximately 68% L-carnitine and 32% L-tartaric acid (see Table 1). It has a molecular weight of 472.5 and CAS Registry Number 36687-82-8. The chemical name is:

3-carboxy-2-hydroxy-N,N,N-trimethyl-(2R)-1-propanaminium,
2:1 salt with (2R,3R)-2,3-dihydroxybutanedioic acid

Its structural formula is:

Specifications

Specifications have been provided by the petitioner (Bioresco, 2003a) and these are shown in Table 1, together with those for L-carnitine for comparison. The purity criteria correspond to those for L-carnitine in the European Pharmacopoeia 4th Edition and in the Food Chemicals Codex 4th Edition and to those for L-tartaric acid in Commission Directive 96/77/EC. A maximum content for D-carnitine has been introduced because D-carnitine does not fulfill the biochemical function of L-carnitine and is antagonistic to L-carnitine.

Table 1: Specifications for L-carnitine-L-tartrate provided by the petitioner

<table>
<thead>
<tr>
<th>Parameter</th>
<th>L-carnitine</th>
<th>L-carnitine-L-tartrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Crystalline powder</td>
<td>Crystalline powder</td>
</tr>
<tr>
<td>Colour</td>
<td>White</td>
<td>White</td>
</tr>
<tr>
<td>L-carnitine [%]</td>
<td>99-101</td>
<td>67.2 - 69.2</td>
</tr>
<tr>
<td>L-tartaric acid [%]</td>
<td></td>
<td>30.8 - 32.8</td>
</tr>
<tr>
<td>D-carnitine [%]</td>
<td>&lt;0.5</td>
<td>&lt;0.35</td>
</tr>
<tr>
<td>Specific rotation [°]</td>
<td>-32.0 to 30.0</td>
<td>-11.0 to 9.5</td>
</tr>
<tr>
<td>Total ash [%]</td>
<td>&lt;0.1</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Water [%]</td>
<td>&lt;1.0</td>
<td>&lt;0.5</td>
</tr>
<tr>
<td>Heavy metals (as Pb) [ppm]</td>
<td>&lt;10</td>
<td>&lt;10</td>
</tr>
<tr>
<td>Lead [ppm]</td>
<td>≤1</td>
<td>≤1</td>
</tr>
<tr>
<td>Aerobic, mesophilic bacteria [CFU/g]</td>
<td>≤50</td>
<td>≤50</td>
</tr>
</tbody>
</table>
Analyses of 8 batches said to be representative of L-carnitine-L-tartrate were in compliance with the above specifications.

**Manufacturing process**

The manufacturing process has been described by the petitioner as follows (Bioresco, 2003a). L-carnitine-L-tartrate is synthesised commercially from food grade L-carnitine and L-tartaric acid. An aqueous solution of crystalline L-carnitine is concentrated under vacuum at \(\leq 50^\circ C\), diluted with ethanol and seeded with crystals of food grade L-carnitine-L-tartrate. Tartaric acid dissolved in absolute ethanol is added slowly to the L-carnitine solution and maintained at 47-55\(^\circ\)C. The solution is cooled to 4\(^\circ\)C and centrifuged. The L-carnitine-L-tartrate crystals are separated from the mother liquor, dried under vacuum at 45-55\(^\circ\)C and stored in polythene bags in airtight drums. The process is performed under Current Good Manufacturing Practice.

**Methods of analysis in food**

Since it dissociates completely on dissolution in water, L-carnitine-L-tartrate can be measured by quantitation of L-carnitine and L-tartaric acid (Schmidbaur et al., 1998).

**Reaction and fate in foods, stability**

According to the petitioner, no interactions of L-carnitine-L-tartrate with food components are known (Bioresco, 2003a). It is stable for 3 years or more if completely protected from humidity. If stored in humid conditions, L-carnitine, and to a lesser extent its salts, may form trimethylamine (TMA) by decomposition. This has a fishy, ammoniacal odour and its presence is undesirable. For sensory reasons, the petitioner has a limit of 5mg/kg TMA in L-carnitine-L-tartrate.

The stability of L-carnitine-L-tartrate under conditions of dry heating and the recovery of L-carnitine during baking of bread have also been investigated (Bioresco, 2003b). When heated dry for 1 hour at 210\(^\circ\)C, conditions that are harsher than those that occur during normal food processing, only about 25% of L-carnitine-L-tartrate remained intact. When L-carnitine was added to a standard dough mixture, either in the form of the tartrate or the hydrochloride, leavened for 1 hour at 32\(^\circ\)C and then baked at 210\(^\circ\)C for 1 hour, 91% of the L-carnitine added as the tartrate and 90% of the L-carnitine added as the hydrochloride was recovered in the bread. Additional studies showed that the disappearance of about 10% of the L-carnitine was due to incomplete analytical recovery rather than chemical degradation.

**Case of need and proposed uses**

The petitioner has proposed the following uses for L-carnitine-L-tartrate:

- Soy-based infant formula and follow-on formula.
- Processed cereal-based foods and baby foods for infants and young children.
- Foods for athletes.
- Foods for energy restricted diets.
- Foods for people with an insufficient dietary supply of L-carnitine.
L-carnitine is extremely hygroscopic and not suitable for use in dry formulations. L-carnitine hydrochloride has a very low pH in aqueous solutions and in dry formulations the hydrochloric acid can result in unwanted reactions if heated. In contrast, L-carnitine-L-tartrate is non-hygroscopic, is stable for long periods in air and has a higher pH in aqueous solution. Thus, according to the petitioner (Bioresco, 2003a), the proposed use of L-carnitine-L-tartrate in powdered infant formula has the technical advantage of increased shelf-life stability. It is also said to be suitable for use in capsules, tablets, cereal bars produced by baking and other solid foods. It is said to be odourless with a pleasant taste.

L-carnitine-L-tartrate is proposed by the petitioner for use in foods for athletes in amounts of up to 1000 mg per one-day quantity. It is also proposed by the petitioner for use in foods for energy restricted diets, because protein sources in meal replacements are usually low in, or free from L-carnitine, and for use in foods for people with an insufficient dietary supply of L-carnitine. No specific daily amounts were proposed for either of these uses or for cereal-based foods or baby foods but the petitioner has suggested amounts of 1 - 2 g L-carnitine/day, corresponding to 1.5 - 3 g/day of L-carnitine-L-tartrate, should be considered for FPNUs (Bioresco, 2003a).

**Exposure**

L-carnitine-L-tartrate does not occur naturally in foods but both L-carnitine and L-tartaric acid do.

**L-carnitine in the diet**

The average non-vegetarian diet provides up to 100 mg L-carnitine daily, or up to 300 mg in high meat eaters (Borum, 1983; Lennon et al., 1986; Feller and Rudman, 1988). The richest sources are from meat, sheep muscle containing the most at around 207 mg/100 g, with milk, rice and bread being lesser sources (Scholte and de Jonge, 1987). Carnitine homeostasis is maintained by absorption from dietary sources, a modest rate of biosynthesis and highly efficient reabsorption of carnitine in the kidney (Rebouche and Seim, 1998). Estimates of the amount of L-carnitine absorbed from the diet vary from about 30 - 40% (Harmeyer, 2000) to 54 - 87% (Rebouche and Seim, 1998). The petitioner has proposed that an intake of 1 g/day could equate to 2.0 - 2.5% of the total body pool of 15-20 g L-carnitine (Harmeyer, 2000). However, there are data to suggest that oral absorption of L-carnitine given as bolus doses of 2 - 2.5 g/day is lower than that of dietary carnitine (Rebouche, 1991; Baker et al., 1992), and that increasing degradation of unabsorbed L-carnitine to trimethylamine and γ-butyrobetaine by intestinal bacteria occurs as the oral bolus dose increases (Rebouche and Seim, 1998). The body can synthesise carnitine from lysine and methionine and this is the origin of most of the body carnitine in strict vegetarians (Rebouche and Seim, 1998), whereas in meat eaters the diet contributes most to body carnitine levels. 98% of the body’s carnitine pool is located in skeletal muscle and heart.

**L-tartaric acid in the diet**

Tartaric acid occurs naturally in fruits and wine (120-180 mg/100 ml) and L-tartaric acid and its salts are approved as food additives, with acidulant, antioxidant synergist, buffer and sequestrant functions. Typical products in which they are used are baking powder, biscuits and jam. No estimates of total daily intake for L-tartaric acid from the diet were
provided by the petitioner. The Acceptable Daily Intake (ADI) for tartaric acid is 0 – 30 mg/kg bodyweight (bw) (JECFA, 1977, 1978; SCF, 1991b, 1994).

**Exposure estimates for L-carnitine-L-tartrate**

The petitioner suggests that for use in FPNUs an exposure of 1 - 2 g/day L-carnitine, corresponding to 1.5 - 3 g/day of L-carnitine-L-tartrate, should be considered. Three g of L-carnitine-L-tartrate contains 960 mg of L-tartaric acid, equivalent to an intake of 16 mg L-tartaric acid/kg bw/day for a 60 kg person.

The highest intakes of L-carnitine-L-tartrate on a body weight basis will be in young infants on formula as their sole source of nutrition. The petitioner has confirmed (Bioresco, 2003c) that the minimum recommended amount of L-carnitine in infant formula for nutritional uses recommended by the SCF (SCF, 2003) of 1.2 mg/100kcal would be used. A 3-month-old infant weighing 6 kg requires a daily energy intake of 600 kcal (100 kcal/kg bw). If the minimum recommended amount of L-carnitine is provided by the addition of L-carnitine-L-tartrate, a 3-month-old infant will consume the equivalent of 6 x 1.2 mg L-carnitine, i.e. 7.2 mg L-carnitine and 3.6 mg L-tartaric acid. This intake of tartaric acid from infant formula would be equivalent to 0.6 mg/kg bw/day.

**Existing authorisations and evaluations**

L-carnitine and L-carnitine hydrochloride were approved by the SCF for use in infant formula, follow-on formula and processed cereal-based and baby foods for infants and young children (SCF, 1989, 1991a) No maximum use levels are laid down in the relevant EC directives.

L-carnitine-L-tartrate was considered by the Conseil Supérieur d’hygiène publique de France in 1997 and approved in France in 1998 for use in infant foods up to 15.4 mg L-carnitine/litre and in foods for particular nutritional uses up to 100 mg L-carnitine/1000 kcal (Journal Officiel, no.37, p.2298, 13-02-1998).

L-carnitine-L-tartrate has self-determined GRAS status in the USA for use in infant formulae, diets high in medium chain triglycerides, foods that mimic L-carnitine-rich foods but are low in carnitine and foods that have lost L-carnitine through processing. The GRAS panel recommended that intakes of up to 20 mg/kg bw/day were safe for adults since there are a few reports from human tolerance studies that higher intakes occasionally result in gastrointestinal disturbances (Blumenthal et al., 1993). It has been sold in the USA under this GRAS status since 1993.

Both the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the SCF have allocated L-tartaric acid and its salts a Group ADI of 0-30 mg/kg bw/day, expressed as the acid (JECFA, 1977, 1978; SCF, 1991b, 1994). The ADI is based on lack of toxicity at the highest dose level tested (about 3g/kg bw/day) in a chronic toxicity/carcinogenicity study in rats, with the application of a 100-fold safety factor.
**Biological and toxicological data**

**Bioavailability and bioequivalence of L-carnitine from L-carnitine-L-tartrate**

Bioequivalence of L-carnitine-L-tartrate to L-carnitine and L-carnitine hydrochloride with respect to L-carnitine can be assumed from the complete dissociation of L-carnitine-L-tartrate upon dissolution, as demonstrated by optical rotation and conductivity measurements and ion chromatography (Schmidbaur et al., 1998). In addition, intake of L-carnitine as a 2 g bolus dose produces a similar increase in serum L-carnitine whether administered as free base or as the L-tartrate salt (see later under “Human data” for full description of this study) (Sewell and Böhles, 2000, 2001).

**Toxicity data on L-carnitine-L-tartrate**

**Acute oral toxicity**

An acute oral gavage toxicity test with L-carnitine-L-tartrate in rats showed no effects at a limit dose of 5000 mg/kg bw (IBR, 1991a).

**Mutagenicity**

A gene mutation test was performed with L-carnitine-L-tartrate in Salmonella Typhimurium strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100 (IBR, 1991b). It was tested at concentrations of 1.6, 8, 40, 200, 1000 and 5000 µg/plate, without and with metabolic activation using rat liver S9 mix. There were two independent experiments using the plate incorporation method. No toxicity was observed up to the maximum dose tested. There was no evidence of gene mutation.

**Human data on L-carnitine-L-tartrate**

**Absorption**

A study comparing the absorption of carnitine base with that of L-carnitine-L-tartrate, carnitine fumarate and acetyl carnitine has been conducted (Sewell and Böhles, 2000, 2001). Five healthy male volunteers aged between 26 and 53 years, were monitored for carnitine excretion for 24 h before the trials. Consumption of meat and dairy products was not allowed for 24 h prior to or during the trials. After an overnight fast, each subject was given single bolus doses each of the carnitine preparations, equivalent to 2g of free L-carnitine, ingested in 50 ml of water. Blood samples were collected from an indwelling catheter at intervals of 0, 0.5, 1.0, 1.5, 2, 3, 4, 10 and 24 h after ingestion. Urine was collected during the trials. Total carnitine (TC), free carnitine (FC) and acylated carnitine were measured in serum and urine, with a detection limit of 5 µmol/L and an inter-assay precision at 40 µmol/L of 5.7%.

All preparations were highly soluble and easily ingested and no subjects complained of adverse effects. The pattern of absorption of L-carnitine-L-tartrate was very similar to that of carnitine base, as reflected in the TC and FC concentration-time curves, which did not differ significantly. Both curves peaked around 4 h after ingestion and returned almost to baseline values by 24 h. AUCs were similar for L-carnitine-L-tartrate and carnitine base for both TC and FC. There were slightly higher median levels of TC and FC following L-carnitine-L-tartrate compared with carnitine base. Acylcarnitine levels...
were within normal range for each time point and the acylcarnitine/FC ratios were normal. Mass spectrometry revealed no abnormal acylcarnitine species, in particular no tartrylcarnitine which would be indicative of tartryl-CoA formation. Urinary organic acid analysis showed no increase in tartaric acid. In contrast, absorption of carnitine fumarate was much less than that of carnitine base and acetylated carnitine scarcely increased baseline TC or FC levels at all.

**Tolerance study**

A tolerance study has been conducted on L-carnitine-L-tartrate in 10 healthy male volunteers, using a random, double-blind, cross-over design, with a one-week washout period (Rubin et al., 2001). L-carnitine-L-tartrate or cellulose placebo was ingested orally as capsules in 2 daily doses of 1.5 g each, taken with meals for 3 weeks. Blood samples were taken at the end of the 3-week period. There were no gastrointestinal effects, no changes in standard haematological or clinical chemistry parameters and no effects on markers of hepatic or renal function.

**Toxicity data on L-carnitine hydrochloride**

Several studies on the safety of L-carnitine hydrochloride were submitted by the petitioner (Bioresco, 2003a). The safety of L-carnitine itself has already been accepted by the SCF and the safety of L-carnitine hydrochloride is not relevant to the safety of L-carnitine-L-tartrate as a source of L-carnitine. Therefore the studies are not further discussed.

**Human tolerance studies on L-carnitine**

Several human tolerance studies on L-carnitine have been conducted indicating that intakes up to 15 g/day were usually tolerated without intestinal side effects. Mild laxative effects were observed in a few cases (Borum and Fisher, 1983; Zhou et al., 1997; Lurz and Fischer, 1998; Brass, 2000). Dosages of L-carnitine causing gastrointestinal distress such as diarrhoea are said to range from 4 - 6 g/day (Rubin et al., 2001).

**Discussion**

Although the available animal, *in vitro* and human studies on L-carnitine-L-tartrate are limited, safety can be inferred from the absorption and excretion study in humans, which showed that that L-carnitine-L-tartrate is dissociated within the gastrointestinal tract and absorbed as free L-carnitine and tartaric acid. The amount of L-carnitine absorbed into the systemic circulation when L-carnitine-L-tartrate is given is similar to that absorbed when L-carnitine is given as the free base.

Dietary intakes of L-carnitine are estimated to range from 100 up to 300 mg/day, depending on the amount of meat in the diet. For FPNUs in general, the petitioner has suggested intakes of L-carnitine of the order of 1 - 2 g/day, which equates to 1.5 - 3 g/day of L-carnitine-L-tartrate.

The only adverse effects noted in humans taking L-carnitine supplements have been gastrointestinal in nature and are said to occur in some subjects consuming 4 - 6 g L-carnitine/day as bolus doses. Much higher levels of L-carnitine (up to 15 g/day) were tolerated without gastrointestinal effects in most subjects. No gastrointestinal distress
was found in the one human tolerance study on L-carnitine-L-tartrate at doses of 3 g/day, equivalent to 2g/day of L-carnitine or 33 mg/kg bw/day as L-carnitine. Thus, intakes of L-carnitine-L-tartrate up to 3 g/day seem unlikely to cause gastrointestinal effects.

The ADI for tartaric acid and its salts is 0 - 30 mg/kg bw. The possible contribution of L-carnitine-L-tartrate in FPNUs to overall adult intakes of tartaric acid would be around 1 g from 3 g of L-carnitine-L-tartrate, equivalent to an intake of 16 mg/kg bw/day for a 60 kg person. This intake of tartaric acid should ideally be assessed alongside other already permitted food additive uses of tartaric acid and its sodium and potassium salts (E334-337). These are permitted additives in the EU for use in foods generally at quantum satis levels (Commission Directive 95/2/EC) but no estimates of daily intake are available. Since the ADI is based on the highest level tested in a chronic rat study, which was non-toxic, the projected additional intake from FPNUs could be judged as unlikely to present any safety problems, even if some people occasionally exceed the ADI.

Addition of L-carnitine-L-tartrate to soy-based infant formula to provide the minimum recommended daily amount of L-carnitine, would result in an intake of tartaric acid equivalent to 0.6 mg/kg bw/day for a 3-month-old infant taking formula as its sole source of nutrition. There are no a priori reasons to assume that tartaric acid would have adverse effects in infants and tartaric acid and its salts are permitted additives in weaning foods (biscuits and rusks, up to 5g/kg as a residue) for infants and young children in good health (EC, 1995).

**CONCLUSIONS AND RECOMMENDATIONS**

Based on the proposed levels of use and the dissociation of L-carnitine-L-tartrate into L-carnitine and L-tartaric acid, it is concluded that L-carnitine-L-tartrate as a source of L-carnitine for use in foods for particular nutritional uses is not of concern from the safety point of view.

It is noted that use of L-carnitine-L-tartrate will add to the intake of tartaric acid and that proposed uses in foods for particular nutritional uses might give rise to intakes of L-carnitine-L-tartrate of 1.5 – 3 g/day. For an adult, this intake would be equivalent to about half the ADI for tartaric acid, which is acceptable provided that the ADI of 0 – 30 mg/kg bw for tartaric acid from all sources is not regularly exceeded.

The petitioners’ proposed use levels of L-carnitine-L-tartrate in soy-based infant formulae (1.2 mg L-carnitine/100kcal) would give daily intakes of 7.2 mg L-carnitine and 3.6 mg tartaric acid for 3-month-old infants. In the case of infants, exposure to tartaric acid from the use of L-carnitine-L-tartrate in infant formulae would not exceed 0.6 mg/kg bw/day.

Human tolerance of L-carnitine-L-tartrate up to 3g/day has been established in adults with respect to gastrointestinal symptoms, haematology and clinical chemistry, including markers of liver and kidney function; this is equivalent to 2g/day L-carnitine. Further assurance that this amount would be unlikely to cause gastrointestinal distress is available from human tolerance studies on L-carnitine given as the free base, in which gastrointestinal distress has only been reported after consumption of 4 - 6g/day.
DOCUMENTATION PROVIDED TO EFSA

Letter from the European Commission to the Chairman of the Scientific Committee on Food on “Evaluation of a number of substances added for specific nutritional uses in foods for particular nutritional uses” dated 03/12/2002, Brussels. SCF/CS/ADD/NUT/50.


REFERENCES


SCIENTIFIC PANEL (AFC) MEMBERS