

## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to branched-chain amino acids (BCAA) and growth or maintenance of muscle mass (ID 442, 444, 445, 447, 448, 451, 1478), attenuation of the decline in muscle power following exercise at high altitude (ID 443), faster recovery from muscle fatigue after exercise (ID 447, 448, 684,1478), improvement of cognitive function after exercise (ID 446), reduction in perceived exertion during exercise (ID 450) and “healthy immune system” (ID 449) 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 branched-chain amino acids and growth or maintenance of muscle mass, attenuation of the decline in muscle power following exercise at high altitude, faster recovery from muscle fatigue after exercise, improvement of cognitive function after exercise, reduction in perceived exertion during exercise and “healthy immune system”. 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.

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<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-1229, EFSA-Q-2008-1230, EFSA-Q-2008-1231, EFSA-Q-2008-1232, EFSA-Q-2008-1233, EFSA-Q-2008-1234, EFSA-Q-2008-1235, EFSA-Q-2008-1236, EFSA-Q-2008-1237, EFSA-Q-2008-1238, EFSA-Q-2008-1471, EFSA-Q-2008-2215, adopted on 10 September 2010.

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<sup>3</sup> Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Weight Management/Satiety/Glucose and Insulin Control/Physical Performance: Kees de Graaf, Joanne Harrold, Mette Hansen, Mette Kristensen, Anders Sjödin and Inge Tetens.

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The food constituent that is the subject of the health claims is branched-chain amino acids (BCAA). The Panel considers that branched-chain amino acids is sufficiently characterised.

### **Growth or maintenance of muscle mass**

The claimed effects are “reduces protein breakdown after exercise”, “increases protein synthesis”, “recovery/increased protein synthesis in skeletal muscle during recovery from sustained strength exercise” and “muscle metabolism”. The target population is assumed to be the general population. The Panel considers that growth or maintenance of muscle mass is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of BCAA and growth or maintenance of muscle mass over and above the well established role of protein on the claimed effect.

### **Attenuation of the decline in muscle power following exercise at high altitude**

The claimed effect is “attenuates the decline in power output following exercise at high altitude”. The target population is assumed to be active individuals performing high altitude training. The Panel considers that attenuation of the decline in muscle power following exercise at high altitude is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of BCAA and attenuation of the decline in muscle power following exercise at high altitude.

### **Faster recovery from muscle fatigue after exercise**

The claimed effects are “muscle metabolism” and “promotes muscle recovery after exercise”. The target population is assumed to be active individuals in the general population. In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to recovery from muscle fatigue after the performance of physical exercise. The Panel considers that faster recovery from muscle fatigue after exercise is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of BCAA and faster recovery from muscle fatigue after exercise.

### **Improvement of cognitive function after exercise**

The claimed effect is “improves mental performance after exercise”. The target population is assumed to be the general population. In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect relates to improving cognitive function after exercise. The Panel considers that improvement of cognitive function after exercise is a beneficial physiological effect.

In weighing the evidence, the Panel noted that only one study using a small number of volunteers showed a significant effect of BCAA consumption compared to a non-isocaloric placebo on one of the cognitive endpoints measured and that two studies which compared the effect of BCAA-containing

drinks to non-isocaloric placebo drinks did not show any significant effect of BCAA on the cognitive endpoints measured.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of BCAA and improvement of cognitive function after exercise.

### **Reduction in perceived exertion during exercise**

The claimed effect is “BCAAs improve performance during sustained exercise”. The target population is assumed to be active individuals in the general population. In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to a reduction in perceived exertion during exercise. The Panel considers that a reduction in perceived exertion during exercise is a beneficial physiological effect.

The Panel notes that in the only human study provided which addressed the effect of BCAA consumption on perceived exertion during exercise the number of subjects recruited was small, and that the study was not adequately controlled for energy intake (i.e. energy content of the BCAA drink was higher than that of placebo), which could have accounted for the differences in RPE observed between groups, all of which greatly limit the conclusions that can be drawn from this study for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of BCAA and a reduction in perceived exertion during exercise.

### **“Healthy immune system”**

The claimed effect is “help maintain a healthy immune system”. The target population is assumed to be the general population. The claimed effect is not sufficiently defined and no further details were provided in the proposed wordings. The clarifications provided by Member States refer to the “improvement of some plasma markers of immune response” and the references provided report on changes in a number of biochemical variables related to the immune system following the administration of BCAA. However, the Panel considers that the evidence provided does not establish that changes in these immune parameters are *per se* a beneficial physiological effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of BCAA and a beneficial physiological effect related to a “healthy immune system”.

### **KEY WORDS**

Branched-chain amino acids, protein, muscle, physical performance, cognitive function, health claims.

## TABLE OF CONTENTS

Summary .....	1
Table of contents .....	4
Background as provided by the European Commission .....	5
Terms of reference as provided by the European Commission .....	5
EFSA Disclaimer.....	5
Information as provided in the consolidated list .....	6
Assessment .....	6
1. Characterisation of the food/constituent .....	6
2. Relevance of the claimed effect to human health.....	6
2.1. Growth or maintenance of muscle mass (ID 442, 444, 445, 447, 448, 451, 1478) .....	6
2.2. Attenuation of the decline in muscle power following exercise at high altitude (ID 443).....	7
2.3. Faster recovery from muscle fatigue after exercise (ID 447, 448, 684, 1478) .....	7
2.4. Improvement of cognitive function after exercise (ID 446) .....	7
2.5. Reduction in perceived exertion during exercise (ID 450).....	7
2.6. “Healthy immune system” (ID 449) .....	8
3. Scientific substantiation of the claimed effect .....	8
3.1. Growth or maintenance of muscle mass (ID 442, 444, 445, 447, 448, 451, 1478) .....	8
3.2. Attenuation of the decline in muscle power following exercise at high altitude (ID 443).....	9
3.3. Faster recovery from muscle fatigue after exercise (ID 447, 448, 684, 1478) .....	9
3.4. Improvement of cognitive function after exercise (ID 446) .....	10
3.5. Reduction in perceived exertion during exercise (ID 450).....	11
Conclusions .....	12
Documentation provided to EFSA .....	13
References .....	13
Appendices .....	15
Glossary and Abbreviations .....	24

**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 subjects of the health claims are proteinogenic branched-chain amino acids (BCAA), which are amino acids having aliphatic side-chains that are non-linear, i.e., leucine, isoleucine and valine. The content of BCAA in foods can be measured by established methods.

Leucine, isoleucine and valine are indispensable amino acids provided by mixed dietary protein intakes from different sources. A claim on protein and growth or maintenance of muscle mass has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2010).

BCAA can also be consumed as food supplements. Different mixtures are available in the market. From the references and conditions of use provided in relation to the health claims considered in this opinion, the Panel assumes that the food constituent under evaluation is BCAA consumed in addition to adequate protein intakes.

The Panel considers that the food constituent, branched chain amino acids, which is the subject of the health claims, is sufficiently characterised.

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

#### 2.1. Growth or maintenance of muscle mass (ID 442, 444, 445, 447, 448, 451, 1478)

The claimed effects are “reduces protein breakdown after exercise”, “increases protein synthesis”, “recovery/increased protein synthesis in skeletal muscle during recovery from sustained strength exercise” and “muscle metabolism”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect relates to the growth or maintenance of muscle mass by either decreasing muscle breakdown, increasing muscle

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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> Briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims: <http://www.efsa.europa.eu/en/ndameetings/docs/nda100601-ax01.pdf>

synthesis or both. Failure to increase muscle mass during growth and development, and the loss of muscle mass at any age, will reduce muscle strength and power.

The Panel considers that growth or maintenance of muscle mass is a beneficial physiological effect.

## **2.2. Attenuation of the decline in muscle power following exercise at high altitude (ID 443)**

The claimed effect is “attenuates the decline in power output following exercise at high altitude”. The Panel assumes that the target population is active individuals performing high altitude training.

Maintaining muscle power may be beneficial during every day life activities at high altitude, and is beneficial for athletic performance in disciplines where loss of muscle power reduces performance at high altitude.

The Panel considers that attenuation of the decline in muscle power following exercise at high altitude is a beneficial physiological effect.

## **2.3. Faster recovery from muscle fatigue after exercise (ID 447, 448, 684, 1478)**

The claimed effects are “muscle metabolism” and “promotes muscle recovery after exercise”. The Panel assumes that the target population is active individuals in the general population.

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to recovery from muscle fatigue after the performance of physical exercise.

Fatigue can be defined as the loss of peak force or power output. Therefore, muscle fatigue recovery can be defined as regaining maximal muscle strength or muscle power after strenuous exercise, which has induced muscle fatigue. Regaining muscle strength/power may be beneficial during every day life activities and it is beneficial for athletic performance in disciplines where loss of muscle strength and power reduce performance.

The Panel considers that faster recovery from muscle fatigue after exercise is a beneficial physiological effect.

## **2.4. Improvement of cognitive function after exercise (ID 446)**

The claimed effect is “improves mental performance after exercise”. The Panel assumes that the target population is active individuals in the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect relates to improving cognitive function after exercise. Cognitive function includes memory, attention (concentration), learning, intelligence and problem solving, which are well defined constructs and can be measured by validated psychometric cognitive tests.

The Panel considers that improvement of cognitive function after exercise is a beneficial physiological effect.

## **2.5. Reduction in perceived exertion during exercise (ID 450)**

The claimed effect is “BCAAs improve performance during sustained exercise”. The Panel assumes that the target population is active individuals in the general population.

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to a reduction in perceived exertion during exercise.

The Panel considers that a reduction in perceived exertion during exercise is a beneficial physiological effect.

## 2.6. “Healthy immune system” (ID 449)

The claimed effect is “help maintain a healthy immune system”. The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined and no more details were provided in the proposed wordings. The clarifications provided by Member States refer to the “improvement of some plasma markers of immune response”, and the references provided report on changes in a number of biochemical variables related to the immune system following the administration of BCAA. However, the Panel considers that the evidence provided does not establish that changes in these immune parameters are *per se* a beneficial physiological effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of BCAA and a beneficial physiological effect related to a “healthy immune system”.

## 3. Scientific substantiation of the claimed effect

### 3.1. Growth or maintenance of muscle mass (ID 442, 444, 445, 447, 448, 451, 1478)

A number of references provided reported on human intervention studies which investigated the effects of BCAA mixtures on measures of physical capacity, physical performance, muscle soreness, muscle fatigue, plasma and muscle concentrations of BCAA, protein synthesis and/or protein breakdown in which changes in muscle mass were not measured. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

Two human intervention studies, which aimed to investigate the effects of BCAA on surrogate measures of muscle mass (i.e. muscle cross-sectional area estimated from skin fold thickness and circumference measurements), were provided (Bigard et al., 1996; Schena et al., 1992).

The study by Bigard et al. (1996) tested the effect of BCAA supplement (BCAA, 7.8 g/d leucine, 3.4 g/d isoleucine and 11.2 g/d valine, corresponding to 35 %, 15 % and 50 % of total BCAA, respectively, 49 % energy from carbohydrate, 13 % from protein, 38 % from fat, n=11) *versus* a carbohydrate supplement (control, 98 % energy from carbohydrate, n=11) on surrogate measures of muscle mass in the arm in highly trained subjects who participated in six successive sessions of ski mountaineering (6-8 hr duration, altitude 2,500-4,100 m). The energy content of the total diet was controlled. The protein content in the diets including the supplements was 1.2 g per kg body weight per day in the control group and 1.44 g per kg body weight per day in the BCAA group. In the study by Schena et al. (1992) with a similar design, the effect of a BCAA supplement (BCAA, 7.8 g/d leucine, 3.4 g/d isoleucine and 11.2 g/d valine, corresponding to 35 %, 15 % and 50 % of total BCAA, 49 % energy from carbohydrate, 13 % from protein, 38 % from fat, n=4) *versus* a carbohydrate supplement (control, 98 % energy from carbohydrate, n=5) on surrogate measures of muscle mass in the arm and thigh was tested during altitude acclimatisation (21-day trekking). The Panel notes that the design of these small studies does not allow any conclusions to be drawn on the effects of BCAA independently of higher protein intakes and that direct comparisons between the intervention (BCAA) and control groups regarding the outcome variables were not reported. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of BCAA and growth or maintenance of muscle mass over and above the well established role of protein on the claimed effect.

### **3.2. Attenuation of the decline in muscle power following exercise at high altitude (ID 443)**

The scientific evidence provided in the consolidated list on the effects of branched chain amino acids on attenuation of the decline in muscle power following exercise at high altitude consisted of 18 references of which 16 were not pertinent to the claimed effect either because muscle power was not reported or exercise was not performed at high altitude. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

Two intervention studies investigated the effects of BCAA on muscle power during exercise performed at high altitude (Bigard et al., 1996; Schena et al., 1992). These studies have been described in detail in section 3.1.

In the study by Bigard et al. (1996), peak power output during an incremental bicycle exercise was tested, whereas in the study by Schena et al. (1992) lower limb muscle power estimated by repeated maximal jump during altitude acclimatisation (21-day trekking) was assessed. The Panel notes that the design of these small studies does not allow any conclusions to be drawn on the effects of BCAA independently of higher protein intakes and that direct comparisons between the intervention (BCAA) and control groups regarding the outcome variables were not reported. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of BCAA and attenuation of the decline in muscle power following exercise at high altitude.

### **3.3. Faster recovery from muscle fatigue after exercise (ID 447, 448, 684, 1478)**

Most of the references provided in relation to this claim reported on intervention studies which did not assess recovery of maximal muscle strength or power after strenuous exercise (but rather other outcomes such as perceived exertion during exercise or measures of physical capacity, physical performance, muscle soreness, muscle fatigue, plasma and muscle concentrations of BCAA, protein synthesis and/or protein breakdown) or where the effect of a mixture of amino acids, and not only BCAA, was investigated, as in Sugita et al. (2003) and Ohtani et al. (2006). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

The remaining six references consisted of one review (Blomstrand et al., 1996) and five intervention studies (Shimomura et al., 2006; Crowe et al., 2006; Watson et al., 2004; Bigard et al., 1996; Schena et al., 1992). Two of the intervention studies were performed at high altitude and have been described in section 3.2 (Bigard et al., 1996; Schena et al., 1992).

In a small randomised, controlled, double-blinded study by Crowe et al. (2006), 13 competitive outrigger canoeists were tested before and after 6 weeks daily supplementation containing either leucine (45 mg/kg body weight/day, n=6) or cornflour (45 mg/kg body weight/day, n=7). Before and after the intervention the following tests were performed: upper body 10 s power test and a row to exhaustion at 70–75 % maximal aerobic power. The Panel notes that a test of muscle fatigue recovery was not included as an outcome parameter, and that the study was not performed with the food constituents that are the subject of the health claim (e.g. a BCAA mixture). The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claimed effect.

In a randomised double-blinded cross-over study by Watson et al. (2004) the effect of a sugar-free fruit drink containing 12 g/L BCAA (6 g/L leucine, 3 g/L valine, and 3 g/L isoleucine) supplementation was tested compared to placebo (sugar-free fruit drink). Eight glycogen-depleted men participated and ingested 250 mL (placebo or BCAA) at 30 min intervals, the last 2 h prior to exercise, and 150 mL every 15 min throughout cycling to exhaustion in a warm environment (30°C). BCAA ingestion had no effect on exercise capacity (placebo 104±27 min; BCAA 111±29 min,  $p=0.13$ ). Because differences in muscle strength and power recovery between groups were not reported, the Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claimed effect.

In a randomised, controlled, blinded cross-over study 16 women and 14 men ingested a BCAA mixture (5 g, Ile:Leu:Val = 1:2.3:1.2), which also contained 1 g of green tea powder and 1.2 g of an energy-free sweetener, or a placebo solution containing the same ingredients as the BCAA solution, but substituting 5 g dextrin for the BCAAs (Shimomura et al., 2006). The solutions were ingested 15 min before a strenuous exercise protocol intended to induce muscle fatigue. Muscle fatigue was evaluated daily using a visual-analogue scale (self-reported) up to five days post-exercise. No significant differences in (self-reported) fatigue between the BCAA and placebo groups were observed. Because changes in objective measures of muscle fatigue recovery (e.g. differences in muscle strength and power recovery) between groups were not reported, the Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of BCAA and faster recovery from muscle fatigue after exercise.

### **3.4. Improvement of cognitive function after exercise (ID 446)**

A total of 21 references were provided to substantiate the claimed effect, including two textbooks, two narrative reviews and 17 human studies.

One textbook described the transport mechanisms of BCAA into the brain. The second textbook provided general information on brain nutrients. One narrative review and 11 human studies addressed the effect of BCAA consumption on muscle metabolism and physical performance. The second narrative review did not address the food constituent which is the subject of the health claims. Two human studies investigated the effect of BCAA consumption on immune parameters. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

A total of five human intervention studies addressed the effect of BCAA consumption on relevant endpoints for the claimed effect.

Two of the studies were randomised double-blind placebo-controlled trials where the effect of a BCAA drink on cognitive function, compared to a control drink, was assessed (Blomstrand et al., 1991a, b). In the first study, the subjects ( $n=16$ ) received either a BCAA drink (50 % valine, 35 % leucine, 15 % isoleucine in a 5 % carbohydrate solution providing 7.5 g BCAA/ subject) or a placebo drink (5 % carbohydrate solution) during a 30 km cross-country race (Blomstrand et al., 1991a). In the second study, six female subjects were given either a 6 % carbohydrate drink containing BCAA (7.5 g/L, 40 % valine, 35 % leucine, 25 % isoleucine) or a 6 % carbohydrate solution (placebo) during two games of soccer (cross-over) (Blomstrand et al., 1991b). The Stroop Colour and Word Test (CWT) was used to assess the cognitive performance before and after physical exercise in both studies. The Panel notes that the designs of these small studies, where the treatment and control drinks were not isocaloric, limit the conclusions that can be drawn on the specific effect of BCAA, and that direct comparisons between the intervention (BCAA) and control groups regarding the outcome

variables were not reported. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claimed effect.

In an article from Hassmen et al. (1994), the results of two studies on the effect of BCAA supplementation during a 30 km competitive run on post-run cognitive performance were reported. The studies involved 23 and 29 subjects, who were randomly assigned to an experimental group (receiving a BCAA drink (40 % valine, 35 % leucine, 25 % isoleucine in a 7 % carbohydrate solution), providing 5.3 g of BCAA/subject) or a placebo group (receiving a 7 % carbohydrate solution) respectively. The Stroop Colour and Word Test (CWT) or five paper-and-pencil tests were respectively used to assess the cognitive performance before and after physical exercise. The two-way ANOVA revealed no significant main effects of treatment compared to placebo in both studies. The Panel notes that the differences in energy content between the treatment and control drinks in these studies, which used a small number of subjects to evaluate multiple endpoints, greatly limits the conclusions that can be drawn for the scientific substantiation of the claimed effect.

In another randomised double-blind placebo-controlled cross-over trial, seven endurance-trained cyclists were given 150-200 mL of either a solution of BCAA (7 g/L of BCAA (40 % valine, 35 % leucine and 25 % isoleucine), lemon flavour, salts, citric acid and artificial sweetener; corresponding to 90 mg BCAA/kg body weight/subject) or flavoured water (placebo; containing lemon flavour, salts, citric acid and artificial sweetener in slightly different proportions), before and every 15 min during an 80 min exercise (60 min 70 %  $VO_{2max}$  + 20 min maximal effort) (Blomstrand et al., 1997). The subjects were given the CWT after the end of the exercise, in order to assess their cognitive performance. The performance in the colour task of CWT was significantly improved in the treatment group compared to the placebo group (83.2 (74-97) *versus* 78.9 (62-97)  $p < 0.05$  for BCAA *versus* placebo; Wilcoxon's signed rank test was applied because of skewed distribution of data in this small sample). For the word and colour-word tasks, no difference was detected between the treatment and placebo groups. The Panel notes that the treatment and placebo drinks were not isocaloric and the use of a non-isocaloric control might explain the significant decrease in muscle glycogen observed in the control group compared with the treatment group. The Panel notes that the number of subjects recruited was small and that the difference in energy intake and glycogen utilisation between the treatment and placebo groups greatly limits the conclusions that can be drawn for the scientific substantiation of the claimed effect.

In weighing the evidence, the Panel noted that only one study using a small number of volunteers showed a significant effect of BCAA consumption compared to a non-isocaloric placebo on one of the cognitive endpoints measured and that two studies which compared the effect of BCAA-containing drinks to non-isocaloric placebo drinks did not show any significant effect of BCAA on the cognitive endpoints measured.

The Panel concludes that a cause and effect relationship has not been established between the consumption of BCAA and improvement of cognitive function after exercise.

### **3.5. Reduction in perceived exertion during exercise (ID 450)**

Only one of the two references provided for the scientific substantiation of this claim addressed the effects of BCAA on perceived exertion during exercise (Blomstrand et al., 1997).

In a randomised double-blind placebo-controlled crossover intervention (Blomstrand et al., 1997), seven endurance-trained cyclists were given 150-200 mL of either a solution of BCAA (7 g/L of BCAA (40 % valine, 35 % leucine and 25 % isoleucine), corresponding to 90 mg BCAA/kg body weight) or flavoured water (placebo) before and every 15 min during an 80 min exercise (60 min 70 %  $VO_{2max}$  + 20 min at maximal effort). Every 10 min during exercise the subjects rated their perceived exertion on the 15 degree (6 to 20) category scale developed and validated by Borg (1970).

The area under the curve for ratings of perceived exertion (RPE) during the 60 min period of exercise at fixed work rate was significantly lower in the intervention group compared to placebo (-7 %). No significant differences were observed between groups with respect to RPE during the last 20 min of exercise performed at maximal intensity. The Panel notes that the number of subjects recruited was small, and that the study was not adequately controlled for energy intake (i.e. energy content of the BCAA drink was higher than that of placebo), which could have accounted for the differences in RPE observed between groups, all of which greatly limit the conclusions that can be drawn from this study for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of BCAA and a reduction in perceived exertion during exercise.

## CONCLUSIONS

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

- The food constituent, branched chain amino acids, which is the subject of the health claims, is sufficiently characterised.

### **Growth or maintenance of muscle mass (ID 442, 444, 445, 447, 448, 451, 1478)**

- The claimed effects are “reduces protein breakdown after exercise”, “increases protein synthesis”, “recovery/increased protein synthesis in skeletal muscle during recovery from sustained strength exercise” and “muscle metabolism”. The target population is assumed to be the general population. Growth or maintenance of muscle mass is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of BCAA and growth or maintenance of muscle mass over and above the well established role of protein on the claimed effect.

### **Attenuation of the decline in muscle power following exercise at high altitude (ID 443)**

- The claimed effect is “attenuates the decline in power output following exercise at high altitude”. The target population is assumed to be active individuals performing high altitude training. Attenuation of the decline in muscle power following exercise at high altitude is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of BCAA and attenuation of the decline in muscle power following exercise at high altitude.

### **Faster recovery from muscle fatigue after exercise (ID 447, 448, 684, 1478)**

- The claimed effects are “muscle metabolism” and “promotes muscle recovery after exercise”. The target population is assumed to be active individuals in the general population. Faster recovery from muscle fatigue after exercise is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of BCAA and faster recovery from muscle fatigue after exercise.

### **Improvement of cognitive function after exercise (ID 446)**

- The claimed effect is “improves mental performance after exercise”. The target population is assumed to be active individuals in the general population. Improvement of cognitive function after exercise is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of BCAA and improvement of cognitive function after exercise.

### Reduction in perceived exertion during exercise (ID 450)

- The claimed effect is “BCAAs improve performance during sustained exercise”. The target population is assumed to be active individuals in the general population. A reduction in perceived exertion during exercise is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of BCAA and a reduction in perceived exertion during exercise.

### “Healthy immune system” (ID 449)

- The claimed effect is “help maintain a healthy immune system”. The target population is assumed to be the general population. The clarifications provided by Member States refer to the “improvement of some plasma markers of immune response” and the references provided report on changes in a number of biochemical variables related to the immune system following the administration of BCAA. However, the evidence provided does not establish that changes in these immune parameters are *per se* a beneficial physiological effect.
- The Panel concludes that a cause and effect relationship has not been established between the consumption of BCAA and a beneficial physiological effect related to a “healthy immune system”.

### DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1229, EFSA-Q-2008-1230, EFSA-Q-2008-1231, EFSA-Q-2008-1232, EFSA-Q-2008-1233, EFSA-Q-2008-1234, EFSA-Q-2008-1235, EFSA-Q-2008-1236, EFSA-Q-2008-1237, EFSA-Q-2008-1238, EFSA-Q-2008-1471, EFSA-Q-2008-2215). The scientific substantiation is based on the information provided by the Members 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

- Bigard AX, Lavier P, Ullmann L, Legrand H, Douce P and Guezennec CY, 1996. Branched-chain amino acid supplementation during repeated prolonged skiing exercises at altitude. *The Journal of the International Society of Sports Nutrition*, 6, 295-306.
- Blomstrand E, Hassmen P, Ekblom B and Newsholme EA, 1991a. Administration of branched-chain amino acids during sustained exercise--effects on performance and on plasma concentration of some amino acids. *European Journal of Applied Physiology and Occupational Physiology*, 63, 83-88.
- Blomstrand E, Hassmen P and Newsholme EA, 1991b. Effect of branched-chain amino acid supplementation on mental performance. *Acta Physiologica Scandinavica*, 143, 225-226.
- Blomstrand E, Ek S and Newsholme EA, 1996. Influence of ingesting a solution of branched-chain amino acids on plasma and muscle concentrations of amino acids during prolonged submaximal exercise. *Nutrition*, 12, 485-490.
- Blomstrand E, Hassmen P, Ek S, Ekblom B and Newsholme EA, 1997. Influence of ingesting a solution of branched-chain amino acids on perceived exertion during exercise. *Acta Physiologica Scandinavica*, 159, 41-49.

- Borg G, 1970. Perceived exertion as an indicator of somatic stress. *Scandinavian Journal of Rehabilitation Medicine*, 2, 92-98.
- Crowe MJ, Weatherson JN and Bowden BF, 2006. Effects of dietary leucine supplementation on exercise performance. *European Journal of Applied Physiology*, 97, 664-672.
- EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2010. Scientific Opinion on the substantiation of health claims related to protein and increase in satiety leading to a reduction in energy intake (ID 414, 616, 730), contribution to the maintenance or achievement of a normal body weight (ID 414, 616, 730), maintenance of normal bone (ID 416) and growth or maintenance of muscle mass (ID 415, 417, 593, 594, 595, 715) pursuant to Article 13(1) of Regulation (EC) No 1924/2006, *EFSA Journal*, 8(10):1811, 24 pp.
- Hassmen P, Blomstrand E, Ekblom B and Newsholme EA, 1994. Branched-chain amino acid supplementation during 30-km competitive run: mood and cognitive performance. *Nutrition*, 10, 405-410.
- Ohtani M, Sugita M and Maruyama K, 2006. Amino acid mixture improves training efficiency in athletes. *Journal of Nutrition*, 136, 538-543.
- Schena F, Guerrini F, Tregnaghi P and Kayser B, 1992. Branched-chain amino acid supplementation during trekking at high altitude. The effects on loss of body mass, body composition, and muscle power. *European Journal of Applied Physiology and Occupational Physiology*, 65, 394-398.
- Shimomura Y, Yamamoto Y, Bajotto G, Sato J, Murakami T, Shimomura N, Kobayashi H and Mawatari K, 2006. Nutraceutical effects of branched-chain amino acids on skeletal muscle. *Journal of Nutrition*, 136, 529-532.
- Sugita M, Ohtani M, Ishii N, Maruyama K and Kobayashi K, 2003. Effect of a selected amino acid mixture on the recovery from muscle fatigue during and after eccentric contraction exercise training. *Bioscience, Biotechnology, and Biochemistry*, 67, 372-375.
- Watson P, Shirreffs SM, and Maughan RJ, 2004. The effect of acute branched-chain amino acid supplementation on prolonged exercise capacity in a warm environment. *European Journal of Applied Physiology*, 93, 306-314.

## 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>6</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>7</sup>

Foods are commonly involved in many different functions<sup>8</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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6 OJ L12, 18/01/2007

7 The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

8 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 branched-chain amino acids, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
442	Branched-chain amino acids	Reduces protein breakdown after exercise	BCAAs aids muscle recovery after exercise
			BCAAs reduce muscle breakdown after exercise
BCAAs have an anabolic effect on protein metabolism after exercise			
BCAAs support muscle growth			
<b>Conditions of use</b>			
- 77 mg per kg of bodyweight prior to exercise			
ID	Food or Food constituent	Health Relationship	Proposed wording
443	Branched-chain amino acids	Attenuates the decline in power output following exercise at high altitude	BCAAs reduce the loss of muscle power following high altitude training
			BCAAs help you maintain muscle power following high altitude exposure
<b>Conditions of use</b>			
- 11.5g per day			
ID	Food or Food constituent	Health Relationship	Proposed wording
444	Branched-chain amino acids	Increases protein synthesis	BCAAs increase protein synthesis, a vital part of the muscle-building process
			BCAAs support muscle growth
<b>Conditions of use</b>			
- A total of 100mg per kg of bodyweight during and after exercise			
ID	Food or Food constituent	Health Relationship	Proposed wording
445	Branched-chain amino acids	Recovery. Increased protein synthesis in skeletal muscle during recovery from sustained strength exercise.	Helps in the repair and recovery of muscle tissue after exercise.
			Helps muscle maintenance and recovery following exercise.
			For the growth, development and maintenance of muscles and strength.

			For muscle building during training.
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Claim to be only used for Foods for sportpeople under the Dir. 89/398/EEC</li> <li>- A ratio of 2:1:1 of essential amino acids L-Leucine, l-Isoleucine and L-Valine and an amount of L-leucine 14mg/kg body weight/day, L-Isoleucine 10 mg/kg body weight/day and L-Valine 10 mg/kg body weight/day is to be fulfilled.</li> <li>- Amount of consumption : Immunonutrition</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
446	Branched-chain amino acids	<p>Improves mental performance after exercise</p> <p><u>Clarification provided</u></p> <p>Taking BCAAs during exercise improves several measures of cognitive performance [i.e. affects recognised criteria as measures of cognitive performance, such as shape-rotation and figure-identification tasks]</p>	BCAAs improve mental performance after exercise
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 5.3g during a race</li> <li>- Gesamtbevölkerung</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
447	Branched-chain amino acids	<p>Promotes recovery after exercise</p> <p><u>Clarification provided</u></p> <p>Reduces the muscle damage associated with exercise and decreases 'delayed onset muscle soreness' and muscle fatigue following exercise</p>	BCAAs aid recovery after exercise
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 77 mg per kg of bodyweight before exercise</li> </ul>		
ID	Food or Food constituent	Health Relationship	Proposed wording
448	Branched-chain amino acids	<p>Promotes muscle recovery after exercise</p> <p><u>Clarification provided</u></p> <p>Reduces the muscle damage associated with endurance exercise and decreases 'delayed onset muscle soreness' and muscle fatigue following exercise</p>	BCAAs aids muscle recovery after training
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- 77 mg per kg of bodyweight before exercise</li> </ul>		

ID	Food or Food constituent	Health Relationship	Proposed wording
449	Branched-chain amino acids	<p>Help maintain a healthy immune system</p> <p><u>Clarification provided</u></p> <p>BCAAs improve some plasma markers of immune response during periods of intense training</p>	<p>BCAAs maintain an optimised immune function during training</p> <p>BCAAs provide essential fuel for the immune system</p>
	<p><b>Conditions of use</b></p> <p>- 6 g per day</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
450	Branched-chain amino acids	<p>BCAAs improve performance during sustained exercise</p> <p><u>Clarification provided</u></p> <p>BCAAs reduce perceived exertion during sustained and vigorous aerobic exercise</p>	<p>BCAAs reduce perceived exertion during exercise</p> <p>BCAAs make your workouts feel easier</p>
	<p><b>Conditions of use</b></p> <p>- 90 mg per kg of bodyweight during exercise 90 mg per kg of bodyweight during exercise.</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
451	Branched-chain amino acids (BCAA)	Improvement of muscle recovery after exercise	Improvement of muscle recovery after exercise
	L-leucine L-valine L-isoleucine	Improvement of muscle protein synthesis	Improvement of muscle protein synthesis
<p><b>Conditions of use</b></p> <p>- Sportler–Tagesdosis L-Leucin: 500 mg</p> <p>- Tagesdosis L-Valin: 500 mg–Erwachsene</p> <p>- Min 3g per day, taken during and immediately following the exercise</p> <p>- AMOUNT RECOMMENDATION: Min 3g ADVISORY STATEMENT: Do not take more than 12 g BCAA per day (higher dose may lead to ammonia build-up) INTAKE RECOMMENDATION: Take during and immediately following the exercise AD HOC RECCOMENDATION: Provide sufficient intake of carbohydrates, fluids</p>			
ID	Food or Food constituent	Health Relationship	Proposed wording
684	Branched chain amino acids (Leucine, Isoleucine, valine)	Muscle metabolism	Helps muscle recovery/supports muscle fatigue recovery
	<p><b>Conditions of use</b></p> <p>- Min 3g per day, taken during and immediately following the exercise</p>		
ID	Food or Food constituent	Health Relationship	Proposed wording
1478	Branched chain amino acids (Leucine, Isoleucine, valine)	<p>Muscle metabolism</p> <p><u>Clarification provided</u></p>	Helps muscle recovery supports muscle

		<p>Help muscle fatigue recovery, by initiating/increasing muscle protein synthesis and decreasing DOMS and muscle fatigue.</p>	<p>fatigue recovery</p>
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Number of nutrients/other substances that are essential to claimed effect:1. Names of nutrient/other substances and Quantity in Average daily serving: 1.5g Leucine. Daily amount to be consumed to produce claimed effect: 1.5 gram(s). Are there factors that could interfere with bioavailability: No. Length of time after consumption for claimed effect to become apparent: It is apparent immediately. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No. Other conditions for use: Product must be used in conjunction with exercise.</li> <li>- Sportler–Tagesdosis L-Isoleucin: 500 mg</li> <li>- Tagesdosis L-Valin: 500 mg–Erwachsene</li> <li>- 420 mg Isoleucin,–480 mg Valin,–660 mg Leucin pro Tag in Zeiten erhöhter Belastung</li> <li>- Min 3g per day, taken during and immediately following the exercise</li> </ul>		

## GLOSSARY AND ABBREVIATIONS

BCAA	Branched-chain amino acids
CWT	Colour word test
RPE	Rating of perceived exertion
VO <sub>2max</sub>	Maximal aerobic power