



Federal Office for
Consumer Protection and
Food Safety

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YOUR REFERENCE
YOUR MESSAGE OF

23. October 2015

REFERENCE NUMBER
(Please specify in response)

BVL-101.11152.0.0171(2015)

DATE 13 November 2015

**Notification of a Food for Special Medical Purposes (balanced diets) according to § 4a
para. 1 of the Ordinance on Dietetic Food (German DiätV)**
Product "Mevalia PKU Balance 1+" with container size 500g

Dear Sir/Madam,

I hereby confirm receipt of your notification according to § 4a Abs. 1 DiätV of 23 October 2015 for the product "Mevalia PKU Balance 1+" with the container size 500g. The present notification is a first notification.

As part of this notification procedure, I will only formally check the submitted documents for their completeness. It is being verified whether the information on the notification is complete and whether the notification falls under the conceptual requirements of one of the groups listed in Annex 8 DiätV. The BVL does not carry out any further examination of the content. For this purpose, the notification shall be forwarded to the regional authority responsible for food control.

The distributor is not exempt from the obligation to comply with food law regulations on his/her own responsibility.

In order to meet the general legal requirements for a dietetic food, the product must meet a special nutritional need of a consumer group according to section 1 paragraph 2 no. 1 DiätV. The second requirement is suitability for the stated intended use (Paragraph 1(2) No. 2 DiätV). In addition, the product must be clearly distinguishable from foods for general consumption, such as food supplements, fortified foods or other foods, due to its special composition or the special method of production.

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The specific legal requirement for balanced diets is the extended definition according to section 1 paragraph 4a DiätV. According to this definition, dietary foods for special medical purposes (balanced diets) are products that are processed or formulated in a special way and are intended for the dietary treatment of patients. They are intended for the exclusive or partial nutrition of patients with reduced or impaired ability to ingest, digest, absorb, metabolise or excrete ordinary foods or certain nutrients contained therein or their metabolites, or for the nutrition of patients with other medically related nutrient requirements for whose dietary management a modification of the normal diet, other foods for special nutrition or a combination of both is not sufficient. In addition, the special nutritional need must be medically related to nutrition.

I would also like to point out that the rules of labelling must be taken into account. For example, the prohibition of disease-related advertising in accordance with Article 7(3) of Regulation (EU) No 1169/2011 (Food Information Regulation - LMIV) also generally applies to balanced diets. However, in deviation from this, the disease-specific statements mentioned in Paragraph 3(2) of the DiätV are permissible for the indications listed therein. Furthermore, paragraph 21 of the DiätV also contains regulations on the special labelling of balanced diets.

If the product is changed (e.g. product name, composition, etc.) a notification of change is required. I would also ask you to inform me if you should take the above product off the market (indicating the date).

The notification procedure of balanced diets is currently free of charge.

Kind regards,

On behalf

Dr. Carolin Bendadani

Referee