

NEW EU INFANT NUTRITION LEGISLATION

Complete list of Dr. Schär food for special medical purposes (FSMP) whose formulations are affected by the new EU Delegated Regulations 2016/127 and 2016/128, and which need to comply by the 22nd of February 2020

The new EU Delegated Regulations 2016/127 and 2016/128 require all FSMPs/foods for special medical purposes (EU Delegated Regulation 2016/128) as well as infant formulas and follow-on formulas (EU Delegated Regulation 2016/127) to be updated by the 22nd of February 2020. Part of the product portfolio of the company Dr. Schär are, among others, FSMPs for the treatment of inborn errors of metabolism for the target group 0-1 years. Dr. Schär is currently working on meeting the requirements of the above-mentioned EU regulations and ensuring compliance while adhering to the specified deadline*.

The updated EU regulations include new minimum and maximum levels of micronutrients, and a mandatory required content of Docosahexaenoic Acid (DHA). We are also taking the opportunity to upgrade our formulations of FSMPs in line with international guidelines. In order to minimise any impact on patients, we are doing our best to limit these changes. Detailed communication regarding the updated formulation of products and the feed will be provided where required. Dr. Schär is committed to supply best quality feeds for the management of the nutritional needs of patients.

Which products of the brand **MEVALIA** are affected by the legislation?

- Mevalia PKU Balance Complete 0-1 / 0-1 +LCP, 500 g

Which products of the brand **COMIDAMED** are affected by the legislation?

- Comidamed comida-PKU A formula, 400 g
- Comidamed comida-MSUD A formula, 400 g
- Comidamed comida-UrC A formula, 400 g
- Comidamed comida-HCys A formula, 400 g
- Comidamed comida-OAc A formula, 400 g
- Comidamed comida-TYRo A formula, 400 g
- Comidamed comida-GAc A formula, 400 g
- Comidamed comida-Leu A formula, 400 g
- Comidamed comida-SOD A formula, 400 g

Which products of the brand **DR. SCHÄR MEDICAL NUTRITION** are affected by the legislation?

- Dr. Schär Medical Nutrition Galacto Start, 400 g

*All companies need their infant feeds to be compliant with the new EU regulations within the 22nd of February 2020. However, as per legislation, feeds produced before this specific date may continue to be sold until stocks are exhausted.