

Title: FSMP (Food for Special Medical Purposes) Product specification

**Marchio / Brand / Marke / Marca:** FLAVIS**Nome prodotto / Product name / Produktname / Nombre del producto:** PASTA PENNE

**Denominazione di vendita:** PASTA APROTEICA  
**Sales description:** LOW PROTEIN PASTA  
**Verkehrsbezeichnung:** -  
**Denominación de venta:** -

**Global Item Number:** 590405**Numero d'articolo / Article number / Artikelnummer / Número de artículo:** 5904050000**VPN (Verpackungsmaterialnummer/Packaging Version Number) Code:** V03

- GRASSI MCT / MCT- FATS / MCT-FETTE / MCT GRASA**  
 Alimento a fini medici speciali. Destinato alla gestione dietetica di maldigestione e malassorbimento dei grassi, disturbi dell'ossidazione degli acidi grassi a catena lunga e nella dieta chetogena.  
*Food for special medical purposes. For use in the dietary management of fat maldigestion and fat malabsorption, oxidation disorders of long fatty acids and in the ketogenic diet.*  
 Lebensmittel für besondere medizinische Zwecke (Bilanzierte Diät). Zum Diätmanagement bei Störungen im Fettstoffwechsel (Fettmaldigestion und Fettmalabsorption), Oxidationsstörungen von langkettigen Fettsäuren und im Rahmen der ketogenen Diät.  
*Alimento para usos médicos especiales. Destinado al manejo dietético de mala digestión y absorción incorrecta de las grasas, trastornos de la oxidación de los ácidos grasos de cadena larga y en la dieta cetogénica.*
- PRODOTTI APROTEICI / LOW PROTEIN PRODUCTS / EIWEISSARME LEBENSMITTEL / PRODUCTOS BAJOS EN PROTEÍNAS**  
 Proteine contenute nel prodotto  $\leq 1\%$  / Im Produkt enthaltenes Eiweiß  $\leq 1\%$  / *Protein content in the product  $\leq 1\%$  / Contenido de proteínas en el producto  $\leq 1\%$ .*  
 Proteine contenute nel prodotto  $\leq 2\%$  / Im Produkt enthaltenes Eiweiß  $\leq 2\%$  / *Protein content in the product  $\leq 2\%$  / Contenido de proteínas en el producto  $\leq 2\%$ .*
- Alimento a fini medici speciali. Destinato alla gestione dietetica di individui affetti da disturbi metabolici congeniti, insufficienza renale cronica o altre malattie che richiedono un regime dietetico ipoproteico. Avvertenze importanti: da utilizzare sotto controllo medico. Non idoneo come unica fonte nutrizionale.  
*Food for Special Medical Purposes. For use in the dietary management of inherited metabolic disorders (e.g. Phenylketonuria), or conditions requiring a low protein diet. Important notice: use under medical supervision. Not suitable as a sole source of nutrition.*  
 Lebensmittel für besondere medizinische Zwecke (Bilanzierte Diät). Zum Diätmanagement bei angeborenen Stoffwechselstörungen oder anderen Erkrankungen, die eine eiweißarme Diät erfordern. Wichtiger Hinweis: das Produkt muss unter ärztlicher Aufsicht verwendet werden und ist nicht zur ausschließlichen Ernährung geeignet.  
*CH: Für besondere Ernährungsbedürfnisse bei angeborenen Stoffwechselstörungen oder anderen Erkrankungen, die eine eiweißarme Diät erfordern /*  
*Indicare il regime alimentare di individui affetti da disturbi metabolici congeniti o altre malattie che richiedono un regime dietetico ipoproteico.*  
 Alimento para usos médicos especiales. Destinado al manejo dietético de errores congénitos del metabolismo e insuficiencia renal que requieran una dieta de bajo contenido en proteínas. Aviso importante: utilizar bajo supervisión médica. No es adecuado como única fuente de nutrición.

**MISCELE AMINOACIDICHE / AMINO ACID MIXES / AMINOSÄUREMISCHUNGEN / MEZCLAS DE AMINOÁCIDOS**

Alimento a fini medici speciali.

Destinato alla gestione dietetica di Fenilchetonuria (PKU) o Iperfenilalaninemia (HPA) o altre disfunzioni metaboliche.

*Food for special medical purposes.*

*For use in the dietary management of Phenylketonuria (PKU) and Hyperphenylalaninemia (HPA) or other metabolic disorders.*

Lebensmittel für besondere medizinische Zwecke (Bilanzierte Diät). Zum Diätmanagement bei Phenylketonurie (PKU) oder Hyperphenylalaninämie (HPA) oder anderen besonderen Ernährungsbedürfnisse.

*Alimento para usos médicos especiales.*

*Destinado al manejo dietético de la fenilcetonuria (PKU) y de la hiperfenilalaninemia (HPA) u otros errores congénitos del metabolismo.*

**Età di utilizzo:** --

**Age of use:** --

**Altersstufe:** --

**Rango de edad de uso:** --

**Descrizione del prodotto:** --

**Product description:** --

**Produktbeschreibung:** --

**Descripción del producto:** --

**Ingredienti:** amido di mais, amido di riso, addensante: cellulosa; sciroppo di zucchero di canna, inulina di cicoria, emulsionante: mono- e digliceridi degli acidi grassi; farina di riso, estratto di cartamo, colorante: beta carotene.

**Ingredients:** maize starch, rice starch, thickener: cellulose; cane sugar syrup, chicory inulin, emulsifier: mono- and diglycerides of fatty acids; rice flour, safflower extract, colour: beta-carotene.

**Zutaten:** --

**Ingredientes:** --

**Può contenere tracce di:** --

**May contain traces of:** --

**Kann Spuren enthalten von:** --

**Puede contener trazas de:** --

**FREE FROM:**

Wheat

Lactose (<0,007g/100g)

Gluten

**Peso netto/ Net weight / Gewicht Verpackung/ Peso neto:**

500 g e = 17,6 oz

N° confezioni per cartone:

*Units per carton:*

6

Verpackungen pro Karton:

*Envases por caja:*

Prodotto confezionato in atmosfera protettiva:

*Product packaged in protective atmosphere:*

Produkt unter Schutzatmosphäre verpackt:

*Producto envasado en atmósfera protectora:*

	Si	No
<input type="checkbox"/>	Yes	<input checked="" type="checkbox"/> No
	Ja	Nein
	Sí	No

Scadenza:

*Shelf life:*

Mindesthaltbarkeit:

*Vida útil:*

	Mesi:
<input checked="" type="checkbox"/>	Months: 24
	Monate:
	Meses:

	Giorni:
<input type="checkbox"/>	Days: <input type="text"/>
	Tage:
	Días:

Conservazione:

*Storage:*

Lagerung:

*Conservación:*

<input checked="" type="checkbox"/>	conservare in luogo fresco e asciutto	
<input checked="" type="checkbox"/>	store in a cool and dry place	<input type="checkbox"/> - 18°C
	bei Raumtemperatur trocken lagern	
	conservar en lugar fresco y seco	

Indicazioni per la cottura:

Cuocere la pasta in abbondante acqua bollente per 5-7 minuti (circa 2 litri di acqua per 100g di pasta, salare l'acqua in base a quanto consigliato dalla dieta) mescolandola regolarmente.

*Cooking-baking instructions:*

Bring a sufficient quantity of water to the boil (2 litres water per 100g pasta). Add Penne and salt according to taste and dietary allowance. Boil for 5-7 mins, stirring regularly.

Koch- bzw. Backanweisung: --

*Indicaciones para la cocción:* --

Modalità di preparazione: --

*How to prepare:* --

Vorbereitungshinweis: --

*Modalidad de preparación:* --

Note: --

*Notes:* --

Anmerkungen: --

*Notas:* --

**Nutrition Declaration for Low protein products****Dichiarazione nutrizionale/ Nutrition declaration / Nährwertdeklaration / Información nutricional:**

Portion	80	g		
Numero e tipo di porzioni Number and type of portions Anzahl und Art der Portionen Número y tipo de porciones	ca. 6 portions	Unit	per 100 g	per Portion
Energia / Energy / Energie / Valor energético		kJ	1485	1188
		kcal	351	280
Grassi / Fat / Fett / Grasas		g	1,1	0,9
di cui acidi grassi saturi / of w hich saturates / davon gesättigte Fettsäuren / de las cuales saturadas		g	0,4	0,3
Carboidrati / Carbohydrate / Kohlenhydrate / Hidratos de carbono		g	81	65
di cui zuccheri / of w hich sugars / davon Zucker / de los cuales azúcares		g	3,2	2,6
Fibre / Fibre / Ballaststoffe / Fibra alimentaria		g	7,3	5,8
Proteine / Protein / Eiw eiß / Proteínas		g	0,5	0,4
di cui fenilalanina / of w hich Phenylalanin / davon Phenylalanin / de las cuales Felinalanina		mg	21	17
di cui tirosina / of w hich Tyrosin / davon Tyrosin / de las cuales Tirosina		mg	14	11
di cui leucina / of w hich Leucine / davon Leucin / de las cuales Leucina		mg	34	27
Sale / Salt / Salz / Sal		g	0,08	0,06
di cui sodio / of w hich Sodium / davon Natrium / de los cuales Sodio		mg	30	24
Potassio / Potassium / Kalium / Potasio		mg	11	9
Fosforo / Phosphorus / Phosphor / Fósforo		mg	20	16

**Valori Microbiologici: / Microbiological analysis: / Mikrobiologische Werte / Valores microbiológicos:**

Conta totale/Total count/ Gesamtkeimzahl / Recuentos totales	< 10.000	UFC/g CFU/g KBE/g UFC/g
Lieviti / Yeast / Hefen / Levaduras	< 100	UFC/g CFU/g KBE/g UFC/g
Muffe / mould / Schimmel / Mohos	< 500	UFC/g CFU/g KBE/g UFC/g
Coliformi/ Coliforms / Coliforme / Coliformes	< 100	UFC/g CFU/g KBE/g UFC/g
Enterobacteriaceae	< 100	UFC/g CFU/g KBE/g UFC/g
Salmonella sp.	< absent	/25g
Staphylococchi coag. +	< 100	UFC/g CFU/g KBE/g UFC/g
Bacillus cereus	< 50	UFC/g CFU/g KBE/g UFC/g
Clostridi solf. rid.	< 50	UFC/g CFU/g KBE/g UFC/g
Listeria monocytogenes	< absent	/25g or CFU/g
Escherichia coli	< 10	UFC/g CFU/g KBE/g UFC/g
Cr. sakazakii	---	UFC/g CFU/g KBE/g UFC/g

<b>FORM</b>			<b>DrSchär</b>
Document no.: 07.03.05	Issue: 03	Date of issue: 28.04.2017	Page: 5 of 5
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### Legal requests

The product corresponds to all relevant legal requirements of the European Community and the Federal Republic of Germany, in particular regulation (EC) no. 178/2002 and regulation (EC) no. 852/2004 and the current version of the Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB).

The product is food for special medical purposes and meets the requirements of commission directive 1999/21/EC and of the current version of the German Diät-Verordnung. The product is a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions.

Full traceability is ensured on each stage of the manufacturing process. In addition each supplier ensures traceability on each stage according to regulation (EC) 178/2002.

With respect to maximum residue limits of pesticides, mycotoxins, heavy metals, pharmacologically active substances and other contaminants the product complies with all relevant regulations of the German and European legislation, in particular with regulation (EC) No. 396/2005, council regulation no. (EEC) No. 2377/90, commission regulation (EC) no. 1881/2006, Rückstandshöchstmengen-Verordnung (RHmV), Mykotoxin-Höchstmengenverordnung (MHmV), Schadstoffhöchstmengen-Verordnung (SHmV) and in particular if the product is intended for nutrition of infants and toddlers it complies with commission directive no. 2006/141/EC, commission directive no. 2006/125/EC, regulation no. 2013/609/EC, commission delegated regulation n° 2016/128/EC and "Diätverordnung".

The supplier herewith confirms that the aforementioned product is not subject to specific labelling under EU regulations (EC) No. 1829/2003 and (EC) No. 1830/2003.

The packaging materials intended to come into contact with the product and transport packaging don't affect the quality of the product and comply with the current requirements in particular of regulation (EC) No. 1935/2004, Commission regulation (EC) no. 10/2011, Commission regulation (EC) no. 2023/2006, Regulation (EC) no. 1907/2006, Bedarfsgegenstände-Verordnung and the Lebensmittel-, Bedarfs-gegenstände- und Futtermittelgesetzbuch (LFGB).

The product meets the requirements of the regulation (EU) No 1169/2011 on the provision of food information to consumers.

If the product is intended for nutrition of infants and toddlers, in this respect meets the requirements of commission directive 2006/141/EC and of the current version of the German Diät-Verordnung. The product only contains food additives and carry-over additives, which are authorized for use in baby food and infant food, and in particular authorized by Regulation (EC) No 1333/2008 on food additives and its corresponding annex' Commission Regulation (EU) No 1129/2011 and Commission Regulation (EU) No 1130/2011.

DR. SCHÄR  
Assicurazione Qualità  
*Quality Assurance*  
Qualitätssicherung  
*Garantía de Calidad*

Data / Date / Datum / Fecha **27.02.2020**

Postal, 30-Sep-20

To whom it may concern

Subject: Declaration on country of origin of raw materials

The company Dr. Schär AG / SPA, Winkelau 9, 39014 Postal/Burgstall (BZ) Italy, is dedicated to the production of gluten-free food and food for special medical purposes (FSMP).

We hereby declare that the country of origin of the raw material "maize starch" used in the Flavis Pasta Penne is the following:

Ingredient	Country of origin
Maize starch	Europe

Dr. Schär AG / SPA is certified according to the BRC Standards.

Yours sincerely,  
Dr. Schär AG / SPA

Head of Corporate Quality Assurance  
Günther Augustin

