

<b>Product</b>	Fish Oil EPAX 4030 TGN Vit E 10 mg softgel capsules.
<b>Format</b>	20 Oblong
<b>Shelf life<sup>(1,2)</sup></b>	3 years from production date, keep closed in the original packing.
<b>Storage</b>	Store in a cool, dry and dark place.

<sup>1</sup>Based on microbiological characteristics.

<sup>2</sup>The Customer is responsible for the stability studies that guarantee product's life.

FORMULA	1 capsule	Active/capsule
<b>Fill Composition</b>		
Fish oil EPAX 4030 TGN	1,000.00 mg	
Omega 3 (min. 80%)		800.00 mg
EPA-Eicosapentaenoic Acid (min. 40%)		400.00 mg
DHA-Docosahexaenoic Acid (min. 30%)		300.00 mg
Natural Vitamin E (D-alpha-tocopherol) 67.1%	10.00 mg	
<b>Shell Composition</b>		
Fish gelatine	260.87 mg	
Vegetal glycerine	130.43 mg	
Water	q.s.	

<b>INGREDIENTS</b>	Fill: <b>Fish</b> oil EPAX 4030 TGN, antioxidant (D-alpha-tocopherol). Shell: <b>Fish</b> gelatine, wetting agent (vegetal glycerine), water.
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PHYSICAL-CHEMICAL PARAMETERS	
Parameter	Specification
Appearance and colour	Natural colour gelatine. Transparent pale-yellow liquid.
Fill weight uniformity	(18/20) 1,010.00 mg ± 7.5%
	(20/20) 1,010.00 mg ± 15%
Capsule weight variation	1,410.00 mg ± 10%
Longitudinal dimensions <sup>1</sup>	25.83 mm ± 0.4%
Diameter dimensions <sup>1</sup>	9.84 mm ± 0.4%
Disintegration test	≤ 30 minutes
Cadmium <sup>2</sup>	≤ 1.0 mg/kg
Lead <sup>2</sup>	≤ 3.0 mg/kg
Mercury <sup>2</sup>	≤ 0.1 mg/kg

<sup>1</sup>Informative values.

<sup>2</sup>Commission Regulation (EC) 1881/2006 setting maximum levels for certain contaminants in foodstuffs and subsequent modifications Regulation (EC) 629/2008. Results obtained from analysis made by our suppliers to the raw materials.

MICROBIOLOGICAL PARAMETERS	
Parameter	Specification
Total aerobic microbial count 30°C	≤ 10 <sup>4</sup> cfu/g
Moulds and yeasts	≤ 10 <sup>2</sup> cfu/g
<i>Enterobacteriaceae</i>	≤ 10 <sup>2</sup> cfu/g
<i>Escherichia coli</i>	Absent/1 g
<i>Staphylococcus aureus</i>	Absent/1 g
<i>Salmonella</i>	Absent/25 g
<i>Listeria monocytogenes</i>	Absent/25 g

<b>ADDITIONAL INFORMATION <sup>(1)</sup></b>	
<b>Determination</b>	<b>Specification</b>
<b>Allergens</b> (Reg. EU 1169/2011 - Annex II)	<b>FISH</b>
<b>NO GMO</b> (According to Reg. EU 1829/2003 y 1830/2003)	
<b>Maximum content of heavy metals</b> (According to Reg. EU 1005/2015, 1006/2015, 1881/2006, 629/2008)	
<b>Absence of heat treatment or irradiation</b> (According to Dir. 1999/2/CE y Reg. EU 1169/2011)	
<b>Free of BSE/TSE</b> (According to Reg. EU 999/2001)	
<b>Pesticides</b> (According to Reg. EU 2075/2015, 396/2005)	
<b>Maximum content of Polycyclic Aromatic Hydrocarbons (PAH's)</b> (According to Reg. EU 1933/2015, 1881/2006)	
<b>Nanomaterials</b> (According to EU Reg.1169/2011)	
<b>Primary conditioning and labelling</b> (According to Reg. EU 1935/2004, 1169/2011, 10/2011, 2023/2006)	
<b>Product manufactured in compliance with Food Safety legislation</b> (According to Reg. EU n° 178/2002)	