

Declaration of Conformity

Of product: Vacuum bags for sterilization

1.	Name and address of the manufacturer:																									
2.	Raw materials and additives used in production	Polyethylene Polyamide Opening additive Slipperiness additive Anti-static additive Additive of the manufacturing process																								
3.	Date of the submission of the declaration	06/03/2020																								
4.	Confirmation that the packaging is in conformity	<p>* With the relevant requirements set out in Article 3 of Regulation (EC) No. 1935/2004 under intended and foreseeable use;</p> <p>*With the relevant requirements set out in Part 5 of Regulation (EC) No. 1935/2004 11;</p> <p>* With the labelling requirements set out in Article 15 of Regulation (EC) No. 1935/2004;</p> <p>* With the traceability requirements set out in Article 17 of Regulation (EC) No. 1935/2004;</p> <p>*The products are manufactured in compliance with the good manufacturing practice as set out in the Commission Regulation (EC) No. 2023/2006;</p> <p>*Conforms to the relevant requirements of composition and declaration set out in Articles II, III and IV of the Regulation (EC) No. 10/2011.</p> <p>*The materials used comply with the requirements set out in the Regulation (EC) No. 1935/2004 and the risk assessment was carried out in accordance with Article 19 of the Regulation (EC) No. 10/2011.</p>																								
5.	Materials and additives with limit values of emissions.	<table border="1"> <thead> <tr> <th>Chemical name:</th> <th>Cas. No.</th> <th>REF. No.</th> <th>SML</th> </tr> </thead> <tbody> <tr> <td>1-octene</td> <td>0000111-66-0</td> <td>22660</td> <td>15mg/kg</td> </tr> <tr> <td>Stearic acid</td> <td>0000057-11-4</td> <td>24550</td> <td>-</td> </tr> <tr> <td>Tris(2,4-di-tret-butilfenil)ester</td> <td>0031570-04-4</td> <td>74240</td> <td>-</td> </tr> <tr> <td>Erucamide</td> <td>0000112-84-5</td> <td>52720</td> <td>-</td> </tr> <tr> <td>Oktadecil 3-(3-(3,5-di-tret-butil-4-hidroksifenil)propionate</td> <td>0002082-79-3</td> <td>68320</td> <td>6mg/kg</td> </tr> </tbody> </table>	Chemical name:	Cas. No.	REF. No.	SML	1-octene	0000111-66-0	22660	15mg/kg	Stearic acid	0000057-11-4	24550	-	Tris(2,4-di-tret-butilfenil)ester	0031570-04-4	74240	-	Erucamide	0000112-84-5	52720	-	Oktadecil 3-(3-(3,5-di-tret-butil-4-hidroksifenil)propionate	0002082-79-3	68320	6mg/kg
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6.	Dual-purpose additives	Chemical name:	Cas. No.	REF. No.		
		Carbonic acid salts	-	42500		
7.	Use of film	The film can be used for contact with all food types.				
8.	Time and temperature when in contact with foods.	Any long-term storage at a room temperature, for no longer than at a 70C for 24 hour and no longer than at a 121C for 2hour.				
9.	General migration in the product.	The analysis of general migration was carried out in accordance with regulation (EC) 10/2011. This analysis confirms that the results of general migration, specified below, do not exceed the limits (10mg/dm ²) of the allowed general migration set out in regulation (EC) specified above. The value of migration shall be expressed in mg/kg applying a surface to volume ratio of 6 dm ² per kg of food. The packaging conforms to the organoleptic requirements. Bisphenol A is not used in manufacturing and during the process of manufacturing.				
		Analyte	Mark of method	Result	Conditions of the analysis	Measuring unit
		Determining of the general migration into a 95% ethanol	LST EN 1186-15:2002	<1,1	In ethanol for 10 days at 20° C	mg/dm ²
		Determining of general migration into isooctane	LST EN 1186-15:2002	<2,6	In Isooctane for 1 day at 20° C	mg/dm ²
		Determining the total migration into the 3% acidic acid	LST EN 1186-15:2002	<0,5	In the acetic acid for 10 days at 40° C	mg/dm ²
Protocol of the chemical analysis: Ch 3287/2019						
10.	Conditions for storage	The products must be stored in covered facilities where there is no direct sunlight, at a (15-30) ° C temperature, relative humidity of 40-65%, at a distance of no less than 1 m. from heating appliances. Before use the film must be stored at an operating temperature for at least 24 hours. The packaging is suitable for use for 18 months from the day of manufacturing, kept in the original packaging according to the conditions specified above.				