

Plastic Packaging

Gerresheimer Bolesławiec S.A.
ul. Bolesława Chrobrego 15
59-700 Bolesławiec
Poland

Management Board:
Michał Malkowski
Carlo Reato



District Court Wrocław - Fabryczna
9th Economic Department of Polish
Court Register No. KRS-0000069325
Share capital: 10.500.000 PLN
Paid-up capital: 10.500.000 PLN

Declaration of conformity

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Declaration of conformity with the general requirements for materials and articles intended to food contact contained in the art. 3 and art. 17 Regulation No. 1935/2004 and the specific measures (e.g. defined in Commission Regulation (EU) No. 10/2011)

Full name and address of producer	Gerresheimer Bolesławiec S.A. ul. Bolesława Chrobrego 15 59-700 Bolesławiec, Poland	
Full name of product which declaration concerns	35037 Bottle 15 ml nature	
Declaration date	01.10.2013	
Declaration of conformity with:		
<ul style="list-style-type: none"> ▪ Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC ▪ Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food ▪ Commission Regulation (EC) No. 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food 		
Information about compatibility of the substances used, which are subject of restrictions or specifications		
Level of all migrating substances - compliance with the global migration limit ($\leq 10 \text{ mg/dm}^2$)	Simulant (3% acetic acid) – $< 0,6 \text{ mg/dm}^2$ Simulant (10% ethanol) – $< 0,5 \text{ mg/dm}^2$ Simulant (50% ethanol) – $< 0,5 \text{ mg/dm}^2$	
Name of the substance (CAS No., Reference No.)	Legal restrictions on the use of substances	Test results (or the specific migration limit determined on the basis of theoretical calculations - the method of calculation should be included in the documentation / reference to document confirming compliance with the restrictions)

-	-	-
Information about compliance with the criteria of purity of the substance - if it is established (in accordance with the regulations concerning specifications and purity criteria for food additives)		
Name of the substance (CAS No., Reference No.)	Legal restrictions on the use of substances	Defined levels of migration (or reference to relevant documents, as above)
-	-	-
Information about the content of dual-use-additives, which are subject of restrictions		
Name of the substance (CAS No., Reference No.)	Legal restrictions on the use of substances	Defined levels of migration (or reference to relevant documents, as above)
-	-	-
Parameters and specifications for the use of materials and products:		
<ul style="list-style-type: none"> ▪ Type(s) of foods, with which material or article is to be put in contact: Eye drop formulation ▪ Time and temperature of processing and storage in contact with food: according to the Minister of Health Regulation of 22 June 2007 (as amended) on the list of substances whose use is permitted in the manufacture or processing of materials and plastic products and way of checking the compatibility of these materials and products with the specified limits - test of global migration is performed at a temperature of 40°C for 10 days. These conditions of time and temperature are conventionally considered to be more severe. ▪ The ratio of food contact surface area to volume used to determine the compatibility of the material or product with the requirements: 35037 Bottle– 3063 mm² 		
Functional barrier in plastics – confirmation the fulfillment of requirements of Section 3, paragraph 2-4 of the Minister of Health Regulation of 22 June 2007		
<ul style="list-style-type: none"> ▪ Not applicable 		
Prepared by:	Approved by:	
Beata Pudelko 	Iwona Araucz 	
Quality Assurance Manager	Quality Manager	
Date: 01.10.2013	Date: 02.10.13	

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Full name and address of producer	Gerresheimer Bolesławiec S.A. ul. Bolesława Chrobrego 15 59-700 Bolesławiec, Poland	
Full name of product which declaration concerns	91176 child resistant tamper evident closure white	
Declaration date	01.10.2013	
Declaration of conformity with:	<ul style="list-style-type: none"> ▪ Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC ▪ Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food ▪ Commission Regulation (EC) No. 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food 	
Information about compatibility of the substances used, which are subject of restrictions or specifications		
Level of all migrating substances - compliance with the global migration limit ($\leq 10 \text{ mg/dm}^2$)	Simulant (3% acetic acid) – $< 0,5 \text{ mg/dm}^2$ Simulant (10% ethanol) – $0,9 \text{ mg/dm}^2$ Simulant (50% ethanol) – $< 0,5 \text{ mg/dm}^2$	
Name of the substance (CAS No., Reference No.)	Legal restrictions on the use of substances	Test results (or the specific migration limit determined on the basis of theoretical calculations - the method of calculation should be included in the documentation / reference to document confirming compliance with the restrictions)

1. 1,1,1-Trimethylpropane CAS No. – 77-99-6	SML= 6 mg/kg	Report of Analysis No. 94043/13/GDY/Z1
Information about compliance with the criteria of purity of the substance - if it is established (in accordance with the regulations concerning specifications and purity criteria for food additives)		
Name of the substance (CAS No., Reference No.)	Legal restrictions on the use of substances	Defined levels of migration (or reference to relevant documents, as above)
-	-	-
Information about the content of dual-use-additives, which are subject of restrictions		
Name of the substance (CAS No., Reference No.)	Legal restrictions on the use of substances	Defined levels of migration (or reference to relevant documents, as above)
-	-	-
Parameters and specifications for the use of materials and products:		
<ul style="list-style-type: none"> ▪ Type(s) of foods, with which material or article is to be put in contact: Eye drop formulation ▪ Time and temperature of processing and storage in contact with food: according to the Minister of Health Regulation of 22 June 2007 (as amended) on the list of substances whose use is permitted in the manufacture or processing of materials and plastic products and way of checking the compatibility of these materials and products with the specified limits - test of global migration is performed at a temperature of 40°C for 10 days. These conditions of time and temperature are conventionally considered to be more severe. ▪ The ratio of food contact surface area to volume used to determine the compatibility of the material or product with the requirements: 91176 closure – 23,9 mm² 		
Functional barrier in plastics – confirmation the fulfillment of requirements of Section 3, paragraph 2-4 of the Minister of Health Regulation of 22 June 2007		
<ul style="list-style-type: none"> ▪ Not applicable 		
Prepared by: Beata Pudelko  Quality Assurance Manager Date: 01.10.2013	Approved by: Iwona Araucz  Quality Manager Date: 02.10.13	