

Declaration of Compliance

500 mL Easy Flow Bottle



A. BUSINESS OPERATOR INFORMATION		
Manufacturer reference number/revision	DOC-QAS-605	A
Manufacturer name and address	Sistema Plastics Limited 15 Te Tiki Road, Mangere Auckland 2022, New Zealand	
Date of the declaration	07 Aug 2025	
B. PRODUCT IDENTITY		
Product code	605	
Product description	500 mL Easy Flow Bottle	
Product type	Hydration bottle	
C. MATERIAL INFORMATION		
Component	Composition	
Lid cap	Polypropylene	
Lid seal	Silicone	
Lid arm	Polypropylene	
Lid body	Polypropylene	
Lid overmoulded housing	Thermoplastic elastomer	
Spout seal	Silicone	
Spout	Polypropylene	
Bottle label	Polyethylene terephthalate	
Bottle	Polypropylene	
D. REGULATORY COMPLIANCE		
<p>The above product complies with the requirements outlined in the following regulations:</p> <ul style="list-style-type: none"> • Regulation (EC) No. 1935/2004 Materials and Articles Intended to Come into Contact with Food • Regulation (EU) No. 10/2011 Plastic Materials and Articles Intended to Come into Contact with Food • Regulation (EC) No. 2023/2006 Good Manufacturing Practice for Materials and Articles Intended to Come into Contact with Food • EN 71-1 Safety of Toys – Mechanical and Physical Properties • FDA 21 CFR 177.1520 Olefin Polymers • FDA 21 CFR 177.1210 Closures with Sealing Gaskets for Food Containers • FDA 16 CFR 1500 Hazardous Substances and Articles: Administration and Enforcement Regulations – Mechanical Hazards Requirements <p>The product also complies with the following annexes of Regulation (EU) No. 10/2011:</p> <ul style="list-style-type: none"> • Annex I: Substances – Union list of authorized monomers, other starting substances, additives, and polymer production aids • Annex II: Restrictions on materials and articles 		
E. PRODUCT MIGRATION TESTING AND LIMITS		
<ul style="list-style-type: none"> • The product was tested in accordance with Regulation (EU) No. 10/2011 and its amendments. Both overall and specific migration levels are within the established limits. 		

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- The raw materials and masterbatches used in this product also comply with various regulations, including Regulation (EC) No. 1935/2004 and Regulation (EU) No. 10/2011, as confirmed by the declarations of compliance provided by the suppliers.

F. SPECIFICATIONS ON THE USE OF THE ARTICLE

(i) Type of food with which it is intended to be put in contact

Liquids at room temperature or below.

(ii) Time and temperature of treatment, and storage in contact with the food

The product is intended for repeated or multiple use.

It is suitable for short-term storage of liquids at room temperature or below. It is not intended for use with hot liquids or carbonated beverages.

It passed the standardized overall migration testing condition of 2 hours at 70°C, as specified in Regulation (EU) 10/2011 and its amendments.

(iii) The ratio of food contact surface area to volume used to establish the compliance of the article

Compliance for this product was established using a surface-to-volume (S/V) contact ratio of 6 dm²/kg of food, in accordance with the conditions set out in Regulation (EU) No. 10/2011.

Note:

Consumers should follow the recommended usage and storage guidelines for any food or liquid stored in this product. These guidelines are based on the consumer's knowledge of the food or liquid, or on the information provided on its label. Additional details regarding proper usage and storage of this product can be found on the product packaging, in accompanying documentation, on the base engraving, in the use and care instructions, or on the Sistema website: www.sistemaplastics.com.

G. DUAL-USE ADDITIVES, PURITY CRITERIA, FUNCTIONAL BARRIER

- No dual-use additives are intentionally added during the manufacturing process of this product.
- No substances subject to purity criteria are added to this product.
- A functional barrier is not present in this product.

H. CHEMICAL SUBSTANCES AND HEAVY METALS

The following chemical substances are not intentionally used or added during the manufacturing process of this product:

- Lead
- Heavy metals
- Primary aromatic amines (PAA)
- Bisphenol A (BPA), Bisphenol F (BPF), Bisphenol S (BPS)
- 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP); 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP); 1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear; 1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear; 1,2-Cyclohexanedicarboxylic acid, diisononyl ester (DINCH); Benzyl butyl phthalate (BBP); Bis(2-ethoxyethyl) phthalate (BEEP); Bis(2-ethylhexyl) phthalate (DEHP); Bis(2-ethylhexyl) terephthalate (DEHT or DOTP); Bis(2-methoxyethyl) phthalate (DMEP); Bis(2-propylheptyl) phthalate (DPHP); Butyl octyl phthalate (BOP); Diallyl phthalate (DAP); Dibutyl phthalate (DBP); Dicyclohexyl phthalate (DCHP); Diethyl phthalate (DEP); Dihexyl phthalate (DHP); Diisobutyl phthalate (DIBP); Di-isodecyl phthalate (DIDP); Diisohexyl phthalate (DIHP); Di-isononyl phthalate (DINP); Diisooctyl phthalate (DIOP); Diisopentyl phthalate (DiPP); Dimethyl phthalate (DMP); Dinonyl

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phthalate (DNP); Dioctyl phthalate (DNOP); Dipentyl phthalate (DnPP); Dipropyl phthalate (DPRP); Diundecyl phthalate (DUP); Monobutyl phthalate (MBP); n-Pentyl-isopentyl phthalate (NIPP)

J. VALIDITY OF THIS DECLARATION OF COMPLIANCE

This Declaration of Compliance is created based on the following:

- Declarations provided by raw material suppliers
- Analyses of overall migration
- Analyses of specific migration
- Analyses of chemical substances
- Product functionality tests

It should be noted that this Declaration of Compliance is valid only when the product described above is used under normal and foreseeable conditions, including appropriate handling, cleaning, and storage. It does not apply to any modifications, such as reprocessing, improper use or storage, or the addition of other articles intended to come into contact with food.

This Declaration of Compliance is issued in accordance with Regulation (EU) No. 10/2011, as specified in Chapter IV, Article 15, and Annex IV. It should be renewed whenever the previous declaration can no longer be guaranteed and/or when changes to the applicable regulations occur.

Note:

This Declaration of Compliance was issued by Myline Dacanay, Regulatory Compliance Manager. It has been approved electronically and is deemed valid.