FRM-QAS-004 Revision D Issued by: General Manager -Technical & Engineering

Declaration of Compliance 350ml Happy Bottle



General Information		
Sistema reference number/revision	DOC-QAS-790	Α
Product code	790	
Product description	350ml Happy Bottle	
Manufacturer	Sistema Plastics Limited 15 Te Tiki Road, Mangere, Auckland 2022 P.O. Box 201202 Auckland Airport Auckland City 2150, New Zealand	
Date of declaration	07 Apr 2020	
Product Details		
Component	Material	
Twist cover	Polypropylene	
Twist nozzle	HDPE	
Twist base	Polypropylene	
Bottle	LDPE	
Feet	HDPE	

Compliance with Food Contact Regulations

The composition of this product meets the material requirements used as articles or components of articles intended for use in contact with food as per the following regulations:

- FDA 21 CFR 177.1520 Olefin Polymers
- Regulation (EU) No. 10/2011 Plastic Materials and Articles Intended to Come into Contact with Food
- Regulation (EC) No. 1935/2004 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

Compliance with Overall Migration Limit

The overall migration values obtained with the tested simulants are below the limits of 10 mg/dm² and 60 mg/kg food as per Regulation (EU) No. 10/2011 Plastic Materials and Articles Intended to Come into Contact with Food. The extractive residue analysis was also conducted as per FDA 21 CFR 177.1520 Olefin Polymers, and the values obtained are below the limits.

Compliance with Specific Migration Limit

The specific migration values obtained with the tested simulants are below the limits as per Regulation (EU) No. 10/2011 Plastic Materials and Articles Intended to Come into Contact with Food.

Compliance with Purity Criteria and Restrictions

There are no substances subject to purity criteria and restrictions for this product.

Compliance with Dual-Use Additives

The dual-use additives are not intentionally added during the manufacturing process of this product.

Functional Barrier

The functional barrier is not present in this product.

Conditions of Use

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

Liquid at room temperature or below. Not intended for hot liquids or carbonated drinks.

Time, temperature, and storage while in contact with food

Any short-term liquid storage, at room temperature or below.

Further information regarding the recommended use and storage can be found in the product's leaflet, label, engravings at the bottom of the product, and on the company website: www.sistemaplastics.com.

The ratio of food contact surface area to the volume used to establish the compliance of the material or article

The compliance testing was done under the conditions set out in Regulation (EU) No. 10/2011 using a surface-to-volume (S/V) contact ratio of 6 dm²/kg food.

Chemical Substances and Heavy Metals

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

- Primary aromatic amines (PAA)
- Bisphenol A (BPA), Bisphenol F (BPF), Bisphenol S (BPS)
- Heavy metals such as lead (Pb), cadmium (Cd), mercury (Hg) and hexavalent chromium (Cr⁺⁶).
- 1,2-Cyclohexane dicarboxylic acid diisononyl ester (DINCH), 12-Acetoxystearic acid,2,3-bis(acetoxy)propyl ester, Acetyl tributyl citrate (ATBC), Acetylated monoglycerides of fatty acids, Benzylbutyl phthalate (BBP), C10-C21 Alkylsulfonic phenyl ester, Di-2-ethylhexyl phthalate (DEHP), Di-2-ethylhexyl sebacate, Diallyl phthalate (DAP), Dibutyl phthalate (DBP), Dibutyl sebacate (DBS), Dicyclohexyl phthalate (DCHP), Diethyl phthalate (DEP), Diethylhexyl adipate (DEHA), Dihexyl phthalate (DHP), Diisobutyl phthalate (DIBP), Diisodecyl phthalate (DIDP), Diisononyl phthalate (DINP), Dimethyl phthalate (DMP), Di-n-octyl phthalate (DNOP), Dioctyl terephthalate (DOTP), Dipentyl phthalate (DNPP), Dipropyl phthalate (DPP), Phthalic anhydride, Triacetin, Triethyl citrate

Claim Substantiation

The tests and evaluations conducted confirmed the following claims for this product:

- Food safe
- Freezer safe
- Dishwasher safe (top rack only)

Validity of the Declaration of Compliance

This Declaration of Compliance is valid only when this product is used under normal and foreseeable conditions, with appropriate handling, cleaning, and storage. It does not cover any modification such as reprocessing, inadequate use or storage, or the addition of any other product.

Note:

This Declaration of Compliance was issued by Mr. Jared Smith, General Manager – Technical & Engineering. This declaration is signed electronically and therefore valid.