

DECLARATION OF MATERIALS COMPLIANCE WE NR 13/2024

1 Name and address of the manufacturer of the product and issuing the declaration:.

FORMASTER S.A.
Fabryczna 24, 25-818 Kielce, Poland

2. Application:

<i>Identification:</i>	<i>Parameters (capacity in L, total volume:</i>
Dafi Solid filtering bottle with exchangeable carbon filter	0,5 0,7

is designed to filter tap water intended for human consumption.

3.Full name of materials, products and substances for the manufacture of products.

In production of bottle with a replaceable carbon filter uses the following materials:
Tritan , ABS, silicon, polypropylene , polyethylene, colours (jeans, sapphire, turquoise, flamingo, cappuccino, lavender, white), carbon block filter, elastomer - no contact with water;

4.Are compatible with the following EU Directives :

Directive No. / Description:	
1935/2004	On materials and articles intended to come into contact with food and repealing Directives 80/590/EEC i 89/109/EEC.
10/2011/WE	Commission regulation(with later amendments) is amending Directive 2007/19/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.
2023/2006	Commission regulation of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.
94/62/EC	European Parliament and Council Directive of 20 December 1994 on packaging and packaging waste.
Recommendation XV	Silicones of the BfR
Resolution AP (89) 1	Resolution AP (89) 1 on the use of colourants in plastic materials coming into contact with food (Adopted by the Committee of Ministers on 13 September 1989 at the 428th meeting of the Ministers' Deputies).

5. Information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II to Regulation 10/2011 to allow the downstream business operators to ensure compliance with those restrictions;

Tritan

Reference number	Substance name	Specific migration limit SML [mg/kg]	Restrictions and specifications
24970	dimethyl terephthalate		
13390	1,4-cyclohexanedimethanol,		
25187	2,2,4,4-tetramethyl cyclobutane-1,3-diol	5	Only for repeated use articles for long term storage at room temperature or below and hotfill
24450	Octadecanoic acid		

Polypropylene

Reference number	Substance name	Specific migration limit SML [mg/kg]	Restrictions and specifications
39815	9,9-bis(methoxymethyl)fluorine	0,05	
68320	Octadecyl 3(3,5-Di-tert-butyl-4-hydroxyphenyl)propionate	6	
39090	N,N-bis(2-hydroxyethyl)alkyl(C8-C18)amine	1,2	Expressed as tertiary amine
39120	N,N-bis(2-hydroxyethyl)alkyl(C8-C18)amine hydrochloride	1,2	Expressed as tertiary amine excluding HCl
	Calcium salts of fatty acids (E470a) (dual-use substance)		
-	Aluminum	1,0	
24550 89040	Stearic acid (dual-use substance)		

Polyethylene

Reference number	Substance name	Specific migration limit SML [mg/kg]	Restrictions and specifications
86240	Silicon dioxide	60	For synthetic amorphous silicon dioxide: primary particles of 1 – 100 nm which are aggregated to a size of 0,1 – 1 µm which may form agglomerates within the size distribution of 0,3 µm to the mm size
68320	Octadecyl 3(3,5-Di-tert-butyl-4-hydroxyphenyl)propionate	6	
68960	Oleamide	60	
	Zinc	5	
	Primary aromatic amines	0,01	The detection limit (0,01 mg/kg applies to the sum of primary aromatic amines released.

Polypropylene, polyethylene dyes

Dyes	Ref. number	Substance name	Specific migration limit SML [mg/kg]	Restrictions and specifications
White	24550 89040	Stearic acid	5	
	68320	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	6	
	46880	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	6	
	42080	Carbon black	60	Primary particles of 10 – 300 nm which are aggregated to a size of 100 – 1 200 nm which may form agglomerates within the size distribution of 300 nm – mm. Toluene extractables: maximum 0,1 %, determined according to ISO method 6209. UV absorption of cyclohexane extract at 386 nm: < 0,02 AU for a 1 cm cell or < 0,1 AU for a 5 cm cell, determined according to a generally recognised method of analysis. Benzo(a)pyrene content: max 0,25 mg/kg carbon black. Maximum use level of carbon black in the polymer: 2,5 % w/w.
	93440	Titanium dioxide (dual-use substance)	60	
		Aluminum(dual-use substance)	1	
	30610	Acids, C2-C24, aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included) (dual-use substance)	60	
		Calciumstearat (E470a) – dual-use-additives	60	

ABS dyes

Dyes	Ref. number	Substance name	Specific migration limit SML [mg/kg]	Restrictions and specifications
White	10120	Acetic acid, vinyl ester	12	
	46640	2,6-di-tert-butyl-p-creso	3	
	46880	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	6	
	11710	acrylic acid, methyl ester	6	expressed as acrylic acid
		Barium	1	
		Manganese	0,6	
		Iron	48	
	93440	Titanium dioxide (dual-use substance)	60	
	46640	2,6-di-tert-butyl-p-cresol (BHT) (dual-use substance)	3	
		Calciumstearat (E470a) – dual-use-additives	60	

Tritan dyes

Dyes	Ref. number	Substance name	Specific migration limit SML [mg/kg]	Restrictions and specifications
Jeans	24910	Terephthalic acid	7,5	expressed as terephthalic acid
	19150	isophthalic acid	5	expressed as isophthalic acid
	16990 53650	Ethyleneglycol	30	expressed as maleic acid
	13326 15760 47680	diethyleneglycol	30	expressed as maleic acid
		Barium	1	
		Antimony	0,04	
		Pierwszorzędowe aminy aromatyczne	0,01	Granica wykrywalności (0,01 mg/kg) dotyczy sumy uwalnianych pierwszorzędowych amin aromatycznych
sapphire	24910	Terephthalic acid	7,5	expressed as terephthalic acid
	19150	isophthalic acid	5	expressed as isophthalic acid
	16990 53650	Ethyleneglycol	30	expressed as maleic acid
	13326 15760 47680	diethyleneglycol	30	expressed as maleic acid
		Antimony	0,04	
		Pierwszorzędowe aminy aromatyczne	0,01	Granica wykrywalności (0,01 mg/kg) dotyczy sumy uwalnianych pierwszorzędowych amin aromatycznych
turquoise	24910	Terephthalic acid	7,5	expressed as terephthalic acid
	19150	isophthalic acid	5	expressed as isophthalic acid
	16990 53650	Ethyleneglycol	30	expressed as maleic acid
	13326 15760 47680	diethyleneglycol	30	expressed as maleic acid
		Antimony	0,04	
		Copper	5	
flamingo	24910	Terephthalic acid	7,5	expressed as terephthalic acid
	19150	isophthalic acid	5	expressed as isophthalic acid
	16990	Ethyleneglycol	30	expressed as maleic acid

	53650			acid
	13326 15760 47680	diethyleneglycol	30	expressed as maleic acid
		Antimony	0,04	
		Pierwszorzędowe aminy aromatyczne	0,01	Granica wykrywalności (0,01 mg/kg) dotyczy sumy uwalnianych pierwszorzędowych amin aromatycznych
cappuccino	24910	Terephthalic acid	7,5	expressed as terephthalic acid
	19150	isophthalic acid	5	expressed as isophthalic acid
	16990 53650	Ethyleneglycol	30	expressed as maleic acid
	13326 15760 47680	diethyleneglycol	30	expressed as maleic acid
		Barium	1	
		Antimony	0,04	
		Pierwszorzędowe aminy aromatyczne	0,01	Granica wykrywalności (0,01 mg/kg) dotyczy sumy uwalnianych pierwszorzędowych amin aromatycznych
lavender	24910	Terephthalic acid	7,5	expressed as terephthalic acid
	19150	isophthalic acid	5	expressed as isophthalic acid
	16990 53650	Ethyleneglycol	30	expressed as maleic acid
	13326 15760 47680	diethyleneglycol	30	expressed as maleic acid
		Antimony	0,04	
		Pierwszorzędowe aminy aromatyczne	0,01	Granica wykrywalności (0,01 mg/kg) dotyczy sumy uwalnianych pierwszorzędowych amin aromatycznych

6. Functional barrier.

In the production of the Dafi Solid filtering bottle with exchangeable carbon filter, no functional barrier was used.

7. Product requirements:

(i) type or types of food with which it is intended to be put in contact;

Dafi Solid filtering bottle with with exchangeable carbon filter has been designed to filter tap water originating from municipal water and private water intakes, which has been tested and approved for human consumption.

Filters only cold water.

(ii) time and temperature of treatment and storage in contact with the food;

The new filter should be stored in a cool place protected from direct sunlight in the packaging. A bottle with a filter and filtered water should be stored in a cool place (15-25°C), preferably without sunlight.

The filter should be replaced every 30 days.

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

6 dm² per 1 kg of water

Summary:

We hereby declare that, the „ Dafi Solid filtering bottle with exchangeable carbon filter” manufactured by FORMASTER S.A. comply with all cited regulations and thus might be used in contact with food.

Place: Kielce

Date: 05-11-2024

FORMASTER®

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Anwar Ismail
signature of person, who prepared this declaration