

DECLARATION OF MATERIALS COMPLIANCE WE NR 1/2023

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> Dafi Soft filtering bottle with exchangeable carbon filter	<i>Parameters (capacity in L, total volume:</i> 0,3 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:

PET , polypropylene , polyethylene, colours (mint, vanilia, clicks, yellow, pink, blue, red, gray, black), carbon block filter, elastomer - no contact with water, SAN (Styrene-Acrylonitrile Resin), - 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.
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;

PET

Reference number	Substance name	Specific migration limit SML [mg/kg]	Restrictions and specifications
24910	Terephthalic acid	7,5	expressed as terephthalic acid
19150	Isophthalic acid	5	expressed as isophthalic acid
16990 53650	Ethyleneglycol	30	expressed as ethyleneglycol
13326 15760 47680	Diethyleneglycol	30	expressed as ethyleneglycol
35760	Antimony trioxide	0,04	SML expressed as antimony
23170 72640	Phosphoric acid (dual use additives)	60	

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
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.

Pink	24550 89040	stearic acid		
	68320	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	6	
	81200	Poly[6-[(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)imino]hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl) imino]	3	
	60800	1-(2-hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	30	
	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)		
	-	Aluminum (dual-use substance)	1	
Blue	-	Zinc expressed as zinc stearate	5	
	94960	1,1,1-trimethylolpropane	6	
	93440	Titanium dioxide (dual-use substance)	60	
	68320	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	6	
	-	Aluminum	1	
Red	93440	Titanium dioxide (dual-use substance)	60	
	76721	Polydimethylsiloxane (Mw > 6 800 Da)	60	Viscosity at 25 °C not less than 100 cSt (100 × 10 ⁻⁶ m ² /s)
		Aluminum	1	
Gray	68320	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	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

Polypropylene, polyethylene dyes

Dyes	Ref. number	Substance name	Specific migration limit SML [mg/kg]	Restrictions and specifications
Mint	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	
	46880	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	6	
	68320	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	6	
		Copper	5	
		Zinc	5	
Vanilla	46880	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	6	
	93440	Titanium dioxide (dual-use substance)	60	
	-	Calciumstearat (E470a) – dual-use-additives	60	
Clicks		Copper	5	
	93440	Titanium dioxide (dual-use substance)	60	
Yellow	68320	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	6	
	-	Zinc expressed as zinc stearate	5	
	-	Aluminum	1	
	93440	Titanium dioxide (dual-use substance)	60	

				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.
		Zinc	5	
	46880	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	6	
	93440	Titanium dioxide (dual-use substance)	60	
	-	Calciumstearat (E470a) – dual-use-additives		
Black	68320	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	6	
	-	Zinc expressed as zinc stearate	5	

6. Functional barrier.

In the production of the Dafi Soft 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 Soft 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 Soft filtering bottle with exchangeable carbon filter” manufactured by FORMASTER S.A. in Kielce, comply with all cited regulations and thus might be used in contact with food. On the basis of declarations received from suppliers of raw materials and on the basis of the test results , we declare that is not restricted substances in filtered water.

Place: Kielce

Date: 26-07-2023

FORMASTER®
25-818 Kielce, ul. Fabryczna 24
signature of person who prepared this declaration
tel. 41/346 48 00; fax: 41/345 20 36
ANNA KORATCZYK