



Declaration of Compliance

with the legislation for materials and articles intended to come into contact with food

PRODUCT NAME: 500ml TEAM BOTTLE BLACK SOFT TOUCH-K277; SCREW CAP MAT BLACK -K285 AND BIDON NOZZLE TPE BLACK- K285			
Item number Flectic B.V.	Item number Eurobottle B.V.	Description	
20029802120071	I0298020277	500ml SOFT TOUCH, LDPE TEAM BOTTLE - BLACK- K277	
20091802120611	I0918060285	BLACK BIOBASED SCREW CAP- K285	
20085502120819	I0855060285	BLACK TPE NOZZLE - K285	
This declaration is intended for:	Eurobottle B.V.		
Use of the article	Bottle for packaging of foodstuffs		
Company Identification	Flectic B.V.		
Phone Number	+31 (0) 321 316510		
Address	Pioniersweg 32, 8251 KN Dronten, The Netherlands		
The Manufacturer Flectic B.V. declares that all of the raw materials used in the making of the above-mentioned products comply with the requirements for use in contact with food of European Commission Regulation (EU) No 10/2011, up to and including the amendment No 2023/1627. All colourants & pigments used during the production of our product comply with Council of Europe Resolution AP(89). If used, printing inks are low migration inks, certified for printing of the exterior surface of plastic bottles intended to be in contact with food and all their ingredients are listed in Annex 1 and/or 10 of Swiss Ordinance-817.023.21 on Materials and Articles in contact with Food. They meet the Regulation EU 2023/2006 covered by the EuPIA-GMP (Good Manufacturing Practices for the Production of Printing inks formulated for use on the non- food contact surfaces of food packaging and articles intended to come into contact with food. Our products meet the legal regulations laid down in the Regulation (EC) No 1935/2004 (on materials and articles intended to come into contact with food); Regulation (EC) No. 2023/2006 (Good Manufacturing Practice) and directive (EC) No. 94/62 (Packaging Waste). Traceability of the product is ensured via the batch number and order number present on the product label. Food safety is fully integrated in the business policy of Flectic B.V. A review of the ISO22000 Food Safety Management System takes place every year.			
Date of Issue:	July 4, 2024		
Our above-mentioned products are made from virgin raw materials, which are approved for use in contact with food. The bottle is made from LDPE, soft touch additive and black colour masterbatch. The screw cap is made from biobased LDPE, colour and slip masterbatch. The nipple is made from SEBS compound, colour and slip masterbatch. All polymers, monomers and additives making up this product are, according to the statements of our raw material suppliers, listed in EU Directives on plastics in contact with food. The product contains:			
Substances with Specific Migration Limits (SML's) present in the bottle			
Name	CAS no.	FCM no.	SML* or SML(T)*
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	2082-79-3	433	SML=6mg/kg



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N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine	/	19	SML(T)=1.2mg/kg /expressed as tertiary amine/
N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine hydrochlorides;	/	20	SML(T)=1.2mg/kg /expressed as tertiary amine excluding HCl/
Tetrahydrofuran	109-99-9	246	SML=0.6mg/kg
Aluminium	/	Annex II	SML(T)=1mg/kg /expressed as Al/
Antimony	/	Annex II	SML(T)=0.04mg/kg /expressed as Sb/
Arsenic	/	Annex II	SML(T)=0.01mg/kg /expressed as As/
Barium	/	Annex II	SML(T)=1mg/kg /expressed as Ba/
Cadmium	/	Annex II	SML(T)=0.01mg/kg /expressed as Cd/
Chromium	/	Annex II	SML(T)=0.01mg/kg /expressed as Cr/
Cobalt	/	Annex II	SML(T)=0.05mg/kg /expressed as Co/
Copper	/	Annex II	SML(T)=5mg/kg /expressed as Cu/
Lead	/	Annex II	SML(T)=0.01mg/kg /expressed as Pb/
Lithium	/	Annex II	SML(T)=0.6mg/kg /expressed as Li/
Manganese	/	Annex II	SML(T)=0.6mg/kg /expressed as Mn/
Mercury	/	Annex II	SML(T)=0.01mg/kg /expressed as Hg/
Nickel	/	Annex II	SML(T)=0.02mg/kg /expressed as Ni/
Zinc	/	Annex II	SML(T)=5mg/kg /expressed as Zn/
Dual Use Substances present in the bottle			
Name, E#	CAS no.	FCM no.	SML* or SML(T)*
Polyethyleneglycol /E1521/	25322-68-3	638	No SML
Calcium salts of fatty acids /E470a/	/	9	No SML
Substances with Specific Migration Limits (SML's) present in the screw cap			
Name	CAS no.	FCM no.	SML* or SML(T)*
N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine	/	19	SML(T)=1.2mg/kg /expressed as tertiary amine/
N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine hydrochlorides	/	20	SML(T)=1.2 mg/kg /expressed as tertiary amine excluding HCl/



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9,9-bis(methoxymethyl)fluorene	182121-12-6	779	SML=0.05mg/kg
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	2082-79-3	433	SML=6mg/kg
1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	27676-62-6	661	SML=5mg/kg
Triisopropanolamine	122-20-3	292	SML=5mg/kg
1,1,1-trimethylolpropane	77-99-6	141	SML=6mg/kg
Aluminium	/	Annex II	SML(T)=1mg/kg /expressed as Al/
Antimony	/	Annex II	SML(T)=0.04mg/kg /expressed as Sb/
Arsenic	/	Annex II	SML(T)=0.01mg/kg /expressed as As/
Barium	/	Annex II	SML(T)=1mg/kg /expressed as Ba/
Cadmium	/	Annex II	SML(T)=0.01mg/kg /expressed as Cd/
Chromium	/	Annex II	SML(T)=0.01mg/kg /expressed as Cr/
Cobalt	/	Annex II	SML(T)=0.05mg/kg /expressed as Co/
Copper	/	Annex II	SML(T)=5mg/kg /expressed as Cu/
Iron	/	Annex II	SML(T)=48mg/kg /expressed as Fe/
Lead	/	Annex II	SML(T)=0.01mg/kg /expressed as Pb/
Lithium	/	Annex II	SML(T)=0.6mg/kg /expressed as Li/
Manganese	/	Annex II	SML(T)=0.6mg/kg /expressed as Mn/
Mercury	/	Annex II	SML(T)=0.01mg/kg /expressed as Hg/
Nickel	/	Annex II	SML(T)=0.02mg/kg /expressed as Ni/
Zinc	/	Annex II	SML(T)=5mg/kg /expressed as Zn/
Dual Use Substances present in the screw cap			
Name, E#	CAS no.	FCM no.	SML* or SML(T)*
Carbonic acid, calcium salts /E170/	/	21	No SML
2,6-di-tert-butyl-p-cresol /E321/	128-37-0	315	SML=3 mg/kg
Magnesium oxide /E530/	1309-48-4	397	No SML



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Silicon dioxide /E551/	7631-86-9	504	No SML
Quartz /E551/	14808-60-7	616	No SML
1,2-propanediol /E1520/	57-55-6	109	No SML
Stearic acid calcium salt /E470a/	/	106	No SML
Carbonic acid, magnesium salt/E504/	/	21	No SML
White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks /E905a/ NIAS	/	95	No SML
Substances with Specific Migration Limits (SML's) present in the nozzle			
Name, E#	CAS no.	FCM no.	SML* or SML(T)*
N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine	/	19	SML(T)=1.2mg/kg /expressed as tertiary amine/
N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine hydrochlorides	/	20	SML(T)=1.2 mg/kg /expressed as tertiary amine excluding HCl/
9,9-bis(methoxymethyl)fluorene	182121-12-6	779	SML=0.05mg/kg
1,3,5-tris(3,5-di-tert-butyl-4-hydroxy benzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	27676-62-6	661	SML=5mg/kg
Butadiene	106-99-0	223	SML= 0.01mg/kg= non detectable
Acetic acid, vinyl ester	108-05-4	231	SML=12mg/kg
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	2082-79-3	433	SML=6mg/kg
1,1,1-trimethylolpropane	77-99-6	141	SML=6mg/kg
Triisopropanolamine	122-20-3	292	SML=5mg/kg
Aluminium	/	Annex II	SML(T)=1mg/kg /expressed as Al/
Antimony	/	Annex II	SML(T)=0.04mg/kg /expressed as Sb/
Arsenic	/	Annex II	SML(T)=0.01mg/kg /expressed as As/
Barium	/	Annex II	SML(T)=1mg/kg /expressed as Ba/
Cadmium	/	Annex II	SML(T)=0.01mg/kg /expressed as Cd/
Chromium	/	Annex II	SML(T)=0.01mg/kg /expressed as Cr/
Cobalt	/	Annex II	SML(T)=0.05mg/kg /expressed as Co/
Copper	/	Annex II	SML(T)=5mg/kg



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			/expressed as Cu/ SML(T)=48mg/kg /expressed as Fe/ SML(T)=0.01mg/kg /expressed as Pb/ SML(T)=0.6mg/kg /expressed as Li/ SML(T)=0.6mg/kg /expressed as Mn/ SML(T)=0.01mg/kg /expressed as Hg/ SML(T)=0.02mg/kg /expressed as Ni/ SML(T)=5mg/kg /expressed as Zn/
Iron	/	Annex II	
Lead	/	Annex II	
Lithium	/	Annex II	
Manganese	/	Annex II	
Mercury	/	Annex II	
Nickel	/	Annex II	
Zinc	/	Annex II	

Dual Use Substances present in the nozzle

Name, E#	CAS no.	FCM no.	SML* or SML(T)*
Carbonic acid, calcium salts /E170/	/	21	No SML
2,6-di-tert-butyl-p-cresol /E321/	128-37-0	315	SML=3 mg/kg
Silicon dioxide /E551/	/	504	No SML
Calcium salts of fatty acids /E470a/	/	9	No SML
1,2-propanediol /E1520/	57-55-6	109	No SML
Silicon dioxide /E551/	7631-86-9	504	No SML
Quartz /E551/	14808-60-7	616	No SML
Magnesium oxide /E530/	1309-48-4	397	No SML
Carbonic acid, magnesium salt/E504/	/	21	No SML
Talc /E553b/	14807-96-6	615	No SML
White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks /E905a/ NIAS	/	95	No SML

*SML- SPECIFIC MIGRATION LIMIT IN FOOD OR IN FOOD SIMULANT

*SML(T)- SPECIFIC MIGRATION LIMIT IN FOOD OR IN FOOD SIMULANT FOR A GROUP OF SUBSTANCES

*FCM No.-UNIQUE IDENTIFICATION NUMBER OF THE SUBSTANCE

SML & OML: Calculation of the “worst case” migration (100%) for above-mentioned substances, or migration experiments with a representative sample during 10 days on 40°C in food simulant B and D1, have shown that none can exceed their respective SML. Calculation is based on the maximum amount of substances found in raw materials according to our supplier’s Declarations of Compliance.

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Reference:

Commission Directive EU No 10/2011 (32): As migration testing is complex, costly and time consuming it should be admissible that compliance can be demonstrated also by calculation “

Migration experiments with a representative sample during 10 days at 40 °C in the simulants: 3% acetic acid /food simulant B/ and 50% ethanol /food simulant D1/, have shown that under these test conditions the overall migration limit (10 mg/dm²) have not been exceeded. The product is suitable for repeated use, for short time storage (several days, depending on the perishability of the drink). Simulant B (3% acetic acid) and D1 (50% ethanol) will cover all aqueous, acidic and alcoholic beverages and milk products.

Reference:

Commission Directive EU No 2016/1416/ ANNEX V, CHAPTER 3, Table 3- Standardised testing conditions- 10 days at 40 °C (test number OM2) is the regime that simulates any long term storage of food at room temperature or below, including when packed under hot-fill conditions, and/or heating up to a temperature T where $70\text{ °C} \leq T \leq 100\text{ °C}$ for a maximum of $t=120/2^{[(T-70)/10]}$ minutes.

This product is not designed for long term cooking applications!

Please consult our Eurobottle flyer for safe product use/cleaning advice.

According to the “worst case” migration calculations and the representative experimental migration test results our product is suitable for use in contact with food. The foodstuffs corresponding with the food simulants are stated in Regulation EU 10/2011 and its amendments published before the print date of this document.

It should be noted that the representative samples have been tested for the above-mentioned conditions only. It is the responsibility of the legal entity responsible for placing on the market of the article to ensure that the usage of the articles is safe, lawful and technically suitable and can be determined through mutual consultation and agreement.

In addition, it is the responsibility of our customers (downstream user(s)) to determine that their use of our product(s) is safe, and according to the information given in this document, lawful and technically suitable so that no change in flavour, taste or organoleptic properties occur. Because use conditions and applicable laws may differ from one location to another, the customer is responsible for determining whether products and information in this document are appropriate for the customer's use. The purchaser remains responsible for determining whether the use complies with all relevant regulations. For guidelines on preventing any changes in organoleptic properties please contact our sales representative.

The information included in this document is valid from the stated version date until this document is superseded. Because of possible changes in the underlying legislation and regulations, as well as possible changes in our products, we cannot guarantee that the status of this document will remain unchanged. We therefore recommend our customers to verify the regulatory status periodically.

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