VITLAB GmbH | Linus-Pauling-Str. 1 | 63757 Grossostheim | Germany

Declaration of conformity

on plastic materials and articles intended to come into contact with food

We declare under our sole responsibility that our products:

Dropping bottles LDPE, with screw cap and dropper insert of HDPE and closure cap of EVA,

item no. 94587, 94687, 94987, 95087, 95187

meet the present requirements of the Ordinance on Materials and Articles and Regulation (EC) No 1935/2004[1] and Commission Regulation (EU) Nr.10/2011[2] in their actual version (inclusive of their amendments), too.

Analyses by an independent, accredited laboratory according to the overall migration limit of the final article validates no overstepping of the regulated limits. Also, during the organoleptic tests no negative interaction with the food (change of taste and odor of the food) could be discovered. The testing has been performed according to article 17 and 18 of Commission Regulation (EU) No 10/2011 in conjunction with Annex V. Therefore, the above-named products comply with the requirements of Commission Regulation (EU) No. 10/2011 and could be used related to the specified limitation of migration limits in contact with food.

According to statements provided by our raw materials supplier we could declare, that the material currently used for production of the above-named products, has been manufactured in accordance with the relevant requirements of good manufacturing practice for articles intended to come into contact with food, according to Commission Regulation (EC) No 2023/2006[3].

Unless the raw material used for the production of the above-named products contains substances with specified limitation (SML / QM) the defined limiting values according to Commission Regulation (EU) No 10/2011 were observed. The actual version of the Commission Regulation can be downloaded from the Internet at http://eur-lex.europa.eu or http://bfr.bund.de.

[1] OJ L 338, 13.11.2004, p. 4–17
[2] OJ L 12, 15.1.2011, p. 1–89
[3] OJ L 384, 29.12.2006, p. 75–78

VITLAB GmbH | Sitz Grossostheim | AG Aschaffenburg HRB 9616 | WEEE-Reg.-Nr. DE30031601
Geschäftsführer: Dr. Christoph Schöler, Wolfgang Nicolaus | USt-IdNr.: DE 111666959

1. Specification for envisaged use or limitations:

- **Kind of food, which could come into contact with the used material:**

  All types of food (dry, aqueous, sour, alcoholic, fatty) - testet according to table 3 annex III with listed food simulants (1. distilled water or water of equivalent quality or food simulant A (Ethanol 10 Vol.-%); 2. food simulant B (Acetic acid 3 Gew.-%); and 3. food simulant D2 (Any vegetable oil with less than 1 % unsaponifiable matter) - with 95% ethanol and isooctane alternatively according to annex V, chapter 2 paragraph 2.1.3 Conditions of contact when using food simulants.).

- **Kind of food, which should not come into contact with the used material:**

  - (non)

2. Information on the intended field of application:

- **Contact time and contact temperature for using and storing food:**

  tested according to table 3 annex IV for all kind of food, for 10 days at 40 °C (Isooctane for 2 days at 20 °C) resp. for 10 days at 60 °C - shall cover all storage times at refrigerated and frozen conditions including hot-fill conditions and/or heating up to a temperature T, between 70 °C ≤ T ≤ 100 °C, for a period of no more than t = 120/2^((T-70)/10) minutes.

3. Research results:

3.1. Organoleptic test (triangle test, 6 persons) acccording DIN EN 10955:2004-06

Test conditions:

Type of contact: *Insert*

Used simulant: *Mineral water after 10 d at 40 °C*

	Intensity	Significance	Limiting value[4]	Assessment
Deterioration of smell	0	> 20 %	max. 2.5	*passed*
Deterioration of taste	0,5	> 20 %	max. 2.5	*passed*

Scale of intensity: 0 = imperceptible
1 = just discernible
2 = discernible
3 = clear
4 = strong

[4] 61st Notification of German Federal Institute for Risk Assessment (BfR), Principles for the Evaluation of Food Contact Materials (Bundesgesundheitsblatt 2003, p. 363)

3.2. Overall migration

Test conditions:

Type of contact: *Fill the bottle, screw it and then store it lying at 40°C for 10 days.*

Method: *DIN EN 1186:2002-07*

Migration with the following used simulants:

Acetic Acid 3 % for 10 d at 40 °C, with a S:V of 1.2 dm²:100 ml

Ethanol 10 % for 10 d at 40 °C, with a S:V of 1.2 dm²:100 ml

Olive oil for 10 d at 40 °C, with a S:V of 2.88 dm²:310 ml

Ethanol 95 % for 10 d at 40 °C, with a S:V of 1.2 dm²:100 ml

Isooctane for 2 d at 20 °C, with a S:V of 1.2 dm²:100 ml

permitted limit value: max. 10,0 mg/dm² [5].

Food-simulant	***Unit***	***Measutrement uncertainty***	***Sample***	***1. Contact***	***2. Contact***	***3. Contact= Measured value***	***Assessment***
Acetic acid 3 %	*mg/dm²*	*10 %*	*1.*	*< 1*	*< 1*	***< 1***	*passed*
			2.	*< 1*	*< 1*	***< 1***	*passed*
			3.	*< 1*	*< 1*	***< 1***	*passed*
Ethanol 10 %	*mg/dm²*	*10 %*	*1.*	*< 1*	*< 1*	***< 1***	*passed*
			2.	*< 1*	*< 1*	***< 1***	*passed*
			3.	*< 1*	*< 1*	***< 1***	*passed*
Olive oil	*mg/dm²*	*30 %*	*1.*	*2.4*	*2.2*	***2.0***	*passed*
			2.	*1.2*	*1.1*	***1.0***	*passed*
			3.	*0.99*	*0.97*	***0.95***	*passed*
Ethanol 95 %	*mg/dm²*	*10 %*	*1.*	*3.2*	*3.0*	***2.7***	*passed*
			2.	*2.3*	*2.2*	***2.1***	*passed*
			3.	*3.3*	*3.1*	***2.9***	*passed*
Isooctane	*mg/dm²*	*10 %*	*1.*	*8.9*	*8.8*	***8.7***	*passed*
			2.	*6.8*	*6.6*	***6.4***	*passed*
			3.	*8.6*	*8.2*	***8.1***	*passed*

According to Article 12 of Regulation (EU) No. 10/2011 plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm² of food contact surface (mg/dm²). With regard to manner and extent of the performed overall migration test the limiting value is met by the present sample.

[5] according to Regulation (EU) No 10/2011 adapted by Regulation (EU) 2016/1416 - OJ L 230, 25.8.2016, p. 22–42

3.3. Specific Migration

3.3.1. Metalls

Test conditions:

Type of contact: *Fill the bottle, screw it and then store it lying at 60°C for 10 days.*

Method: *DIN EN ISO 17294-2:2014-01*

Used simulant: *Acetic Acid 3 %, for 10 d at 60 °C, with a S:V of 1.2 dm²:100 ml*

Parameter	***Limiting value[5]:***	***Unit***	***1. Contact****	***2. Contact****	***3. Contact*= Measured value***	***Assessment:***
Aluminium [5]	*≤ 1.0*	*mg/kg*	*< 0.1*	*< 0.1*	***< 0.1***	*passed*
Antimony [8]	*≤ 0.04*	*mg/kg*	*< 0.01*	*< 0.01*	***< 0.01***	*passed*
Arsenic [8]	*≤ 0.01*	*mg/kg*	*< 0.002*	*< 0.002*	***< 0.002***	*passed*
Barium [6]	*≤ 1.0*	*mg/kg*	*< 0.01*	*< 0.01*	***< 0.01***	*passed*
Lead [8]	*≤ 0.01*	*mg/kg*	*< 0.002*	*< 0.002*	***< 0.002***	*passed*
Cadmium [8]	*≤ 0.002*	*mg/kg*	*< 0.001*	*< 0.001*	***< 0.001***	*passed*
Chromium [8]	*≤ 0.01*	*mg/kg*	*< 0.01*	*< 0.01*	***< 0.01***	*passed*
Cobalt [6]	*≤ 0.05*	*mg/kg*	*< 0.01*	*< 0.01*	***< 0.01***	*passed*
Iron [6]	*≤ 48.0*	*mg/kg*	*< 0.1*	*< 0.1*	***< 0.1***	*passed*
Copper [6]	*≤ 5.0*	*mg/kg*	*< 0.01*	*< 0.01*	***< 0.01***	*passed*
Lithium [6]	*≤ 0.6*	*mg/kg*	*< 0.01*	*< 0.01*	***< 0.01***	*passed*
Manganese [6]	*≤ 0.6*	*mg/kg*	*< 0.01*	*< 0.01*	***< 0.01***	*passed*
Nickel [7]	*≤ 0.02*	*mg/kg*	*< 0.01*	*< 0.01*	***< 0.01***	*passed*
Mercury [8]	*≤ 0.01*	*mg/kg*	*< 0.001*	*< 0.001*	***< 0.001***	*passed*
Zinc [5]	*≤ 5.0*	*mg/kg*	*< 0.05*	*< 0.05*	***< 0.05***	*passed*
Europium [8]	*≤ 0.05*	*mg/kg*	*< 0.01*	*< 0.01*	***< 0.01***	*passed*
Gadolinium [8]		*mg/kg*	*< 0.01*	*< 0.01*	***< 0.01***	*passed*
Lanthanum [8]		*mg/kg*	*< 0.01*	*< 0.01*	***< 0.01***	*passed*
Terbium [8]		*mg/kg*	*< 0.01*	*< 0.01*	***< 0.01***	*passed*

* *relative measurement uncertainty 30 %*

[5] according to Regulation (EU) No 10/2011 adapted by Regulation (EU) 2016/1416 - OJ L 230, 25.8.2016, p. 22–42

[6] according to Regulation (EU) No 10/2011 - OJ L 12, 15.1.2011, p. 1–89

[7] according to Regulation (EU) No 10/2011 adapted by Regulation (EU) 2017/752 - OJ L 113, 29.4.2017, p. 18–23

[8] according to Regulation (EU) No 10/2011 adapted by Regulation (EU) 2020/1245 - OJ L 288, 03.9.2020, S. 1–19

According to information provided by our raw material supplier no monomers or additives are used, which are controlled by a specific migration limit:

3.3.2. N,N-Bis(2-hydroxyethyl)alkyl(C8-C18)amin [FCM 19; Ref.-no: 39090] and N,N-Bis(2-hydroxyethyl)alkyl(C8-C18)aminhydrochloride [FCM 20; Ref.-no: 39120]

Test conditions:

Type of Contact: *Fill the bottle, screw it and then store it lying at 60°C for 10 days.*

Method: *WEX 1022*

Used Simulant: *Olive oil, for 10 d at 60 °C, with a S:V of 1.8 dm²:100 ml*

Limiting value [5]:	***Unit***	***1. Contact***	***2. Contact***	***3. Contact***	***Assessment:***
< 1.20	*mg/kg*	*< 1.00*	*< 1.00*	*< 1.00*	*passed*

**SML(T) calculated as tertiary amine*

3.3.3. Octadecyl-3-(3,5-di-ter-butyl-4-hydroxyphenyl)propionat [FCM 433; Ref.-no. 68320]

Test conditions:

Type of Contact: *Fill the bottle, screw it and then store it lying at 60°C for 10 days.*

Method: *WBSE-89 (GC-MS)*

Used Simulant: *Olive oil, for 10 d at 60 °C, with a S:V of 1.8 dm²:100 ml*

Limiting value [5]:	***Unit***	***1. Contact***	***2. Contact***	***3. Contact***	***Assessment:***
< 6.00	*mg/kg*	*< 1.00*	*< 1.00*	*< 1.00*	*passed*

3.3.4. Vinylacetat [FCM Stoff 231; Ref.-Nr. 10120]

Test conditions:

Type of Contact: *Fill the bottle, screw it and then store it lying at 60°C for 10 days.*

Method: *CEN/TS 13130-9:2005*

Used Simulant: *Olive oil, for 10 d at 60 °C, with a S:V of 1.8 dm²:100 ml*

Limiting value [5]:	***Unit***	***1. Contact***	***2. Contact***	***3. Contact***	***Assessment:***
< 12.00	*mg/kg*	*< 1.00*	*< 1.00*	*< 1.00*	*passed*

[5] according to Regulation (EU) No 10/2011 adapted by Regulation (EU) 2016/1416 - OJ L 230, 25.8.2016, p. 22–42

3.3.5. 2,6-Di-tert-butyl-4-ethylphenol [FCM 477; Ref.-no. 46720]

Test conditions:

Type of Contact: *Fill the bottle, screw it and then store it lying at 60°C for 10 days.*

Method: *WEX 1982 (GC-MS)*

Used Simulant: *Olive oil, for 10 d at 60 °C, with a S:V of 2.5 dm²:250 ml*

Limiting value [5]:	***Unit***	***1. Contact***	***2. Contact***	***3. Contact***	***Assessment:***
4.80	*mg/kg*	*< 0.05*	*< 0.05*	*< 0.05*	*passed*

3.3.6. Butyl Hydroxytoluene

Test conditions:

Type of Contact: *Fill the bottle, screw it and then store it lying at 60°C for 10 days.*

Method: *WEX 1982 (GC-MS)*

Used Simulant: *Olive oil, for 10 d at 60 °C, with a S:V of 2.4 dm²:200 ml*

Limiting value [5]:	***Unit***	***1. Contact***	***2. Contact***	***3. Contact***	***Assessment:***
3.00	*mg/kg*	*< 0.05*	*< 0.05*	*< 0.05*	*passed*

* *calculated with the norm cube of 6 dm²/kg according to Article 17 of Regulation (EU) No 10/2011*

[5] according to Regulation (EU) No 10/2011 adapted by Regulation (EU) 2016/1416 - OJ L 230, 25.8.2016, p. 22–42

3.4. GC-MS-Overview analysis (NIAS[6]-Screening) by means of the EPA Method 8270D:

Test conditions:

Type of Contact: *Fill the bottle, screw it and then store it lying at 60°C for 10 days.*

Method: EPA 8270D (GC-MS)

Used Simulant *Ethanol 95 %, for 10 d at 60 °C, with a S:V of 1.8 dm²:100 ml*

The migrate was analyzed gas chromatographically by means of mass spectrometric detection. For the identification of the signals in the chromatogram a commercial mass spectra library was used. Results are expressed in hexadecane (SVOCs) equivalents and may vary to the real amount. We point out that the mentioned amounts may vary to the real amounts as this is a screening approach.

Non-volatile substancen (SVOCs):		
Substance	***CAS***	***Concentration[#] [mg/kg]***
*Aliphatic hydrocarbons (C12-C16) (**Sum**) (1)*	*-*	*0.02*
*Aliphatic hydrocarbons (C16+) (**Sum**) (1)*	*-*	*1.63*
Octadecanoic acid, ethyl ester (Ethyl stearate) (4)	*111-61-5*	*0.01*
*Not identified alcohols (**Sum**) (3)*	*-*	*0.37*
Not identified ketone (2)	*-*	*0.01*
Not identified organic acid ester (2)	*-*	*0.01*

[#]*Measurement uncertainty 65% (the repeatability within a measurement series of a sample (same substance) < 10%)*

[6] according to Regulation (EU) Nr. 10/2011 - OJ L 12, 15.1.2011, p. 1–89

Assessment of NIAS[6] screening results

Aliphatic hydrocarbons (1)

Aliphatic hydrocarbons were detected during the investigation. Currently, no assessment values for the migration of hydrocarbons exist within the framework of Regulation (EU) 10/2011. As the sample at hand is made of polyolefin plastic, it is possible that the hydrocarbons originate from the plastic material itself.

Not identified compounds (2)

According to the type and scope of the investigations carried out, compounds that were not clearly identified were recorded. Since no clear identification is possible based on the mass spectrum, a final evaluation cannot be made at this point.

Aliphatic unbranched alcohols (C4-C24) (3)

According to the type and extent of the investigation carried out, aliphatic unbranched alcohols were detected. According to Regulation (EU) No. 10/2011 Annex I, aliphatic, monohydric, saturated, degree-chain, primary alcohols (C4 -C24) are listed without a specific migration limit. The content is therefore assessed as inconspicuous.

Fatty acid, -esters, -amides (4)

According to the type and extent of the investigations carried out, fatty acid derivatives were detected. According to Regulation (EU) No 10/2011 Annex I, the derivatives detected here (from animal or vegetable oils) with linear or branched, monohydric, primary, saturated, aliphatic alcohols (C 1-C 22) and the amides detected here are listed without a specific migration limit. In view of this, the content recorded here is judged to be inconspicuous.

[6] according to Regulation (EU) Nr. 10/2011 - OJ L 12, 15.1.2011, p. 1–89

4. Reference to „Dual-Use-Substances“:

The raw material does not contain substances also authorised as direct food additives ("Dual use additives") according to Regulation (EG) No 1333/2008[9] in its actual version.

FCM-material 009; Ref.-no. 30610 - Lubricant: Calciumstearate (E470a)

No functional barrier of plastic material is used.

To ensure the traceability of the product according to Regulation (EC) No 1935/2004 a date-stamp is used at the product itself or a LOT No. is printed on the product label.

In addition, we have to point out that the used raw material is not intended to be used for medical, pharmaceutical or healthcare applications and the manufacturer do not support their use for such applications. This product is neither tested nor represented as suitable for medical or pharmaceutical uses by us. It is in the scope of the end-user to validate the product for applications which differs from the guidelines of the Commission Regulation (EU) No 10/2011.

VITLAB GmbH

Grossostheim, 11. February 2025

Wolfgang Nicolaus	i.A. Dr. Stephan Schmidt
Geschäftsführer Managing Director	Beauftragter Product Compliance Regulatory Affairs

This letter has been typed and is valid without signature.

[9] according to Regulation (EU) No 1333/2008 - OJ L 354, 31.12.2008, p. 16–33