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:

Scoops HDPE, black,

item no. 4069440, 407944

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 odour 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) according 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	> 20 %	max. 2.5	*passed*

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

3.2. Colour fastness (BfR-Recommendation IX 2010-01)

Colourfast against…	dist. water	acetic acid 2 %	ethanol 10 %	peanut oil
Result for sample	*„colourfast“*	*„colourfast“*	*„colourfast“*	*„colourfast“*

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

3.3. Overall migration

Test conditions:

Type of contact: *Insert*

Method: *DIN EN 1186:2002-07*

Migration mit den folgenden verwendeten Simulanzien:

Acetic Acid 3 % for 10 d at 40 °C, with a S:V of 0.6 dm²:100 ml

Ethanol 10 % for 10 d at 40 °C, with a S:V of 0.6 dm²:100 ml

Olive öl for 10 d at 40 °C, with a S:V of 2.0 dm²:200 ml

Ethanol 95 % for 10 d at 40 °C, with a S:V of 0.6 dm²:100 ml

Isooctane for 2 d at 20 °C, with a S:V of 0.6 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.*	*1.7*	*1.6*	***1.4***	*passed*
			2.	*1.2*	*1.4*	***1.3***	*passed*
			3.	*1.7*	*1.5*	***1.3***	*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.*	*1.9*	*1.7*	***1.6***	*passed*
			2.	*1.2*	*1.5*	***1.3***	*passed*
			3.	*1.3*	*1.4*	***1.1***	*passed*
Ethanol 95 %	*mg/dm²*	*10 %*	*1.*	*< 1*	*< 1*	***< 1***	*passed*
			2.	*< 1*	*< 1*	***< 1***	*passed*
			3.	*< 1*	*< 1*	***< 1***	*passed*
Isooctane	*mg/dm²*	*10 %*	*1.*	*< 1*	*< 1*	***< 1***	*passed*
			2.	*< 1*	*< 1*	***< 1***	*passed*
			3.	*< 1*	*< 1*	***< 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

3.4. Specific migrations

3.4.1. Metalls

Test conditions:

Type of Contact: *Insert*

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

Used Simulant: *Acetic Acid 3 % for 10 d at 60 °C, with a S:V of 3.8 dm²:2000 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*
Cupper [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*
Lanthan [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 monomers or additives are used, which are controlled by a specific migration limit:

3.4.2. Primary aromatic amines, calculated as aniline hydrochloride

Test conditions:

Type of Contact: *Filled*

Method: *ASU L 00.00-6 (1995-01) + (2002-12)*

Used Simulant: *Acetic acid 3 % for 10 d at 60 °C, with a S:V of 3.8 dm²:2000 ml*

Limiting value[6]: max.	***Unit***	***1. Contact ****	***2. Contact ****	***3. Contact ****	***Assessment:***
< 0,01	*mg/kg*	*< 0,002*	*< 0,002*	***< 0,002***	*passed*

* *relative Measurement uncertainty 35 %*

3.4.3. Primary aromatic amines (single substances)

Test conditions:

Type of Contact: *Filled*

Method: *WBSE-98 (LC-MS/MS)*

Used Simulant: *Acetic acid 3 % for 10 d at 60 °C, with a S:V of 3.4 dm²:560 ml*

Parameter	***CAS***	***Limiting value [5]:***	***Unit***	***Measured value*:***	***Assessment:***
Aniline [c]	*62-53-3*	*10 [b]*	*µg/kg*	***< 0.1***	*passed*
o-Toluidine [c]	*95-53-4*	*2*	*µg/kg*	***< 0.1***	*passed*
o-Anisidine [c]	*90-04-0*	*2*	*µg/kg*	***< 0.1***	*passed*
4-Chloroaniline [c]	*106-47-8*	*2*	*µg/kg*	***< 0.1***	*passed*
p-Cresidine [c]	*120-71-8*	*2*	*µg/kg*	***< 0.1***	*passed*
4-Chloro-o-toluidine [c]	*95-69-25*	*2*	*µg/kg*	***< 0.1***	*passed*
2-Methyl-5-nitroaniline [c]	*99-55-8*	*2*	*µg/kg*	***< 0.25***	*passed*
4-Aminodiphenyle [c]	*92-67-1*	*2*	*µg/kg*	***< 0.1***	*passed*
4,4'-Oxydianiline [c]	*101-80-4*	*2*	*µg/kg*	***< 0.1***	*passed*
3,3'-Dimethylbenzidine [c]	*119-93-7*	*2*	*µg/kg*	***< 0.1***	*passed*
4,4'-Thiodianiline [c]	*139-65-1*	*2*	*µg/kg*	***< 0.1***	*passed*
3,3'-Dimethyl-4,4'-diaminodiphenylmethane [c]	*838-88-0*	*2*	*µg/kg*	***< 0.1***	*Passed*
4,4'-Methylen-bis-(2-chloroaniline) [c]	*101-14-4*	*2*	*µg/kg*	***< 0.1***	*passed*

[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

Parameter	CAS	Limiting value [5]:	Unit	Measured value*:	Assessment:
p-Toluidine	106-49-0	10 [b]	µg/kg	**< 0.25** [d]	passed
2,4-Toluylendiamine [c]	95-80-7	2	µg/kg	**< 0.1**	passed
2,4-Diaminoanisole [c]	615-05-4	2	µg/kg	**< 0.1**	passed
2-Naphthylamine [c]	91-59-8	2	µg/kg	**< 0.1**	passed
Benzidine [c]	92-87-5	2	µg/kg	**< 0.1**	passed
4,4'-Diaminodiphenylmethane [c]	101-77-9	2	µg/kg	**< 0.1**	passed
o-Aminoazotoluene [c]	97-56-3	2	µg/kg	**< 0.1**	passed
3,3'-Dimethoxybenzidine [c]	119-90-4	2	µg/kg	**< 0.1**	passed
3,3'-Dichlorobenzidine [c]	91-94-1	2	µg/kg	**< 0.1**	passed
2,4,5_Trimethylaniline [c]	137-17-7	2	µg/kg	**< 0.1**	passed
4-Aminoazobenzene [c]	60-09-3	2	µg/kg	**< 0.1**	passed

* *Measured value = Mean value from triple determination*
[c] *in Appendix 8 of Regulation (EC) No. 1907/2006*
[b] *Limiting value of the sum*
[d] *The LOQ of p-Toulidine had to be increased due to matrix effect.*

3.4.4. Octadecyl-3-(3,5-di-ter-butyl-4-hydroxyphenyl)propionate [FCM 433; Ref.-No. 68320]

Test conditions:

Type of Contact: *Insert*

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

Used Simulant: *Ethanol 95 % for 10 d at 60 °C, with a S:V of 3.8 dm²:2000 ml*

Limiting value [6]:	Unit	1. Contact*	2. Contact*	3. Contact*= Measured value	Assessment:
< 6.00	mg/kg	< 1.0	< 1.0	**< 1.0**	passed

3.4.5. Zinc-Stearate calculated as zinc [FCM 106; Ref.-No. 89040]

Test conditions:

Type of Contact: *Insert*

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

Used Simulant: *Ethanol 95 % for 10 d at 60 °C, with a S:V of 3.8 dm²:2000 ml*

Limiting value [6]:	Unit	1. Contact*	2. Contact*	3. Contact*= Measured value	Assessment:
< 5.00	mg/kg	< 0.05	< 0.05	**< 0.05**	passed

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

3.4.6. Substance B

Test conditions:

Type of Contact: *Insert*

Method: *DIN EN ISO 17294-2:2017-1*

Used Simulant: *Acetic Acid 3 % for 2 h at 70 °C then for 10 d at 40 °C, witch a S:V of 10.7 dm²:2000 ml*

Limiting value [6]:	***Unit***	***1. Contact****	***2. Contact****	***3. Contact*= Measured value***	***Assessment:***
< 1.00	*mg/kg*	*< 0.01*	*< 0.01*	***< 0.01***	*passed*

* *relative measurement uncertainty 30 %*

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

3.5. GC-MS-Overview analysis (NIAS[6] - screening) according to EPA Method 8270D:

Test conditions:

Type of Contact: *Insert*

Method: *EPA 8270D (GC-MS)*

Used Simulant: *Ethanol 95 % for 10 d at 60 °C, with a S:V of 10.7 dm²:2000 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]***
Tetradecane (1)	*629-59-4*	***0.02***
Octadecane (1)	*593-45-33*	***0.05***
Eicosane (1)	*112-95-8*	***0.04***
Docosane (1)	*629-97-0*	***0.03***
Tetracosane (1)	*646-31-1*	***0.02***
Hexacosane (1)	*630-01-3*	***0.01***
*7,9-Di-tert-butyl-1-oxaspiro(4,5)deca-6,9-dien-2,8-dione (3)****	*82304-66-3*	***0.01***
Irgafos 168 (2)	*31570-04-4*	***0.35***
Oxidised Irgafos 168 (2)	*95906-11-9*	***0.19***

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

**Cramer-Class I: Limiting value: (sTDI) of 0,03 mg/kg b.w./day resulting in a derived SML value of 1,8 mg/kg foodstuff*

***Cramer-Class II: Limiting value: (sTDI) of 0,009 mg/kg b.w./day resulting in a derived SML value of 0,54 mg/kg foodstuff0*

****Cramer-Class III: Limiting value: (sTDI) of 0,0015 mg/kg b.w./day resulting in a derived SML value of 0,09 mg/kg foodstuff*

[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.

Irgafos 168 and and degradation product (Oxidised Irgafos 168) (2)

With regards to manner and extent of the performed GC-MS analysis, oxidized Irgafos 168 and Irgafos 168 were recorded. Oxidized Irgafos 168 is may be degradation or reaction product of Irgafos 168. Irgafos 168 is used as an antioxidant in plastics production and is listed in Annex I of Regulation (EU) No. 10/2011 without restriction. The risk assessment of this substance should cover the substance itself and its oxidized form and degradation products, as an antioxidant can be expected to oxidize during processing or storage of the plastic. From this point of view, the concentration in the migrate of the present sample is judged to be unremarkable.

Other substances: 7,9-Di-tert-butyl-1-oxaspiro(4,5)deca-6,9-diene-2,8-dione (3)

With regards to manner and extent of the performed GC-MS analysis, 7,9-di-tert-butyl-1-oxaspiro(4,5)deca-6,9-diene-2,8-dione was detected. This may be degradation or reactivity product of Irganox 1010. Irganox 1010 is used as an antioxidant in the production of plastics and is listed in Annex I of Regulation (EU) No. 10/2011 without restriction. The risk assessment of this substance should cover the substance itself and its oxidized form, since an antioxidant is expected to oxidize during processing or storage of the plastic. Under this aspect, the concentration in the migrate of the present sample is judged to be inconspicuous.

Specific migration limits do not currently exist in Regulation (EU) 10/2011 for these substances. They are not listed in Annex I of Regulation (EU) No. 10/2011, i.e. the guideline value for non-listed substances of < 0.01 mg/kg (non-detectable) in the sense of this regulation should be used as a guideline here.

In addition, Article 19 of Regulation (EU) No 10/2011 stipulates mutatis mutandis that substances that have been detected and are not included in Annex I of the Union list must be subject to a risk assessment in accordance with scientifically recognized principles. A specific migration limit of 0.01 mg/kg exists in Annex 10 of the Ordinance of the FDHA on materials and articles intended to come into contact with foodstuffs (as of 15 October 2022, "List of permitted substances for the manufacture of printing inks and requirements for these substances"). According to the type and scope of the tests carried out, this orientation value is not complied with by the sample at hand.

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

Migration limits for the detected substances do not exist at present, toxicological studies on these substances are also not available to us. We are therefore guided by the classification of substances into Cramer classes based on structural properties. This was done according to the "Threshold of Toxicological Concern" (TTC) concept using the software "Toxtree 3.1.0, Revised Cramer Decision Tree".

The underlying structure of 7,9-Di-tert-butyl-1-oxaspiro(4,5)deca-6,9-diene-2,8-dione, leads to a classification of Cramer Class III, for which an intake of up to 1,5 µg/kg body weight/day is considered tolerable. Assuming a person weighing 60 kg, this corresponds to a permitted limiting value of 90 µg substance/person per day.

Considering all substances, for which a classification into a Cramer class is given, taking into account the different hazard classes, a daily consumption of < 690 g kg of food, that has been in contact with the article under similar conditions and has comparable dissolving properties with regard to the substance, will not exceed the limiting value and therefore the content of the other detected substances can be regarded as 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 contains substances also authorised as direct food additives ("Dual use additives") according to Regulation (EG) No 1333/2008 [9] in its actual version.

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

FCM 575; Ref.-no. 76721 - Lubricant: Polydimethylsiloxane (MG > 6800 Da)

FCM 610; Ref.-no. 93440 - Pigment: Titanium dioxide TiO_2 (E171)

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	Beauftragter Product Compliance
Managing Director	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