

relating to plastic materials and articles intended to come into contact with foodstuffs

Document translated from German.

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Date:	03.04.2019	<b>In case of differences, the current version of the German version is valid.</b>		
Customer:	Rink GmbH	Page 1 of 8		
Designation of article:	Tecobag 3 Liter	Tecobag 5 Liter	Tecobag 10 Liter	Tecobag 20 Liter
Tesseraux material no.:	30002400320w	3003950290d	30003700500u	30004600640b
Customer material no.:	without			

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### 1. Issuer of the declaration

Name: **Tesseraux Spezialverpackungen GmbH**

Street, no. Zum Mühlgraben 1 Phone: +49-6206-98 72-0

Postal code, city: 68642 Bürstadt Fax: +49-6206-98 72-72

Country: Germany E-Mail: [info@tesseraux.de](mailto:info@tesseraux.de)

The issuer of this declaration is also the manufacturer of the above-mentioned packaging.

### 2. Used materials

#### 2.1. Designation of the materials

Outer film: 66 µm EVOH, transparent

Inner film: 50 µm LLD/LDPE, transparent / 20 Literausführung 2 x 50µm LLD/LDPE

Spout: amkf, transparent

Adapter: without

Cap: Vitop, red/black

#### 2.2. Inks

We do not print large-scale prints on the product. The product receives only a small-area traceability printing on the outer surface (no contact with the fill good). According to the declaration from our ink supplier the used inking systems comply with the Regulation (EC) No. 1935/2004. When used appropriately the ink is physiologically harmless and can be used for small-area marking of food packaging.

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In particular we like to point out that under no circumstances a contact is allowed between printing inks and foodstuff.

### 2.3. Sterilisation of product by gamma irradiation

Has the product been irradiated by gamma rays?

 YES     NO

Dose: -/- kGy

### 3. Declaration of conformity

As a manufacturer of flexible packaging (bags) from plastic films and laminates we only assemble purchased raw materials, e.g. films and spouts. All information about critical substances in the single components of the packaging is based on available statements from our suppliers.

According to the available information our products and the used materials comply with the following legal regulations or recommendations:

#### Germany:

- German Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch – LFGB) §§ 30 and 31.
- German Foods and Commodities Ordinance (Bedarfsgegenständeverordnung) from 10.04.1992 and its amendments.
- Requirements of the respective relevant recommendations of the Federal Institute for Risk Assessment (BfR).

#### Europe:

- EU Frame Regulation (EC) No. 1935/2004.
- Regulation (EU) No. 10/2011 and its amendments.
- EU Packaging Directive 94/62/EC, article 11 concerning the concentration of heavy metals (plumb, cadmium, mercurial and hexavalent chromium).

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- Regulation (EC) 2023/2006 (GMP regulation) article 5 and 7 concerning the requirements on quality assurance, quality control system and documentation.

Swiss:

- Bundesgesetz über Lebensmittel und Gebrauchsgegenstände (Lebensmittelgesetz, LMG 817.0) und Lebensmittel- und Gebrauchsgegenständeverordnung (LGV 817.023.21)

USA:

- We have confirmations from our suppliers, that the used raw materials comply with the following paragraphs of the *Code of Federal Regulations* of the *Food and Drug Administration* (FDA):

Material	Components	comply with the requirements of:
66 µm EVOH, transparent	Polyolefine	177.1520
	Additive	177.1520
	HV	175.105
	EVOH	177.1360
50 µm LLD/LDPE,	Olefin polymers	21 CFR 177.1520
amkf, transparent	Polyolefine	21 CFR 177.1520
	Polyolefine	21 CFR 178.1520
Vitop, schwarz/rot		21 CFR

4. Migration

The compliance has been assessed by:

- Regulation (EU) No 10/2011 der Commission on plastic materials and articles intended to come into contact with food (see transitional arrangements),
- Worst-case calculations,
- Supplier confirmations.

This declaration is exclusively designed for the above-mentioned company and replaces all former declarations of compliance for the mentioned product. This declaration is valid for maximum two years or until a new declaration is issued. Following an interruption of delivery for more than 12 months the declaration will lose its validity for the next deliveries of the product this document relates to. This declaration is issued by: Tesseraux SPEZIALverpackungen GmbH • Zum Mühlgraben 1 • D-68642 Bürstadt/Germany • Phone.: +49 (0) 62 06-98 72-0 • Fax: +49 (0) 62 06-98 72-72 • E-Mail: info@tesseraux.de

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The inspection reports and the supplier confirmations concerning migration tests are part of our internal documentation. They can be viewed in the course of an audit.

#### 4.1. Overall migration

The overall migration of the above mentioned films has been tested under the following test conditions:

Material	Simulant	Method	Time	Temperature
50 µm LLD/LDPE, transparent	3% Essig Olivenöl 10% Ethanol 50% Ethanol		10 Day	60°C
66 µm EVOH, transparent	Essigsäure 3 % Wasser Ethanol 10 % ISO-Octane		4 h	100°C 100°C 100°C 60°C
amkf, transparent	Dest. Wasser Essigsäure 3% Ethanol 50% Olivenöl	gravimetric	10 Day	40°C
Vitop, schwarz/rot	Dest. Wasser Essigsäure 3% Ethanol 50% Olivenöl	gravimetric	10 day	40°C

Under the chosen test conditions the legally required limit of 10 mg/dm<sup>2</sup> or 60 mg/kg of food according to Regulation (EU) No. 10/2011 has not been exceeded.

#### 4.2. Substances with specific migration limits (SML) and residual contents (QM)

According to the information of our suppliers the following substances with a specific migration limit are contained in the used materials:

Ref.-No./CAS-No.	Substance	Restrictions (SML, QM)*
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Inner film (with direct food contact): <b>50 µm LLD/LDPE, transparent</b>		
0002082-79-3	octadecyl-3-(3,5-ditertbutyl-4-hydroxyphenyl)propionate	6 ppm/kg
0000557-05-1	zincstearate	25 mg/kg (Zinc)
0000116-15-4	Hexafluorpropylen	Not detectable
0000075-38-7	Vinylidene fluoride	5 mg/kg
Outer film (without food contact): <b>66 µm EVOH, transparent</b>		
000111-66-0	1-Octen	15 mg/kg
000592-41-6	1-Hexene	3 mg/kg
010043-35-3	Borsäure	6mg/kg
000116-15-4	Hexafluorpropylen	0,01 mg/kg (nicht
000108-31-6	Maleinsäureanhydrid	30mg/kg
002082-79-3	Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionat)	6 mg/kg
000057-11-4	Stearinsäure	25mg/kg
(Ref. 74400)	Tris(nonyl- und oder phenyl)phosphite	30 mg/kg
000108-05-4	Vinylacetat	12 mg/kg
000075-38-7	Vinylidenfluorid	5mg/kg
001314-13-2	Zinkoxid	25mg/kg
000471-34-1	Calciumcarbonat	ohne
000112-84-5+	Erucasäureamid + Polymer Processing Aid	BfR und FDA 6,6%
000116-15-4+		
000075-38-7		
Cap: <b>Vitop black/red</b>		
According to supplier's statements, raw materials used to manufacture the abovementioned products, contain one or more substance/s which is/are regulated with a specific migration limit. The identity of this/these substance/s can be disclosed upon special request and under maintaining secrecy.		

\* SML = the specific migration limit applicable for the substance. It is expressed in mg substance per kg food, QM = maximum permitted quantity of the substance in the finished material or article

### 4.3. Dual-Use-Additives

According to the information provided by our raw material suppliers following dual use additives are included in the above mentioned articles. Please note, that the information about dual use substances from our raw material suppliers and their suppliers may be incomplete, since there is no legally regulated and complete list of this substance group.

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CAS no.	Substance	Restrictions (SML, QM)*
Inner film (with direct food contact): <b>50 µm LLD/LDPE, transparent</b>		
0007631-86-9	Silicium Dioxide	
0014807-96-6	Talc	
0012141-46-7	Aluminium silicate	
Outer film (without food contact): <b>66 µm EVOH, transparent</b>		
000471-34-1	Calciumcarbonat	
000057-11-4	Stearinsäure	
014807-96-6	Talkum	
Cap: <b>Vitop black/red</b>		
According to supplier's statements, raw materials used to manufacture the abovementioned products, contain one or more substance/s which is/are regulated with a specific migration limit. The identity of this/these substance/s can be disclosed upon special request and under maintaining secrecy.		

#### 4.4. 10 ppb-Screening

Tesseraux Spezialverpackungen Artikel			30002400320w					
Material	-		1 x LLD/LDPE					
Raytreatment	-		50µm					
limit		IST	15 kGy					
Width (inside) in mm	-	-	240,0					
Length (inside) in mm	-	-	320,0					
Filling quantity in kg			<b>3,00</b>					
Contact area in dm <sup>2</sup> (related to filling quantity)			<b>15,4</b>					
<b>Packaging/food surface ratio in dm<sup>2</sup>/kg</b>			<b>5,1</b>					
EU Convention in accordance with Regulation (EU) 10/2011								
	[µg/kg]	[µg/dm <sup>2</sup> ]	[µg/kg]					
Erucamid (ESA)	60.000	70,7	362,0					
Irgafos 168ox	60.000	24,3	124,4					
Irgafos 168	60.000	4,7	24,1					
Irganox 1076	6.000	4,1	21,0					
Tesseraux Spezialverpackungen Artikel			30003950290d		30003700500u		30004600640b	
Material	-		1 x LLD/LDPE 50µm		1 x LLD/LDPE 50µm		2 x LLD/LDPE 50µm	
Raytreatment	-		15 kGy		15 kGy		15 kGy	
limit		IST			IST		IST	
Width (inside) in mm	-	-	290,0		370,0		460,0	

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	-	-	395,0	-	500,0		640,0
Length (inside) in mm							
Filling quantity in kg			<b>5,00</b>		<b>10,00</b>		<b>20</b>
Contact area in dm <sup>2</sup> (related to filling)			<b>22,9</b>		<b>37,0</b>		<b>58,9</b>
<b>Packaging/food surface ratio in dm<sup>2</sup>/kg</b>			<b>4,6</b>		<b>3,7</b>		<b>2,9</b>
EU Convention in accordance with Regulation							
	[µg/kg]	[µg/dm <sup>2</sup> ]	[µg/kg]	[µg/dm <sup>2</sup> ]	[µg/kg]	[µg/dm <sup>2</sup> ]	[µg/kg]
Erucamid (ESA)	60.000	70,7	323,9	70,7	261,6	70,7	208,1
Irgafos 168ox	60.000	24,3	111,3	24,3	89,9	24,3	71,5
Irgafos 168	60.000	4,7	21,5	4,7	17,4	4,7	13,8
Irganox 1076	6.000	4,1	18,8	4,1	15,2	4,1	12,1

## 5. Absence of substances

### 5.1. Phthalates and Bisphenol A

According to the statements of our film suppliers no phthalates or Bisphenol A are intentionally added during the manufacturing of the raw materials or during the further processing.

### Declaration to chapter 5

Tesseraux Spezialverpackungen GmbH hereby declares that for the production of the above mentioned products supplied to your company no above mentioned substances are introduced during the whole manufacturing process. Therefore the products have not been tested for these substances.

## 6. Specifications on the use of the product

### 6.1. Type of food with which it is intended to come into contact

All food that is corresponding with simulants A, B, D1 and D2 in Annex III in COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011

### 6.2. Time and temperature of treatment and storage in contact with the food

Testing cover long term storage above 6 months at room temperature and below including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes. If the times are exceeded, active cooling must be used.

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### 6.3. Ratio of food contact surface area to volume

See table chapter 4.4

### 6.4. Functional barriers

When using a functional barrier in our product, we confirm that it complies with the requirements of article 13, paragraphs 2, 3 and 4, or article 14, paragraphs 2 and 3 of Regulation (EU) no. 10/2011.

### 7. Remarks

The responsibility for the acceptance tests concerning the suitability of the product for the intended use - filling of the product under the actual conditions - falls to the food packers. Tesseraux Spezialverpackungen GmbH is not responsible for the quality changes of the food caused by interactions with the packaging materials and their components.

The package is not generally provided to hold the filling material during the cooking and pasteurization.

Best regards  
TESSERAUX SPEZIALverpackungen GmbH



i.A. Andreas Hamenstädt  
Qualitätsmanagement

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