

Aktum A/S
Møllehaven 10
4040 Jyllinge
Tel.: +45 88445566

Tuesday, 21 October 2014

Declaration of Conformity

for the productgroup(s):

side seal (SR) / tubular bags (SL) PA/PE

We confirm that products mentioned above are in conformity with the following laws and standards:

- Regulation 1935/2004 EC, in particular Article 17 (Traceability)
- Directive 10/2011 EC including current amendments
- Legislation of the Federal Republic of Germany concerning foodstuffs and consumer goods (Deutsches Lebensmittel- und Futtermittelgesetzbuch -LFGB-)
- Recommendations by the Federal Institute of Risk Assessment, BfR, part A
- Regulation (EC) no. 2023/2006 (GMP).
- FDA-Regulations, 21 CFR, lastly amended 01.04.2009
- For printed films:

EUPIA Guideline on printing inks; applied to the non-food contact surface of food packaging materials, November 2011, and exclusion list for printing inks and related products, April 2011 (Publisher: CEPE Conseil European de L'Industrie des Peintures, des Encres d' Imprimerie et des Couleurs d'Art, Brussels)

- Directive 94/62/EC, lastly amended by 2013/2/EC on 07.02.2013 (heavy metal concentration < 100 ppm)
- Ordinance (Verpackungsverordnung), lastly amended on 09.11.2010.

Application conditions:

a) Kinds of food, which is to come into contact with the material:

- Fatty, aqueous and dry filling goods

b) Kinds of food, which is not to come into contact with the material:

- Alcoholic and sour filling goods (pH-value <4,5)

c) Duration and temperature of the treatment and storage with contact with the food:

- Each storage duration under cooling and freezing conditions, including heating up to 70°C for a duration of up to 2 hours

Conformity was approved by:

- Migration analysis according to directive 82/711 EC (and amendments) and directive 85/572 EC
(Testing reports are available and can be disclosed to the competent authority)
- Worst-case-calculations
- Certificates of suppliers

Migration limits are in compliance under the following conditions (6 dm² film/1 kg food)

Simulant	According to food type / food contact conditions	Test conditions
D (oil)	Olive oil	10 d / 40 ° C
A (aqueous)	Distilled water	10 d / 40 ° C
B (acidic)	3 % acetic acid	10 d / 40 ° C

Simulant D (oil/fat) is deemed to be the strictest simulant regarding the extraction ability

List of substances with specific migration limits (SML) as well as additives which are subject to restrictions in relevant food legislation (“Dual Use Additives”), see appendix:

Type*)	SML-Substances*)	Dual-Use-Additives*)	Others*)
SR	3/4/5/6/9/11/15/16	A/B	A1
SL	3/4/6/7/8/9/11/12/16/25		

*) (item/character see appendix)

The information about the use of additives which are limited in foodstuff (“dual use additives”) is made on the basis of our current knowledge. As there is no official list of “dual use additives”, we refer to the “EUPC Study on Dual Use Additives” (PACK Co.srl, Mailand 2006), which is not complete. As our suppliers are also facing the problem of missing information about this group of additives, we cannot confirm the completeness of these information.

The directive 85/572 EC is a guideline to select the test method for different foods. Above mentioned materials fulfill the defaults of these guidelines for the packing of the indicated filling materials with attention of the indicated food contact contacts.

Beside directive 85/572 EC the user of our films should satisfy himself as to the suitability of our products for the intended application. Therefore we disclaim any liability for damages arising from the non-suitability of our products for the effected application.

Our films do not contain plasticizers, phthalates, BADGE, BFDGE, NOGE as well as no primary aromatic amines (PAA). Photoinitiators (benzophenone, ITX etc.) are not included. Other additives such as BPA or BPS are not used.

Adhesives/glue are not used in the production.

For the used powder (only side seal bags) relevant food law confirmations are given, GMOs and allergens do not come in use in the manufacturing of our products.

Recycled materials within the meaning of Regulation (EC) 282/2008 are not used, substances of very high concern (SVHC) acc. Regulation (EC) 1907/2006 in current version are not included.

We pursue new publications and changes of all relevant laws and regulations, which are of importance in connection with the production and use of our products and adapt our documents automatically accordingly for the information of our customers.

Our company is certified according to BRC Global Standard for Packaging and Packaging Materials.



i.V. Harald Wörner
allfo Vakuumverpackungen
Hans Bresele KG

SML				
	substance	Ref.-Nr	CAS	SML(mg/kg)
1	1,3-Benzoldimethanamine	13000	1477-55-0	0,05
2	1-Hexene	18820	000592-41-6	3
3	1-Octene	22660	111-66-0	15
4	Caprolactam	14200	105-60-2	15
5	Ethyleneimine	17005	009002-98-6	NN (NG=0,01 mg/kg)
6	Hexafluorpropylene	18430	116-15-4	NN (NG=0,01 mg/kg)
7	Hexamethylenediamine	18460	124-09-4	2,4
8	Isophthalic acid	19150	121-91-5	5
9	Maleic anhydride	19960	108-31-6	30
10	Methacrylic acid	20020	79-41-4	6
11	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	68320	002082-79-3	6
12	Stearic acid	89040	000057-11-4	25
13	Terephthalic acid	24910	100-21-0	7,5
14	Phosphorous acid, tris (nonyl- and/or dinonylphenyl) ester	74400	---	30
15	Acetic acid, vinyl ester	10120	000108-05-4	12
16	Vinylidene fluoride	26140	75-38-7	5
17	Zinc oxide	96240	1314-13-2	25
18	Diocyladipat		103-21-1	18
19	2,6-Di-tert-butyl-p-cresol (BHT)	46640	128-37-0	3
20	1,2-Benzisothiazolin-3-on	37520	2634-33-5	5
21	Zinc stearate		557-05-1	25
22	Glycol			30
23	Adipic acid, bis(2-ethylhexyl) ester	31920	103-23-1	18
24	Boron		19287-88-8	6 mg/kg
25	Isophorondiamin		2855-13-2	6 mg/kg

Additive (dual use)				
	substance	Ref.-Nr	CAS	
A	Silicon dioxide	86240	7631-86-9	
B	Vitamin E		10191-41-0	
C	Acids, aliph., monocarb. (C6-C22), esters with polyglycerol	30960	---	
D	Sucrose acetate isobutyrate	91200	126-13-6	
E	2,6-Di-tert-butyl-p-cresol (BHT)	46640	128-37-0	
F	Talc	92080	14807-96-6	
G	Carbonic acid, salts	42500	---	
H	Polyethyleneglycol sorbitan monolaurate	79040	9005-64-5	
I	Calcium stearate		1592-23-0	
J	Phosphoric acid	72640	7664-38-2	
K	Silicates, natural'	85600	---	
L	Titanium dioxide	93440	13463-67-7	
M				
N				
O				

Other Substances (without restrictions)				
	substance			
A1	Potato Starch			
A2				