

20.01.16

for the film productgroup(s):

**PA/PE-films for side seal bags**

We confirm that the above mentioned plastic products comply with the following legal requirements or recommendations:

- Regulation (EC) 1935/2004, in particular Article 17 (traceability)
- Regulation (EC) 10/2011 including all current amendments/additions
- Regulation (EC) 2023/2006 (Good Manufacturing Practice-GMP)
- German Food and Feed Code (LFGB) §§30 and 31
- Packaging Ordinance
- Recommendations of the Federal Institute for Risk Assessment, BfR (e.g. III PE, IX Colouration, X PA)
- Directive 94/62/EC, lastly amended by 2013/2/EC on 07.02.2013/US CONEG  
(Total concentration of heavy metals < 100 ppm)
- FDA-Regulations, 21 CFR
- California Proposition 65

Application conditions:

- a) Kinds of food, which is to come into contact with the material:
  - Fatty, aqueous, acidic and dry goods
- b) Kinds of food, which is not to come into contact with the material:
  - Alcoholic goods
- c) Duration and temperature of treatment and storage in contact with the food:
  - Each storage period under cooling and freezing conditions, including heating up to 70°C for a period of up to 2 hours

Conformity has been established by:

- Migration tests under Article 17 and 18 of Regulation (EC) 10/2011 in conjunction with Annex V  
*(Testing reports are available and can be submitted to the competent authority)*
- Worst-case-calculations
- Supplier Confirmations

Migration limits are respected under the following test conditions (6 dm<sup>2</sup> film/1 kg food)

Test	Simulant	Test conditions
Global Migration (OML)	3 % acetic acid; 10% Ethanol; olive oil	10 d/40°C
Specific Migration (SML)	3 % acetic acid; 95% Ethanol	10 d/40°C

List of substances with specific migration limits (SML) and maximum residue levels (QM) and list of additives with limits in food (“dual use Additives”):

<b>SML</b>			
<b>Substance</b>	<b>Ref.-Nr</b>	<b>CAS</b>	<b>SML(mg/kg)</b>
Caprolactam	14200	000105-60-2	15
Ethyleneimine	17005	000151-56-4	ND (DL=0,01 mg/kg)
Hexamethylenediamine	18460	000124-09-4	2,4
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	68320	002082-79-3	6
Acetic acid, vinyl ester	10120	000108-05-4	12
Polyethyleneglycol ethers	77708	---	1,8

<b>Additive (dual use)</b>			
<b>Substance</b>	<b>Ref.-Nr</b>	<b>CAS</b>	<b>SML(mg/kg)</b>
Vitamin E	---	010191-41-0	
Talc	92080	014807-96-6	
Polyethyleneglycol	76960	---	
<b>Other Substances (without restrictions)</b>			
<b>Substance</b>			
Potato Starch			

The information on additives which are also food additives and flavourings (“dual use additives”) are based on our present knowledge. Since there is no official list of “dual use additives”, we refer to the “EUPC study of dual use additives” (PACK Co.srl, Milano 2006), which is incomplete. The lack of information about this group of additives of certain suppliers, which are facing the same difficulties, does not allow us to ensure the completeness of our information.

**Allergens/GMO**

For the used spray powder (releasing agent) appropriate food legislation confirmations are given. Genetically modified organisms (GMO) and allergenic substances are not used in the manufacture of our products.

**Constituents of animal origin**

Neither in the production of basic raw materials used by us nor in the production of our PA/PE composite films constituents of animal origin are used (neither as additives nor as formulation constituents) The films are, therefore, also not assayed for the presence of these ingredients.

**Epoxy derivatives/Plasticizers/Other chemical substances**

Our films do not contain

- Plasticizers based on phthalates and/or daipates such as DEHP or DEHA, bisphenols such as BPA or BPS or polychlorinated biphenyls (PCBs)
- BADGE, BFDGE, NOGE acc. Regulation (EC) 1895/2005 as well as no primary aromatic amines (PAA)
- Photoinitiators (benzphenone, ITX etc.)
- Latexes, silicones, silicates

**Recyclates**

Recyclates acc. Regulation (EC) 282/2008 are not used.

**REACH/SVHC**

Substances of very high concern (SVHC) acc. Regulation (EC) 1907/2006 (REACH Regulation) in the current version are not included.

**Adhesives/Solvent**

During the extrusion of our products adhesives and/or solvents are not used.

Regulation (EC) 10/2011 provides guidelines for selecting the applicable test conditions for different foods. Subsequently the above mentioned products comply with the provisions of this Regulation for the packaging of the products with observance of the specified food-contact conditions. Beyond Regulation (EC) 10/2011 the user of our films should satisfy himself as to the suitability of our products for the intended application. Therefore we can assume no liability for damages caused by a lack of suitability of our products for the used filling goods.

We pursue new releases and changes in all relevant laws and regulations that are related to the production and use of our products and adapt our documents automatically accordingly for the information of our customers.

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

Allfo Vakuumverpackungen



i.V. Harald Wörner