

25.06.2020

for the product group(s):

PA/PE side seal bags (-unprinted-)

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, 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 (after corresponding practical test)
- 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 dm² film/1 kg food)

Test	Simulant	Test conditions
Global Migration (OML)	3 % acetic acid; 10% Ethanol; Olive oil	10d/40°C
Screening (SML)	95% Ethanol	10d/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"):

SML			
Stoff	Ref.-Nr	CAS	SML(mg/kg)
Caprolactam	14200	105-60-2	15
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	68320	2082-79-3	6
Acetic acid, vinyl ester	10120	108-05-4	12
Ethyleneimine	17005	151-56-4	NN (NG=0,01 mg/kg)
Hexamethylenediamine	18460	1241-09-4	2,4
Polyethylenglycol ethers	77708	-----	1,8
1-Hexene	18820	592-41-6	3
Maleic anhydride	19960	108-31-6	30
Hexafluorpropylene	18430	116-15-4	N.N. (NG=0,01)
Vinyliden fluoride	26140	75-38-7	5
Tetrafluorethylene	25120	116-14-3	0,05
Isophthalic acid	19150	121-95-5	5
Zink oxyde	96240	1314-2	5
Methacrylic acid, diester with 1,4-butanediol	20410	2082-81-7	0,05
Additive (dual use)			
Stoff	Ref.-Nr	CAS	E-Nr.
Vitamin E	---	10191-41-0	307
Polyethylenglycol	76960	---	1521
Siliciumdioxide	86240	7631-86-9	551
Talcum	92080	14807-96-6	553b
Citric acid	14680	77-92-9	330
Carbon acid salts	42500	471-34-1	170
Stearic acid	24550/89040	57-11-4	---
Sonstige (Stoffe unterliegen keiner gesetzl. Beschränkung)			
Stoff			
Potato Starch			

The information on the substances with SML and on additives, which are also food additives and flavorings ("Dual Use Additives"), are based on information from our suppliers and represent our current state of knowledge.

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/Metals/PAA

Our films do not contain

- Plasticizers based on phthalates and/or adipates such as DEHP or DEHA, bisphenols such as BPA or BPS or polychlorinated biphenyls (PCBs)
- BADGE, BFDGE, NOGE acc. Regulation (EC) 1895/2005
- Photoinitiators (benzophenone, ITX etc.)
- Latexes, silicones, silicates

Our films comply with the restrictions listed in Annex II of Regulation (EC) 10/2011 for metals and primary aromatic amines (PAA), including amendments and supplements pursuant to (EC) 2016/1416.

NIAS (not intentionally added substances)

According to a risk assessment Article 19 of Regulation (EC) 10/2011 migration testings (10ppb screening) or assessments are carried out.

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 products mentioned above 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. Therefor 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 Hans Bresele KG
-Quality Management-



i.A. Dieter Öfner