

04.06.2021

for the product group(s):

Side seal bags
(PA/PE side seal bags, transparent or coloured black -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
- Recommendations of the Federal Institute for Risk Assessment, BfR (e.g. III PE, X PA)
- Directive 94/62/EC; US CONEG (Total concentration of heavy metals < 100 ppm)
- Lebensmittel- und Gebrauchsgegenständeverordnung (LGV) 817.02 -Switzerland-
- Verordnung des EDI über Bedarfsgegenstände 817.023.21 -Switzerland-
- Resolution AP (89)1
- FDA-Regulations 21 CFR 174.5; 175.105; 176.170, 177.1500, 177.1520, 177.1350, 177.1395, 178.3297, 178.3400, 177.1680, 177.1640, 176.130, 176.180, 184.1, 175.300, 177.1390
- 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. (Depending on the respective technical application and the packaged product, variations in temperatures and times may be possible. However, this is to be tested in individual cases by the user.)

Conformity has been established by:

- 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			
Substance	Ref.-No	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	124-09-4	2,4
Polyethylen glycol 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)
Vinylidene fluoride	26140	75-38-7	5
Tetrafluorethylene	25120	116-14-3	0,05
Isophthalic acid	19150	121-95-5	5
Methacrylic acid, diester with 1,4 butanediol	20410	2082-81-7	0,05
Zinc oxide	96240	1314-13-2	5
Erucamide	52720	112-84-5	60
Ethylene	16950	74-85-1	60
Zinc			5
Aluminium			1
N,N'-Ethylene-bis(stearamide)	53520	110-30-5	60
Srearcic acid (calc. ss zinc)	89040/24550	57-11-4/557-05-1	5
1-octene	22660	111-66-0	15
Polyethylene wax	80000	9002-88-4	60
Additive (dual use)			
Substance	Ref.-No	CAS	E-No
Vitamine E	---	10191-41-0	307
Polyethylen glycole	76960	---	1521
Silicon dioxide	86240	7631-86-9	551
Talc	92080	14807-96-6	553b
Cidric acid	14680	77-92-9	330
Calcium carbonate	42500	471-34-1	170
Stearic acid	24550/89040	57-11-4	-----
Other substances (without restriction)			
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.

Halal/Kosher

In the production of our bags made of composite films, no components of animal origin or recycling materials are used. However we would like to point out, that some of alcohol or alcoholic beverages have been used in some cases for cleaning purposes in our production facilities (but due to the evaporation of alcohol, no product contamination can be expected).

Other chemical substances

Our bags 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

Other chemical substances (continuation)

- Photoinitiators (benzophenone, ITX etc.)
- Latexes, silicones, silicates
- Primary aromatic amines (PAA)
- PVC/PVDC
- PFOA/PFOS

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.

Nano materials

During bag production made of processed multilayer films no substances with nano structure are used.

MOSH/MOAH

Neither in the production of our processed composite films nor in the production of our bags mineral oil components are used as recipe components. Therefore, we can confirm that our products do not contain "Mineral oil saturated hydrocarbons" (MOSH) or "Mineral oil aromatic" (MOAH).

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 or not > 0,1 mass percent included.

Adhesives/Solvent

In 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. 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 BRCGS Packaging.

alfo GmbH & Co.KG
-Regulatory Affairs-



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