

10.03.2025

for the product group(s):

**Tubular bags - boilable-
PA/PE tubular bags, transparent (-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)
- Verordnung des EDI über Bedarfsgegenstände 817.023.21 -Schweiz-

Application conditions:

- a) Kinds of food, which is to come into contact with the material:
 - Any kind of food
- b) Kinds of food, which is not to come into contact with the material:
 - ---
- c) Duration and temperature of treatment and storage in contact with the food:
 - Each storage period under cooling and freezing conditions including long term storage at room temperature, including heating up to 100°C – 115°C for a period of up to 1 hour. (Depending on the respective technical application and the packaged product, variations in temperatures and times may be possible, e.g. FDS 176.170, table 2(C-G) -no cooking, no sterilization. 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; 95% Ethanol	2h/135°C
Screening (SML)	Tenax®	2h/185°C

The global migration values are below the required limit of 10 mg/dm² according to Regulation (EG) 10/2011 for the selected conditions.

In SML screening, no substances exceed the required limit according to Regulation (EG) 10/2011 for the selected conditions.

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
Isophorondiamine		2855-13-2	6
Hexamezhyliendiamine		124-09-4	2,4
1-Octene	22660	111-66-0	15
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
1-Octene	22660	111-66-0	15
Isophtalic acid	19150	121-91-5	5
Stearic acid	89040	57-11-4	25
Zinkstearate		557-05-1	5
Zinkoxide	96240	1314-13-2	5
Additive (dual use)			
Stoff	Ref.-Nr	CAS	E-Nr.
Vitamin E		10191-41-0	307
Carbonic acid, salts	42500	---	290
Talkum	92080	14807-96-6	553b
Polyethyleneglycol sorbitan monolaurate	79040	9005-64-5	432
Aluminium silicate		12141-46-7	559

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

Allergens are not intentionally added in our production process.
To prevent cross-contamination, appropriate internal measures are taken.

GMO

Genetically modified organisms (GMO) are not used in the manufacture of our products.

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

Our bags comply with the restrictions listed in Annex II of Regulation (EC) 10/2011 for metals and primary aromatic amines (PAA).

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) 1616/2022 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.

Certification

- BRCGS packaging
- Halal
- Kosher

allfo GmbH & Co.KG
-Regulatory Affairs-

(This document is made automatically and valid without signature)