

Product Stewardship Information

Product name
Issue date 10/June/2022

COMPLIANCE TO FOOD CONTACT REGULATIONS

This product is meant for pallet wrapping and transport safety, thus secondary packaging. However, it is guaranteed that occasional food contact does not imply any risk to human and animal health.

European Union

This product complies with the requirements of Regulation 1935/2004/EC (Framework Regulation) as applicable for plastic packaging that comes into contact with food.

This product complies with Regulation 2023/2006/EC for Good Manufacturing Practice regarding those materials that come into contact with food.

This product complies to the relevant requirements of Regulation 10/2011/EC (PIM) and subsequent amendments. We confirm that this product controlled according to test procedure and Union List of Authorized Substances of Regulation 10/2011/EC.

i - Overall Migration

Maximum overall migration is specified by Regulation 10/2011/EC not to exceed 10 mg/dm² from finished plastic food contact material. The overall migration tests have been carried out using the following chemical simulators and in test condition hereunder specified, with test conditions 40°C for 10 days:

- Chemical simulator 1: solution to the 3% p/v of acetic acid
- Chemical simulator 2: solution to the 10% v/v of ethylic alcohol
- Chemical simulator 3: rectified olive oil

Overall migration from this product has been validated to be lower than 10 mg/dm² overall migration limit (OML) as set by Regulation 10/2011/EC. Furthermore, we confirm that this product does not impair the organoleptic properties of packaged foodstuff.

ii – Specific Migration

This product contains one or more components with specific migration limit (SMLs).

- Ref. No. 16950; Ethylene; SML = 60 mg/kg
- Ref. No. 46880; 3,5-Di-tert-butyl-4-hydroxybenzylphosphonic acid; SML = 6 mg/kg
- Ref. No. 68320; Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate; SML = 6 mg/kg
- Ref. No. 96240; Zinc oxide; SML = 5 mg/kg (expressed as Zinc)

The chemical substances with specific migration limits have been validated not to exceed the limitations as set by Regulation 10/2011/EC and its amendments.

iii – Dual Use Additives

This product does not contain any dual use additives as defined in Regulation 10/2011/EC.

Germany

Konformität mit Bedarfsgegenständeverordnung vom 23.12.1997 in der Fassung vom 24.06.2013 (bezugnehmend auf Verordnung 10/2011/EC), sowie BfR-Empfehlungen III und VII.

Phthalates

Polyolefins do not require the use of plasticizers (such as phthalates) to make them soft and flexible. We do not add phthalates during the manufacture of this product. However, traces of phthalates may be present in some products as impurities from the catalytic system. We confirm that the total content of phthalates has been validated to be less than 10 ppm. Therefore, this product can be regarded as phthalate-free.

Metals content - EU Packaging and Packaging Waste

This product complies with Regulation 94/62/CE and its further amendments. It has been validated that heavy metals content sum does not exceed 100ppm.

Hygiene control

This product is monitored for potential microbial contamination, by means of bacterial count, which is an indicator of the microbial status of the production and environmental conditions. Furthermore, this product is checked to be free of specific pathogens (Enterobacteria, E. coli, Coliforms, Coag.-pos. Staphylococcus, Yeasts, Funghi, Salmonella).

REACH Substances of Very High Concern (SVHC)

This product does not contain any of the Annex XIV candidate chemicals proposed to be Substances of Very High Concern (List as of 10th of June 2022). The current list of all SVHCs is provided by ECHA website <http://echa.europa.eu/web/guest/candidate-list-table>

Non-Intentionally Added Substances (NIAS)

We confirm that the following substances are not intentionally used during the manufacture of this product, However, we do not test this product for these substances.

1	ALLERGEN SUBSTANCES as listed in Annex II of Regulation (EU) 1169/2011, replacing Directive 2007/68/EC	
2	ANIMAL BASED RAW MATERIALS	This product does not contain substances that fulfil the requirements laid down in the Regulations 1069/2009/EC, and the "Note for Guidance EMEA/410/01, rev. 3".
3	ANTIMONY TRIOXIDE	CAS No 1309-64-4
4	AROMATIC AMINES as listed in Regulation 1907/2006/EC Annex XVII Appendix 8	Replaces Directive 2002/61/EC (19th amendment of Directive 76/769/EEC).
5	ASBESTOS as listed in Regulation 1907/2006/EC Annex XVII	Replaces Directive 2003/18/EC (amending Council Directive 83/477/EC)
6	AZOCOLORANTS as listed in Regulation 1907/2006 Annex XVII Appendixes 8 and 9	Replaces Directive 2002/61/EC (19th amendment of Directive 76/769/EEC).
7	BENZOPHENONE DERIVATIVES	We mean the following substances by benzophenone derivatives : Benzophenone (CAS No 119-61-9), 2-hydroxybenzophenone (CAS No 117-99-7), 3-hydroxybenzophenone (CAS No 13020-57-0), 4-hydroxybenzophenone (CAS No 1137-42-4), 4-methylbenzophenone (CAS No 134-84-9),
8	BIOCIDAL PRODUCTS as defined in Article 3(1)(a) of the Regulation (EU) No 528/2012	We can hereby confirm that we do not intentionally incorporate any biocidal products as additive* in the here above mentioned products
9	BISPHENOL A, BISPHENOL F and BISPHENOL S	CAS No 80-05-7, CAS No 620-92-8 and CAS No 80-09-1
10	BHA (ter-Butyl-4-hydroxyanisole)	CAS No 25013-16-5
11	BHT (2,6-di-ter-butyl-p-cresol)	CAS No 128-37-0
12	CHLORINATED ALIPHATIC COMPOUNDS	We mean the following substances by chlorinated aliphatic compounds: tetrachloromethane (CAS No 56-23-5), 1,1,2,2-tetrachloroethane (CAS No 79-34-5), 1,1,1,2-tetrachloroethane (CAS No: 630-20-6), pentachloroethane (CAS No 76-01-7), trichloromethane (chloroform; CAS No 67-66-3), 1,1,2-trichloroethane (CAS No 79-00-5), 1,1-dichloroethylene (CAS No 75-35-4), 1,1,1-trichloroethane (CAS No 71-55-6).
13	CHLOROFLUOROCARBONS (CFC), HYDROGENATED CHLOROFLUOROCARBONS (HCFC) AND HALONES	

14	CMR SUBSTANCES as listed in Regulation 1272/2008/EC Annex VI	We can hereby confirm that we do not use substances classified Carcinogens, Mutagens or toxic to Reproduction categories 1 and 2 as listed in Regulation 1272/2008/EC, as additive*
15	CONFLICT MINERALS (Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Act)	We can hereby confirm that we do not use the following conflict minerals as additive*: cassiterite, columbite-tantalite, wolframite, tin, tantalum, tungsten and gold
16	COSMETIC prohibited ingredients as listed in Annex II of the REGULATION (EC) 1223/2009 on COSMETIC PRODUCTS	We can hereby confirm that we do not use substances mentioned in Annex II of the REGULATION (EC) 1223/2009 as additive*
17	DIMETHYLFUMARATE Directive 2009/251/EC	CAS No 624-49-7
18	DIOXINS AND DIFURANS	
19	EPOXIDIZED SOYA BEAN OIL (ESBO)	CAS No 8013-07-8
20	EPOXY DERIVATIVES Regulation 1895/2005/EC	2,2-bis (4-hydroxyphenyl) propane bis (2,3-epoxypropyl) ether ('BADGE'), bis(hydroxyphenyl) methane bis (2,3-epoxypropyl) ethers ('BFDGE') and novolac glycidyl ethers ('NOGE')
21	ETHANOL	CAS No 64-17-5
22	FLAME RETARDANTS	
23	FORMALDEHYDE	CAS No 50-00-0
24	HALOGENS	Fluorine (CAS No 7782-41-4), Chlorine (CAS No 7782-50-5), Bromine (CAS No 7726-95-6), Iodine (CAS No 7553-56-2)
25	ISOPROPYLTHIOXANTHONE (ITX)	CAS No 5495-84-1 and CAS No 83846-86-0
26	LATEX	We mean the following by latex: "a white, tacky, aqueous suspension of a hydrocarbon polymer occurring naturally in some species of trees, shrubs, or plants, or made synthetically".
27	MELAMINE and CYANURIC ACID	CAS No 108-78-1 / CAS No 108-80-5
28	MOSH (Mineral Oil Saturated Hydrocarbons), MOAH (Mineral Oil Aromatic Hydrocarbons), & Mineral Oil	We can hereby confirm that we do not use MOSH, MOAH nor Mineral Oil as additive*. However, we inform you that some trace amount of Mineral Oil can be present in some of here above mentioned products as a manufacturing process residue. This Mineral Oil is included in the Union List of the authorized substances for the manufacturing of plastic materials intended to come into contact with food
29	N_METHYLPYRROLIDONE (NMP)	CAS No 872-50-4
30	NANOMATERIALS	Nanomaterials of which one or more external particle dimensions is less than 100 ppm. This complies to recommendation of recommendation 2011/696/EU.
31	NONYLPHENOL AND NONYLPHENOLETHOXYLATES as listed in Regulation 1907/2006/EC Annex XVII	Replaces Directive 2003/53/EC (26 th amendment of Directive 76/769/EEC).
32	ORGANOTIN COMPOUNDS Decision 2009/425/EC	We mean the following substances by organotin compounds: Monobutyltin compounds (MBT), Dibutyltin compounds (DBT), Dioctyl Tin compounds (DOT), Tributyltin compounds (TBT), Triphenyltin compounds (TPT) and Tributyltin Oxide (TBTO)
33	OZONE-DEPLETING SUBSTANCES - Regulation 1005/2009/EC - The Montreal Protocol on Substances that deplete the Ozone Layer, as last adjusted and/or amended in Beijing 9-1999 (UNEP-United Nation Environment Program) - The United States (Clean Air Act, as amended in 1990, title VI, section 602 (a), class I and II.	CFCs, Halons, Other fully halogenated CFCs, Carbon tetrachloride, 1,1,1-Trichloroethane (Methyl chloroform), Hydrochlorofluorocarbons (HCFC), Hydrobromofluorocarbons (HBFC), Methyl bromide, Bromochloromethane.
34	PENTACHLOROPHENOL as listed in Regulation 1907/2006/EC Annex XVII	Replaces Directive 1999/51/EC
35	PERFLUOROCTANE SULFONATE (PFOS) AND PERFLUOROCTANOIC ACID (PFOA) as listed in Regulation 1907/2006/EC Annex XVII	Replaces Directive 2006/122/EC (30 th amendment of Directive 76/769/EEC)

36	PESTICIDES, HERBICIDES as defined in Directive 91/414/EC	To the best of our knowledge, we do not use as additive* any pesticides and herbicides that: - protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances - influence the life processes of plants, other than a nutrient (e.g. growth regulators); - preserve plant products, in so far as such substances or products are not subject to special Council of Commission provisions on preservatives; - destroy undesired plants; or - destroy parts of plants, check or prevent undesired growth of plants; in the finished article
37	POLYBROMOBIPHENYLS and POLYBROMODIPHENYLETERS - Regulation 1907/2006/EC Annex XVII - Directive 2002/96/EC - Directive 2002/95/EC, Directive 2011/65/EU	Regulation 1907/2006/EC replaces Directive 2003/11/EC (24 th amendment of Directive 76/769/EEC) This includes penta-, octa-, decabromobiphenylethers.
38	POLYCHLORINATED BIPHENYLS (PCB)	
39	POLYCHLORINATED NAPHTHALENES (PCN)	
40	POLYCHLORINATED TERPHENYLS (PCT)	
41	POLYCYCLIC AROMATIC HYDROCARBONS (PAH) as listed in Regulation 1907/2006/EC Annex XVII (1272/2013/EC)	Replaces Directive 2005/69/EC (27 th amendment to Directive 76/769/EC).
42	POLYVINYLCHLORIDE (PVC) and VINYLCHLORIDE MONOMER	
43	RADIOACTIVE SUBSTANCES as defined in Directive 96/29/EURATOM	Laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.
44	RECYCLED MATERIALS	Following definition of Commission Regulation 282/2008/EC
45	SEMICARBAZIDE and AZODICARBONAMIDE as defined in Directive 2004/1/EC	
46	SHORT CHAINED CHLORINATED PARAFFINS as listed in Regulation 1907/2006/EC Annex XVII	Replaces Directive 2002/45/EC (20 th amendment of Directive 76/769/EEC)
47	SILICONE	CASNo 63148-53-8, 63394-02-5, 90337-93-2, 63148-62-9
48	TITANIUM ACETYL ACETONATE (TAA)	CAS No 77927-72-9
49	TRICLOSAN (2,4,4'-Trichloro-2'-hydroxydiphenyl Ether) Decision 2010/169/EU	CAS No 3380-34-5
50	TRIS(NONYLPHENYL) PHOSPHITE (TNPP)	CAS No 26523-78-4

Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS)

RoHS requirements refers to electrical and electronic equipment and not specifically to flexible packaging. However, this product complies with Directives 2002/95/EC and 2011/65/EU and amendments. We confirm based on analytics and documentation from raw material supplier that heavy metal content such as from cadmium, lead, mercury, hexavalent chromium is not exceeded (Total heavy metal content less than 100 ppm). Substances such as polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl)phthalate (DEHP), butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) are not intentionally added in the processing of this product.

CEN Standard prEN 13432

This product is not suitable for composting.

Disclaimer

All the stated declarations are related to film as directly supplied and produced by Manupackaging Deutschland GmbH. It remains responsibility of the customer to ensure that Manupackaging Deutschland GmbH materials are suitable for the particular applications and that all regulatory requirements are met; moreover, due to possible changes in laws and regulations, customers should verify regulatory status periodically. If the supplied film is used in conversion processes (i.e. metallization, printing, lamination, etc), it is responsibility of the customer to assure that the final product complies with the appropriate regulatory requirements.

In order to avoid any risk of contamination on the extreme parts of the film, it is recommended to remove the first and the last layers of the reels.

Please refer to Manupackaging Deutschland GmbH for additional information.

Expire date of this declaration

This document is valid until the next relevant legislative, regulatory and/or compositional change.

Manupackaging Deutschland GmbH
Dr. Isabell Stolte
Research & Development / Quality Assurance

This document is created electronically and is valid without signature