

Rohmaterial (Thermoplast/Duroplast) Raw material (thermoplastic/thermosetting plastic)

Artikelnummer (article number)	:	001002
Artikel (article)	:	PP Homopolymer
Basismaterial (basic material)	:	PP
Füllstoff/Hilfsstoff (filler/auxiliary agent)	:	---
Dichte (density)	[g/cm ³]:	0,90
Schmelzindex (melt-flow-rate)	:	2-14 g/10min (230° C / 2,16 kg) acc. ISO 1133
Streckspannung (tensile strength at yield)	[MPa]:	32-37 ISO 527-2
Härte (hardness)	:	---
E-Modul (modulus of elasticity)	[MPa]:	1400 – 1800 MPa ISO 527-2
Temperaturbeständigkeit (temperature resistance)	[°C]:	60°C / 121°C (screwed / loose)

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STATEMENT ON SUBSTANCES OF VERY HIGH CONCERN

Our supplier certify that no substances listed in the ECHA candidate list of substances of very high concern (SVHC) for authorisation up-dated on *16 January 2020* are present above 0.1% by weight in this product.

Declaration of Compliance to Food Contact Regulations

It is confirmed that this product fulfils the applicable requirements on substances used for the manufacturing of materials and articles or components of articles intended to come into contact with food as described in the below cited legislation and standards.

EU

The below listed regulations represent harmonised EU legislation and are applicable unchanged in all EU-member states. National legislation implementing such regulations is therefore not separately cited in this document.

Our supplier would like to stress that this product is an intermediate plastic material as defined in chapter 3.1. of Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain, from 28.11.2013. Therefore this confirmation is restricted to the requirements as applicable for intermediate plastic materials used for the manufacturing of materials and articles or components of articles intended to come into contact with food.

- Commission Regulation (EC) No 1935/2004. The organoleptic characteristics of food contact materials are influenced by converting conditions, time and temperature of storage and type of food, therefore compliance with article 3, §1, c must be verified and tested by the producer of the final packaging material.
- Commission Regulation (EU) 10/2011 as amended. All used monomers and additives are listed in Annex I of this regulation. For any applicable restrictions see chapter "migration testing".
- Commission Regulation (EC) 1895/2005 - BADGE, NOGE and BFDGE are not used for the production of this grade.
- Commission Regulation (EC) 2023/2006. This material has been manufactured in accordance with the relevant requirements of good manufacturing practice for materials articles intended to come into contact with food, as described in more detail in the statement of our supplier "Food hygiene demands and standards".
- Commission regulation (EC) No 450/2009 on active and intelligent materials and articles is not applicable to polymer resins.

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Additional national legislation in EU-member states

Polymerisation production aids, aids to polymerisation, colorants and solvents, if not already listed in Annex I of Regulation (EU) 10/2011 can be used based on their national approval and are subject to mutual recognition. The process chemicals used for the manufacturing of this grade are permitted by at least one of the following national regulations/recommendations, or were rated as safe in a risk assessment acc. article 19 of Regulation (EU) 10/2011

France:

Décret No. 2007-766 du 10 mai 2007 portant application du code de la consommation en ce qui concerne les matériaux et les objets destinés à entrer en contact avec les denrées alimentaires, as amended and the French DGCCRF guidelines on food contact plastics.

Germany:

BfR-Empfehlung
VII Polypropylen, Stand 01.09.2017

The Netherlands:

Verpakkingen- en Gebruiksartikelenbesluit, 2014 (Warenwet), Deel A, Hoofdstuk 1, Kunststoffen, as amended (last update from 26.10.2016).

Europe (Non-EU-countries)

Norway:

Sosial- og helsedepartementets forskrift 1993-12-21-1381 – as amended (referring to Regulation EU 2011/10).

Switzerland:

Verordnung der EDI über Bedarfsgegenstände vom 16.12.2016 (817.023.21); Stand 01.05.2017
5.Abschnitt Bedarfsgegenstände aus Kunststoff.

World

China:

GB9685-2016 - National standard on the use of additives in food containers and packaging materials
GB 4806.1-2016 - National standard on general safety requirements for materials and articles in food contact - so far applicable to polymer resins.
GB 4806.6-2016 - National standard on plastic resins for food contact use - Appendix A - 74 Propylene homopolymer

USA:

FDA, CFR, Title 21, 177.1520 (a)(1)(i), (b) and (c)1. 1a Olefin polymers

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Limits of use (FDA)

Test samples made from this product fulfilled the extraction requirements according to FDA CFR 21 §177.1520(c), as defined for the type of polymer described above. Therefore this product may be used in contact with all food types as described in table 1 of CFR 21 §176.170(c), under conditions of use A through H as described in table 2 of CFR 21 §176.170(c) (including articles used for packing or holding food during cooking).

It is the responsibility of the food packer to control that the final packaging complies with the requirements of the intended and foreseeable conditions of use.

Migration limits and testing

Migration limits

The product contains traces of Aluminium, which is regulated with a specific migration limit in EU (Commission Regulation 2011/10; Article 6.3.a and Annex II) and Switzerland (Bedarfsgegenständeverordnung 817.023.21, Anhang 2.3.1); (1 mg/kg expressed as Al). Representative worst case tests (3% acetic acid; 4h/100°C) did not show any migration above 0,04 mg/kg.

The product may contain a residual component from the catalyst system which is regulated with a specific migration limit in EU. Migration tests in 95% Ethanol for 10 days at 60°C showed a migration level significantly below the SML, so when applying a standard surface volume ratio of 6, this SML cannot be exceeded under any foreseeable conditions of use.

Other used monomers and additives are not regulated with specific migration limits.

Substances also authorized as direct food additives (“Dual Use additives”) are either not used for the manufacturing of this product, kind of not migrating, or only present in quantities that in case of their migration don't allow relevant contribution to exceed of these limits as set in the applicable food legislation.

The polypropylene grade based on non-phthalate containing catalyst may contain up to max. 1 ppm FCM 779 (9,9-bis(methoxymethyl)fluorene / CAS 182121-12-6, SML = 0,05 mg/kg). Migration tests 10d/60°C at 1 mm plaques, typically showed migration results in the range of the analytical threshold (currently 0,02 mg/kg).

Migration testing

In accordance with article 12 of Commission Regulation (EU) 10/2011, article 12 of Swiss ordinance 817.023.21 and article 2.12 of Chinese standard GB4806.1 the overall migration shall not exceed 10 mg/dm² from plastic materials and articles, with the exception for plastic materials and articles intended to contact infant or child food (60mg/kg)

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A representative sample from this or a comparable material, tested for 2d at 20°C in isooctane (1 mm plate / total immersion) did not exceed the limit of 10mg/dm² for overall migration. This test result is only valid for orientation purposes but must not be used to confirm legal compliance of the finished article.

Compliance with the overall and specific migration limits as described above must be measured from the final packaging intended to come into contact with foodstuff by using real food or appropriate food stimulants at the intended and foreseeable conditions of use as specified in Annex III of Commission Regulation (EU) 2011/10; Annex 4 of Swiss Ordinance 817.023.21; Chinese standard GB31604.8- 2016. It is the responsibility of the food packer to verify that the final packaging complies with the overall and specific migration limits as set out by the applicable legislation.

Non-intentionally added substances - NIAS (EU)

Commission Regulation (EU) 2011/10 notes that not all contaminants and reaction products of authorised monomers and additives can be listed in its Annex I. The identification of non-listed migrants may therefore not be an exclusion criterion in itself. However, a toxicological evaluation of these migrants needs to be performed.

The major fractions of NIAS in Polyolefins are the oligomers, which are unavoidably formed during polymerisation and cannot be removed. A recent joint study of polyolefin producers demonstrated that oligomers migrating from all types of polyolefins only consist of linear and branched alkanes (POSH) and alkenes (POMH), no cyclic or aromatic compounds were found. The toxicological assessment of such migrants concluded that they are sufficiently characterised by the existing overall migration limit.

Further a variety of representative products of our supplier, covering the whole product spectrum of him, was assessed in relation to migrating NIAS by renowned test institutes. Beside oligomers the typical NIAS are reaction- and decomposition products from antioxidants, many of them known as “Arvin-substances”. Another joint industry study confirmed that none of these Arvin-substances are genotoxic and can therefore be rated at least as “Cramer-class III”, allowing a daily consumption of 90 µg/person/day.

However, our supplier wish to stress that a NIAS-assessment is subject to the finished food contact article and the formation of NIAS is influenced by thermal and mechanical treatment during conversion, mixture with other substances and the applied test conditions. A raw material screening therefore can never monitor all potential criteria, so our supplier cannot provide a final answer in this regard.

STATEMENT ON CHEMICALS, REGULATIONS AND STANDARDS

Our supplier certifies that during manufacturing of this product, he does not use or intentionally add any of the chemicals restricted by the following regulations and their subsequent amendments in amounts which exceed the applicable limits.

- Annex XVII of the Reach Regulation 1907/2006/EC (superseding Directive 76/769/EEC) – Restrictions on the manufacturing, placing on the market and use of certain dangerous substances,

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mixtures and articles

- CONEG “Toxics in Packaging” Model Legislation, rev. 2008
Directive 94/62/EC (Packaging and Packaging waste – PPW) and related EN13428 and CR13695
-Sum of Cd, Cr, Hg and Pb < 100 ppm
- Directive 2000/53/EC (End of life vehicles – ELV) – Cr(VI), Hg and Pb < 0.1wt%,
Cd < 0.01 wt%
- Directive 2011/65/EU (Restrictions of the use of certain Hazardous Substances in electrical and
electronic equipment – ROHS, repealing 2002/95/EC) – Cr(VI), Hg, Pb, PBB and PBDE
< 0.1wt%, Cd < 0.01wt%
- Directive 2012/19/EU (Waste Electrical & Electronic Equipment - WEEE, repealing 2002/96/EC)
- Annex VII - No ingredients used which require selective waste treatment (As, Hg, PCB, PCT,
CFC, HCFC, HFC, brominated FR)
- Proposition 65 list of Chemicals known to the State of California to cause Cancer or Reproductive
Toxicity. It remains the responsibility of the final article’s distributing company to ensure
compliance with California Proposition 65 requirements
- Regulation 1005/2009/EC (Substances that deplete the ozone layer)
- Prohibition of CFC`s, HCFC`s, Halons, CCl₄, Trichloroethane, HBFC`s
- US Clean Air Act, Title VI, Classes I and II (EPA Final rule; Federal Register 8136, 11.2.1993) on
substances that deplete the ozone layer
- Regulation 850/2004/EC on persistent organic pollutants (POPs)
- Regulation 1169/2011/EC - Annex II (allergens) repealing Annex IIIa of Directives 2003/89/EC,
2006/142/EC, 2007/68/EC
- Global Automotive Declarable Substance List (GADSL) and VDA232-101
-No use of prohibited or declarable substances above threshold limits
- Swiss SR 814.018 (Verordnung über die Lenkungsabgabe auf flüchtigen organischen
Verbindungen – VOCV) – VOC`s according to Annexes 1 & 2 < 3 wt%
- Regulation 1223/2009/EC "on cosmetic products" - prohibited and restricted substances
- Directive 2009/48/EC (safety of toys)
- European Standard EN 71-3:2013+A1:2014 "Safety of Toys", Part 3: "Migration of certain
elements" - Migration below limits for toy material category III in Table 2, and EN 71-
9:2005+A1:2007 “Organic chemical compounds – Requirements” (Tables 2 A-I)

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- Japanese CSCL; Class I and II Specified Chemical Substances
- Japanese PRTR law; Class I or Class II Designated Chemical Substances

Regarding classification of the above product according to REGULATION (EC) No 1272/2008 and its subsequent amendments, reference is made in the SDS/PSIS for the above product.

None of the following substances are used or intentionally incorporated into it during the manufacturing of the above product:

- Acrylamide
- Antimony, Arsenic, Beryllium, Bismuth
- Aromatic amines (restricted in Regulation 1907/2006/EC, Annex XVII)
- Artificial Musks
- Asbestos
- Azocolorants (restricted in Regulation 1907/2006/EC, Annex XVII)
- Azodicarbonamide, semicarbazide
- Benzophenones (e.g. 4-MBP, 4-HBP, 2,2'-Dimethoxy-2-phenylacetophenone)
- BHA or BHT
- Biocides (Pesti-, Herbi-, Insecti-, Fungi-, Bactericides)
- Bisphenol and their compound (e.g. NOGE, BFDGE, BADGE)
- Cadmium, Chromium (VI), Lead, Mercury
- CFC, HCFC
- CMR substances Categories 1A, 1B according to Regulation 1272/2008/EC
- Colophony (rosin)
- 4,4'-Diaminodiphenylmethane (MDA)
- Di-2-ethyl-hexyl maleate (DEHM)
- Dimethylfumarate (DMF), Dibutylfumarate
- 1,4-Dioxane
- Endocrine disruptors: Category 1 substances in the European Commission EDS database
- 2-Ethylhexanoic acid, Ethoxyquin, ITX, Thiurams
- Flame retardants (halogenated or phosphorus based)
- Formaldehyde
- Fragrances
- Furfural
- Glycol ethers (EGME, EGMEA, EGEEE, EGEEA)
- Glyoxal
- Gold, Indium, Nickel, Palladium
- Halogenated organic compounds
- Melamine, Cyanuric acid
- MOAH (mineral oil aromatic hydrocarbons)
- Nanomaterials (>50% of particles <100 nm)
- Natural rubbers, Latex
- Nitrosamines, Nitrates, Nitrites
- Octyl- and Nonylphenols and Octyl- or Nonylphenoethoxylates; TNPP
- Organotin compounds

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- Parabens
- PBT and vPvB substances according to EC Regulation No.1907/2006 (REACH)
- PFOA, PFOS
- Phthalates
- Plasticisers (e.g. Adipates, ESBO, Phthalates)
- Polychlorinated Bi-, Terphenyls and Naphthalenes
- Polychlorinated dibenzodioxins and dibenzofurans
- Polycyclic aromatic hydrocarbons (PAH) *as restricted in regulation 1907/2006/EC, Annex XVII*
- *Quaternary ammonium compounds*
- Radioactive substances
- Recycled materials
- Selenium, Silver, Tellurium, Thorium
- Styrene, Polystyrene
- SVHC on "Candidate List of Substances of Very High Concern for Authorisation"
- Thiuram mix
- Tin, Gold, Tantalum, Tungsten
- UV-hardeners (e.g. ITX, Titanyl-acetylacetone)
- Vinylchloride, Vinylidenechloride, PVC or PVDC

The substances used in the manufacturing of the above product, and if applicable the basic polymer(s), are listed in the following chemical inventories:

Australia/AICS
Canada/DSL
China/IECSC
Europe/EINECS or ELINCS or NLP
Japan/ENCS
Korea/KECL
New Zealand/NZIoC
Philippines/PICCS
Taiwan/TCSI
USA/TSCA (*all relevant ingredients designated as active*)

Statement on Origin of raw materials

Animal based materials and BSE/TSE

Our supplier certifies that manufacturing this product, he does not use or intentionally add into it any substances of animal origin. He therefore state that his product is to be considered safe with respect to BSE and TSE transmissions.

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Genetically modified organisms (GMO)

Our supplier certifies that manufacturing this product, he does not use or intentionally add into it any substances derived from genetically modified organisms.

Halal certification

This product does not have an official Halal certification. Our supplier certifies that manufacturing this product, he does not use or intentionally add into it any substances of animal origin or drinkable alcohol (ethanol).

Kosher certification

This product does not have an official Kosher certification. Our supplier certifies that manufacturing this product, he does not use or intentionally add into it any substances of animal origin, wine, dairy products, marine products or their derivatives.

Palm oil, palm kernel oil and their derivatives

In this product our supplier incorporate small amounts of stearates or other materials derived from fatty acids. These are derived from vegetable oils that can be of palm oil or palm kernel oil origin.

Statement on Impurities

The below listed substance is not used or intentionally added during manufacturing and therefore are not expected to be present in the above mentioned grade. However, this product has not been specifically analysed for the presence of this substance.

- Polyurethane
- gluten
- doping agents listed on the "PROHIBITED LIST" of January 2019 issued by the World Anti-Doping Agency (WADA)

STATEMENT ON "CONFLICT MINERALS"

Our supplier certifies that during the manufacturing of his products he do not use any material derived from "conflict minerals" from the Democratic Republic of Congo or an adjoining country falling under Section 1502 of the US "Wall Street Reform and Consumer Protection Act" (H.R. 4173), also known as "Dodd-Frank Act".

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The following four minerals and their derivatives are designated as “conflict minerals” by the Secretary of State:

- columbite-tantalite (coltan, niobium, tantalum)
- cassiterite (tin)
- wolframite (tungsten)
- gold

Statement on Annex XIV Substances

Our supplier certify that no substances listed in the Regulation 1907/2006/EC (the “REACH Regulation”) Annex XIV (the “Authorisation List”) are intentionally included in unreacted form in polyolefin products manufactured by our supplier*.

* The intermediate use of DEHP (Bis(2-ethylhexyl) phthalate, EC No. 204-211-0) and DIBP (Diisobutyl phthalate EC No. 201-553-2) in the catalyst system required for the production of polypropylene may result in traces of these phthalates in the final products, typically less than 1 ppm.

Ausschluss

Die KISICO GmbH führt keine Untersuchungen zur Bestimmung

- Alle zukünftigen Veränderungen des Produktes durch hinzugefügte Substanzen
- von Veränderungen des Produktes während der Verarbeitung (NIAS)
- des Migrationsverhalten des fertigen Produktes (Extraktions-Tests gem. den gültigen Bestimmungen) und des organoleptische Verhalten von verpackten Lebensmitteln.

Diese sind, wie in den entsprechenden Regularien vorgesehen, am Endartikel vorzunehmen und müssen vom Verpacker/Inverkehrbringer gegebenenfalls durchgeführt werden.

Alle Angaben basieren auf den Analysen und Informationen unserer Lieferanten!

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Exclusion

The KISICO GmbH does not carry out investigations to

- any future modification of the product whatever the nature of the added substances
- any processing likely to alter the product (NIAS)
- any checking of the inert nature of the finished product (extraction test according to the current regulations) and the non-modification of the organoleptic behaviour of the packed foodstuffs.

These are, how in the suitable regulations intended, to carry out in the final article and if necessary has to be done by the packager.

All information is based on the analyses and information of our suppliers!

Zusätzliche Informationen

Sämtliche Angaben beruhen auf den Analysen und Angaben unserer Vorlieferanten und basieren auf unserem aktuellen Wissensstand. Die Spezifikation stellt keine Garantie über die Eigenschaften des Produktes dar. Es liegt in der Verantwortlichkeit des Verpackers, dass die Produkte den Anforderungen der beabsichtigten Anwendung entsprechen. Bei Änderung einer der o.g. Richtlinien verliert die Spezifikation ihre Gültigkeit.

Disclaimer

To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication, however we do not assume any liability whatsoever for the accuracy and completeness of such information.

We make no warranties which extend beyond the description contained herein. Nothing herein shall constitute any warranty of merchantability or fitness for a particular purpose.

It is the customer's responsibility to inspect and test our products in order to satisfy itself as to the suitability of the products for the customer's particular purpose. The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.

No liability can be accepted in respect of the use of our products in conjunction with other materials. The information contain herein relates exclusively to our products when not used in conjunction with any third party materials.

Any change to an above-mentioned regulation will result in the specification losing its validity.