

Conformity RoHS Directive 2011/65/EU, REACH and California Proposition 65 and various US, EU, CH and CN directives and regulations for Food Contact

ROLASERIT® PP01, ROLASERIT® PP05, ROLASERIT® PP030

AM POLYMERS

Material-No.		Revision date:	18.11.2020
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Product information

Trade name : **ROLASERIT® PP01, ROLASERIT® PP05, ROLASERIT® PP030**

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Use of the substance / preparation : Additive Manufacturing Powder Bed Fusion Grade
Please call us at the above telephone number to clarify further uses.
We will connect you with the Applications Engineering staff who can help you.

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Dear customer,

herewith we confirm that **ROLASERIT® PP01, ROLASERIT® PP05 and ROLASERIT® PP030** supplied by AM POLYMERS GmbH meet the relevant requirements of the following Directives or Regulations:

I. EUROPEAN:

- 1. This grade complies with the relevant requirements of:**
Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.
- 2. Commission Regulation (EU) No 10/2011** of 14 January 2011 on plastic materials and articles intended to come into contact with food, 321/2011 (01/04/2011), 1282/2011 (28/11/2011), 1183/2012 (30/11/2012), 202/2014 (03/03/2014), 865/2014 (08/08/2014), 2015/174 (05/02/2015), 2016/1416 (24/08/2016), 2017/752 (28/04/2017), 2018/79(18/01/2018), 2018/213 (12/02/2018), 2018/831 (05/06/2018), 2019/37 (10/01/2019), 2019/988 (17/06/2019), 2019/1338 (08/08/2019).
- 3. Commission Regulation (EC) No 2023/2006** of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (GMP) as amended.

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- 4. The NIAS (Non Intentionally Added Substances)** and the identified IAS (Intentionally Added Substances) present in this grade have been risk assessed in accordance with Art 19 of the Plastics Regulation (10/2011) and comply with the relevant requirements of the Framework Regulation (1935/2004). More relevant information necessary for a risk assessment of the NIAS by the downstream operator will be communicated upon request. The conversion process can indeed affect the type and quantity of NIAS present in the articles and the converter must reassess them to guarantee their compliance. The compliance of the IAS present in this product will remain valid as no new IAS will be formed during the processing steps.
- 5. Toys:** The above grade meets the relevant requirements of Directive 2009/48/EC as amended and referred Community legal acts, and of the European Standard EN 71-3:2013+A1:2014.
- 6. Adequate information on the substances used for which restrictions are set out**

No monomers subject to Specific Migration Limit (SML) are used.

This grade contains at least one additive subject to Specific Migration Limits (SML) of 18 mg/kg.

This (these) additive(s) will be disclosed on request. As the conversion process can affect migration, only the converter can guarantee the compliance of his own articles with the above limits.

This grade contains at least one aluminium-based additive for which an SML of 1 mg/kg food or food simulant (expressed as aluminium) is set up. These additives will be disclosed on request. As the conversion process can affect migration, only the converter can guarantee the compliance of his own articles with the above limits.

Indicative modelling results under the new more severe testing conditions 10 days / 60°C, in food simulants A, B, C, D1 and D2, and at a surface volume ratio of 6 dm⁻¹ ('EU cube') indicate that the above SML(s) may be exceeded with food simulants D1 and D2.

The converter is thus advised to run a simulation with his own specific parameters (S/V ratio, time/temperature conditions, wall thickness, type of food) or perform a real migration test to verify the compliance of his own articles.

Indicative overall migration tests carried on this type of polymer on film or thin plaque, under the conditions 10 days / 40°C, in the food simulants A, B and D2 show that the Overall Migration Limit of 10 mg/dm² is not exceeded for this grade.

As the conversion process can affect migration, only the converter can guarantee the compliance of his own articles to the OML.

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7. Adequate information relative to the substances which are subject to a restriction in food.

Calcium Stearate (E470) (CAS nb 1592-23-0) is approved as food additive (dual-use additive). It is present, as additive, in the above grade.

Silica (E551) (CAS nb 7631-86-9) is approved as food additive (dual-use additive). It is present, as additive, in the above grade.

8. Specifications on the use of the material or article.

No other limitation or restriction than those listed in § I.6 and I.7 of this EU DoC applies to this grade.

9. When a functional barrier is used, confirmation that the article complies with this legislation.

This information does not apply to the plastic manufacturer.

Whereas AM Polymers GmbH supplies to its customers the adequate information to allow them to fulfil their own responsibilities, the converters do have to check and confirm that the final article meets both the technical and regulatory requirements of the application.

10. RoHS:

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic Equipment, as amended, including Commission Delegated Directive (EU) 2015/863 of 31 March 2015

11. REACH:

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended.

12. CLP:

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, as amended.

13. Cosmetic:

This grade meets the relevant requirements of the Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, as amended. In particular, none of substances listed in Annex II & Annex III of the Regulation (EU) No 1223/2009 is used as additive or raw material.

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14. Regulations: Hazardous Substances, WEEE, EoL Vehicles, Packaging Waste, CONEG (Heavy Metals), Environment (France)

This grade meets the relevant requirements of the following Directives or Regulations:

Restriction of Hazardous Substances: Directive 2003/11/EC of the European Parliament and of the Council of 6 February 2003 amending for the 24th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (pentabromodiphenyl ether, octabromodiphenyl ether), as amended

WEEE: Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment, as amended

EoL Vehicles: Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles, as amended

Packaging Waste: European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, as amended

Environment Code (France): Décret n°2007-1467 du 12 octobre 2007 and Code de l'environnement, section 5-Emballages, sub-section 1, Articles R 543-42 to R 543-52, as amended.

II. USA:

Under 21 CFR 177.1520(c)3.1a, this resin may be safely used in articles that contact food except for articles used for packing or holding food during cooking.

All adjuvants used in the manufacture of this resin are cleared for use in 21 CFR 170-189 by specific citation, generally recognized as safe (GRAS), prior sanctioned or under a specific Food Contact Notification (FCN).

No further restrictions apply to the finished polymer.

California Proposition 65:

This grade is in compliance with the Safe Drinking Water and Toxic Enforcement Act of 1986, also known as California Proposition 65.

This grade may contain n-hexane, CAS 110-54-3, listed as Toxic for Male Reproduction in California Proposition 65 list of chemicals known to the state of California to cause cancer or reproductive toxicity.

A Risk Assessment has been performed taking into consideration the Maximum Allowable Dose Levels (MADLs) published by the Office of Administrative Law under the amendment of Title 27, California Code of Regulations, section 25805.

Our conclusion is that there is no significant risk of exposure.

It remains the responsibility of the final article's producer to ensure compliance with California Proposition 65 requirements.

Coalition of Northeastern Governors (CONEG):

USA CONEG Regulation, as amended

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III. CHINA:

Standard GB 31603-2015

This grade has been manufactured according to the requirements laid down by the General Hygiene Norm GB 31603-2015.

Standards GB 4806.1-2016 and GB 9685-2016

This grade is in compliance with the Standards GB 4806.1-2016 (General Safety Requirements for Food Contact Materials & Articles) and GB 9685-2016 (National Food Safety Standard: Standard for Uses of Additives in Food Contact Materials and Their Products).

For more details about eventual restrictions related to the use of particular monomers or additives, please refer to the § I. 6 and I. 7 of the EU DoC of the present Certificate. The restrictions listed in the new Chinese Standards are indeed fully aligned with those of the Annex 1 of the Regulation (EU) 10/2011.

Standard GB 4806.6-2016

This grade also fulfils the requirements of the Standard GB 4806.6-2016 (Plastic Resin Standard). For more details about eventual restrictions related to SML, SML(T) and QM, please refer to the § I.6 and I.7 of the EU DoC of the present certificate. The restrictions applying to Plastics Resins are indeed fully aligned to those set by the Regulation (EU) 10/2011.

Standard GB 4806.7-2016

Indicative results performed on resins similar to this one show that if used under normal conditions, the articles produced should meet the requirements of Standard 4806.7-2016 (Plastic Articles Standard). It remains however the responsibility of the converter to assess the compliance of his articles with this standard.

IV. SWITZERLAND:

This product is in compliance with **Swiss SR 814.018** "Ordinance on the Incentive Tax on Volatile Organic Compounds (OCOV) of 12 November 1997" as amended, about Volatile Organic Content (VOC).

This product meets the requirements of the **Swiss Ordinance 817.023.21** "Ordinance on Materials and Articles in Contact with Food" of 16th of December 2016 in the frame of the Ordinance 817.02 "Foodstuffs and Utility Articles Ordinance" of 16th of December 2016, as amended.

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V. INVENTORIES for the Polymer:

The above product is in compliance with following inventories:

- Australian Inventory of Chemical Substances: AICS
- Canadian Chemical Registration Regulations: NDSL/DSL
- Chinese List on New Chemical Substances: IECS (Inventory of Existing Chemical Substances in China)
- European Inventory of Existing Chemical Substances: EINECS/ELINCS
- Japanese Chemical Substances Control Law under METI: CSCL
- Korean Existing Chemicals List: (K)ECL
- Philippine Inventory of Chemicals and Chemical Substances: PICCS
- US EPA Toxic Substance Control Act: TSCA
- New Zealand HSNO - Hazardous Substances and New Organisms

VI. Absence of substances and chemicals

None of the following substances are used as additives or raw materials in the manufacture of this grade:

However, since we do not systematically perform specific tests to verify the absence of these substances, we cannot guarantee that there is no trace amount of these substances, as impurity or otherwise, in this grade.

Acrylamide

Alkylphenol Ethoxylates (APEOs)

Allergens (as defined in Regulation (EU) No 1169/2011, as amended)

Aromatic amines

Asbestos

Azodicarbonamide or semi-carbazide compounds

Benzophenone, hydroxybenzophenone and 4-methyl benzophenone

Biocides

Bisphenols (A, AF, AP, B, BP, C, E, F, FL, G, M, P, PH, S, TMC, Z)

Brominated flame retardants

Chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC), hydrofluorocarbons (HFC)

Chlorinated Paraffins

Conflict minerals:

Columbite-tantalite (Coltan, Niobium, Tantalum)

Cassiterite (Tin)

Wolframite (Tungsten)

Gold

Decabromodiphenylether (decaBDE)

2-Ethylhexanoic Acid (2-EHA)

Di(ethylhexyl) adipate (DEHA) and di(ethylhexyl) maleate (DEHM)

Dimethyl Fumarate (DMF)

Dioxins and furans

Endocrine Disruptors listed in the Japanese authority list "Strategic Programs on Environmental Endocrine Disruptors '98 (SPEED '98) - Table-3: Chemicals Suspected of Having Endocrine Disrupting Effects"

Epoxy derivatives:

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BADGE [2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether],
BFDGE [bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ether],
NOGE [novolac glycidyl ether]
as defined in Directive 2002/16/EC amended by 2004/13/EC, repealed by the Regulation 1895/2005/EC
Epoxidised Soya Bean Oil (ESBO)
Formaldehyde (formol)
Halogens and halogenated compounds
(Heavy) metals: Antimony, Arsenic, Beryllium, Cadmium, Cobalt, Copper, Hexavalent Chromium, Lead, Mercury, Nickel, Selenium, Titanium
Isopropylthioxanthone (ITX)
Latexes and elastomers
Melamine and cyanuric acid
Mercapto mix
N-ethyl-o,p-toluolsulfonamide (NETSA) (CAS nb 1077-66-1)
N-ethyl-p-toluenesulphonamide (NE-PTSA) (CAS nb 80-39-7)
Nitrosamines
Nonylphenol and its derivatives including Tris(nonylphenyl) Phosphite (TNPP)
Organo-tin compounds
Pentabromodiphenyl ether, octabromodiphenyl ether
Per- and polyfluoroalkyl substances (PFAS)
Perfluorinated compounds (PFC), Perfluorinated tenside (PFT), Perfluorooctanoic acid (PFOA) & Perfluorooctane sulfonate (PFOS) listed in Directive 2006/122/EC
Persistent Organic Pollutants (POPs) as listed in Annexes I to IV of Regulation (EU) 2019/1021 (a recast of Regulation (EC) 850/2004 and all its amendments) and in Annexes A, B and C of Stockholm Convention as amended
Poly(aromatic hydrocarbons) according to US Environmental Protection Agency Method 610 (EPA 610)
Polybrominated biphenyls (PBBs), polybrominated diphenyl ethers (PBDEs), polybrominated terphenyls (PBTs)
Polychlorinated biphenyls (PCBs), polychlorinated terphenyls (PCTs), polychlorinated naphthalenes (PCNs)
Polycyclic Aromatic Hydrocarbons (PAH)
Recycled products as defined by Regulation (EC) 282/2008
Short-chain chlorinated paraffins
Silicone
Tert-butyl-4-hydroxyanisole (BHA) and 2,6-di-tert-butyl-p-cresol (BHT)
Thiuram mix
Titanium Acetyl Acetone (TAA)
Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) (CAS nb 3380-34-5)
Vinyl chloride monomer (VCM) and its polymers or copolymers (PVC, PVDC, ...)
Substances listed in:
GADSL, "Global Automotive Declarable Substance List", as amended
IKEA Specification, IOS-MAT-0010 ("General Requirements" & "Plastics"), as amended
IKEA Specification, IOS-MAT-0054, as amended

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Analyses for trace impurities in the products are not conducted as part of routine lot certification procedures.

It remains however the responsibility of the converter to assess the compliance of his articles.

This letter shall be construed and interpreted according to the laws of Germany. Please do not hesitate to contact us if you have any further questions.

Yours faithfully,
Dipl. Ing. Timur Ünlü