

Product Safety Information

Evonik Operations GmbH

Product Name: ACEMATT® HK 440
 Chemical Name: Silicon dioxide, chemically prepared
 CAS-No.: 112926-00-8, 7631-86-9
 Customs Tariff Number: 281122

How to find specific information in this document

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Regulations Brazil

Domain	Legal Record	Registration	Remarks
Food contact articles	MERCOSUR/GMC/RES. No. 39/19 Mercosur technical regulation on "positive list of additives for plastic materials intended for the manufacture of food contact packages and equipment"	List of authorized Additives for plastic materials and polymeric coatings Appendix I: Mercosur substance number: 504, European reference number: 86240	The particle size specification for silicon dioxide will be fulfilled.

Regulations China

Domain	Legal Record	Registration	Remarks
Food contact additive	GB 9685-2016	FCA0782 (A 1, A 2, A 3, A 4, A 6)	Application in plastic, coating, rubberink, and paper - dosage as necessary

Regulations Europe

Domain	Legal Record	Registration	Remarks
Food contact articles	CoE Resolution AP 2002 (1), paper and boards, V4 – 12.02.2009	Ref.-No.: 86240 - Silicon dioxide	A. List 1 of Additives
Food contact articles	CoE Resolution AP 2004 (1), coatings, V3 - 12.02.2009	Ref.-No.: 86240 - Silicon dioxide	C. List 1 of additives
Food contact articles	CoE Resolution AP 2004 (4), rubber products, V1 - 10.06.2004	Ref.-No.: 86240 - Silicon dioxide	Appendix 1 - Index list of additives
Food contact articles	CoE Resolution AP 2004 (5), silicones, V1 - 10.06.2004	Ref.-No.: 86240 - Silicon dioxide	List 1 - No. 3. Additives
Food contact articles	CoE Resolution AP 2005 (2), packaging Inks, 21 December 2006	Ref.-No.: 86240 - Silicon dioxide	3.1 Additives List 1 substances evaluated by SCF/EFSA

Regulations Europe

Domain	Legal Record	Registration	Remarks
Food contact articles	Regulation (EU) 10/2011	FCM substance No.: 504, Ref.-No.: 86240 - Silicon dioxide	Annex I, Substances For more information please see below the chapter "More information regarding regulation (EU) 10/2011"

Regulations Germany

Domain	Legal Record	Registration	Remarks
Food contact articles	BfR recommendations: II, III, VII, XIV, XV, XXI, XXXVI, XXXVI/1, XXXVI/2, XLIV, LII	CAS-No.: 7631-86-9 - Silicon dioxide, Silicic acid	Purity criteria acc. to BfR recommendation LII are met
Umweltbundesamt - Assessment Basis for plastics and other organic materials in contact with drinking water (KTW-BWGL)	Attachments for Plastics and other organic Materials in contact with drinking water - Polymer specific part	B.3.1 Positive list of starting materials for the production of organic coatings; B.3.1.2 Fillers/colourants; Ref.-No.: 86240 - Silicon dioxide	The purity criteria according KTW-BWGL, 5.4.2 Requirements for fillers will be fulfilled

Regulations Japan

Domain	Legal Record	Registration	Remarks
Food contact articles	Japan's positive list for plastic as Food Contact Materials, Section 1, Table 2 - Additives	Reference number: 378, serial number: 625, substance: silicon oxide (including silica)	Please consider the distinction limit for the use of synthetic resins, special notes and other limitations.

Regulations Switzerland

Domain	Legal Record	Registration	Remarks
Switzerland - SR 817.023.21	Annex 10; Additives for printing inks Table 1 - List of additives	FCM substance No.: 1809, Ref.-No.: 86240 - Silicon dioxide	For more information please see below the chapter "More information regarding regulation (CH) 817.023.21"
Switzerland - SR 817.023.21	Annex 2; Additives for plastics Table 1 - List of additives	FCM substance No.: 1809, Ref.-No.: 86240 - Silicon dioxide	For more information please see below the chapter "More information regarding regulation (CH) 817.023.21"
Switzerland - SR 817.023.21	Annex 9; Additives for silicones Table 1 - List of additives	FCM substance No.: 1809, Ref.-No.: 86240 - Silicon dioxide	For more information please see below the chapter "More information regarding regulation (CH) 817.023.21"

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives	21 CFR 175.105 (c)(5)	Adhesives	silicon dioxide - as defined in 21 CFR 172.480

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.105 (2)(c)(1) and (2)(c)(5)	Silicon dioxide for use only as component of adhesives	(2)(c)(1) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (silicon dioxide) - (SAS) (2)(c)(5) Silicon dioxide as defined in §172.480(a)
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.125 (a)(1), (a)(3) and (b)(1)	Substances for use only as components of adhesives; Pressure-sensitive adhesives	(a)(1) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (silicon dioxide) - (SAS) (a)(3) Color Additives listed for use in or on food in 21 CFR 73 and 74
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.230 (b)(1)	Hot-melt strippable food coatings	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.300 (b)(1)	Resinous and polymeric coatings	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.320 (b)(1)	Resinous and polymeric coatings for polyolefin films	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.350 (d)(1), (d)(3)	Vinyl acetate/crotonic acid copolymer	(d)(1) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS) (d)(3) Listed as Silica
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.380 (a)	Xylene-formaldehyde resins condensed with 4,4'-isopropylidenediphenol-epichlorohydrin epoxy resins	substances identified in §175.300(b)(3), with the exception of paragraph (b)(3)(xxxi) and (xxxii) of that section

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.390 (b)(1)	Zinc-silicon dioxide matrix coatings	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Adjuvants, Production Aids and Sanitizers	21 CFR 178.1005 (b)	Hydrogen peroxide solution	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Adjuvants, Production Aids and Sanitizers	21 CFR 178.3120 (d)(1)	Animal glue	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Adjuvants, Production Aids and Sanitizers	21 CFR 178.3297 (a), (d) and (e)	Colorants for polymers	The color effect as described in 21 CFR 178.3297 (a) - to affect the color of a food-contact material - must be given.
Indirect Food Additives; Adjuvants, Production Aids and Sanitizers	21 CFR 178.3570 (a)(1)	Lubricants with incidental food contact	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Adjuvants, Production Aids and Sanitizers	21 CFR 178.3850 (d)(1)	Reinforced wax	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Paper and paperboard components	21 CFR 176.170 (a)(1)	Components of paper and paperboard in contact with aqueous and fatty foods	(a)(1) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Paper and paperboard components	21 CFR 176.180 (b)(1)	Components of paper and paperboard in contact with dry food	Substances that by §176.170 and other applicable regulations in parts 170 through 189 of this chapter may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard, subject to the provisions of such regulation.

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives; Paper and paperboard components	21 CFR 176.200 (d)(1), (d)(3)	Defoaming agents used in coatings	(d)(1) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS) (d)(3) Listed as Silica
Indirect Food Additives; Paper and paperboard components	21 CFR 176.210 (d) and (d)(3)	Defoaming agents used in the manufacture of paper and paperboard	(d) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS); Also listed in (d)(3) as silica
Indirect Food Additives; Polymers	21 CFR 177.1010 (a)	Acrylic and modified acrylic plastics, semirigid and rigid	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1020 (2)(b)	Acrylonitrile/butadiene/styrene copolymer	Adjuvants. The copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted in this part ...; Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1030 (b)	Acrylonitrile/butadiene/styrene/ methyl methacrylate copolymer	Adjuvants. The copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted in this part ...; Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives; Polymers	21 CFR 177.1050 (b)	Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer	Adjuvants. The copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted in this part ...; Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1200 (b)(1) and (c)	Cellophane	(b)(1) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS) (c) listed as Silica
Indirect Food Additives; Polymers	21 CFR 177.1211 (b)	Cross-linked polyacrylate copolymers	Adjuvants. The copolymers identified in paragraph (a) of this section ... The optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 179 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.
Indirect Food Additives; Polymers	21 CFR 177.1240 (d)(1)	1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate copolymer	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1320 (a)(1)	Ethylene-ethyl acrylate copolymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1350 (a)(1)(i)	Ethylene-vinyl acetate copolymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives; Polymers	21 CFR 177.1400 (b)(1)	Hydroxyethyl cellulose film, water-insoluble	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1440 (b)	4,4'-Isopropylidenediphenol-epichlorohydrin resins minimum molecular weight 10,000	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1500 (c)(3)(iv)(A)	Nylon resins	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1520 (b)	Olefin polymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1550 (b)(1)	Perfluorocarbon resins	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1560 (b)	Polyarylsulfone resins	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1580 (b)	Polycarbonate resins	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1630 (e)(1)	Polyethylene phthalate polymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1635 (b)	Poly(p-methylstyrene) and rubber-modified poly(p-methylstyrene)	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives; Polymers	21 CFR 177.1640 (b)	Polystyrene and rubber-modified polystyrene	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1650 (a)(1)	Polysulfide polymer - polyepoxyresin	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1660 (b)	Poly (tetramethylene terephthalate)	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1950 (b)	Vinyl chloride-ethylene copolymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1970 (b)	Vinyl chloride-lauryl vinyl ether copolymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1980 (b)	Vinyl chloride-propylene copolymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1990 (b)	Vinylidene chloride/methyl acrylate copolymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.2000 (b)	Vinylidene chloride/methyl acrylate/methyl methacrylate polymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.2250 (a)	Filters, microporous polymeric	Finely divided silicon dioxide
Indirect Food Additives; Polymers	21 CFR 177.2420 (b)(6)	Polyester resin, cross-linked	Listed as Silicon Dioxide

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives; Polymers	21 CFR 177.2500 (b)	Polyphenylene sulfone resins	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.2550 (b), (c)	Reverse osmosis membranes	(b), (c) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.2600 (c)(1)	Rubber articles intended for repeated use	(c)(1) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS) (d)(v) Fillers: Silica
Indirect Food Additives; Polymers	21 CFR 177.2800 (d)(1) and (d)(3)	Textiles and textile fibers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)

Composition / substances

Above mentioned product is a single substance and not a mixture.

Purity Criteria

This product meets specific purity criteria (e.g. for heavy metals) and can therefore be used in regulated applications. The purity criteria were determined from mean values of arbitrarily selected samples. The data provided are therefore representative values and do not represent specifications. The analysis of these purity criteria is not part of our routine standard quality and production control.

Amorphous structure

Synthetic amorphous silica manufactured by flame hydrolysis or by precipitation in an aqueous solution is characterized by its amorphous structure. The determination method used on typical samples is enrichment of the crystalline fraction followed by X-ray Diffraction. The detection limit of this method is less than 0.1% by weight. The determination of arbitrarily selected samples shows no crystalline fraction above the detection limit. Under consideration of this result above mentioned silica is considered to be amorphous.

Safety of toys – directive 2009/48/EG, EN 71-3

Concerning the qualification for above mentioned application please visit the chapters 'Heavy metals' and 'Substance declaration'.

Community eco-label to outdoor and indoor paints according to Commission Decision 2014/312/EU

Criterion 4 - Content of Volatile and Semi-volatile Organic Compounds (VOCs, SVOCs)

During the production process of this product we do not intentionally use or add any volatile organic compounds (VOC's) and/or semi-volatile organic compounds. According to the production process and to the best of our knowledge we do not expect any VOC's/SVOC's in this product.

The analysis on above mentioned substances is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

Criterion 5 - Restriction of hazardous substances and mixtures

This product is not a hazardous substance and not listed as SVHC-Substance. Please visit the product safety information and safety data sheet for detailed information.

Allergens

This product is a pure substance. During the production process we do not intentionally use or add any ingredients usually mentioned to be allergens

- according to EU-Directive 2000/13/EC and amendments
- according Regulation (EU) No 1169/2011 - Food information to consumers
- according the Brazilian resolution RDC No. 26 – requirements for labeling of main foods that cause food allergies
- according to the ALBA-list: Cereals containing gluten (e.g. Wheat, Rye, Barley, Oat, Spelt, Kamut), Maize, Crustaceans, Molluscs, Egg, Fish, Milk, Lactose, Ox, Pig, Hen/Chicken, Peanuts, Soybeans, Almonds, Hazelnut, Walnut, Cashew nut, Pecan nut, Brazil nut, Pistachio, Macadamia nut, Queensland nut, Celery, Mustard, Sesame, Lupines, Leguminous plants, Cinnamon, Vanilla, Coriander, Cocoa, Sulphur dioxide, Sulphites, Yeast, Glutamate (E620 – E625), Benzoic acid (E210 – E219) Azo-colorants/pigments
- Pine, Chestnuts
- Other additives, preservatives, flavors/fragrances or natural latex.

Since testing of these substances is not part of our standard routine quality control and production testing procedures, we therefore cannot warrant or guarantee the absence of these substances in this product.

GMO

In the production process of this product we do not use any Genetically Modified Organisms (GMOs). This product is non-GMO, it does not contain any GMO and has not been in contact with any GMO. Therefore Regulations (EC) No. 1829/2003 (as amended) and No. 1830/2003 (as amended) are not applicable.

Information concerning Regulation (EC) No 1935/2004 on materials and articles

This product meets the requirements of the Framework Regulation (EC) 1935/2004 for substances in contact with food.

More information regarding Regulation (EU) 10/2011

• Declaration of compliance (DoC)

This product is in line with the specification and standards of Regulation (EU) 10/2011.

The production process is not under the hygienic conditions of Regulation (EU) 852/2004 (HACCP).

• Dual use additive

This product is a dual use additive. The purity criteria of E 551 are met.

More information regarding Regulation (CH) 817.023.21

• Declaration of compliance (DoC)

This product is in line with the specification and standards of regulation (CH) 817.023.21.

Origin - TSE/BSE and Materials of animal or plant origin

This product is chemically produced. In the production process we do not use any raw material of animal or plant origin (as mentioned in EMEA/410/01, current version). In our manufacturing facilities we generally do not use any material of animal or plant origin. Our product is not contaminated with any animal- or plant-based material when it leaves the manufacturing sites and warehouses of the manufacturing company.

Information on REACH / Substances of Very High Concern (SVHC)

According to Regulation (EU) 1907/2006 (REACH) substances of very high concern (SVHC) must be mentioned in the safety data sheet (SDS) when the content is above the threshold limit of 0.1% w/w. Please visit the current safety data sheet for more information regarding this issue.

Please use the following e-mail address to order the current SDS: sds-hu@evonik.com

Information on REACH / PBT- and vPvB - substances

This product is not a PBT, vPvB substance as per the criteria of the REACH Regulation.

Information on REACH / Annex XIV or Annex XVII

This product is not a substance and does not contain any substances subject to authorization and/or restriction according to Annex XIV or Annex XVII of the REACH Regulation (EC) No. 1907/2006, respectively. However, testing of these substances is not part of our standard routine quality control and production testing procedures.

RoHS and WEEE Directives

This product fulfils the limitations and requirements of the EU-Directives 2011/65/EU (RoHS), 2012/19/EU (WEEE) and amendments. It is chemically produced. In the production process we do not use or intentionally add the following substances:

pentabromodiphenylether, octabromodiphenylether, lead, cadmium, chromium (total), mercury, polybrominated biphenyls (PBBs), polybrominated diphenylethers (PBDE), Di(2-ethylhexyl)phthalate (DEHP), Butylbenzylphthalate (BBP), Dibutylphthalate (DBP), Diisobutylphthalate (DIBP), chlorinated organic compounds, such as PCB, PCN, CP, mirex, organic tin compounds, asbestos, azo compounds, polyvinyl chloride (PVC) and PVC-blends.

The analysis on above mentioned substances is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

EuPIA exclusion policy for printing inks

During the production process of this product we do not intentionally use or add any substance from the EuPIA exclusion policy for printing inks. Since testing of these substances is not part of our standard routine quality control and production testing procedures, we therefore cannot warrant or guarantee the absence of these substances in this product.

California List of Chemicals, Proposition 65 (USA)

In the production process of this product we do not intentionally use or add any of the substances on the California list of chemicals (USA), Proposition 65, in the current published version. The analysis on above mentioned substances is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

Oeko-Tex Standard 100

For limit values please visit the chapters "Heavy metals" and "Substance declaration".

C.M.R. classified substances

The following EU-Directives are since 2008 no longer in force:

2003/34/EC, 2003/36/EC and 76/769/EEC ("restrictions of dangerous substances and preparations"). This class of substances is now regulated under REACH-SVHC.

End-of life vehicles

This product fulfils the limitations and requirements of the EU Directive 2000/53/EC. For limit values, please visit the chapters "Heavy metals" and "Substance declaration".

Volatile Organic Compounds (VOC 's)

Volatile Organic Compounds are not used or intentionally added during production process of this product. To the best of our knowledge this product does not contain any Volatile Organic Compounds. The analysis on above mentioned substances is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

“Substance declaration”

During the production process of this product we do not intentionally use or add any of the following substances:
 Aromatic amines according to EU Directive 2002/61/EC.

Volatile aromatic hydrocarbons, alkylphenol-ethoxylates, glycol ethers, isothiazolinone compounds, formaldehyde or formaldehyde donators as mentioned in Commission Directive 2002/739/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) as mentioned in Regulation (EC) No 1895/2005.

Substances mentioned in the “VDA-List of Substances to be Declared” version 2005, in the IMDS International list of reportable substances (ILRS-list), in 2005 replaced by GADSL, version 2019 or its subsequent revision, respectively.

Polychlorinated biphenyls (PCB), polychlorinated naphthalenes (PCN), polychlorinated terphenyls (PCT), pentachlorophenol (PCP) and PCP-salts, chlorinated paraffins (CP), Mirex (perchlorodecone), polycyclic aromatic hydrocarbons (PAHs), polybrominated biphenyls (PBB), polybrominated terphenyls (PBT), polybrominated diphenylethers (PBDE), tetrabromobisphenol-A-bis-(2,3-dibromopropylether) (TBBP-A-bis), halogenated solvents, other halogens, organic tin compounds, asbestos, azo dye, polyvinyl chloride (PVC) and PVC-blends, latex, ozone depleting substances, phthalates, cyanides, radioactive materials, pesticides, biocides, 1,4-Dioxane

Substances listed in Sony’s Technical Standards “SS-00259” 15th edition 2017.

Perfluorooctanoic acid (PFOA), Perfluorononanoic acid (PFNA), Perfluorohexane sulfonic acid (PFHxS), Perfluorooctane sulfonates (PFOS) or other PFAS as described in the Scientific Opinion of EFSA (j.efsa.2020.6223) formerly regulated in in EC-Directive 2006/122/EC.

Antibiotics

Any kind of Bisphenol

Asbestos

Boron

Cobalt

DEHP (diethylhexyl phthalate) and DINP (diisononyl phthalate) or any other phthalates

Dimethylfumarat (DMF)

Ethanol (alcohol)

Ethylene oxide

Gold, Tantalum, Tin, Tungsten

Iodine

Isocyanate

Melamine

Mineral oil aromatic hydrocarbons (MOAH)

Mineral oil saturated hydrocarbons (MOSH)

Narcotic products

Nitrite, Nitrate

Quaternary ammonium compounds

Sodium, Sodium chloride

Steroidal anabolic

Sweeteners (e.g. Aspartame, Saccharin, Steviosid)

Uranium

Zinc oxide

The analysis on above mentioned substances is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

Registration Status

The above mentioned product is registered in the following inventories:

Australia	AICS (Australian Inventory of Chemical Substances)	registered
Canada	DSL (Domestic Substance List)	registered
China	IECSC (Inventory of Existing Chemical Substances in China)	registered
Europe	REACH (Registration, Evaluation, Authorisation and Restrictions of Chemicals)	registered (01-2119379499-16-0000)
Europe	EC (European Community)	registered (231-545-4)
Japan	ENCS (Existing and New Chemical Substances)	registered
Korea	KECI (Korea Existing Chemicals Inventory)	registered
New Zealand	NZIoC (New Zealand Inventory of Chemicals)	registered
Philippines	PICCS (Philippine Inventory of Chemicals and Chemical Substances)	registered
Taiwan	TCSI (Chemical Substances Nomination and Notification)	registered
USA	TSCA (Toxic Substances Control Act)	registered

The following information is available in our Safety Data Sheet (SDS):

Hazard Identification, Composition/Information on Ingredients, REACH-Registration number (if available), (SVHC) Substances of high concern (if applicable), First Aid, Fire Fighting Measures, Accidental Release Measures, Handling and Storage, Exposure Control/Personal Protection, Physical and Chemical Properties, Stability and Reactivity, Toxicological and Ecological Information, Disposal Considerations, Risk Information (e.g. Transportation, Labeling, Risk Phrases). The Water Hazard Class (WGK) is only in the German version of the safety data sheet available. Please, pay attention to the national edition of the SDS!

The following e-mail address should be used in order to request the SDS: sds-hu@evonik.com

Heavy metals and other metal traces

In the production process of this product we do not intentionally use or add any heavy metal constituents. The overall content of these elements, in their entirety, lies below 100 ppm and is therefore in line with the limits set by the EU Packaging Directive 94/62/EU.

It is also compliant with the requirements of the Coalition of Northeastern Governors (CONEG) model legislation limiting heavy metals (January 1994).

Heavy metals

Substance	Concentration
Cadmium (Cd)	≤ 1 ppm
Chromium, total (Cr)	≤ 10 ppm
Mercury (Hg)	≤ 1 ppm
Lead (Pb)	≤ 5 ppm

Other metal-traces

Substance	Concentration
Antimony (Sb)	≤ 5 ppm
Arsenic (As)	≤ 3 ppm
Selenium (Se)	≤ 1 ppm
Barium (Ba)	≤ 50 ppm
Zinc (Zn)	≤ 10 ppm
Iron (Fe)	≤ 400 ppm
Copper (Cu)	≤ 6 ppm

Nickel (Ni)

≤ 3 ppm

(The analysis for heavy metals or other metals traces is not part of our standard quality and production analyses. The limits given represent typical values from arbitrarily selected samples, but do not represent any specifications)

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Legend

BfR:	Bundesinstitut für Risikobewertung
CAS:	Chemical Abstract Services Register Number
CoE:	Council of Europe
CONEG:	Coalition of Northeastern Governors
CosIng	European Commission database for information on cosmetic substances and ingredients
FDA:	Food and Drug Administration
FSMA	Food safety modernisation act
INCI:	International Nomenclature Cosmetic Ingredients
JHOSPA:	Japan Hygienic Olefin and Styrene Plastics Association
PBT:	Persistent, Bioaccumulative, Toxic
PCPC	Personal Care Products Council
SAS:	Synthetic Amorphous Silicon dioxide, Synthetic Amorphous Silica
vPvB:	very Persistent, very Bioaccumulative