

Product Safety Information**Evonik Operations GmbH**

Product Name: **ACEMATT® OK 520**
Chemical Name: Silicon dioxide, chemically prepared / ethene homopolymer
CAS-No.: 112926-00-8, 7631-86-9 and 9002-88-4
Customs Tariff Number: 382499

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, EU-Reference-no: 86240 Mercosur substance number: 549, EU-Reference-no: 80000	No restrictions

Regulations China

Domain	Legal Record	Registration	Remarks
Food contact additive	GB 9685-2016	Ethylene homopolymer, registration number FCA0953 (A1)	Application in plastic, PE, PP, PS, AS, ABS, PC, PVDC: dosage as necessary; PET: 0.5%
Food contact additive	GB 9685-2016	Silicon dioxide, registration-number FCA0782 (A 1), Ethene, homopolymer, registration-number FCA0953	Application in plastic, dosage as necessary
Food contact additive	NHFPC Year 2018 No. 11	Ethylene homopolymer; no registration necessary	Application in coating, max. use: 3% The coatings with the added substance shall not be used at a temperature of over 121°C.
Food contact additive	NHFPC Year 2020 No. 6	Ethylene homopolymer; no registration necessary	Application in rubber, max. use: 2%. It is only used for the production of reusable rubber materials and products.
Food contact additive	NHFPC Year 2020 No. 8	Ethylene homopolymer; no registration necessary	Application in plastic, max. use: 0.3%. The use temperature of POM plastic materials and articles with the substance added shall not exceed 121°C.

Regulations European Union (EU)

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, Ref.-No.: 16950 - Ethylene, Ref.-No.: 80000 - Polyethylene wax	A. List 1 of Additives
Food contact articles	CoE Resolution AP 2004 (1), coatings, V3 - 12.02.2009	Ref.-No.: 86240 - Silicon dioxide, Ref.-No.: 16950 - Ethylene, Ref.-No.: 80000 - Ethene Homopolymer (polyethylene wax)	C. List 1 of additives A. List 1 of Monomers
Food contact articles	CoE Resolution AP 2004 (4), rubber products, V1 - 10.06.2004	Ref.-No.: 86240 - Silicon dioxide, Ref.-No.: 16950 - Ethylene, Ref.-No.: 76951 - Ethene Homopolymer (polyethylene wax)	Appendix 1 - Index list of Monomers ... Appendix 1 - Index list of Additives ...
Food contact articles	CoE Resolution AP 2005 (2), packaging Inks, 21 December 2006	Ref.-No.: 86240 - Silicon dioxide, Ref.-No.: 80000 - Polyethylene wax	3.1 Additives List 1 substances evaluated by SCF/EFSA
Food contact articles	Regulation (EU) 10/2011	FCM substance No.: 504 - Ref.-No.: 86240 - Silicon dioxide, FCM substance No.: 125 - Ref.-No.: 16950 - Ethylene, FCM substance No.: 549 - Ref.-No.: 80000 - Polyethylene wax	Annex I, Substances For more information please see below the chapter "More information regarding Regulation (EU) 10/2011"

Regulations Japan

Domain	Legal Record	Registration	Remarks
Food contact articles	Japan's positive list for food appliances, containers and packaging, Appended Table 1, Table 2 (Reference Information)	Reference number: 378, serial number: 625, substance: silicon oxide (including silica, silica gel); Reference number: 441, serial number: 1429, substance: polyethylene wax	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; FCM substance No.: 1933, Ref.-No.: 80000 - Polyethylene wax	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; FCM substance No.: 1933, Ref.-No.: 80000 - Polyethylene wax	For more information please see below the chapter "More information regarding regulation (CH) 817.023.21"

Regulations USA

Domain	Legal Record	Registration	Remarks
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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 175.105 (b)(5)	Polymers: Homopolymers and copolymers of the following monomers:	listed as ethylene
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 175.300 (b)(3)(xxiii) and (xviii)	Resinous and polymeric coatings	(xxiii) Waxes: Polyethylene wax (xviii) Polyethylene and its copolymers as the basic polymer: Polyethylene
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.300 (b)(3)(xxvi)	Resinous and polymeric coatings	(b)(3)(xviii) Polyethylene and its copolymers as the basic polymer: Polyethylene
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 178.3570 (a)(3)	Lubricants with incidental food contact	(a)(3) List of substances - polyethylene; Limitation: Addition to food not to exceed 10 parts per million.
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; Adjuvants, Production Aids and Sanitizers	21 CFR 178.3850 (d)(3)	Reinforced wax	(d)(3) List of substances - polyethylene
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 176.180 (b)(2)	Components of paper and paperboard in contact with dry food	listed as ethylene
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 177.1200 (c)	Cellophane	(c) List of substances - polyethylene
Indirect Food Additives; Polymers	21 CFR 177.2600 (c)(1) and (d)(v)	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 177.2600 (c)(4)(v)	Rubber articles intended for repeated use	(c)(4)(v) List of substances / Fillers - Polyethylene

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 silicon dioxide 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 silicon dioxide 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)

The content of VOCs ($\leq 0.1\%$) and SVOCs ($\leq 0.1\%$) of this product were checked as mean-values of arbitrarily selected samples; they are therefore physical-chemical benchmarks (approximate values), and not specifications.

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 safety data sheet for detailed information - see chapter "Information on REACH / Substances of Very High Concern (SVHC)".

Allergens

During the production process we do not intentionally use or add any ingredients usually mentioned to be allergens

- according Regulation (EU) No 1169/2011 - Food information to consumers
- according Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004
- 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 are 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.

Suitability

This product is chemically produced. During the production process we do not intentionally use or add gluten, lactose or any other materials of animal or plant origin. Therefore we confirm that this product is suitable for vegan lifestyle.

Any testing for these materials is not part of our routine quality and production processes and therefore, we do not guarantee their absence in our product specifications.

Irradiation

This product is chemically produced. During the production process we do not intentionally use or add any irradiated or radioactive raw materials. The product is also not irradiated for preservative purposes. Since testing on irradiation is not part of our standard routine quality control and production testing procedures, we therefore cannot warrant or guarantee the absence of irradiation in this product.

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.

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 EMA/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 (persistent, bioaccumulative, toxic) and vPvB (very persistent, very bioaccumulative) substance as per the criteria of the REACH Regulation.

Information on REACH / Annex XIV or Annex XVII

The above-mentioned product is not a substance nor does contain any substances that are subject to authorization and/or restriction according to Annex XIV or Annex XVII of the REACH Regulation, respectively. However, testing of these substances is not part of our standard routine quality control and production testing procedures.

Please, note, the following EU Directives are not in force anymore: 76/769/EEC (restrictions of dangerous substances and preparations) and its amendments 2003/34/EC and 2003/36/EC.

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:

lead, cadmium, chromium (total), mercury, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), asbestos, polybrominated biphenyl compounds (PCB)

The analysis on these 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 further information please visit the chapters "Heavy metals" and "Substance declaration".

CMR or SVHC classified substances / Genotoxic Impurities

Based on our data, the above-mentioned product is a non-hazardous substance according to criteria of CLP Regulation 1272/2008/EC. It is not carcinogenic, mutagenic or toxic for reproduction (CMR). Above-mentioned product is a pure substance. During the manufacturing process of above-mentioned product, we do not intentionally use or add any CMR or SVHC classified substances.

The analysis of CMR and SVHC 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.

The following EU-Directives are no longer in force since 2008: 2003/34/EC, 2003/36/EC and 76/769/EEC ("restriction of dangerous substances and preparations"). CMR classified substances are part of the SVHC classified substances. 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".

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 Information on REACH Regulation (EU) 1907/2006 (Annex XVII)

Aromatic hydrocarbons with a boiling point lower than 250 °C, Alkylphenol ethoxylates (APEOs), Diethylene glycol methyl ether (DEGME), Isothiazolinone compounds, Formaldehyde or Formaldehyde donators

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 GADSL (version 2022), 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), solvents, halogens, fluorinated compounds, brominated compounds, iodized compounds, 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" (version 2021).

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 these 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	AIIC (Australian Inventory of Industrial Chemicals)	registered
Canada	DSL (Domestic Substance List)	registered
China	IECSC (Inventory of Existing Chemical Substances in China)	registered
European Union	REACH - all basic substances and treatment agents are registered and therefore it is	exempted
European Union	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
Turkey	KKDIK (Chemicals Registration Evaluation Authorisation Restriction)	pre-registered
United Kingdom	UK REACH	please contact: reach-im@evonik.com
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 very 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 Model Toxics in Packaging Legislation (formerly known as CONEG Legislation, February 2021) with respect to the content of heavy metals (Lead (Pb), Cadmium (Cd), Mercury (Hg) and Chromium (Cr total)). Concerning the compliance with this regulation concerning the PFAS and phthalates content, please visit the chapter Substance Declaration.

Heavy metals

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

Other metal-traces

Substance	Concentration
Antimony (Sb)	≤ 5 ppm
Arsenic (As)	≤ 3 ppm
Barium (Ba)	≤ 50 ppm
Copper (Cu)	≤ 6 ppm
Iron (Fe)	≤ 400 ppm
Nickel (Ni)	≤ 3 ppm

Selenium (Se)	≤ 1 ppm
Zinc (Zn)	≤ 10 ppm

The analysis for heavy metals or other metals traces is not part of our standard quality and production analysis. The limits given represent typical values from arbitrarily selected samples, but do not represent any specifications. A total content method was used.

This product safety information sheet replaces all previous versions.

Disclaimer

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Evonik Operations GmbH | Smart Materials | Production & Technology | Product Safety | Special Regulations & Applications
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Registered Office: Essen | Register Court: Essen | Local Court | Commercial Registry B 20227

Legend

BfR:	Bundesinstitut für Risikobewertung (German institute for risk assessment)
CAS:	Chemical Abstract Services Register Number
CFR:	Code of Federal Regulation
CoE:	Council of Europe
CosIng:	European Commission database for information on cosmetic substances and ingredients
FCM:	Food contact material
FDA:	Food and Drug Administration
FSMA:	Food safety modernisation act
GRAS:	Generally Recognized As Safe
INCI:	International Nomenclature Cosmetic Ingredients
NHFPC:	National Health and Family Planning Commission of the People's Republic of China
PCPC:	Personal Care Products Council