

Product Safety Information

Evonik Resource Efficiency GmbH

Product Name: SIPERNAT® D 17
Chemical Name: Silicones and siloxanes, dimethyl-, reaction products with silica
CAS-No.: 67762-90-7,
Customs Tariff Number: 382499

How to find specific information in this document

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Regulations China

Domain	Legal Record	Registration	Remarks
Food contact additive	NHFPC Year 2018 No.9	No registration	application in ink, max. use: 0.038%

Regulations Europe

Domain	Legal Record	Registration	Remarks
Animal nutrition	European Union Register of Feed Additives (current version)	As E 551 a (Silicic acid, precipitated and dried)	Purity criteria are met; Only products ex Wesseling/Germany fulfill FAMI-QS and HACCP.
Food contact articles	CoE Resolution AP 2002 (1), paper and boards, V4 – 12.02.2009	Ref.-No.: 86000 - Silicic acid, silylated, Ref.-No.: 86285 - Silicon dioxide, silanated	A. List 1 of Additives
Food contact articles	CoE Resolution AP 2004 (1), coatings, V3 - 12.02.2009	Ref.-No.: 86000 - Silicic acid, silylated, Ref.-No.: 86285 - Silicon dioxide, silanated	C. List 1 of additives
Food contact articles	CoE Resolution AP 2004 (4), rubber products, V1 - 10.06.2004	Ref.-No.: 86000 - Silicic acid, silanated	Appendix 1 - Index list of additives
Food contact articles	CoE Resolution AP 2004 (5), silicones, V1 - 10.06.2004	Ref.-No.: 86285 - Silicon Dioxide, silanated	List 1 - No. 3. Additives
Food contact articles	CoE Resolution AP 2005 (2), packaging Inks, 21 December 2006	FCM substance No.: 87 - Ref.-No.: 86285 Silicon dioxide, silanated	List 1 of Additives
Food contact articles	Regulation (EU) 10/2011	FCM substance No.: 87 - Ref.-No.: 86285 Silicon dioxide, silanated	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
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Regulations Germany

Domain	Legal Record	Registration	Remarks
Food contact articles	BfR recommendations: XV, XXI, LII	"Silicic acid, also in silylated form"	Purity criteria acc. to BfR recommendation LII are met
Umweltbundesamt - KTW Guideline for drinking water	Guideline for the Hygienic Assessment of Organic Coatings in Contact with Drinking water	Ref.-No.: 86000 - Silicic acid, silanated	Annex 1: Positive List for coatings in drinking water; 1.5 Additives and accessory agents
Umweltbundesamt - KTW Guideline for drinking water	Water, Drinking Water, and Water Protection - Lubricant Guideline	Ref.-No.: 86285 - Silicium dioxide, reaction product with polydimethylsiloxane	Annex 1: White list for lubricants
Umweltbundesamt - KTW Guideline for drinking water	Water, Drinking Water, and Water Protection - Rubber materials	Ref.-No.: 86000 - Silicic acid, silanated	List 1.1.2 Fillers (Purity requirements according to BfR Recommendation LII. Fillers)

Regulations Switzerland

Domain	Legal Record	Registration	Remarks
Switzerland - SR 817.023.21	Annex 10; Additives for printing inks Table 1 - List of additives	Ref-No.: 86000 - Silicic acid, silylated, Ref-No.: 86285 - Silicon dioxide, silanated	For more information please see below the chapter "More information regarding hydrophobic silica and Ordinance SR 817.023.21"
Switzerland - SR 817.023.21	Annex 2; Additives for plastics Table 1 - List of additives	Ref-No.: 86000 - Silicic acid, silylated, Ref-No.: 86285 - Silicon dioxide, silanated	For more information please see below the chapter "More information regarding hydrophobic silica and Ordinance SR 817.023.21"
Switzerland - SR 817.023.21	Annex 9; Additives for silicones Table 1 - List of additives	Listed as substance- No.: 8190 - Silicic acid, silanated	For more information please see below the chapter "More information regarding hydrophobic silica and Ordinance SR 817.023.21"

Regulations USA

Domain	Legal Record	Registration	Remarks
O_ Food Additive and Animal Nutrition	21 CFR 117	Only the product ex plant Wesseling/Germany (FDA Facility Registration Number 17445635392) is represented as suitable for use in animal nutrition in the United States of America. Safety Modernization Act (FSMA).	We gladly confirm that Evonik Resource Efficiency GmbH plant site located in Wesseling (Germany) with 21 Code of Federal Regulations (CFR) part 117, Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food, which was implemented as a result of the FDA Food.

Regulations USA

Domain	Legal Record	Registration	Remarks
Animal nutrition	21 CFR 584.700	Compliant with regulations and maybe used at levels up to 5.0 % as anti-caking/free-flow agent in vitamin preparations for animal feed	No remarks
Animal nutrition	FDA	"No objection letter" from the FDA for use as anticaking agent in mineral premixes for animal feed.	No remarks
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.105 (a)(1)	(1) The adhesive is prepared from one or more of the optional substances named in paragraph (c) of this section, subject to any prescribed limitations. (Listed as Silicon dioxide, limitation: Not to exceed 2% by weight)	Regulation stipulates that adhesives must be separated from the food by a functional barrier and assumed that cannot be otherwise be reasonably expected to become a component of the food in significant amounts
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.300 (c) - (e)	Resinous and polymeric coatings	Criteria for finished coating must be met (specific end tests are stipulated). Chloroform soluble extractive limitation of < 0.5 mg/sq. inch must also be met
Indirect Food Additives; Paper and paperboard components	21 CFR 176.170 (5)	Components of paper and paperboard in contact with aqueous and fatty foods	(5) List of substances: Mentioned as silica and dimethylpolysiloxane, 100 centistokes viscosity
Indirect Food Additives; Paper and paperboard components	21 CFR 176.180 (b)(1)	Components of paper and paperboard in contact with dry food	In reference to the listing in 21 CFR 176.210
Indirect Food Additives; Paper and paperboard components	21 CFR 176.200 (c)	Defoaming agents used in coatings	In reference to the listing in 21 CFR 176.210
Indirect Food Additives; Paper and paperboard components	21 CFR 176.210 (d)(3)	Defoaming agents used in the manufacture of paper and paperboard	Listed as silica and dimethylpolysiloxane

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)

The content of VOC's ($\leq 0.1\%$) and SVOC's ($\leq 0.1\%$) 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 product safety information and safety data sheet for detailed information.

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.

Allergens

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

Cereals containing gluten (e.g. Wheat, Rye, Barley, Oat, Spelt, Kamut), Maize, Crustaceans, Molluscs, Egg, Fish, 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, other additives, preservatives, flavors/fragrances.

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

Aflatoxins

This product is chemically produced. During the production process, there is practically no risk of contamination.

Therefore, to the best of our knowledge, aflatoxins are not contained in this product.

Analysis on aflatoxins 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.

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 hydrophobic silica and Ordinance SR 817.023.21

The current version does not contain a particle specification for hydrophobic silica. From the Swiss authority

(Eidgenössisches Departement des Innern EDI) we received the following statement:

The Commission Regulation (EU) 2016/1416 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, will be included in the next revision of the Ordinance.

The additive list from the EDI's old regulation on commodities (SR 817.023.21), in contrast to EU Regulation 10/2011 and the new Regulation (SR 817.023.21, Mai 2017), was not a "positive" list. It was not exhaustive and complete. A manufacturer could use an additive which is not listed in the current list if the general requirements (Art. 49 of the Food and Consumer Goods Ordinance SR 817.02) are met. An additive which is listed in Regulation 10/2011 (with its possible restrictions (SML, QM, etc.) fulfils these requirements.

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.

Animal nutrition - undesirable Substances according to Directive 2002/32/EC

During the production process of this product we do not intentionally use or add any undesirable substances according to EU-Directive 2002/32/EC (and amendments). 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.

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".

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 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-Dioxan

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

Perfluorooctane sulfonates (PFOS) and Perfluorooctanoic acid (PFOA) as described 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)	registered
Europe	REACH - all basic substances and treatment agents are registered and therefore it is	exempted
Europe	EC (European Community)	registered
Japan	ENCS (Existing and New Chemical Substances)	registered
Korea	KECI (Korea Existing Chemicals Inventory)	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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Evonik Resource Efficiency GmbH | Environment, Safety, Health & Quality | Product Safety | Special Regulations and Applications | RE-ES-PS-SRA/713-303 | Rodenbacher Chaussee 4 | 63457 Hanau-Wolfgang | Germany

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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
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