**Product Safety Information**

**Product Name:** AEROSIL® R 805  
**Chemical Name:** Silane, trimethoxyoctyl-, hydrolysis products with silica  
**CAS-No.:** 92797–60–9  
**Customs Tariff Number:** 382490

### Regulations EU and Germany (FRG)

<table>
<thead>
<tr>
<th>Domain</th>
<th>Legal Record</th>
<th>Registration</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food contact articles (FRG)</td>
<td>BfR recommendations: XV, XXI, LII</td>
<td>&quot;Silicic acid, also silylated&quot;</td>
<td>Purity criteria acc. to BfR recommendation LII. are met</td>
</tr>
<tr>
<td>Food contact articles (EU)</td>
<td>VO (EU) 10/2011</td>
<td>Ref.-No.: 86285 Silicon dioxide, silanated</td>
<td>Annex I, Substances  &lt;br&gt; For more information please see below the chapter &quot;More information regarding VO (EU) 10/2011&quot;</td>
</tr>
<tr>
<td>Food contact articles (EU)</td>
<td>CoE Resolution AP 2002 (1) &quot;paper and boards&quot;</td>
<td>Ref.-No.: 86000 Silicon dioxide, silylated</td>
<td>List 1 of Additives</td>
</tr>
<tr>
<td>Food contact articles (EU)</td>
<td>CoE Resolution AP 2004 (1) &quot;coatings&quot;</td>
<td>Ref.-No.: 86285 Silicon dioxide, silanated</td>
<td>C. List 1 – Additives</td>
</tr>
<tr>
<td>Food contact articles (EU)</td>
<td>CoE Resolution AP 2004 (4) &quot;rubber&quot;</td>
<td>Ref.-No.: 86000 Silicon dioxide (silanated)</td>
<td>Appendix 1 – Index list of additives</td>
</tr>
<tr>
<td>Food contact articles (EU)</td>
<td>CoE Resolution AP 2004 (5) &quot;silicones&quot;</td>
<td>Ref.-No.: 86000 Silicon dioxide (silanated)</td>
<td>List 1 No. 3. Additives</td>
</tr>
<tr>
<td>Food contact articles (EU)</td>
<td>CoE Resolution AP 2005 (2) &quot;packaging inks&quot;</td>
<td>Ref.-No.: 86285 Silicon Dioxide, silanated</td>
<td>List 1 of Additives</td>
</tr>
<tr>
<td>Cosmetics (EU)</td>
<td>VO (EC) 1223/2009</td>
<td>INCI CosIng: Silica Silylate</td>
<td>No negative–listing, positive listing not necessary</td>
</tr>
</tbody>
</table>

### Regulations Canada

<table>
<thead>
<tr>
<th>Domain</th>
<th>Legal Record</th>
<th>Registration</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cosmetics Regulations</td>
<td>Silica dimethyl silylate is included in the ICI dictionary</td>
<td>From the Cosmetic regulations, CRC c 869, ingredients included in the International Cosmetic Ingredient Dictionary (ICI), and materials with INCI are recognized as possible approve ingredients for cosmetic use.</td>
<td>Used as slip agents, silicones</td>
</tr>
</tbody>
</table>

### Regulations USA

<table>
<thead>
<tr>
<th>Domain</th>
<th>Legal Record</th>
<th>Registration</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cosmetics (USA)</td>
<td>PCPC – Monograph ID No. 2791</td>
<td>INCI PCPC: Silica Silylate</td>
<td></td>
</tr>
</tbody>
</table>

Because above mentioned product meets specific purity criteria (i.e. for heavy metals), it may be used accordingly. The purity criteria were checked as mean–values of arbitrarily selected samples; they are therefore physical–chemical benchmarks (approximate values), and not specifications. Purity criteria analysis is not used as part of our standard quality and production control.
More information regarding VO (EU) 10/2011 (hydrophobic silica)
Hydrophobic synthetic amorphous silica is considered as “silicon dioxide, silanated”, Ref. No 86285 according to Commission Regulation (EU) No 10/2011. The core material for this product group is silicon dioxide, Ref. No 86240, which is in compliance with above mentioned regulation. The silanization of synthetic amorphous silicon dioxide does not change the internal structure or the particle sizes of the core material. Base and silanated silicon dioxide are “nano structured” materials according to the specification ISO/WD 80004-4 of the ISO Technical Committee 229 “Nanotechnologies” and have the same particle morphology. Hence, the particle size specification which is defined in (EU) No 10/2011 for silicon dioxide, Ref. No 86240, is also valid for silicon dioxide, silanated”, Ref. No 86285. Subsequently the product group “silicon dioxide, silanated”, Ref. No 86285, is also in compliance with the Commission Regulation (EU) No 10/2011.

Hydrophobic synthetic amorphous silica have been safely used in many applications for decades. Today’s production processes are based on technologies established since the 1940’s. These processes have been optimized and improved since that time while maintaining the same technological principles. While the particle morphology and structure of our products have not been changed, the physical and chemical properties as well as safety aspects have been extensively checked and assessed regularly throughout the decades. Therefore, Silicon dioxide, silanated (PM Ref. No 86285) is considered to be safe for use in consumer products like e.g. plastic materials coming into contact with food.

Concerning the qualification for above mentioned application please visit the chapter heavy metals.

Heavy metals
The above mentioned product does not contain 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) as well as the Consumer Product Safety Improvement Act of 2008 (H.R. 4040 – Public Law No. 110–314, August 14, 2008) establishing consumer product safety standards and other safety requirements for children’s product.

<table>
<thead>
<tr>
<th>Antimony</th>
<th>Cadmium</th>
<th>Mercury</th>
<th>Arsenic</th>
<th>Chromium, total</th>
<th>Selenium</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Barium</th>
<th>Lead</th>
<th>Zinc</th>
<th>Iron</th>
<th>Copper</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 5 ppm</td>
<td>&lt; 1 ppm</td>
</tr>
</tbody>
</table>

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

Registration Status
Above mentioned product is registered in the following inventories:

<table>
<thead>
<tr>
<th>Country</th>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>AICS (Australian Inventory of Chemical Substances)</td>
<td>registered</td>
</tr>
<tr>
<td>Canada</td>
<td>DSL (Domestic Substance List)</td>
<td>registered</td>
</tr>
<tr>
<td>China</td>
<td>IECSC (Inventory of Existing Chemical Substances)</td>
<td>registered</td>
</tr>
<tr>
<td>Europe</td>
<td>EINECS (European Inventory of Existing Commercial Chemical Substances)</td>
<td>296–597–2</td>
</tr>
<tr>
<td>Europe</td>
<td>REACH (Registration, Evaluation, Authorisation and Restrictions of Chemicals)</td>
<td>exempted</td>
</tr>
<tr>
<td>Europe</td>
<td>C&amp;L inventory (classification and labelling inventory)</td>
<td>exempted</td>
</tr>
<tr>
<td>Japan</td>
<td>ENCS (Existing and New Chemical Substances)</td>
<td>registered</td>
</tr>
<tr>
<td>Korea</td>
<td>KECI (Korea Existing Chemicals Inventory)</td>
<td>registered</td>
</tr>
<tr>
<td>New Zealand</td>
<td>NZIoC (New Zealand Inventory of Chemicals)</td>
<td>registered</td>
</tr>
<tr>
<td>Philippines</td>
<td>PICCS (Philippine Inventory of Chemicals and Chemical Substances)</td>
<td>registered</td>
</tr>
<tr>
<td>Taiwan</td>
<td>CSNN (Existing Chemical Substances Inventory)</td>
<td>registered</td>
</tr>
<tr>
<td>USA</td>
<td>TSCA (Toxic Substances Control Act)</td>
<td>registered</td>
</tr>
</tbody>
</table>
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 0.05 % by weight. Under consideration of this detection limit above mentioned silica are considered to be amorphous.

Information on REACH / Substances of Very High Concern (SVHC)
During the production process of the above mentioned product we do not use or add intentionally any SVHC (according to current release of the candidate list) above the threshold limit of 0.1 % w/w.

Origin – TSE/ BSE and Materials of animal or plant origin
The above mentioned 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.

GMO
In the production process of the above mentioned product we do not use any genetically modified organisms (GMO). The above mentioned product is no GMO, it does not contain any GMO and has not been in contact with any GMO. Therefore the Regulations (EC) No 1829/2003 (as amended) and No 1830/2003 (as amended) are not applicable.

Allergens
The above mentioned product is a pure substance. We do not use or add intentionally any additives, preservatives, flavours etc. Above mentioned product constitutionally does not contain any sulphur dioxide or sulphites. It is latex free.

Because of the chemical production of above mentioned product and the raw materials used, this product constitutionally does not contain any of the ingredients usually mentioned to be allergens according to EU-Directive 2000/13/EC and amendments (such as 2003/89/EC, Appendix III a, 2006/142/EC, 2007/68/EC, (EC) No. 1332/2008) and according to the ALBA-list. The analysis on above mentioned substances is not part of our standard quality and production analyses.

Irradiation
The above mentioned product is chemically produced and is constitutionally not irradiated in our production process. Irradiated or radioactive raw-materials are not used.

Animal Testing
Above mentioned product was tested on animals only in connection with requirements of the current Chemical Laws (i.e. EU–Regulation 793/93/EEC). Animal tests on our product have never been performed because of cosmetic questions.

Cosmetics Ordinance – Germany (FRG)
The above mentioned product is neither colorant nor preservative nor UV-Filter, therefore a positive listing is not necessary. As it is not listed on the list of forbidden substances it complies with the Cosmetics Ordinance (FRG).

Cosmetics – EU-Directive 76/768/EC and Amendments – EU
The above mentioned product is in line with EU-Directive 76/768/EC and amendments.

The above mentioned product is in line with Directive (EU) 1223/2009.

Cosmetics – Allergens
Because of the chemical production of the above mentioned product and the raw materials used, it constitutionally does not contain any of the substances usually mentioned to be allergens. This includes also the 26 substances mentioned in Cosmetics Directive 76/768/EC and amendments.
RoHS and WEEE Directives
The above mentioned product fulfils the limitations and requirements of the EU-Directives 2011/65/EU (RoHS), 2002/96/EG (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 (PBB’s), polybrominated diphenylethers (PBDE), 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.

Ozone Depleting Chemicals
For the above mentioned product we do not use any Class I or Class II Ozone Depleting Chemicals in its production process.

California List of Chemicals, Proposition 65 (USA)
In the production process of above mentioned product we do not use or add intentionally any of the substances on the California list of chemicals (USA), Proposition 65, published November 2, 2012. The analysis on above mentioned chemicals is not part of our standard quality and production analyses.

C.M.R. classified substances
On the basis of our data, above mentioned product is classified as a non–hazardous substance as defined by the CLP directive 1272/2008/EC. It is not carcinogenic, mutagenic or toxic for reproduction. Above mentioned product is a pure substance and constitutionally does not contain any C.M.R. classified substances mentioned in the EU–Directives 2003/34/EC and 2003/36/EC. It is not a PBT, vPvB substance as per the criteria of the REACH Ordinance.

End–of–life vehicles
We herewith confirm that the above mentioned product is in line with the EU–Directive 2000/53/EC.

During the production process of the above mentioned product we do not use or intentionally 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 EU directive 2002/16/EC
- 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 January 2012 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), polychlorinated biphenyls (PBB), polychlorinated terphenyls (PBT), polybrominated diphenylethers (PBDE), tetrabromobisphenol–A–bis–(2,3–dibromopropylether) (TBBP–A–bis), organic tin compounds, asbestos, azo dye, polyvinyl chloride (PVC) and PVC–blends, latex, ozone depleting substances, phthalates, cyanides, radioactive materials, pesticides, biocides
- Perfluorooctane sulfonates (PFOS) and Perfluorooctanoic acid (PFOA) as described in EC–directive 2006/122/EC
- Melamine
- Bisphenol A, Bisphenol F
- Dimethylfumarat (DMF)
- Asbestos
- DEHP (diethylhexyl phthalate) and DINP (diisononyl phthalate) or any other phthalates
- Ethanol (alcohol)
• quaternary ammonium compounds
• antibiotics
• narcotic products
• steroidal anabolic

The analysis on above mentioned substances does not belong to our standard quality and production analyses.

The following information can be found in our Material Safety Data Sheet (MSDS):
Hazards Identification, REACH–Registration number (if already available), 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, Water Hazard Class).
Please, pay attention to the national edition of the MSDS!
The following e-mail address should be used in order to request the MSDS: sds-im@evonik.com

Evonik Industries AG

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