

<b>Product Name:</b>	<b>ZEOSIL® &amp; TIXOSIL®</b>
<b>Production plants:</b>	Collonges (FR), Livorno (IT), Wloclawek (PL)
<b>Chemical Name:</b>	Silicon Dioxide
<b>CAS Number:</b>	112926-00-8 (generic : 7631-86-9)
<b>EINECS Number:</b>	601-214-2 (generic 231-545-4)
<b>Generic Name:</b>	Synthetic Amorphous Silica
<b>Aspect:</b>	White powder

### **Zeosil® & Tixosil®, Amorphous synthetic silica**

Zeosil® & Tixosil® are produced by precipitation, in water, of sodium silicate (sand and sodium carbonate) and sulphuric acid. This reaction mode doesn't lead to any crystalline phase inside our product. By DRX measurement we cannot find any crystallites in our silicas.

### **European Regulations / EEA = EU + Island, Norway, Liechtenstein**

MARKET	LEGAL RECORD (LAST UPDATE)	REGISTRATION CODE	COMMENTS
Human nutrition (Food)	178/2002/EC (596/2009)		General principles food, feed, food contact
	1129/2011	E551	General max dosage ≤ 10 g/kg See the annex IV for specific usage
	231/2012 (817/2013)	E551	Purity criteria in accordance to E551 description in annex I
	852/2004/EC (219/2009)		HACCP in place (except for Tixosil 38) Collonges registration n°: 622 037 083 00129
	257/2010/EC	E551	Re-evaluation of existing food additive, dead line 31/12/2016
	1333/2008 (25/2013)	E551	Food additive list : annex 2 part B
Animal nutrition (Feed)	178/2002/EC (CE 596/2009)		General principles food, feed, food contact
	1831/2003/EC (CE 767/2009)	E551a (Silicic acid, precipitated and dried)	Zeosil® & Tixosil® registered Listed in community register
	2002/32/EC (UE 107/2013)	E551a	In compliance with the maximum tolerances allowed in the undesirable substances list.
	183/2005/EC (UE 225/2012)		EU Solvay plants sanitary codes Collonges (registration number): 622 037 083 00129 Wloclawek : αPL0464011p Livorno : n°1 of the 23/12/2005 (production of additives - precipitated silica E551a). FAMI'QS certification / HACCP in place
Food contact	178/2002/EC (CE 596/2009)		General principles food, feed, food contact
	1935/2004/EC (CE 596/2009)	Annex I	General principles
	(CE) 10/2011 + amendment 202/2014 (UE 1183/2012)	FCM substance number : 504 (plastic usage)	For SAS : primary particles of 1 – 100 nm are aggregated to a size of 0,1 – 1 µm could form agglomerates reaching the size distribution of 0,3 µm to the mm size.
	CoE	Paper : ResAP(2002)1	
		Coating : ResAP(2004)1	
		Rubber : ResAP(2004)4	
Cosmetics	(CE) 1223/2009 Regulation	Silica not mentioned in Annex II & Annex III	With regards to the cosmetic regulation silica is not considered as a nano material.
	PCPC Buyers' guide	INCI – Hydrated silica	
EU Pharmacopoeia	Dental type silica	8 <sup>th</sup> Edition (8.0)	Tixosil® only = Compliant

### **Heavy Metals**

**Zeosil® & Tixosil® heavy metals content conforms to all relevant regulations**

Arsenic	< 2 ppm	Lead	< 5 ppm	Total of heavy metals (As, Cd, Hg, Pb, Sb, Cr VI) < 25 ppm
Cadmium	< 2 ppm	Mercury	< 0,1ppm	
Iron	< 400 ppm	Fluorine	< 150 ppm	

## Others

**Zeosil® & Tixosil® are pure substances. It does not contain any additives, colorants, preservatives, flavours. The raw materials & process used to manufacture Zeosil® & Tixosil® do not contain any of the following substances:**

- Volatile organic compounds (VOC's) as defined in directive 2004/42/EC latest version 2010/79/UE.
- Pesticides as defined in European regulation N° 1107/2009
- Substances of Very High Concern (SVHC) and Polycyclic Aromatic Hydrocarbons (PAHs) as described in REACH regulation 1907/2006/EC, N° 50, Annexe XIV and XVII, latest version UE/836/2012 up dated June 15, 2015 (163 substances).
- Solvents as defined in directive 2010/59/UE and regulation 2009/32/EC.
- Allergens as defined in regulation 1169/2011.
- Dioxins as defined in directives 2002/69/EC last version CE1883/2006, 199/2006/EC.
- GMO (genetically modified organisms), TSE (transmissible spongiform encephalopathies), BSE (bovine spongiform encephalopathies) as defined in regulations N°1829/2003 last version regulation CE 298/2008 & N°1830/2003 last version regulation CE 1137/2008.
- Melamine as defined in the regulation 594/2012
- Ionisation free as defined by directive 1999/2/EC last version regulation CE 1137/2008
- Restriction of the use of certain Hazardous Substances (RoHS) as defined in directives 2002/95/EC last version 2011/534/UE & 2008/35/EC .

## Certifications

- ISO TS 16949 2009 = COLLONGES and LIVORNO
- ISO 9001/2008 = COLLONGES, LIVORNO and WLOCLAWEK
- ISO 14001/2004 = COLLONGES and LIVORNO
- FAMI'QS = COLLONGES, LIVORNO and WLOCLAWEK
- OSHAS 18001 = LIVORNO
- KOSHER (France)
- Zeosil® & Tixosil® meets HALAL requirements.

## Inventories

Europe	EINECS	Registered
New Zealand	NZIoC	Listed
Canada	CEPA DSL	Listed
USA	TSCA (8b)	Listed
Japan	ENCS	1-548
China	IECSC	Listed
Korea	KECI	KE-32733 (KE-31032)
Taiwan	TSCI	Listed
Philippines	PICCS	Listed
Mexico	INSQ	Listed
Australia	AICS	Listed

## REACH

Rhodia Operations has registered precipitated amorphous silica (Tixosil® and Zeosil® ranges) in June 2009 :  
 under number 01-2119379499-16-0017

Rhodia Italia has registered precipitated amorphous silica (Tixosil® and Zeosil® ranges) in June 2009 :  
 under number 01-2119379499-16-0023.

Solvay advanced silicas Poland S.P Z.O.O has registered precipitated amorphous silica (Tixosil® and Zeosil® ranges) in July 2015 :  
 under the number 01-2119379499-16-0129.

## NANO

Silica is registered as a nanostructured material in the French decree 2012 ( TR247-2015-02965807) and Belgian royal decree (BE-000185) . Considering the Cosmetic regulation 1223/2009 EU and the food regulation 1129/2011/EU, Synthetic Amorphous Silica is not considered as "nano" since silica has a partial water solubility as well as a non-bio persistence behaviour, and is not intentionally produced as a nanoscale substance.



Philippe COCHET : Quality and Product stewardship for the silica GBU

*The information provided in this technical data sheet is correct to the best of our knowledge, information and belief at the date of its publication. Thus, the information only relates to the designated specific product and may not be applicable if such product is used in combination with other materials or in another manufacturing process, unless otherwise specifically indicated. It does not release the user from ensuring he is in conformity with all regulations linked to its activity*