

1. Identification of the substance or mixture and of the company

1.1. Product ID

Trade name: Titanceramix ceramic microspheres

Trade code: TMX055, TMX165, TMX825

Registration number: Not applicable.

A registration number is available for the other substances in the mixture (see sect. 3.1 ingredients) because the substance or its uses are not exempt from registration or the annual tonnage requires registration.

1.2. Relevant identified uses of the substance or mixture and non-recommended uses

The product can be used as a light additive for construction, chemistry and others. Industrial, professional uses.

SU22 Professional uses

Non-recommended uses

None in particular. This material should not be used for any purpose other than those indicated without expert advice.

1.3. Details of the supplier of the safety data sheet

Supplier	Ediltermika S.r.l. S.S. 11 - Km 321 - 37038 Soave (VR) Tel. +39 045 7612321 Fax +39 045 6100997 E-mail ediltermika@ediltermika.it
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1.4. Emergency telephone number

Poison Control Centre (CAV)

800 011 858 Azienda Ospedaliera Universitaria Integrata di Verona, piazzale Stefani 1. Available 24 hours, 7 days a week.

+39 02 66101029 Niguarda Ca' Granda Hospital, Milan

+39 0382 24444 National Centre for Toxicological Information, Pavia

800 883 300 'Papa Giovanni XXIII' Hospital, Bergamo

+39 055 7947819 'Careggi' Hospital, Florence

+39 06 68593726 'Bambino Gesù Children's Hospital', Rome

+39 06 49978000 'Umberto I' General Hospital, Rome

+39 06 3054343 'A. Gemelli' General Hospital, Rome

+39 081 7472870 'A. Cardarelli' Hospital, Naples

800 183 459 University Hospital, Foggia

2. Hazard Identification

2.1. Classification of the substance or mixture

2.1.1. Classification according to Regulation (EC) No. 1272/2008

The mixture is not classified.

2.1.2. More information

This product does not meet the criteria for classification in any hazard class in accordance with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. However, it is supplied with a safety data sheet on request, as it contains a component for which there is an EU workplace exposure limit.

2.2. Label Elements

Labelling according to Regulation (EC) No. 1272/2008 (CLP):

This product is labelled as non-hazardous.

Hazard pictogram:	None
Hazard indications:	None
Precautionary statements:	None

2.3. Other hazards

Physical / Chemical	None.	None.
Health	None.	None.
Environment	None.	None.
Contaminants	None.	None.

This mixture does not meet the PBT/vPvB criteria of REACH, Appendix XIII.

The mixture is not included in the list established according to Article 59(1) of REACH for endocrine disrupting properties.

The mixture is not a substance identified as having endocrine disrupting properties in accordance with the criteria set out in Regulation (EU) No 2017/2100 or Regulation (EU) No 2018/605.

The use of this chemical agent entails the obligation for the employer to perform a 'risk assessment' in accordance with the provisions of Italian Legislative Decree no. 81 of 9 April 2008. Workers exposed to this chemical agent do not have to undergo health surveillance if the results of the risk assessment show that, in relation to the type and quantity of the hazardous chemical agent and the manner and frequency of exposure to that agent, there is only an 'insignificant risk' to the health and safety of workers and that the measures set forth in the Legislative Decree itself are sufficient to reduce the risk.

3. Composition/information about ingredients

3.1. Substances

Refer to point 16 for the full text of the R-phrases and hazard statements.

Mixture	% by weight in the product	Classification	CAS	EINECS	REACH
Expanded perlite	< 40 %	Non-hazardous	93763-70-3	310-127-6	-
Nanoceramix	< 10 %	Non-hazardous	1302-98-8 1335-30-4	-	-
Ashes, kenospheres	< 10 %	Non-hazardous	93924-19-7	300-212-6	01-2119563688-21-XXXX
Silicon Dioxide	< 20 %	Non-hazardous	112926-00-8	231-545-4	-
Titanium dioxide	< 30 %	Non-hazardous *	13463-67-7	236-675-5	01-2119489379-17-0013

* Commission Delegated Regulation (EU) No 2020/217 has classified titanium dioxide (TiO₂) in powder form containing 1 % or more particles with an aerodynamic diameter ≤ 10 µm as a category 2 carcinogen by inhalation. Particle analysis confirms that the product does not require classification as indicated in its SDS.

3.2. Mixtures

Refer to point 16 for the full text of the R-phrases and hazard statements.

Mixture	% by weight in the product	Classification	Index	CAS	EINECS	REACH
Pico Compound	< 20 %	Non-hazardous	-	65997-17-3	266-046-0	-

4. First Aid Measures

4.1. Description of first aid measures

- GENERAL CASE

If in doubt or if the symptoms of poisoning persist, seek medical advice. Never make an unconscious person drink fluids.

- INHALATION

Move the person away from the hazard area. Have the person breathe fresh air and seek medical advice. If symptoms persist, seek medical advice.

- DIRECT SKIN CONTACT

Wash thoroughly with water. In the event of skin irritation (redness, etc.), seek medical advice.

- DIRECT EYE CONTACT

Contact lenses, if worn, must be removed. Rinse thoroughly with water for at least 10 minutes, keeping the eyelids open. If symptoms persist, consult a doctor and/or ophthalmologist.

- SWALLOWING

Swallowing of a product is a very unlikely event. If swallowed, do not induce vomiting in order to avoid the risk of aspiration of the product in the airway, with possible lung congestion. Seek medical advice immediately.

4.2. Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in section 11.

4.3. Indication of any need for immediate medical attention and special treatment needed

Notes for the physician: none.

5. Fire-fighting measures

5.1. Extinguishing agents

- RECOMMENDED EXTINGUISHING AGENTS

In the event of a fire, use water mist or chemical powder or foam products or carbon dioxide.

5.2. Special hazards arising from the substance or mixture

No data available.

5.3. Recommendations for firefighters

Exposure to combustion gases can pose health risks: use a mask against fire fumes and vapours. Water mist can be used to protect people engaged in the extinguishing operations.

NOTES: dispose of contaminated water used to extinguish fires in accordance with current regulations.

6. Measures in case of accidental spill

6.1. Personal precautions, protective equipment and emergency procedures

For people not directly involved in the operations:

- Move away from the area around the spill or leak.
- Do not smoke.
- There are no known unsuitable materials.

For those who intervene directly:

- Wear all required Personal Protective Equipment (PPE) (see section 8).
- Eliminate all open flames and possible sources of ignition.
- Avoid dust formation.
- Avoid breathing vapours/mist/gas. Do not inhale dust.
- Do not smoke.
- Ensure adequate ventilation.
- Evacuate the danger area and, if necessary, consult an expert.

6.2. Environmental precautions

If the product has spilled into a water course, sewer system or has contaminated soil or vegetation, notify the relevant authorities.

Dispose of the residue in accordance with current regulations.

6.3. Methods and materials for containment and reclamation

- Contain spillage.
- Collect the product rapidly while wearing a mask and protective clothing.
- Collect and arrange for disposal without creating dust.
- Sweep and shovel, wetting the product first.
- Store in suitable, closed containers for disposal.
- Collect the product for re-use, if possible, or for disposal. If necessary, absorb it with inert material.
- Prevent it from entering the sewer system.

6.4. Reference to other sections

Please refer to points 8 and 13 for further information.

7. Handling and storage

In addition to the information provided in this section, other relevant information can be found in Sections 6.1 and 8.

7.1. Precautions for safe handling

- If not already present, adequate ventilation must be provided in rooms where dust develops.
- Avoid contact and inhalation of vapours.
- Do not eat or drink while working.
- Observe the indications on the label and the instructions for use.
- Follow the general rules of hygiene for chemicals.
- Normal fire prevention measures.

7.2. Conditions for safe storage, including any incompatibilities

- Keep in the tightly closed original container. Do not store in open or unlabelled containers.
- Store in a cool, dry place.
- Keep the container tightly closed in a dry, well-ventilated environment. The product is moisture sensitive.
- Keep containers upright and secure against the possibility of falling or being knocked over.
- Store in a cool place, away from any source of heat and direct sunlight.

7.3. Specific end uses

Professional, industrial uses: handle with care. Store in a ventilated place and away from heat sources. Keep the container tightly closed.

8. Exposure control/personal protection

In general: Ensure sufficient ventilation. Reduce the risk of inhalation. Respect the exposure limits set by local regulations. Wear personal protective equipment and work in compliance with best practices

8.1. Control parameters

Of the contained substances:

- **Aluminium Silicate**

TLV: 10^{mg/m³} (OHS PEL); 10^{mg/m³} (ACGIH).

- **Titanium dioxide**

DNEL: 10^{mg/m³}, chronic through inhalation.

PNEC:

Water (fresh) 0.127 mg/Lt Water (salt) 1 mg/Lt

Water (occasional spillages) 0.61 mg/Lt

Sediment (freshwater) 1000 mg/kg sediment dw

Sediment (salt water) 100 mg/kg sediment dw

Soil 100 mg/kg soil dw

Waste water purifier 100 mg/Lt Oral, mammals

8.2. Exposure controls

a) Technical controls:

Provide an appropriate local ventilation system for the work.

Use generalised and/or localised ventilation to keep airborne exposure below occupational exposure limits and/or to control dust/fume/gas/mist/vapour/spray emissions. If ventilation is inadequate, use respiratory protection.

Handle in accordance with good industrial hygiene and safety practices. Wash hands before breaks and at the end of the working day.

b) Individual protection measures

i. **Eye/face protection**

Use safety glasses (goggles) (EN 166) when handling the pure product.



ii. **Skin protection**

- Hand protection

Select and use protective gloves/protective clothing approved according to current regulations to prevent skin contact, based on the results of an exposure assessment. The choice should be based on use factors such as exposure levels, concentration of the substance or mixture, frequency and duration, physical factors such as extreme temperatures and other conditions of use. The appropriate types of gloves/protective clothing can be chosen with the advice of a personal protective equipment manufacturer

Note: Nitrile gloves can be worn over polymer laminate gloves to improve dexterity.

The use of gloves tested according to EN 374 is recommended.

- Miscellaneous



Wear normal work clothes.



iii. Respiratory protection

An exposure assessment may be necessary to decide whether respiratory protection is required. Use dust masks with FFP 3S filters (EN 149).



iv. Thermal hazards

No hazard to report.

c) Environmental exposure controls:

Minimise the release of product into the environment. Monitor emissions from fans and work equipment to ensure compliance with environmental protection requirements. In some cases it may be necessary to use scrubbers, filters or other technical treatments to reduce emissions to the permissible limit.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical and chemical properties	Value
Physical state	Powder solid (µm)
Colour	White
Odour	None
Olfactory threshold	Not determined
pH	Not measurable
Melting point / freezing point	Not measurable
Initial boiling point and boiling range	Not applicable
Flash point	Not applicable
Evaporation rate	Not determined
Humidity	1,3 ± 0,3 %
Flammability (solids, gases)	Non-flammable
Upper / lower flammability or explosion limits	Not determined
Vapour pressure	Not determined
Vapour density	Not determined
Density	0,49 ± 0,05 g/cm ³ 20 °C
Solubility	Not determined
Water solubility	Not determined
Partition coefficient: n-octanol/water	Not determined
Self-ignition temperature	Non-flammable
Decomposition temperature	Not determined
Viscosity	Not determined
Explosive properties	Non-explosive
Oxidising properties	Non-oxidising

9.2. Other information

No data available.

10. Stability and reactivity

10.1. Reactivity

No danger of reactivity.

10.2. Chemical stability

Stable under normal conditions of use and storage.

10.3. Possibility of dangerous reactions

No dangerous reactions are foreseen.

10.4. Conditions to avoid

None to report.

10.5. Incompatible materials

None to report.

10.6. Hazardous decomposition products

No hazardous decomposition products.

11. Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No. 1272/2008

Acute oral toxicity

LD50 Oral - rat - 5,000 mg/Kg Harmful if
swallowed

Acute inhalation toxicity

LD50 Oral - rat - 5.7 mg/L exposure 4h May
be harmful if inhaled

Acute dermal toxicity

LD50 Oral - rat - 5,000 mg/Kg
Can cause an allergic skin reaction

Corrosion/skin irritation Skin -
on rabbit

May be harmful through skin contact

Serious eye injury/irritation

May cause serious eye injury / may be irritating in the case of eye contact

Respiratory or skin sensitisation Skin contact

Species: Guinea pig May irritate the
respiratory tract

Germ cell mutagenicity

Based on the available data, the classification criteria are not met

Carcinogenicity

It has been observed that the carcinogenic hazard of this substance arises when respirable dust is inhaled in quantities leading to significant impairment of the pulmonary mechanisms of particle expulsion. Classification amended by EU Delegated Reg. 2020/217 of the Commission of 04/10/2020. Hazard class Carc. 2 inal, hazard statements H351

Reproductive toxicity

Based on the available data, the classification criteria are not met

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure
No data available

Inhalation hazard
No data available

EXPOSURE ROUTES: The substance can be absorbed into the body mainly through inhalation of dust or through contact or ingestion.

Inhalation: Prolonged exposure to product vapours or mists may cause irritation of the respiratory tract. Symptoms may include pain in the nose and throat, coughing, sneezing, nasal discharge, migraine, hoarseness. Allergic reactions of the respiratory system: symptoms may include difficulty breathing, chest constriction, wheezing and coughing. It may cause other health effects.

Eye contact: Accidental contact of the product with the eyes causes irritation.

Skin contact: Accidental contact of the product with the skin may cause skin irritation. *Swallowing:* If swallowed, the product may cause irritation of the mucous membranes of the throat and digestive tract, leading to abnormal digestive symptoms and intestinal disorders.

11.2. Information on other hazards

No further hazards to report.

12. Ecological information

12.1. Toxicity

Of the contained substances:

- **Aluminium Silicate**

Product test data not available.

- **Titanium dioxide**

Acute aquatic toxicity - fish

All reliable acute toxicity tests performed on fish (4 different genres in both fresh and salt water) resulted in LC50 values in the range of >1 to >10,000 mg TiO₂/Lt. Applying the reliability of evidence approach, it was determined that the substance does not manifest acute toxicity for fish at a concentration >1,000 mg TiO₂/Lt in freshwater and at a concentration >10,000 mg TiO₂/Lt in seawater.

Acute toxicity results on fish

Pimephales promelas LC50 (96 h): >1000 mg/L, tested according to EPA-540/9-85-006, Acute Toxicity Test for Freshwater Fish

Oncorhynchus mykiss LC50 (96 h): >100 mg/L, tested in fresh water, according to OECD Guideline 203 (Fish, Acute Toxicity Test)

Oncorhynchus mykiss LC50 (14 d): >1 mg/L, tested in fresh water where the fish were exposed to various concentrations of the test material and the biochemical characteristics of the different organs were then measured.

Danio rerio LC50 (48 hours): >10 mg/L, tested in fresh water, according to American Society of Testing and Materials (ASTM), 2002

Cyprinodon variegatus LC50 (96 hours): >10000 mg/L, tested in seawater according to OECD Guideline 203 (Fish, Acute Toxicity Test) and according to OSPARCOM (2005-11), Protocol for a fish acute toxicity test.

Acute aquatic toxicity - invertebrates

All reliable acute toxicity tests carried out on invertebrates (4 different genres in both fresh and salt water) resulted in LC50 values in the range of >10 to >10,000 mg TiO₂/Lt. Applying the reliability of evidence approach, it was determined that the substance does not manifest acute toxicity for invertebrates at a concentration >1,000 mg TiO₂/Lt in freshwater and at a concentration >10,000 mg TiO₂/Lt in seawater.

Acute toxicity results on invertebrates:

Daphnia magna LC50 (48 hours): >100 mg/Lt, tested in fresh water according to OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

Daphnia pulex LC50 (48 hours): >10 mg/Lt tested in fresh water, according to American Society for Testing and Materials: Standard guide for conducting acute toxicity tests on test materials with fishes, macro invertebrates and amphibians.

Ceriodaphnia dubia LC50 (48 hours): >10 mg/Lt tested in fresh water, according to American Society for Testing and Materials: Standard guide for conducting acute toxicity tests on test materials with fishes, macro invertebrates and amphibians.

Daphnia magna EC50 (48 hours): >1,000 mg/Lt tested in fresh water according to EPA-660/8-87/011, 1987 and ASTM Standard E729 (1986) and OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test) and U.S. Environmental Protection Agency (660/3-75-009), 1975: Methods for Acute Toxicity Tests with Fish, Macro- invertebrates and Amphibians

Daphnia magna LC50 (48 h): ≥500 mg/Lt tested in fresh water, according to U.S. EPA standard operating procedure 2024

Acartia tonsa LC50 (48 hours): >10,000 mg/L, tested in seawater, according to ISO 14669 (1999) Water quality determination of acute lethal toxicity to marine copepods (copepoda: crustacea) and ISO 5667-16 (1998) Water quality sampling-guidance on biotesting of samples

Chronic aquatic toxicity

No reliable test results known. Since all acute toxicity tests were found to be free of toxic effects, no further testing is required for this substance.

Toxicity for algae and aquatic plants

The lowest value for algae was noted for Pseudokirchneriella subcapitata in fresh water: EC50 (72 h) 61 mg/Lt (growth rate, test according to OECD Guideline 201 (Algae, Growth Inhibition Test) with corresponding EC10 (72 h) 12.7 mg TiO₂/Lt. Tests with Skeletonema costatum in seawater resulted in EC50 >10,000 and NOEC 5,600 mg TiO₂/Lt (growth rate, test according to ISO 10253 (Water quality - Marine Algal Growth Inhibition Test with Skeletonema costatum and Phaeodactylum tricornutum).

Toxicity for sedimentary organisms

EC50/LC50 for marine sediment: 14.989 mg/kg (using the Corophium volutator test according to OSPARCOM guidelines (1995) A sediment bioassay using an amphipod corophium sp.);

EC10/LC10 for freshwater sediment: 100.000 mg/kg sediment (using the Hyalella azteca test according to ASTM E1706).

Toxicity for soil macro-organisms

Long-term EC10/LC10 or NOEC for soil anthropods: 1.000 mg/kg soil (tested for Folsomia candida according to ISO 11267 (Inhibition of Reproduction of Collembola by Soil Pollutants).

Toxicity for plants

Long-term EC10/LC10 or NOEC for plants: 100.000 mg/kg soil (tested for Hordeum vulgare (Monocotyledonae (monocots) and Lactuca sativa (Dicotyledonae (dicots)), according to the ISO 11269-2 protocol).

Toxicity for soil micro-organisms

Long-term EC10/LC10 or NOEC for soil microorganisms: 10.000 mg/kg soil (tested per species/Inoculum: soil, according to ISO 14238).

Toxicity for aquatic micro-organisms in sewage treatment plants

EC10/LC10 or NOEC aquatic microorganisms: 1.000 mg/Lt (tested activated sludge from predominantly domestic waste, in fresh water, according to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test).

12.2. Persistence and degradability

No or insufficient data available for classification.

12.3. Bioaccumulative potential

No or insufficient data available for classification.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No chemical safety report.

12.6. Endocrine-disrupting properties

No endocrine disrupting properties are identified.

12.7. Other adverse effects

No adverse effects observed.

13. Considerations on disposal

13.1. Waste treatment methods

Hazardous waste: Based on the available information, the substance is not classified as hazardous waste.

Do not discharge into sewers, drains or watercourses.

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues must be disposed of according to good working practice, avoiding dispersal in the environment. Comply with current legislation on the protection of water and soil from pollution (Legislative Decree No. 152 of 3/4/2006).

Dispose of used product and containers using authorised companies, in accordance with the provisions of Legislative Decree No. 152/2006 as amended.

Depending on the specific use and disposal characteristics of the user, different EWC codes may be assigned (2008/98/EC).

Recover if possible. Send to authorised disposal plants or for incineration under controlled conditions. Operate in accordance with current local and national regulations.

14. Transport information

14.1. UN or ID number

Not covered by EU directives and Italian legislation concerning the inland transport of hazardous substances, by road (A.D.R.) by rail (R.I.D.), by sea (I.M.D.G.).

14.2. Official UN transport designation

None.

14.3. Transport hazard classes

None.

14.4. Packaging group

None.

14.5. Environmental hazards

None.

14.6. Special precautions for users

Unless otherwise specified, the relevant general measures usually in use must be observed in order to carry out safe transport.

14.7. Maritime transport in bulk according to IMO Acts

Not a dangerous good according to the aforementioned legislation.

15. Regulatory information

15.1. Safety, health and environmental regulations specific to the substance or mixture

Regulation (EU) No. 878/2020 amending Annex II of Regulation (EC) No. 1907/2006 as amended.

Regulation (EC) No. 1907/2006 and related national and EU legislation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), and subsequent adaptations to technical and scientific progress.

Regulation (EC) No. 1272/2008 and related national and EU legislation on classification, labelling and packaging of substances and mixtures and subsequent adaptations to technical and scientific progress.

Regulation (EU) No. 453/2010 amending Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), as adapted to technical and scientific progress.

Legislative Decree No. 81 of 09/04/2008 (Consolidation Act on Safety) as amended, concerning the improvement of workers' health and safety.

Legislative Decree. 238/2005 (Seveso ter) - transposition of Directive 2003/105/EC amending Directive 96/82/EC on the control of major-accident hazards involving dangerous substances.

15.2. Chemical Safety Assessment

A chemical safety assessment was not performed for this mixture. Chemical safety assessments for contained substances may have been conducted by substance registrants in accordance with Regulation (EC) No. 1907/2006 (REACH) as amended.

No relevant exposure patterns exist for the substance in question.

16. Other information

16.1. Other information

Description of the hazard statements (H) and precautionary measures (P) set out in section 3.

- None

Classification based on raw material data of all mixture components.

The information in this safety data sheet describes the product with reference to necessary safety measures, it does not guarantee certain characteristics and is based on currently available data and our best knowledge regarding the most suitable criteria for handling the product under normal conditions. Any other use of the product not in accordance with the indications in this data sheet or the use of the product in combination with any other product or in any other process is the sole responsibility of the user. Moreover, this SDS is provided to convey health and safety information. The official importer of this product into the European Union is responsible for all regulatory requirements, including but not limited to product registrations/notifications, volume calculation and potential registration of substances.

Form filled in in accordance with the requirements of Annex I of Regulation (EU) No. 453/2010, as well as the provisions of Regulation (EC) No. 1272/2008 and Regulation (EU) No. 878/2020 amending Annex II of Regulation (EC) No. 1907/2006 as amended.

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Replacing version 2.0 of 16/04/2021.

*** End of Safety Data Sheet. This cancels and replaces all previous editions. ***