

**TONSIL 8120-D FF**

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Substance key: SC0000107385

Revision Date: 10.02.2014

Version : 1 - 1 / EU

Date of printing : 05.08.2015

## **SECTION 1: Identification of the substance/mixture and of the company/undertaking**

### **1.1. Product identifier**

**Trade name**

**TONSIL 8120-D FF**

**Material number:** 246739

**REACH - Registration number** 01-2119485596-21-0000, 01-2119485596-21-0012  
**according to article 20(3):**

**CAS number :** 70131-50-9

**EC number :** 274-324-8

### **1.2. Relevant identified uses of the substance or mixture and uses advised against**

**Relevant identified uses of the substance or mixture**

Type of use : Bentonite, acid-leached has a variety of uses.  
It can be used as an adsorbing agent, filler, flame retardant, pH  
regulating agent, bleaching agent, corrosion inhibitor, water  
treatment chemicals and anti-scaling agent.

**Uses advised against**

Type of use : There are no uses advised against.

### **1.3. Details of the supplier of the safety data sheet**

**Identification of the company**

Clariant Produkte (Deutschland) GmbH

Ostenriederstrasse 15

85368 Moosburg

Telephone no. : +49 (0)8761/82-0

**Information about the substance/mixture**

Business Unit Functional Minerals

Product Stewardship

e-mail: SDS-contact@clariant.com

### **1.4. Emergency telephone number**

00800-5121 5121 (24 h)

## **SECTION 2: Hazards identification**

### **2.1. Classification of the substance or mixture**

**Classification according CLP regulation (Regulation (EC) No. 1272/2008, as amended)**

Not classified, Bentonite, acid-leached does not meet the criteria for classification.

**Classification according EC Directive (67/548/EEC or 1999/45/EC, as amended)**

Not classified, Bentonite, acid-leached does not meet the criteria for classification.

## 2.2. Label elements

### Labelling according CLP regulation (Regulation (EC) No. 1272/2008, as amended)

Not a dangerous substance according to GHS.

## 2.3. Other hazards

The product contains less than 0.1% w/w RCS (respirable crystalline silica) as determined by the SWERF method. The respirable crystalline silica content can be measured using the "Size-Weighted Respirable Fraction – SWERF" method. All details about the SWERF method is available at [www.crystallinesilica.eu](http://www.crystallinesilica.eu)

Depending on the handling and use (grinding, drying, bagging), airborne respirable dust may be generated. Dust contains respirable crystalline silica. Prolonged and or massive inhalation of respirable crystalline silica dust may cause lung fibrosis, commonly referred to as silicosis. Principal symptoms of silicosis are cough and breathlessness. Occupational exposure to respirable dust should be monitored and controlled. The product should be handled using methods and techniques that minimize or eliminate dust generation.

The substance does not meet the criteria for PBT or vPvB substance.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

#### Chemical characterization

Bentonite, acid-leached is a UVCB substance, sub-type 4. The purity of the product is 100 % w/w.

Impurities are not applicable for a UVCB substance.

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## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### General information

No known delayed effects. Consult a physician for all exposures except for minor instances.

#### After inhalation

Remove to fresh air immediately. Get medical attention immediately.

#### After contact with skin

Wash off immediately with soap and plenty of water.

#### After contact with eyes

Rinse thoroughly with plenty of water, also under the eyelids.  
If symptoms persist, call a physician.

#### After ingestion

Clean mouth with water and drink afterwards plenty of water.

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

#### Symptoms

There are no acute and delayed symptoms and effects observed.

**Hazards**

No information available.

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

**Treatment**

Treat symptomatically.

**SECTION 5: Firefighting measures**

**5.1. Extinguishing media**

**Suitable extinguishing media**

The product itself does not burn.

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Water spray jet

Dry powder

Foam

Carbon dioxide (CO<sub>2</sub>)

**Extinguishing media that must not be used for safety reasons**

no restrictions

**5.2. Special hazards arising from the substance or mixture**

The product is not flammable.

Does not sustain combustion.

No hazardous decomposition products are known.

**5.3. Advice for firefighters**

**Special protective equipment for firefighting**

In the event of fire, wear self-contained breathing apparatus.

Special sliding risk through leaking of spilled product in connection with water.

**SECTION 6: Accidental release measures**

**6.1. Personal precautions, protective equipment and emergency procedures**

Ensure adequate ventilation.

Avoid dust formation.

Evacuate personnel to safe areas.

Avoid contact with skin, eyes and clothing.

Wear personal protective equipment.

Avoid breathing dust.

Use the indicated respiratory protection if the occupational exposure limit is exceeded and/or in case of product release (dust).

Special sliding risk through leaking of spilled product in connection with water.

**6.2. Environmental precautions**

No special environmental precautions required.

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## 6.3. Methods and material for containment and cleaning up

Pick up and transfer to properly labelled containers.  
If product is released from trucks in roads, place signposts and remove the spill using vacuum cleaning systems.

## 6.4. Reference to other sections

### Additional information

see point 8, 13  
Avoid dust formation; avoid dry sweeping  
Use vacuum suction unit, or shovel into bags.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Advice on safe handling

Avoid dust formation.  
Provide sufficient air exchange and/or exhaust in work rooms.  
In case of insufficient ventilation, wear suitable respiratory equipment.  
For personal protection see section 8.  
Handle and open container with care.  
If you require advice on safe handling techniques or specific uses, please contact your supplier or check the further information referred to in section 16.

#### Hygiene measures

Wash hands before breaks and at the end of workday.

### 7.2. Conditions for safe storage, including any incompatibilities

#### Requirements for storage areas and containers

Minimize airborne dust generation and prevent wind dispersal during loading and unloading.  
Keep containers closed and store packaged products so as to prevent accidental bursting.

#### Advice on storage compatibility

No conditions to be specially mentioned.

#### Storage stability

Stable under recommended storage conditions.

### 7.3. Specific end use(s)

Not relevant

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Exposure limit values

Bentonite (dust)

Regulatory basis / Regulatory list	Revision	Type of value	Values	Remarks
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Nepsi (European Network on Silica)	1/2006	Exposure limit(s) Total dust	10 mg/m3	
Nepsi (European Network on Silica)	1/2006	Exposure limit(s) Respirable fraction	3 mg/m3	<a href="http://www.nepsi.eu/agreement-good-practice-guide/occupational-exposure-limits.aspx">http://www.nepsi.eu/agreement-good-practice-guide/occupational-exposure-limits.aspx</a>

## DNEL/DMEL values

DNEL/DMEL values are not available.

## PNEC values

PNEC values are not available.

## 8.2. Exposure controls

### Appropriate engineering controls

Minimize airborne dust generation. Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below specified exposure limits. If user operations generate dust, fumes or mist, use ventilation to keep exposure to airborne particles below the exposure limit. Apply organizational measures e.g. by isolating personnel from dusty areas. Remove and wash soiled clothing

### Respiratory protection :

Local ventilation to keep levels below established threshold values is recommended. In case of prolonged exposure to airborne dust concentrations, a suitable particle filter mask that complies with the requirements of national legislation is recommended, depending on the expected exposure levels.

### Hand protection :

Use a high fat protective cream after cleaning skin.  
Wear suitable gloves.

### Eye protection :

Do not wear contact lenses.  
Safety glasses with side-shields  
Ensure that eyewash stations and safety showers are close to the workstation location.

### Body protection :

Long sleeved clothing

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : solid

Form : powder, granular

Colour : bright to earthy

Odour : none

pH value : > 2 - 8,6 (20 °C)

Method : Aqueous suspension

For detail information please refer to our physical & chemical data sheet.

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<b>Melting point/range :</b>	> 450 °C Method : EU A.1
<b>Boiling point/boiling range :</b>	not applicable (solid with a melting point > 450 °C)
<b>Flash point :</b>	not applicable (solid with a melting point > 450 °C)
<b>Evaporation rate :</b>	not applicable (solid with a melting point > 450 °C)
<b>Flammability :</b>	does not ignite Method : EU A.10
<b>Lower explosion limit :</b>	non explosive (void of any chemical structures commonly associated with explosive properties)
<b>Vapour pressure :</b>	not applicable (solid with a melting point > 450 °C)
<b>Vapour density relative to air :</b>	not applicable
<b>Solubility in water :</b>	< 0,9 g/l (20 °C) Method : Directive 84/449/EEC, A.6
<b>Octanol/water partition coefficient (log Pow) :</b>	not applicable inorganic
<b>Self-ignition temperature :</b>	Method : 92/69/EEC, A.6. no relative self-ignition temperature below 400 °C
<b>Thermal decomposition :</b>	No decomposition if used as directed.
<b>Viscosity (dynamic) :</b>	not applicable (solid with a melting point > 450 °C)
<b>Oxidizing properties :</b>	no oxidizing properties (Based on the chemical structure, the substance does not contain a surplus of oxygen or any structural groups known to be correlated with a tendency to react exothermally with combustible material)

**9.2. Other information**

<b>Density :</b>	2,6 g/cm <sup>3</sup>
<b>Bulk density :</b>	140 - 900 kg/m <sup>3</sup> For detail information please refer to our physical & chemical data sheet.

**SECTION 10: Stability and reactivity**

**10.1. Reactivity**

Stable under recommended storage conditions.

**10.2. Chemical stability**

The product is chemically stable.

**10.3. Possibility of hazardous reactions**

None known.

**10.4. Conditions to avoid**

Forms slippery/greasy layers with water.

#### 10.5. Incompatible materials

inert, not reactive

Avoid storing together with materials that may be affected by dust.

#### 10.6. Hazardous decomposition products

Not relevant

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

##### Information related to the product itself:

<b>Acute oral toxicity :</b>	LD50 > 2 g/kg (rat) Method : OECD Test Guideline 401 Not acutely toxic by the oral route.
<b>Acute dermal toxicity :</b>	LD50 > 2 g/kg (rat) Method : OECD Test Guideline 402 Not acutely toxic by the dermal route.
<b>Acute inhalation toxicity :</b>	LC50 50 mg/l (rat) Method : OECD Test Guideline 403 Not acutely toxic by the inhalation route.
<b>Irritant effect on skin :</b>	non-irritant (rabbit) Method : OECD Test Guideline 404
<b>Irritant effect on eyes :</b>	non-irritant (rabbit) Method : OECD Test Guideline 405
<b>Sensitization :</b>	non-sensitizing (mouse) Method : OECD Test Guideline 429
<b>Genetic toxicity in vitro :</b>	Test type : In vitro gene mutation study in bacteria Result : negative Method : OECD Test Guideline 471 Test type : Chromosome aberration test in vitro Result : negative Method : OECD Test Guideline 473 Test type : In vitro gene mutation study in mammalian cells Result : negative Method : OECD Test Guideline 476
<b>Carcinogenicity :</b>	Based on available data, the classification criteria are not met.
<b>Toxicity to reproduction/fertility :</b>	Based on available data, the classification criteria are not met.
<b>Specific target organ toxicity (STOT) - single exposure :</b>	Based on available data, the classification criteria are not met.

**Aspiration hazard :**

No aspiration toxicity classification

**Remarks**

**Specific symptoms in animal studies (likely route of exposure):**

In case of ingestion:

No acute or long term effects were seen in animal studies following oral exposure.

In case of skin contact:

No acute effects were seen in an animal study following acute dermal exposure.

Bentonite acid leached is not a skin irritant

In case of inhalation:

No acute effects were seen in an animal study following acute inhalation exposure.

Bentonite acid leached contains crystalline silica, which is a known cause of silicosis, a progressive, sometimes fatal lung disease. In a 1997 monograph (Volume 68, "Silica, Some Silicates, Coal Dust and Para-aramid Fibrils"), the International Agency for Research on cancer (IARC) has classified "inhaled crystalline silica from occupational sources" in Group 1 as a substance "carcinogenic to humans". In making the overall evaluation, the IARC Working Group noted that carcinogenicity in humans was not detected in all industrial circumstances studied. Crystalline silica has also been classified by the German MAK Commission as a human carcinogen (Category A1).

Although bentonite acid-leached contains quartz, an intratracheal study (Creutzenberg 2008) on the read across substance bentonite demonstrated significant differences in toxicity following administration of equivalent doses of quartz as either bentonite (15.2 mg of bentonite with 60% quartz) or reference quartz (10.5 mg of 87% quartz). The reference-quartz caused significant, self-perpetuating lung toxicity while bentonite demonstrated significantly less toxicity and partial recovery during the study period. The main effect of bentonite was slight fibrosis and inflammation of the lung. The study demonstrated that a simple bridging of toxicity data from quartz to bentonite acid-leached is not appropriate.

Occupational exposure to respirable dust should be monitored and controlled

## SECTION 12: Ecological information

### 12.1. Toxicity

**Information related to the product itself:**

**Fish toxicity :**

No data. Unlikely to be toxic to fish based on low solubility in water and results from algal and invertebrate studies.

**Daphnia toxicity :**

EC50 > 100 mg/l (48 h, Daphnia magna (Water flea))

Method : OECD Test Guideline 202

Due to the low solubility of substance study was performed on the eluate.

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<b>Algae toxicity :</b>	EC50 > 100 mg/l (72 h, Desmodesmus subspicatus (green algae)) Method : OECD Test Guideline 201 Due to the low solubility of substance study was performed on the eluate.
<b>Bacteria toxicity :</b>	EC50 > 1 g/l (3 h, activated sludge) Method : OECD Test Guideline 209 Harmless to STP microorganisms

#### 12.2. Persistence and degradability

##### Information related to the product itself:

<b>Biodegradability :</b>	The methods for determining biodegradability are not applicable to inorganic substances.
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#### 12.3. Bioaccumulative potential

##### Information related to the product itself:

<b>Bioaccumulation:</b>	Not relevant for inorganic substances
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#### 12.4. Mobility in soil

##### Information related to the product itself:

<b>Transport and distribution between environmental compartments :</b>	Bentonite, acid-leached is almost insoluble and thus presents a low mobility in most soils.
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#### 12.5. Results of PBT and vPvB assessment

##### Information related to the product itself:

The substance does not meet the criteria for PBT or vPvB substance.

#### 12.6. Other adverse effects

##### Information related to the product itself:

**Additional ecotoxicological remarks**  
none

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

##### Product

Can be disposed of as solid waste in a suitable installation subject to the Environmental Protection (Duty of Care) Regulations.  
Avoid dust formation.  
Where possible recycling is preferred to disposal or incineration.

##### Uncleaned packaging

No specific requirements.

## SECTION 14: Transport information

### Section 14.1. to 14.5.

ADR	not restricted
ADN	not restricted
RID	not restricted
IATA	not restricted
IMDG	not restricted

### 14.6. Special precautions for user

See sections 6 to 8 of this Safety Data Sheet.

### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code (International Bulk Chemicals Code)

No transport as bulk according IBC - Code.

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

**Water Hazard Class (Ger.) :** not water endangering

#### Other regulations

Bentonite is not a SEVESO substance, not an ozone depleting substance and not a persistent organic pollutant.

The product (bentonite) is not separately classified by the Occupational Health and Safety Administration (OSHA). The product has not been classified as a human carcinogen by OSHA, the International Agency for Research on Cancer (IARC) and the National Toxicology Program (NTP).

### 15.2. Chemical safety assessment

A hazard assessment has been conducted under the umbrella of the European Bentonite Association (EUBA) and the outcome was that bentonite is not a hazardous substances. Therefore, in absence of identified hazard, the substance is safe and presents no risk.

## SECTION 16: Other information

Social Dialogue on Respirable Crystalline Silica:

A multi-sectoral social dialogue agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products Containing it was signed on 25 April 2006. This autonomous agreement, which receives the European Commission's financial support, is based on a Good Practices Guide. The requirements of the Agreement came into force on 25 October 2006. The Agreement was published in the Official Journal of the European Union (2006/C 279/02). The text of the Agreement and its annexes, including the Good Practices Guide, are available from <http://www.nepsi.eu> and provide useful information and guidance for the handling of products containing respirable crystalline silica. Literature references are available on

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request from EUROSIL, the European Association of Industrial Silica Producers.

Prolonged and/or massive exposure to respirable crystalline silica-containing dust may cause silicosis, a nodular pulmonary fibrosis caused by deposition in the lungs of fine respirable particles of crystal

In 1997, IARC (the International Agency for Research on Cancer) concluded that crystalline silica inhaled from occupational sources can cause lung cancer in humans. However it pointed out that not all industrial circumstances, nor all crystalline silica types, were to be incriminated. (IARC Monographs on the evaluation of the carcinogenic risks of chemicals to humans, Silica, silicates dust and organic fibres, 1997, Vol. 68, IARC, Lyon, France.)

In June 2003, SCOEL (the EU Scientific Committee on Occupational Exposure Limits) concluded that the main effect in humans of the inhalation of respirable crystalline silica dust is silicosis.

"There is sufficient information to conclude that the relative risk of lung cancer is increased in persons with silicosis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore preventing the onset of silicosis will also reduce the cancer risk..." (SCOEL SUM Doc 94-final, June 2003.

So there is a body of evidence supporting the fact that increased cancer risk would be limited to people already suffering from silicosis. Worker protection against silicosis should be assured by respecting the existing regulatory occupational exposure limits and implementing additional risk management measures where required (see section 16 below).

**Training advice:**

Workers must be informed of the presence of crystalline silica and trained in the proper use and handling of this product as required under applicable regulations.

**Sources of the key data used to compile the Safety Data Sheet:**

Creutzenberg O, Hansen T, Ernst H & Muhle H (2008)  
Toxicity of a quartz with occluded surfaces in a 90 day intratracheal instillation study in rats; Inhalation toxicology. 20: 995-1008

This safety data sheet (SDS) is based on the legal provisions of the REACH Regulation (EC 1907/2006; article 31 and Annex II), as amended. Its contents are intended as a guide to the appropriate precautionary handling of the material. It is the responsibility of recipients of this SDS to ensure that the information contained therein is properly read and understood by all people who may use, handle, dispose or in any way come in contact with the product. Information and instructions provided in this SDS are based on the current state of scientific and technical knowledge at the date of issue indicated. It should not be construed as any guarantee of technical performance, suitability for particular applications, and does not establish a legally valid contractual relationship. This version of the SDS supersedes all previous versions.

**Legend**

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
AOX	Adsorbable organic bound halogens
CAS	Chemical Abstracts Service
DMEL	Derived Minimal Effect Level (genotoxic substances)
DNEL	Derived No Effect Level
EC50	Half maximal effective concentration
GHS	Globally Harmonized System
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Lethal Concentration 50%
LD50	Lethal Dose 50%

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MARPOL	International Convention for the Prevention of Pollution From Ships
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOEC	Non Observed Effect Concentration
OEL	Occupational Exposure Limit
PBT	Persistent, Bioaccumulative, Toxic
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	International Rule for Transport of Dangerous Substances by Railway
SVHC	Substances of Very High Concern
vPvB	very Persistent and very Bioaccumulative

Decimal notation: "thousands" places are identified with a dot (for example, "2.000 mg/kg" means "two thousand mg/kg"). Decimal places are identified with a comma (for example, "1,35 g/cm<sup>3</sup>" means "one point three five g/cm<sup>3</sup>").

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