

Safety Data Sheet

According to Regulation (EU) 2015/830

IMPORTANT

Read this SDS before handling and disposing of this product and pass this information on to employees, customers and users of this product.

1. IDENTIFICATION

1.1 Product Identifier

Product Name	Impress-E Putty Hard
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1.2 Relevant identified uses of the substance of mixture and uses advised against

Product Use	(SU22) professional uses: Public domain (administration, education, entertainment, services, craftsmen); (SU20) Health services;
Restricted Use	None known
Description	Dental Product

1.3 Supplier of the Safety Data Sheet

Company Name	Perfection Plus Ltd
Company Address	6 Westwood Court, Brunel Road, Totton, Hants. SO40 3WX. UK
Company Phone No.	+44 (0) 2380 866 677
Website	www.perfectionplus.com
Telephone	0044 (0) 2380 866677
Email	Regulatory@perfectionplus.com
Email address of Competent Person	Regulatory@perfectionplus.com

1.4 Emergency telephone number

Emergency telephone number	0044 (0) 230 866 677 (8am – 5pm Monday to Friday)
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2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

	<p>The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) and subsequent amendments and adjustments.</p> <p>Mixture classification has been determined by the physical state in which it is commercialized and in which it can be reasonably consider will be used.</p> <p>Hazard classification and indication:</p>
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2.2 Label Elements

Hazard Pictograms	
Signal Word	
Hazard Statement	
Precautionary Statement: Prevention	

2.3 Other hazards

Other hazards	<p>The hazardous characteristics of the raw materials listed below are in any case lost the moment those substances are mixed with other fluid components, generating the final product, which, in its pasty form, does not generate dust given it is contained within a matrix constituted by silicone oils. Similarly, for the use of the hardened material it is not possible to foresee any processing that will allow the dusting of the components in the environment; same considerations for the disposal of the hardened product. It is therefore reasonable to expect, in normal conditions of use, the impossibility for the operator to inhale any type of dust during the entire life cycle of the product. It is, however, recommended to adopt all the precautions in order that the product not deteriorate and in order to avoid the improbable possibility of dust formation hazardous for the human health.</p>
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Further information

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%. For further information see section 7 of the sheet.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	CONC. (%)	Classification
Quartz (Free crystalline silica, respirable fraction)	-	14808-60-7	238-878-4		5.0 ≤x< 15.0	Carc. 1A: H350i; STOT RE 1: H372
Cristobalite		14464-46-1	238-455-4		30.0<x<50.0	Carc.1A: H350i; STOT RE 1: H372

The product contains crystalline silica (respirable fraction) in concentration more than 10%; crystalline silica is classified as Carc. 1A for inhalation and STOT RE1.

The full wording of hazard (H) phrases is given in section 16 of the sheet.

4. FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.
Eye Contact	Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
Skin contact	Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.
Ingestion	Get medical advice/attention immediately. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorized by a doctor.

4.2 Most important symptoms and effects, both acute and delayed

Effects on the health of the quartz and cristobalite (respirable fraction) dust are not applicable to this product, since it is in a solid state so not subject to dusting in normal use conditions. However, it is important to underline that the cristobalite respirable fraction may cause cancer by inhalation on the basis of epidemiological studies. The risk of cancer depends on the exposure time and level. For further information, see chap. 11. Prolonged and/or massive inhalation of respirable cristobalite dust may cause lung fibrosis, commonly referred to as silicosis. Principal symptoms of silicosis are cough and breathlessness.

4.3 Indication of any immediate medical attention and special treatment needed

Inhalation	Information not available
Eye Contact	Information not available
Skin contact	Information not available
Ingestion	Information not available

General information

	In case of accident or illness get medical advice/attention immediately (if possible show instruction for use or safety data sheet).
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5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

	The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray
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5.2 Special hazards arising from the substance or mixture

	Do not breathe combustion products
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5.3 Advice for firefighters

	<p>Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.</p> <p>Wear normal firefighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).</p>
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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

	<p>Do not start any action which can implies any personal risks or without an appropriate training. Block the leakage if there is no hazard. Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.</p>
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6.2 Environmental precautions

	<p>This product must not penetrate into the sewer system or come in to contact with surface water or ground water.</p>
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6.3 Methods and material for containment and cleaning up

	<p>Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.</p> <p>Make sure the leakage site is well aired. Check incompatibility for container material in section 7. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.</p>
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6.4 Reference to other sections

	<p>See section 13 for disposal information. See section 8 for exposure controls/personal protection.</p>
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7. HANDLING AND STORAGE

7.1 Precautions for safe handling

	<p>Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.</p>
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7.2 Conditions for safe storage, including any incompatibilities

	<p>Store only in the original container. Store the containers sealed, in a well-ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.</p>
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7.3 Specific end use(S)

	<p>No use other than specified in Section 1.2 of this SDS.</p>
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Regulatory references:

EU - OEL EU - Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 91/322/EEC.

TLV-ACGIH - ACGIH 2018

8.1.1 Exposure Limit Values

QUARTZ						
Threshold Limit Value						
Type	Country	TWA/8h mg/m3	Ppm	STEL/15min mg/m3	Ppm	
OEL	EU	0.1				INHAL
TLV-ACGIH		0.025				RESP
CRISTOLBALITE						
Threshold Limit Value						
Type	Country	TWA/8h mg/m3	Ppm	STEL/15min mg/m3	Ppm	
TLV-ACGIH		0.025				RESP

Even if it is not mandatory to declare the substance below in section 3.2 of this Safety data Sheet (because par. 3.2.1 of Annex of Reg. (EU) 830/2015 requirements are not subsistent), this is however cited in this section in compliance with the provisions of par. 8.1.1. of Annex of Reg. (EU) 830/2015.

FORMALDEHYDE						
Threshold Limit Value						
Type	Country	TWA/8h mg/m3	Ppm	STEL/15min mg/m3	Ppm	
TLV-ACGIH			0.1		0.3	

Monitoring procedures recommended

This product contains substances with limit of exposure, so could be requested a personal monitoring, a work environmental atmosphere monitoring and a biological monitoring in order to determine the efficiency of the ventilation or of other control measures and/or the needed to use respiratory protective device.

The recommended European Standard are:

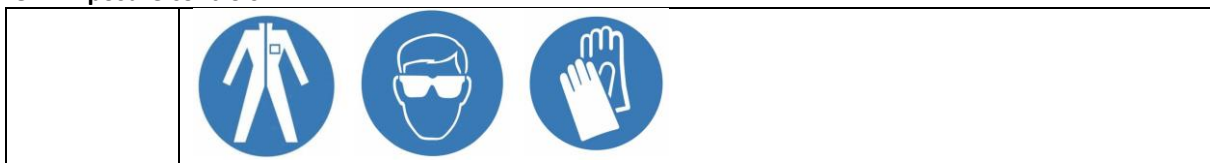
- ≈ UNI EN 689:2018 "Workplace exposure - Measurement of exposure by inhalation to chemical agents - Strategy for testing compliance with occupational exposure limit values";
- ≈ UNI EN 482:1998 "Workplace atmospheres. General requirements for the performance of procedures for the measurement of chemical agents".

Legend:

(C) = CEILING; INHAL = Inhalable Fraction; RESP = Respirable Fraction; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available; NEA = no exposure expected; NPI = no hazard identified.

8.2 Exposure controls



8.2.1 Appropriate engineering controls

	<p>As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.</p> <p>As indicated in section 2.3 of this Safety Data Sheet, it is not possible to foresee any processing that will allow the dusting of the components in the environment both in pasty form and in the hardened material, during the entire life cycle of the product. However, in the improbable possibility of dust formation during not predictable process, the product must be mixed in a close cycle, in a strongly aerate room and in presence of strong localized aspiration. It should be maintained the lowest possible exposure limit in order to avoid accumulation in the body. Manage the individual protection devices in such a way to assure the max protection.</p>
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8.2.2 Individual protection measures

Skin protection	Wear category I professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.
Eye/face protection	Wear airtight protective goggles (see standard EN 166).

Hand protection	Protect hands with category III work gloves (see standard EN 374). The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability. The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.
Respiratory protection	If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required. Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited. If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

8.2.3 Environmental Exposure controls

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	High viscosity paste	Lower explosive limit.	Not available.
Colour	Pink	Upper explosive limit.	Not available.
Odour	Spearmint	Vapour pressure	Not available.
Odour threshold	Not available.	Vapour density	Not available.
pH	Not available.	Relative density	1.7 Kg/l
Melting/freezing point	Not available.	Solubility	Insoluble in water
Initial boiling point	Not available.	Partition coefficient	Not available.
Boiling range	Not available.	Autoignition temperature	Not available.
Flash point	360°C	Decomposition temp.	150°C
Evaporation rate	Not available.	Viscosity	Not available.
Flammability (solid, gas)	Not available.	Explosive properties	Not explosive.
Lower flammability limit.	Not available.	Oxidising properties	Not oxidant.
Upper flammability limit.	Not available.		

9.2. Other information

Conductivity	No data available
Surface tension	No data available
Gas group	No data available
Benzene content	No data available
Lead content	No data available
VOC (Volatile organic compounds)	No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

	There are no particular risks of reaction with other substances in normal conditions of use.
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10.2 Chemical stability

	Stable under normal conditions of use and storage
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10.3 Possibility of hazardous reactions

	No hazardous reactions are foreseeable in normal conditions of use and storage
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10.4 Conditions to avoid

	Avoid accumulation of dust in the environment.
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10.5 Incompatible materials

	Strong oxidising agent. Acids and bases.
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10.6 Hazardous decomposition products

	Cristobalite reacts with hydrofluoric acid forming silicon tetrafluoride. Reaction with acids produces heat, other than the formation of hydrogen gas.
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11. TOXICOLOGICAL INFORMATION
11.1 Information on toxicological effects

In the absence of experimental toxicological data on the product, the health potential hazards have been evaluated on the basis of the properties of the raw materials, following the criteria laid down the reference standard for the classification.

For this reason, in order to evaluate the toxicological effects deriving from the exposure to the product, have to be considered the concentration of the single hazard substances listed in section 3.

ACUTE TOXICITY	
LC50 (Inhalation) of the mixture:	Not classified (no relevant component)
LD50 (Oral) of the mixture:	Not classified (no relevant component)
LD50 (Dermal) of the mixture:	Not classified (no relevant component)

Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	<p>Based on available data, the classification criteria are not met.</p> <p>Crystalline silica, quartz Crystalline silica (CS) is considered to be at risk for inhalation. IARC has classified CS as carcinogenic to humans (Group 1). CS is present in the NTP list of carcinogenic known for the human (National Toxicology Program Department of Health and Human Services-USA). The inhalation of CS may cause silicosis, a nodular pulmonary fibrosis. The respirable fraction of crystalline silica is classified by ACGIH as A2 probably carcinogenic to humans. Data on humans, even if proper in quality, are disputable or not enough to classify the agent as carcinogenic to humans; OR, the agent is resulted carcinogenic in the experimental animals. The A2 classification is applied, primarily, when there is both a reduced evidence of carcinogenic to humans and enough evidence of carcinogenic in the experimental animals with relevance on human. (From: <i>Giornale Italiano di Igiene Industriale e Ambientale – ACGIH 2014</i>).</p> <p>Cristobalite IARC has classified this substance as carcinogenic to humans by inhalation. Cristobalite, as respirable fraction, is classified by ACGIH as A2 probably carcinogenic to humans. Data on humans, even if proper in quality, are disputable or not enough to classified the agent as carcinogenic to humans; OR, the agent is resulted carcinogenic in the experimental animals. The A2 classification is applied, primarily, when there is both a reduced evidence of carcinogenic to humans and enough evidence of carcinogenic in the experimental animals with relevance on human. (From: <i>Giornale Italiano di Igiene Industriale e Ambientale – ACGIH 2014</i>).</p>

Reproductive Toxicity	Based on available data, the classification criteria are not met.
STOT-Single Exposure	Based on available data, the classification criteria are not met.
STOT-Repeated Exposure	<p>Based on available data, the classification criteria are not met.</p> <p>Crystalline silica, quartz Causes lung damage in case of prolonged or repeated exposure by inhalation. Prolonged inhalation of crystalline silica may cause silicosis, a nodular pulmonary fibrosis. Crystalline silica is classified by IARC as Group 1 "Carcinogenic to humans" and have "enough evidence" of carcinogenesis for NTP. Chronic risks for the health are associated to the respirable particles (3-4 um) on prolonged period of exposure. Today, exists only a limited comprehension of the quartz's toxicity mechanisms, included those for the carcinogenesis to lungs. Further studies are needed to determine if the cell transformation activity of the quartz is related to its carcinogenic potential. (IMA-Europe, Position Paper Classification of RCS (Gennaio 2014))</p> <p>Cristoballite (IMA-Europe, Position Paper Classification of RCS (Gennaio 2014)) Causes lung damage in case of prolonged or repeated exposure by inhalation. Prolonged inhalation may cause silicosis, a nodular pulmonary fibrosis.</p>
Crystalline silica, quartz and Cristobalite - Target Organs	Lungs
Crystalline silica, quartz and Cristobalite - Exposure Routes	Inhalation
Aspiration hazard	Based on available data, the classification criteria are not met.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

	Information not available.
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12.2 Persistence and degradability

	Information not available.
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12.3 Bio accumulative potential

	Information not available.
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12.4 Mobility in soil

	Information not available.
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12.5 Results of PBT and vPvB assessment

	On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.
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12.6 Other adverse effects

	Information not available.
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13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

	Dispose of in compliance with all local and national regulations.
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General information

	Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.
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Disposal Methods

	Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
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Disposal of packaging

	Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.
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14. TRANSPORT INFORMATION
14.1 UN number

	Not applicable.
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14.2 UN proper shipping name

	Not applicable.
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14.3 Transport hazard class(es)

ADR/RID	Not applicable.
Subsidiary risk IMDG	Not applicable.
Subsidiary risk IATA	Not applicable.
Subsidiary risk	

14.4 Packing group

Packing Group	Not applicable.
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14.5 Environmental hazards

Environmental hazards Marine pollutant	Not applicable.
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14.6 Special precautions for user

	Not applicable.
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14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code.

	Information not relevant.
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15. REGULATORY INFORMATION
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Seveso category	None.
Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.	None.
Contained substances	Point 72 FORMALDEHYDE
Substances in Candidate List (Art. 59 REACH).	None.
Substances subject to authorisation (Annex XIV REACH).	None.
Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:	None.
Substances subject to the Rotterdam Convention:	None.
Substances subject to the Stockholm Convention:	None.
Healthcare controls.	Information not available.
German regulation on the classification of substances hazardous to water (VwVwS 2005).	WGK 1: Low hazard to waters

15.2 Chemical Safety Assessment

	No chemical safety assessment has been processed for the mixture and the substances it contains.
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16. OTHER INFORMATION
Other information

Text of Hazard Statements in Section 2 and 3	Carc. 1A - Carcinogenicity, cat 1A STS RE 1 – Specific target organ toxicity – repeated exposure, category 1. H372 – causes damage to organs through prolonged or repeated exposure.
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Legend	<p>H350i – May cause cancer if inhaled.</p> <ul style="list-style-type: none"> - ADR: European Agreement concerning the carriage of Dangerous goods by Road - CAS NUMBER: Chemical Abstract Service Number - CE50: Effective concentration (required to induce a 50% effect) - CE NUMBER: Identifier in ESIS (European archive of existing substances) - CLP: EC Regulation 1272/2008 - DNEL: Derived No Effect Level - EmS: Emergency Schedule - GHS: Globally Harmonized System of classification and labeling of chemicals - IATA DGR: International Air Transport Association Dangerous Goods Regulation - IC50: Immobilization Concentration 50% - IMDG: International Maritime Code for dangerous goods - IMO: International Maritime Organization - INDEX NUMBER: Identifier in Annex VI of CLP - LC50: Lethal Concentration 50% - LD50: Lethal dose 50% - OEL: Occupational Exposure Level - PBT: Persistent bioaccumulative and toxic as REACH Regulation - PEC: Predicted environmental Concentration - PEL: Predicted exposure level - PNEC: Predicted no effect concentration - REACH: EC Regulation 1907/2006 - RID: Regulation concerning the international transport of dangerous goods by train - TLV: Threshold Limit Value - TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure. - TWA STEL: Short-term exposure limit - TWA: Time-weighted average exposure limit - VOC: Volatile organic Compounds - vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation - WGK: Water hazard classes (German).
GENERAL BIBLIOGRAPHY	<ol style="list-style-type: none"> 1. Regulation (EU) 1907/2006 (REACH) of the European Parliament 2. Regulation (EU) 1272/2008 (CLP) of the European Parliament 3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament 4. Regulation (EU) 2015/830 of the European Parliament 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament 10. Regulation (EU) 1221/2015 (VII Atp. CLP) of the European Parliament 11. Regulation (EU) 918/2016 (VIII Atp. CLP) of the European Parliament 12. Regulation (EU) 1179/2016 (IX Atp. CLP) of the European Parliament 13. Regulation (EU) 776/2017 (X Atp. CLP) of the European Parliament <ul style="list-style-type: none"> - The Merck Index. - 10th Edition - Handling Chemical Safety - INRS - Fiche Toxicologique (toxicological sheet) - Patty - Industrial Hygiene and Toxicology - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition - ECHA website - IFA GESTIS website

Further information

The information used in this SDS is believed to be correct however, the information is provided without any warranty, neither expressed nor implied, regarding its correctness.

This SDS is relevant for large quantities of product, the instructions for safe use of quantities typically used during a normal procedure is as referenced in the Instructions for Use.

The conditions or methods for handling, storage, lone use and/or in combination with other products and disposal are beyond our control.

For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.

This SDS was prepared and is to be used only for this product. If the product is used as a component in or in combination with another product, this SDS information may not be applicable.