

# Safety Data Sheet

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

### 1.1. Product identifier

Code: C207002  
Product name: HYDRORISE EXTRA LIGHT NORMAL SET - BASE

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

Intended use: For professional use only. Addition silicone for dental impression.

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

Name: Zhermack S.p.a  
Full address: Via Bovazecchino 100  
District and Country: 45021 Badia Polesine (RO)  
Italy  
Tel. +39 0425-597611  
Fax +39 0425-597689

e-mail address of the competent person responsible for the Safety Data Sheet: msds@zhermack.com

### 1.4. Emergency telephone number

For urgent inquiries refer to: 0039 0425597611

## SECTION 2. Hazards identification

### 2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2015/830. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Hazardous to the aquatic environment, chronic toxicity, category 3 H412 Harmful to aquatic life with long lasting effects.

### 2.2. Label elements

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 1.5, letter d). Therefore the product is exempted from the CLP labeling requirements.

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

**C207002 - HYDRORISE EXTRA LIGHT NORMAL SET - BASE**

Signal words: --

Hazard statements:

**H412** Harmful to aquatic life with long lasting effects.

Precautionary statements:

**P273** Avoid release to the environment.**2.3. Other hazards**

There is no exposure to breathable free crystalline silica during normal use of this product. For more information see section 11.

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

**SECTION 3. Composition/information on ingredients****3.2. Mixtures**

Contains:

Identification	x = Conc. %	Classification 1272/2008 (CLP)
<b>QUARTZ</b>		
CAS 14808-60-7	$30 \leq x < 45$	STOT RE 1 H372
EC 238-878-4		
INDEX -		
<b>POLYALKYLENEOXIDE MODIFIED HEPTAMETHYLTRISILOXANE</b>		
CAS 27306-78-1	$3 \leq x < 5$	Acute Tox. 4 H332, Eye Irrit. 2 H319, Aquatic Chronic 2 H411
EC		
INDEX -		

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

**SECTION 4. First aid measures****4.1. Description of first aid measures**

EYES: 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: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Information not available

## **SECTION 5. Firefighting measures**

### **5.1. Extinguishing media**

#### SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

#### UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

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

#### HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products.

### **5.3. Advice for firefighters**

#### GENERAL INFORMATION

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.

#### SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting 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).

## **SECTION 6. Accidental release measures**

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

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.

### **6.2. Environmental precautions**

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

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

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.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

### **6.4. Reference to other sections**

Any information on personal protection and disposal is given in sections 8 and 13.

## **SECTION 7. Handling and storage**

### **7.1. Precautions for safe handling**

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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.

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

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.

**7.3. Specific end use(s)**

Information not available

**SECTION 8. Exposure controls/personal protection****8.1. Control parameters**

Regulatory References:

CZE	Česká Republika	Nařízení vlády č. 361/2007 Sb. kterým se stanoví podmínky ochrany zdraví při práci
DEU	Deutschland	TRGS 900 (Fassung 31.1.2018 ber.) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2017
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
GBR	United Kingdom	EH40/2005 Workplace exposure limits
NLD	Nederland	Databank of the social and Economic Council of Netherlands (SER) Values, AF 2011:18
NOR	Norge	Veiledning om Administrative normer for forurensning i arbeidsatmosfære
SWE	Sverige	Occupational Exposure Limit Values, AF 2011:18
	TLV-ACGIH	ACGIH 2018

**QUARTZ****Threshold Limit Value**

Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
TLV	CZE	0,1			
MAK	DEU	0,15			
VLA	ESP	0,1			
VLEP	FRA	0,1			RESP
WEL	GBR	0,3			
OEL	NLD	0,075			RESP
TLV	NOR	0,1			RESP
MAK	SWE	0,1			RESP
TLV-ACGIH		0,025			RESP

Legend:

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

**8.2. Exposure controls**

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.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).

#### 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.

#### SKIN PROTECTION

Wear category III 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 PROTECTION

Wear airtight protective goggles (see standard EN 166).

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

#### 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 B 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.

#### ENVIRONMENTAL EXPOSURE CONTROLS

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

Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

## SECTION 9. Physical and chemical properties

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

Appearance	fluid
Colour	yellow
Odour	mint
Odour threshold	Not applicable
pH	Not applicable
Melting point / freezing point	Not available
Initial boiling point	Not available
Boiling range	Not available
Flash point	Not available
Evaporation Rate	Not available
Flammability of solids and gases	not applicable
Lower inflammability limit	Not available

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Upper inflammability limit	Not available
Lower explosive limit	Not available
Upper explosive limit	Not available
Vapour pressure	Not available
Vapour density	Not available
Relative density	Not available
Solubility	insoluble in water
Partition coefficient: n-octanol/water	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
Explosive properties	Not available
Oxidising properties	Not available

**9.2. Other information**

Information not available

**SECTION 10. Stability and reactivity****10.1. Reactivity**

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

**10.2. Chemical stability**

The product is stable in normal conditions of use and storage.

**10.3. Possibility of hazardous reactions**

No hazardous reactions are foreseeable in normal conditions of use and storage.

**10.4. Conditions to avoid**

None in particular. However the usual precautions used for chemical products should be respected.

**10.5. Incompatible materials**

Information not available

**10.6. Hazardous decomposition products**

Information not available

**SECTION 11. Toxicological information****11.1. Information on toxicological effects**

Metabolism, toxicokinetics, mechanism of action and other information

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Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

LC50 (Inhalation) of the mixture:

> 20 mg/l

LD50 (Oral) of the mixture:

Not classified (no significant component)

LD50 (Dermal) of the mixture:

Not classified (no significant component)

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

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Does not meet the classification criteria for this hazard class

**ASPIRATION HAZARD**

Does not meet the classification criteria for this hazard class

**POLYALKYLENEOXIDE MODIFIED HEPTAMETHYLTRISILOXANE**

LD50 (Oral).> 2000 mg/l (rat, MSDS supplier).

LD50 (Dermal).> 2000 mg/l (rat, MSDS supplier)

LC50 (Inhalation).2 mg/l (rat, 4h, MSDS supplier)

Irritation/Corrosion

Skin irritation: Not irritating (Rat, MSDS supplier).

Eye irritation: Strongly irritating (Rabbit, MSDS supplier).

Sensitization: negative (Guinea Pig, MSDS supplier).

STOT- Repeated/ Single exposure: No data available.

Genotoxicity in vitro: Negative (test di ames, MSDS supplier).

Genotoxicity in vivo: Negative (mouse, MSDS supplier).

Carcinogenicity: No data available.

Toxicity to reproduction: No data available.

Aspiration toxicity: No data available.

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Acute Toxicity: No data available.

Irritation/Corrosion

Skin irritation: Not irritating (MSDS supplier).

Eye irritation: Slightly irritating (MSDS supplier).

Sensitization: Not sensitizing (MSDS supplier).

Mutagenicity: Does not meet the classification criteria for this hazard class (MSDS supplier).

Carcinogenicity: IARC (group 1), NTP (RAHC), ACGIH (A2) (MSDS supplier).

Toxicity to reproduction: Does not meet the classification criteria for this hazard class (MSDS supplier).

Toxicity for aspiration: Not applicable.

STOT Repeated Exposure: Adverse effects on lungs (fibrosis-silicosis)(MSDS supplier).

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).

There is a body of evidence supporting the fact that increased cancer risk would not be limited to people already suffering from silicosis. According to the current state of the art, worker protection against silicosis can be consistently assured by respecting the existing regulatory occupational exposure limits. Occupational exposure to nuisance dust (total and respirable) and respirable crystalline silica should be monitored and controlled.

"For the purposes of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified (annex I, section 1.1.1.5, EC Regulation 1272/2008)".

Monitoring activities conducted at the company related to possible inhalation exposure, in accordance with industrial hygiene standards for paste and fluid products, showed levels of exposure to free crystalline silica (breathable part) below the limit of quantification of the method, therefore exposure is not expected during the use indicated in section 1.2 for this specific product.

However, the actual levels of free crystalline silica (breathable part) present in the workplace must be obtained through monitoring as required by regulations for the safety and health of workers.

**SECTION 12. Ecological information**

This product is dangerous for the environment and the aquatic organisms. In the long term, it have negative effects on aquatic environment.

**12.1. Toxicity**

POLYALKYLENEOXIDE MODIFIED  
HEPTAMETHYLTRISILOXANE

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LC50 - for Fish	6,8 mg/l/96h (Brachydanio rerio, MSDS supplier)
EC50 - for Crustacea	25 mg/l/48h (Daphnia similis, MSDS supplier).
EC50 - for Algae / Aquatic Plants	32 mg/l/72h (Pseudokirchneriella subcapitata, MSDS supplier)

**12.2. Persistence and degradability**

POLYALKYLENEOXIDE MODIFIED  
HEPTAMETHYLTRISILOXANE  
NOT rapidly degradable

QUARTZ

NOT rapidly degradable

**12.3. Bioaccumulative potential**

Information not available

**12.4. Mobility in soil**

Information not available

**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%.

**12.6. Other adverse effects**

Information not available

**SECTION 13. Disposal considerations****13.1. Waste treatment methods**

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.

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

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

**SECTION 14. Transport information**

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

**14.1. UN number**

Not applicable

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**14.2. UN proper shipping name**

Not applicable

**14.3. Transport hazard class(es)**

Not applicable

**14.4. Packing group**

Not applicable

**14.5. Environmental hazards**

Not applicable

**14.6. Special precautions for user**

Not applicable

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

Information not relevant

**SECTION 15. Regulatory information**

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

Seveso Category - Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

Product

Point 3

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

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

**15.2. Chemical safety assessment**

No chemical safety assessment has been processed for the mixture and the substances it contains.

**SECTION 16. Other information**

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

<b>Acute Tox. 4</b>	Acute toxicity, category 4
<b>STOT RE 1</b>	Specific target organ toxicity - repeated exposure, category 1
<b>Eye Irrit. 2</b>	Eye irritation, category 2
<b>Aquatic Chronic 2</b>	Hazardous to the aquatic environment, chronic toxicity, category 2
<b>Aquatic Chronic 3</b>	Hazardous to the aquatic environment, chronic toxicity, category 3
<b>H332</b>	Harmful if inhaled.
<b>H372</b>	Causes damage to organs through prolonged or repeated exposure.
<b>H319</b>	Causes serious eye irritation.
<b>H411</b>	Toxic to aquatic life with long lasting effects.
<b>H412</b>	Harmful to aquatic life with long lasting effects.

## LEGEND:

- 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

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- 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**

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
  2. Regulation (EC) 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) 2015/1221 (VII Atp. CLP) of the European Parliament
  11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
  12. Regulation (EU) 2016/1179 (IX Atp. CLP)
  13. Regulation (EU) 2017/776 (X Atp. CLP)
- 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
  - IFA GESTIS website
  - ECHA website
  - Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

**Note for users:**

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC.

This safety data sheet has been created on a voluntary basis.

**Changes to previous review:**

The following sections were modified:

01 / 02 / 03 / 04 / 05 / 08 / 09 / 11 / 12 / 14 / 16.