

Safety Data Sheet

HYDRORISE LIGHT NORMAL SET - BASE

Revision nr. 5
Dated 06/05/2020

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

1.1. Product identifier

Mixture identification:

Product Name: HYDRORISE LIGHT NORMAL SET - BASE

Code: C207000, C207084, C207080

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

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

Via Bovazecchino 100

45021 Badia Polesine (RO)

Italy

tel. +39 0425-597611

fax +39 0425-597689

Competent person responsible for the safety data sheet:

msds@zhermack.com

1.4. Emergency telephone number

UK Emergency number: 999 (24 hours)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

Aquatic Chronic 3, Harmful to aquatic life with long lasting effects.

Adverse physicochemical, human health and environmental effects:

No other hazards

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 pictograms:

None

Hazard statements:

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P273 Avoid release to the environment.

Special Provisions:

None

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

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.

PBT Substances:

>= 0.1% - < 0.25% octamethylcyclotetrasiloxane - Index number: 014-018-00-1, CAS: 556-67-2, EC: 209-136-7

vPvB Substances:

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>= 0.1% - < 0.25% octamethylcyclotetrasiloxane - Index number: 014-018-00-1, CAS: 556-67-2, EC: 209-136-7

Other Hazards:
No other hazards







SECTION 3: Composition/information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Hazardous components within the meaning of the CLP regulation and related classification:

Qty	Name	Ident. Number	Classification
>= 15% - < 20%	Cristobalite	CAS: 14464-46-1 EC: 238-455-4	 3.9/1 STOT RE 1 H372
>= 3% - < 5%	Polyalkyleneoxide modified heptamethyltrisiloxane	CAS: 27306-78-1	 4.1/C2 Aquatic Chronic 2 H411  3.1/4/Inhal Acute Tox. 4 H332  3.3/2 Eye Irrit. 2 H319
>= 0.1% - < 0.25%	octamethylcyclotetrasiloxane	Index number: 014-018-00-1 CAS: 556-67-2 EC: 209-136-7	 3.7/2 Repr. 2 H361f 4.1/C4 Aquatic Chronic 4 H413  2.6/3 Flam. Liq. 3 H226

SVHC Substances:

>= 0.1% - < 0.25% octamethylcyclotetrasiloxane
Index number: 014-018-00-1, CAS: 556-67-2, EC: 209-136-7
Substance PBT and vPvB and SVHC

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

In case of Ingestion:

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

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

None

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

Treatment:

None

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO₂).

Extinguishing media which must not be used for safety reasons:

None in particular.

5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.

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Burning produces heavy smoke.

5.3. Advice for firefighters

Use suitable breathing apparatus .

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non emergency personnel:

Wear personal protection equipment.

Remove persons to safety.

See protective measures under point 7 and 8.

For emergency responders:

Wear personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

6.3. Methods and material for containment and cleaning up

Wash with plenty of water.

6.4. Reference to other sections

See also section 8 and 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.

Don't use empty container before they have been cleaned.

Before making transfer operations, assure that there aren't any incompatible material residuals in the containers.

See also section 8 for recommended protective equipment.

Advice on general occupational hygiene:

Contaminated clothing should be changed before entering eating areas.

Do not eat or drink while working.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from food, drink and feed.

Incompatible materials:

See section 10.5.

Instructions as regards storage premises:

Adequately ventilated premises.

7.3. Specific end use(s)

See section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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Cristobalite - CAS: 14464-46-1

OEL Type	TWA		Duratio n	STEL		Duratio n	Notes	Country
VEL	0.15 mg/m3		8h				Respirable (aerosol)	SWITZERLA ND
AK	0.15		8h				Respirable	HUNGARY

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	mg/m ³						(aerosol)	
OELV	0.1 mg/m ³		8h				Respirable	IRELAND
NGV/KGV	0.05 mg/m ³		8h				Respirable	SWEDEN
VLEP	0.05 mg/m ³		8h				Respirable (aerosol)	FRANCE
VLEP	0.05 mg/m ³		8h					BELGIUM
TLV	0.15 mg/m ³		8h	0.3 mg/m ³		15min		DENMARK
VLA	0.05 mg/m ³		8h				Respirable	SPAIN
TLV-ACGIH	0.025 mg/m ³		8h					
TLV	0.075 mg/m ³		8h				Respirable	NETHERLANDS
NIOSH	0.05 mg/m ³							UNITED STATES
ACGIH	0.025 mg/m ³		8h				(R), A2 - Pulm fibrosis, lung cancer	

Polyalkyleneoxide modified heptamethyltrisiloxane - CAS: 27306-78-1

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
No data available								

octamethylcyclotetrasiloxane - CAS: 556-67-2

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
No data available								

DNEL Exposure Limit Values

Not available

PNEC Exposure Limit Values

Not available

8.2. Exposure controls

Precautionary measures:

Give adequate ventilation to the premises where the product is stored and/or handled.

Eye protection:

Wear airtight protective goggles.

Protection for skin:

Wear professional overalls and safety footwear.

Protection for hands:

Protect hands with work gloves.

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:

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Use respiratory protection where ventilation is insufficient or exposure is prolonged. 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 (e.g. TLV-TWA).

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Method:	Notes
Appearance and colour:	Fluid,Fuchsia	--	--
Odour:	mint	--	--
Odour threshold:	Not available	--	--
pH:	Not Relevant	--	--
Melting point / freezing point:	Not available	--	--
Initial boiling point and boiling range:	Not available	--	--
Flash point:	> 135°C ° C	--	--
Evaporation rate:	Not available	--	--
Solid/gas flammability:	Not Relevant	--	--
Upper/lower flammability or explosive limits:	Not available	--	--
Vapour pressure:	Not available	--	--
Vapour density:	Not available	--	--
Relative density:	Not available	--	--
Solubility in water:	Insoluble	--	--
Solubility in oil:	Not available	--	--
Partition coefficient (n-octanol/water):	Not available	--	--
Auto-ignition temperature:	Not available	--	--
Decomposition temperature:	Not available	--	--
Viscosity:	Not available	--	--
Explosive properties:	Not available	--	--
Oxidizing properties:	Not available	--	--

9.2. Other information

Properties	Value	Method:	Notes
Miscibility:	Not available	--	--
Fat Solubility:	Not available	--	--
Conductivity:	Not available	--	--
Substance Groups relevant properties	Not available	--	--

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions

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10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

None

10.4. Conditions to avoid

Stable under normal conditions.

10.5. Incompatible materials

None in particular.

10.6. Hazardous decomposition products

None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

"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.

Toxicological information of the product:

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a) acute toxicity

Not classified

b) skin corrosion/irritation

Not classified

c) serious eye damage/irritation

Not classified

d) respiratory or skin sensitisation

Not classified

e) germ cell mutagenicity

Not classified

f) carcinogenicity

Not classified

g) reproductive toxicity

Not classified

h) STOT-single exposure

Not classified

i) STOT-repeated exposure

Not classified

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- j) aspiration hazard
Not classified

Toxicological information of the main substances found in the product:

Cristobalite - CAS: 14464-46-1

- i) STOT-repeated exposure:

Route: Inhalation - Notes: Target organ: lungs - Positive - Source: (MSDS supplier).

Polyalkyleneoxide modified heptamethyltrisiloxane - CAS: 27306-78-1

- a) acute toxicity:

Test: LC50 - Route: Inhalation - Species: Rat 2 mg/l - Duration: 4h - Source: (MSDS supplier)

Test: LD50 - Route: Skin - Species: Rat > 2000 mg/l - Source: (MSDS supplier)

Test: LD50 - Route: Oral - Species: Rat > 2000 mg/l - Source: (MSDS supplier).

- b) skin corrosion/irritation:

Species: Rat - Based on available data, the classification criteria are not met - Source: (MSDS supplier).

- c) serious eye damage/irritation:

Species: Rabbit - Eye Irritant - Source: (MSDS supplier).

- d) respiratory or skin sensitisation:

Test: Skin Sensitization - Species: Guinea pig - Based on available data, the classification criteria are not met - Source: (MSDS supplier).

- e) germ cell mutagenicity:

Test: In vitro - Negative - Source: (Test di ames, MSDS supplier).

Test: In vivo - Species: Mouse - Negative - Source: (MSDS supplier).

- f) carcinogenicity:

No data available for the product

- g) reproductive toxicity:

No data available for the product

- h) STOT-single exposure:

No data available for the product

- i) STOT-repeated exposure:

No data available for the product

- j) aspiration hazard:

No data available for the product

octamethylcyclotetrasiloxane - CAS: 556-67-2

- a) acute toxicity:

Test: LC50 - Species: Rat 36 mg/l - Source: (OECD 403, GLP, rat, 4 h, ECHA dossier).

Test: LD50 - Route: Skin - Species: Rat > 2000 mg/kg - Source: (similar to OECD 402, rat, ECHA dossier).

Test: LD50 - Route: Oral - Species: Rat 4800 mg/kg - Source: (similar to OECD 401, rat, ECHA dossier).

SECTION 12: Ecological information

12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment.

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The product is classified: Aquatic Chronic 3 - H412

Polyalkyleneoxide modified heptamethyltrisiloxane - CAS: 27306-78-1

- a) Aquatic acute toxicity:

Endpoint: LC50 - Species: Fish 6.8 mg/l - Duration h: 96h (Brachydanio rerio, MSDS supplier)

Endpoint: IC50 - Species: Algae 32 mg/l - Duration h: 72h (Pseudokirchneriella subcapitata, MSDS supplier)

Endpoint: EC50 - Species: Daphnia 25 mg/l - Duration h: 48h (Daphnia similis, MSDS supplier).

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Endpoint: NOEC - Species: Fish 3.2 mg/l (Oncorhynchus mykiss, 96h, MSDS supplier).

Endpoint: NOEC - Species: Daphnia 5.6 mg/l (Daphnia magna, 48h, MSDS supplier).

octamethylcyclotetrasiloxane - CAS: 556-67-2

a) Aquatic acute toxicity:

Endpoint: IC50 - Species: Algae > 0.0022 mg/l - Duration h: 72h (EPA OTS 797.1050, Selenastrum capricornutum, freshwater, ECHA dossier).

Endpoint: LC50 - Species: Fish > 0.0022 mg/l (Oncorhynchus mykiss, GLP, ECHA dossier).

Endpoint: NOEC - Species: Fish > 0.0044 mg/l (publication, Oncorhynchus mykiss, GLP, ECHA dossier).

12.2. Persistence and degradability

Cristobalite - CAS: 14464-46-1

Biodegradability: Non-readily biodegradable

Polyalkyleneoxide modified heptamethyltrisiloxane - CAS: 27306-78-1

Biodegradability: Non-readily biodegradable

12.3. Bioaccumulative potential

Cristobalite - CAS: 14464-46-1

Not bioaccumulative

octamethylcyclotetrasiloxane - CAS: 556-67-2

Test: Kow - Partition coefficient 6.49 - Notes: (Log Pow, ECHA dossier).

12.4. Mobility in soil

Not available

12.5. Results of PBT and vPvB assessment

PBT Substances:

>= 0.1% - < 0.25% octamethylcyclotetrasiloxane - CAS: 556-67-2

vPvB Substances:

>= 0.1% - < 0.25% octamethylcyclotetrasiloxane - CAS: 556-67-2

12.6. Other adverse effects

None

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recover if possible. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

14.1. UN number

Not classified as dangerous in the meaning of transport regulations.

14.2. UN proper shipping name

Not available

14.3. Transport hazard class(es)

Not available

14.4. Packing group

Not available

14.5. Environmental hazards

ADR-Environmental Pollutant: No

IMDG-Marine pollutant: No

14.6. Special precautions for user

Not available

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

Not available

SECTION 15: Regulatory information

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

Dir. 98/24/EC (Risks related to chemical agents at work)
Dir. 2000/39/EC (Occupational exposure limit values)
Regulation (EC) n. 1907/2006 (REACH)
Regulation (EC) n. 1272/2008 (CLP)
Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013
Regulation (EU) 2015/830
Regulation (EU) n. 286/2011 (ATP 2 CLP)
Regulation (EU) n. 618/2012 (ATP 3 CLP)
Regulation (EU) n. 487/2013 (ATP 4 CLP)
Regulation (EU) n. 944/2013 (ATP 5 CLP)
Regulation (EU) n. 605/2014 (ATP 6 CLP)
Regulation (EU) n. 2015/1221 (ATP 7 CLP)
Regulation (EU) n. 2016/918 (ATP 8 CLP)
Regulation (EU) n. 2016/1179 (ATP 9 CLP)
Regulation (EU) n. 2017/776 (ATP 10 CLP)
Regulation (EU) n. 2018/669 (ATP 11 CLP)
Regulation (EU) n. 2018/1480 (ATP 13 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:

No restriction.

Restrictions related to the substances contained:

No restriction.

SVHC Substances:

Substances in candidate list (Art. 59 Reg. 1907/2006, REACH):

octamethylcyclotetrasiloxane

PBT, vPvB

Provisions related to directive EU 2012/18 (Seveso III):

Seveso III category according to Annex 1, part 1

None

WGK Classification (Water hazard class - Verwaltungsvorschrift wassergefährdende Stoffe)

WGK1 - Slightly hazardous for water

Lagerklasse according to TRGS 510:

LGK10: Combustible liquids

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None.

California Proposition 65

Substance(s) listed under California Proposition 65:

Cristobalite - Listed as carcinogen.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for the mixture.

Substances for which a Chemical Safety Assessment has been carried out:

None

SECTION 16: Other information

Full text of phrases referred to in Section 3:

H361f Suspected of damaging fertility.

H413 May cause long lasting harmful effects to aquatic life.

H226 Flammable liquid and vapour.

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H372 Causes damage to organs (lungs) through prolonged or repeated exposure if inhaled.
 H411 Toxic to aquatic life with long lasting effects.
 H332 Harmful if inhaled.
 H319 Causes serious eye irritation.

Hazard class and hazard category	Code	Description
Flam. Liq. 3	2.6/3	Flammable liquid, Category 3
Acute Tox. 4	3.1/4/Inhal	Acute toxicity (inhalation), Category 4
Eye Irrit. 2	3.3/2	Eye irritation, Category 2
Repr. 2	3.7/2	Reproductive toxicity, Category 2
STOT RE 1	3.9/1	Specific target organ toxicity - repeated exposure, Category 1
Aquatic Chronic 2	4.1/C2	Chronic (long term) aquatic hazard, category 2
Aquatic Chronic 3	4.1/C3	Chronic (long term) aquatic hazard, category 3
Aquatic Chronic 4	4.1/C4	Chronic (long term) aquatic hazard, category 4

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Classification according to Regulation (EC) Nr. 1272/2008	Classification procedure
Aquatic Chronic 3, H412	Calculation method

This document was prepared by a competent person who has received appropriate training.
 Main bibliographic sources:

ECHA – European Chemical Agency
 GESTIS - Information system on hazardous substances of the German Social Accident Insurance
 IARC – International Agency for Research on Cancer
 IPCS INCHEM – International Programme on Chemical Safety
 ISS – Istituto Superiore di Sanità
 PubChem - open chemistry database at the National Institutes of Health (NIH)

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.

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.
 It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
 ATE: Acute Toxicity Estimate
 ATEmix: Acute toxicity Estimate (Mixtures)
 CAS: Chemical Abstracts Service (division of the American Chemical Society).
 CLP: Classification, Labeling, Packaging.
 DNEL: Derived No Effect Level.
 EINECS: European Inventory of Existing Commercial Chemical Substances.
 GefStoffVO: Ordinance on Hazardous Substances, Germany.
 GHS: Globally Harmonized System of Classification and Labeling of Chemicals.

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IATA:	International Air Transport Association.
IATA-DGR:	Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
ICAO:	International Civil Aviation Organization.
ICAO-TI:	Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG:	International Maritime Code for Dangerous Goods.
INCI:	International Nomenclature of Cosmetic Ingredients.
KSt:	Explosion coefficient.
LC50:	Lethal concentration, for 50 percent of test population.
LD50:	Lethal dose, for 50 percent of test population.
PNEC:	Predicted No Effect Concentration.
RID:	Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL:	Short Term Exposure limit.
STOT:	Specific Target Organ Toxicity.
TLV:	Threshold Limiting Value.
TWA:	Time-weighted average
WGK:	German Water Hazard Class.