



LASCOD SPA

KROMOPAN SIL REGULAR BODY

Revision nr. 0

Dated 11/02/2020

Printed on 10/11/2020

Page nr. 1/14

Safety data sheet

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

1.1. Product identifier

Product name

**KROMOPAN SIL REGULAR BODY
normal set**

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

Intended use

Addition curing silicone for dental impression. Professional use only. Different uses other than that mentioned above.

Uses advised against

1.3. Details of the supplier of the safety data sheet

Name

LASCOD SPA

Full address

Via Luigi Longo, 18

District and Country

50019 Sesto Fiorentino (FI)

ITALY

tel. +39 055/4215768

fax +39 055/4210421

e-mail address of the competent person responsible for the Safety Data Sheet

ricerca@lascod.it

1.4. Emergency telephone number

For urgent inquiries refer to

CAV Italia: Centro Antiveleni di Milano: 02 66101029; Centro Antiveleni di Firenze: 055

7947819; Centro Antiveleni di Roma: 06 3054343; Centro Antiveleni di Roma: 06

49978000; Centro Antiveleni di Napoli: 081 7472870

Austria Poison Control Centre Emergency helpline: +43 1 406 43 43

Belgium Centre Antipoisons: 070 245 245

Bulgaria National Toxicology Center, Hospital for Active Medical Treatment and Emergency Medicine "N.I.Pirogov": +359 2 9154 409

Czech Republic Toxikologické informační středisko: Telefon: +420 224 919 293, +420 224 915 402

Hungary National Emergency Phone Number: +36 80 20 11 99

Lithuania National Emergency Telephone Number (Neatidėliotina informacija apsinuodijus): +370 5 236 20 52 or +370 687 53378

Portugal Centro di informazioni Antiveleni: 808 250 143

Romania Biroul pentru Regulamentul Sanitar International si Informare Toxicologica

Tel. 021.318.36.06 (direct)

Poland KRAJOWE CENTRUM INFORMACJI TOKSYKOLOGICZNEJ tel.: 42 631 47 24 , 42 631 47 25

España:Servicio de Información Toxicológica (SIT) + 34 91 562 04 20 (24h/365 días)

France:Numéro ORFILA (INRS-France): + 33 (0)1 45 42 59 59 (24h/ 7 jours sur 7)

UK Emergency number: 844 892 0111 (24 hours)

Deutschland, Berlin Tel.: 030/19240 (Notruf), Fax: 030/30 686 799

USA Emergency Phone Number (24 hours) CHEMTREC (800-424-9300)



LASCOD SPA : tel. + 39 055/4215768 (8:00-18:00, technical support)

SECTION 2. Hazards identification.

2.1. Classification of the substance or mixture.

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) and subsequent amendments and adjustments.

Mixture classification has been determined by the physical state in which it is commercialized and in which it can be reasonably considered will be used.

Hazard classification and indication:

2.2. Label elements.

Hazard pictograms: --
Signal words: --
Hazard statements: --
Precautionary statements: --

The product does not request hazard labeling in accordance with (CE) 1272/2008 (CLP) and subsequent amendments and adjustments.

2.3. Other hazards.

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.

For further information see section 7 of the sheet.

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.

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Conc. %.	Classification 1272/2008 (CLP).
CRISTOBALITE		
CAS 14464-46-1	30.0 ≤ x < 50.0	Carc. 1A H350i, STOT RE 1 H372



CE 238-455-4

INDEX -

Nr. Reg. -

The product contains cristobalite (respirable fraction) in concentration more than 10%; cristobalite (respirable fraction) 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.

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 authorized by a doctor.

PROTECTIVE EQUIPMENT FOR FIRST RESPONDERS: for the needed DPIs for the first responders see section 8.2 of this sheet.

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

Effects on the health of 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.

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

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.

Do not start any action which can imply 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.

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. Check incompatibility for container material in section 7. 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.

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.

Storage class TRGS 510 (Germany):

10

7.3. Specific end use(s).

No different use from that indicate in section 1.2 of this sheet.

SECTION 8. Exposure controls/personal protection.

8.1. Control parameters.

Regulatory References:

EU	OEL EU	Direttiva (UE) 2017/2398; Direttiva (UE) 2017/164; Direttiva 2009/161/UE; Direttiva 2006/15/CE; Direttiva 2004/37/CE; Direttiva 2000/39/CE; Direttiva 91/322/CEE.
	TLV-ACGIH	ACGIH 2018

CRISTOBALITE

Threshold Limit Value.

Type	Country	TWA/8h	STEL/15min		
		mg/m3	ppm	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		STEL/15min	
		mg/m ³	ppm	mg/m ³	ppm
TLV-ACGIH			0,1		0,3

CRYSTALLINE SILICA, QUARTZ

Threshold Limit Value.					
Type	Country	TWA/8h		STEL/15min	
		mg/m ³	ppm	mg/m ³	ppm
OEL	EU	0,1			INHAL
TLV-ACGIH		0,025			RESP

It is recommended to consider in the risk evaluation process the limit values of professional exposure expected by ACGIH for inert dusts not otherwise classified (PNOC respirable fraction: 3 mg/mc; PNOC inhalable fraction: 10 mg/mc). In case of these limits are exceeded, it is recommended the use of type P filter, whose class (1,2 or 3) will be chosen on the basis of the results of the risk evaluation process.

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.

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.

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 aerated 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.

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 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 PROTECTION

Wear airtight protective goggles (see standard EN 166).

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.

ENVIRONMENTAL EXPOSURE CONTROLS.

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

SECTION 9. Physical and chemical properties.**9.1. Information on basic physical and chemical properties.**

Appearance	Fluid paste
Colour	Pink
Odour	None
Odour threshold.	Not available.
pH.	Not available.
Melting point / freezing point.	Not available.
Initial boiling point.	Not available.
Boiling range.	Not available.
Flash point.	360 °C.
Evaporation Rate	Not available.
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
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.	1.17 Kg/l
Solubility	insoluble in water
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.



Decomposition temperature.	150 °C
Viscosity	Not available.
Explosive properties	Not explosive.
Oxidising properties	Not oxidant.

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.

Avoid the accumulation of dust in the environment.

10.5. Incompatible materials.

Strong oxidizing agent. Acids and bases.

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.

SECTION 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.

11.1. Information on toxicological effects

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

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

CRISTOBALITE

Quartz and cristobalite (the mainly minerals present in the respirable fraction of FCS, free crystalline silica) are considered risks substances by inhalation. IARC has classified FCS as carcinogenic to humans (Group 1). FCS is present in the NTP list of carcinogenic known for the human (National Toxicology Program Department of Health and Human Services-USA).

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 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: *Giornale Italiano di Igiene Industriale e Ambientale* – ACGIH 2014).

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

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

CRISTOBALITE

(*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.

Target organs:

CRISTOBALITE

lungs.

Exposure route

CRISTOBALITE

inhalation.

ASPIRATION HAZARD

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

SECTION 12. Ecological information.

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity.

Information not available.

12.2. Persistence and degradability.

Information not available.

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. Neat product residues should be considered special non-hazardous waste.

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 to be considered not hazardous pursuant to the existing provisions set for the transport of dangerous goods by road (A.D.R.), by rail (RID), by water on vessel (IMDG Code), and by air (IATA).

14.1. UN number.

Not applicable.

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 MARPOL73/78 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. 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.

SECTION 16. Other information.

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

Carc. 1A	Carcinogenicity, cat. 1A
STOT RE 1	Specific target organ toxicity - repeated exposure, category 1
H372	Causes damage to organs through prolonged or repeated exposure.
H350i	May cause cancer if inhaled.

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
- 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 (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
- 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

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.