

The product is not classified as dangerous according to Regulation (EC) No 1272/2008 (CLP), is not persistent, bioaccumulative, toxic (PBT) or very persistent and very bioaccumulative (vPvB) as defined in Annex XIII of Regulation (EC) no. 1907/2006 (REACH), is not included in the candidate list of highly disturbing substances (SVHC). Therefore the provision of a Safety Data Sheet is not mandatory (REACH Art. 31). This Information is a voluntary submission of some information that may assist the downstream user in handling the substance.

INFORMATIVE SHEET

PrincipHYAL[®] LINE

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

1.1. Product identifier

Trade name: PrincipHYAL[®] LINE

CAS number: 9067-32-7

EC number: --- (Polymer)

REACH: PrincipHYAL[®] Line, according to Article 2(9), polymers are exempted from the provisions on regulation of Title II of REACH.

Sodium Hyaluronate meets the criteria set for a polymer defined in Article 3(5). Its monomers can be considered as non-isolated intermediates, for which REACH regulation is not applicable according to Article 2(1). Based on the available data, the criteria for exemption from REACH registration are fulfilled for Sodium Hyaluronate (CAS: 9067-32-7).

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

1.3. Details of the supplier of the safety data sheet

Company:

Roelmi HPC S.r.l. - Via Celeste Milani, 24/26 - 21040 Origgio (VA) - ITALY

Tel: (+39) 02-33510150

Fax (+39) 02-33549210

Competent person responsible for the safety data sheet:

info.msds@roelmihpc.com

1.4. Emergency telephone number

Roelmi HPC Tel: (+39) 02-33510150 (mon-fri 8.30-17.30)

Outside office hours please refer to :

CAV "Osp. Pediatrico Bambino Gesù" Dip. Emergenza e Accettazione DEA	Roma	(+39) 06 68593726
Az. Osp. Univ. Foggia	Foggia	(+39) 800183459
Az. Osp. "A. Cardarelli"	Napoli	(+39) 081-7472870
CAV Policlinico "Umberto I"	Roma	(+39) 06-49978000
CAV Policlinico "A. Gemelli"	Roma	(+39) 06-3054343
Az. Osp. "Careggi" U.O. Tossicologia Medica	Firenze	(+39) 055-7947819
CAV Centro Nazionale di Informazione Tossicologica	Pavia	(+39) 0382-24444

INFORMATIVE SHEET

PrincipHYAL[®] LINE

Osp. Niguarda Ca' Granda
Azienda Ospedaliera Papa Giovanni XXII

Milano (+39) 02-66101029
Bergamo (+39) 80088330

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP):

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

Hazard pictograms:

None

Hazard statements:

None

Precautionary statements:

None

Special Provisions:

None

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

None

2.3. Other hazards

vPvB Substances: None - PBT Substances: None

Other Hazards:

No other hazards

SECTION 3: Composition/information on ingredients

3.1. Substances

Identification of the substance

Chemical characterization: Sodium hyaluronate

CAS number: 9067-32-7

EC number: --- (Polymer)

3.2. Mixtures

N.A.

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:

INFORMATIVE SHEET

PrincipHYAL[®] LINE

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.

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

Wear personal protection equipment.

Remove persons to safety.

See protective measures under point 7 and 8.

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

INFORMATIVE SHEET

PrincipHYAL[®] LINE

7.1. Precautions for safe handling

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

Do not eat or drink while working.

See also section 8 for recommended protective equipment.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in the original container well closed in fresh and dry place, repaired from humidity, light or heat sources.

Keep away from food, drink and feed.

Incompatible materials:

None in particular.

Instructions as regards storage premises:

Adequately ventilated premises.

7.3. Specific end use(s)

None in particular

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

NA

8.2. Exposure controls

Eye protection:

Not needed for normal use. Anyway, operate according good working practices.

Protection for skin:

No special precaution must be adopted for normal use.

Protection for hands:

Not needed for normal use.

Respiratory protection:

Not needed for normal use.

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
Appearance and colour:	White powder
Odour:	Characteristic
Odour threshold:	N.A.
pH:	6,0 – 8,0
Melting point / freezing	N.A.

INFORMATIVE SHEET

PrincipHYAL[®] LINE

point:	
Initial boiling point and boiling range:	N.A.
Flash point:	N.A.
Evaporation rate:	N.A.
Solid/gas flammability:	N.A.
Upper/lower flammability or explosive limits:	N.A.
Vapour pressure:	N.A.
Vapour density:	N.A.
Relative density:	N.A.
Solubility in water:	Slowly but fully dissolves in water to give viscous, clear to slightly opalescent and colourless solutions.
Solubility in oil:	Not soluble
Partition coefficient (n-octanol/water):	N.A.
Auto-ignition temperature:	N.A.
Decomposition temperature:	N.A.
Viscosity:	N.A.
Explosive properties:	N.A.
Oxidizing properties:	N.A.

9.2. Other information

Properties	Value
Miscibility:	N.A.
Fat Solubility:	N.A.
Conductivity:	N.A.
Substance Groups relevant properties	N.A.

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

None.

10.4. Conditions to avoid

INFORMATIVE SHEET

PrincipHYAL[®] LINE

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

Toxicological information of the substance:

a) acute toxicity

Not classified

Based on available data, the classification criteria are not met

b) skin corrosion/irritation

Not classified

Based on available data, the classification criteria are not met

c) serious eye damage/irritation

Not classified

Based on available data, the classification criteria are not met

d) respiratory or skin sensitisation

Not classified

Based on available data, the classification criteria are not met

e) germ cell mutagenicity

Not classified

Based on available data, the classification criteria are not met

f) carcinogenicity

Not classified

Based on available data, the classification criteria are not met

g) reproductive toxicity

Not classified

Based on available data, the classification criteria are not met

h) STOT-single exposure

Not classified

Based on available data, the classification criteria are not met

i) STOT-repeated exposure

Not classified

Based on available data, the classification criteria are not met

j) aspiration hazard

Not classified

Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

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

INFORMATIVE SHEET

PrincipHYAL[®] LINE

Not classified for environmental hazards

Based on available data, the classification criteria are not met

12.2. Persistence and degradability

N.A.

12.3. Bioaccumulative potential

N.A.

12.4. Mobility in soil

N.A.

12.5. Results of PBT and vPvB assessment

vPvB Substances: None - PBT Substances: None

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

14.2. UN proper shipping name

ADR-Shipping Name: NA

IATA-Shipping Name: NA

IMDG-Shipping Name: NA

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

Marine pollutant: No

14.6. Special precautions for user

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

No

SECTION 15: Regulatory information

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)

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:

INFORMATIVE SHEET

PrincipHYAL[®] LINE

No restriction.

Restrictions related to the substances contained:

No restriction.

Where applicable, refer to the following regulatory provisions :

Directive 2012/18/EU (Seveso III)

Regulation (EC) nr 648/2004 (detergents).

Dir. 2004/42/EC (VOC directive)

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

N.A.

15.2. Chemical safety assessment

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

SECTION 16: Other information

This document was prepared by a competent person who has received appropriate training.

Main bibliographic sources:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre,
Commission of the European Communities

SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van
Nostrand Reinold

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.
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.
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).

INFORMATIVE SHEET

PrincipHYAL[®] LINE

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.