Safety Data Sheet
HYDROCOLOR 5

Revision nr. 5
Dated 13/04/2023

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

1.1. Product identifier

Mixture identification:

Product Name: HYDROCOLOR 5

Code: C302120, C302130

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

For professional use only. Alginate 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)

STOT RE 2, H373 May cause damage to organs through prolonged or repeated exposure.

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:



Warning

Hazard statements:

H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements:

P260 Do not breathe dust.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P314 Get medical advice/attention if you feel unwell.

Special Provisions:

EUH208 Contains 2,5-Dimethyl-4-hydroxy-3-furanone. May produce an allergic reaction.

Contains

Cristobalite

Special provisions according to Annex XVII of REACH and subsequent amendments:
None

2.3. Other hazards
No PBT, vPvB or endocrine disruptor substances present in concentration >= 0.1%
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
>= 5% - < 8%	Cristobalite	CAS: 14464-46-1 EC: 238-455-4	STOT RE 1 H372 Causes damage to organs (lungs) through prolonged or repeated exposure if inhaled.
>= 3% - < 5%	Dipotassium exafluorotitanate	CAS: 16919-27-0 EC: 240-969-9 REACH No.: 01-2119978268-20-XXXX	Acute Tox. 4 H302 Harmful if swallowed. Eye Dam. 1 H318 Causes serious eye damage. Acute Toxicity Estimate: ATE - Oral 324 mg/kg bw
>= 0,1% - < 0,3%	phenolphthalein	Index number: 604-076-00-1 CAS: 77-09-8 EC: 201-004-7 REACH No.: 01-2119498295-24-XXXX	Muta. 2 H341 Suspected of causing genetic defects. Carc. 1B H350 May cause cancer. Repr. 2 H361f Suspected of damaging fertility. Specific Concentration Limits: C >= 1%: Muta. 2 H341 C >= 1%: Carc. 1B H350
<0,1%	2,5-Dimethyl-4-hydroxy-3-furanone	CAS: 3658-77-3 EC: 222-908-8 REACH No.: 01-2120754473-52-XXXX	Skin Sens. 1A H317 May cause an allergic skin reaction. Acute Tox. 4 H302 Harmful if swallowed. Skin Corr. 1B H314 Causes severe skin burns and eye damage. Specific Concentration Limits: C >= 0,1%: Skin Sens. 1A H317 Acute Toxicity Estimate: ATE - Oral 500 mg/kg bw

SVHC, PBT, vPvB, endocrine disruptor substances:
>= 0,1% - < 0,3% phenolphthalein
REACH No.: 01-2119498295-24-XXXX, Index number: 604-076-00-1, CAS: 77-09-8, EC: 201-004-7
SVHC
Substances in nanoform:
>= 3% - < 5% Dipotassium exafluorotitanate
REACH No.: 01-2119978268-20-XXXX, CAS: 16919-27-0, EC: 240-969-9

>= 0,5% - < 2,5% Silicic acid, calcium salt
REACH No.: 01-2119427745-34-XXXX, CAS: 1344-95-2, EC: 215-710-8

>= 0,5% - < 2,5% Magnesium hydroxide
REACH No.: 01-2119488756-18-XXXX, CAS: 1309-42-8, EC: 215-170-3

>= 0,5% - < 2,5% Trisodium orthophosphate
REACH No.: 01-2119489800-32-XXXX, CAS: 7601-54-9, EC: 231-509-8

<0,1% 29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32 copper - Nanoform
CAS: 147-14-8, EC: 205-685-1

<0,1% Silicon dioxide, amorphous
REACH No.: 01-2119379499-16-XXXX, CAS: 7631-86-9, EC: 231-545-4

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:
Areas of the body that have - or are only even suspected of having - come into contact with the product must be rinsed immediately with plenty of running water and possibly with soap.
Wash with plenty of water and soap.
Wash thoroughly the body (shower or bath).
Remove contaminated clothing immediatley and dispose off safely.

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

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).
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

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:
Contamined 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		Duration	STEL		Duration	Notes	Country
EU	0.1 mg/m3		8h				Respirable	
TLV	0.1 mg/m3		8h				Respirable	ITALY
ACGIH	0.025		8h				(R), A2 -	

	mg/m3						Pulm fibrosis, lung cancer	

Dipotassium exafluorotitanate - CAS: 16919-27-0

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
No data available								

phenolphthalein - CAS: 77-09-8

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
No data available								

2,5-Dimethyl-4-hydroxy-3-furanone - CAS: 3658-77-3

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
No data available								

DNEL Exposure Limit Values

Dipotassium exafluorotitanate - CAS: 16919-27-0

Worker Professional: 5.2 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, local effects
Worker Professional: 5.2 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, systemic effects
Worker Professional: 5.2 mg/m3 - Exposure: Human Inhalation - Frequency: Short Term, systemic effects
Worker Professional: 75 mg/kg bw/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects
Worker Professional: 75 mg/kg bw/d - Exposure: Human Dermal - Frequency: Short Term, systemic effects
Consumer: 37.5 mg/kg bw/d - Exposure: Human Dermal - Frequency: Short Term, systemic effects
Consumer: 37.5 mg/kg bw/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects

PNEC Exposure Limit Values

Dipotassium exafluorotitanate - CAS: 16919-27-0

Target: Fresh Water - Value: 0.131 mg/l
Target: Marine water - Value: 0.131 mg/l
Target: Freshwater sediments - Value: 24.45 03
Target: Marine water sediments - Value: 4.89 03
Target: Microorganisms in sewage treatments - Value: 1.5 mg/l
Target: Soil (agricultural) - Value: 19.1 mg/kg
Target: intermittent release - Value: 0.108 mg/l

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 (EN 166).

Protection for skin:

Wear professional overalls and safety footwear (EN 14605).

Protection for hands:
Protect hands with work gloves (EN 374).
The following should be considered when choosing work glove material (EN 374): 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:
Mask with filter "P2 or P3".
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
Physical state:	Dust	--	--
Colour:	Light blue	--	--
Odour:		--	--
Melting point/freezing point:	Not available	--	--
Boiling point or initial boiling point and boiling range:	Not available	--	--
Flammability:	Not available	--	--
Lower and upper explosion limit:	Not available	--	--
Flash point:	Not available	--	--
Auto-ignition temperature:	Not available	--	--
Decomposition temperature:	Not available	--	--
pH:	Not available	--	--
Kinematic viscosity:	Not available	--	--
Solubility in water:	Partially soluble	--	--
Solubility in oil:	Not available	--	--
Partition coefficient n-octanol/water (log value):	Not available	--	--
Vapour pressure:	Not available	--	--
Density and/or relative density:	0.2 - 0.5 g/cm3	--	--
Relative vapour density:	Not available	--	--
Particle characteristics:			
Particle size:	Not available	--	--

9.2. Other information
No other relevant information

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

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 hazard classes as defined in Regulation (EC) No 1272/2008

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

Test: In vitro - Notes: Bridging principle, OECD 437 resp. EU Method B.47, GLP, study report 2019. - Based on available data, the classification criteria are not met

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

The product is classified: STOT RE 2 H373

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: Silicosis, pulmonary fibrosis; Target organ: lungs - Source: (MSDS supplier).

Dipotassium exafluorotitanate - CAS: 16919-27-0

a) acute toxicity

ATE - Oral 324 mg/kg bw

Test: LD50 - Route: Oral - Species: Rat 324 mg/kg - Source: (OECD 401, ECHA dossier).

b) skin corrosion/irritation:

Species: Rabbit - Based on available data, the classification criteria are not met - Source: (OECD 404, MSDS supplier).

c) serious eye damage/irritation:

Species: Rabbit - Eye Corrosive - Source: (OECD 405, MSDS supplier).

d) respiratory or skin sensitisation:

Test: Skin Sensitization - Species: Guinea pig - Based on available data, the classification criteria are not met - Source: (OECD 406, MSDS supplier).

e) germ cell mutagenicity:

Test: In vitro - Species: Salmonella Typhimurium - Negative - Source: (OECD 471, MSDS supplier).

Test: In vitro - Positive - Source: (OECD 487, MSDS supplier).

Test: In vitro - Negative - Source: (OECD 476, MSDS supplier).

Test: In vivo - Species: Rat - Negative - Source: (OECD 474, MSDS supplier).

phenolphthalein - CAS: 77-09-8

a) acute toxicity:

Test: LD50 - Route: Oral - Species: Rat > 1000 mg/kg - Source: (MSDS supplier).

b) skin corrosion/irritation:

Based on available data, the classification criteria are not met - Source: (OECD 431, in vitro, ECHA dossier).

c) serious eye damage/irritation:

Based on available data, the classification criteria are not met - Source: (OECD 437, in vitro, ECHA dossier).

d) respiratory or skin sensitisation:

Test: Skin Sensitization - Species: Mouse - Based on available data, the classification criteria are not met - Source: (OECD 429, ECHA dossier).

e) germ cell mutagenicity:

Test: In vitro - Negative - Source: (OECD 471, ECHA dossier).

f) carcinogenicity:

Route: Oral - Species: Rat - Positive - Source: (NTP, ECHA dossier).

g) reproductive toxicity:

Route: Oral - Species: Mouse - Positive - Source: (ECHA dossier).

i) STOT-repeated exposure:

Route: Oral - Species: Rat - Negative - Source: (OECD 407, ECHA dossier).

2,5-Dimethyl-4-hydroxy-3-furanone - CAS: 3658-77-3

a) acute toxicity

ATE - Oral 500 mg/kg bw

Test: STA - Route: Oral 500 mg/kg bw - Source: Annex I, table 3.1.2 - CLP

11.2. Information on other hazards

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration >= 0.1%

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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Not classified for environmental hazards

Based on available data, the classification criteria are not met

Dipotassium exafluorotitanate - CAS: 16919-27-0

a) Aquatic acute toxicity:

Endpoint: LC50 - Species: Fish 172 mg/l - Duration h: 96h (OECD 203, Danio rerio, ECHA dossier).

Endpoint: EC50 - Species: Daphnia 48.2 mg/l - Duration h: 48h (OECD 203, Daphnia magna, ECHA dossier).
Endpoint: IC50 - Species: Algae 10.81 mg/l - Duration h: 72h (OECD 201, Pseudokirchneriella subcapitata, ECHA dossier).
Endpoint: NOEC - Species: Algae 1.31 mg/l (OECD 201, Pseudokirchneriella subcapitata, ECHA dossier).

phenolphthalein - CAS: 77-09-8

a) Aquatic acute toxicity:

Endpoint: IC50 - Species: Algae 8.9 mg/l - Duration h: 72h (OECD 201, Desmodesmus subspicatus, ECHA dossier).

12.2. Persistence and degradability

Cristobalite - CAS: 14464-46-1

Biodegradability: Non-readily biodegradable

Dipotassium exafluorotitanate - CAS: 16919-27-0

Biodegradability: Non-readily biodegradable

phenolphthalein - CAS: 77-09-8

Biodegradability: Readily biodegradable

12.3. Bioaccumulative potential

Cristobalite - CAS: 14464-46-1

Not bioaccumulative

12.4. Mobility in soil

Not available

12.5. Results of PBT and vPvB assessment

vPvB Substances: None - PBT Substances: None

12.6. Endocrine disrupting properties

No endocrine disruptor substances present in concentration >= 0.1%

12.7. Other adverse effects

None

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recover, if possible. Send to authorised disposal plants or for incineration under controlled conditions. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

14.1. UN number or ID 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-Enviromental Pollutant: No
IMDG-Marine pollutant: No

14.6. Special precautions for user

Not available

14.7. Maritime transport in bulk according to IMO instruments

Not Applicable

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)
Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013
Regulation (EU) n. 2020/878
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)
Regulation (EU) n. 2019/521 (ATP 12 CLP)
Regulation (EU) n. 2020/217 (ATP 14 CLP)
Regulation (EU) n. 2020/1182 (ATP 15 CLP)
Regulation (EU) n. 2021/643 (ATP 16 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:

Restriction 3
Restriction 40

Restrictions related to the substances contained:

Restriction 28
Restriction 75

SVHC Substances:

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

phenolphthalein

Carcinogenic

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)

Lagerklasse according to TRGS 510:

LGK 10: 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
phenolphthalein - 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:

Dipotassium exafluorotitanate

SECTION 16: Other information

Full text of phrases referred to in Section 3:

H341 Suspected of causing genetic defects.
H350 May cause cancer.
H361f Suspected of damaging fertility.
H317 May cause an allergic skin reaction.

Hazard class and hazard category	Code	Description
Acute Tox. 4	3.1/4/Oral	Acute toxicity (oral), Category 4
Skin Corr. 1B	3.2/1B	Skin corrosion, Category 1B
Eye Dam. 1	3.3/1	Serious eye damage, Category 1
Skin Sens. 1A	3.4.2/1A	Skin Sensitisation, Category 1A
Muta. 2	3.5/2	Germ cell mutagenicity, Category 2
Carc. 1B	3.6/1B	Carcinogenicity, Category 1B
Repr. 2	3.7/2	Reproductive toxicity, Category 2
STOT RE 1	3.9/1	Specific target organ toxicity - repeated exposure, Category 1
STOT RE 2	3.9/2	Specific target organ toxicity - repeated exposure, Category 2

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
STOT RE 2, H373	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.
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.