

Safety Data Sheet

According to Annex II to REACH - Regulation 2020/878 and to Annex II to UK REACH

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

1.1. Product identifier

Product name **POLYREN® 5102**
UFI : **VP01-30CY-V00J-5PA6**

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

Intended use **Cationic flocculant in emulsion**

Identified Uses	Industrial	Professional	Consumer
Flocculant additive	✓	✓	-
Uses Advised Against			
Any use not included among those recommended			

1.3. Details of the supplier of the safety data sheet

Name **N.C.R. BIOCHEMICAL S.p.A.**
Full address **Via dei Carpenteri, 8-Zona Industriale il Prato**
District and Country **40050 Castello d'Argile (BO) Italia**
Tel. **+39 051 6869611 Lun-Ven 8.30-13.00/14.00-16.30**
Fax **+39 051 6869617**
e-mail address of the competent person responsible for the Safety Data Sheet **regulatory@ncr-biochemical.com**

1.4. Emergency telephone number

For urgent inquiries refer to **Italy:**
CAV Ospedale Niguarda Ca' Granda - Milano 02 66101029
CAV Azienda Ospedaliera Papa Giovanni XXII - Bergamo 800 883300
CAV Centro Nazionale di Informazione Tossicologica - Pavia 0382 24444
CAV Az. Osp. Careggi - Firenze 055 7947819
CAV Policlinico Gemelli - Roma 06 3054343
CAV Policlinico Umberto I - Roma 06 49978000
CAV Osp. Pediatrico Bambino Gesù - Roma 06 68593726
CAV Az. Osp. Cardarelli - Napoli 081 7472870
CAV Az. Osp. Univ. Foggia - Foggia 800183459

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 2020/878.
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:
Eye irritation, category 2 **H319** Causes serious eye irritation.

2.2. Label elements

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

Hazard pictograms:



SECTION 2. Hazards identification ... / >>

Signal words: Warning

Hazard statements:

H319 Causes serious eye irritation.
EUH066 Repeated exposure may cause skin dryness or cracking.

Precautionary statements:

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P280 Wear protective gloves/ protective clothing / eye protection / face protection.
P337+P313 If eye irritation persists: Get medical advice / attention.
P264 Wash hands thoroughly after handling.

2.3. Other hazards

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

The product does not contain substances with endocrine disrupting properties in concentration \geq 0.1%.

SECTION 3. Composition/information on ingredients

Citric acid monohydrate

The substance may be present in the monohydrate form (CAS: 5949-29-1) or in the anhydrous form (CAS: 77-92-9), both with the same classification.

3.1. Substances

Information not relevant

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics		
CAS	25 \leq x < 50	Asp. Tox. 1 H304, EUH066
EC		
INDEX		
REACH Reg.	01-2119453414-43-XXXX	
Citric acid monohydrate		
CAS	5949-29-1	Eye Irrit. 2 H319, STOT SE 3 H335
EC	201-069-1	
INDEX		
REACH Reg.	01-2119457026-42-XXXX	
Alcohols, C10-16, ethoxylated		
CAS	68002-97-1	Acute Tox. 4 H302, Eye Dam. 1 H318, Aquatic Chronic 3 H412
EC		STA Oral: 500 mg/kg
INDEX		

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

The substance Hydrocarbons, C12-C15, n-alkanes, isoalkanes < 2% aromatics may be replaced by the substances Hydrocarbons, C13-C16, n-alkanes, isoalkanes, cyclics, < 0.03% aromatics (reg. num. 01-2119826592-36-XXXX) or Hydrocarbons, C13-C18, n-alkanes, isoalkanes, cyclics, <2% aromatics (reg. num. 01-2119485032-45-XXXX), that have the same classification, based on their availability. The substance Alcohols, C10-16, ethoxylated may be replaced by the substances Alcohols, C12-14, ethoxylated (CAS 68439-50-9) or Alcohols, C12-16, ethoxylated (CAS 68551-12-2), that have the same classification, based on their availability.

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. Rinse skin with a shower immediately. Get medical advice/attention immediately. Wash contaminated

SECTION 4. First aid measures ... / >>

clothing before using it again.

INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately.

INGESTION: Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly 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**

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

SECTION 7. Handling and storage ... / >>

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.

Non-suitable materials: do not use iron, copper or aluminum containers or equipment. Materials to be avoided: strong oxidizing agents.
Storage temperature 4-32 °C, protect from frost, store away from moisture.

Storage class TRGS 510 (Germany): 12

7.3. Specific end use(s)

See the exposure scenarios attached to this safety datasheet.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory References:

DEU	Deutschland	Technischen Regeln für Gefahrstoffe (TRGS 900) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte. MAK- und BAT-Werte-Liste 2020, Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Mitteilung 56
FIN	Suomi	HTP-VÄRDEN 2020. Koncentrationer som befunnits skadliga. SOCIAL - OCH HÄLSOVÄRDSMINISTERIETS PUBLIKATIONER 2020:25

Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics

Threshold Limit Value

Type	Country	TWA/8h mg/m3 ppm	STEL/15min mg/m3 ppm	Remarks / Observations
AGW	DEU	600	1200	
HTP	FIN	500		

Citric acid monohydrate

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,44	mg/l
Normal value in marine water	0,044	mg/l
Normal value for fresh water sediment	34,6	mg/kg
Normal value for marine water sediment	3,46	mg/kg
Normal value of STP microorganisms	1000	mg/l
Normal value for the terrestrial compartment	33,1	mg/kg

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.

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.

When choosing risk management measures and operating conditions, consult the exposure scenarios attached.

Provide an emergency shower with face and eye wash station.

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 Regulation 2016/425 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

SECTION 8. Exposure controls/personal 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.

For information on controlling environmental exposure, see the exposure scenarios attached to this safety datasheet.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	viscous liquid	
Colour	ivory white	
Odour	light	
Odour threshold	Not determined	
Melting point / freezing point	Not determined	
Initial boiling point	100 °C	
Flammability	not flammable	
Lower explosive limit	Not applicable	
Upper explosive limit	Not applicable	
Flash point	> 93 °C	
Auto-ignition temperature	> 150 °C	
Decomposition temperature	> 200 °C	
pH	3,0 ÷ 6,0	Concentration: 0,5 % Temperature: 25 °C Temperature: 40 °C
Kinematic viscosity	> 20,5 mm²/s	
Solubility	limited by the viscosity	
Partition coefficient: n-octanol/water	Not applicable	
Vapour pressure	Not available	
Density and/or relative density	1,04 g/cm³	Temperature: 25 °C
Relative vapour density	Not available	
Particle characteristics	Not applicable	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Evaporation rate	simile all'acqua
Explosive properties	not applicable because it does not contain any explosives functional groups
Oxidising properties	not applicable because it does not contain any oxidizing functional groups

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.

SECTION 10. Stability and reactivity ... / >>

Citric acid monohydrate

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

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics

Unless otherwise specified in the following paragraphs, for the involved substance toxicological data in the following list are considered not available: acute toxicity, skin corrosion/irritation, serious eye damage/irritation, respiratory or skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT - single exposure, STOT - repeated exposure, aspiration hazard.

Citric acid monohydrate

Unless otherwise specified in the following paragraphs, for the involved substance toxicological data in the following list are considered not available: acute toxicity, skin corrosion/irritation, serious eye damage/irritation, respiratory or skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT - single exposure, STOT - repeated exposure, aspiration hazard.

Metabolism, toxicokinetics, mechanism of action and other information

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

Citric acid monohydrate

Inhalation of significant quantities may cause irritation of the respiratory system.

Ingestion of significant quantities may cause gastrointestinal disturbances.

Contact with the skin may cause irritation.

Repeated or prolonged exposure may cause allergic reactions in some sensitive individuals.

Acute effects: contact with eyes causes irritation; symptoms may include: redness, edema, pain and tearing.

Ingestion can cause abdominal pain with burning, nausea and vomiting.

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture:

Not classified (no significant component)

ATE (Oral) of the mixture:

>2000 mg/kg

ATE (Dermal) of the mixture:

Not classified (no significant component)

SECTION 11. Toxicological information ... / >>

Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics
LD50 (Dermal): > 5000 mg/kg Rabbit, equivalent or similar to OECD Guideline 402, reliability 2
LD50 (Oral): > 5000 mg/kg Rat, equivalent or similar to OECD Guideline 401, reliability 1
LC50 (Inhalation vapours): 4951 mg/l/4h Rat, equivalent or similar to OECD Guideline 403, reliability 1

Citric acid monohydrate
LD50 (Dermal): > 2000 mg/kg Rat, according to OECD Guideline 402, reliability 1
LD50 (Oral): 5400 mg/kg Mouse, equivalent to OECD Guideline 401, reliability 2

Alcohols, C10-16, ethoxylated
STA (Oral): 500 mg/kg estimate from table 3.1.2 of Annex I of the CLP
(figure used for calculation of the acute toxicity estimate of the mixture)

The following data refer to the product and may not be related to tests on it but extrapolated from similar products.

Acute oral toxicity: LD50 (rat) 5000 mg/kg (calculated)
Acute dermal toxicity: LD50 (rabbit) > 2000 mg/kg (calculated)
Acute inhalation toxicity: LC50 (4h, rat) > 20 mg/l (calculated).

Citric acid monohydrate
Acute toxicity, intraperitoneal route:
LD50 (mouse): 940 mg/kg bw
LD50 (rat): 725 mg/kg bw
The data refer to the publication Yokotani et al. (1971), reliability 2.

SKIN CORROSION / IRRITATION

Repeated exposure may cause skin dryness or cracking.

The product does not cause skin irritation.

Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics
Based on available data, the classification criteria are not met.

Citric acid monohydrate
The substance was not irritating to the skin; the test was conducted on rabbit according to OECD Guideline 404, reliability 1.
The substance may cause skin irritation to predisposed persons.

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

The product causes severe eye irritation.

Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics
Based on available data, the classification criteria are not met.

Citric acid monohydrate
The substance is irritating to the eyes. The test was performed on rabbit according to OECD Guideline 405.

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics
Based on available data, the classification criteria are not met.

Respiratory sensitization

Information not available

Skin sensitization

Citric acid monohydrate
Based on available data, the classification criteria are not met. The substance does not cause skin sensitization.
The test (Maximization Test) was performed on guinea pig, according to OECD Guideline 406.

SECTION 11. Toxicological information ... / >>GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics
Based on available data, the classification criteria are not met.

Citric acid monohydrate
Based on available data, the classification criteria are not met. The substance is not mutagenic in in vivo experiments.
The tests were performed on rat, in a manner that is equivalent to the methods OECD Guideline 475 and EU B.22, reliability 2.

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics
Based on available data, the classification criteria are not met.

Citric acid monohydrate
The substance did not show carcinogenic or teratogenic effects during experiments on animals.

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics
No reprotoxicity is expected by analogy with similar substances.
NOAEL = 300 ppm (rat, OECD 421).

Citric acid monohydrate
Based on available data, the classification criteria are not met. The substance is not toxic for reproduction.

Adverse effects on sexual function and fertility

Information not available

Adverse effects on development of the offspring

Citric acid monohydrate
Based on available data, the classification criteria are not met. The substance has no developmental toxicity.
The test was performed on mouse, rat and rabbit, ECHA data, reliability 2.

Effects on or via lactation

Information not available

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics
No known effect.

Target organs

Information not available

Route of exposure

Information not available

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics
NOAEL (oral, 90 days) >= 3000 mg/kg bw/day (rat, OECD 408, read-across).

SECTION 11. Toxicological information ... / >>

Citric acid monohydrate
Repeated dose toxicity, oral route:
NOAEL (rat): 4000 mg/kg bw/day
LOAEL (rat): 8000 mg/kg bw/day
The data are from ECHA, reliability 2.

Target organs

Information not available

Route of exposure

Information not available

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class Viscosity: > 20,5 mm²/s

Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics
It may be fatal if swallowed and enters airways.

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

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

Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics
Toxicity to microorganisms: EL50/48h > 1000 mg/l (Tetrahymena pyriformis, (Q)SAR, reliability 2).

Citric acid monohydrate
Toxicity to microorganisms:
TT (Toxicity threshold, 16 h, Pseudomonas putida): > 10000 mg/L
The data refer to the publication Bringmann G, Kuhn R (1980), reliability 2.

Citric acid monohydrate	
LC50 - for Fish	440 mg/l/48h Leuciscus idus melanotus, static, equivalent to OECD Guideline 203, reliability 2
EC50 - for Crustacea	1535 mg/l/24h Daphnia magna, static, according to Bringmann and Kuhn (1977), reliability 2
Chronic NOEC for Algae / Aquatic Plants	425 mg/l Scenedesmus quadricauda, 8 d, static, according to Bringmann and Kuhn (1974), reliability 2
Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics	
LC50 - for Fish	1000 mg/l/96h LL0, Oncorhynchus mykiss, according to OECD Guideline 203, reliability 1
EC50 - for Crustacea	1000 mg/l/48h EL0, Daphnia magna, according to OECD Guideline 202, reliability 1
EC50 - for Algae / Aquatic Plants	> 1000 mg/l/72h IC0, Pseudokirchneriella subcapitata, OECD 201
Chronic NOEC for Fish	> 1000 mg/l NOELR, 28d, Oncorhynchus mykiss, (Q)SAR, reliability 2
Chronic NOEC for Crustacea	> 1000 mg/l NOELR, 21d, Daphnia magna, (Q)SAR, reliability 2

The following data refer to the product and derive from studies conducted on a structurally similar product.
Acute toxicity to fish: LC50/96h >1-10 mg/l (Branchydanio rerio, OECD 203)
Acute toxicity to aquatic invertebrates: EC50/48h >10-100 mg/l (Daphnia magna, OECD 202)
Acute toxicity to algae: IC50/72h = 14,7 mg/l (Skeletonema costatum, OECD 201).

12.2. Persistence and degradability

SECTION 12. Ecological information ... / >>

Citric acid monohydrate
Rapidly degradable 97%, 28 d, OECD Guideline 301 B, reliability 2

Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics
Rapidly degradable

The polymeric component is not easily biodegradable, but degrades by hydrolysis.

12.3. Bioaccumulative potential

Citric acid monohydrate
Partition coefficient: n-octanol/water -1,72

Not biaccumulabile. The polymer has a high molecular weight and therefore cannot penetrate the cell membranes.

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 \geq than 0,1%.

12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. 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 or ID 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

SECTION 14. Transport information ... / >>

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

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/EU: None

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

Product
Point 3

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors
Not applicable

Substances in Candidate List (Art. 59 REACH)
On the basis of available data, the product does not contain any SVHC in percentage \geq than 0,1%.

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:
None

Substances subject to the Rotterdam Convention:
None

Substances subject to the Stockholm Convention:
None

Healthcare controls
Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

German regulation on the classification of substances hazardous to water (AwSV, vom 18. April 2017)
WGK 1: Low hazard to waters

15.2. Chemical safety assessment

A chemical safety assessment has been performed for the following contained substances
Citric acid monohydrate

SECTION 16. Other information

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

Acute Tox. 4	Acute toxicity, category 4
Asp. Tox. 1	Aspiration hazard, category 1
Eye Dam. 1	Serious eye damage, category 1
Eye Irrit. 2	Eye irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic toxicity, category 3
H302	Harmful if swallowed.
H304	May be fatal if swallowed and enters airways.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.
EUH066	Repeated exposure may cause skin dryness or cracking.

SECTION 16. Other information ... / >>**LEGEND:**

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 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: 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: Regulation (EC) 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: Time-weighted average exposure limit
- TWA STEL: Short-term 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) 2020/878 (II Annex of REACH Regulation)
4. Regulation (EC) 790/2009 (I Atp. CLP) 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)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2019/521 (XII Atp. CLP)
16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
21. Delegated Regulation (UE) 2021/849 (XVII 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.

SECTION 16. Other information ... / >>

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.

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review:
The following sections were modified:
01 / 02 / 03 / 09 / 11 / 12 / 16.

Exposure Scenarios

Substance	Citric acid monohydrate
Scenario Title	SE_Acido citrico monoidrato
Revision nr.	1
File	EN_SEACIDOCITRICO_1.pdf