L(+) TARTARIC ACID

SAFETY DATA SHEET

in compliance with Regulation (EU) 2020/878

Revision n° **15** of **08.02.2023**
Replaces previous version of **23.12.2022**

SECTION 1: Identification of the substance and of the company

1.1. Product identifier

EC name:	L(+)-Tartaric Acid
EC Number:	201-766-0
CAS Number:	87-69-4
Reference number:	01-2119537204-47-0005
Other means of identification:	Natural Tartaric Acid

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

Relevant identified uses:
Acidifier, antioxidant, flavour enhancer and stabilising agent.
Food industry (production of tinned food, jam, jelly, confectionery and biscuits in general, soft drinks and table waters; acidifyer in wine-making field). Pharmaceutical and Cosmetic Industry (preparation of medicines, effervescent tablets and soluble drubs; excipient, acidifier in syrups and antibiotics and food additive; production of natural beauty cream for face and body) and Industrial and Technical (retarding agent in the preparation of gypsum, used in the formulation of waterproof cements and heat-insulator; it is also used in textiles, tannings, ceramics, galvanoplastics, cleaning agents, used as laboratory reagent, mining and offshore industries).

Uses advised against:
There are no uses advised against.

1.3. Details of the supplier of the safety data sheet

Company:	Distillerie Mazzari S.p.A.
Address:	Via Giardino, 6 - Sant'Agata sul Santerno (RA) - Italia
Telephone:	+39 0545 45014
Website:	www.mazzarispa.com
E-mail:	ivan@mazzarispa.com (person responsible for the sheet drafting)

1.4. Emergency telephone number

NHS Direct in England or Wales +44 0845 46 47 or NHS 24 in Scotland +44 08454 24 24 24 (UK only) or direct 111.

SECTION 2: Hazards identification

Physicochemical hazards:
The substance is solid and does not present any physicochemical hazards arising from its intrinsic properties.

Hazards to human health:
The substance causes serious eye damage.

Environmental hazards:
The substance is not dangerous for the environment.

PBT/vPvB evaluation:
The substance does not meet the PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative) criteria as per Annex XIII to REACH Regulations.

2.1. Classification of the substance or mixture

Classification according to EC Regulation 1272/2008 (CLP):

Eye Dam.: 1 H318
Serious eye damage, hazard category 1; Causes serious eye damage.

2.2. Label elements

GHS pictogram:
GHS05: Corrosion

Signal word:
Danger.

Hazard statements:
H318: Causes serius eye damage.

Precautionary statements:
P264: Wash hands thoroughly after handling
P280: Wear protective gloves/ protective clothing/eye protection/face protection.
P310: Immediately call a POISON CENTER/doctor.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3. Other hazards

The substance is solid: consider – and when required control – hazards arising from dust formation during use. No further dangers have been identified.

Tartaric acid is not considered to be PBT / vPvB (persistent, bioaccumulative and toxic / very persistent and very bioaccumulative).

SECTION 3: Composition/information on ingredients

3.1 Substances

Tartaric Acid is a mono-constituent substance, of organic origin, identified as stated below:
EC Name: L(+)-tartaric acid
EC Number: 201-766-0
CAS Number: 87-69-4
Reference number: 01-2119537204-47-0005

Constituent	Typical concentration	Concentration range
Tartaric acid	99,9%	>99,7%

3.2 Mixtures

Not applicable.

SECTION 4: First aid measures

4.1. Description of first aid measures

General first aid principles – Important information:
In the event of doubts, or if symptoms occur, contact a physician and show this Safety Data Sheet. In the presence of more serious symptoms, call the national emergency service to obtain immediate first aid. Call a poison control centre to receive detailed information for the clinical management of the poisoning case. Never give anything by mouth to a victim who is unconscious.

General first aid principles – Inhalatio:
Remove the injured person from the source of exposure. In case of respiratory symptoms (cough, dyspnea, respiratory

difficulty, asthma), keep the injured person in a semi-seated position and administer oxygen if necessary. If the subject stops breathing, administer artificial respiration.

General first aid principles – Contact with the skin:
Wash the affected area with plenty of water (and soap if possible) for 15 minutes. In case of irritation or pain, get medical advice.

General first aid principles – Contact with the eyes:
Remove contact lenses, if this can easily be done. Wash with plenty of water for at least 15 minutes, opening the eyelids fully. In any case, especially in the presence of symptoms of irritation (redness, lacrimation, pain, foreign body sensation), immediately consult an ophthalmologist.

General first aid principles – Ingestion:
Do not induce vomiting. Do not administer anything by mouth without prior indications given by a poison control centre. Wash the oral cavity with running water and consult a doctor.

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

Acute effects:
At the date of drawing up of this Safety Data Sheet, no cases of acute human poisoning from exposure to this substance are known. On the basis of the experimental data observed, irritant or corrosives effects may occur when skin and mucous membranes come into contact with the substance (skin, eyes).

Delayed effects:
At the date of drawing up of this safety sheet, no effects in human beings arising from chronic exposure to this substance are known.

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

Need for medical attention:
In case the victim shows serious symptoms call the national emergency service immediately to obtain first aid. In any case it is recommended to contact a poison control centre to get expert toxicological advice right from the very first steps of first aid. If symptoms persist – even minor ones – get medical attention.

Special treatments and antidotes that must be available at the workplace:
Water for skin and eye wash. Oxygen.

Personal protective equipment for first aid responders:
Wear protective clothing to avoid contamination of responders during first aid operations.

Removal and handling of contaminated clothing:
In the event of important contamination, remove the clothing and put it into a closed container away from the work area.

SECTION 5: Firefighting measures

General information:
Remove the non-specialists and stay upwind. Do not enter in closed spaces without an appropriate protection.

5.1. Extinguishing media

Suitable extinguishing media:
The extinction equipment used should be of the conventional kind. The suggested devices are nebulized water, foam, powder. In selecting the extinguishing media, take into account the other materials involved in the fire.

Extinguishing media which shall not be used for safety reasons:
None in particular.

5.2. Special hazards arising from the substance or mixture

In case of fire, irritant or toxic fumes can develop from the substance or the other materials. Compounds like carbon monoxide (CO) and carbon dioxide (CO2) can develop because of heating at temperatures exceeding the decomposition temperature.

5.3. Advice for firefighters

In case of fire, when this substance is involved, a special protective equipment is not needed. Wear fireproof clothing, like firemen's one. In case of fire in enclosed and inadequately ventilated spaces, wear a complete fireproof protective equipment and a self-respirator.

SECTION 6: Accidental release measure

6.1. Personal precautions, protective equipment and emergency procedures

Remove the employees that are not involved from the spillage area and call the emergency teams. Stop or contain the spillage at source, if security conditions permit. Avoid direct contact with the released material. Stay upwind. In case of small spillages, the working clothes are generally adequate. In case of big spillages, a protective equipment made of appropriate material may be necessary. Protective devices may also be necessary, as stated in Section 8.

6.2. Environmental precautions

Collect the spilled substance in appropriate containers. In order to prevent the formation of dusts, humidify the substance before doing it if necessary. Collect the residue cautiously and apply it for correct disposal. Avoid the product discharging into the sewerage system, rivers or other water bodies. In case of contamination of rivers, lakes or sewers, inform the competent authorities.

6.3. Methods and material for containment and cleaning up

Land spreading:
Big overflows of substance can be mechanically removed and the residues can be washed with water. Operate in accordance with the good working practices and refer to specialized services, if necessary.

Spillages in water:
At the time of drafting this Safety Data Sheet, indications concerning specific procedures to adopt, to contain and clean up after the spillage in water of the substance, are not known. Operate in accordance with the good working practices and refer to specialized services, if necessary.

6.4. Reference to other sections

Any other information is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

General recommendations:
While handling the substance, you have to avoid the formation of dusts and the release of the product in the air. Specialized staff have to be in charge of loading, unloading and handling. The substance has to be handled in an adequately ventilated space. Clean the equipment and the working area regularly. Avoid the contact with the skin and the eyes. In case of possible contact with the skin and the eyes, protective gloves and glasses have to be worn.

Recommendations on personal care:
Do not breath dust. Avoid the contact with the skin and the eyes. Do not eat, drink or smoke in the working area. Wash hands thoroughly after handling. Do not reuse contaminated clothes and wash them before wearing again.

7.2. Conditions for safe storage, including any incompatibilities

The structure of the storage area, the features of the tanks, the systems and the operative procedures have to be in line with the relevant legislation on a European, national and local level. The storage plants have to be equipped with appropriate systems to prevent the soil and water contamination, in case of leakages or spillages. Keep in closed containers, far from incompatible products (oxidizing substances, bases, reducing agents and silver), avoiding high temperatures and freezing.

7.3. Specific end uses

There are no specific indication concerning handling and storage, with respect to the end uses of the substance.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No specific occupational exposure limit values have been set for this substance on a national or European level. Other occupational exposure limit values, which have been determined, are listed here below:

Countries	Limit values (8 hours)		Limit values (short term)	
	ppm	mg/m³	ppm	mg/m³
Germany (AGS)	-	2 (1)	-	4 (1) (2)
Germany (DFG)	-	2 (1)	-	4 (1) (2)
Switzerland	-	2 (1)	-	4 (1) (2)

(1): inhalable fraction; (2): 15 minutes, average value

DNEL (Derived No-Effect Level):
Tartaric acid exerts its irritant/corrosive effect without evidence of a dose-response relationship. Hence, available data do not allow to establish a threshold above which the substance exerts its irritant/corrosive effect. Consequently, no DNEL value has been set. For a proper management of the risks associated to the occupational use of this substance, a qualitative approach appears to be the most appropriate, as described in the Annex to the Safety Data Sheet.

PNEC (Predicted No-Effect Concentration):
No adverse effect has been observed in studies at the highest recommended concentrations/doses tested. For this reason, the definition of PNEC values is not required for environmental compartments.

8.2. Exposure control

Adequate technical controls:
Minimize exposure to dusts. When the substance is not produced, used or transformed in a closed and controlled system, risk reduction measures can be necessary (for example, Local Exhaust Ventilation System for dust capturing, protective gloves, protective glasses)

Measures and devices for individual protection:
Eyes protection: In case of possible contact with the eyes, wear a visor or protective gloves in accordance with the regulation EN166.

Skin protection: In case of possible contact with the skin, wear chemical-resistant category II gloves (EN 374), in adequate material, also suitable for direct and prolonged contact (for example, PVC, butyl and fluorinated rubber). The gloves have to be regularly inspected and replaced in case of usury, perforation or contamination.

Body protection: Select the adequate protective media, depending on the activity and exposition (apron, boots, adequate clothes). In particular, in case of potential prolonged exposition, select at least category II clothes. Replace and wash the means of protection at the end of the working time, so as to avoid any transfer of product to the personal clothes.

Respiratory protection: It is recommended to minimize the exposure in case of dust formation, so as to avoid the irritation of the respiratory track. In case of doubt, use a FFP1 category filtering facemask.

Control of environmental exposure: The storage plants have to be equipped with appropriate systems, to avoid the soil and water contamination, in case of leakages or spillages.

SECTION 9: Physical and chemical properties

For a proper interpretation of the information set out in this section, please refer to the information provided in section 16 of this Data Sheet under heading "Data on intrinsic properties and category approach".

9.1. Information on basic physical and chemical properties

Physical state:	crystalline solid (20°C at 101.3 kPa)

Colour:	white
Odour:	odourless
Melting point/freezing point:	168 - 171°C (REACH dossier - secondary source)
Boiling point or initial boiling point and boiling range:	179.1 °C (ASTM E537/07) 399°C (REACH dossier - secondary source)
Flammability:	not flammable (NF T 20-042:1985) > 200°C (REACH dossier - secondary source)
Lower and upper explosion limit:	not necessary, the substance is not explosive
Flash point:	> 100 °C (ASTM D93/07) > 200°C (REACH dossier - secondary source)
Auto-ignition temperature:	375 °C a 1013 hPa (NFT 20-036) > 400°C (REACH dossier - secondary source)
Decomposition temperature:	425 °C (Dossier REACH) > 170°C (Dossier REACH – secondary source)

pH: below the pH values of the different solutions of tartaric acid (internal method):

Concentration w/w (%)	1	5	10	20
pH value	2.17	1.65	1.52	1.19

- pH value 2.2 (1470 g/l in water solution @ 25 °C)

Kinematic viscosity:	not applicable: the substance is a solid
Solubility:	Partition coefficient n-octanol/water (log value): water = 1390 g/l @ 20 °C (Dossier REACH) ethanol = 33 g/100 ml @ 25 °C (Dossier REACH) ether = 0.4 g/100 ml @ 25 °C (Dossier REACH)
Partition coefficient n-octanol/water (log value):	log Pow = -1.91 (OECD 107) logKow < 0 (REACH dossier - secondary source)
Vapour pressure:	< 5.23·10-2 mPa = < 5.23·10-5 Pa < 3.93·10-7 mmHg a 40°C (EU Method A.4) < 5 Pa a 20 °C (NTF 20-048)
Density and/or relative density:	1.76 g/cm³ (Dossier REACH)
Relative vapour density:	not determined (the substance is solid)
Particle characteristics:	fine powders/coarse granules (OECD 110 Particle Size Distribution / Fibre Length and Diameter Distributions). Particles (fine powders, granules) smaller than 1000 µm

9.2. Other information

9.2.1. Information with regard to physical hazard classes

- **Explosive properties:** Not explosive (in the molecule there are no groups that can be associated with explosive properties)
- **Flammable solids:** The substance was not found to be flammable (EU method A.10.: Flammability (solids))
- **Pyrophoric solid:** Experience gained from handling the product shows that the substance does not ignite spontaneously when it comes into contact with air at normal temperatures (i.e. the substance is known to be stable at room temperature for extended periods of time (days)).
- **Substances and mixtures which emit flammable gases in contact with water:** The product is not combustible, does not emit flammable gases in contact with water and does not have pyrophoric properties.
- **Oxidizing solids:** Not oxidant; in the molecular structure of the substance there are no oxidizing groups, all the oxygen atoms are bonded directly to the carbon or hydrogen and there are also no halogen atoms.
- **Organic peroxides:** The chemical structure of the substance does not contain peroxide groups.

9.2.2. Other safety characteristics

No other safety characteristics.

SECTION 10: Stability and reactivity

10.1. Reactivity

The substance presents no limits related to reactivity.

10.2. Chemical stability

The substance is stable in every ordinary circumstance and under normal conditions of use.

10.3. Possibility of hazardous reactions

The substance is stable in every ordinary circumstance and under normal conditions of use.

10.4. Conditions to avoid

Avoid dust formation and exposure to heat sources. Keep separated from oxidizing agents.

10.5. Incompatible materials

Oxidizing agents, bases, reducers and silver.

10.6. Hazardous decomposition products

The substance does not decompose, if used as expected. Among combustion products, carbon monoxide can develop (CO). When the substance decomposes, the smell it emits is similar to the sugar's one.

SECTION 11: Toxicological information

For a proper interpretation of the information set out in this section, please refer to the information provided in section 16 of this Data Sheet under heading "Data on intrinsic properties and category approach".

Animal metabolism:
Experiments on a rabbit show that the tartaric acid absorbed is eliminated through urine, and only to a lesser extent through biliary excretion and/or faeces. Oral administration of 50 mg/kg doses leads to a quick urine excretion, but after increasing doses up to 300 mg/kg, excretion is reduced to 3%. Intramuscular administration of 50 mg/kg doses of tartaric acid also leads to nearly complete urinary excretion, whereas dose increase reduces urine excretion, up to 12%, with 300 mg/kg doses. It has been observed that tartrate administration in a dog, both oral and parenteral, determines a renal excretion similar to that of substances that are not modified in the organism.

Human metabolism:
Some studies on human beings have shown that intravenous and intramuscular administration of tartaric acid determines nearly complete excretion of the compound as such. Oral administration instead shows that 20% of the substance is eliminated as such and the remaining part is metabolized by the intestinal flora.

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

a) Acute toxicity:

Acute Oral and Dermal Toxicity
Acute toxicity of tartaric acid and its salts has been studied through several tests, carried out mainly through oral and subcutaneous administration. Nearly all data support the absence of a significant acute toxicity for both exposure routes. Such results are observed with high doses that do not lead to a classification, as evidenced by the values of the lethal dose 50 (LD50):
Experimental studies (Tartaric acid)
Acute oral toxicity (rat) LD50 >2000 mg/kg OECD423
Acute dermal toxicity (rat) LD50 >2000 mg/kg OECD402

Other data:

-	Tartaric acid	LD50 oral rat:	920 mg/kg
-	Tartaric acid	LD50 oral rat:	> 5000 mg/kg

- Tartaric acid	LD50 oral mouse:	4109 mg/kg
- Monosodium tartrate	LD50 oral rat:	> 2000 mg/kg
- Disodium tartrate	LD50 oral rat:	> 5000 mg/kg
- Tartaric acid	LD50 subcutaneous dog:	> 2000 mg/kg
- Monosodium tartrate	LD50 subcutaneous cat:	> 2000 mg/kg

Data are considered as conclusive for establishing non-classification of the substance.
Inhalation Toxicity
No data relevant to this hazard class are available.

b) Skin corrosion/skin irritation:

With a view to evaluation of its irritant potential, tartaric acid has been considered independently of its salts. The acid shows a low pH value (about 2), whereas its salts` values are greater than or equal to 3. On the basis of clinical investigations (data collected from human beings), tartaric acid is considered irritant for skin. Signs of skin irritation have been observed in different workers who handled the substance. The most frequent symptoms in the group of exposed workers were: skin irritation; hands irritation; face and scalp irritation; chronic skin alterations; ulcers and periungueal splits. On the other hand, in vitro and in vivo experimental studies conducted with the substance in the solid state did not show any corrosive or irritant effects.
Based on experimental data, the substance in the solid state is not classified for skin corrosion or irritation effects.

c) Serious eye damage/serious eye irritations:

With a view to evaluation of its potential eye irritant, tartaric acid has been considered independently of its salts. The acid shows a low pH value (about 2), whereas its salts` values are greater than or equal to 3. Potassium bitartrate powder was instilled into the anterior chamber of a rabbit`s eye and didn`t produce any reaction. On the basis of experimental data deriving from a hygiene/health survey (data collected from human beings), tartaric acid is considered irritant for eyes. Taking into account the extreme pH (equal to 2) of the substance, capable of producing serious eye damage, and in light of the signs of eye irritation observed in a large amount of workers exposed to the substance, tartaric acid is considered a strong eye irritant, capable of causing serious eye injuries.
Moreover, the following experimental study conducted on tartaric acid is available:
Bovine Corneal Opacity and Permeability (BCOP) (OECD 437)
Irritation Parameter - Corneal Opacity Score - Value: 118.765 [Test criterion > 80.1 severe eye irritant]
Based on the evaluation criteria of the test performed, tartaric acid was classified as a severe eye irritant.
Available data are considered conclusive for classification of the substance as Eye Dam. 1; H318 (Causes serious eye damage).

d) Respiratory or skin sensitivity:

No cases of skin or respiratory sensitization have been observed in health surveillance studies on workers exposed to tartaric acid. The workers only showed signs of respiratory tract irritation, attributable to the general dustiness of the work environment.
In addition, the following experimental study conducted on tartaric acid is available:
Local Lymph Node Assay (OECD 429)
Result: not sensitizing
The available data are considered conclusive for not classifying the substance for these hazard classes.

e) Germ cell mutagenicity:

Tartaric acid has been subjected to different mutagenesis and clastogenesis tests, both in vitro and in vivo. Particularly, tests included in vivo and in vitro chromosome aberration tests in mammals, bacterial reverse mutation tests (Ames test), in vitro DNA repair tests in mammalian cells. No mutagenic or clastogenic activities were shown by the substance in nearly every test, except for a positive result in yeast (Saccharomyces D3) and an ambiguous result in a dominant lethal mutation test. Yet, in both cases, repetition of the tests gave negative results. The available data about the tartaric acid`s salts also confirm the absence of mutagenicity and clastogenicity for this category of substances. Particularly, (i) a series of bacterial reverse mutation tests and an in vitro chromosome aberration test in mammals showed negative results with potassium hydrogen tartrate (ii) a single negative result in a bacterial reverse mutation tests with sodium hydrogen tartrate; (iii) a negative result in the bacterial reverse mutation tests is available for sodium tartrate which, on the contrary, resulted positive in an in vitro chromosome aberration test in mammals. This positive result was weakened by the absence of clastogenicity recorded in the in vivo micronucleus test carried out both with single doses first and with repeated administrations afterwards. Below is a short list of data reported in literature. The available data are considered conclusive for establishing non-classification of the substance for this hazard class.

In vitro studies:	
- Tartaric acid, OECD Guideline 471 Bacteria reversal test	Negative
- Tartaric acid, OECD Guideline 473 Chromosome aberration test in mammals	Negative
- Monopotassium Tartrate, OECD Guideline 471 Bacteria reversal test	Negative
In vivo studies:	
- Tartaric acid, OECD Guideline 475 Chromosome aberration test on mammals' bone marrow	Negative
- Sodium Tartrate, OECD Guideline 474 Micronucleus test on mammals' erythrocytes	Negative

The available data are considered conclusive for establishing non-classification of the substance for this hazard class.

f) Carcinogenicity:

In the available chronic toxicity studies, no cases of tumours were observed. The substance is not classified for this hazard class.

g) Reproductive toxicity:

Tartaric acid has been studied for its reproductive toxicity in rabbits, rats, mice and hamsters. The substance has not affected the parameters relevant to the reproductive activity. Particularly, it has not caused an increase in skeletal anomalies and a reduction in the foetal survival over the control groups. Particularly, a study (EPA OTS 798.4700 on reproductive toxicity and on fertility) assessed the teratogenic effect of tartaric acid on mice. All the animals were observed every day as to their appearance and behaviour, with a particular attention to food consumption and weight variations, in order to exclude any anomaly due to maternal toxicity. On day 17 of gestation, all females underwent a caesarean section, and the number of implantation sites, resorption sites, and of foetuses born alive or dead were recorded. Body weights of the puppies alive were also recorded. The urogenital tract of every female was examined in detail in order to assess its normal anatomy. All foetuses were subjected to assessment as to the presence of congenital anomalies. Administration of tartaric acid (274 mg/kg of body weight) for ten consecutive days (7-15 day of gestation) did not determine any variation on the sexual function, on fertility and on development of the offspring. Moreover, in another study, the administration of tartaric acid (215 mg/kg of body weight) to rabbit females (day of gestation not reported), for 13 consecutive days, did not have any effect on implantation, on maternal or foetal survival. The number of anomalies observed both in the soft and skeletal tissues of the test groups did not differ from the anomalies occurring spontaneously during controls. The available data are considered conclusive for establishing non-classification of the substance for this hazard class.

h) Specific target organ toxicity (STOT SE) – single exposure:

No organ damages were observed after single exposure to the substance.

i) Specific target organ toxicity (STOT RE) – repeated exposure:

Toxicity after repeated doses of tartaric acid and its salts has been assessed through oral route. Administration of sodium tartrate following a 2-year diet with doses of 25600, 42240, 60160 and 76800 ppm (equivalent to a level of edible tartaric acid of 20000, 33000, 47000 or 60000 ppm, respectively), did not cause adverse effects. Particularly, assessment of animal blood and urine parameters did not reveal any reaction to the treatment. Similarly, in relation to such treatment no necroscopic changes or variations in the weight of the organs of rats, sacrificed after 104 weeks, were observed. Histological examination of the tissues did not show any evidence of toxicity or tumor induction that could be attributed to the treatment with sodium tartrate. Moreover, another study administering tartaric acid to rats through a 104-week diet showed a low toxicity degree of the substance. No significant variations of the examined parameters such as necroscopic changes, weight variations and variations in food consumption were observed, and no case of mortality was reported. The available data are considered conclusive for establishing non-classification of the substance for this hazard class.

j) Aspiration hazard:

No data relevant to this hazard class are available. Yet, on the basis of the physicochemical properties of the substance, such hazard is not expected. Hence, classification of the substance for this hazard is excluded.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties:
Tartaric acid does not have endocrine disruptive properties. It is not listed in the most important databases of substances with endocrine disruptive properties.

11.2.2. Other information:

No further toxicological information is available.

SECTION 12: Ecological information

For a proper interpretation of the information set out in this section, please refer to the information provided in section 16 of this Data Sheet under heading "Data on intrinsic properties and category approach".

12.1. Toxicity

Considering the ecotoxicological data and the absence of bioaccumulation potential, the substance is not dangerous for the aquatic environment. Here below the main data concerning aquatic toxicity:

Short-term effects on fish:
OECD 203 Fish, Acute Toxicity Tes (tartaric acid)
LC50 (96h): >100 mg/L

Short-term toxicity to aquatic invertebrates:
OECD 202: Daphnia sp. Acute Immobilisation Test (tartaric acid)
EC50 (48h): 93.31 mg/l

Short-term toxicity to aquatic algae and aquatic plants:
OECD 201: Alga Growth Inhibition Test (tartaric acid)
EC50 - Alga - 51.4 mg/l 72 h
NOEC - Alga - 3.125 mg/l 72h

Microorganisms toxicity:
OECD 209: Activated Sludge, Respiration Inhibition Test (tartaric acid)
EC50 Activated Sludge>1000 mg/l 3 h

Long-term toxicity to fish:
NOEC (30 days): 43.141 g/L (estimated on tartaric acid))

Long-term effects on aquatic invertebrates:
NOEC 11.88 g/L (estimated on tartaric acid)

12.2. Persistence and degradability

Degradability:
Several studies in the scientific literature have investigated biodegradability of tartaric acid in water with regulated methods, whereas just one study is available for sodium tartrate. All results confirm biodegradability of such substances, with the exception of a study carried out by Sharma et al reporting a BOD5/COD ratio slightly less than 0,5 (cut-off value between biodegradability and non-biodegradability in accordance with CLP regulation) for tartaric acid. On the whole, such a low value is considered to be due to experimental variability. Below is a short list of some data obtained from the tests carried out on tartaric acid. Readily biodegradable.

OECD guidelines 301 C (Determination of timely biodegradability) ESSAY M.I.T.I. (C.4-F Method)

76% after 14 days (O2 consumotion)
100% after 14 days (TOC total organic carbon removal)
100% after 14 days (Tested material) Readily biodegradable

OECD guidelines 301 C (Determination of timely biodegradability) ESSAY M.I.T.I. (C.4-F Method)

75% 14 days (O2 consumotion)
92% 14 days (TOC total organic carbon removal)
100% 14 days (Tested material) Readily biodegradable

Degradation - biochemical oxygen demand (BOD5)
Readily biodegradable.

Hydrolysis	Hydrolytically stable	OECD 111
Biodegradation (water)	85% (28 days)	OECD 306
Biodegradation (soil)	DT50 = 9.6 h	OECD 307

12.3. Bioaccumulative potential

Tartaric acid is an organic acid naturally present in several plants and particularly in grapes, abundant both in its free form and in the form of salt. No bioaccumulation data are available on the relevant aquatic species. Yet, with a measured value of octanol-water partition coefficient (log Kow) < 3, the substance is not expected to be bioaccumulative.

12.4. Mobility in soil

No data on the substance`s mobility in soil are available. Such data were not generated, as direct or indirect exposure in soil is unlikely to occur, since the expected working conditions assure the absence of environmental release by the substance. Moreover, according to column 2 of Annex VIII to REACH Regulation, the study does not need to be conducted, because tartaric acid and its salts have a low potential for absorption, as confirmed by a low octanol-water partition coefficient.

12.5. Results of PBT and vPvB assessment

The substance does not meet the criteria for PBT and vPvB, set out in the Annex XIII of REACH Regulation.

12.6. Endocrine disrupting properties

Tartaric acid does not have endocrine disruptive properties. It is not listed in the most important databases of substances with endocrine disruptive properties.

12.7. Other adverse effects

No further relevant information is available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product residues have to be considered special hazardous waste. Disposal have to be performed through an authorized waste management firm, in compliance with national and local regulations. If possible, employ an incineration plant.
Contaminated packaging and containers have to be recovered or disposed of, in compliance with national waste management regulations. They have to be sent to a company specialized in incineration, recycling or landfilling. Containers have to be cleaned by washing them with water, which will be destined to waste water treatment.

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

Information not relevant: the substance is not classified as dangerous for transport.

14.2. UN proper shipping name

Information not relevant: the substance is not classified as dangerous for transport.

14.3. Transport hazard classes

Information not relevant: the substance is not classified as dangerous for transport.

14.4. Packing group

Information not relevant: the substance is not classified as dangerous for transport.

14.5. Environmental hazards

Information not relevant: the substance is not classified as dangerous for transport.

14.6. Special precautions for user

Information not relevant: the substance is not classified as dangerous for transport.

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant: the substance is not classified as dangerous for transport.

SECTION 15: Regulatory information

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

REACH Regulation CE n. 1907/2006 and s.m.i.:
Product not contained in the list of substances of very high concern (SVHC), applicants for authorization.
Product is not subject to restriction.

Other EU regulations and national transpositions:
Chemical dangerous agent, according to Dir. 98/24/CE and Chapter I, Title IX of Legislative Decree 81/08 and s.m.i.; chemical agent that is not subject to SEVESO regulation; chemical agent that is not subject to Rotterdam Convention.

Check the following provisions:
Regulation N. 10/2011 on plastic materials and articles intended to come into contact with food. Tartaric acid is present in the union list of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids
Directive 2007/42/CE relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs. Tartaric acid is present in the list of substances authorised in the manufacture of regenerated cellulose film

15.2. Chemical safety assessment

A chemical safety assessment has been performed for this substance, as provided for in Regulation (EC) 1907/2006.

SECTION 16: Other information

Data on intrinsic properties and category approach:
Data on tartaric acid intrinsic properties are consistent with the information contained in the registration dossier of the substance in compliance with REACH Regulations. Particularly, they derive from the information worked out for the specific category of tartaric acid and its salts. Such category is based on the hypothesis that all members represent the different ionized forms of tartaric acid. The main prerequisite is that the presence of sodium, potassium and calcium in the molecule is a non-significant one with respect to the intrinsic properties of tartaric acid. By evaluating the physicochemical behaviour of its salts, it is assumed that the latter do not behave differently from the acid when in watery solution and under specific pH conditions. This is the why some properties of the salts (measured or expressed in aqueous environment) can be directly transferred by use of "read-across" to the "parent" acid and viceversa. In relation to irritation/corrosion properties, the acid is considered separately from its salts. When considering the stereochemistry of the substances in the category, in the absence of biological effects caused by stereoselective interactions with chiral "targets", data relevant to a specific molecule stereoform can be used to predict the same properties to their enantiomers and diastereoisomers by the read-across approach.

Other information:
The information contained in the present Safety Data Sheet are based on the data that are currently available to us and aim at describing the product with respect to safety and health purposes. Therefore, it mustn't be regarded as a guarantee on the specific product properties. The information contained in this Safety Data Sheet comply with the current regulation on a national and community level, regarding classification and labelling of substances and dangerous preparations. It is the responsibility of the user to take the necessary measures to comply with national and local regulations.

Indications on the training:
Provide appointed staff, potentially exposed to the substance, with adequate training, on the basis of the contents of this Safety Data Sheet.

Abbreviations and acronyms:
DL50: Lethal Dose 50;
CL50: Lethal Concentration 50;
EC50: Effective Concentration 50;
NOEC: No observed effect concentration;
DT50: Half-life in the soil.

Revisions:
Revision n. **15** of **08.02.2023**
Revision reason: Previous version amendment.

Bibliography:
Reference to the REACH registration dossier of tartaric acid.

9.1a. Manufacture of Substance – Industrial

9.1.1 Exposure Scenario

Section 1	**Exposure Scenario Title**
Title	Manufacture of substances, (tartaric acid, CAS 87-69-4)
Sector of Use	Industrial (SU3, SU8, SU9)
Process Category	PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC9
Product Category / Article Category	PC35, PC39, AC4
Environmental Release Category	ERC1
Processes, tasks, activities covered	Manufacture of the substance. Includes, material transfers, storage, maintenance and loading (including marine vessel/barge, road/rail car and bulk container), sampling.
Section 2	**Operational conditions and risk management measures**
Section 2.1	**Control of worker exposure**
Product characteristics	
Physical form of product	Solid
Vapour pressure	< 5 Pa at 20 °C
Concentration of substance in product	Covers percentage substance in the product up to 100%
Amounts used	not applicable
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently)
Human factors not influenced by risk management	not applicable
Other Operational Conditions affecting worker exposure	
Operational Conditions	**Risk management measures**
1 - Use in closed process, no likelihood of exposure	No specific measures identified
2 - Use in closed, continuous process with occasional controlled exposure	No specific measures identified
3 - Use in closed batch process (synthesis or formulation)	No specific measures identified
4 - Use in batch and other process (synthesis) where opportunity for exposure arises	Provide a good standard of general ventilation. Natural ventilation is from doors, windows etc. Wear chemically resistant gloves (effectiveness 90% - tested to EN374) in combination with ‘basic’ employee training
8a -Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	Wear a respirator conforming to EN140/143 (effectiveness 80%) with Type P1 filter or better Wear chemically resistant gloves (effectiveness 90% - tested to EN374) in combination with ‘basic’ employee training PPE16
8b -Transfer of chemicals from/to vessels/ large containers at dedicated facilities	Wear a respirator conforming to EN140/143 (effectiveness 80%) with Type P1 filter or better Wear suitable gloves tested to EN374 - effectiveness 80%
9 -Transfer of chemicals into small containers (dedicated filling line)	Wear a respirator conforming to EN140/143 (effectiveness 80%) with Type P1 filter or better Wear suitable gloves tested to EN374 - effectiveness 80%
Section 2.2	**Control of environmental exposure**

	No exposure assessment presented for the environment.
Section 3	**Exposure Estimation**
3.1. Health	
Health sub-headings	Predicted exposures are not expected to exceed the applicable exposure limits (given in section 8 of the SDS) when the operational conditions/risk management measures given in section 2 are implemented.
Section 4	**Guidance to check compliance with the Exposure Scenario**
4.1. Health	
Health sub-headings	The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Additional good practices (Operational Conditions and Risk Management Measures) beyond the REACH Chemical Safety Assessment established within Chemical Industry are also advised and communicated through Safety Data Sheets but are not necessarily required to control risk as laid out in section 10.1.

9.1.2 Exposure Estimation

9.1.2.1 Human Health

The endpoint for which the available data may trigger a qualitative risk characterization includes eye irritation and is described in section 10. This qualitative CSA approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health endpoint, i.e. when the available data for this effect do not provide quantitative dose-response information, but there exist toxicity data of a qualitative nature.

Exposure Estimation for all other human health endpoint covered by DNEL or DMEL is performed in context of risk assessment and set in relation to the respective DNEL/DMEL(s) as shown in the Appendix to section 10. Resulting risk characterization ratios (RCR) are presented in section 10.1.

9.1.2.2 Environment

In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/ vPvB Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) an exposure estimation and risk characterization is not necessary; however a qualitative risk assessment is provided in section 10.

9.2 Formulation & (Re)packing of Substances and Mixtures – Industrial

9.2.1 Exposure Scenario

Section 1	**Exposure Scenario Title**
Title	Formulation & (re)packing of substances and mixtures (tartaric acid, CAS 87-69-4)
Sector of Use	Industrial (SU3, SU10)
Process Category	PROC 5, PROC8a, PROC8b, PROC 9
Product Category / Article Category	PC35, PC39, AC4
Environmental Release Category	ERC2

Processes, tasks, activities covered	Formulation, packing and re-packing of the substance and its mixtures in batch or continuous operations, including storage, materials transfers, mixing, large and small scale packing, sampling, maintenance.
Section 2	**Operational conditions and risk management measures**
Section 2.1	**Control of worker exposure**
Product characteristics	
Physical form of product	Solid
Vapour pressure	< 5 Pa at 20 °C
Concentration of substance in product	Covers percentage substance in the product up to 100%
Amounts used	not applicable
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently)
Human factors not influenced by risk management	not applicable
Other Operational Conditions affecting worker exposure	
Operational Conditions	**Risk management measures**
8a -Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	Wear a respirator conforming to EN140/143 (effectiveness 80%) with Type P1 filter or better Wear chemically resistant gloves (tested to EN374 – effectiveness 90%) in combination with 'basic' employee training
5 -Mixing or blending in batch processes (multistage and/or significant contact)	Wear a respirator conforming to EN140/143 (effectiveness 80%) with Type P1 filter or better Wear chemically resistant gloves (tested to EN374 – effectiveness 90%) in combination with 'basic' employee training
8b -Transfer of chemicals from/to vessels/ large containers at dedicated facilities	Wear a respirator conforming to EN140/143 (effectiveness 80%) with Type P1 filter or better Wear suitable gloves tested to EN374 (effectiveness 80%)
9 -Transfer of chemicals into small containers (dedicated filling line)	Wear a respirator conforming to EN140/143 (effectiveness 80%) with Type P1 filter or better Wear suitable gloves tested to EN374 (effectiveness 80%)
Section 2.2	**Control of environmental exposure**
	No exposure assessment presented for the environment
Section 3	**Exposure Estimation**
3.1. Health	
Health sub-headings	Predicted exposures are not expected to exceed the applicable exposure limits (given in section 8 of the SDS) when the operational conditions/risk management measures given in section 2 are implemented.
Section 4	**Guidance to check compliance with the Exposure Scenario**
4.1. Health	
Health sub-headings	The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Additional good practices (Operational Conditions and Risk Management Measures) beyond the REACH Chemical Safety Assessment established within Chemical Industry are also advised and communicated through Safety Data Sheets but are not necessarily required to control risk as laid out in section 10.2.

9.2.2 Exposure Estimation

9.2.2.1 Human Health

The endpoint for which the available data may trigger a qualitative risk characterization includes eye irritation and is described in section 10. This qualitative CSA approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health endpoint, i.e. when the available data for this effect do not provide quantitative dose-response information, but there exist toxicity data of a qualitative nature.

Exposure Estimation for all other human health endpoint covered by DNEL or DMEL is performed in context of risk assessment and set in relation to the respective DNEL/DMEL(s) as shown in the Appendix to section 10. Resulting risk characterization ratios (RCR) are presented in section 10.2.

9.2.2.2 Environment

In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/ vPvB Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) an exposure estimation and risk characterization is not necessary; however a qualitative risk assessment is provided in section 10.

9.3 Use at industrial site – Intermediate

9.3.1 Exposure Scenario

Section 1	**Exposure Scenario Title**
Title	Use as Intermediate, (tartaric acid, CAS 87-69-4)
Sector of Use	Industrial (SU3, SU8, SU9)
Process Category	PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC9
Product Category / Article Category	PC35, PC39, AC4
Environmental Release Category	ERC6a, ERC6b
Processes, tasks, activities covered	Use as an intermediate of the substance. Includes, material transfers, storage, maintenance and loading (including marine vessel/barge, road/rail car and bulk container), sampling.
Section 2	**Operational conditions and risk management measures**
Section 2.1	**Control of worker exposure**
Product characteristics	
Physical form of product	Solid
Vapour pressure	< 5 Pa at 20 °C
Concentration of substance in product	Covers percentage substance in the product up to 100%
Amounts used	not applicable
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently)
Human factors not influenced by risk management	not applicable
Other Operational Conditions affecting worker exposure	
Operational Conditions	**Risk management measures**
1 - Use in closed process, no likelihood of exposure	No specific measures identified
2 - Use in closed, continuous process with occasional	No specific measures identified

controlled exposure	
3 - Use in closed batch process (synthesis or formulation)	No specific measures identified
4 - Use in batch and other process (synthesis) where opportunity for exposure arises	Provide a good standard of general ventilation. Natural ventilation is from doors, windows etc. Wear chemically resistant gloves (effectiveness 90% - tested to EN374) in combination with 'basic' employee training
8a -Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	Wear a respirator conforming to EN140/143 (effectiveness 80%) with Type P1 filter or better Wear chemically resistant gloves (effectiveness 90% - tested to EN374) in combination with 'basic' employee training PPE16
8b -Transfer of chemicals from/to vessels/ large containers at dedicated facilities	Wear a respirator conforming to EN140/143 (effectiveness 80%) with Type P1 filter or better Wear suitable gloves tested to EN374 - effectiveness 80%
9 -Transfer of chemicals into small containers (dedicated filling line)	Wear a respirator conforming to EN140/143 (effectiveness 80%) with Type P1 filter or better Wear suitable gloves tested to EN374 - effectiveness 80%
Section 2.2	**Control of environmental exposure**
	No exposure assessment presented for the environment.
Section 3	**Exposure Estimation**
3.1. Health	
Health sub-headings	Predicted exposures are not expected to exceed the applicable exposure limits (given in section 8 of the SDS) when the operational conditions/risk management measures given in section 2 are implemented.
Section 4	**Guidance to check compliance with the Exposure Scenario**
4.1. Health	
Health sub-headings	The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Additional good practices (Operational Conditions and Risk Management Measures) beyond the REACH Chemical Safety Assessment established within Chemical Industry are also advised and communicated through Safety Data Sheets but are not necessarily required to control risk as laid out in section 10.1.

9.3.2 Exposure Estimation

9.3.2.1 Human Health

The endpoint for which the available data may trigger a qualitative risk characterization includes eye irritation and is described in section 10. This qualitative CSA approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health endpoint, i.e. when the available data for this effect do not provide quantitative dose-response information, but there exist toxicity data of a qualitative nature.

Exposure Estimation for all other human health endpoint covered by DNEL or DMEL is performed in context of risk assessment and set in relation to the respective DNEL/DMEL(s) as shown in the Appendix to section 10. Resulting risk characterization ratios (RCR) are presented in section 10.1.

9.3.2.2 Environment

In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/ vPvB Assessment) no hazard was identified. Therefore

according to REACH Annex I (5.0) an exposure estimation and risk characterization is not necessary; however a qualitative risk assessment is provided in section 10.

9.4 Uses in Construction application –Professional

9.4.1 Exposure Scenario

Section 1	**Exposure Scenario Title**
Title	**Construction (Professional Application);** tartaric acid, CAS 87-69-4
Use Descriptor	Sector of Use: Professional (SU22)
Process Categories	PROC8a, PROC8b, PROC9
Environmental Release Categories	ERC 8c, ERC 8f
Processes, tasks, activities covered	Covers the use in construction (application of concrete in construction activities)
Section 2	**Operational conditions and risk management measures**
Section 2.1	**Control of worker exposure**
Product characteristics	
Physical form of product	Solid
Vapour pressure	< 5 Pa at 20 °C
Concentration of substance in product	Covers percentage substance in the product up to 100 %
Amounts used	*Not applicable*
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently)
Human factors not influenced by risk management	*Not applicable*
Other Operational Conditions affecting worker exposure	Assumes a good basic standard of occupational hygiene is implemented
Operational Conditions	**Risk Management Measures**
8a -Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	Wear a respirator conforming to EN140/143 (effectiveness 80%) with Type P1 filter or better Wear chemically resistant gloves (tested to EN374 – effectiveness 90%) in combination with 'basic' employee training PPE16
8b -Transfer of chemicals from/to vessels/ large containers at dedicated facilities	Wear a respirator conforming to EN140/143 (effectiveness 80%) with Type P1 filter or better Wear suitable gloves tested to EN374 (effectiveness 80%)
9 -Transfer of chemicals into small containers (dedicated filling line)	Wear a respirator conforming to EN140/143 (effectiveness 80%) with Type P1 filter or better Wear suitable gloves tested to EN374 (effectiveness 80%)
Section 2.2	**Control of environmental exposure**
	No exposure assessment presented for the environment.
Section 3	**Exposure Estimation**
3.1. Health	Predicted exposures are not expected to exceed the applicable exposure

	limits (given in section 8 of the SDS) when the operational conditions/risk management measures given in section 2 are implemented.
Section 4	**Guidance to check compliance with the Exposure Scenario**
4.1. Health	The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated. G21 Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels. G23

Additional good practices (Operational Conditions and Risk Management Measures) beyond the REACH Chemical Safety Assessment established within Chemical Industry are also advised and communicated through Safety Data Sheets but are not necessarily required to control risk as laid out in section 10.3.

9.4.2 Exposure Estimation

9.4.2.1 Human Health

The endpoint for which the available data may trigger a qualitative risk characterization includes eye irritation and is described in section 10. This qualitative CSA approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health endpoint, i.e. when the available data for this effect do not provide quantitative dose-response information, but there exist toxicity data of a qualitative nature.

Exposure Estimation for all other human health endpoint covered by DNEL or DMEL is performed in context of risk assessment and set in relation to the respective DNEL/DMEL(s) as shown in the Appendix to section 10. Resulting risk characterization ratios (RCR) are presented in section 10.3.

9.4.2.2 Environment

In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/ vPvB Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) an exposure estimation and risk characterization is not necessary; however a qualitative risk assessment is provided in section 10.

9.5 Uses in Construction application – Consumer

9.5.1 Exposure Scenario

Section 1		**Exposure Scenario Title**
Title		**Construction (Consumer Application);** tartaric acid, CAS 87-69-4
Sector of Use (SU code)		21
Use Descriptor (AC codes)		AC4
Processes, tasks, activities covered		Covers the use in construction (stone, plaster, cement)
Environmental Release Category		ERC10a, ERC11a
Specific Environmental Release Category		
Section 2		**Operational conditions and risk management measures**
Section 2.1		**Control of consumer exposure**
Product characteristics		

Physical form of product		solid
Vapour pressure		< 5 Pa at 20 °C
Concentration of substance in product		Unless otherwise stated, cover concentrations up to 1%
Amounts used		Unless otherwise stated, covers use amounts up to130g; covers skin contact area up to 1000 cm2
Frequency and duration of use/exposure		Unless otherwise stated, covers use frequency up to 1 times every 3 months; covers exposure up to 2 hour per event
Other Operational Conditions affecting exposure		Unless otherwise stated assumes use at ambient temperatures; assumes use in a 20 m^3 room; assumes use with typical ventilation
Section 2.1.1		**Product categories**
AC4: stone, plaster, cement	OC	Unless otherwise stated, covers concentrations up to 1%; covers use up to 4 events / year; covers use up to 1 time/on day of use; covers skin contact area up to 1000 cm2 for each use event, covers use amounts up to 130g; covers use in room size of 20m3; for each use event, covers exposure up to 2hr/event
	RMM	No specific RMMs identified beyond those OCs stated
Section 2.2		**Exposure Estimation**
	No exposure assessment presented for the environment.	
Section 3		**Exposure Estimation**
3.1. Health		
Health sub-headings		Predicted exposures are not expected to exceed the applicable consumer reference values when the operational conditions/risk management measures given in section 2 are implemented.
Section 4		**Guidance to check compliance with the Exposure Scenario**
4.1. Health		
Health sub-headings		The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Additional good practices (Operational Conditions and Risk Management Measures) beyond the REACH Chemical Safety Assessment established within Chemical Industry are also advised and communicated through Safety Data Sheets but are not necessarily required to control risk as laid out in section 10.4.

These additional measures are presented in the appendix to section 10 and are coded blue. To control risks as described by RCRs presented in section 10.1a only Operational Conditions and Risk Management measures as described in section 2.2 above (coded black in the appendix to section 10) have been taken into account.

9.5.2 Exposure Estimation

9.5.2.1 Human Health

The endpoint for which the available data may trigger a qualitative risk characterization includes eye irritation and is described in section 10. This qualitative CSA approach aims to reduce/avoid contact when there is no

basis for setting a DNEL or DMEL for a certain human health endpoint, i.e. when the available data for this effect do not provide quantitative dose-response information, but there exist toxicity data of a qualitative nature.

Exposure Estimation for all other human health endpoint covered by DNEL or DMEL is performed in context of risk assessment and set in relation to the respective DNEL/DMEL(s) as shown in the Appendix to section 10. Resulting risk characterization ratios (RCR) are presented in section 10.4.

9.6 Uses in Ceramics application – Professional

9.6.1 Exposure Scenario

Section 1	**Exposure Scenario Title**
Title	**Ceramics (Professional Application);** tartaric acid, CAS 87-69-4
Use Descriptor	Sector of Use: Professional (SU22)
Process Categories	PROC8a, PROC8b, PROC9
Environmental Release Categories:	ERC8c, ERC8f
Processes, tasks, activities covered	Covers the application of ceramics in construction activities
Section 2	**Operational conditions and risk management measures**
Section 2.1	**Control of worker exposure**
Product characteristics	
Physical form of product	Solid
Vapour pressure	< 5 Pa at 20 °C
Concentration of substance in product	Covers percentage substance in the product up to 100 %
Amounts used	*Not applicable*
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently)
Human factors not influenced by risk management	*Not applicable*
Other Operational Conditions affecting worker exposure	Assumes a good basic standard of occupational hygiene is implemented
Risk Management Measures	
8a -Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	Provide a good standard of general ventilation. Natural ventilation is from doors, windows etc. Wear chemically resistant gloves (tested to EN374 – effectiveness 90%) in combination with 'basic' employee training
8b -Transfer of chemicals from/to vessels/ large containers at dedicated facilities	Wear a respirator conforming to EN140/143 (effectiveness 80%) with Type P1 filter or better Wear suitable gloves tested to EN374 (effectiveness 80%)
9 -Transfer of chemicals into small containers (dedicated filling line)	Wear a respirator conforming to EN140/143 (effectiveness 80%) with Type P1 filter or better Wear suitable gloves tested to EN374 (effectiveness 80%)
Section 2.2	**Control of environmental exposure**
	No exposure assessment presented for the environment.
Section 3	**Exposure Estimation**

3.1. Health	
Health sub-headings	Predicted exposures are not expected to exceed the applicable exposure limits (given in section 8 of the SDS) when the operational conditions/risk management measures given in section 2 are implemented.
Section 4	**Guidance to check compliance with the Exposure Scenario**
4.1. Health	
Health sub-headings	The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Additional good practices (Operational Conditions and Risk Management Measures) beyond the REACH Chemical Safety Assessment established within Chemical Industry are also advised and communicated through Safety Data Sheets but are not necessarily required to control risk as laid out in section 10.5.

9.6.2 Exposure Estimation

9.6.2.1 Human Health

The endpoint for which the available data may trigger a qualitative risk characterization includes eye irritation and is described in section 10. This qualitative CSA approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health endpoint, i.e. when the available data for this effect do not provide quantitative dose-response information, but there exist toxicity data of a qualitative nature.

Exposure Estimation for all other human health endpoint covered by DNEL or DMEL is performed in context of risk assessment and set in relation to the respective DNEL/DMEL(s) as shown in the Appendix to section 10. Resulting risk characterization ratios (RCR) are presented in section 10.5.

9.6.2.2 Environment

In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/ vPvB Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) an exposure estimation and risk characterization is not necessary; however a qualitative risk assessment is provided in section 10.

9.7 Uses in Ceramics application – Consumer

9.7.1 Exposure Scenario

Section 1		**Exposure Scenario Title**
Title		**Ceramics (Consumer Use);** tartaric acid, CAS 87-69-4
Sector of Use (SU code)		21
Use Descriptor (AC codes)		AC4
Processes, tasks, activities covered		Covers general exposures to consumers arising from the use of ceramic tiles for flooring and walls
Environmental Release Category		ERC 10a, ERC 11a
Specific Environmental Release Category		
Section 2		**Operational conditions and risk management measures**

Section 2.1		**Control of consumer exposure**
Product characteristics		
Physical form of product		solid
Vapour pressure		< 5 Pa at 20 °C
Concentration of substance in product		Unless otherwise stated, cover concentrations up to 1%
Amounts used		Unless otherwise stated, covers use amounts up to 1350g; covers skin contact area up to 1000 cm2;
Frequency and duration of use/exposure		Unless otherwise stated, covers use frequency up to 1 times every 4 months; covers exposure up to 2 hours per event
Other Operational Conditions affecting exposure		Unless otherwise stated assumes use at ambient temperatures; assumes use in a 20 m^3 room; assumes use with typical ventilation.
Section 2.1.1		**Product categories**
AC4: ceramics	OC	Unless otherwise stated, covers concentrations up to 1%; covers use up to 3 events/year; covers use up to 1 time/on day of use; covers skin contact area up to 1000 cm2; for each use event, covers use amounts up to 1350g; covers use in room size of 20m3; for each use event, covers exposure up to 2hr/event.
	RMM	No specific RMMs identified beyond those OCs stated
Section 2.2		**Control of environmental exposure - these can be hidden or removed in this consumer GES**
	No exposure assessment presented for the environment.	
3.1. Health		
Health sub-headings		Predicted exposures are not expected to exceed the applicable consumer reference values when the operational conditions/risk management measures given in section 2 are implemented.
Section 4		**Guidance to check compliance with the Exposure Scenario**
4.1. Health		
Health sub-headings		The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Additional good practices (Operational Conditions and Risk Management Measures) beyond the REACH Chemical Safety Assessment established within Chemical Industry are also advised and communicated through Safety Data Sheets but are not necessarily required to control risk as laid out in section 10.6.

9.7.2 Exposure Estimation

9.7.2.1 Human Health

The endpoint for which the available data may trigger a qualitative risk characterization includes eye irritation and is described in section 10. This qualitative CSA approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health endpoint, i.e. when the available data for this effect do not provide quantitative dose-response information, but there exist toxicity data of a qualitative nature.

Exposure Estimation for all other human health endpoint covered by DNEL or DMEL is performed in context of

risk assessment and set in relation to the respective DNEL/DMEL(s) as shown in the Appendix to section 10. Resulting risk characterization ratios (RCR) are presented in section 10.6.

9.7.2.2 Environment

In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/ vPvB Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) an exposure estimation and risk characterization is not necessary; however a qualitative risk assessment is provided in section 10.

9.8 Uses in cleaning agents – Consumer

9.8.1 Exposure Scenario

Section 1		**Exposure Scenario Title**
Title		Uses in cleaning agents – Consumer, tartaric acid, CAS 87-69-4
Sector of Use (SU code)		21
Use Descriptor (PC codes)		PC35
Processes, tasks, activities covered		Covers general exposures to consumers arising from washing and cleaning products.
Environmental Release Category		ERC 8a
Section 2		**Operational conditions and risk management measures**
Section 2.1		**Control of consumer exposure**
Section 2.1.1		**1. Contributing scenario – Laundry hand wash**
Product characteristics		
Physical form of product		liquid
Vapour pressure		< 5 Pa at 20 °C
Concentration of substance in product		Unless otherwise stated, cover concentrations up to 5%
Amounts used		Unless otherwise stated, covers use amounts up to 7.8g; covers skin contact area up to 35.7 cm2 (finger tips);
Frequency and duration of use/exposure		Unless otherwise stated, covers use frequency up to 4 times Per week; covers exposure up to 1 hour per event
Other Operational Conditions affecting exposure		Unless otherwise stated assumes use at ambient temperatures; assumes use in a 20 m^3 room; assumes use with typical ventilation.
		Product categories
PC 35 washing and cleaning products – laundry hand wash	OC	Unless otherwise stated, covers concentrations up to 15%; covers use up to 2 events/week; covers skin contact area up to 35.7 cm2 (finger tips); for each use event, covers use amounts up to 7.8g (considering 1% wash solution); covers use in room size of 20m3; for each use event, covers exposure up to 1hr/event.
	RMM	Wear suitable gloves
Section 2.1.2		**2. Contributing scenario – Hand dishwashing**
Product characteristics		
Physical form of product		liquid
Vapour pressure		< 5 Pa at 20 °C
Concentration of substance in product		Unless otherwise stated, cover concentrations up to 5%

Amounts used		Unless otherwise stated, covers use amounts up to 3g; covers skin contact area up to 35.7 cm2 (finger tips);
Frequency and duration of use/exposure		Unless otherwise stated, covers use frequency up to2 times per day; covers exposure up to 1 hours per event
Other Operational Conditions affecting exposure		Unless otherwise stated assumes use at ambient temperatures; assumes use in a 20 m^3 room; assumes use with typical ventilation.
		Product categories
PC 35 washing and cleaning products – hand dishwashing	OC	Unless otherwise stated, covers concentrations up to 5%; covers use up to 2 events/day; covers skin contact area up to 35.7 cm2; for each use event, covers use amounts up to 3g; covers use in room size of 20m3; for each use event, covers exposure up to 1hr/event.
	RMM	Wear suitable gloves
Section 2.1.3		**3. Contributing scenario – surface cleaners (powder)**
Product characteristics		
Physical form of product		solid
Vapour pressure		< 5 Pa at 20 °C
Concentration of substance in product		Unless otherwise stated, cover concentrations up to 5%
Amounts used		Unless otherwise stated, covers use amounts up to 20g; covers skin contact area up to 35.7 cm2;
Frequency and duration of use/exposure		Unless otherwise stated, covers use frequency up to 2 times per week; covers exposure up to 1 hour per event
Other Operational Conditions affecting exposure		Unless otherwise stated assumes use at ambient temperatures; assumes use in a 20 m^3 room; assumes use with typical ventilation.
		Product categories
PC 35 washing and cleaning products – surface cleaners (powder)	OC	Unless otherwise stated, covers concentrations up to 1%; covers use up to 2 events/week; covers skin contact area up to 35.7 cm2 (finger tips); for each use event, covers use amounts up to 20g; covers use in room size of 20m3; for each use event, covers exposure up to 1hr/event.
	RMM	Wear suitable gloves.
Section 2.1.4		**3. Contributing scenario – surface cleaners (spray)**
Product characteristics		
Physical form of product		liquid
Vapour pressure		< 5 Pa at 20 °C
Concentration of substance in product		Unless otherwise stated, cover concentrations up to 5%
Amounts used		Unless otherwise stated, covers use amounts up to 5g; covers skin contact area up to 35.7 cm2 (finger tips);
Frequency and duration of use/exposure		Unless otherwise stated, covers use frequency up to 1 times Per week; covers exposure up to 1 hour per event
Other Operational Conditions affecting exposure		Unless otherwise stated assumes use at ambient temperatures; assumes use in a 20 m^3 room; assumes use with typical ventilation.
		Product categories
PC 35 washing and cleaning products – surface cleaners (spray)	OC	Unless otherwise stated, covers concentrations up to 5%; covers use up to 1 events/week; covers skin contact area up to 35.7 cm2 (finger tips); for each use event, covers use amounts up to 5g; covers use in room size of 20m3; for each use event, covers exposure up to 1hr/event.

	RMM	Wear suitable gloves.
Section 2.2		**Control of environmental exposure**
	No exposure assessment presented for the environment.	
3.1. Health		
Health sub-headings		Predicted exposures are not expected to exceed the applicable consumer reference values when the operational conditions/risk management measures given in section 2 are implemented.
Section 4		**Guidance to check compliance with the Exposure Scenario**
4.1. Health		
Health sub-headings		The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated. The "Table of habits and practices for consumer products in Western Europe" Developed by A.I.S.E. (2002) has been used to set the operational condition as listed in section 2.1. The table can be found in the A.I.S.E. web site: ***http://www.aise.eu/reach/?page=exposureass_sub3*** Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Additional good practices (Operational Conditions and Risk Management Measures) beyond the REACH Chemical Safety Assessment established within Chemical Industry are also advised and communicated through Safety Data Sheets but are not necessarily required to control risk as laid out in section 10.6.

9.8.2 Exposure Estimation

9.8.2.1 Human Health

The endpoint for which the available data may trigger a qualitative risk characterization includes eye irritation and is described in section 10. This qualitative CSA approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health endpoint, i.e. when the available data for this effect do not provide quantitative dose-response information, but there exist toxicity data of a qualitative nature.

Exposure Estimation for all other human health endpoint covered by DNEL or DMEL is performed in context of risk assessment and set in relation to the respective DNEL/DMEL(s) as shown in the Appendix to section 10. Resulting risk characterization ratios (RCR) are presented in section 10.6.

9.8.2.2 Environment

In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/ vPvB Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) an exposure estimation and risk characterization is not necessary; however a qualitative risk assessment is provided in section 10.

10. RISK CHARACTERISATION

QUALITATIVE RISK ASSESSMENT OF RISKS FROM EYE IRRITATING SUBSTANCES

Eye damage - Risk of serious damage to eye (R41) QUALITATIVE CSA

The purpose of the qualitative risk characterisation is to assess " the likelihood that effects are avoided when implementing the exposure scenario…" (REACH Annex 1, Section 6.5).

This qualitative Chemical Safety Assessment (CSA) approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health adverse effect, i.e. when the available data for this adverse effect do not provide quantitative dose-response information, but there exist toxicity data appropriate to allow a qualitative risk characterisation. The end points for which the available data may trigger a qualitative risk characterisation includes eye damage (R41).

This general qualitative CSA approach aims to reduce/avoid contact or incidents with the substance. However, implementation of risk management measures (RMMs) and operational conditions (OCs) need to be proportional to the degree of concern for the health hazard presented by the substance. Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.

For eye damage a qualitative risk characterisation was conducted.

A review of these RMMs indicates that if the user complies with the following generic statements, risks due to eye damage can be considered to be adequately controlled; as eye exposure often arises via skin (people rub their eyes with fingers) also skin protection has been taken into account:

The implementation of relevant RMMs will ensure that the likelihood of an event occurring due to the substance hazard of eye irritation is negligible and the risk is considered to be controlled to a level of no concern.

For the eye damage (R41) hazard a qualitative risk characterisation has been conducted consistent with the considerations and risk management measures identified in the Table below.

Solid substance that causes eye damage, classified R41 (Risk of serious damage to eyes) respectively H318 (Causes serious eye damage).

Precautionary Statements	**Components of the Qualitative Risk Assessment**	**PPE**
Prevention: • P280: Wear protective gloves/protective clothing/eye protection/face protection. Response: • P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	• Containment as appropriate; • Minimise number of staff exposed; • Wear gloves (tested to EN374) if direct hand contact with the substance is likely; wash off skin contamination immediately; • Segregation of the emitting process; • Good standard of general ventilation; • Minimization of manual phases; • Avoidance of conctact with contaminated tools and objects; • Regular cleaning of equipment and work area; • Ensure suitable management/supervision is in place to check that the RMMs in place are being used correctly and OCs followed; • Train staff on good practice to prevent / minimise exposures and to report any eye problems that may develop;	• Chemical googles

	• Adopt good standards of personal hygiene.	

QUALITATIVE CHEMICAL RISK ASSESSMENT FOR THE ENVIRONMENT

On the basis of currently available data on physico-chemical properties, environmental fate and behaviour, ecotoxicity and toxicity to humans, the substance has been assessed not to be a PBT or vPvB. In addition, the substance is neither legally classified as 'dangerous for the environment' according to directive 67/548/EEC nor according to Table 3.1 of regulation (EC) No 1272/2008. Consequently, according to REACH regulation (EC) No 1907/2006, Article 14.4, an exposure assessment and risk characterisation for the environment, addressing quantitatively all identified uses of the registrant, is not required.

The purpose of this chapter is to reflect qualitatively the exposure and risk situation in the EU that results from industrial sources of substance production and subsequent uses.

ENVIRONMENTAL DISTRIBUTION AND BEHAVIOUR

Tartaric acid has a high solubility in water. Besides that, the substance has a low log POW and hence sorption to solid mater (soil and sediment) is expected to be low.

PRODUCTION

Aquatic environment

Most production sites are equipped with best available techniques for waste water such as sewage treatment plants that result in the efficient removal of the substance prior to entering natural water resources.

Consequently, release from production is expected to be low and risks are controlled.

Atmosphere

Releases to the atmosphere are expected to be low as major production sites are equipped with risk management measures in order to comply with regulatory requirements for discharges to air.

USES

The major use of the substance is industrial whereas the other main uses are professional and consumer uses in construction and ceramics applications. All such uses release mainly to the waste water stream and due to the very good biodegradability of the substance such waste water can be easily cleaned in industrial or municipal waste water treatment plants. Consequently, release from production is expected to be low and risks are controlled.

Aquatic environment and soil

The substance as such has shown no significant toxicity in acute tests performed with aquatic species. The fish, daphnia, and algae acute aquatic toxicity are greater than 10 mg/l and lower than 100 mg/L (96h LC50 (fish) > 100 mg/L, 48h EC50 (daphnia) = 93.3mg/L, and 72h ErC50 (algae) =51.4 mg/L). As well, the substance is very soluble and ready biodegradable.

As a conclusion from Log Kow of -1.91, it can be stated that the substance has only a very low bioaccumulation potential. Consequently, the substance is not considered to be persistent and will be easily removed from any water stream by microbial activity - this holds true also for biodegradability in sediment as well as soil. Sorption to sediment or soil is considered to be very low according to low log POW data. Hence, it is unlikely that relevant concentration could build up in the environment.

In all cases waste should become collected and recycled whenever technically feasible in accordance with regulations.

Atmosphere

Release to the atmosphere from industrial and large professional sites are expected to comply with regulatory

requirements for discharges to air. Releases from other professional uses and consumer uses are diffuse and expected to be low.

INDIRECT EXPOSURE OF HUMANS VIA THE ENVIRONMENT

Tartaric acid has a low bioaccumulation potential in the environment and is readily biodegradable. The bioconcentration factor for fish is considered to be very low and hence it is not expected that there is a significant exposure for humans or predators via the local environment.

Summary

From the above, it can be seen that tartaric acid presents very little hazard to the aquatic and terrestrial environment. Exposure to the environment is also expected to be low as the largest releases are likely to come from industrial activities, which are controlled by employing standard practices such as reducing emission to air, good housekeeping and discharging to waste water treatment. It can therefore be concluded that under normal circumstances, tartaric acid does not pose a risk to the environment. Indirect exposure of humans via the environment is considered to be negligible.

10.1. Manufacture of Substance – Industrial

10.1.1 Human Health

The following provides an overview on Risk Characterization Ratios (RCR) derived by using the parameters (Control of workers exposure, Operational Conditions and Risk Management measures) as specified in the Section 2.1 of the Exposure scenario in section 9.1.1.

For all calculations the DNELs as described in section 5.11 of this Chemical Safety Report have been used.

Sector of use	PROC/PC	RCR inhalative	RCR dermal	RCR combined
Industrial - SU8/9/3	PROC1 Closed process (no sampling)	0.002	0.118	0.120
Industrial - SU8/9/3	PROC2 Closed continuous process (with sampling)	0.096	0.472	0.569
Industrial - SU8/9/3	PROC3 Closed batch process (with sampling)	0.192	0.118	0.310
Industrial - SU8/9/3	PROC4 batch process with exposure	0.673	0.236	0.909
Industrial - SU8/9/3	PROC8a Non dedicated discharging to/from vessels	0.192	0.473	0.665
Industrial - SU8/9/3	PROC8b Dedicated discharging to/from vessels	0.192	0.473	0.665
Industrial - SU3/ SU10	PROC9 Transfer of chemicals into small containers (dedicated filling line)	0.192	0.473	0.665

A screen of the tool used with all parameters and values can be seen in the Appendix to this section, part 1.

10.1.2 Indirect Exposure of humans via the environment

Indirect exposure of humans to tartaric acid via the environment is considered to be negligible do to the intrinsic properties of tartaric acid (readily biodegradability, no potential for bioaccumulation, non-persistent).

10.2 Formulation & (Re)packing of Substances and Mixtures – Industrial

10.2.1 Human Health

The following provides an overview on Risk Characterization Ratios (RCR) derived by using the parameters (Control of workers exposure, Operational Conditions and Risk Management measures) as specified in the Section 2.1 of the Exposure scenario in section 9.2.1.

For all calculations the DNELs as described in section 5.11 of this Chemical Safety Report have been used.

Sector of use	PROC/PC	RCR inhalative	RCR dermal	RCR combined
Industrial - SU3/ SU10	PROC5 Mixing or blending	0.192	0.473	0.665

Industrial - SU3/ SU10	PROC8a Non-dedicated discharging to/from vessels	0.192	0.473	0.665
Industrial - SU3/ SU10	PROC8b Dedicated discharging to/from vessels	0.192	0.473	0.665
Industrial - SU3/ SU10	PROC9 Transfer of substance/mixture into small containers	0.192	0.473	0.665

A screen of the tool used with all parameters and values can be seen in the Appendix to this section, part 2.

10.2.2 Indirect Exposure of humans via the environment

Indirect exposure of humans to tartaric acid via the environment is considered to be negligible do to the intrinsic properties of tartaric acid (readily biodegradability, no potential for bioaccumulation, non-persistent).

10.3. Use at industrial sites – Intermediate

10.3.1 Human Health

The following provides an overview on Risk Characterization Ratios (RCR) derived by using the parameters (Control of workers exposure, Operational Conditions and Risk Management measures) as specified in the Section 2.1 of the Exposure scenario in section 9.1.1.

For all calculations the DNELs as described in section 5.11 of this Chemical Safety Report have been used.

Sector of use	PROC/PC	RCR inhalative	RCR dermal	RCR combined
Industrial - SU8/9/3	PROC1 Closed process (no sampling)	0.002	0.118	0.120
Industrial - SU8/9/3	PROC2 Closed continuous process (with sampling)	0.096	0.472	0.569
Industrial - SU8/9/3	PROC3 Closed batch process (with sampling)	0.192	0.118	0.310
Industrial - SU8/9/3	PROC4 batch process with exposure	0.673	0.236	0.909
Industrial - SU8/9/3	PROC8a Non dedicated discharging to/from vessels	0.192	0.473	0.665
Industrial - SU8/9/3	PROC8b Dedicated discharging to/from vessels	0.192	0.473	0.665
Industrial - SU3/ SU10	PROC9 Transfer of chemicals into small containers (dedicated filling line)	0.192	0.473	0.665

A screen of the tool used with all parameters and values can be seen in the Appendix to this section, part 1.

10.3.2 Indirect Exposure of humans via the environment

Indirect exposure of humans to tartaric acid via the environment is considered to be negligible do to the intrinsic properties of tartaric acid (readily biodegradability, no potential for bioaccumulation, non-persistent).

10.4 Uses in Construction application –Professional

10.4.1 Human Health

The following provides an overview on Risk Characterization Ratios (RCR) derived by using the parameters (Control of workers exposure, Operational Conditions and Risk Management measures) as specified in the Section 2.1 of the Exposure scenario in section 9.3.1.

For all calculations the DNELs as described in section 5.11 of this Chemical Safety Report have been used.

Sector of use	PROC/PC	RCR inhalative	RCR dermal	RCR combined
Professional - SU22	PROC 8a -Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	0.192	0.473	0.665
Professional - SU22	PROC 8b -Transfer of chemicals from/to vessels/ large containers at dedicated facilities	0.192	0.473	0.665
Professional - SU22	PROC 9 -Transfer of chemicals into small containers (dedicated filling line)	0.192	0.473	0.665

A screen of the tool used with all parameters and values can be seen in the Appendix to this section, part 3.

10.4.2 Indirect Exposure of humans via the environment

Indirect exposure of humans to tartaric acid via the environment is considered to be negligible do to the intrinsic properties of tartaric acid (readily biodegradability, no potential for bioaccumulation, non-persistent).

10.5 Uses in Construction application – Consumer

10.5.1 Human Health

The following provides an overview on Risk Characterization Ratios (RCR) derived by using the parameters (Control of workers exposure, Operational Conditions and Risk Management measures) as specified in the Section 2.1 of the Exposure scenario in section 9.4.1.

For all calculations the DNELs as described in section 5.11 of this Chemical Safety Report have been used.

Sector of use	AC	RCR inhalative	RCR dermal	RCR combined
Consumer - SU21	AC4: stone, plaster, cement	2.50E-02	4.44E-01	4.44E-01

A screen of the tool used with all parameters and values can be seen in the Appendix to this section, part 4.

10.5.2 Indirect Exposure of humans via the environment

Indirect exposure of humans to tartaric acid via the environment is considered to be negligible do to the intrinsic properties of tartaric acid (readily biodegradability, no potential for bioaccumulation, non-persistent).

10.6 Uses in Ceramic application – Professional

10.6.1 Human Health

The following provides an overview on Risk Characterization Ratios (RCR) derived by using the parameters (Control of workers exposure, Operational Conditions and Risk Management measures) as specified in the Section 2.1 of the Exposure scenario in section 9.5.1.

For all calculations the DNELs as described in section 5.11 of this Chemical Safety Report have been used.

Sector of use	PROC/PC	RCR inhalative	RCR dermal	RCR combined
Professional - SU22	PROC 8a -Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	0.192	0.473	0.665
Professional - SU22	PROC 8b -Transfer of chemicals from/to vessels/ large containers at dedicated facilities	0.192	0.473	0.665
Professional - SU22	PROC 9 -Transfer of chemicals into small containers (dedicated filling line)	0.192	0.473	0.665

A screen of the tool used with all parameters and values can be seen in the Appendix to this section, part 5.

10.6.2 Indirect Exposure of humans via the environment

Indirect exposure of humans to tartaric acid via the environment is considered to be negligible do to the intrinsic properties of tartaric acid (readily biodegradability, no potential for bioaccumulation, non-persistent).

10.7 Uses in Ceramic application – Consumer

10.7.1 Human Health

The following provides an overview on Risk Characterization Ratios (RCR) derived by using the parameters (Control of workers exposure, Operational Conditions and Risk Management measures) as specified in the Section 2.1 of the Exposure scenario in section 9.6.1.

For all calculations the DNELs as described in section 5.11 of this Chemical Safety Report have been used.

Sector of use	AC	RCR inhalative	RCR dermal	RCR combined
Consumer - SU21	AC4: ceramic articles	2.60E-01	7.11E-01	9.71E-01

A screen of the tool used with all parameters and values can be seen in the Appendix to this section, part 6.

10.7.2 Indirect Exposure of humans via the environment

Indirect exposure of humans to tartaric acid via the environment is considered to be negligible do to the intrinsic properties of tartaric acid (readily biodegradability, no potential for bioaccumulation, non-persistent).

10.8 Uses in Cleaning agents – Consumer

10.8.1 Human Health

The following provides an overview on Risk Characterization Ratios (RCR) derived by using the parameters (Control of workers exposure, Operational Conditions and Risk Management measures) as specified in the Section 2.1 of the Exposure scenario in section 9.6.1.

For all calculations the DNELs as described in section 5.11 of this Chemical Safety Report have been used.

Sector of use	PC	RCR inhalative	RCR dermal	RCR combined
Consumer - SU21	PC35:Washing and cleaning products (including solvent based products) – Laundry hand wash	6.09E-01	9.92E-02	7.09E-01
Consumer - 21	PC35:Washing and cleaning products (including solvent based products) – Hand dishwashing	5.36E-01	3.97E-01	9.33E-01
Consumer - 21	PC35:Washing and cleaning products (including solvent based products) – Surface cleaners (powder)	9.38E-01	5.95E-03	9.43E-01
Consumer - 21	PC35:Washing and cleaning products (including solvent based products) – surface cleaners - spray	7.81E-01	1.98E-02	8.01E-01

A screen of the tool used with all parameters and values can be seen in the Appendix to this section, part 6.

10.8.2 Indirect Exposure of humans via the environment

Indirect exposure of humans to tartaric acid via the environment is considered to be negligible do to the intrinsic properties of tartaric acid (readily biodegradability, no potential for bioaccumulation, non-persistent).

9.1. Exposure scenario 1: Use at industrial site - Use at industrial site

Environment contributing scenario(s):	
Use at industrial site	ERC 6a
Worker contributing scenario(s):	
Use as laboratory reagent	PROC 15

9.1.1. Environmental contributing scenario 1: Use at industrial site

On the basis of currently available data on physico-chemical properties, environmental fate and behaviour, ecotoxicity and toxicity to humans, the substance has been assessed not to be a PBT or vPvB. In addition, the substance is neither legally classified as 'dangerous for the environment' according to directive 67/548/EEC nor according to Table 3.1 of regulation (EC) No 1272/2008. Consequently, according to REACH regulation (EC) No 1907/2006, Article 14.4, an exposure assessment and risk characterisation for the environment, addressing quantitatively all identified uses of the registrant, is not required.

Table 1. Contribution to oral intake for man via the environment from local contribution

Tartaric acid has a low bioaccumulation potential in the environment and is readily biodegradable. The bioconcentration factor for fish is considered to be very low and hence it is not expected that there is a significant exposure for humans or predators via the local environment.

9.1.2. Worker contributing scenario 1: Use as laboratory reagent (PROC 15)

9.1.2.1. Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: High	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Good general ventilation (3-5 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: No [Effectiveness Dermal: 0%]	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3

9.1.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 2. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**3.5 mg/m³** (TRA Worker v3)	RCR = 0.673
Dermal, systemic, long-term	**0.34 mg/kg bw/day** (TRA Worker v3)	RCR = 0.117
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.79

Conclusion on risk characterisation

Eye damage - Risk of serious damage to eye (R41, H318) QUALITATIVE CSA
The purpose of the qualitative risk characterisation is to assess " the likelihood that effects are avoided when implementing the exposure scenario…" (REACH Annex 1, Section 6.5).
This qualitative Chemical Safety Assessment (CSA) approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health adverse effect, i.e. when the available data for this adverse effect do not provide quantitative dose-response information, but there exist toxicity data appropriate to allow a qualitative risk characterisation. The end points for which the available data may trigger a qualitative risk characterisation includes eye damage.
This general qualitative CSA approach aims to reduce/avoid contact or incidents with the substance. However, implementation of risk management measures (RMMs) and operational conditions (OCs) need to be proportional to the degree of concern for the health hazard presented by the substance. Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.
For eye damage a qualitative risk characterisation was conducted.
A review of these RMMs indicates that if the user complies with the following generic statements, risks due to eye damage can be considered to be adequately controlled; as eye exposure often arises via skin (people rub their eyes with fingers) also skin protection has been taken into account:
The implementation of relevant RMMs will ensure that the likelihood of an event occurring due to the substance hazard of eye irritation is negligible and the risk is considered to be controlled to a level of no concern.
For the eye damage hazard a qualitative risk characterisation has been conducted consistent with the considerations and risk management measures identified below.

Components of the Qualitative Risk Assessment
- Containment as appropriate;
- Minimise number of staff exposed;
- Wear gloves (tested to EN374) if direct hand contact with the substance is likely; wash off skin contamination immediately;
- Segregation of the emitting process;
- Good standard of general ventilation;
- Minimization of manual phases;
- Avoidance of contact with contaminated tools and objects;
- Regular cleaning of equipment and work area;
- Ensure suitable management/supervision is in place to check that the RMMs in place are being used correctly and OCs followed;
- Train staff on good practice to prevent / minimise exposures and to report any eye problems that may develop;
- Adopt good standards of personal hygiene.

PPE
- Chemical googles

9.2. Exposure scenario 2: Use at industrial site - Industrial use in oilfield industries

Sector of use:
SU 2a, Mining, (without offshore industries)
SU 2b, Offshore industries

Environment contributing scenario(s):	
Industrial use in Construction Application	ERC 5
Worker contributing scenario(s):	
Use in closed process, no likelihood of exposure	PROC 1
Use in closed, continuous process with occasional controlled exposure	PROC 2
Use in closed batch process (synthesis or formulation)	PROC 3
Use in batch and other process (synthesis) where opportunity for exposure arises	PROC 4
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	PROC 5
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	PROC 8a
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	PROC 8b
Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	PROC 9
Use as laboratory reagent	PROC 15

9.2.1. Environmental contributing scenario 1: Industrial use in oilfield industries

On the basis of currently available data on physico-chemical properties, environmental fate and behaviour, ecotoxicity and toxicity to humans, the substance has been assessed not to be a PBT or vPvB. In addition, the substance is neither legally classified as ‘dangerous for the environment’ according to directive 67/548/EEC nor according to Table 3.1 of regulation (EC) No 1272/2008. Consequently, according to REACH regulation (EC) No 1907/2006, Article 14.4, an exposure assessment and risk characterisation for the environment, addressing quantitatively all identified uses of the registrant, is not required.

Table 3. Contribution to oral intake for man via the environment from local contribution

Tartaric acid has a low bioaccumulation potential in the environment and is readily biodegradable. The bioconcentration factor for fish is considered to be very low and hence it is not expected that there is a significant exposure for humans or predators via the local environment.

9.2.2. Worker contributing scenario 1: Use in closed process, no likelihood of exposure (PROC 1)

9.2.2.1. Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: High	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Closed system (minimal contact during routine operations)	TRA Worker v3

	Method
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: No [Effectiveness Dermal: 0%]	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3

9.2.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 4. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.01 mg/m³** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, long-term	**0.034 mg/kg bw/day** (TRA Worker v3)	RCR = 0.012
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.014

Conclusion on risk characterisation

Eye damage - Risk of serious damage to eye (R41, H318) QUALITATIVE CSA
The purpose of the qualitative risk characterisation is to assess " the likelihood that effects are avoided when implementing the exposure scenario…" (REACH Annex 1, Section 6.5).
This qualitative Chemical Safety Assessment (CSA) approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health adverse effect, i.e. when the available data for this adverse effect do not provide quantitative dose-response information, but there exist toxicity data appropriate to allow a qualitative risk characterisation. The end points for which the available data may trigger a qualitative risk characterisation includes eye damage.
This general qualitative CSA approach aims to reduce/avoid contact or incidents with the substance. However, implementation of risk management measures (RMMs) and operational conditions (OCs) need to be proportional to the degree of concern for the health hazard presented by the substance. Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.
For eye damage a qualitative risk characterisation was conducted.
A review of these RMMs indicates that if the user complies with the following generic statements, risks due to eye damage can be considered to be adequately controlled; as eye exposure often arises via skin (people rub their eyes with fingers) also skin protection has been taken into account:
The implementation of relevant RMMs will ensure that the likelihood of an event occurring due to the substance hazard of eye irritation is negligible and the risk is considered to be controlled to a level of no concern.
For the eye damage hazard a qualitative risk characterisation has been conducted consistent with the considerations and risk management measures identified below.

Components of the Qualitative Risk Assessment
- Containment as appropriate;
- Minimise number of staff exposed;
- Wear gloves (tested to EN374) if direct hand contact with the substance is likely; wash off skin contamination immediately;
- Segregation of the emitting process;
- Good standard of general ventilation;
- Minimization of manual phases;
- Avoidance of contact with contaminated tools and objects;
- Regular cleaning of equipment and work area;

- Ensure suitable management/supervision is in place to check that the RMMs in place are being used correctly and OCs followed;
- Train staff on good practice to prevent / minimise exposures and to report any eye problems that may develop;
- Adopt good standards of personal hygiene.

PPE

- Chemical googles

9.2.3. Worker contributing scenario 2: Use in closed, continuous process with occasional controlled exposure (PROC 2)

9.2.3.1. Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: High	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Closed continuous process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: No [Effectiveness Dermal: 0%]	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3

9.2.3.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 5. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**1 mg/m³** (TRA Worker v3)	RCR = 0.192
Dermal, systemic, long-term	**1.37 mg/kg bw/day** (TRA Worker v3)	RCR = 0.472
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.665

Conclusion on risk characterisation

Eye damage - Risk of serious damage to eye (R41, H318) QUALITATIVE CSA
The purpose of the qualitative risk characterisation is to assess " the likelihood that effects are avoided when implementing the exposure scenario…" (REACH Annex 1, Section 6.5).
This qualitative Chemical Safety Assessment (CSA) approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health adverse effect, i.e. when the available data for this adverse effect do not provide quantitative dose-response information, but there exist toxicity data appropriate to allow a qualitative risk characterisation. The end points for which the available data may trigger a qualitative risk characterisation includes eye damage.
This general qualitative CSA approach aims to reduce/avoid contact or incidents with the substance. However,

implementation of risk management measures (RMMs) and operational conditions (OCs) need to be proportional to the degree of concern for the health hazard presented by the substance. Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.
For eye damage a qualitative risk characterisation was conducted.
A review of these RMMs indicates that if the user complies with the following generic statements, risks due to eye damage can be considered to be adequately controlled; as eye exposure often arises via skin (people rub their eyes with fingers) also skin protection has been taken into account:
The implementation of relevant RMMs will ensure that the likelihood of an event occurring due to the substance hazard of eye irritation is negligible and the risk is considered to be controlled to a level of no concern.
For the eye damage hazard a qualitative risk characterisation has been conducted consistent with the considerations and risk management measures identified below.

Components of the Qualitative Risk Assessment
- Containment as appropriate;
- Minimise number of staff exposed;
- Wear gloves (tested to EN374) if direct hand contact with the substance is likely; wash off skin contamination immediately;
- Segregation of the emitting process;
- Good standard of general ventilation;
- Minimization of manual phases;
- Avoidance of contact with contaminated tools and objects;
- Regular cleaning of equipment and work area;
- Ensure suitable management/supervision is in place to check that the RMMs in place are being used correctly and OCs followed;
- Train staff on good practice to prevent / minimise exposures and to report any eye problems that may develop;
- Adopt good standards of personal hygiene.

PPE
- Chemical googles

9.2.4. Worker contributing scenario 3: Use in closed batch process (synthesis or formulation) (PROC 3)

9.2.4.1. Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: High	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Closed batch process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: No [Effectiveness Dermal: 0%]	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3

9.2.4.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 6. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**1 mg/m³** (TRA Worker v3)	RCR = 0.192
Dermal, systemic, long-term	**0.69 mg/kg bw/day** (TRA Worker v3)	RCR = 0.238
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.43

Conclusion on risk characterisation

Eye damage - Risk of serious damage to eye (R41, H318) QUALITATIVE CSA
The purpose of the qualitative risk characterisation is to assess " the likelihood that effects are avoided when implementing the exposure scenario…" (REACH Annex 1, Section 6.5).
This qualitative Chemical Safety Assessment (CSA) approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health adverse effect, i.e. when the available data for this adverse effect do not provide quantitative dose-response information, but there exist toxicity data appropriate to allow a qualitative risk characterisation. The end points for which the available data may trigger a qualitative risk characterisation includes eye damage.
This general qualitative CSA approach aims to reduce/avoid contact or incidents with the substance. However, implementation of risk management measures (RMMs) and operational conditions (OCs) need to be proportional to the degree of concern for the health hazard presented by the substance. Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.
For eye damage a qualitative risk characterisation was conducted.
A review of these RMMs indicates that if the user complies with the following generic statements, risks due to eye damage can be considered to be adequately controlled; as eye exposure often arises via skin (people rub their eyes with fingers) also skin protection has been taken into account:
The implementation of relevant RMMs will ensure that the likelihood of an event occurring due to the substance hazard of eye irritation is negligible and the risk is considered to be controlled to a level of no concern.
For the eye damage hazard a qualitative risk characterisation has been conducted consistent with the considerations and risk management measures identified below.

Components of the Qualitative Risk Assessment

- Containment as appropriate;
- Minimise number of staff exposed;
- Wear gloves (tested to EN374) if direct hand contact with the substance is likely; wash off skin contamination immediately;
- Segregation of the emitting process;
- Good standard of general ventilation;
- Minimization of manual phases;
- Avoidance of contact with contaminated tools and objects;
- Regular cleaning of equipment and work area;
- Ensure suitable management/supervision is in place to check that the RMMs in place are being used correctly and OCs followed;
- Train staff on good practice to prevent / minimise exposures and to report any eye problems that may develop;
- Adopt good standards of personal hygiene.

PPE

- Chemical googles

9.2.5. Worker contributing scenario 4: Use in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)

9.2.5.1. Conditions of use

	Method
Product (article) characteristics	

	Method
• Dustiness of material: High	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374) [Effectiveness Dermal: 80%]	TRA Worker v3
• Respiratory Protection: Yes (Respirator with APF of 10) [Effectiveness Inhal: 90%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Outdoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3

9.2.5.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 7. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**1.75 mg/m³** (TRA Worker v3)	RCR = 0.336
Dermal, systemic, long-term	**1.372 mg/kg bw/day** (TRA Worker v3)	RCR = 0.473
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.81

Conclusion on risk characterisation

Eye damage - Risk of serious damage to eye (R41, H318) QUALITATIVE CSA

The purpose of the qualitative risk characterization is to assess " the likelihood that effects are avoided when implementing the exposure scenario…" (REACH Annex 1, Section 6.5).

This qualitative Chemical Safety Assessment (CSA) approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health adverse effect, i.e. when the available data for this adverse effect do not provide quantitative dose-response information, but there exist toxicity data appropriate to allow a qualitative risk characterization. The end points for which the available data may trigger a qualitative risk characterization includes eye damage.

This general qualitative CSA approach aims to reduce/avoid contact or incidents with the substance. However, implementation of risk management measures (RMMs) and operational conditions (OCs) need to be proportional to the degree of concern for the health hazard presented by the substance. Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.

For eye damage a qualitative risk characterization was conducted.

A review of these RMMs indicates that if the user complies with the following generic statements, risks due to eye damage can be considered to be adequately controlled; as eye exposure often arises via skin (people rub their eyes with fingers) also skin protection has been taken into account:

The implementation of relevant RMMs will ensure that the likelihood of an event occurring due to the substance hazard of eye irritation is negligible and the risk is considered to be controlled to a level of no concern.
For the eye damage hazard a qualitative risk characterization has been conducted consistent with the considerations and risk management measures identified below.

Components of the Qualitative Risk Assessment

- Containment as appropriate;
- Minimise number of staff exposed;

- Wear gloves (tested to EN374) if direct hand contact with the substance is likely; wash off skin contamination immediately;
- Segregation of the emitting process;
- Good standard of general ventilation;
- Minimization of manual phases;
- Avoidance of contact with contaminated tools and objects;
- Regular cleaning of equipment and work area;
- Ensure suitable management/supervision is in place to check that the RMMs in place are being used correctly and OCs followed;
- Train staff on good practice to prevent / minimise exposures and to report any eye problems that may develop;
- Adopt good standards of personal hygiene.

PPE

- Chemical googles

9.2.6. Worker contributing scenario 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (PROC 5)

9.2.6.1. Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: High	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• Containment: No	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%]	TRA Worker v3
• Respiratory Protection: Yes (Respirator with APF of 10) [Effectiveness Inhal: 90%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Outdoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3

9.2.6.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 8. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**1.75 mg/m³** (TRA Worker v3)	RCR = 0.336
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.473
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.809

Conclusion on risk characterisation

Eye damage - Risk of serious damage to eye (R41, H318) QUALITATIVE CSA
The purpose of the qualitative risk characterisation is to assess " the likelihood that effects are avoided when implementing the exposure scenario…" (REACH Annex 1, Section 6.5).
This qualitative Chemical Safety Assessment (CSA) approach aims to reduce/avoid contact when there is no basis for

setting a DNEL or DMEL for a certain human health adverse effect, i.e. when the available data for this adverse effect do not provide quantitative dose-response information, but there exist toxicity data appropriate to allow a qualitative risk characterisation. The end points for which the available data may trigger a qualitative risk characterisation includes eye damage.
This general qualitative CSA approach aims to reduce/avoid contact or incidents with the substance. However, implementation of risk management measures (RMMs) and operational conditions (OCs) need to be proportional to the degree of concern for the health hazard presented by the substance. Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.
For eye damage a qualitative risk characterisation was conducted.
A review of these RMMs indicates that if the user complies with the following generic statements, risks due to eye damage can be considered to be adequately controlled; as eye exposure often arises via skin (people rub their eyes with fingers) also skin protection has been taken into account:
The implementation of relevant RMMs will ensure that the likelihood of an event occurring due to the substance hazard of eye irritation is negligible and the risk is considered to be controlled to a level of no concern.
For the eye damage hazard a qualitative risk characterisation has been conducted consistent with the considerations and risk management measures identified below.

Components of the Qualitative Risk Assessment
- Containment as appropriate;
- Minimise number of staff exposed;
- Wear gloves (tested to EN374) if direct hand contact with the substance is likely; wash off skin contamination immediately;
- Segregation of the emitting process;
- Good standard of general ventilation;
- Minimization of manual phases;
- Avoidance of contact with contaminated tools and objects;
- Regular cleaning of equipment and work area;
- Ensure suitable management/supervision is in place to check that the RMMs in place are being used correctly and OCs followed;
- Train staff on good practice to prevent / minimise exposures and to report any eye problems that may develop;
- Adopt good standards of personal hygiene.

PPE
- Chemical googles

9.2.7. Worker contributing scenario 6: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities (PROC 8a)

9.2.7.1. Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: High	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• Containment: No	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with specific activity training) [Effectiveness Dermal: 95%]	TRA Worker v3
• Respiratory Protection: Yes (Respirator with APF of 10) [Effectiveness Inhal: 90%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Outdoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3

	Method
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3

9.2.7.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**3.5 mg/m³** (TRA Worker v3)	RCR = 0.673
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.236
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.91

Conclusion on risk characterisation

Eye damage - Risk of serious damage to eye (R41, H318) QUALITATIVE CSA
The purpose of the qualitative risk characterisation is to assess " the likelihood that effects are avoided when implementing the exposure scenario…" (REACH Annex 1, Section 6.5).
This qualitative Chemical Safety Assessment (CSA) approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health adverse effect, i.e. when the available data for this adverse effect do not provide quantitative dose-response information, but there exist toxicity data appropriate to allow a qualitative risk characterisation. The end points for which the available data may trigger a qualitative risk characterisation includes eye damage.
This general qualitative CSA approach aims to reduce/avoid contact or incidents with the substance. However, implementation of risk management measures (RMMs) and operational conditions (OCs) need to be proportional to the degree of concern for the health hazard presented by the substance. Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.
For eye damage a qualitative risk characterisation was conducted.
A review of these RMMs indicates that if the user complies with the following generic statements, risks due to eye damage can be considered to be adequately controlled; as eye exposure often arises via skin (people rub their eyes with fingers) also skin protection has been taken into account:
The implementation of relevant RMMs will ensure that the likelihood of an event occurring due to the substance hazard of eye irritation is negligible and the risk is considered to be controlled to a level of no concern.
For the eye damage hazard a qualitative risk characterisation has been conducted consistent with the considerations and risk management measures identified below.

Components of the Qualitative Risk Assessment
- Containment as appropriate;
- Minimise number of staff exposed;
- Wear gloves (tested to EN374) if direct hand contact with the substance is likely; wash off skin contamination immediately;
- Segregation of the emitting process;
- Good standard of general ventilation;
- Minimization of manual phases;
- Avoidance of contact with contaminated tools and objects;
- Regular cleaning of equipment and work area;
- Ensure suitable management/supervision is in place to check that the RMMs in place are being used correctly and OCs followed;
- Train staff on good practice to prevent / minimise exposures and to report any eye problems that may develop;
- Adopt good standards of personal hygiene.

PPE
- Chemical googles

9.2.8. Worker contributing scenario 7: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities (PROC 8b)

9.2.8.1. Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: High	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%]	TRA Worker v3
• Respiratory Protection: Yes (Respirator with APF of 10) [Effectiveness Inhal: 90%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Outdoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3

9.2.8.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 10. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**1.75 mg/m³** (TRA Worker v3)	RCR = 0.336
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.473
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.809

Conclusion on risk characterisation

Eye damage - Risk of serious damage to eye (R41, H318) QUALITATIVE CSA
The purpose of the qualitative risk characterisation is to assess " the likelihood that effects are avoided when implementing the exposure scenario…" (REACH Annex 1, Section 6.5).
This qualitative Chemical Safety Assessment (CSA) approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health adverse effect, i.e. when the available data for this adverse effect do not provide quantitative dose-response information, but there exist toxicity data appropriate to allow a qualitative risk characterisation. The end points for which the available data may trigger a qualitative risk characterisation includes eye damage.
This general qualitative CSA approach aims to reduce/avoid contact or incidents with the substance. However, implementation of risk management measures (RMMs) and operational conditions (OCs) need to be proportional to the degree of concern for the health hazard presented by the substance. Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.
For eye damage a qualitative risk characterisation was conducted.
A review of these RMMs indicates that if the user complies with the following generic statements, risks due to eye damage can be considered to be adequately controlled; as eye exposure often arises via skin (people rub their eyes with fingers) also skin protection has been taken into account:
The implementation of relevant RMMs will ensure that the likelihood of an event occurring due to the substance hazard of eye irritation is negligible and the risk is considered to be controlled to a level of no concern.
For the eye damage hazard a qualitative risk characterisation has been conducted consistent with the considerations and risk management measures identified below.

Components of the Qualitative Risk Assessment
- Containment as appropriate;
- Minimise number of staff exposed;
- Wear gloves (tested to EN374) if direct hand contact with the substance is likely; wash off skin contamination immediately;
- Segregation of the emitting process;
- Good standard of general ventilation;
- Minimization of manual phases;
- Avoidance of contact with contaminated tools and objects;
- Regular cleaning of equipment and work area;
- Ensure suitable management/supervision is in place to check that the RMMs in place are being used correctly and OCs followed;
- Train staff on good practice to prevent / minimise exposures and to report any eye problems that may develop;
- Adopt good standards of personal hygiene.

PPE
- Chemical googles

9.2.9. Worker contributing scenario 8: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) (PROC 9)

9.2.9.1. Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: High	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374) [Effectiveness Dermal: 80%]	TRA Worker v3
• Respiratory Protection: Yes (Respirator with APF of 10) [Effectiveness Inhal: 90%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Outdoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3

9.2.9.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 11. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**1.4 mg/m³** (TRA Worker v3)	RCR = 0.269
Dermal, systemic, long-term	**1.372 mg/kg bw/day** (TRA Worker v3)	RCR = 0.473
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.742

Conclusion on risk characterisation

Eye damage - Risk of serious damage to eye (R41, H318) QUALITATIVE CSA

The purpose of the qualitative risk characterisation is to assess " the likelihood that effects are avoided when implementing the exposure scenario…" (REACH Annex 1, Section 6.5).
This qualitative Chemical Safety Assessment (CSA) approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health adverse effect, i.e. when the available data for this adverse effect do not provide quantitative dose-response information, but there exist toxicity data appropriate to allow a qualitative risk characterisation. The end points for which the available data may trigger a qualitative risk characterisation includes eye damage.
This general qualitative CSA approach aims to reduce/avoid contact or incidents with the substance. However, implementation of risk management measures (RMMs) and operational conditions (OCs) need to be proportional to the degree of concern for the health hazard presented by the substance. Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.
For eye damage a qualitative risk characterisation was conducted.
A review of these RMMs indicates that if the user complies with the following generic statements, risks due to eye damage can be considered to be adequately controlled; as eye exposure often arises via skin (people rub their eyes with fingers) also skin protection has been taken into account:
The implementation of relevant RMMs will ensure that the likelihood of an event occurring due to the substance hazard of eye irritation is negligible and the risk is considered to be controlled to a level of no concern.
For the eye damage hazard a qualitative risk characterisation has been conducted consistent with the considerations and risk management measures identified below.

Components of the Qualitative Risk Assessment
- Containment as appropriate;
- Minimise number of staff exposed;
- Wear gloves (tested to EN374) if direct hand contact with the substance is likely; wash off skin contamination immediately;
- Segregation of the emitting process;
- Good standard of general ventilation;
- Minimization of manual phases;
- Avoidance of contact with contaminated tools and objects;
- Regular cleaning of equipment and work area;
- Ensure suitable management/supervision is in place to check that the RMMs in place are being used correctly and OCs followed;
- Train staff on good practice to prevent / minimise exposures and to report any eye problems that may develop;
- Adopt good standards of personal hygiene.

PPE
- Chemical googles

9.2.10. Worker contributing scenario 9: Use as laboratory reagent (PROC 15)

9.2.10.1. Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: High	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Good general ventilation (3-5 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: No [Effectiveness Dermal: 0%]	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3

	Method
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3

9.2.10.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 12. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**3.5 mg/m³** (TRA Worker v3)	RCR = 0.673
Dermal, systemic, long-term	**0.34 mg/kg bw/day** (TRA Worker v3)	RCR = 0.117
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.79

Conclusion on risk characterisation

Eye damage - Risk of serious damage to eye (R41, H318) QUALITATIVE CSA
The purpose of the qualitative risk characterisation is to assess " the likelihood that effects are avoided when implementing the exposure scenario…" (REACH Annex 1, Section 6.5).
This qualitative Chemical Safety Assessment (CSA) approach aims to reduce/avoid contact when there is no basis for setting a DNEL or DMEL for a certain human health adverse effect, i.e. when the available data for this adverse effect do not provide quantitative dose-response information, but there exist toxicity data appropriate to allow a qualitative risk characterisation. The end points for which the available data may trigger a qualitative risk characterisation includes eye damage.
This general qualitative CSA approach aims to reduce/avoid contact or incidents with the substance. However, implementation of risk management measures (RMMs) and operational conditions (OCs) need to be proportional to the degree of concern for the health hazard presented by the substance. Exposures should be controlled to at least the levels that represent an acceptable level of risk, i.e. implementation of the chosen RMMs will ensure that the likelihood of an event occurring due to the hazard of the substance is negligible, and the risk is considered to be controlled to a level of no concern.
For eye damage a qualitative risk characterisation was conducted.
A review of these RMMs indicates that if the user complies with the following generic statements, risks due to eye damage can be considered to be adequately controlled; as eye exposure often arises via skin (people rub their eyes with fingers) also skin protection has been taken into account:
The implementation of relevant RMMs will ensure that the likelihood of an event occurring due to the substance hazard of eye irritation is negligible and the risk is considered to be controlled to a level of no concern.
For the eye damage hazard a qualitative risk characterisation has been conducted consistent with the considerations and risk management measures identified below.

Components of the Qualitative Risk Assessment
- Containment as appropriate;
- Minimise number of staff exposed;
- Wear gloves (tested to EN374) if direct hand contact with the substance is likely; wash off skin contamination immediately;
- Segregation of the emitting process;
- Good standard of general ventilation;
- Minimization of manual phases;
- Avoidance of contact with contaminated tools and objects;
- Regular cleaning of equipment and work area;
- Ensure suitable management/supervision is in place to check that the RMMs in place are being used correctly and OCs followed;
- Train staff on good practice to prevent / minimise exposures and to report any eye problems that may develop;
- Adopt good standards of personal hygiene.

PPE
- Chemical googles

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health

10.1.1. Workers

10.1.2. Consumer

10.2. Environment (combined for all emission sources)

10.2.1. All uses (regional scale)

10.2.1.1. Total releases

On the basis of currently available data on physico-chemical properties, environmental fate and behaviour, ecotoxicity and toxicity to humans, the substance has been assessed not to be a PBT or vPvB. In addition, the substance is neither legally classified as ‘dangerous for the environment’ according to directive 67/548/EEC nor according to Table 3.1 of regulation (EC) No 1272/2008. Consequently, according to REACH regulation (EC) No 1907/2006, Article 14.4, an exposure assessment and risk characterisation for the environment, addressing quantitatively all identified uses of the registrant, is not required.

10.2.1.2. Regional exposure

On the basis of currently available data on physico-chemical properties, environmental fate and behaviour, ecotoxicity and toxicity to humans, the substance has been assessed not to be a PBT or vPvB. In addition, the substance is neither legally classified as ‘dangerous for the environment’ according to directive 67/548/EEC nor according to Table 3.1 of regulation (EC) No 1272/2008. Consequently, according to REACH regulation (EC) No 1907/2006, Article 14.4, an exposure assessment and risk characterisation for the environment, addressing quantitatively all identified uses of the registrant, is not required.

Man via environment

Tartaric acid has a low bioaccumulation potential in the environment and is readily biodegradable. The bioconcentration factor for fish is considered to be very low and hence it is not expected that there is a significant exposure for humans or predators via the local environment.

10.2.2. Local exposure due to all wide dispersive uses

Not relevant, since environmental risk assessment is not required.

10.2.3. Local exposure due to combined uses at a site

Not relevant, since environmental risk assessment is not required.