revision date : 01/06/2017

SAFETY DATA SHEET

in compliance with EC Regulation No. 1907/2006 and EC Regulation No. 830/2015

1 IDENTIFICATION OF SUBSTANCE AND COMPANY

1.1 *PRODUCT IDENTIFIER*

Name of the substance:	L (+) Tartaric Acid (99+%)
Trade name:	Natural Tartaric Acid
CAS Number:	87-69-4 (99+%)
EC Number:	201-766-0
Reach Registration Nr.	01-2119537204-47-0005

1.2 IDENTIFIED RELEVANT USES OF THE SUBSTANCE

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 and acidifier in syrups and antibiotics; 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).

1.3. DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company: Distillerie Mazzari SpA - Via Giardino, 6 48020 S.Agata sul Santerno (RA) – ITALY
Tel. +39 0545 45014 - www.mazzarispa.com - distillerie@mazzarispa.com
Person responsible for the sheet drafting: ivan@mazzarispa.com

1.4. EMERGENCY TELEPHONE NUMBER

+39 0545 45014 - +39 (0)545 915711

2 HAZARDS IDENTIFICATION

2.1. CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification pursuant to EC REG. No. 1272/2008
Causes serious eye damage, Cat.1 H318

2.2. LABEL ELEMENTS

Classification pursuant to EC REG. No. 1272/2008
Hazard pictograms

CORROSION

Signal Word:
Danger

Hazard statements:
H318: Causes serious eye damage

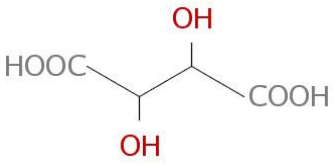
Precautionary statements:
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a POISON CENTER/doctor

2.3. OTHER HAZARDS

No information available.

3 COMPOSITION / INFORMATION ON INGREDIENTS

CAS Number:	87-69-4 (99+%)
IUPAC Name:	Tartaric Acid
CAS Name:	Butanedioic acid, 2,3-dihydroxy- [R-(R,R)]-
EC Number:	201-766-0
Molecular weight:	150.09 g/mol
Formula:	$C_4H_6O_6$
Chemical formula:	HOOCCH(OH)CH(OH)COOH



4 FIRST AID MEASURES

4.1. DESCRIPTION OF FIRST AID MEASURES

Inhalation:	Remove victim from exposure and to open air. Seek medical advice, if necessary.
Skin contact:	Wash off with soap and plenty of water. Take off contaminated garments. If skin irritation persists, consult a specialist.
Eye contact:	Rinse immediately with running water with eyelids held open, for at least 10 minutes. Call an eye specialist, if necessary.
Ingestion:	Make the victim drink plenty of water. Call a doctor, if necessary.

4.2. MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Irritating effects.

4.3. INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

Call a doctor in case of exposure.

5 FIRE FIGHTING MEASURES

5.1. EXTINGUISHING MEDIA

Suitable extinguishing media: Water, CO_2, Foam, Powder.
Extinguishing media not to be used: No limits.

5.2. SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

In case of fire, gas and hazardous vapours may be formed.

5.3. ADVICE FOR FIREFIGHTERS

Protective equipment: Do not stay in the hazardous area without a self-contained breathing apparatus.

6 ACCIDENTAL RELEASE MEASURES

6.1. PERSONAL PRECAUTIONS, PROTECTION DEVICES AND ~~IN CASE OF~~ EMERGENCY PROCEDURES

6.1.1. For non-emergency personnel

Avoid generation of dust, do not inhale dust. Avoid contact with the substance. Ensure the supply of fresh air in closed rooms.

6.1.2. For emergency responders

Personal protective clothing, take note of any information in Section 8 on suitable and unsuitable materials.

6.2. ENVIRONMENTAL PRECAUTIONS

Avoid penetration into the sewerage system.

6.3. METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Collect and place them in a container suitable for recovery. Avoid generation of dust. After collection, flush away traces with water.

6.4. REFERENCE TO OTHER SECTIONS

For instructions on waste treatment, see section 13.

7 HANDLING AND STORAGE

7.1. PRECAUTIONS FOR SAFE HANDLING

Use with adequate ventilation system. Minimise dust generation and accumulation. Avoid contact with eyes, skin and clothing. Keep the container tightly closed. Avoid ingestion and inhalation.

7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Store in a tightly closed container. Store in a fresh and dry area.

7.3. SPECIFIC END USES

See paragraph 1.2

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. CONTROL PARAMETERS

DN(M)ELs for workers

EXPOSURE PATTERN	*ROUTE*	*DESCRIPTOR*	*DNEL / DMEL*	*(CORRECTED) DOSE DESCRIPTOR*
Long-term - systemic effects	Dermal	DNEL (Derived No Effect Level)	2.9 mg/kg bw/day	NOAEL: 145 mg/kg bw/day (based on AF of 50)
Long-term - systemic effects	Inhalation	DNEL (Derived No Effect Level)	5,2 mg/m³	NOAEC: 260.0 mg/m³ (based on AF of 50)

DN(M)ELs for the general population

EXPOSURE PATTERN	*ROUTE*	*DESCRIPTOR*	*DNEL / DMEL*	*(CORRECTED) DOSE DESCRIPTOR*
Long-term - systemic effects	Dermal	DNEL (Derived No Effect Level)	1.5 mg/kg bw/day	NOAEL: 150 mg/kg bw/day (based on AF of 100)
Long-term - systemic effects	Inhalation	DNEL (Derived No Effect Level)	1.3 mg/m³	NOAEC: 130 mg/m³ (based on AF of 100)
Long-term - systemic effects	Oral	DNEL (Derived No Effect Level)	8.1 mg/kg bw/day	NOAEL: 810 mg/kg bw/day (based on AF of 100)

8.2. EXPOSURE CONTROLS

8.2.1*. Appropriate engineering controls*

Ensure adequate ventilation, especially in confined areas.

8.2.2. *Individual protection measures, such as personal protective equipment*

Protective clothing should be selected specifically for the working place and type of work. Take off any contaminated garments. It is advisable to apply protective cream for the skin. Wash hands after handling this substance.

Eyes/face protections

Wear protective goggles against chemicals.

Skin protection

If hands contact is likely to occur, wear suitable gloves tested according to EN374. Suitable gloves and protection garments should be worn.

Respiratory protection

Wear a protective mask in the presence of dust. Use the P2 Filter for solid particles.

8.2.3. Environment exposure controls

Do not pour waste waters directly into the environment.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1. INFORMATION ON THE MAIN PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	White solid crystalline
Colour:	*White*
Odour:	Odourless
Odour threshold:	*No information available*
pH:	2.2 (Solution 0.1 N)
Melting point:	169 °C at 1013 hPa (mbar)
Boiling point:	179.1 °C at 1013 hPa (mbar)
Flash point:	> 100 °C at 102.3 kPa (mbar)
Evaporation rate:	*No information available*
Flammability (solids, gases):	*Non-flammable*
Lower flash point:	*No information available*
Upper flash point:	*No information available*
Vapour pressure:	< 5 Pa at 20 °C
Vapour density:	*No information available*
Relative density (water=1):	1.76 g/cm³ at 20°C
Solubility:	1,390 g/L at 20 °C.
Partition coefficient:	n-Octanol/water: Log Kow (Pow): - 1.91 at 20 °C
Decomposition temperature:	*No information available.*
Viscosity:	*No information available.*
Auto-Flammability in clouds:	*490 °C a 1013 hPa (mbar)*

K_{St} max: *49 bar m/s*
(dP/dt) max – increasing pressure: *182 bar/s*
Auto-Ignition temperature: *No auto-ignition till the test maximum temperature (400 °C)*
Minimum ignition energy: *540 mJ*
Oxidising properties: *Not oxidising.*

9.2. OTHER INFORMATION
No data

10 STABILITY AND REACTIVITY

10.1. REACTIVITY
Stable under normal conditions.

10.2. CHEMICAL STABILITY
The product is chemically stable under standard environmental conditions.

10.3. POSSIBILITY OF HAZARDOUS REACTIONS
Fluorine, metals, silver

10.4. CONDITIONS TO AVOID
Strong heating.

10.5. INCOMPATIBLE MATERIALS
No information available.

10.6. HAZARDOUS DECOMPOSITION PRODUCTS
No information available.

11 TOXICOLOGICAL INFORMATION

11.1. INFORMATION ON TOXICOLOGICAL EFFECTS

ACUTE TOXICITY
Oral: LD50: > 2000 mg/kg bw for rat
Dermal: LD50: > 2000 mg/kg bw for rat
Value used for CSA:
LD50 (oral): 2000 mg/kg bw
LD50 (dermal): 2000 mg/kg bw
Justification for classification or non classification
According to Official Journal of the European Union 1272/2008 (CLP) dated December 16th 2008, tartaric acid is non-classified in the acute toxicity hazard categories. But it is necessary to emphasize that tartaric acid is classified in category 5 of acute oral toxicity in the GHS classification system.

SKIN IRRITATION:
A test of the registered substance was performed on skin irritation/corrosion *in vivo* according to OECD Guideline 404: acute dermal irritation/corrosion in a certified GLP lab. The study can be ranked according to the klimisch code as 1: reliable without restrictions. The results showed that no toxic effect was found. And other two *in vitro* studies also support this result. So the irritating effect of tartaric acid can be concluded as no irritating.
Value used for CSA: Skin irritation / corrosion: not irritating.

EYE IRRITATION:
An in vitro test of the registered substance was performed on eye irritation complying with OECD Guideline 437: Bovine Corneal Opacity and Permeability Test Method for identifying ocular corrosives and severe irritants. This study is regarded as key study as it can be ranked according to the klimisch code as 1: reliable without restrictions. And the test result showed that tartaric acid is highly irritating.
Value used for CSA: Eye irritation: highly irritating

SKIN SENSITISATION
The following information is taken into account for any hazard / risk assessment:
Skin sensitisation (OECD 429): not sensitising.
Value used for CSA: Not sensitising.

RESPIRATORY SENSITISATION
Values used for CSA: No data available.

REPEATED DOSE TOXICITY
NOAEL of repeated oral dose toxicity of tartaric acid is derived from the key study 004 through read across. In this study, Monosodium L(+) -tartrate was fed to rats in their diet for a total of two years at levels of 25600, 42240, 60160 and 76800 ppm and no adverse effect was observed in the highest concentration of L(+) -tartrate. So it is reasonable to choose 76800 ppm tartrate, which is equal to 2460 mg/kg bw/day, as NOAEL of tartaric acid.

Furthermore, in the key study, the test material used was Monosodium L (+) -tartrate, a sodium salt of tartaric acid. It can be served as a read across study, because the basic chemical structures are the same in such two chemicals.
The following information is taken into account for any hazard / risk assessment:
No evidence of an adverse effect was seen in the dose of 3.1 g/kg bw/day and 4.1 g/kg bw/day L(+) -tartrate for male and female rats respectively, corresponding to 2.46 g/kg bw/day and 3.2 g/kg bw/day L(+) -tartaric acid for male and female rats respectively.
Value used for CSA (route: oral):
NOAEL: 2460 mg/kg bw/day (chronic; rat)
Justification for classification or non classification
The DNEL of repeated oral dose toxicity of tartaric acid is 2460 mg/kg bw/day, no specific organ toxicity was found here, so non-classification will be justified.

SINGLE DOSE TOXICITY
No data available

MUTAGENICITY
The FDA report, mutagenic evaluation of compound FDA 71-55, comprises several studies investigating genotoxicity of this substance in vitro and in vivo. In the in vitro studies, 4 host-mediated assays including two bacteria (S. typhimurium) and two yeast (Saccharomyces cerevisiae) tests, and a mammalian chromosome aberration test (Human embryonic lung cultures) were conducted at different concentration levels. In the in vivo studies, two dominant lethal tests and two mammalian bone marrow chromosome aberration tests were carried out in different series of concentrations in rats. No genetic toxicity was found in those tests in all investigated concentrations. So it can be concluded that L(+) -tartaric acid is non-mutagenic.
The following information is taken into account for any hazard / risk assessment: no genetic toxicity of tartaric acid was found through in vitro and in vivo experiments.
Value used for CSA: Genetic toxicity: negative

CARCINOGENICITY
No data available.
Combined chronic Toxicity/Carcinogenicity study equivalent or similar to OECD Guideline 453 is available under repeated dose toxicity.

REPRODUCTIVE TOXICITY
The FDA report, teratologic evaluation of FDA 71-55, summarised studies of the teratogenicity of tartaric acid in different species: mouse, rat, hamster and rabbit, using prenatal developmental toxicity test. It is found that administrations of the highest dosage, 274 mg/kg bw in mice, 181 mg/kg bw in rats, 225 mg/kg bw in hamsters and 215 mg/kg bw in rabbits, did not generate any teratogenic effects on tested animals. So these dose levels could be set as NOAELs in each individual test. In order to guarantee safety, also considering that the toxicokinetics of tartaric acid in rat is well studied, NOAEL of rat is chosen as the dose descriptor starting point for further calculation.
The following information is taken into account for any hazard/risk assessment: The FDA report, teratologic evaluation of FDA 71-55, includes 4 key studies carried out in different species investigating the developmental toxicity/teratogenicity. No teratogenic effect was found in these studies.
Value used for CSA (route: oral): NOAEL: 181 mg/kg bw/day

ASPIRATION HAZARD
No inhalation toxicity classification

12 ECOLOGICAL INFORMATION

12.1 TOXICITY

ACUTE AQUATIC TOXICITY
The fish, daphnia, and algae acute aquatic toxicity levels are greater than 1 mg/L (96h LC50 (fish) > 100 mg/L, 48h EC50 (daphnia) = 93.3mg/L, and 72h ErC50 (algae) =51.4 mg/L). As a result, the substance does not meet the criteria for acute classification according to Regulation (EC) No. 1272/2008, Annex I section 4.1.

CHRONIC AQUATIC TOXICITY
The fish, daphnia, and algae acute aquatic toxicity levels 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, ready biodegradable and has a Log Kow of -1.91. As a result, the substance does not meet the criteria for chronic classification according to Regulation (EC) No. 1272/2008, Annex I section 4.1.

According to Annex XIII of regulation 1907/2006/EC and according to the Guidance on information requirements and chemical safety assessment Chapter R.11 PBT assessment, a substance does not fulfil the criterion if there is no evidence of chronic toxicity and no classification as carcinogenic (Cat. 1, 2), mutagenic (Cat. 1, 2) or toxic

for reproduction (Cat 1, 2, 3) considering human health. As the substance is not toxic and not classified for human health, these criteria are not fulfilled. Furthermore, the substance is not toxic for aquatic organisms.

12.2 PERSISTENCE AND DEGRADABILITY

According to Annex XIII of regulation 1907/2006/EC and according to the Guidance on information requirements and chemical safety assessment Chapter R.11 PBT assessment, a substance does not fulfil the criterion "persistent (P)" and "very persistent (vP)" if it is readily biodegradable. As the substance is shown to be readily biodegradable with a biodegradation of above 80% it is not regarded as persistent or very persistent.

12.3 BIOACCUMULATIVE POTENTIAL

According to Annex XIII of regulation 1907/2006/EC and according to the Guidance on information requirements and chemical safety assessment Chapter R.11 PBT assessment, a substance does not fulfil the criterion "bioaccumulative (B)" or "very bioaccumulative (vB)" if the BCF is below 2000 or the log Kow is below 4.5.
There is no experimental data on BCF. However, the log Kow is negative and below the criterion for bioaccumulation (log Kow 4.5). Therefore, it can be concluded that the substance is neither bioaccumulative nor very bioaccumulative.

12.4 MOBILITY IN SOIL

No data available

12.5 RESULTS OF PBT AND VPVB ASSESSMENT

The substance does not fulfil the criteria for PBT or vPvB properties.

12.6 OTHER ADVERSE EFFECTS

No more data

13 DISPOSAL CONSIDERATIONS

13.1. *WASTE TREATMENT METHODS*

In general, the disposal of chemical residues irregulated in each European country by specific laws and regulations.
In Italy, the disposal must occur according to the laws in force and in compliance with local laws. Therefore, it is recommended to contact the Authorities in charge or specialised Companies authorised to provide indications on how to arrange the disposal.
Packing material must be disposed of in accordance with national regulations. Contaminated packing material must be handled with the same caution used for dangerous substances. Non-contaminated packing material can be treated or recycled as normal residues, unless otherwise indicated.

14 TRANSPORT INFORMATION

14.1. UN Number

Not classified as dangerous goods for transport.

14.2. UN SHIPPING NAME

Not classified as dangerous goods for transport.

14.3. TYPES OF HAZARD RELATED TO TRANSPORT

Road and Railway Transport:
Not classified as dangerous goods for transport.

Sea Transport:
Not classified as dangerous goods for transport.

Air Transport:
Not classified as dangerous goods for transport.

14.4. PACKAGING GROUP

Not classified as dangerous goods for transport.

14.5. ENVIRONMENTAL HAZARDS

Not classified as dangerous goods for transport.

14.6. SPECIAL PRECAUTIONS FOR USERS

Not classified as dangerous goods for transport.

14.7. TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL AND THE IBC CODE

Not classified as dangerous goods for transport.

15 REGULATORY INFORMATION

15.1. SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Authorisation pursuant to REACH Regulations:
It is not on the list of substances of very high concern (SVHC) applicable for the authorisation.

Restrictions on use pursuant to REACH Regulations:
It is not subject to restrictions pursuant to Title VII (Annex XVII, Appendix 2, paragraph 28)

15.2 CHEMICAL SAFETY ASSESSMENT

An assessment of the chemical safety has been carried out

16 OTHER INFORMATION

List of the relevant H hazard indications:
H318: Causes serious eye damage

Instructions on training:
Properly train those workers potentially exposed to this substance on the basis of the contents of this safety data sheet.

Main bibliographical references and data sources:
Registration Dossier of Tartaric Acid

Key of abbreviations and acronyms:
DNEL = Derived No Effect Level
DMEL = Derived Minimum Effect Level
EC50 = Median effective concentration
IC50 = Inhibition concentration, 50%
LC50 = Lethal concentration, 50%
LD50 = Median lethal dose
PNEC = Predicted No-Effect Concentration
PBT = Persistent, Bioaccumulative and Toxic substance
TLV®/TWA = Threshold limit value – time-weighted average
TLV®STEL = Threshold limit value – short-time exposure limit
vPvB = very Persistent and very Bioaccumulative

Revision date:	revision on 01/06/2017
Reason to change the data sheet:	EC Regulation No.830/2015

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.