2014.12.16 felülv.

BIZTONSÁGI ADATLAP

készült az 1907/2006/EK rendeletnek megfelelően azt 453/2010/EK rendeletnek

1 AZ ANYAG ÉS A VÁLLALAT AZONOSÍTÁSA

1.1 *TERMÉKAZONOSÍTÓ*

Az anyag megnevezése: Tartársav (L+) (99+%)
Kereskedelmi megnevezés: Természetes tartársav
Nincs regisztráció Reach: 01-2119537204-47-0005

1.2 AZ ANYAG SZOKÁSOS FELHASZNÁLÁSA

Savasító, antioxidáns, ízfokozó és íz stabilizátor.
Élelmiszeripar (tartósítószerek, lekvárok, zselék és kekszfélék gyártásánál, valamint az édesiparban).
Gyógyszer- és kozmetikai ipar (gyógyszerek, pezsgőtabletták és oldható aszpirin gyártásában, antibiotikum-szirupoknál vivőanyag és savanyítószer természetes arckrémek és testápolók gyártásánál).
Műszaki ipar (gipszkészítésnél késleltetőszer, használják vízálló cementek és hőszigetelő anyagok kialakításánál. Használatos a textiliparban, bőriparban, kerámiaiparban, galvániparban és tisztítószerekben, használják laboratóriumi vegyszerként, a bányászatban és az offshore iparban).

1.3. A BIZTONSÁGI ADATLAP SZÁLLÍTÓJÁNAK ADATAI

Forgalmazó: Kévés Béla Kft.
6230 Soltvadkert, Árpád u. 16.
Tel.: 06 78 481 368 e-mail: bolt@floravita.hu

1.4. SÜRGŐSSÉGI TELEFONSZÁM

Egészségügyi Toxikológiai Tájékoztató Szolgálat H-1096 Budapest, Nagyvárad tér 2.
Tel: +36 80 201-199 (ingyenes, éjjel-nappal hívható szám) +36 1 476-6464, e-mail: ettsz@okbi.antsz.hu

2 VESZÉLYESSÉG SZERINTI BESOROLÁS

2.1. AZ ANYAG VAGY A KEVERÉK OSZTÁLYOZÁSA

1272/2008/EK rendelet szerinti osztályozás
GHS05: maró anyagok
H318: Súlyos szemkárosodást okoz
P280: Védőkesztyű/védőruha/szemvédő/arcvédő használata kötelező.
P305+P351+P338: SZEMBE KERÜLÉS ESETÉN: Óvatos öblítés vízzel több percen keresztül. Adott esetben kontaktlencsék eltávolítása, ha könnyen megoldható. Az öblítés folytatása.

67/54/EGK és 1999/45/EK rendelet szerinti osztályozás
Xi - IRRITATÍV
R41 – súlyos szemkárosodást okozhat
S36/37/39 - megfelelő védőruházatot, védőkesztyűt, és szem-/arcvédőt kell viselni
S26 – Ha szembe jut, bő vízzel azonnal ki kell mosni, és orvoshoz kell fordulni.
A veszély leírásokat és az R mondatok teljes szövegét lásd a 16. szakaszban

2.2. CÍMKÉZÉSI ELEMEK

1272/2008/EK rendelet szerinti osztályozás
Veszélyességi piktogramok

MARÓ ANYAGOK

Avvertenza:
Figyelmeztetés
Veszély

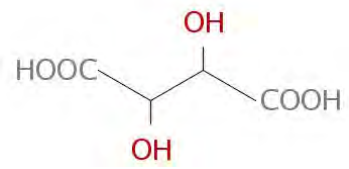
A veszély azonosítása
Súlyos szemkárosodást okoz

Javasolt óvintézkedések
Védőkesztyű/védőruha/szemvédő/arcvédő használata kötelező.
SZEMBE KERÜLÉS ESETÉN: Óvatos öblítés vízzel több percen keresztül. Adott esetben kontaktlencsék eltávolítása, ha könnyen megoldható. Az öblítés folytatása.

2.3. EGYÉB VESZÉLYEK
Nem áll rendelkezésre információ.

3 ÖSSZETÉTEL/AZ ÖSSZETEVŐKRE VONATKOZÓ ADATOK

CAS-szám:	87-69-4 (99+%)
IUPAC név:	Tartársav
CAS név:	Butándisav, 2,3-dihidroxi- [R-(R,R)]-
EK-szám:	201-766-0
Molekulasúly:	150,09 g/mol
Képlet:	$C_4H_6O_6$
Molekuláris képlet:	HOOCCH(OH)CH(OH)COOH



4 ELSŐSEGÉLY-NYÚJTÁSI INTÉZKEDÉSEK

4.1. AZ ELSŐSEGÉLY-NYÚJTÁSI INTÉZKEDÉSEK ISMERTETÉSE

Belélegzés esetén:	A sérültet távolítsuk el az érintett területről, és tartsuk szabad levegőn. Ha szükséges, hívjunk orvost.
Ha bőrre kerül:	Mossuk le bő vízzel és szappannal. Vegyük le a szennyezett ruházatot. Ha az irritáció továbbra is fennáll, forduljunk orvoshoz.
Ha szembe kerül:	Azonnal mossuk, legalább 10 percen át folyóvízzel a szemhéjszélek széthúzásával. Ha szükséges, hívjunk szemorvost.
Lenyelés esetén:	Itassunk a sérülttel sok vizet. Ha szükséges, hívjunk orvost.

4.2. A LEGFONTOSABB – AKUT ÉS KÉSLELTETETT – TÜNETEK ÉS HATÁSOK
Irritáció.

4.3. A SZÜKSÉGES AZONNALI ORVOSI ELLÁTÁS ÉS KÜLÖNLEGES ELLÁTÁS JELZÉSE
Expozíció esetén forduljunk orvoshoz.

5 TŰZVÉDELMI INTÉZKEDÉSEK

5.1. OLTÓANYAG

A megfelelő oltóanyag:	Víz, CO_2, oltóhab, oltópor.
Az alkalmatlan oltóanyag:	Nincs korlátozás.

5.2. AZ ANYAGBÓL VAGY A KEVERÉKBŐL SZÁRMAZÓ KÜLÖNLEGES VESZÉLYEK
Tűz esetén veszélyes gázok és gőzök képződhetnek.

5.3. TŰZOLTÓKNAK SZÓLÓ JAVASLAT

Védőfelszerelés:	Ne tartózkodjunk a veszélyes zónában önlélegző készülék nélkül.

6 INTÉZKEDÉSEK VÉLETLENSZERŰ EXPOZÍCIÓNÁL

6.1. SZEMÉLYI ÓVINTÉZKEDÉSEK, EGYÉNI VÉDŐESZKÖZÖK ÉS VÉSZHELYZETI ELJÁRÁSOK
Kerüljük el a porképződést, és ne lélegezzük be a keletkező port. Kerüljük az anyaggal való érintkezést. Zárt helyiségekben biztosítsuk a friss levegő bejutását.

6.2. KÖRNYEZETVÉDELMI ÓVINTÉZKEDÉSEK
Ne engedjük meg, hogy az anyag a csatornába kerüljön.

6.3. A TERÜLETI ELHATÁROLÁS ÉS A SZENNYEZÉS-MENTESÍTÉS MÓDSZEREI ÉS ANYAGAI
Gyűjtsük be, és a visszanyeréshez megfelelő tartályban tároljuk. Kerüljük a porképzést. Az összegyűjtést követően az esetleges maradványokat vízzel tisztítsuk.

6.4. HIVATKOZÁS MÁS SZAKASZOKRA
Hulladékkezelési információk, lásd a 13. szakaszt.

7 KEZELÉS ÉS TÁROLÁS

7.1. A BIZTONSÁGOS KEZELÉSRE IRÁNYULÓ ÓVINTÉZKEDÉSEK

Megfelelő elszívó rendszerrel. Korlátozzuk a porképződést. Kerüljük az anyag szembe, bőrre, vagy ruhára kerülését. A tartályt tároljuk légmentesen lezárva. Kerüljük az anyag lenyelését és belélegzését.

7.2. A BIZTONSÁGOS TÁROLÁS FELTÉTELEI, AZ ESETLEGES ÖSSZEFÉRHETETLENSÉGGEL EGYÜTT

Jól lezárva. Friss levegőjű, száraz helyen.

7.3. MEGHATÁROZOTT VÉGFELHASZNÁLÁS (VÉGFELHASZNÁLÁSOK)

Lásd az 1.2 pontot

8 AZ EXPOZÍCIÓ ELLENŐRZÉS/EGYÉNI VÉDELEM

8.1. ELLENŐRZÉSI PARAMÉTEREK:

DN(M)EL-ek a dolgozók számára

EXPOZÍCIÓS MINTÁZAT	*ÚT*	*LEÍRÁS*	*DNEL / DMEL*	*(HELYESBÍTETT) DÓZIS LEÍRÁS*
Hosszútávú – általános hatások	Bőrön át	DNEL (Származtatott hatásmentes szint)	2.9 mg/tt kg/nap	NOAEL: 145 mg/tt kg/nap (50-es AF-et alapul véve)
Hosszútávú – általános hatások	Belégzés	DNEL (Származtatott hatásmentes szint)	5,2 mg/m³	NOAEC: 260.0 mg/m³ (50-es AF-et alapul véve)

DN(M)EL-ek a lakosság számára

EXPOZÍCIÓS MINTÁZAT	*ÚT*	*LEÍRÁS*	*DNEL / DMEL*	*(HELYESBÍTETT) DÓZIS LEÍRÁS*
Hosszútávú – általános hatások	Bőrön át	DNEL (Származtatott hatásmentes szint)	1,5 mg/tt kg/nap	NOAEL: 150 mg/tt kg/nap (100-as AF-et alapul véve)
Hosszútávú – általános hatások	Belégzés	DNEL (Származtatott hatásmentes szint)	1,3 mg/m³	NOAEC: 130 mg/m³ (100-as AF-et alapul véve)
Hosszútávú – általános hatások	Szájon át	DNEL (Származtatott hatásmentes szint)	8,1 mg/tt kg/nap	NOAEL: 810 mg/tt kg/nap (100-as AF-et alapul véve)

8.2. AZ EXPOZÍCIÓ ELLENŐRZÉSE

8.2.1. ***Megfelelő műszaki ellenőrzés***

Gondoskodjunk a megfelelő szellőzésről, különösen zárt helyen.

8.2.2. ***Egyéni óvintézkedések***

A védőruházatot a hely és a munka típusa szerint kell megválasztani. Vegyük le az esetleges szennyezett ruházatot. Javasoljuk a bőr krémmel történő védelmét. Az anyaggal folytatott munkavégzést követően mossunk kezet.

Szem-/arcvédelem

Használjunk vegyszer elleni védő szemüveget.

Kézvédelem

Olyan helyzetben, amikor az anyag a kézzel érintkezhet, viseljünk az EN374 szerint tesztelt megfelelő kesztyűt. Megfelelő védőkesztyűt és védőruházatot kell használni.

Légutak védelme

Amikor por keletkezik, használjunk védőmaszkot. Használjunk P2 szilárd részecske szűrőt.

8.2.3. Környezeti expozíció-ellenőrzések

A szennyvizet ne engedjük ki közvetlenül a környezetbe.

9 FIZIKAI ÉS KÉMIAI TULAJDONSÁGOK

9.1. AZ ALAPVETŐ FIZIKAI ÉS KÉMIAI TULAJDONSÁGOKRA VONATKOZÓ INFORMÁCIÓ

Halmazállapot:	Szilárd fehér kristály
Szín:	*Fehér*
Szag:	Szagtalan
Szagküszöbérték:	*Nem áll rendelkezésre információ*
pH:	2,2 Solution 0,1 N
Olvadáspont:	169 °C 1013 hPa-nál
Forráspont:	179,1 °C 1013 hPa (mbar)-nál

Gyulladáspont:	> 100 °C 102,3 kPa (mbar)-nál
Párolgási sebesség:	*Nem áll rendelkezésre információ*
Gyúlékonyság (szilárd, gáz):	*Nem gyúlékony*
Gyúlékonyság alsó határa:	*Nem áll rendelkezésre információ*
Gyúlékonyság felső határa:	*Nem áll rendelkezésre információ*
Gőznyomás:	< 5 Pa 20 °C-on
Gőzsűrűség:	*Nem áll rendelkezésre információ*
Relatív sűrűség (víz=1):	1,76 g/cm^3 20°C-on
Oldékonyság:	1.390 g/l 20 °C-on.
Megoszlási hányados:	n-oktanol/víz: Log Kow (Pow): -1,91 20 °C-on
Öngyulladási hőmérséklet:	375 °C 1.013 hPa-nál
Bomlási hőmérséklet:	*Nem áll rendelkezésre információ*
Viszkozitás:	*Nem áll rendelkezésre információ*
Robbanásveszélyes tulajdonságok:	*Nem robbanásveszélyes.*
Oxidáló tulajdonságok:	*Nem oxidáló.*

10 STABILITÁS ÉS REAKCIÓKÉSZSÉG

10.1. REAKCIÓKÉSZSÉG
Normál körülmények között stabil.

10.2. KÉMIAI STABILITÁS
A termék normál környezeti feltételek között kémiailag stabil.

10.3. A VESZÉLYES REAKCIÓK LEHETŐSÉGE
Fluór, fémek, ezüst

10.4. KERÜLENDŐ KÖRÜLMÉNYEK
Erős melegítés.

10.5. NEM ÖSSZEFÉRHETŐ ANYAGOK
Nem áll rendelkezésre információ

10.6. VESZÉLYES BOMLÁSTERMÉKEK
Nem áll rendelkezésre információ

11 TOXIKOLÓGIAI ADATOK

11.1. A TOXIKOLÓGIAI HATÁSOKRA VONATKOZÓ INFORMÁCIÓ

Akut toxicitás

Szájon át: LD50: > 2000 mg/tt kg patkány számára
Bőrön át: LD50: > 2000 mg/tt kg patkány számára
CSA-hoz használt értékek:
LD50 (szájon át): 2000 mg/tt kg
LD50 (bőrőn át): 2000 mg/tt kg
A besorolás vagy be nem sorolás indoklása
Az Európai Unió Hivatalos Lapja 1272/2008 (CLP) 2008 December 16-i kiadása szerint a tartársav nem tartozik az akut toxicitás veszélyességi kategóriába. Ellenben hangsúlyozni kell, hogy a tartársav a GHS osztályozási rendszerben az akut orális toxicitás 5. kategóriájába tartozik.

BŐRIRRITÁCIÓ:

A regisztrált anyag *in vivo* bőrirritációs/korróziós tesztjét az OECD 404-es irányelvének megfelelően hajtották végre: akut bőrirritáció/korrózió hiteles GLP laboratóriumban. A tanulmányt az 1-es klimisch kód hatálya alá tartozónak lehet tekinteni: fenntartás nélkül megbízható. Az eredmények szerint toxikus hatás nem volt észlelhető. Két másik *in vitro* tanulmány is megerősítette ezt az eredményt. Tehát a tartársav irritatív hatását nem irritálónak lehet tekinteni.
CSA-hoz használt értékek: Bőrirritáció/korrózió: nem irritáló.

SZEMIRRITÁCIÓ:

A regisztrált anyag in vitro szemirritációs tesztjét az OECD 437-es irányelvének megfelelően hajtották végre: Szarvasmarha-szaruhártya opacitásának és permeabilitásának mérésén alapuló vizsgálati módszer a szemkorróziót és a súlyos szemirritációt okozó anyagok azonosítására. A tanulmányt az 1-es klimisch kód hatálya alá tartozónak és kulcs tanulmánynak tekintjük: fenntartás nélkül megbízható. És a teszteredmény szerint a tartársav erősen irritáló hatású.
CSA-hoz használt értékek: Szemirritáció: erősen irritáló

BŐRSZENZIBILIZÁCIÓ

A következő információt kell tekintetbe venni bármely veszély / kockázatmegítélésnél:
Bőrszenzitizáció (OECD 429): nem szenzitizáló.
CSA-hoz használt értékek: nem szenzitizáló.

LÉGZŐSZERVI SZENZIBILIZÁCIÓ

CSA-hoz használt értékek. Nincs rendelkezésre álló adat.

ISMÉTELT DÓZISÚ TOXICITÁS

A tartársav ismételt orális dózisú toxicitása a 004-es kulcstanulmányból vezethető le interpolációval. Ebben a tanulmányban Monoszódium L(+)-tartrátot etettek patkányokkal rendes étrendjük részeként két évig, 25600, 42240, 60160 és 76800 ppm-es mennyiségben, és az L(+)-tartrát legmagasabb koncentrációjánál sem volt káros hatás tapasztalható. Ezért ésszerű a 76800 ppm-es tartrátot, ami egyenlő 2460 mg/tt kg/nappal, a tartársav NOAEL-jének választani. Továbbá a kulcstanulmányban a tesztanyag Monoszódium L (+) –tartrát volt, a tartársav nátriummmal képzett sója. Használható interpoláció alapjául szolgáló tanulmánynak, mivel a két vegyi anyag alapvető kémiai felépítése azonos.
A következő információt kell tekintetbe venni bármely veszély / kockázatmegítélésnél:
Nem tapasztaltak káros hatást nőstény és hím patkányoknál 3.1 g/tt kg/nap és 4.1 g/tt kg/nap L(+) –tartrát dózis esetén, amely 2.46 g/tt kg/nap és 3.2 g/tt kg/nap L(+) –tartársavnak felel meg.
CSA-hoz használt értékek: (bevitel: szájon át):
NOAEL: 2460 mg/tt kg/nap (krónikus; patkány)
A besorolás vagy be nem sorolás indoklása
A tartársav ismételt orális dózisú toxicitásának DNEL-je 2460 mg/tt kg/nap, specifikus szervi toxicitás nem volt észlelhető, ezért a be nem sorolás indokolt.

MUTAGENITÁS

Az FDA 71-55 vegyület mutagenikus kiértékeléséről szóló FDA jelentés több tanulmányból áll, melyek a szóban forgó anyag genotoxicitását in vitro és in vivo körülmények közt vizsgálják. Az in vitro tanulmányokban 4 host-mediated assay-t végeztek, kettő teszt készült baktériumokkal (S. typhimurium) és kettő élesztőgombával (Saccharomyces cerevisiae), valamint egy emlős kromoszómaaberrációs tesztet (emberi embrionikus tüdőszövettel) folytattak le, különböző koncentrációs szinteken. Az in vivo tanulmányok közül két domináns halálozási tesztet és két emlős csontvelő kromoszómaaberrációs tesztet végeztek különböző koncentrációk sorozataival patkányokon. Egyik vizsgált koncentráció esetében sem találtak genetikus toxicitást. Így levonható a következtetés, hogy az L(+) –tartársav nem mutagenikus.
A következő információt kell tekintetbe venni bármely veszély / kockázatmegítélésnél: in vitro és in vivo kísérletek során nem találták nyomát a tartársav genetikus toxicitásának.
CSA-hoz használt értékek: Genetikus toxicitás: negatív

RÁKKELTŐ HATÁS

Nincs rendelkezésre álló adat.
Az OECD 453-as irányelvéhez hasonló, vagy azzal megegyező kombinált krónikus toxicitás/karcinogenicitás tanulmány megtalálható az ismételt dózisú toxicitás alatt.

REPRODUKCIÓS TOXICITÁS

Az FDA 71-55 teratológiai kiértékeléséről szóló FDA jelentés több tanulmány összegzése, melyek a tartársav teratogenicitását különböző fajokban vizsgálják: egér, patkány, hörcsög és nyúl, születés előtti fejlődési toxicitás teszt használatával. Az eredmények szerint a legnagyobb adagú dózis, egereknél 274 mg/tt kg, patkányoknál 181 mg/tt kg, hörcsögöknél 225 mg/tt kg, és nyulaknál 215 mg/tt kg, beadása esetén sem keletkeztek a tesztállatokban teratogenikus hatások. Ezért ezeket a szinteket meg lehet határozni, mint az egyes tesztek NOAEL-jei. A biztonságosság biztosítása érdekében, tekintetbe véve azt is, hogy a tartársav toxikokinetikája patkányokban alaposan kutatott területnek számít, a patkány NOAEL-jét választottuk a további számításokhoz dózisleíró kezdőpontnak.
A következő információt kell tekintetbe venni bármely veszély / kockázatmegítélésnél: Az FDA 71-55 teratológiai kiértékeléséről szóló FDA jelentés 4 kulcstanulmányt tartalmaz, melyekben különböző fajokon vizsgálták a fejlődési toxicitást/teratogenicitást. A tanulmányokban nem találtak teratogenikus hatást.
CSA-hoz használt értékek: (bevitel: szájon át): NOAEL: 181 mg/tt kg/nap

ASPIRÁCIÓ VESZÉLY

Nincs aspirációs toxicitási besorolás.

12 ÖKOLÓGIAI INFORMÁCIÓK

12.1 TOXICITÁS

AKUT VÍZBELI TOXICITÁS

A halakkal, vízibolhákkal és algákkal szembeni akut vízbeli toxicitás nagyobb, mint 1 mg/l (96h LC50 (halak) > 100 mg/l, 48h EC50 (vízibolhák) = 93.3mg/l, és 72h ErC50 (algák) =51.4 mg/l). Ennek eredményeképp az

anyag nem felel meg az akut besorolás követelményeinek az 1272/2008/EK Rendelet I. Melléklet 4.1. szakasza szerint.

KRÓNIKUS VÍZBELI TOXICITÁS

A halakkal, vízibolhákkal és algákkal szembeni akut vízbeli toxicitás nagyobb, mint 10 mg/l és alacsonyabb, mint 100 mg/l (96h LC50 (halak) > 100 mg/l, 48h EC50 (vízibolhák) = 93.3mg/l, és 72h ErC50 (algák) =51.4 mg/l). Ezen felül az anyag nagyon oldékony, biológiailag könnyen lebomló, és Log Kow-ja -1.91. Ennek eredményeképp az anyag nem felel meg az krónikus besorolás követelményeinek az 1272/2008/EK Rendelet I. Melléklet 4.1. szakasza szerint.

12.2 PERZISZTENCIA ÉRTÉKELÉS

Az 1907/2006/EK rendelet XIII. Melléklete és az Útmutató a tájékoztatási követelményekhez és a kémiai biztonsági értékeléshez R.11 PBT értékelés fejezete alapján egy anyag nem felel meg a „perzisztens (P)" és „nagyon perzisztens (vP)" kritériumoknak ha biológiailag könnyen lebomló. Mivel az anyag bizonyítottan biológiailag könnyen lebomló, 80% fölötti biodegradációval, nem tekinthető perzisztensnek vagy nagyon perzisztensnek.

12.3 BIOAKKUMULÁCIÓS ÉRTÉKELÉS

Az 1907/2006/EK rendelet XIII. Melléklete és az Útmutató a tájékoztatási követelményekhez és a kémiai biztonsági értékeléshez R.11 PBT értékelés fejezete alapján egy anyag nem felel meg a „bioakkumulatív (B)" és „nagyon bioakkumulatív (nB)" kritériumoknak ha BCF-e 2000 alatt van vagy log Kow-ja 4.5 alatt van.

A BCF-et illetően nincs kísérleti adat. Ugyanakkor a log Kow negatív, és a bioakkumuláció kritériuma alatt van (log Kow 4.5). Így levonható a következtetés, hogy az anyag nem bioakkumulatív vagy nagyon bioakkumulatív.

12.4 TOXICITÁS ÉRTÉKELÉS

Az 1907/2006/EK rendelet XIII. Melléklete és az Útmutató a tájékoztatási követelményekhez és a kémiai biztonsági értékeléshez R.11 PBT értékelés fejezete alapján egy anyag nem felel meg a kritériumnak, ha nincs bizonyíték krónikus toxicitására és nincs az emberi egészségre nézve karcinogénként, (1.,2. kategória), mutagénként (1., 2. kategória) vagy a reprodukciót károsítóként (1., 2., 3. kategória) besorolva. Mivel az anyag nem mérgező és nincs az emberi egészségre károsként besorolva, ezek a kritériumok nem teljesülnek. Ezen felül az anyag vízi organizmusok számára sem toxikus.

12.5 ÖSSZEFOGLALÁS ÉS VÉGSŐ KÖVETKEZTETÉSEK A PBT-RŐL VAGY A VPVB-RŐL

Az anyag nem felel meg a PBT vagy vPvB tulajdonságok kritériumainak.

12.6 KIBOCSÁTÁS JELLEMZŐK

Mivel az anyag nem felel meg a PBT vagy vPvB tulajdonságok kritériumainak, nincs szükség kibocsátási kiértékelésre.

13 ÁRTALMATLANÍTÁSI SZEMPONTOK

13.1. HULLADÉKKEZELÉSI MÓDSZEREK

A kémiai maradványanyagok ártalmatlanítását általában az egyes EK országokban specifikus törvények és rendeletek szabályozzák.

Olaszországban az ártalmatlanítás a hatályos jogszabályok szerint és a helyi törvényeknek megfelelően kell történjen. Javasoljuk, hogy vegyék fel a kapcsolatot az illetékes hatóságokkal vagy a felhatalmazott szakcégekkel, akik tájékoztatást tudnak adni az ártalmatlanítás módjáról.

A csomagolóanyagok ártalmatlanítása a nemzeti jogszabályok szerint kell történjen. A szennyezett csomagolóanyagokat ugyanolyan gondosan kell kezelni, mint a veszélyes anyagokat. A nem szennyezett csomagolóanyagok, amennyiben eltérő szabályozás nem érvényes, normál hulladékként kezelhetők és újrahasznosíthatók.

14 SZÁLLÍTÁSRA VONATKOZÓ INFORMÁCIÓK

KÖZÚTI/VASÚTI SZÁLLÍTÁS ADR/RID

Az anyag szállítás szempontjából nincs veszélyes termékként besorolva.

TENGERI SZÁLLÍTÁS IMDG

Az anyag szállítás szempontjából nincs veszélyes termékként besorolva.

LÉGI SZÁLLÍTÁS ICAO ÉS IATA

Az anyag szállítás szempontjából nincs veszélyes termékként besorolva.

15 SZABÁLYOZÁSSAL KAPCSOLATOS INFORMÁCIÓK

15.1. AZ ANYAGGAL KAPCSOLATOS BIZTONSÁGI, EGÉSZSÉGÜGYI ÉS KÖRNYEZETVÉDELMI ELŐÍRÁSOK/JOGSZABÁLYOK

A REACH rendelet szerinti engedélyezés:
Nem szerepel az engedélyköteles különösen aggályos anyagok (SVHC) listáján

A REACH rendelet szerinti felhasználás korlátozás:
A VIII. Cím (XVII. Melléklet, 2. Függelék, 28. pont) értelmében nem esik korlátozás alá.

15.2 KÉMIAI BIZTONSÁGI ÉRTÉKELÉS
A kémiai biztonsági értékelés el lett végezve.

16 EGYÉB INIFORMÁCIÓK

A vonatkozó H mondatok felsorolása:
H318: Súlyos szemkárosodást okoz

A vonatkozó R mondatok felsorolása:
R41 – súlyos szemkárosodást okozhat

EXPOZÍCIÓS KIÉRTÉKELÉS
A tartársav expozíciós forgatókönyveinek áttekintése EF # Expozíciós forgatókönyv

1 Az anyag gyártása - ipari
2 Készítmény és (Újra)csomagolt anyagok és keverékek - ipari
3 Az anyag ipari felhasználása - köztes
4 Felhasználás építőipari területen - szakmai
5 Felhasználás építőipari területen - fogyasztói
6 Felhasználás kerámiagyártásban - szakmai
7 Felhasználás kerámiagyártásban területen - fogyasztói
8 Felhasználása tisztítószerekben - fogyasztói

Oktatásra vonatkozó információk:
A potenciálisan az anyagnak kitett dolgozókat a jelen biztonsági adatlap tartalma alapján megfelelő oktatásban kell részesíteni.

A legfontosabb szakirodalmi hivatkozások és adatforrások:
Természetes tartársav regisztrációs dosszié

A rövidítések és betűszók feloldása:
DNEL = Származtatott hatásmentes szint
DMEL = Származtatott minimális hatású szint
EC50 = Effektív koncentráció
IC50 = Gátló koncentráció, 50%
LC50 = Halálos koncentráció, 50%
LD50 = Közepes halálos dózis
PNEC = Becsült hatásmentes koncentráció
PBT = Perzisztens, bioakkumulatív és mérgező anyag
TLV®TWA = Küszöbérték korlát – idővel súlyozott átlag
TLV®STEL = Küszöbérték korlát – rövididejű expozíciós korlát
vPvB = nagyon perzisztens és nagyon bioakkumulatív

Felülvizsgálat időpontja: 2014.12.16 sz. felülv.
A biztonsági adatlap készítésének oka: az expozíciós előírások frissítése (mellékelve)

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.