

Cefic/DUCC Workshop on Exposure Scenarios Brussels ,21 October 2011

12:30 → 12:45 Example 3 “Distributors” uses (formulating)

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Refreshing chemical distribution

Exposure Scenario citric acid

- SDS check List for ES :
 - ❖ Is substance **registered** under REACH ?
 - ❖ Is the substance **classified** as hazardous?
 - ❖ Have sections of the main part of the SDS been modified ?
 - ❖ Is your **use covered** ? See **ES title** and **Use description**
 - ❖ If use covered → are **OCs and RMMs** appropriate for environnement and **human health**?

Is substance registered under REACH ?

1.1 Product identifier:

Identification on the label/Trade name:

Citric acid

Additional identification:

2-hydroxy-1,2,3-propanetricarboxylic acid

Identification of the product:

CAS#77-92-9; EC#201-069-1

Index Number:

Not available

REACH registration No.:

01 XXXXXXXXXX

Is the substance classified as hazardous?

2.1.1 Classification:

The substance is classified as following according to 67/548/EEC and REGULATION (EC) No 1272/2008:

EU CLP 1272/2008	
Hazard classes/Hazard categories	Hazard statement
Eye Irrit. 2	H319

For full text of H- phrases: see section 2.2.

67/548/EEC	
Hazards characteristics	R-Phrases
Xi	R36

For full text of R- phrases: see section 16.

Have sections of the main part of the SDS been modified ?

8 Exposure control/personal protection

8.1 Control parameters:

8.1.1 Occupational exposure limits: Not listed.

8.1.2 Additional exposure limits under the conditions of use: Not available.

8.1.3 DNEL/DMEL and PNEC-Values: Not available.

9 Physical and chemical properties


11 Toxicological information

Is your use covered ? See ES title and Use description

1.2 Relevant identified uses of the substance and uses advised against:

1.2.1 Identified uses:

Use as an intermediate in the production of other organic chemicals.

 Formulation into preparations.

Use in personal care products.

Use in detergent/cleaning and other household products.

Use in paper making.

Use in construction products

Use in polymers and plastics products.

Use in the oil industry.

Use in the textile industry.

Use in paints and coatings.

Use in photography products.

Use in laboratory reagents.

Use in water treatment.

Use in the treatment of metal surfaces.

Use in agricultural applications.

Use in medical devices

Is your use covered ? See ES title and Use description

Substance / User identity		
Registration number(s)	01- [REDACTED]	
Substance identity	CAS#77-92-9; EC#201-069-1	
1	Short title of the exposure scenario	<u>3. Formulation of citric acid into preparations</u>
	Processes and activities covered by the exposure scenario	<u>SU3, 10, SU5, SU13, 20</u> PROC2, PROC3, PROC4, <u>PROC5</u> , PROC7, PROC8a, PROC8b, PROC9, PROC13, PROC14, PROC15, PROC19

EX: « I am using citric acid in preparations, with significant contact at any stage »

1. Short Title OK
2. Check « SU » : OK « SU3 » more accurate « SU 10 »
3. Check « PROC » : OK « PROC 5 »

Are OCs and RMMs appropriate for human health?

2	<u>Operational conditions and risk management measures</u>	
	Duration an frequency of use	
	Worker <u>All applicable PROCs</u>	<u>>4h</u>
	Physical form of substance:	solid
	Concentration of substance in preparation or article	
	Other relevant operational conditions of use	<p>The citrates used in the formulation of products are generally solids which may be mixed with other solids or dissolved in aqueous solution. There is some potential for airborne release of citric acid (or citrate) particulates on charging (transfer, dosing) to the process equipment used, especially if containment is not good. However, the most likely release will be to waste water via clean out or spillage.</p> <p>Taking the HERA figure of approx. 100 000 tpa [HERA, 2005] for total use of citrates in detergents, and realistic values of 10% formulated in a single region, and 60% of that at a single location, gives a volume of 6,000 tpa citrates formulated at a single location.</p> <p>For this generic site, the daily loss rate to waste water is $6000 \text{ t} \times 1000 \text{ kg/t} \times 0.0009 / 300 \text{ d} = 18 \text{ kg/d}$.</p> <p>The tonnage to be covered is now 150 000 tpa, but the site size is retained. The loss rate is considered to be a reasonable worst case for a large site. At smaller formulation sites the amount handled per day would be lower and the controls could be less, but overall rates per day would be similar.</p>

My « PROC5 » is here covered
 « > 4h » : duration of
 exposure on a day in safe
 conditions

Are OCs and RMMs appropriate for human health?

Risk management measures:				
2.1	Control of worker exposure			
	<u>Containment and local exhaust ventilation</u>	Information type	Data field	Explanation
		Containment plus good work practice required	Yes	General good hygiene and housekeeping
		Local exhaust ventilation required plus good work practice.	Yes	Typical practice of chemical industry.
	<u>Personal protective equipment (PPE)</u>	Information type	Data field	Explanation
		Skin protection	Protective gloves	
		Eye protection	Safety glasses	
Clothing		Working clothing worn.		

See details in point 8 of SDS : means specific training and instructions of workers

Data base can help too for instructions :

Ex : <http://www.hse.gov.uk/coshh/essentials/index.htm>

Are OCs and RMMs appropriate for human health?

3

Exposure estimation and reference to its source:

Occupational exposure:

Dermal	Process category	Description	Dermal exposure?	Predicted exposure ($\mu\text{g}/\text{cm}^2/\text{day}$)	Exposed skin surface area (cm^2)	Dermal exposure ($\text{mg}/\text{kg}/\text{day}$) ^a
	PROC5	Mixing or blending in batch processes (multistage and/or significant contact)	Yes	200	480	1.37

b) Results are calculated as mg/m^3 for solids and ppm for non-solids
 c) Calculated assuming a default bodyweight of 70 kg for workers and a default respiratory volume of 10 m^3 , light activity, for an 8 hour work shift

Data are coming from : ECETOC Targeted Risk Assessment - Worker Exposure Estimation - V 2.0
 Part : **Generic Exposure Scenarios for Tier 1 Assessment**

Are OCs and RMMs appropriate for human health?

Inhalation	Process category	Description	LEV present ?	Predicted exposure (ppm)	Predicted exposure (mg/m ³) ^c	Inhalation Exposure (mg/kg/day) ^d
	PROC5	Mixing or blending in batch processes (multistage and/or significant contact)	Yes	0.31	2.5	0.36

b) Results are calculated as mg/m³ for solids and ppm for non-solids
 c) Calculated assuming a default bodyweight of 70 kg for workers and a default respiratory volume of 10 m³, light activity, for an 8 hour work shift

« LEV » : Local exhaust ventilation

Are OCs and RMMs appropriate for human health?

→ long-term exposure concentration to workers

Definition: "Continued *exposure* or exposures occurring over an extended period of time, or a significant fraction of the test species' or of the group of individuals', or of the population's life-time"

Routes of exposure	Concentration	Justification
Dermal local exposure (in $\mu\text{g}/\text{cm}^2$)	3	ECETOC TRA prediction for PROC19, multiplied by an uptake factor of 0.006.
Dermal systemic exposure (in mg/kg bw/d)	0.08	ECETOC TRA prediction for PROC19, multiplied by an uptake factor of 0.006.
Inhalation exposure (in mg/m^3)/8h workday	10	ECETOC TRA prediction for PROC7
Inhalation exposure (in $\text{mg}/\text{kg}/\text{d}$)/8h workday	1.43	ECETOC TRA prediction for PROC7

→ Predicted Exposure Concentrations (PEC)

Definition : "Measured or calculated amount or mass *concentration* of a substance to which an organism is likely to be *exposed*, considering *exposure* by all sources and routes."

	PEC	unit
AIR		
Annual average local PEC in air (total)	1.4×10^{-15}	$[\text{mg} \cdot \text{m}^{-3}]$

Glossary



**Guidance on
information requirements and
chemical safety assessment**
Chapter R.14: Occupational exposure
estimation

THANK YOU

<http://www.azelis.com>

QUESTIONS ?