Identification and assessing critical components for defining conditions of use of mixtures

Steven Van de Broeck
svb@essenscia.be

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Introduction

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- Presented approach aims to
  - identify a critical component
    = component resulting in the highest RCR
  - define conditions of safe use of a mixture
    - based on an assessment of the critical component
    - taking into account the composition of the mixture
    - focussing on the most critical processes related to the use of the mixture
- applied on a mixture containing 3 (more or less) similar dangerous substances
- focus on
  - industrial use
  - worker exposure through inhalation
  - ECETOC TRA

Identification of a critical component

- Relevant aspects taken into account to identify a critical component:
  - substance specific information (DNEL + vapour pressure)
  - processes related to the use of the mixture (process categories)
  - composition of the mixture
- Critical component is identified as the component with the lowest corrected DNEL ($DNEL_{corr}$)

$$DNEL_{corr}\ [ppm] = DNEL\ [ppm] / (C_{vp} \times C_c)$$

C_{vp} = factor depending on vapour pressure and process categories

C_c = factor depending on the concentration in the mixture

Determination of C_{vp} – stepwise approach

- determine / component the according volatilility band used in ECETOC TRA
- determine PROCs relevant for the use of the mixture

  for each relevant PROC:
  - determine initial exposure per volatility band
  - calculate ratio's :
    initial exposure medium / low
    initial exposure high / low
    initial exposure high / medium
  - select relevant ratio's (depending on the volatility band of the components)
  - Assign C_{vp}
    - = 1 for components belonging to the lowest volitilty band
    - C_{vp} = lowest of calculated relevant ratio's

Determination of C_{vp} – example

components	A	B	C
vapour pressure [Pa]	4200	5726	12600
volatility band ECETOC	medium	medium	high
Cvp	1	1	4

1

6

	initial exposure [ppm]			ratio's initial exposure		
	low	med	high	med/low	high/low	high/med
proc1	0,01	0,01	0,01	1	1	1
proc2	1	5	25	5	25	5
proc3	3	10	50	3	17	5
proc4	5	20	100	4	20	5
proc5	5	50	250	10	50	5
proc6	5	50	250	10	50	5
proc8a	10	50	250	5	25	5
proc8b	5	25	150	5	30	6
proc9	5	50	200	10	40	4
proc10	10	50	250	5	25	5
proc12	2	20	100	10	50	5
proc13	10	50	250	5	25	5
proc14	5	50	250	10	50	5

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3

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Not relevant as no component is within the low volatility band

PROCs related to the use of the mixture

ECETOC TRA

Calculated ratio's

Determination of C_{vp}

- determine / component the according concentration band used in ECETOC TRA
- C_c depends on concentration band ECETOC TRA

Concentration in mixture (w/w)	Cc
> 25%	1
5 – 25%	0,6
1 – 5%	0,2
< 1 %	0,1

- applied to the mixture:

components	A	B	C
concentration	30%	10%	20%
Cc	1	0,6	0,6

Identification of a critical component

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- Final result

components	A	B	C
DNEL [mg/m³]	500	950	600
DNEL [ppm]	200	496	200
vapour pressure [Pa]	4200	5726	12600
volatility band ECETOC	medium	medium	high
Cvp	1	1	4
concentration	30%	10%	20%
Cc	1	0,6	0,6
DNELcorr	200	827	83

Exposure assessment of the critical component

- taking into account several combinations of OCs and RMMs which are reflecting the conditions of use of the mixture
- Focus on PROCs with highest initial exposure

	initial exposure [ppm]		
	low	med	high
proc1	0,01	0,01	0,01
proc2	1	5	25
proc3	3	10	50
proc4	5	20	100
proc5	5	50	250
proc6	5	50	250
proc8a	10	50	250
proc8b	5	25	150
proc9	5	50	200
proc10	10	50	250
proc12	2	20	100
proc13	10	50	250
proc14	5	50	250

Exposure assessment of the critical component

- Outcome assessment

exp. Time	LEV	ventilation	RPE?	posure [mg/n	RCR DNEL
8 h	no	general	no	315	0,53
8 h	no	general	half mask	32	0,05
8 h	no	enhanced	no	135	0,23
8 h	no	enhanced	half mask	14	0,02
8 h	yes	no	no	45	0,08
8 h	no	general	no	87,5	0,18

Validation: exposure related to component A

Safe use reccomandation:
Provide a good standard of general ventilation
(not less than 3 to 5 air changes per hour)

Conclusions

- Methodology is straight forward and focusses on critical aspects
- Can be automated to a certain extend
- Can be used in a flexible way (≠ max. concentration lead substance, ≠ use conditions / PROCs)
  - eg. If PROC 7 is to be included and/or [C] > 25%
- Recommanded OCs / RMMs take into account composition mixture + use conditions -> avoiding overprecautionary measures

Remaining questions

- Usable for other combinations of DNEL / vapour pressure / PROCs?
- Availibility substance specific information (DNELs)?
- Feasibility of similar approaches for dermal exposure, professional uses, environment and consumers?
- Feasible for assessment methods other than ECETOC TRA?
- Feasible for more complex mixtures?

➲ Further elaboration of approach is required

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