
Exposure Scenarios in the new extended SDS (REACH opportunities for the occupational hygienist)

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Content

- Requirements new extended Safety Data Sheet (eSDS)
- Exposure Scenario (ES) format
- Substance versus product ES
- Building product ES: DPD+ methodology
- Example "Adhesive" (construction chemicals)
- Changing Risk Management Measures/Operational Conditions (RMM/OC) within the boundaries of the ES
- Opportunities for the occupational hygienist



Key requirements new eSDS (1)

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|--|--|
| ■ Section 1: Identification of substance/mixture | ■ 1.1. Registration no for registered substances
■ 1.2. List of identified uses/uses advised against (reference to ESs in section 16) |
| ■ Section 2: Hazard identification | ■ substance classification:
■ till May 2015: according to 67/548/EEC (DSD) + EC/1272/2008 (CLP)
■ after May 2015: according to EC/1272/2008
■ mixture classification:
■ till May 2015: according to 1999/45//EC (DPD) or + 1999/45//EC (DPD) + EC/1272/2008
■ after May 2015: according to EC/1272/2008 |
| ■ Section 3: Composition information | ■ PBT/vPvB substances and registration no. |
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Key requirements new eSDS (2)

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|--|--|
| ▪ Section 7: Handling and storage | ▪ 7.1 consistent with info in ES |
| ▪ Section 8: Exposure controls/personal protection | ▪ 8.1 DN(M)ELs, PNECs
▪ 8.2 engineering controls + organisational measures + personal protection (consistent with info in ES; e.g. more specific details in main body of SDS) |
| ▪ Section 13: Disposal considerations | ▪ consistent with info in ES |
| ▪ Section 15: Regulatory information | ▪ information on authorized/restricted substances |
| ▪ Section 16: Other information | ▪ e.g. list of ESs |

Exposure Scenario format (general)



Section 1	Exposure Scenario:
Title	
Life cycle stage	
Sector of Use	
Process Category	
Product Category	
Article Category	
Environmental Release Category	
Processes, tasks, activities covered	
Section 2	Operational conditions and risk management measures
Product characteristics	
Physical form of product	
Vapour pressure	
Durability	
Concentration in a preparation	
Type of packaging	
Section 2.1	Control of exposure
Operational conditions	
Amount used	
Frequency and duration of use	
Human factors not influenced by risk management	
Other Operational Conditions affecting worker/consumer exposure	
Risk Management Measures	
Contributing Scenarios	<i>RMMs in hierarchical order are listed according to the following control hierarchy: 1. Technical measures to prevent dispersion, 2. Organisation of measures, 3. Personal protection</i>
Section 2.2	Control of environmental exposure
ETC, ETC, ETC.	
Section 3	Exposure Estimation
3.1. Health	
When the recommended risk management measures and operational conditions are observed, exposures are not expected to exceed the predicted DNELs and the resulting risk characterisation is expected to be less than 1. For more information, refer to [Link, CIG, ?].	
3.2. Environment	
When the recommended risk management measures and operational conditions are observed, exposures are not expected to exceed the predicted PNECs and the resulting risk characterisation is expected to be less than 1. For more information, refer to [Link, CIG, ?].	
Section 4	Guidance to check compliance with the Exposure Scenario
4.1. Health	
Text still to be determined	
4.2. Environment	
Text still to be determined	
Section 5	Additional good practice advice beyond the REACH Assessment
The measures reported in this section have not been taken into account in the exposure estimator related to the exposure scenario above. They are not subject to obligation laid down in Article (4) of REACH.	
Control of Worker Exposure	
Control of environmental exposure	

industry proposed (GES format)
slight modifications by Dow

RMMs in hierarchical order:

- technical: prevention
- technical: dispersion
- organisational
- personal protection

standard text; reference
to other company
information source

standard text (?TBD);
reference to estimation
tools (?)

section 5 information not
mandatory (not based on
CSR); good practice
advice

Exposure Scenario format (worker part)



Section 1	
Exposure Scenario: for workers	
Title	Industrial use in coatings
Life cycle stage	End use
Sector of Use	SU3, SU8, SU9
Process Category	PROC1, PROC2, PROC3, PROC4, PROC7, ROC8a, PROC8b, PROC10, PROC13, PROC15
Product Category	n/a
Article Category	n/a
Environmental Release Category	ERC4a, ERC4b
Processes, tasks, activities covered	Covers the use in coatings (paints, inks, adhesives, etc) including exposures during use (including materials receipt, storage, preparation and transfer from bulk and semi-bulk, application by spray, roller, spreader, dip, flow, fluidised bed on production lines and film formation) and equipment cleaning, maintenance and associated laboratory activities.
Section 2	
Operational conditions and risk management measures	
Product characteristics	
Physical form of product	Liquid
Vapour pressure	1000 Pa
Dustiness	n/a
Concentration in a preparation	> 25 %
Type of packaging	containers
Section 2.1	
Control of worker exposure	
Operational conditions	
Amounts used	n/a
Frequency and duration of use	covers daily exposures up to
Human factors not influenced by risk management	n/a
Other Operational Conditions affecting worker/consumer exposure	assumes a basic standard of occupational hygiene is implemented
Risk Management Measures	
Contributing Scenarios	
general exposures; with sampling collection	Handle substance within a closed system; Ensure material transfers are under containment or extract ventilation
sample collection	Ensure material transfers are under containment or extract ventilation
bulk transfers	Ensure material transfers are under containment or extract ventilation; Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training.

2 sub versions:
 • worker
 • worker (article)

contributing scenarios:
 activities within application
 that contribute to exposure;
 multiple contributing
 scenarios possible

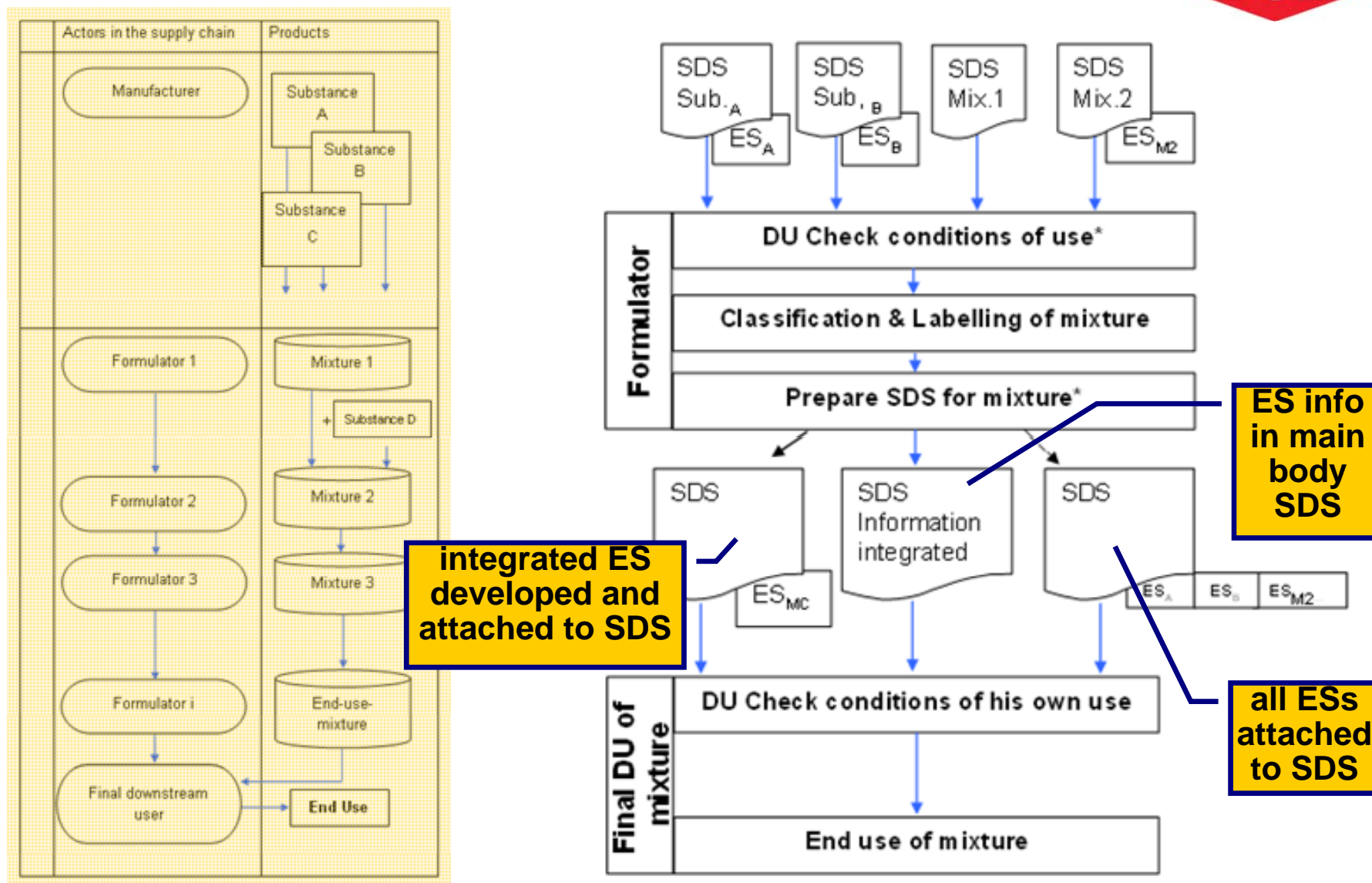
generic description of
 RMMs; specific details in
 main body SDS (e.g.
 glove material (neoprene
 or butylrubber))



Substance versus product ES

- REACH only requires ES for substances (to be developed and communicated by registrant: manufacturer or importer)
- most products used down the supply chain are mixtures
- no obligation for Downstream Users (DU) to develop ES for mixtures
- Options for the DU (e.g. formulator):
 1. integrate RMM/OCs in main body SDS
 2. attach all ESs from all REACH substances to SDS mixture
 3. develop integrated ES
- Option 3 is preferred option

Developing SDS for mixtures



copied from VCI guide (draft): REACH Practical Guide on Exposure Assessment and Communication in the Supply Chain



Developing integrated ESs for mixtures

- How to identify hazardous substances that 'drive' Risk Management Measures?
- Approach: DPD+ methodology
 - Identify lead substance for each relevant exposure pathway (inhalation, skin, oral, eyes, aquatic)
 - based on DPD classification criteria + exposure potential (vapour pressure)
- Not applicable for CMRs (cat 1+2), respiratory sensitizers, PBT- or vPvB-substances (advanced approach needed)

Principle of DPD+

- Impact of a substance on the classification of a mixture is determined as the ratio of the substance concentration (C_i) to the concentration limit (CL) where classification is not required anymore. This is termed the "lead substance indicator (LSI). Note: for inhalation the role of the vapour pressure in the exposure potential is accounted for.
- The substance with the highest LSI is assumed to have the highest impact for a given exposure or emission pathway



Algorithm of DPD+

Lead Substance Indicator (LSI):

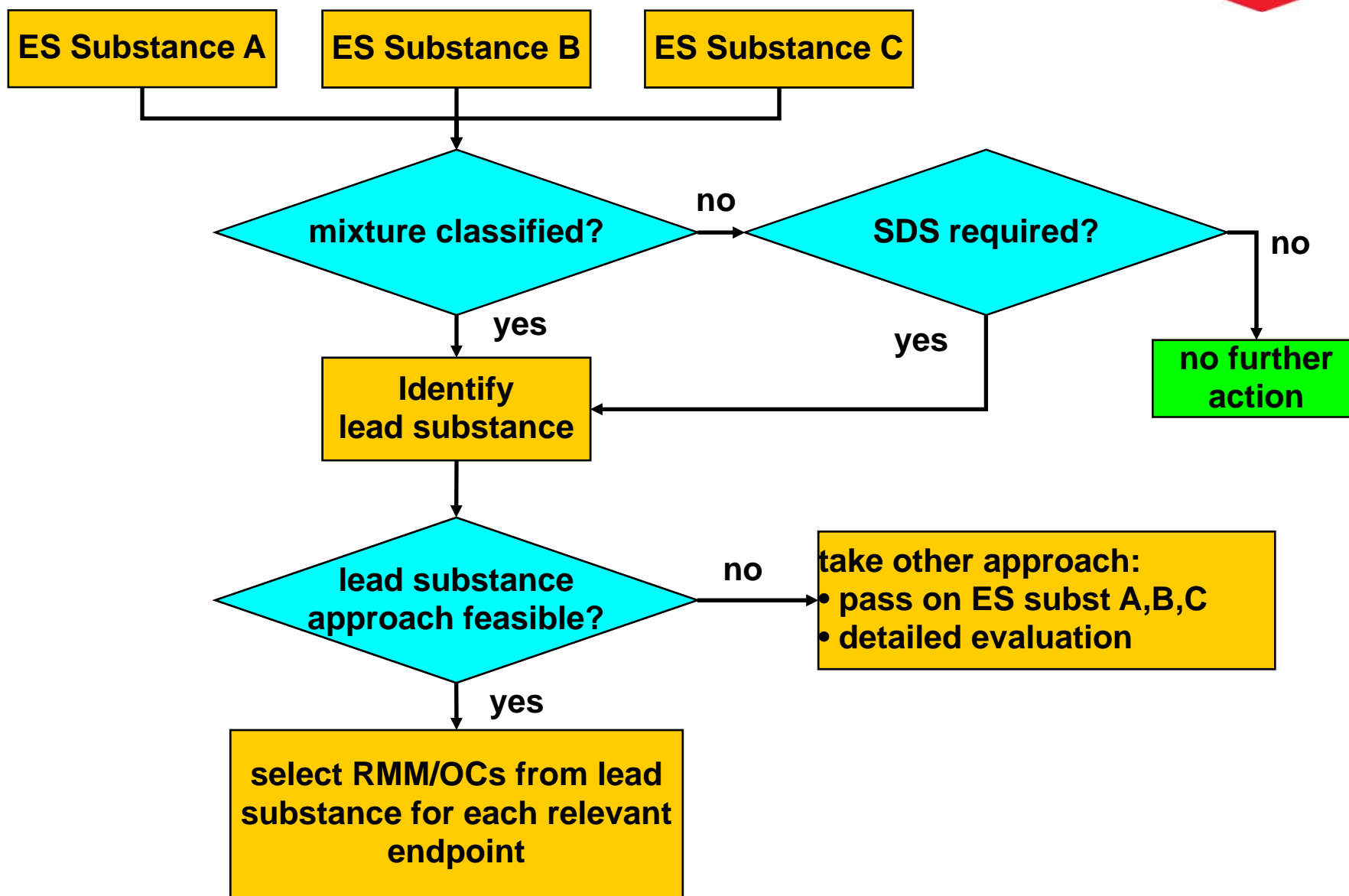
$$LSI = C_i / C_T \quad \text{or} \quad LSI_{\text{(inhalation)}} = C_i * V_i / C_T$$

C_i : Substance concentration in the preparation

C_T : Concentration limit triggering the classification

V_i : Vapour Pressure of Substance

Overview of methodology





Workflow

- Calculate LSI for each dangerous substances and..
- For each exposure pathway:
 - ingestion, inhalation, skin contact, eye contact, emission to aquatic environment
- The substance with the highest LSI is assumed to have the highest impact for a given exposure or emission pathway
- OCs/RMMs of LSI (for relevant pathway) are selected for mixture ES (note: concentration of compound in mixture needs to be considered)



Example of a fictitious “adhesive” product

- Example of construction chemicals
- Compounds are blended in situ and are applied immediately (note: professional use! no DIY product)
- Primarily indoor use (large scale, e.g. factory buildings, car parks), occasionally outdoor use (e.g. bridges)
- Composition:

<i>substance name</i>	<i>CAS</i>	<i>Conc.</i>	<i>Classification</i>
Bisphenol-A, Epichlorohydrin Poly	25068-38-6	60	Xi;N - R36/38;R43;R51/53
Ethanol	64-17-5	2	F - R11
Isophorone diamine	2855-13-2	18	C - R21/22;R34;R43;R52/53
Xylene	1330-20-7	10	Xn - R10;R20/21R38
Benzyl alcohol	100-51-6	10	Xn - R20/22

DPD+ : Input



Overall Composition		Vapour pressure (hPa at 25°C)	R-phrases					default concentration limit (%)	specific concentration limit (%)
Component	%		inhalation	dermal	eye	ingestion	aquatic		
BPA-resin	60,00%	niedrig		R38				20,00%	5,00%
BPA-resin	60,00%	niedrig			R36			20,00%	5,00%
BPA-resin	60,00%	niedrig		R43				1,00%	1,00%
BPA-resin	60,00%	niedrig					R51/53	2,50%	25,00%
Xylene	10,00%	10,65	R20					25,00%	12,50%
Xylene	10,00%	10,65		R21				25,00%	12,50%
Xylene	10,00%	10,65		R38				20,00%	20,00%
Isophorone diamine	18,00%	0,0258		R21				25,00%	25,00%
Isophorone diamine	18,00%	0,0258				R22		25,00%	25,00%
Isophorone diamine	18,00%	0,0258		R34				5,00%	5,00%
Isophorone diamine	18,00%	0,0258			R34			5,00%	10,00%
Isophorone diamine	18,00%	0,0258		R43				1,00%	1,00%
Isophorone diamine	18,00%	0,0258					R52/53	25,00%	25,00%
Benzyl alcohol	10,00%	0,13	R20					25,00%	25,00%
Benzyl alcohol	10,00%	0,13				R22		25,00%	25,00%
Ethanol	2,00%	78,91							

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DPD+ : Output



Overall composition		Inhalation		dermal		eye		Ingestion		aquatic	
Component	%	R	LSI	R	LSI	R	LSI	R	LSI	R	LSI
BPA-resin	60,00%			R38	12,0						
BPA-resin	60,00%					R36	12,0				
BPA-resin	60,00%			R43	60,0						
BPA-resin	60,00%									R51/53	2,4
Xylene	10,00%	R20	8,5								
Xylene	10,00%			R21	0,8						
Xylene	10,00%			R38	0,5						
Isophorone diamine	18,00%			R21	0,7						
Isophorone diamine	18,00%							R22	0,7		
Isophorone diamine	18,00%			R34	3,6						
Isophorone diamine	18,00%					R34	1,8				
Isophorone diamine	18,00%			R43	18,0						
Isophorone diamine	18,00%									R52/53	0,7
Benzyl alcohol	10,00%	R20	0,1								
Benzyl alcohol	10,00%							R22	0,4		
Ethanol	2,00%										



Result DPD+ calculations

- Lead compounds of "Fictitious Adhesive" are:
 - Inhalation : Xylene
 - Dermal : BPA-resin
 - Eyes : BPA-resin
 - Ingestion : Isophorone diamine
 - Aquatic : BPA-resin

- Next step: create integrated ES for worker based on RMM/OCs for xylene (inhalation), BPA-resin (dermal + eyes + aquatic)

varying RMM/OCs within boundaries of ES



same contributing scenario (PROC13)

all estimates by ECETOC TRA tool

Risk Characterization Ratio (RCR) has to be < 1

RMMs linked to exposure reduction

Contributing Scenarios	TRA Predicted Exposure (ppm) - modified	TRA Predicted Exposure (mg/m ³) - modified	Dilution ventilation effectiveness (%)	TRA concentration factor	TRA duration factor	TRA RPE factor	Predicted Exposure (mg/m ³) - modified	TRA Predicted Dermal exposure (mg/kg/d) - modified	PPE factor	Predicted Dermal Exposure (mg/kg/d) - modified	RCR (inhalation)	RCR (dermal)	RCR (all routes)	RMMs for communication - Consolidate into GES or e-SDS REACH ADVISED: phrase [RMM code]
Ad hoc manual application via trigger sprays, dipping, etc. [CS27].	100	375.42	70				112.63	13.71		13.7	0.31	0.27	0.58	Provide a good standard of general or controlled ventilation (5 to 15 air changes per hour) [E40].
Ad hoc manual application via trigger sprays, dipping, etc. [CS27].	100	375.42	30				262.79	13.71		13.7	0.71	0.27	0.98	Provide a good standard of general ventilation. Natural ventilation is from windows and doors etc. Controlled ventilation means air is supplied or removed by a powered fan. [E1].
Ad hoc manual application via trigger sprays, dipping, etc. [CS27].	100	375.42	30				262.79	13.71	gloves	2.7	0.71	0.05	0.77	Provide a good standard of general ventilation. Natural ventilation is from windows and doors etc. Controlled ventilation means air is supplied or removed by a powered fan. [E1]. Wear
Ad hoc manual application via trigger sprays, dipping, etc. [CS27].	100	375.42	30	5-25%			157.68	13.71		13.7	0.43	0.27	0.70	Limit the substance content in the product to 25% [OC18]. Provide a good standard of general ventilation. Natural ventilation is from windows and doors etc. Controlled ventilation
Ad hoc manual application via trigger sprays, dipping etc. [CS27].	100	375.42		5-25%			225.25	13.71		13.7	0.61	0.27	0.88	Limit the substance content in the product to 25% [OC18].
Ad hoc manual application via trigger sprays, dipping, etc. [CS27].	100	375.42			1-4 hours		225.25	13.71		13.7	0.61	0.27	0.88	Avoid carrying out operation for more than 4 hours [OC12]
Ad hoc manual application via trigger sprays, dipping, etc. [CS27].	100	375.42		5-25%	1-4 hours		135.15	13.71		13.7	0.37	0.27	0.64	Limit the substance content in the product to 25% [OC18]. Avoid carrying out operation for more than 4 hours [OC12]

controlled ventilation (RCR 0.58)

general ventilation (RCR 0.98)

gen. ventilation + conc. limitation (RCR 0.70)

conc. + durat. limitation (RCR 0.64)

duration limitation (RCR 0.88)

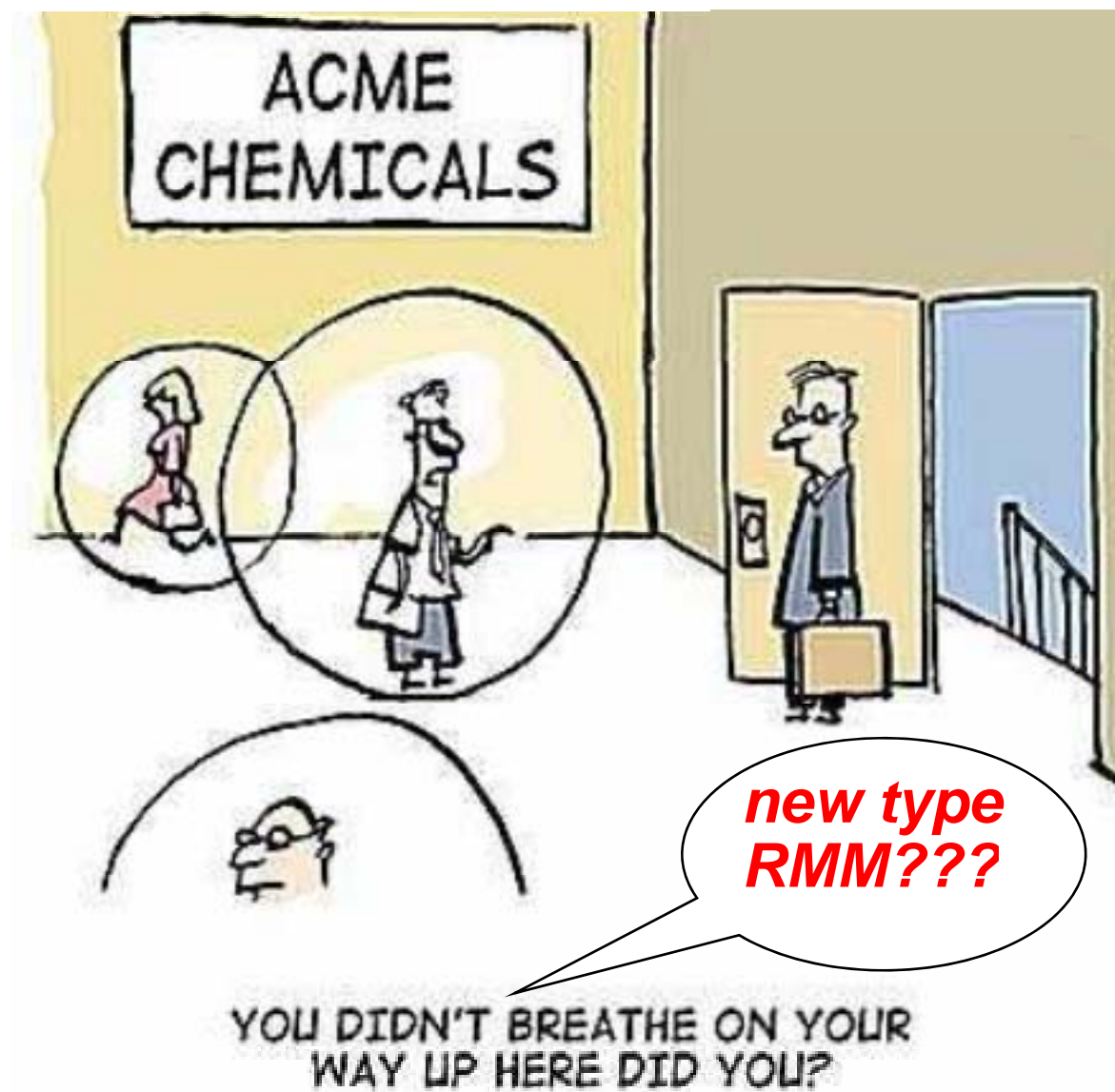
conc. limitation (RCR 0.88)

gen. ventilation + PPE (gloves) (RCR 0.77)



Opportunities for the occupational hygienist

- information/training on new eSDS and its requirements
- translating generic RMMs into specific equipment (e.g. 'use LEV' vs detailed description (LEV type, dimensions, positioning, flowrate, etc.))
- checking compliance with additional RMM/OCs (justification, documentation)
- varying RMM/OCs within boundaries of ES (justification, documentation)
- implementation of additional RMMs, where needed
- support of formulators in building integrated ESs



**Thank
you!!**