

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

Dook Noij NVvA symposium, Zeist, 24 maart 2010



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)

- 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.



Key requirements new eSDS (2)

- 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)



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Exposure Scenario format (worker part)



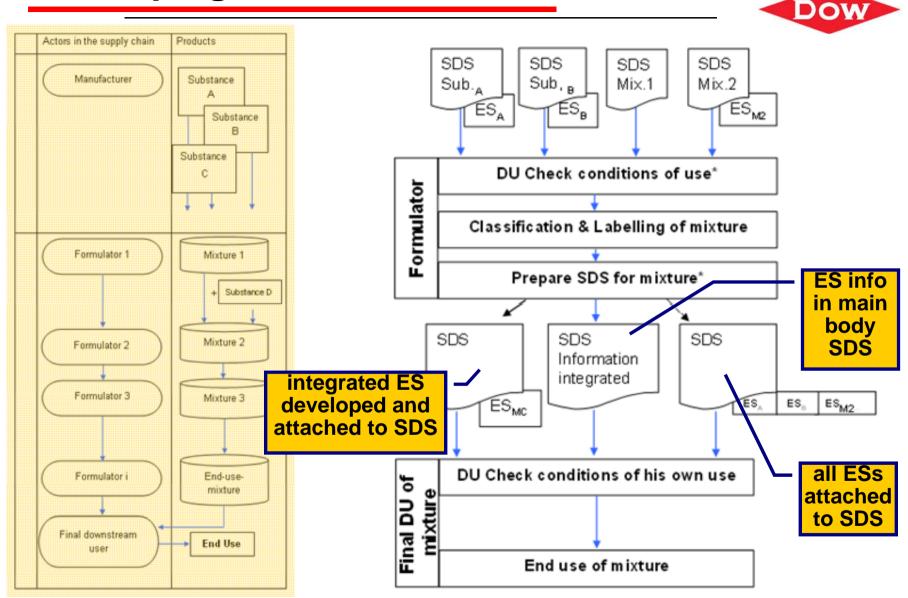
		DOW
Section 1	Exposure Scenario: for workers	
Title	Industrial use in coatings	
Life cycle stage	End use	
Sector of Use	\$U3, \$U8, \$U9	2 sub versions:
Process Category	PROC1, PROC2, PROC3, PROC4, PROC7, ROC8ь, PROC8ь, PROC10, PROC13, PROC15	• worker
Product Category	nla	• worker (article)
Article Category	nla	Worker (article)
Environmental Release Category	ERC4s, ERC4b	
Processes, tasks, activities covered	Covers the use in coatings (paints, inks, adhesives, etc) including exposure during use (including materials receipt, storage, preparation and transfer from bulk and semi-bulk, application by spray, roller, spreader, dip, flow, fluidise on production lines and film formation) and equipment cleaning, maintenanclessociated laboratory activities.	om dbed
Section 2	Operational conditions and risk management measure	es
Product characteristics		
Physical form of product	Liquid	
Vapour pressure		buting scenarios:
Dustiness	n/s activit	ies within application
Concentration in a preparation	>25 % that co	ontribute to exposure;
Type of packaging		ole contributing
Section 2.1	Control of worker appareura	
Operational conditions	scena	rios possible /
Amounts used	n/a	
Frequency and duration of use	covers daily exposures up	
Human factors not influenced by risk management	n/o	ganaria description of
Other Operational Conditions affecting	assumes a Dasic standard of occupational hygiene is implemented	generic description of
worker/consumer exposure		RMMs; specific details in
Risk Management Measures		main body SDS (e.g.
Contributing Scenarios		glove material (neoprene
general exposures; with sampling collection	Handle substance within a closed system; Ensure material transfers are containment or extract ventilation	or butylrubber)
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.	



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 sentitizers, 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 (Ci) 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):

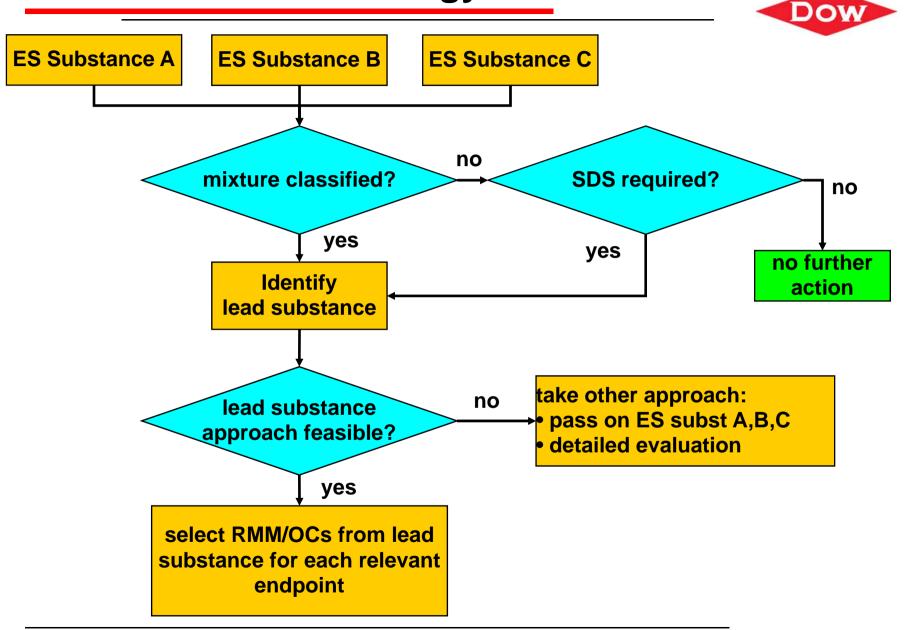
LSI =
$$C_i / C_T$$
 or LSI _(inhalation) = $C_i * V_i / C_T$

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:

substance name	CAS	Conc.	Classification
Bisphenol-A, Epichlorohydrin Poly	25068-38-6	60	V. I. 500 50 540 554 50
			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 Composit	Vapour			default	specific				
Component	%	pressure (hPa at 25°C)	inhalation	dermal	eye	ingestion	aquatic	concentration limit (%)	concentration limit (%)
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							

DPD+: Output



Overall composi	tion	inhal	ation	derr	mal	еу	eye		ition	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	8,0						
Xylene	10,00%			R38	0,5						
sophorone diamine	18,00%			R21	0,7						
sophorone diamine	18,00%							R22	0,7		
sophorone diamine	18,00%			R34	3,6						
sophorone diamine	18,00%					R34	1,8				
sophorone diamine	18,00%			R43	18,0						
sophorone 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

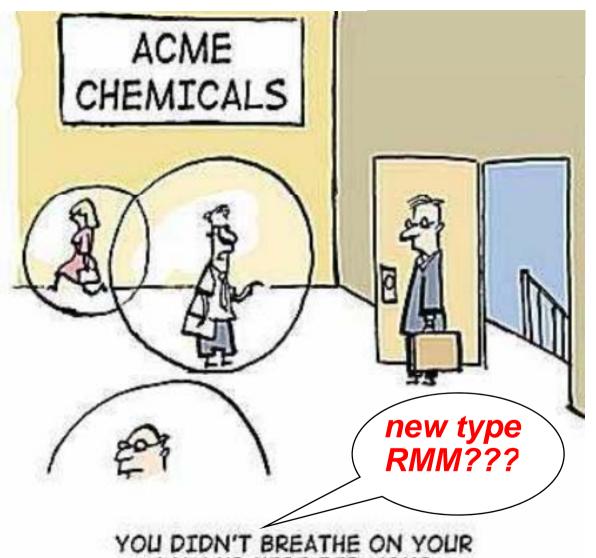
														DOW	
same contr	ibuting	7	all est		,		Risk Characterization Ratio RMMs linked to								
scenario (F	PROC	<mark>13)</mark>	ECET	OC TE	RA to	ol	RC	R) has	to be •	< 1		exposu	re redu	ction	
Contributing Scenarios	TRAProdicted Expanse (ppm) - mm mudifiers	TRAProduce - (mq/m3) - madifiers	Dilution ventilation offectiveness (%)	TRA concentration factor	TRA duration factor	TRARPE factor	Prodicted Exparare- (mg/m3)- madified	TRAProdicted Dormal expurure (mq/kq/d) - nm mmdifiers	PPEfactor	Prodictod Dormal Exparuro (mg/kg/d) - madified	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].	10/4	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	70		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		13:3	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)		gener ventilat RCR 0	ion	gen. + con (R		nitatio	on	onc. + d limitati (RCR 0.	on	durat limita (RCR (tion	conc. Iimitatio RCR 0.	on +	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!!

YOU DIDN'T BREATHE ON YOUR WAY UP HERE DID YOU?