



# Lead substance identification: "CLPplus" by BASF

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ENES 4, 16-17 May 2013, Helsinki*

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# Exposure information for mixtures: the DPD plus method

- Determination of so-called "Lead substance(s)":
  - Inhalation, Dermal, Eye, Oral, Environment
  - Expo info for mixture is based on ES from Lead substance(s) only
- based on **D**angerous **P**reparations **D**irective, 1999/45/EU



REACH: Exposure scenarios for preparations  
Methodology for the identification of substances that represent the dominant risks to human health and/or the environment and the drivers for risk management measures





# Changeover to "CLPplus" required

## ■ Timelines for CLP-Regulation (EC) No 1272/2008:

Year	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019 onwards
CLP timeline	Substances		Classified, labelled and packaged under DSD. If CLP is applied in full as well, no DSD labelling and packaging			Classified under both DSD and CLP; labelled and packaged under CLP.			Classified, labelled and packaged under CLP				
	Mixtures		Classified, labelled and packaged under DPD. If CLP is applied in full as well, no DPD labelling and packaging						Classified, labelled and packaged under CLP				

**Today**

**June 01, 2015**

from: *Introductory Guidance on the CLP Regulation, European Chemicals Agency, 2009*

# Environment: PNEC approach

- Per component:  
select **lowest PNEC** of all compartments (disregard units)
- Per component:  
**Lead Substance Indicator (LSI) = Concentration in mixture / lowest PNEC**
- **Substance with highest LSI = Lead substance environment**
  
- *The PNEC approach is only applicable for mixtures, where PNECs are available for **ALL** ingredients which are classified as hazardous to the environment*
- *Otherwise, the classification approach should be used (see next page)*

# Environment: classification approach

Classification	Calculation of LSI (Lead Substance Indicator)
Aquatic Acute 1	Concentration in mixture x $M_{acute}$ x 33
Aquatic Chronic 1	Concentration in mixture x $M_{chronic}$ x 100
Aquatic Chronic 2	Concentration in mixture x 10
Aquatic Chronic 3	Concentration in mixture
Aquatic Chronic 4	Concentration in mixture

- Substances classified for acute and chronic hazard:  $LSI_{total} = LSI_{acute} + LSI_{chronic}$
- **Substance with highest LSI = Lead substance environment**

# Environment: CLPplus vs DPDplus

LSI <b>DPDplus</b>	Classification
$C_i / (0.25\% \times 3^*)$	R50
$C_i / 0.25\%$	R50/53
$C_i / 2.5\%$	R51/53
$C_i / 25\%$	R52/53
$C_i / 25\%$	R53

Classification	LSI <b>CLPplus</b>
Aquatic Acute 1	$C_i \times M_{acute} \times 33$
Aquatic Chronic 1	$C_i \times M_{chronic} \times 100$
Aquatic Chronic 2	$C_i \times 10$
Aquatic Chronic 3	$C_i$
Aquatic Chronic 4	$C_i$

■  $C_i$  = concentration of substance in mixture

■ \*correction factor of 3:

in order to reflect increased removal efficiency of R50 vs R50/53 substances

# Example: environment

## DPDplus

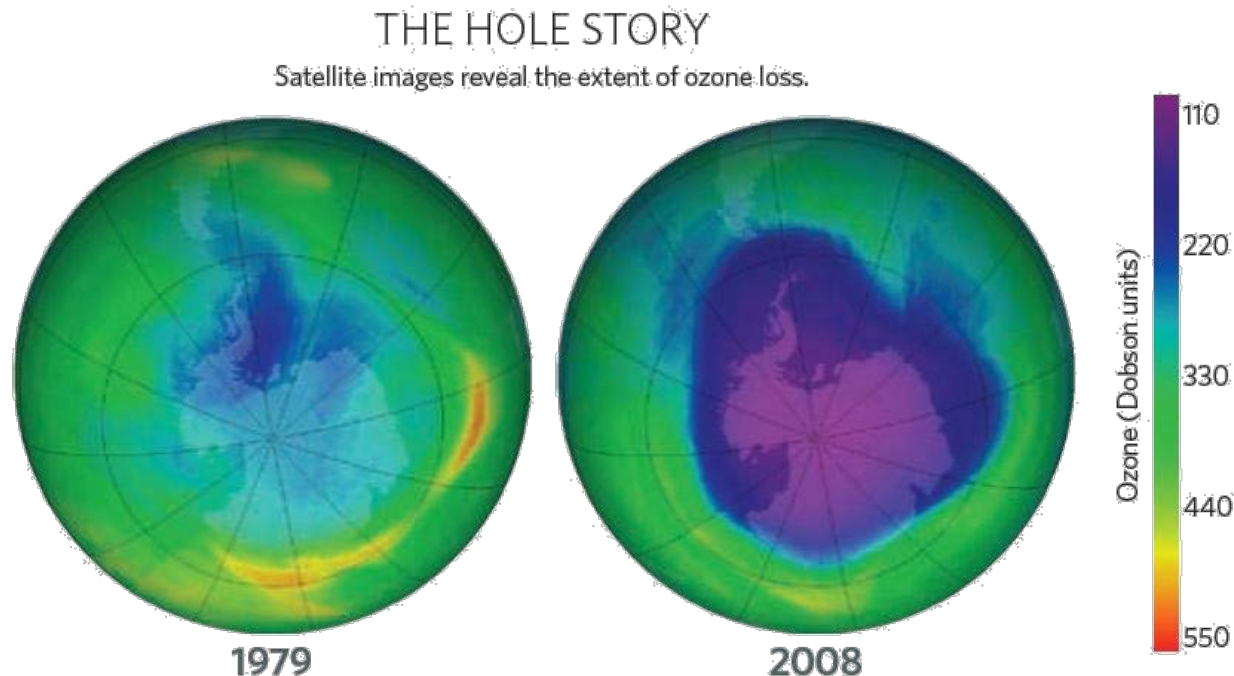
1	2	3	16	17	18
Substance (Col H)	Conc'n in prep (Col F) (%)	Vapour press (Col G) (hPa)	Aquatic		
			R phrase (s) (Col J)	Conc'n limit (Col K or M) (%)	LSI [Col 2/Col 14; If R50:Col 2/ (3 X Col 17)]
Ethyl Acetate	30.0	103			
Cyclo-hexane	30.0	104	R50/53	0.25	120
n-Hexane (Annex 1)	2.5	160	R51/53	2.5	1
Naphtha	20.0	120	R51/53	2.5	8
hydrotreated light					
Rosin	0.5	< 10 <sup>-6</sup>	-	-	-
Polychlorobutiene	17	< 10 <sup>-6</sup>	-	-	-

## CLPplus

classification	M factor	LSI
Acute 1	1	990
Chronic 1	1	3000
		<b>3990</b>
Chronic 2	n.a.	<b>25</b>
Chronic 2	n.a	<b>200</b>

# Components classified as hazardous to the ozone layer

- Components classified as hazardous to the ozone layer category 1:  
**LSI = Concentration in mixture**
- **Substance with highest LSI = Lead substance ozone layer**





# Human Health Approaches

- Acute toxicity

$$\text{LSI} = \frac{\text{concentration in mixture}}{\text{LD}_{50}, \text{LC}_{50} \text{ or ATE}}$$

- Acute/ long term/ reproductive toxicity; STOT SE/ RE Cat. 1&2

$$\text{LSI} = \frac{\text{concentration in mixture}}{\text{DNEL}}$$

- Local Effects qualitative or

$$\text{LSI} = \frac{\text{concentration in mixture}}{\text{spec./ generic conc. limit}}$$

# Human Health Considerations

- A DNEL is always superior to a concentration limit
- Carcinogenic/ mutagenic substances determine the exposure scenarios of the mixture
- Long term supersedes acute exposure in cases where there is more than one lead substance per route
- Acute lead substances are ignored if a long term systemic DNEL is available for the same substance because long term effects are thought to be of higher relevance
- Respiratory sensitizers are always considered
- STOT SE Cat. 3 are only considered if no inhalation lead substance is available

# Example: Human Health

Substance	Conc in prep [%]	Inhalation			Ingestion		
			Conc limit [%] or DNEL	LSI		Conc limit [%]	LSI
Ethyl Acetate	30.00	STOT SE 3	20	1.50			
Cyclohexane	30.00	STOT SE 3	20	1.50	Aspiration 1	10	<b>3</b>
n-Hexane	2.50	STOT SE 3	5	0.50			
	2.50	STOT RE 2	93	<b>0.03</b>	Aspiration 1	5	<b>0.5</b>
	2.50	Repr 2	93	<b>0.03</b>			
Naphtha, hydrotreated light	20.00	STOT SE 3	20	1.00	Aspiration 1	10	<b>2</b>
Rosin	0.50						
Polychlorobutiene	17.00						

taken from: *DPDplus methodology, Table 3.1: determination of lead substance(s) - Example: Contact adhesive*

# THANK YOU for your attention!

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# DPDplus - example

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Substance (Col H)	Conc'n in prep (Col F) (%)	Vapour press (Col G) (hPa)	Inhalation			Dermal			Eyes			Ingestion			Aquatic		
			R phrase (s) (Col J)	Conc'n limit (Col K or M) (%)	LSI [Col 3 x Col 2/Col 5]	R phrase (s) (Col J)	Conc'n limit (Col K or M) (%)	LSI [Col 2/ Col 8]	R phrase (s) (Col J)	Conc'n limit (Col K or M) (%)	LSI [Col 2/ Col 11]	R phrase (s) (Col J)	Conc'n limit (Col K or M) (%)	LSI [Col 2/ Col 14]	R phrase (s) (Col J)	Conc'n limit (Col K or M) (%)	LSI [Col 2/Col 14; If R50:Col 2/ (3 X Col 17)]
Ethyl Acetate	30.0	103	R67	25	124	R66	20	1.5	R36	20	1.5						
Cyclo-hexane	30.0	104	R67	25	125	R38	20	1.5			1.5	R65			R50/53	0.25	120
n-Hexane (Annex 1)	2.5	160	R48/20 R62 R67	5 5 25	80 80 16	R38 R48/20 R62	20 20 5	0.125 0.125 0.5				R65			R51/53	2.5	1
Naphtha hydrotreated light	20.0	120	R67	25	96	R66	20	1				R65			R51/53	2.5	8
Rosin	0.5	< 10 <sup>-6</sup>	-	-	-	R43	-	-							-	-	-
Polychlorobutiene	17	< 10 <sup>-6</sup>	-	-	-	-	-	-							-	-	-



# Example: Human Health

Substance	Conc in prep [%]	Inhalation			Dermal			Eyes			Ingestion		
		Conc limit [%] or DNEL	LSI		Conc limit [%] or DNEL	LSI		Conc limit [%]	LSI		Conc limit [%]	LSI	
Ethyl Acetate	30.00	STOT SE 3	20	1.50				Irritant 2A	10	3			
Cyclohexane	30.00	STOT SE 3	20	1.50	Skin irritation 2	10	3.00				Aspiration 1	10	3
n-Hexane	2.50	STOT SE 3	5	0.50									
	2.50	STOT RE 2	93	0.03	STOT RE	13	0.19				Aspiration 1	5	0.5
	2.50	Repr 2	93	0.03	Repr 2	13	0.19						
	2.50				Skin irritation 2	5	0.50						
Naphtha, hydrotreated light	20.00	STOT SE 3	20	1.00							Aspiration 1	10	2
Rosin	0.50				Sens 1	1	0.50						
Polychlorobutene	17.00												