The most comprehensive database of OEL's and measurement methods

Kick-Off Limit Values for substances with limited human health-hazard information

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DOHSBASE BV

The most comprehensive database of OEL's and measurement methods

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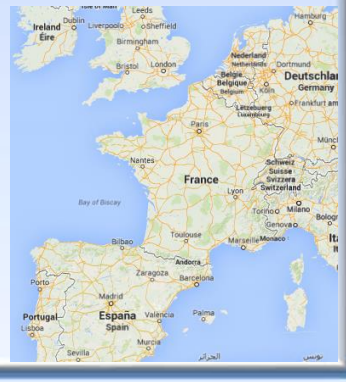
Consultancy

- Dangerous substances
- Exposure assessment
- OELV & DNEL
- REACH & CLP



Dohsbase Compare

- Database (search & find)
- Subscription

DOHSBASE COMPARE

- Data license

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DOHSBase Compare
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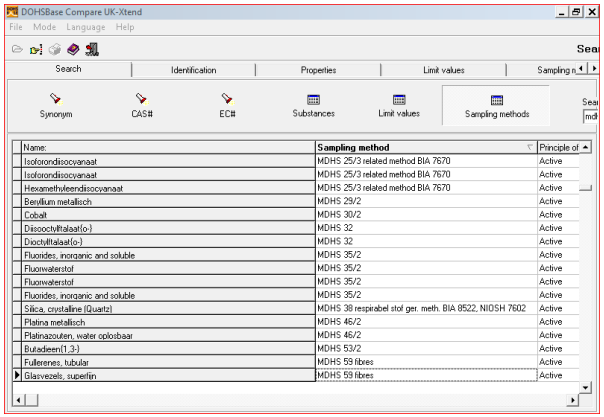
172000 substances
225000 synonyms
40000 PhysChem properties
8000 harmonized CLPs
6000 OELV
- 2000 Kickoff levels
- 2000 REACH DN/MELs

2500 measurement methods!



Situation

- Worldwide: > 64 million substances (CAS-register)
- EINECS: approx. 140 thousand substances
- REACH: 12,276 unique substances disseminated (> 100 t/a or >10 t/a if CMR);
- about 2600 substances: no workplace exposure
- # of 2018 registered substances (the REACH deadline for 1 – 10/100 t/a) with CSR/DNEL: probably zero

Situation

- Workplace exposure in EU: > 9700 substances

- DOHSBase Compare database: approx. 3800 substances with OEL
- REACH-CSR substances with DNEL/DMELs and no OELV: 1600 (400 with both)

Conclusion:

- EU substances with workplace exposure and no OELV or DNEL: >> 4300

Philosophy behind kick-off values

Target group:

- Substances with no OEL or DNEL, but with (limited) health-hazard information (H3###-statements)

Basis:

- control banding systems, like COSHH Essentials, German TGRS 440, 600, ECTETOC, ILO, Dutch SOMS
- CB-systems: supporting SME's in taking appropriate measures in controlling exposure
- Substances classified on toxicological properties: R-phrases/H3##-statements

Philosophy behind kick-off values

- Relationship between distribution of OELs of substances in hazard classes of different CB-schemes
- Definition of kick-off value: 10% lower tolerance limit per hazard class of CB-scheme
- If this value is feasible in practice, no extensive toxicological research is needed to establish a health-based company limit

3 Control Band Schemes

- COSHH Essentials (HSE: Health and Safety Executive)
- Einfache Maßnahmenkonzept Gefahrstoffe (EMKG)
  (BAuA: Federal Institute for Occupational Safety and Health)
- GHS Spaltenmodell; based on TRGS600 (DGUV IFA:
  Institute for Occupational Safety and Health of the German Social Accident Insurance)

Classification in Control Banding Schemes

Hazard category	DGUV IFA Spaltenmodell (TRGS600)	COSHH Essentials	BAUA EMKG (Einfaches Maßnahmenkonzept) (inhalation)
4/E	H300, H310, H330, EU032 H340 (AGS Mut 1AB) H350, H350i (AGS K1/2 & TRGS 906)	H334, H340, H341, H350, H350i	H340, H350, H350i, H360F (TRGS 905 & 906)
3/D	H301, H311, H331 EUH070, EUH029, EUH031 H370, H317 (Sh), H334 (Sa), H318 $H360_{xy}$ (AGS R_{EF}1/2) H351 (AGS K3), H341 (AGS M3), H372	H300, H310, H330 H351, $H360_{xy}$, H361, H362, H372	H300, H330, H360D, H372, EUH032
2/C	H302, H312, H332 H314 (pH ≥ 11,5, pH ≤ 2), H371, EUH071 $H361_{f/d}$, H373, H362 non-toxic gases which may cause asphyxiation	H301, H311, H331 H314, H317, H318 , H335, H370, H373, EUH071	H301, H331, H314, H334, H341, H351, H361f/d, H370, H371, H373, EUH031 (TRGS 907)
1/B	H315, H319 damage to the skin during wet work H304, EUH066, H335, H336 Substances chronically harmful in other ways (no H-statement, but still hazardous)	H302, H312, H332 H371	H302, H332, H318
0/A	substances which experience shows to be harmless (e.g. water, sugar, paraffin etc.)	H303, H304, H305, H313, H315, H316, H319, H320, H333, H336, EUH066 and all H-numbers not otherwise listed	H319, H335, H336, H304 No health hazard H-statements

Why update the kick-off values of 2005?

- Introduction CLP: different classifications, R-phrases → H-sentences
- Adjustments of CB-schemes since 2005
- More substances with harmonized (CLP-)classification
- Tendancy to lower OELVs
- Our database with OELVs: much larger than in 2005

Legal status kick-off value

Substances with kick-off value have no formal OEL and no DNEL/DMEL → exposure assessment is not possible.

Is this acceptable?

Paradigm shift in NL: for all substances a company limit is compulsory

Kick-off values are additional if no OEL/DNEL is available

In the Netherlands: kick-off values are accepted by Labour Inspectorate for substances with no formal OEL or DNEL

Method to derive Kick-off values

1. Transposition R-phrases to H-statements
2. Exposure as gas/vapor or dust/aerosol?
3. Selection of OELs
4. Grouping of substances in hazard classes CB-schemes
5. Statistical analysis: OELV distribution and 10%-tile estimation

Step 1: Conversion R→ H

DSD → CLP:

- More hazard classes
- Different ranges classification: 1 R-phrase → 2 H-sentences, based on LD_{50}

Nature, time and exposure	Dose (LD50)	Units	R-phrase/	CLP hazard class & -category	H-Statement
Acute toxicity: LD50 - oral	5	mg/kg	28	Acute Tox 1	300
Acute toxicity: LD50 - oral	5-25	mg/kg	28	Acute Tox 2	300
Acute toxicity: LD50 - oral	25-50	mg/kg	25	Acute Tox 2	300
Acute toxicity: LD50 - oral	50-200	mg/kg	25	Acute Tox 3	301
Acute toxicity: LD50 - oral	200-300	mg/kg	22	Acute Tox 3	301
Acute toxicity: LD50 - oral	300-2000	mg/kg	22	Acute Tox 4	302

Step 2: Physical appearance/exposure

For each substance:

- Exposure as vapor or as dust/mist

If:

- OEL << Cmax: vapor
- OEL >> Cmax: aerosol
- Other: exposure to vapor or aerosol possible

Step 3: removal of OELs

- Group OELVs reduced to 1 OELV
- “Metal + compounds” => 1 entry
- Dutch Health Council advice on Xylene (o, m, p, mix) => 1 entry

Step 4: grouping CB-schemes

All substances with OEL or DNEL and known exposure type are grouped in the hazard classes of the CB-schemes:

- COSHH Essentials
- EMKG
- IFA Spaltenmodell (TRGS 600)

→ Statistical analysis

Step 5: Statistical Analysis

- Distribution of OELVs per hazard group
- Log Normal? Regression-analysis
- Analysis of variance (differences between groups): ANOVA

The number of substances

	Total	E/4	D/3	C/2	B/1	A/0
TRGS600 (IFA)						
vapors	631	182	246	119	84	
dusts	338	162	123	43	10	
EMKG						
vapors	629	110	180	122	112	105
dusts	338	143	68	71	43	13
COSHH						
vapors	631	134	225	148	56	68
dustst	334	148	93	54	31	8

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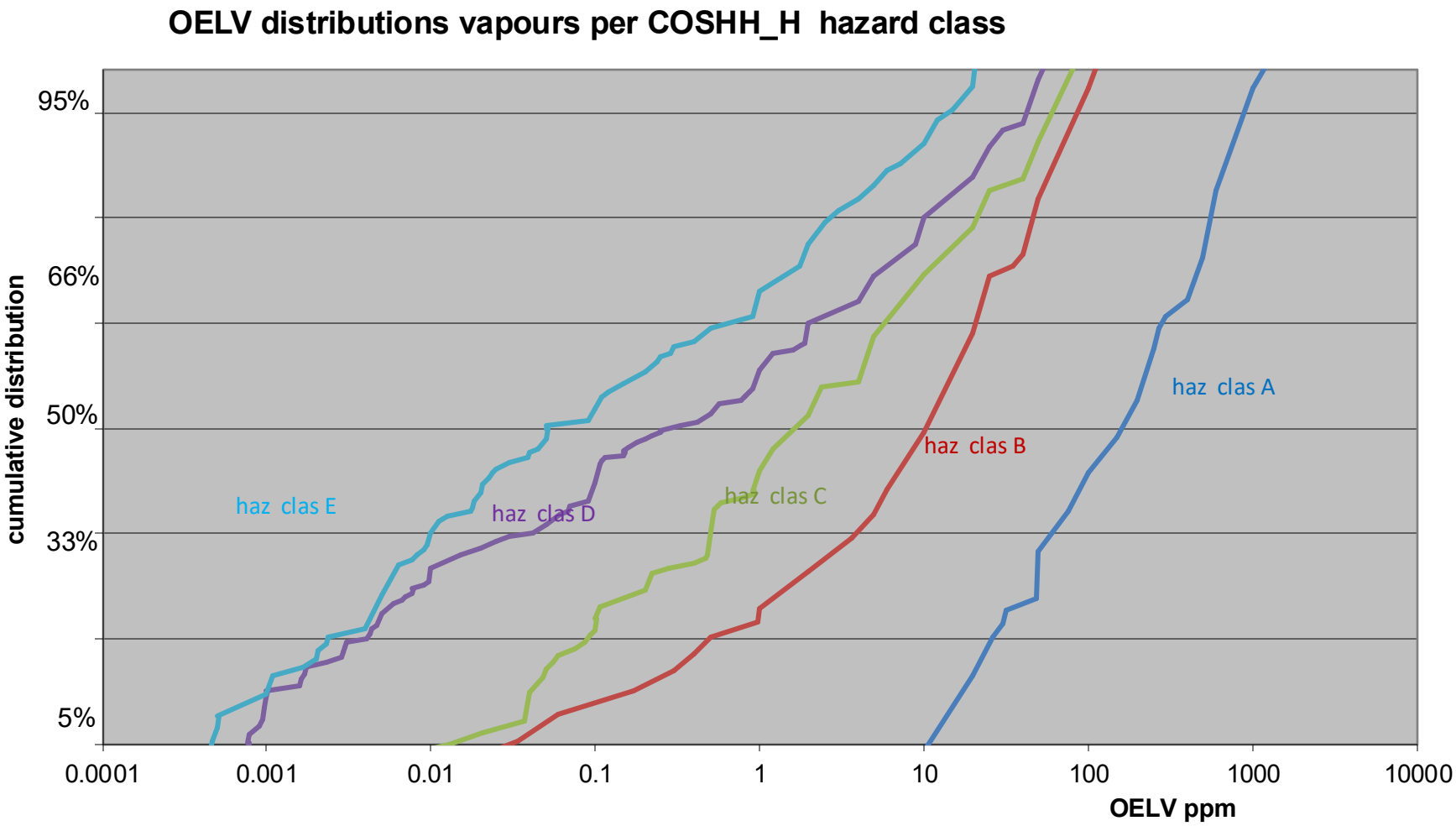
Results - COSHH



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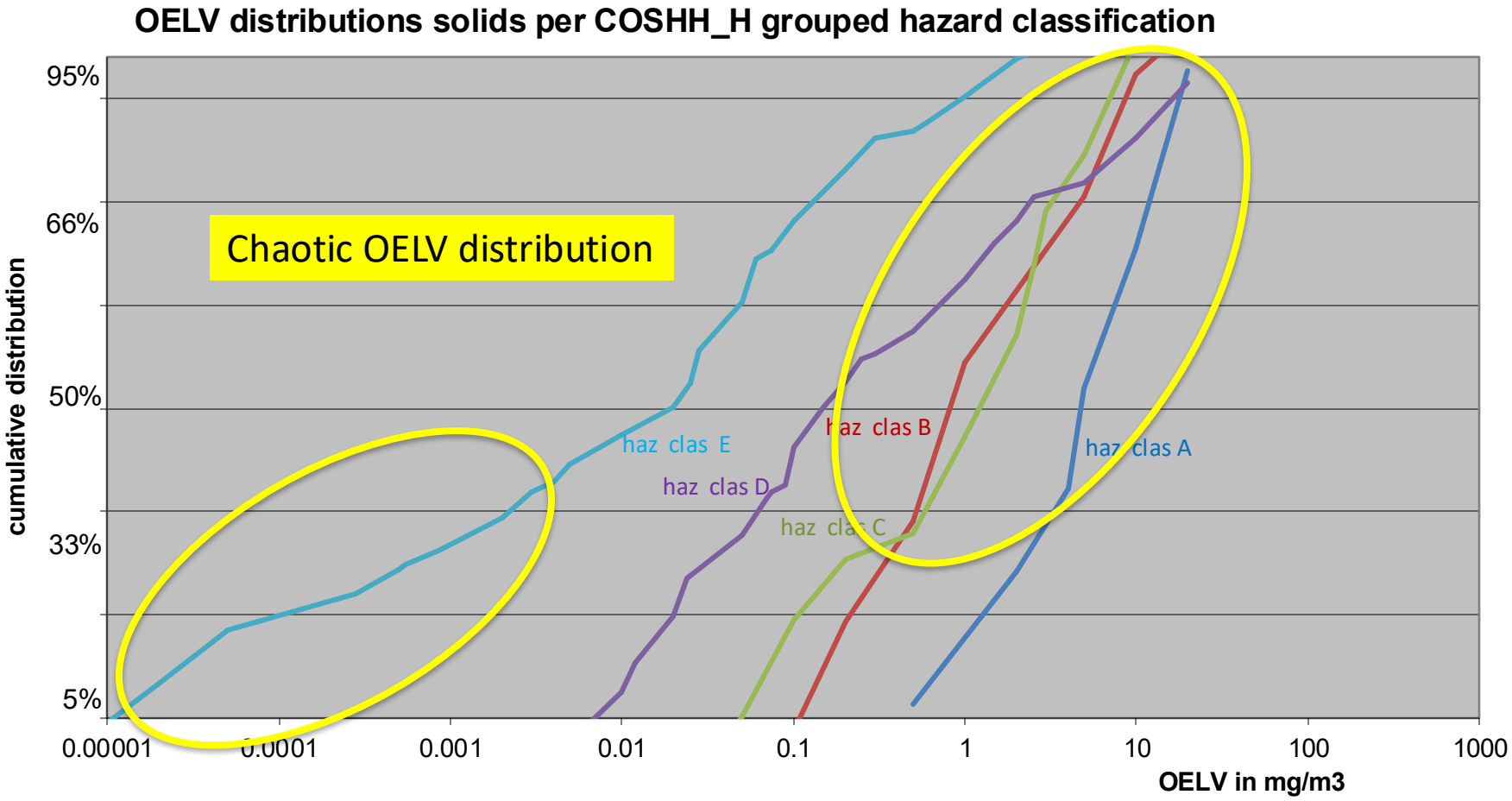

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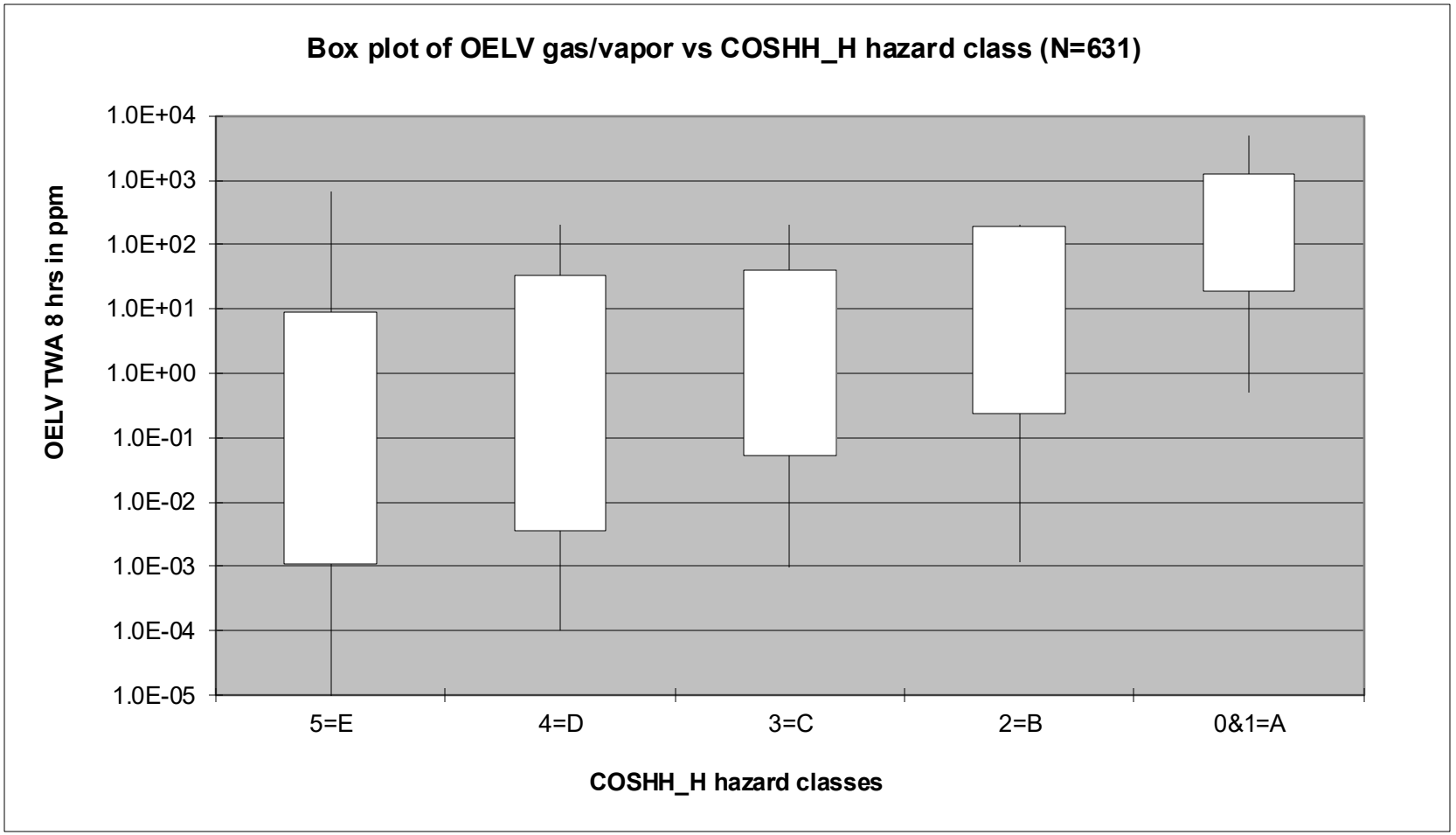

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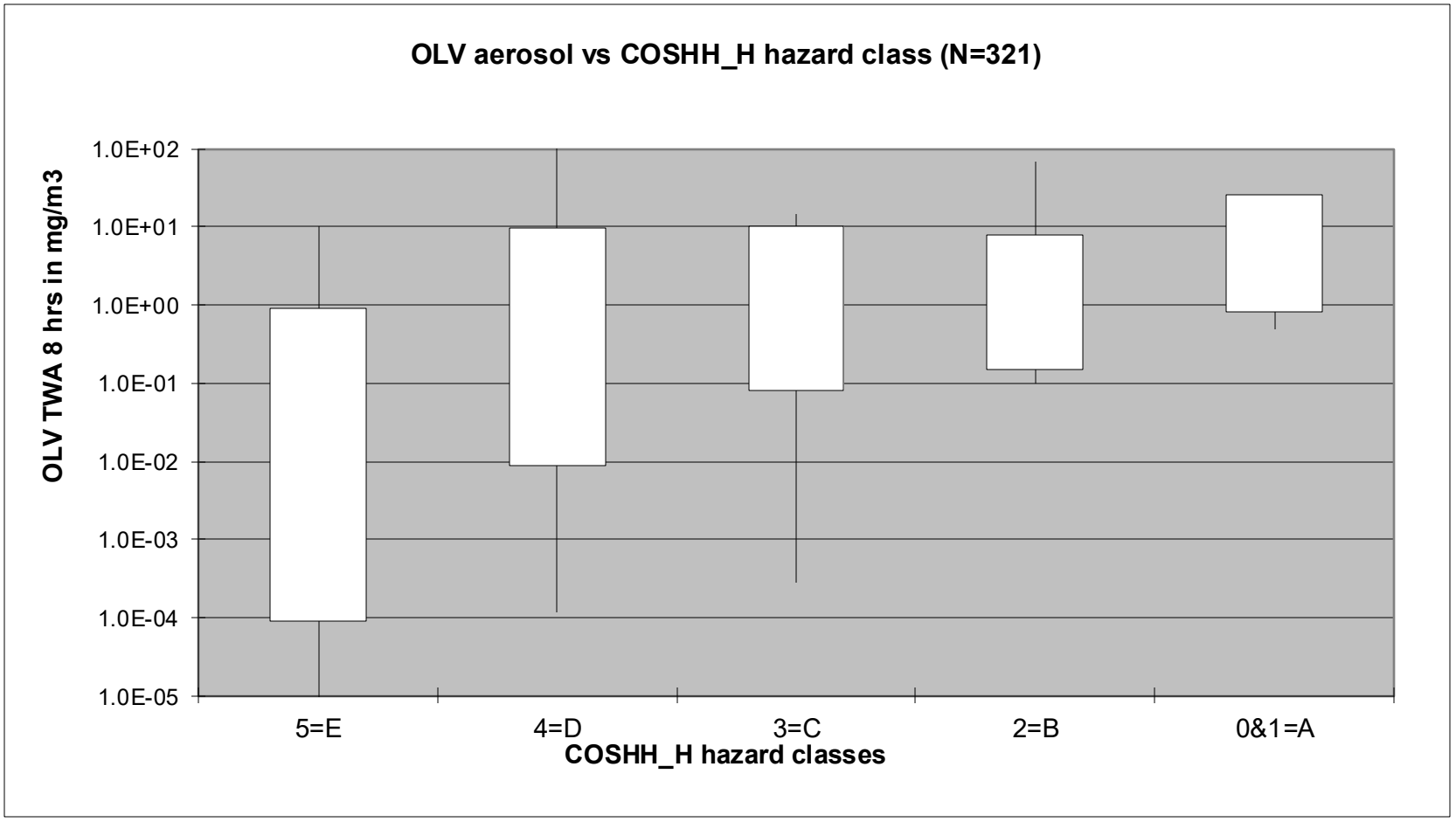
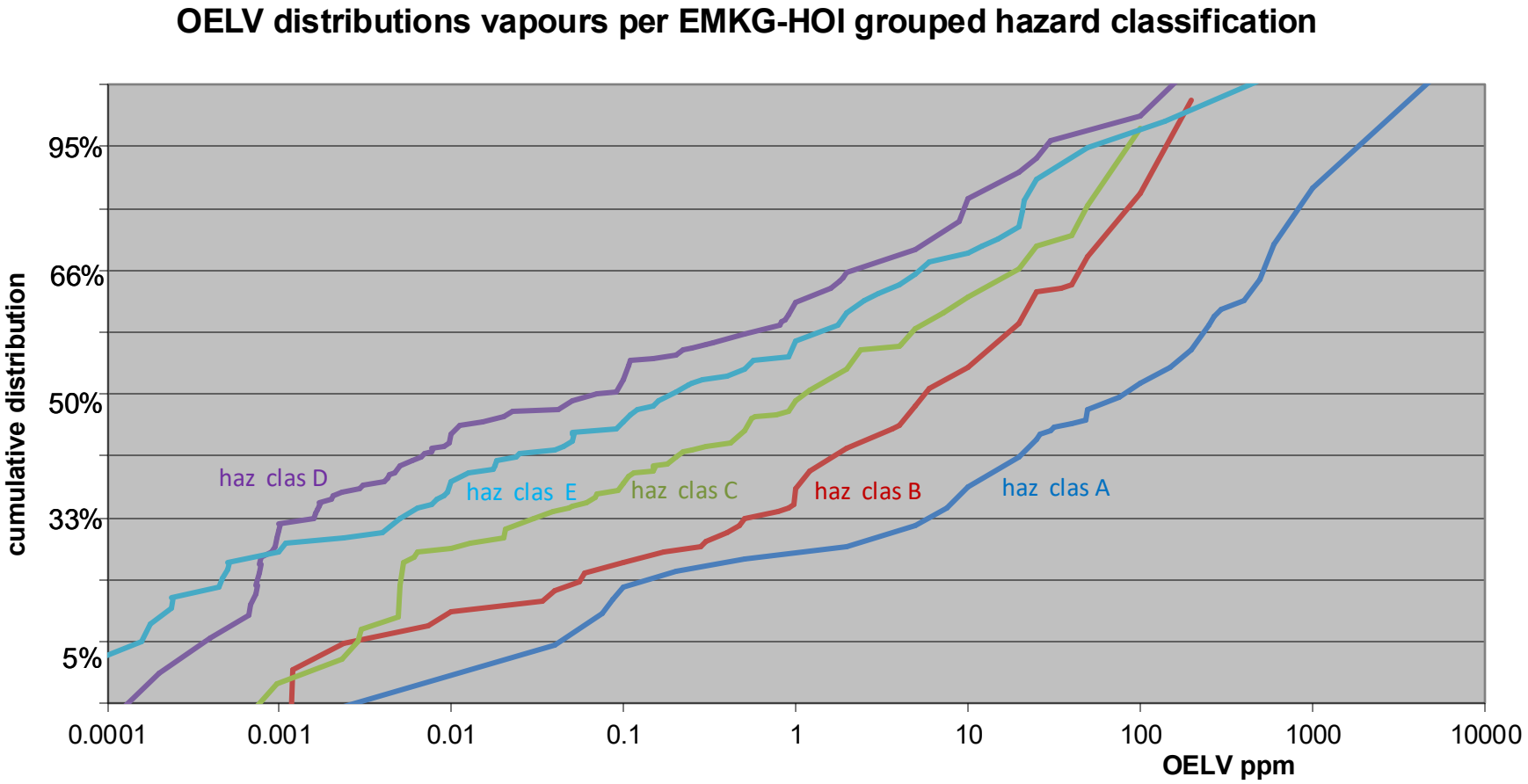


Results – EMKG (inhalation)



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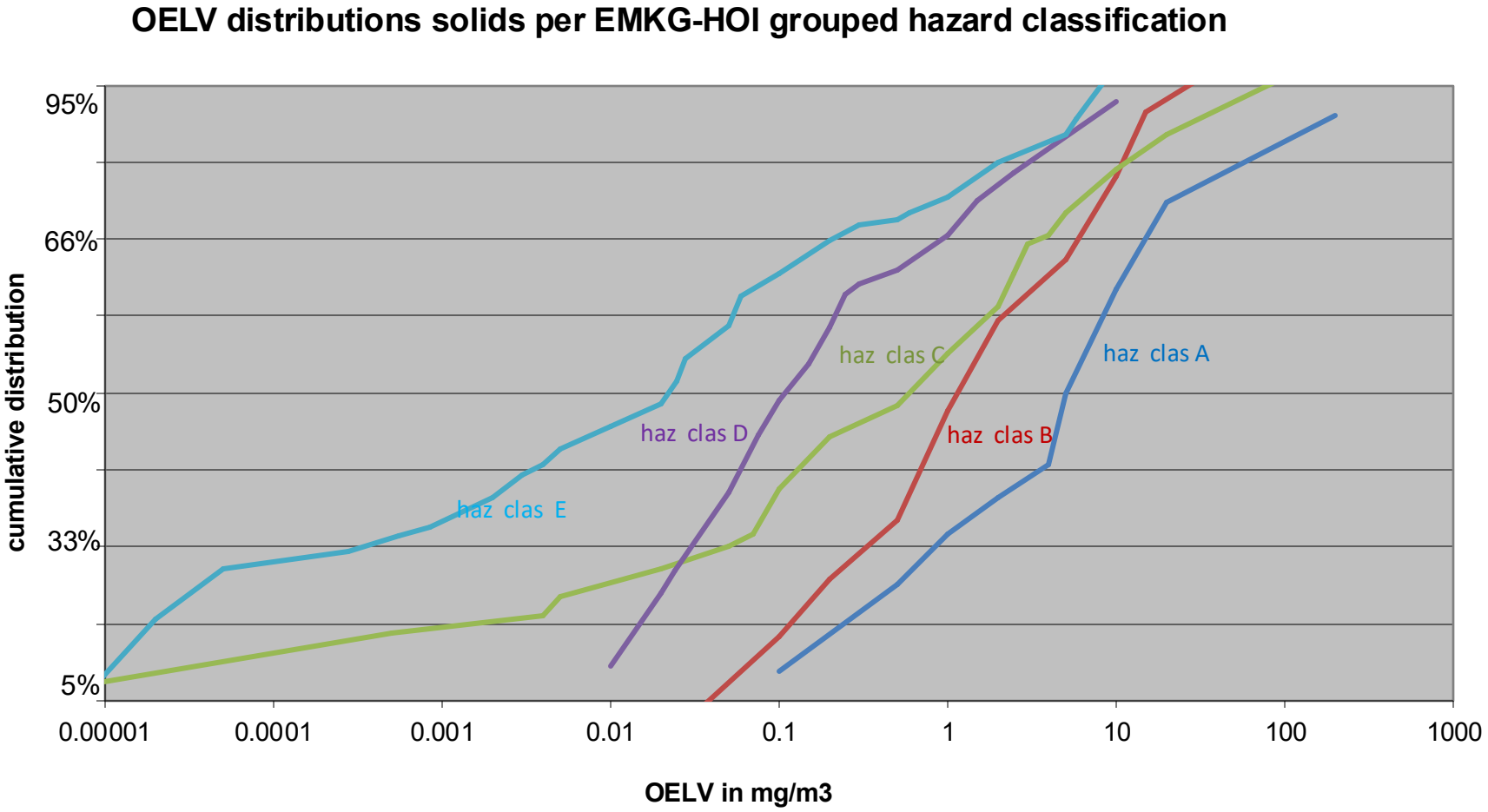

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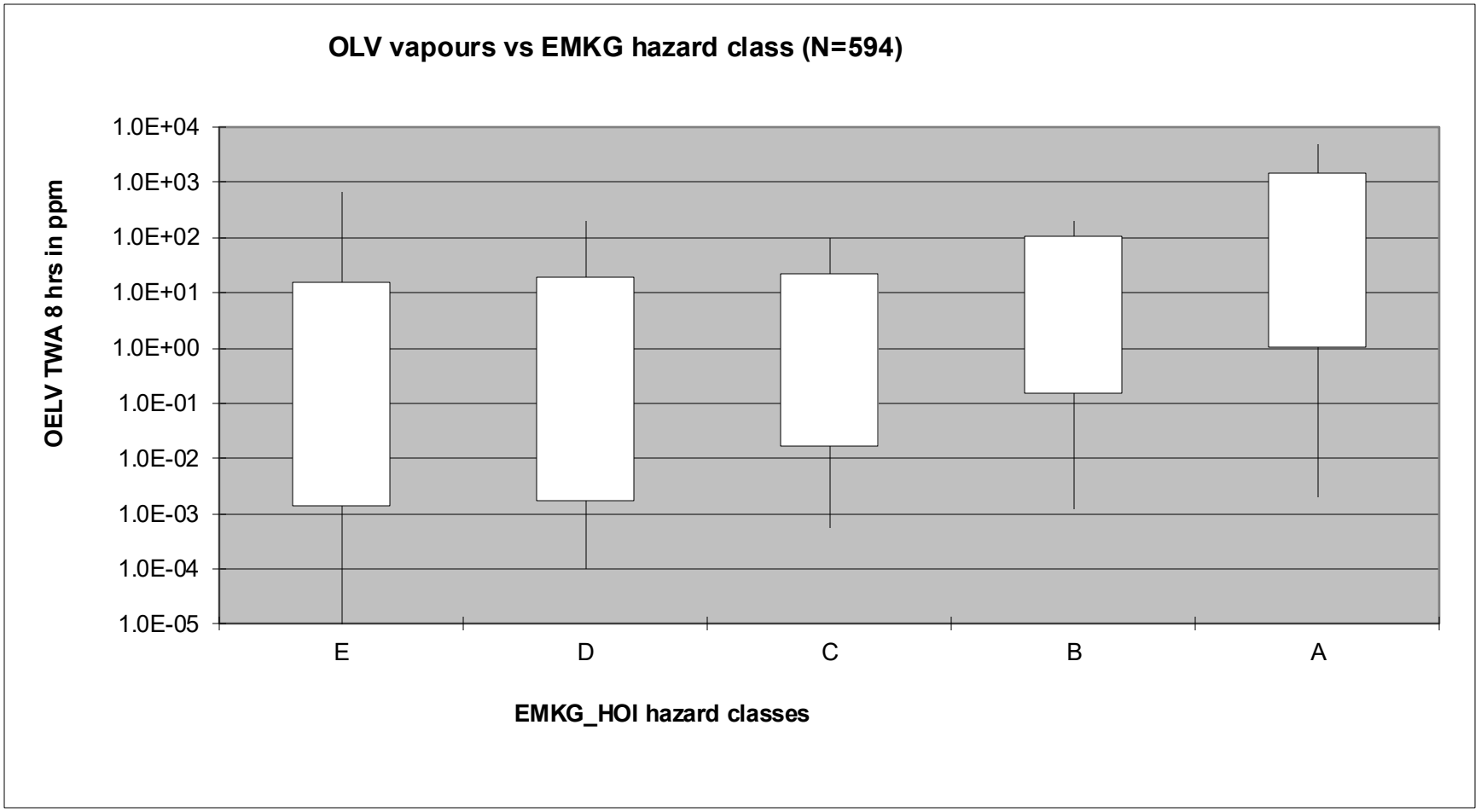
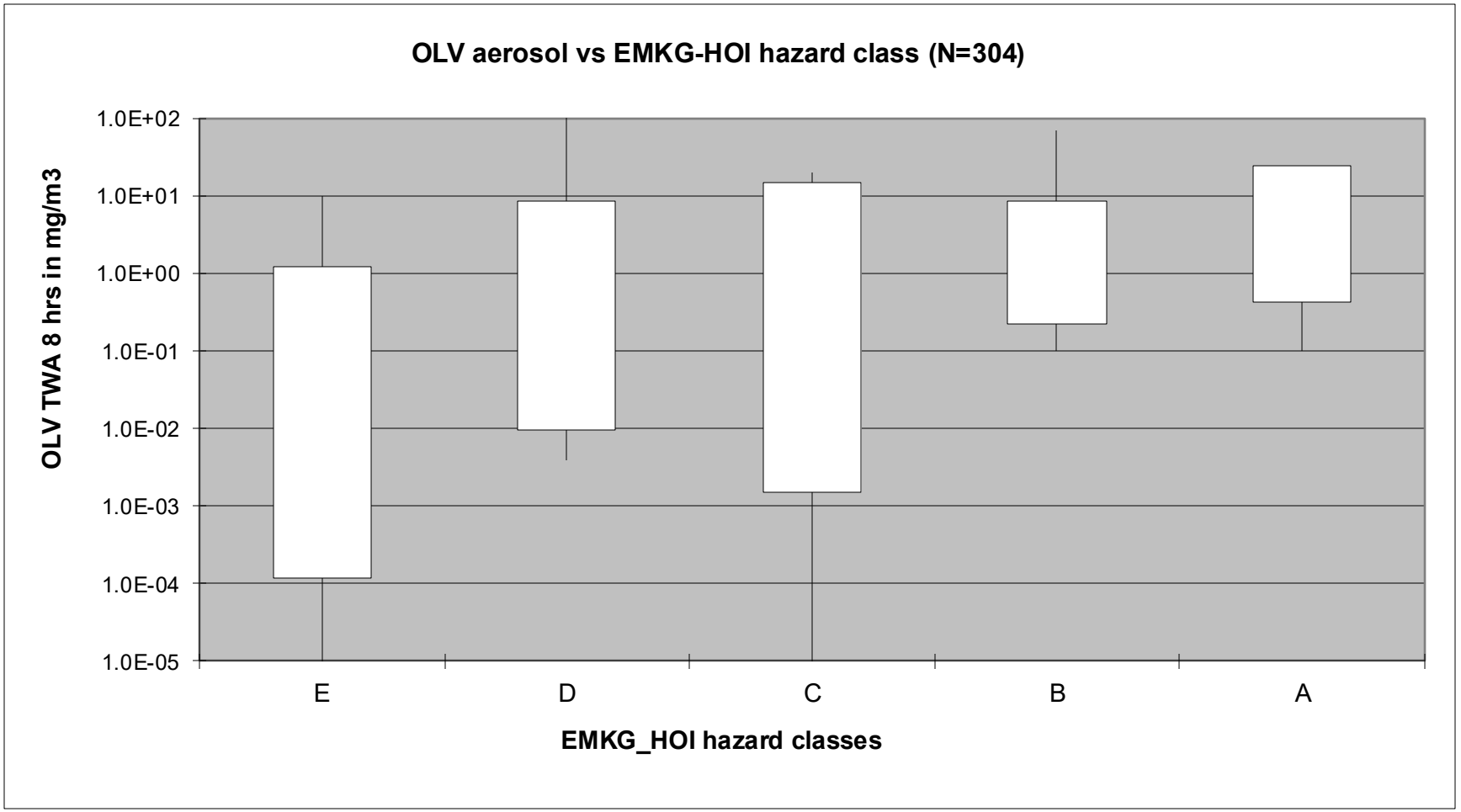
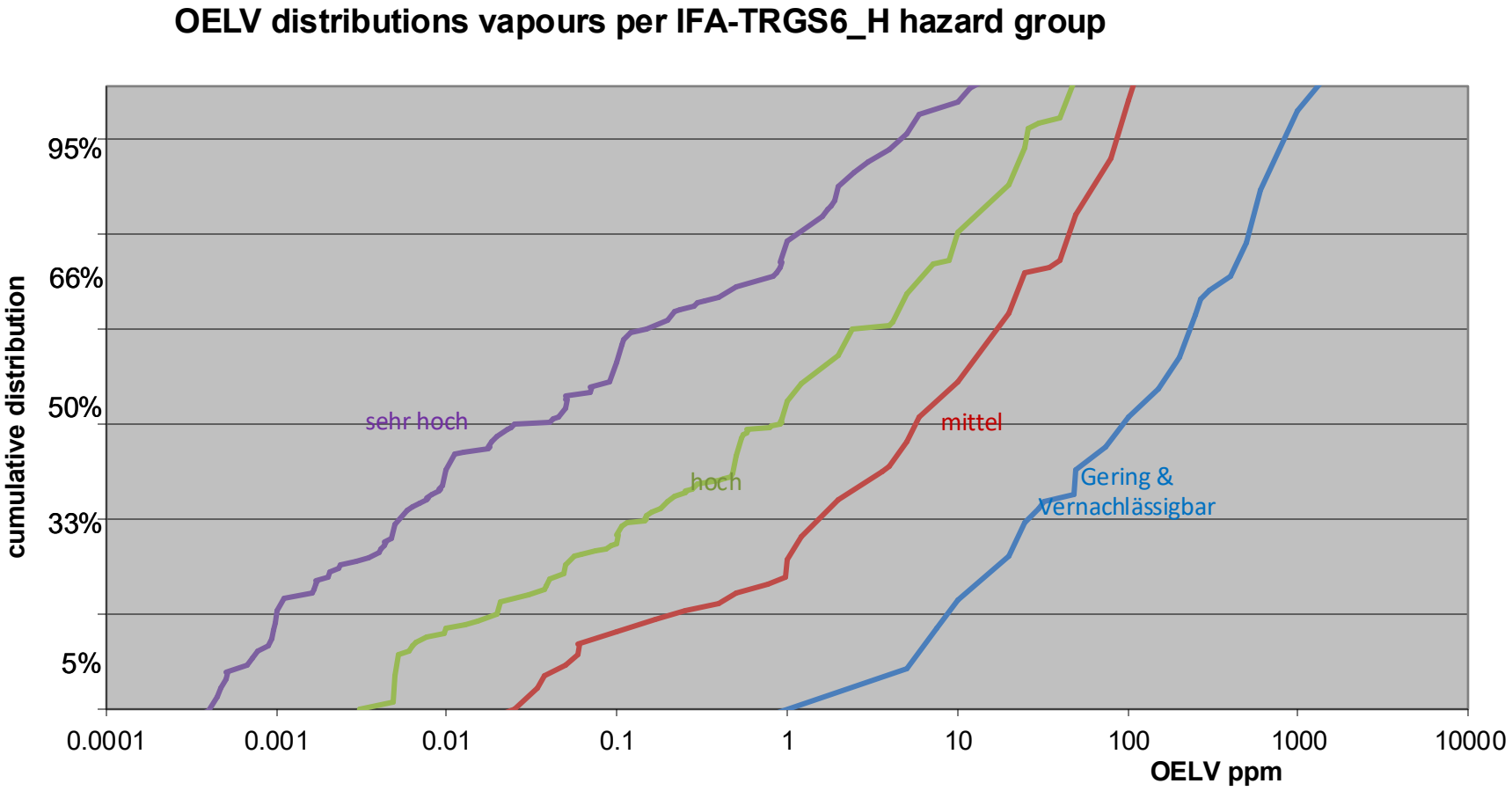


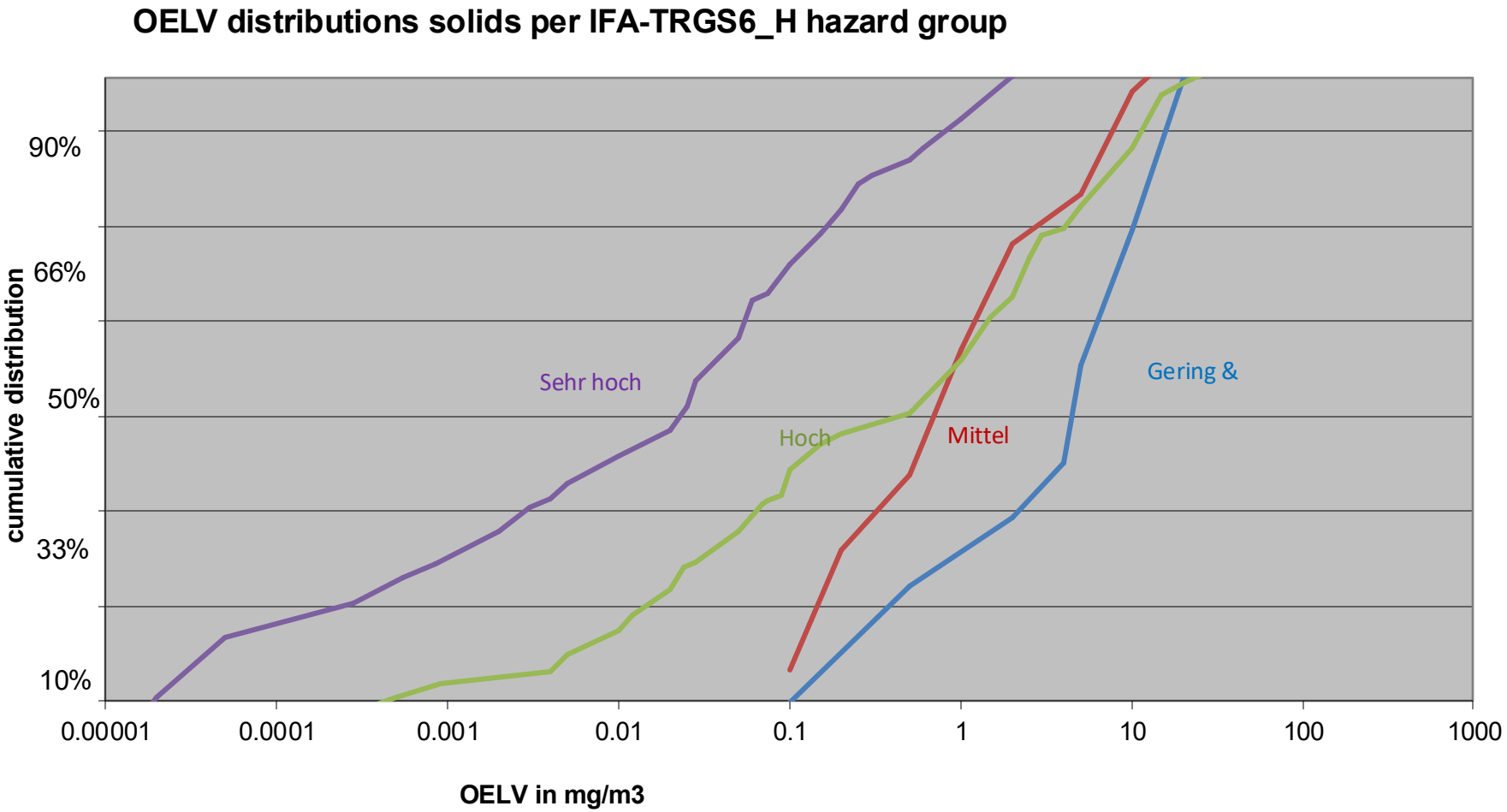
Results – EMKG (inhalation)



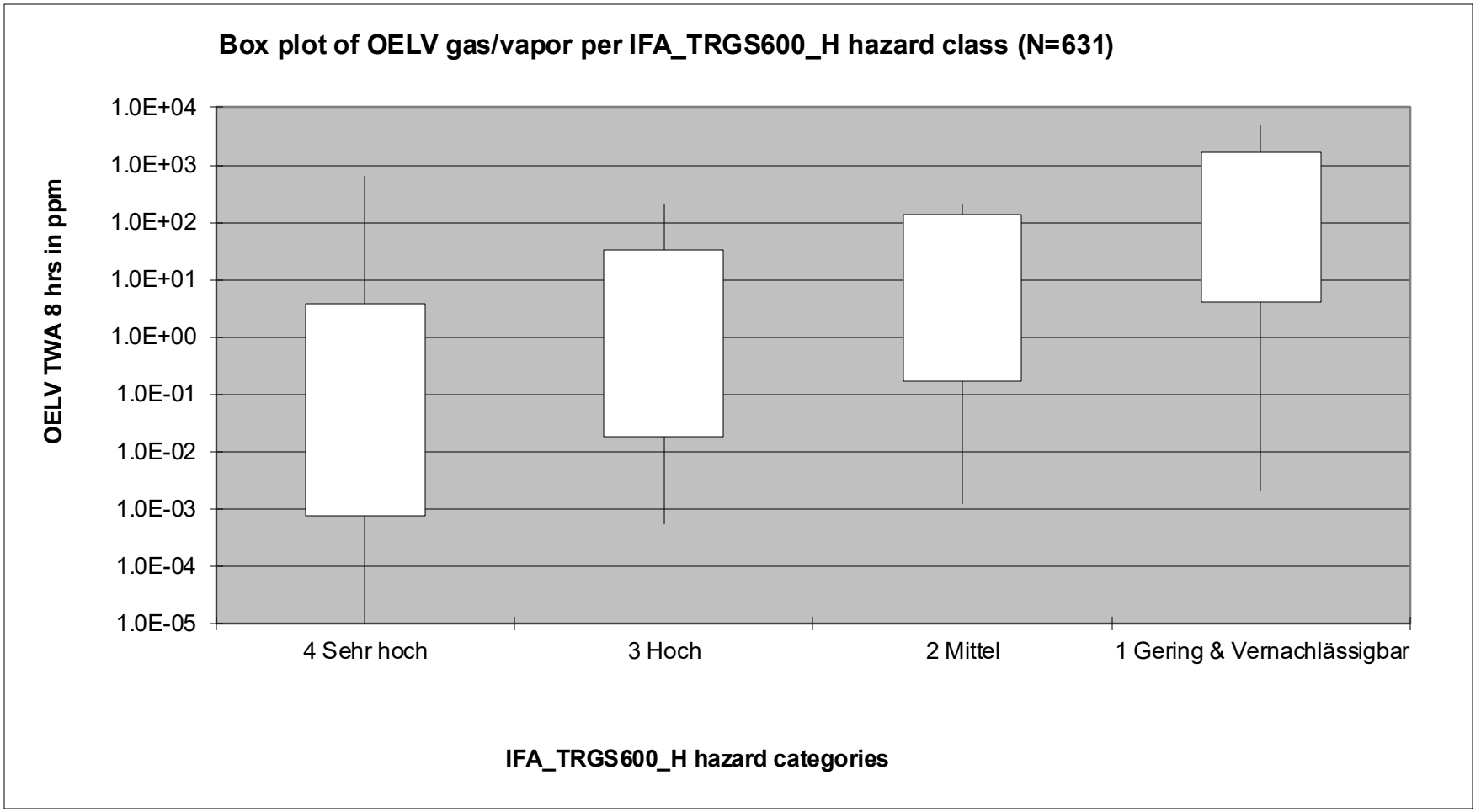
Results – IFA/TRGS600



Results – IFA/TRGS600



Results – IFA/TRGS600



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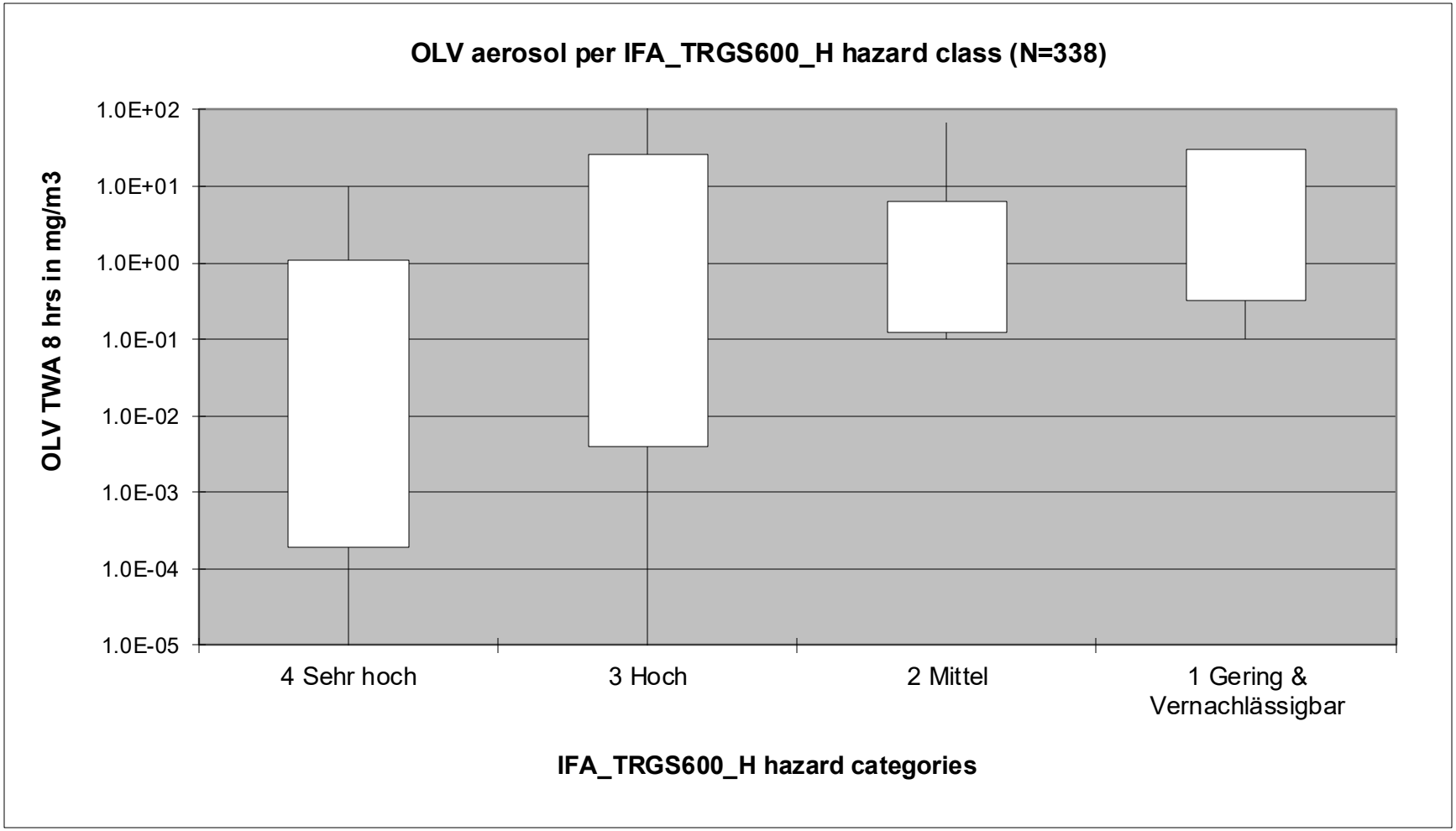

Conclusions

- The OELV distributions per hazard group can, within the 10 to 90%-tile, in some cases be described by Lognormal distribution

- TRGS600 differentiates at this moment best the contributing OELV distributions per hazard group.

Proposed kick-off values 2014

Basis: DGUV IFA Spaltenmodell (TRGS600)

Hazard Group	1	2	3	4
H-statements	H300, H310, H330, H340, H350, H350i, EUH032	H301, H311, H317, H318, H331, H334, H341, H351, H360, H360F, H360D, H360FD, H360Fd, H360Df, H370, H372, EUH029, EUH031, EUH070	H302, H312, H314, H332, H361, H361f, H361d, H361fd, H362, H371, H373, EUH071	H304, H315, H319, H335, H336, EUH066, no H3##-statements
Gases/vapors (ppm)	0,001	0,01	0,1	5
Dusts (mg/m^3)	0,0001	0,01	0,1	0,5

Differences kick-offs 2005 and 2014

Hazard Group	1	2	3	4
H-statements (R-phrases)	H300 (R28), H310 (R27), *H330 (R26)*, H340 (R46), H350 (R45), H350i (R49), EUH032 (R32), 2005: R48/23,24,25 (H372)	H301 (R25), H311 (R24), H317 (R43), H331 (R23), H334 (R42), H341 (R68), H351 (R40), H360F (R60), H360D (R61), H360FD (R60+R61), *H360Fd (R60)*, H360Df (R61), EUH029 (R29), EUH031 (R31), 2014: H318 (R41), H360, H370 (R39/23..28), H372 (R48/23,24,25), EUH070 (R39-41), 2005: R33 (H373), R35 (H314), *R23 (H330)*, R48/20,21,22 (H373)	H302 (R22), H312 (R21), H314 (R34), H332 (R20), H361f (R62), H361d (R63), H361fd (R62), H362 (R64), 2014: H361, H371 (R68/20..22), H373 (R48/23,24,25, R33), EUH071, 2005: R41 (H318), *R63 (H360Fd)*, *R62 (360Df)*	H304 (R65), H315 (R38), H319 (R36), H335 (R37), H336 (R67), EUH066 (R66), no H3##-statements (no R-phrases health)
Gases/vapors (ppm)	2014: 0,001 2005: 0,001	2014: 0,01 2005: 0,01	2014: 0,1 2005: 0,2	2014: 5 2005: 4
Dusts (mg/m^3)	2014:0,0001 2005: 0,01	2014: 0,01 2005: 0,02	2014: 0,1 2005: 0,06	2014: 0,5 2005: 0,24

Conclusions

- Differences in Hazard groups 2005 and 2014
- Kick-offs group 4 (lowest health hazard): higher
- Kick-offs in group 1 (highest health hazard): lower

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Thanks!!

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