



POISONS CENTRES DATA FOR EXPERT JUDGEMENT WITHIN CLP REGULATION: SOLID HOUSEHOLD AUTOMATIC DISHWASHING PRODUCTS DO NOT CAUSE SERIOUS EYE DAMAGE

XXX INTERNATIONAL CONGRESS
OF THE EUROPEAN ASSOCIATION OF POISONS CENTRES
AND CLINICAL TOXICOLOGISTS



11-14 MAY 2010 - BORDEAUX - FRANCE

ANDREAS STÜRER

C. SEIDEL, O. SAUER, I. KOCH, T. ZILKER, M. HERMANN-SCLAUSEN,
K. HRUBY, G. HÜLLER, E. TUTDIBI, HJ. HEPPNER, H. DESEL

KLINI**T**ox + STIZ ZUERICH

OBJECTIVE

- On January 20th 2009 the Regulation (EC) on Classification, Labelling and Packaging (**CLP**, N° 1272/2008) entered into force
- Globally Harmonised System (**GHS**) is applied
- New calculation method results in the classification „serious eye damage“ (hazard category 1) and labelling with GHS05 (corrosion ) for many products (previously: irritant ) , e.g.:
solid household automatic dishwashing products

OBJECTIVE

- Appropriate labelling is a prerequisite for the best possible medical advice and treatment in case of suspected poisoning
- A labelling which overemphasizes existing hazards known from experience in clinical toxicology could lead to:
 - Inappropriate medical treatment
 - Human health damage
 - Unnecessarily increasing costs for health care sector

OBJECTIVE

- CLP Regulation Annex I (p 36-37/1355)
No. 1.1.1. The role and application of expert judgement and weight of evidence determination
 - Expert judgement should be applied where weight of evidence determinations are needed
 - No. 1.1.1.3: „A weight of evidence determination means that all available information bearing on the determination of hazard is considered together, such as ... human experience ... data from accident databases, epidemiological and clinical studies and well documented case reports and observations.“

MAGAM STUDY



Oktober 2008
11 PCs
in DE, AT and CH
launched the

MAGAM-Study*

supported by the IKW
(German Cosmetic,
Toiletry, Perfumery and
Detergent Association;
Frankfurt/Main)

* **M**ULTINATIONAL, **R**ETROSPEKTIVE **A**NALYSIS OF **P**OISONS CENTRES DATA
ON THE QUESTION OF CORROSIVE **E**YE LESIONS CAUSED BY
SOLID **A**UTOMATIC DISHWASHING PRODUCTS
AND OTHER DETERGENTS, CARE AND CLEANING PRODUCTS

QUESTIONS

- Do solid automatic dishwashing products (powder or tabs) and other detergents and cleaning products, exploited for domestic use, cause severe or lasting eye lesions?
- What is the correct classification and labelling for solid household automatic dishwashing products?



- Are poisons centres' data suitable for expert judgement within CLP?

METHODS

- Retrospective study
- Area: 11 PCs DE–AT–CH; ~100 m inhab.
- Period: Jan 1st 1998 to Dec 31st 2007
- Agents:
Detergents, care and cleaning products
for household use
 - Solid automatic dishwashing prod. (ADW)
 - Drain cleaners
 - All-purpose cleaners
 - Manual dishwashing products
 - Laundry detergents
 - Toilet cleaners

METHODS – STEPS / TIME

Product/Case Identification

(11 PCs; TDI-Categories)

10/08

- 2/09

Cases -> Database

(www; 1st quality control)

3/09

- 6/09

Moderate + Severe Cases

(anonymised pdf's; 2nd quality control)

7/09

- 8/09

Product Identification via IKW

(+ manufacturers; Class./Label./Use)

7/09

- 4/10

ADW ✓

(Drain Cleaner)

Analysis and Statistics

9/09

- 9/10

- CLP Regulation Annex I No. 3.3. (p 91)
PART 3: HEALTH HAZARDS
3.3. Serious eye damage/eye irritation

3.3. Serious eye damage/eye irritation

3.3.1. *Definitions*

3.3.1.1. Serious eye damage means the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application.

Eye irritation means the production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application.

METHODS – SEVERITY GRADING

MAGAM-SYMPOMS		POISONING-SEVERITY-SCORE [PSS]*
unknown		unknown
asymptomatic		no symptoms or signs
irritation	MINOR	irritation
redness		redness
burning		-
pain, indisposition		-
foreign body sensation		-
lacrimation		lacrimation
mild palpebral oedema		mild palpebral oedema
conjunctivitis, slight		-
crying, uneasiness		-
slightly impaired vision (short, self limited)		-
intense irritation		MODERATE
foreign body sensation, severe (treatment necessary)	-	
blepharospasm	-	
conjunctivitis, severe/purulent	-	
corneal abrasion	corneal abrasion	
minor (punctate) corneas ulcers	minor (punctate) corneas ulcers	
acide burn, not specified	-	
moderately impaired vision	-	
cornela ulcers (other than punctate)	SEVERE	cornela ulcers (other than punctate)
perforation		perforation
permanent damage		permanent damage
permanent impaired vision		-
amaurosis		-
other eye symptoms (not mentioned above)		-

*) Persson HE, Sjöberg GK, Haines JA, Pronczuk de Garbino J.
Poisoning Severity Score. Grading of acute poisoning.
J Toxicol Clin Toxicol 1998; 36: 205-13.



Product/Case Identification (11 PCs; TDI-Categories) => **Stockholm 2009**

162

NO	PRODUCT GROUP	%	TOTAL
1	all agents		1'841'438
1a	all agents - eye exposure	1.6	28'956
2	all household cleaning products	11.3	207'779
2a	all household cleaning products - eye	3.1	6'423
3	dishwashing tabs and powders	0.9	16'755
3a	dishwashing tabs and powders - eye	1.0	162
4	all purpose cleaners	0.7	12'779
4a	all purpose cleaners - eye	4.3	547
5	manual dishwashing products	2.2	40'008
5a	manual dishwashing products - eye	0.7	300
6	laundry detergents	1.3	23'361
6a	laundry detergents - eye	2.9	668
7	drain cleaners	0.2	3'732
7a	drain cleaners - eye	2.9	108
8	toilet cleaners	0.8	13'936
8a	toilet cleaners - eye	2.9	400
TOTAL 3-8			110'571
TOTAL 3a-8a			2'185

RESULTS



Product/Case Identification
(11 PCs; TDI-Categories)

162


Cases -> Database
(www; 1st quality control)

142

GFKT-Datenbank - Windows Internet Explorer bereitgestellt von UniversitätsSpital Zürich

https://www.klinitox.de/

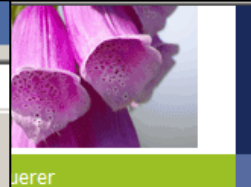
GFKT-Datenbank

 **Datenbank für Vergiftungsfälle**

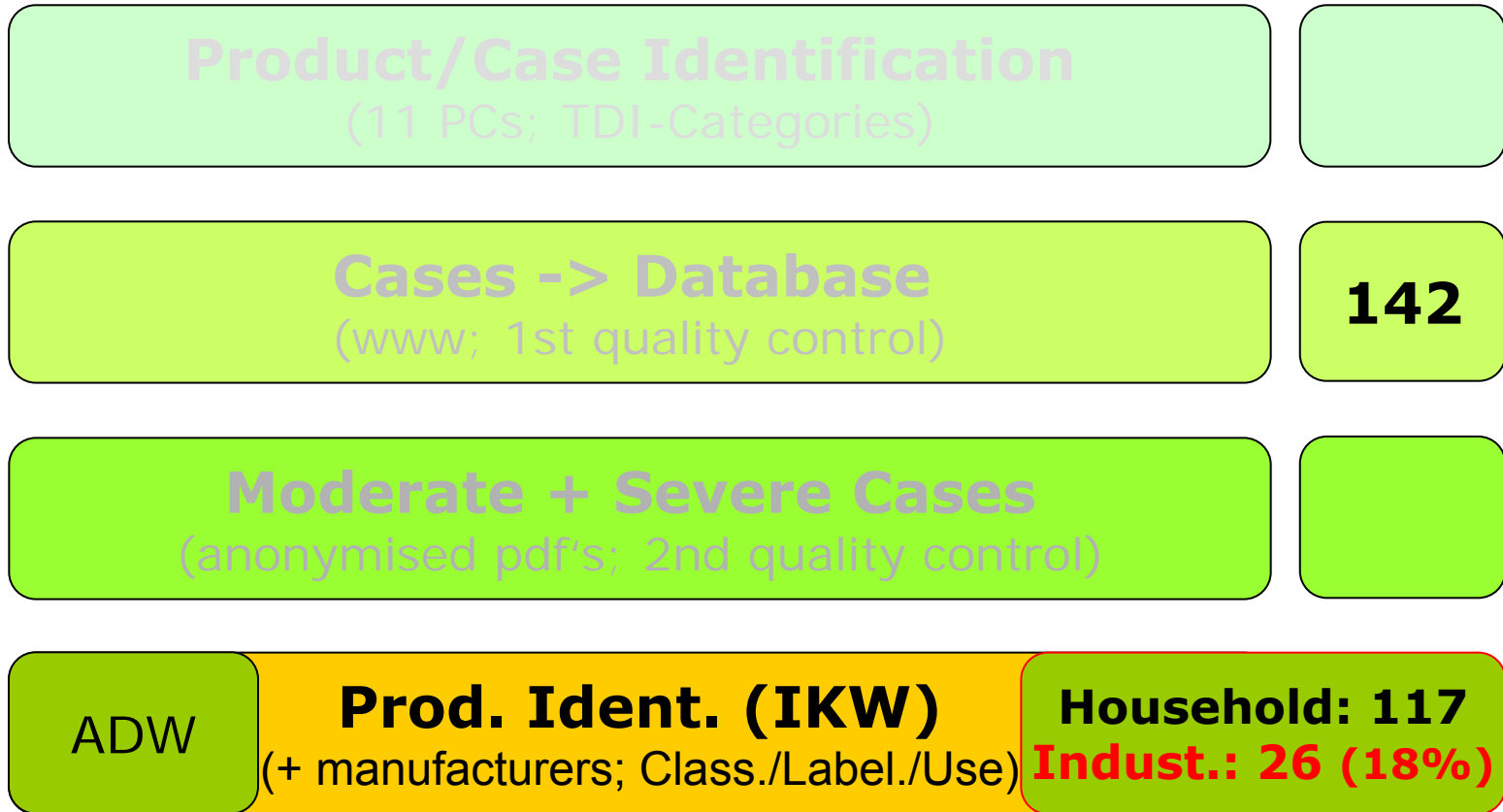
gewähltes Projekt **MAGAM mit 2230 Datensätzen** - [Zur Projektauswahl](#)

[zur Datenbank](#)

GFKT FALL-NR	UPLOAD AM/EINGABE AM-GIZ	REGIONALE FALL-NR	KATEGORIE CODE	NOXE	WIRKSTOFF
3295	- 15.01.2009, 14:48:50 - MAI - 1998003608 - ECRB03B - wc stein - - - Andere - Kleinkind/er - 1 Jahr/e - a				
3296	- 15.01.2009, 14:48:50 - MAI - 1998006739 - ECRT01A - rei ultra - - - oculoär - Ältere/r - 67 Jahr/e - akziden				
3297	- 15.01.2009, 14:48:50 - MAI - 1998007911 - ECRA01A - a&p kompaktreiniger - - - Andere - Kleinkind/er -				

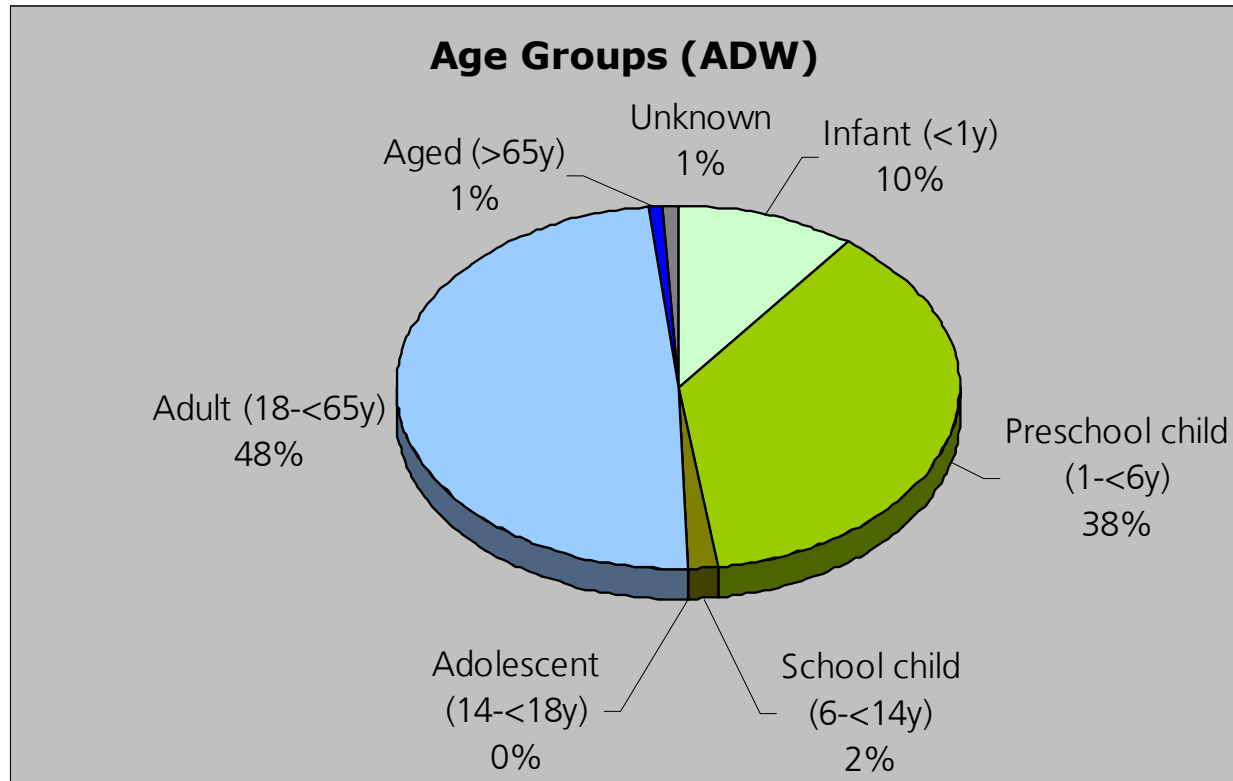


RESULTS



- 27% unspecific names of product groups => no identification
- 23% incomplete product names => identification not possible
- 50% specific product names => identification possible

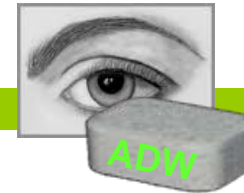
RESULTS - ADW (n=117)



- Latency period [median]: 15 min.

RESULTS

(household)



Household ADW Products

Severity Grading [PSS]	Cases	%
asymptomatic	29	25
minor symptoms	74	63
moderate symptoms	1	1
severe symptoms	0	0
unknown	13	11
TOTAL	117	100

RESULTS

(household/indust.)




Severity Grading [PSS]	Household ADW Products		<i>Industrial ADW Products</i>	
	Cases	%	Cases	%
asymptomatic	29	25	1	3.8
minor symptoms	74	63	16	62
moderate symptoms	1	1	8	31
severe symptoms	0	0	0	0
unknown	13	11	1	3.8
TOTAL	117	100	26	100

=> Dropouts

RESULTS



- ▶ **Case 3766 (household product)**
- 3-year old girl
- Mother called 6h after accidental self-exposure
- Automatic dishwashing product retrospectively identified (powder, R36 )
- Initially red eyes, slept in the meantime, woke up after 5½ hours, cried and „did not open her eyes“
=> blepharospasm => moderate severe
- Ophthalmologic examination recommended
- No follow up (full recovery expected)

RESULTS



- 74 cases with minor symptoms
(spontaneous recovery expected)
- 11 cases with follow up (15%)
 - 9 cases with full recovery
 - 2 cases with unknown outcome
 - ophthalmologic examination
 - no check up was planned as symptoms were mild
 - feedback was sent back to PC too early to document full recovery
 - complete recovery expected

CONCLUSION

- Due to the dataset of 11 PCs no serious eye damage can be expected as a result of eye exposure to solid household automatic dishwashing products
- Hazard category 2, „eye irritation“ with the symbol GHS07 (exclamation mark) seems to be an adequate classification and labelling



- PC data can provide a solid basis of expert judgement for CLP

LIMITATIONS

- Retrospective Study
- Data of 11 differently working and documenting PCs
- Product category
 - primarily classified by the individual PCs and
 - secondarily classified in accordance to the common TDI Classification System for Agents in PCs
- Low number of follow up as the PCs are not equipped for routinely follow up

FUTURE

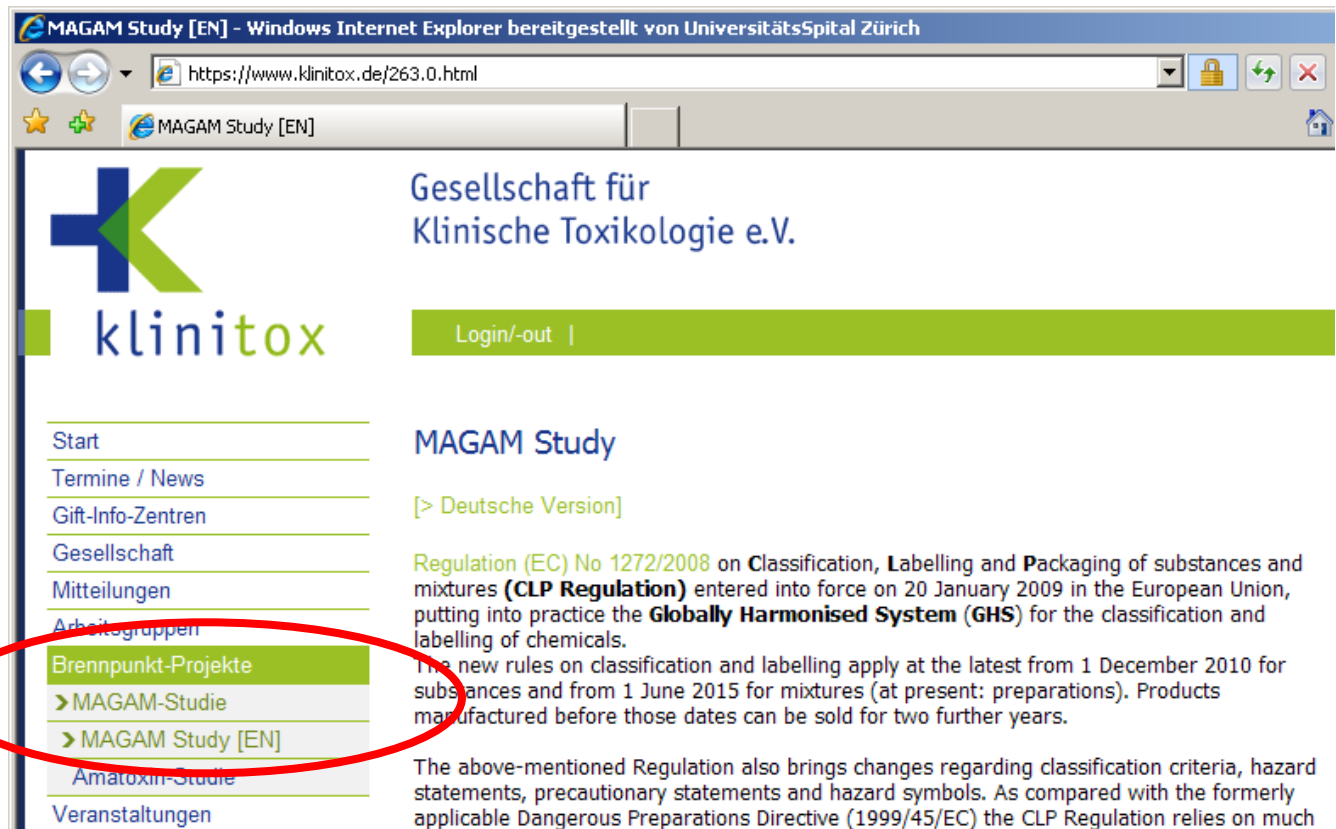
- Evaluation of the remaining 5 product groups
 - Drain Cleaner: n=119, 24 moderate, 1 severe
- More similar studies need to be done
 - Prove the value of PCs data
- Prospective studies should be achieved
 - Higher follow up rates
- Product names, product categories and unique identifiers should be transferred electronically to PCs before consultation to improve the data quality

THANKS

- Ingrid Koch, Torsten Binscheck – GIZ Berlin
- Carola Seidel – GIZ Bonn
- Georg Hüller, Helmut Hentschel – GGIZ Erfurt
- Maren Hermanns-Clausen – VIZ Freiburg
- Rafael Wagner, Herbert Desel – GIZ Göttingen
- Mario Scheer, Erol Tutdibi – GIZ Homburg
- Oliver Sauer, Sacha Weilemann – GIZ Mainz
- Martin Ganzert, Thomas Zilker – GIZ München
- Hans Jürgen Heppner – GIZ Nürnberg
- Dieter Genser, Karl Hruby – VIZ Wien
- Anna Ostini, Hugo Kupferschmidt – STIZ Zürich
- Bernd Glassl – IKW Frankfurt (+ Indust. Partners)

QUESTIONS ?

>>> www.klinitox.de/263.0.html
>>> andreas.stuerer@toxi.ch



MAGAM Study [EN] - Windows Internet Explorer bereitgestellt von UniversitätsSpital Zürich

https://www.klinitox.de/263.0.html

MAGAM Study [EN]

Gesellschaft für
Klinische Toxikologie e.V.

Login/-out |

Start

Termine / News

Gift-Info-Zentren

Gesellschaft

Mitteilungen

Arbeitsgruppen

Brennpunkt-Projekte

- > MAGAM-Studie
- > **MAGAM Study [EN]**
- Amatoxin-Studie

Veranstaltungen

MAGAM Study

[> Deutsche Version]

Regulation (EC) No 1272/2008 on **Classification, Labelling and Packaging** of substances and mixtures (**CLP Regulation**) entered into force on 20 January 2009 in the European Union, putting into practice the **Globally Harmonised System (GHS)** for the classification and labelling of chemicals.

The new rules on classification and labelling apply at the latest from 1 December 2010 for substances and from 1 June 2015 for mixtures (at present: preparations). Products manufactured before those dates can be sold for two further years.

The above-mentioned Regulation also brings changes regarding classification criteria, hazard statements, precautionary statements and hazard symbols. As compared with the formerly applicable Dangerous Preparations Directive (1999/45/EC) the CLP Regulation relies on much