Levels of occupational exposure to sensitisers: data stored in the COLCHIC database

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Introduction : what is a sensitizer?

Introduction : hurdles

- Establishing limit values
  - Shall it rely on sensitization or elicitation?
  - Few data available for human, missing tests protocols for animals
  - Exposure route

- The substances
  - Multiple exposure : isocyanates are versatile with different allergen potentials
  - Allergens may appear through chemical reactions

Introduction : identification of sensitizers

TABLE III. Qualitative Hazard Notations Designations for Chemical Allergens

Organization	Designation	Definition	Reference
ACGIH	SEN	• Potential for an agent to produce sensitization, as confirmed by human or animal data; may refer to dermal and/or inhalation sensitization	ACGIH[101]
	RSEN	• Respiratory sensitization notation - used in place of the SEN notation when specific evidence of sensitization by the respiratory route; does not imply that sensitization is the critical effect on which the TLV is based	
	DSEN	• Dermal sensitization notation used in place of the SEN notation when specific evidence of sensitization by the dermal route; does not imply that sensitization is the critical effect on which the TLV is based	
CAL/OSH	"D" SEN	• Substances can cause occupational dermal sensitization responses even when exposures do not exceed the values (i.e., PEL)	CAL/OSHA[112]
	"R" SEN	• Substances can cause respiratory sensitization	
GHS	Hazard statement 317 Skin sensitizer – Category 1	• May cause an allergic skin reaction • Substance causes skin sensitization within humans or animals	UNECE[109], EC[113]*
	Hazard statement 334*	• May cause allergy or asthma symptoms or breathing difficulties if inhaled	
	Respiratory sensitizer – Category 1	• Substance causes respiratory sensitization within humans or animals	
NIOSH	SEN	• Potential for immune-mediated reactions following exposure(s) of the skin	NIOSH[98]

ACGIH = American Conference of Governmental Industrial Hygienists; CA OSHA = California Occupational Safety and Health Administration; GHS = Globally Harmonized System for the Classification and Labeling of Chemicals; DSEN = dermal sensitization; PEL = permissible exposure limit; RSEN = respiratory sensitization; SEN = sensitization

G. S. Dotson et Al., Setting Occupational Exposure Limits for Chemical Allergens—Understanding the Challenges, Journal of Occupational and Environmental Hygiene, 12: S82–S98, 2016

Introduction : identification of sensitizers

Hazard statement 317	• May cause an allergic skin reaction
Hazard statement 334*	• May cause allergy or asthma symptoms or breathing difficulties if inhaled

Methodology : focus on substances

- Numerous labelled sensitizers :
  - More than 10 000 in OECD database
  - Need to focus on « famous » substances
  - 50 out of the 311 *Fiches toxicologiques INRS*
    - >30 Substances with H317 statement only
    - >4 substances with H334 statement only
    - >16 substances with both statements

Methodology : COLCHIC database

Not representative of all the workplace and companies

French Insurance and INRS laboratories

- Individual exposure measurements (56%)
- Ambiant concentration measurements (40%)
- Process emission (2%)
- Product composition (2%)

Which sensitizers are in the occupational atmosphere ?

Which exposure for the worker ?

… But strong database

COLCHIC

384 557 Measurements

20 123 Measurements campaign

1 163 Substances

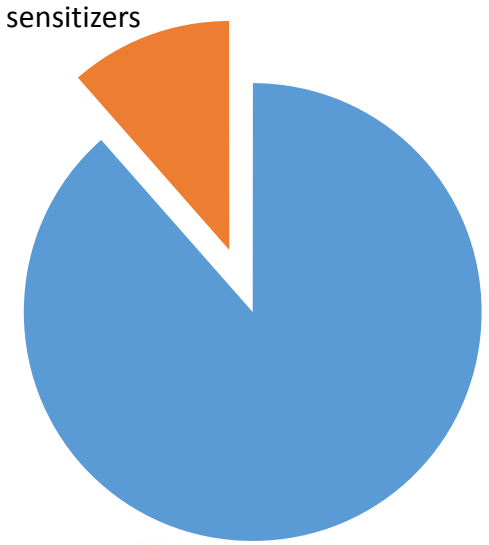
INRS validation

Methodology : data analysis

- Group the 50 substances into 7 categories
  - > Metals : nickel beryllium chromium cobalt
  - > Biocides : glutaral
  - > Formaldehyde
  - > Benzo[a]pyrene
  - > Isocyanates
  - > Other

- Total of 44 157 measurements of sensitizers out of 384 557 (11%)

Data for 22 substances, represent 99.5% of measurements of sensitizers in COLCHIC



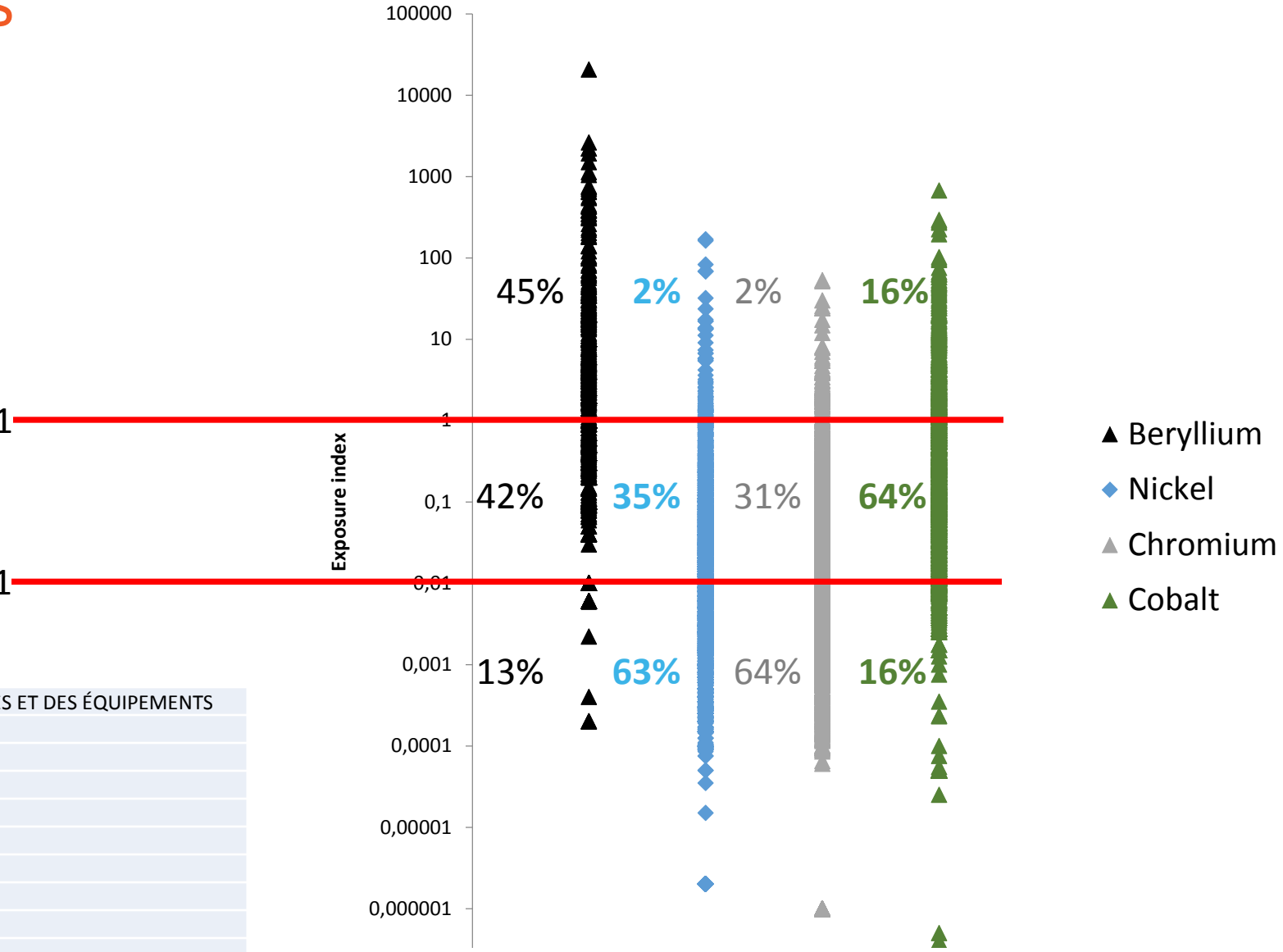
Results : metals

14 301 measurements

	Nb mes.	OEL (mg/m³)	source
Beryllium	1046	0,00005*	ACGIH
Nickel	4785	1	France
Total Chromium	5448	1	OSHA
Cobalt (metal)	3022	0,02	Sweden, Netherlands, Spain, Finland, Belgium, Poland Japan, Singapore, Korea, Canada

* Based on immune mediated endpoints

Results : metals



FABRICATION DE PRODUITS MÉTALLIQUES, À L'EXCEPTION DES MACHINES ET DES ÉQUIPEMENTS
MÉTALLURGIE
FABRICATION DE MACHINES ET ÉQUIPEMENTS N.C.A.
AUTRES INDUSTRIES MANUFACTURIÈRES
RÉPARATION ET INSTALLATION DE MACHINES ET D'ÉQUIPEMENTS
COLLECTE, TRAITEMENT ET ÉLIMINATION DES DÉCHETS ; RÉCUPÉRATION
TRAVAUX DE CONSTRUCTION SPÉCIALISÉS
FABRICATION D'AUTRES MATÉRIELS DE TRANSPORT
FABRICATION D'AUTRES PRODUITS MINÉRAUX NON MÉTALLIQUES
INDUSTRIES ALIMENTAIRES
COMMERCE DE GROS, À L'EXCEPTION DES AUTOMOBILES ET DES MOTOCYCLES
FABRICATION D'ÉQUIPEMENTS ÉLECTRIQUES

Results : isocyanates

647 measurements

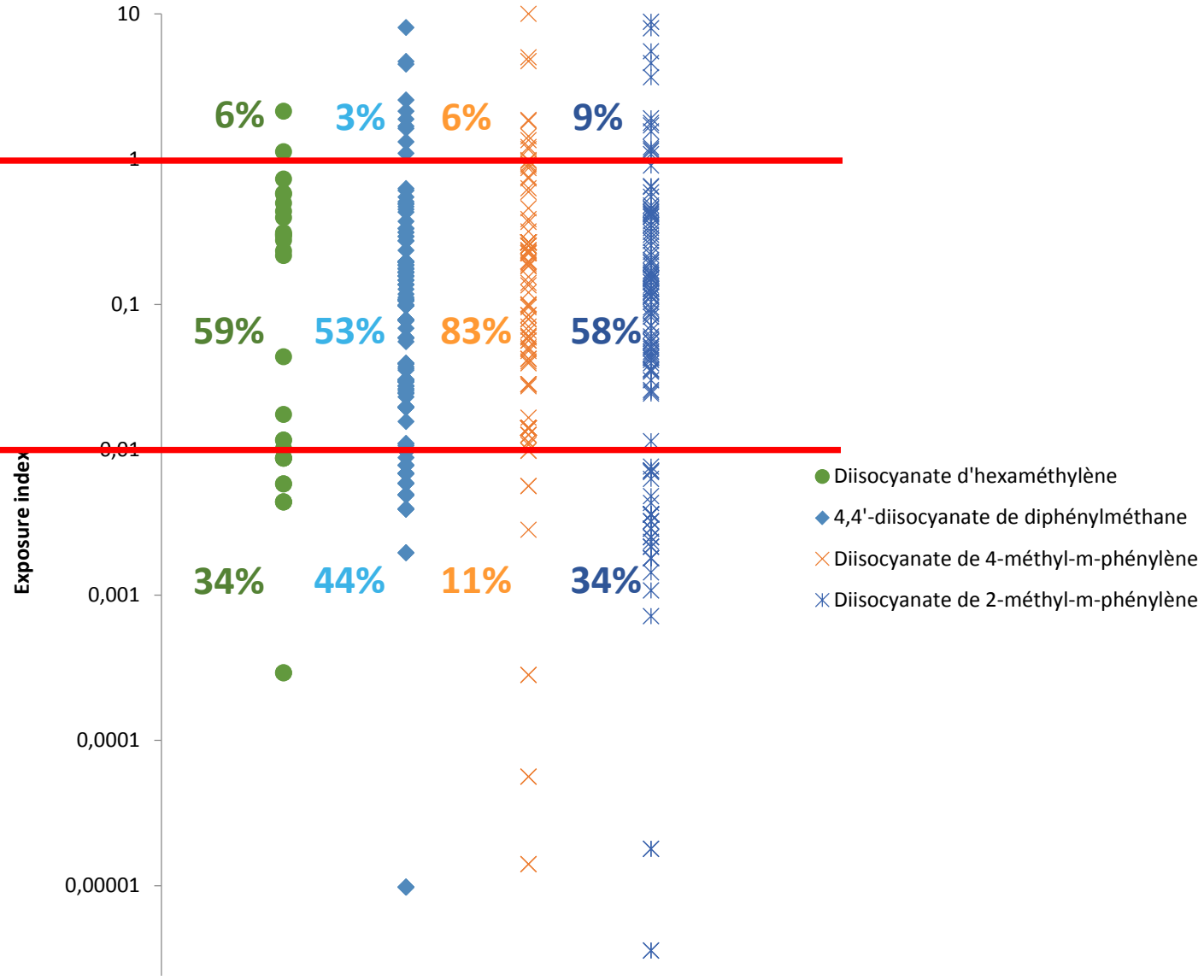
	N°CAS	Nb mes.	OEL (mg/m³)	source
4,4'-diisocyanate de diphénylméthane	101-68-8	315	0,05118*	ACGIH
Diisocyanate de 4-méthyl-m-phénylène	584-84-9	150	0,03562*	ACGIH
Diisocyanate de 2-méthyl-m-phénylène	91-08-7	151	0,14*	ACGIH
Diisocyanate d'hexaméthylène	822-06-0	31	0,03439*	ACGIH

* Based on immune mediated endpoints

Results : isocyanates

8h OEL - Exposure Index = 1

1% of 8h OEL - Exposure Index = 0,01



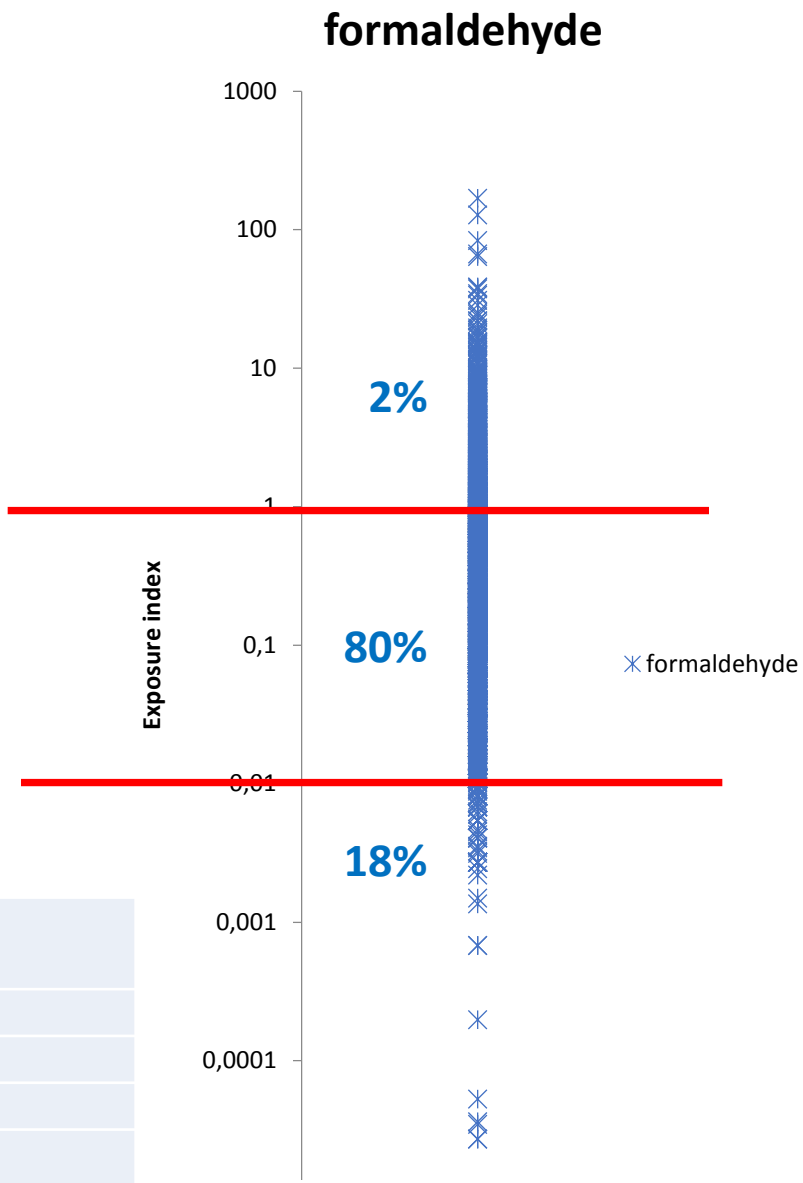
FABRICATION DE PRODUITS EN CAOUTCHOUC ET EN PLASTIQUE

Results : formaldehyde

SCOEL OEL = 0,3ppm = 0,369mg/m3
5747 measurements

8h OEL - Exposure Index = 1

1% 8h OEL - Exposure Index = 0.01



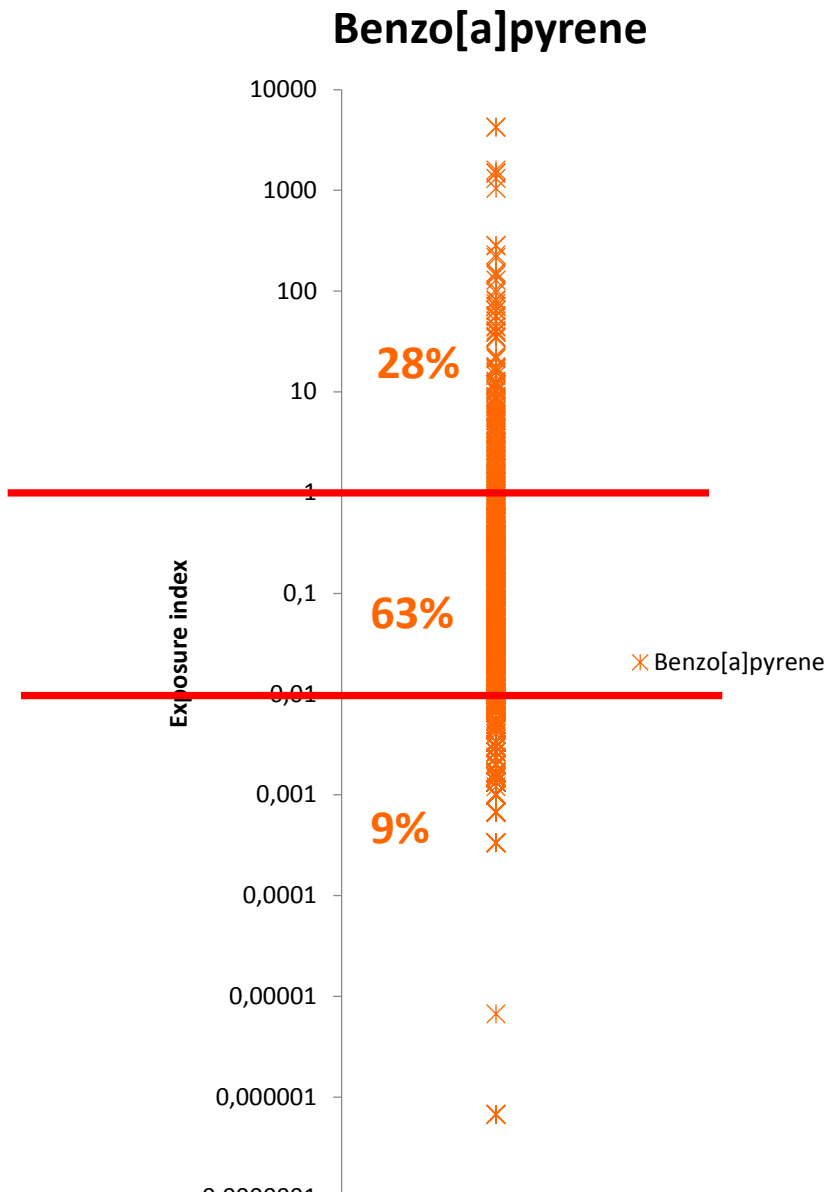
FABRICATION DE PRODUITS MÉTALLIQUES, À L'EXCEPTION DES MACHINES ET DES ÉQUIPEMENTS
MÉTALLURGIE
FABRICATION DE PRODUITS EN CAOUTCHOUC ET EN PLASTIQUE
ACTIVITÉS POUR LA SANTÉ HUMAINE
TRAVAIL DU BOIS ET FABRICATION D'ARTICLES EN BOIS ET EN LIÈGE, À L'EXCEPTION DES MEUBLES ; FABRICATION D'ARTICLES EN VANNERIE ET SPARTERIE
INDUSTRIE CHIMIQUE

Results : BaP

OEL = 150 ng/m3 (France)
1662 measurements

8h OEL - Exposure Index = 1

1% 8h OEL - Exposure Index = 0.01



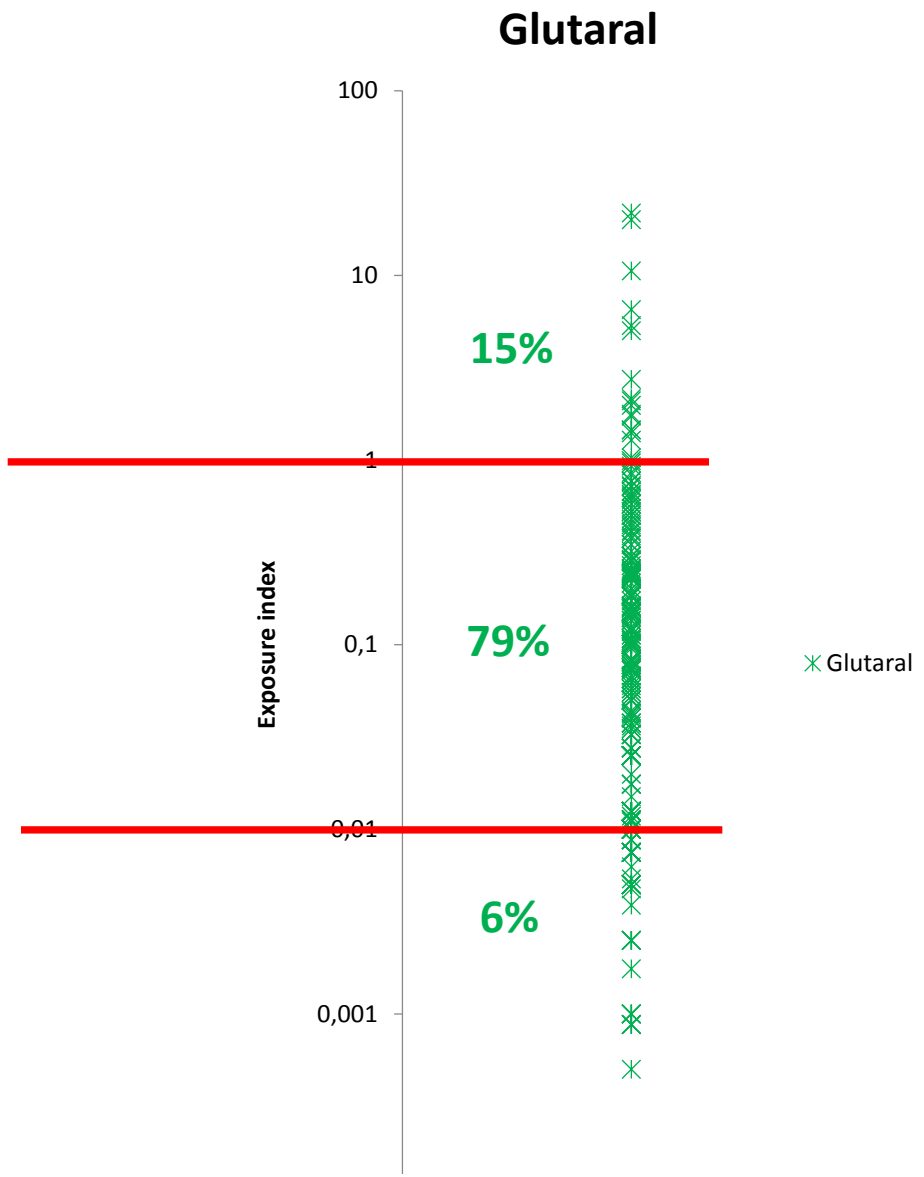
TRAVAIL DU BOIS ET FABRICATION D'ARTICLES EN BOIS ET EN LIÈGE, À L'EXCEPTION DES MEUBLES ; FABRICATION D'ARTICLES EN VANNERIE ET SPARTERIE

Results : Biocides

OEL Glutaral = 0,4 mg/m3 (France)
288 measurements

8h OEL - Exposure Index = 1

1% 8h OEL - Exposure Index = 0.01



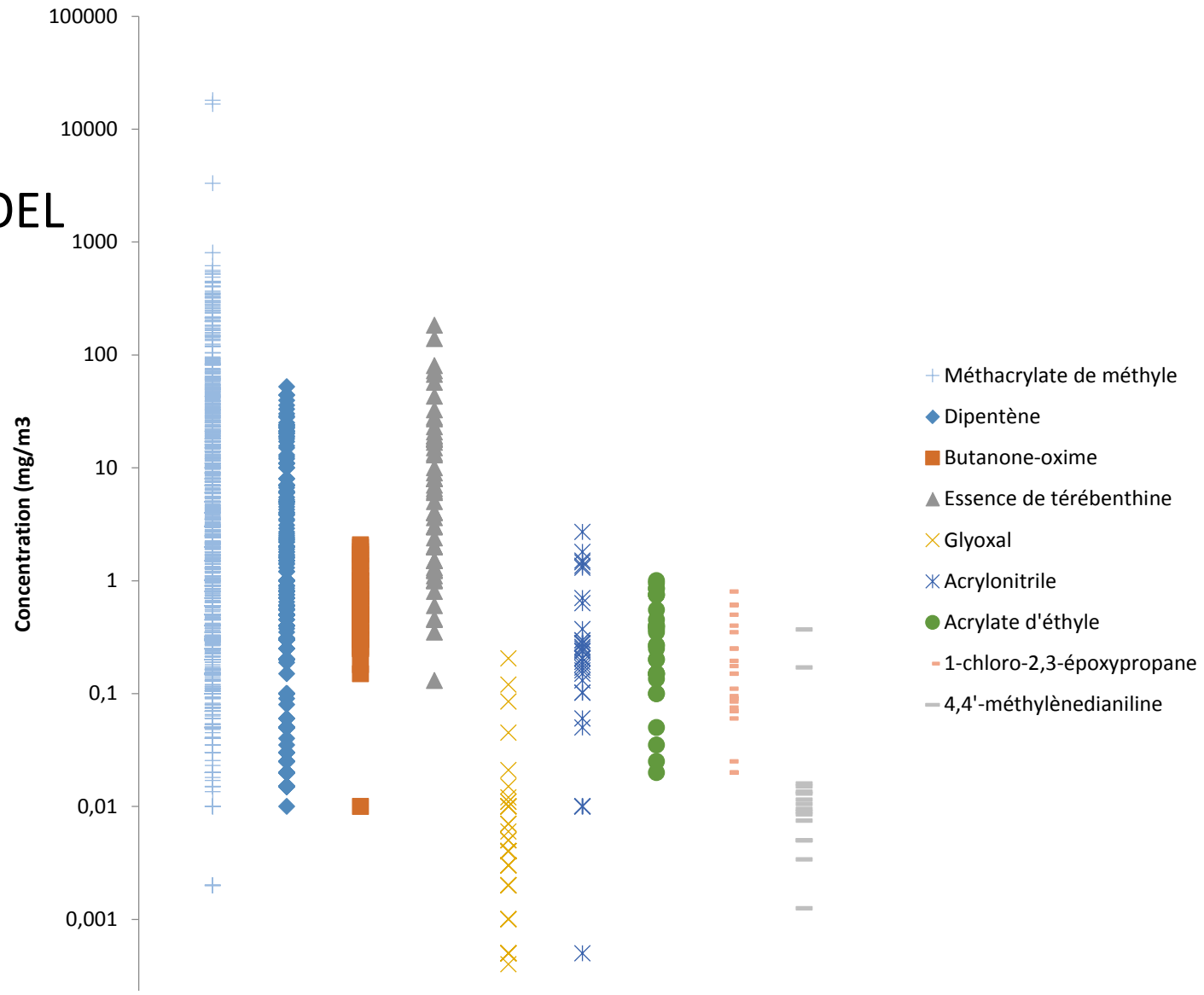
ACTIVITÉS POUR LA SANTÉ HUMAINE

Results : other

Not all substances have 8h-OEL
3628 measurements

Méthacrylate de méthyle	3008
Dipentène	327
Butanone-oxime	61
Essence de térébenthine	65
Glyoxal	52
Acrylonitrile	38
Acrylate d'éthyle	31
1-chloro-2,3-époxypropane	26
4,4'-méthylènedianiline	20

FABRICATION DE PRODUITS EN CAOUTCHOUC ET EN PLASTIQUE



Mitigating the risk : worker's health

- Specific medical surveillance for exposed workers

- Identification of symptoms
  - questionnaires
  - tests

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Mitigating the risk

TABLE V. Checklist Summary of Key Considerations During Assessment of Health Risks Associated with Chemical Allergens

Critical Question(s)
Is there an allergen risk for this task/workplace?
Is the chemical an allergen?
■ What guidelines are available (i.e., OELs, hazard notations)?
■ What data are available (i.e., epidemiology, animal, in vitro)?
■ How can data be integrated?
What are the exposure levels within the workplace?
■ What exposure pathways are important?
■ What are the temporal patterns (i.e., acute [peak] exposure vs. full shift exposure)?
■ What physical forms (particulates, gases/vapors) are important?
For the task/workplace, is there an allergen risk? If so, what is the severity of the risk?
■ Are data capable of deriving an OEL?
■ Are data capable of assigning a hazard band?
■ Are data capable of assigning a hazard notation?
What control strategies are needed to mitigate the risk?
■ Manage to prevent sensitization?
■ Manage to prevent elicitation?
Strategy for communicating in place?

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Mitigating the risk : discussion and conclusions

- Lack of OEL that suit sensitization effects
  - Gather data
  - Avoid (or limit) exposure
- Develop strategies BEFORE workers become sensibilized
- Need for hazard identification
  - Identify all products and substances
  - Specific assessment for sensitizers

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Institut National de Recherche et de Sécurité

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Thanks for your attention

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