

Occupational Exposure Bands (OEBs)

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What is an Occupational Exposure Band (OEB) ?

- A mechanism to quickly and accurately assign chemicals into “categories” or “bands” based on their health outcomes and potency considerations

A

B

C

D

E

Least hazardous

Most hazardous



Why do we need OEBs?





Chemicals in Commerce

Occupational Exposure Limits

- Approximately 1,000 chemicals with authoritative OELs
 - NIOSH RELs
 - OSHA PELs
 - California PELs
 - TLVs
 - WEELs
 - MAKs



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Dr. David Michaels
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The promise of Occupational Exposure Banding

- NIOSH
 - Facilitates more rapid evaluation of health risk
 - Used with minimal data
 - Highlights areas where data are missing
 - Supports the application of OEL-ranges for families of materials
 - Provides a screening tool for the development of RELs
- Stakeholders
 - Provides guidance for materials without OELs
 - Identifies hazards to be evaluated for elimination or substitution
 - Aligned with GHS for hazard communication
 - Facilitates the application of Prevention through Design principles

Is Occupational Exposure Banding the same as Control Banding?

- *COSHH Essentials* is

A control banding tool that helps small and medium-sized enterprises to do risk assessments for chemicals and mixtures of chemicals

- identifies the control band (control approach),
- produces advice on controlling risk from the chemical used in the specified task, and
- provides written guidance and documentation as a result of the assessment



What is Control Banding?

Table 1. Control bands for exposures to chemicals by inhalation

Band No.	Target Range of Exposure Concentration	Hazard group	Control
1	>1 to 10 mg/m ³ dust >50 to 500 ppm vapor	Skin and eye irritants	Use good industrial hygiene practice and general ventilation.
2	>0.1 to 1 mg/m ³ dust >5 to 50 ppm vapor	Harmful on single exposure	Use local exhaust ventilation.
3	>0.01 to 0.1 mg/m ³ dust >0.5 to 5 ppm vapor	Severely irritating and corrosive	Enclose the process.
4	<0.01 mg/m ³ dust <0.5 ppm vapor	Very toxic on single exposure, reproductive hazard, sensitizer*	Seek expert advice

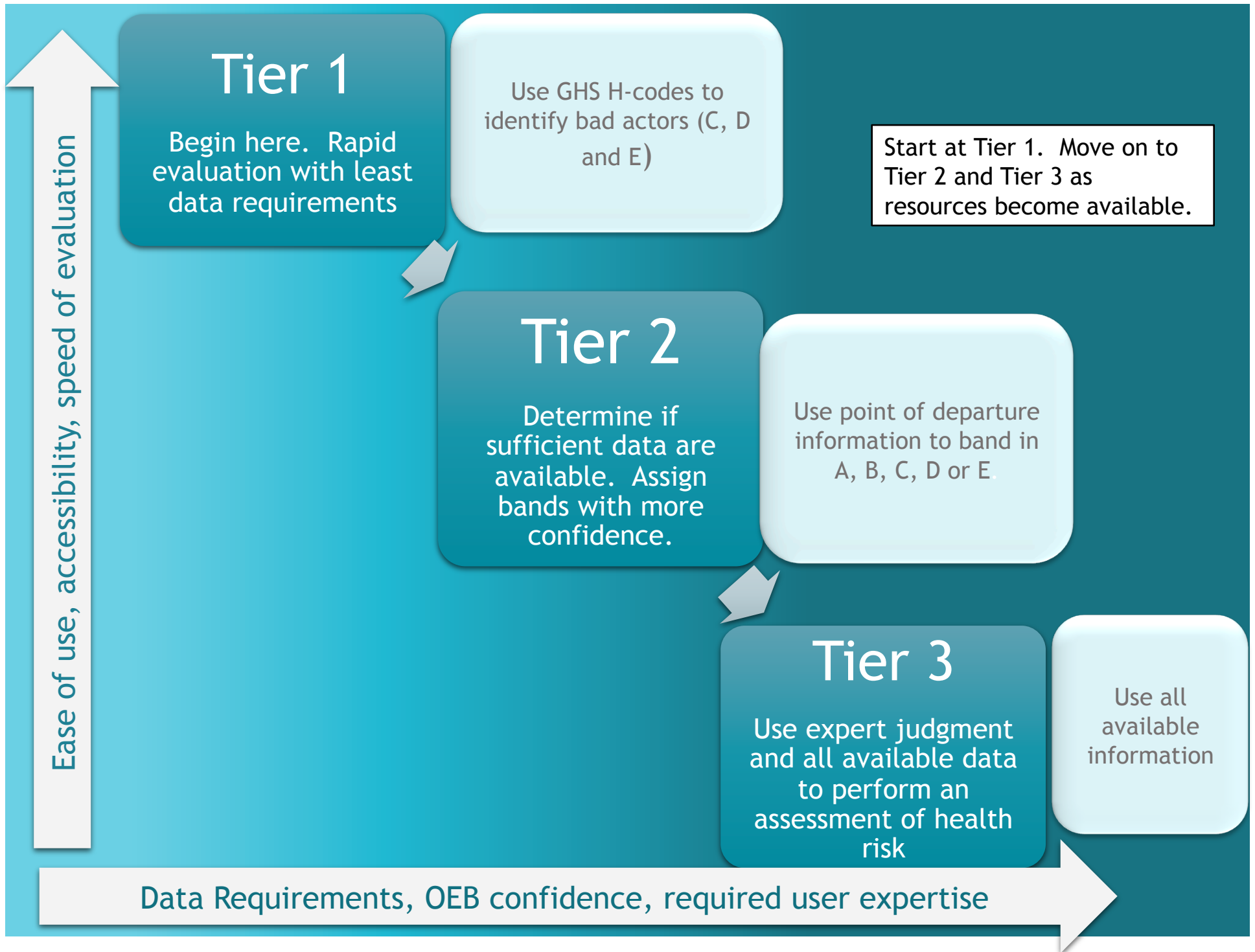
Occupational Exposure Banding is different!

- OEBs derived from toxicology and potency
- OEBs can be used to identify a control strategy



Tools for the Occupational Hygienist





Tier 1 —Qualitative

User: Health and safety generalist

A Tier 1 evaluation utilizes GHS Hazard Statements and Categories to identify chemicals that have the potential to cause irreversible health effects



Tier 2—Semi-Quantitative

User: Properly trained occupational hygienist

A Tier 2 evaluation produces a more refined OEB, based on point of departure data from reliable sources. Data availability and quality are considered.



Tier 3—Weight of Evidence

User: Toxicologist or experienced occupational hygienist

Tier 3 involves the integration of all available data and determining the degree of conviction of the outcome.

Why a Tiered Approach?

- In many cases detailed expertise needed to make judgements about these various types of toxicity endpoints
- Thus we can:
 - Tier 1: Rely on existing hazard classifications - does not require any independent toxicology evaluation
 - Tier 2: Be adequately familiar to find summary from authoritative reviews and in some cases weigh among studies with well defined criteria
 - Tier 3: Be able to review primary data and make judgments about effect adversity



How is the process organized?

Tiers 1 and 2 are based on the findings for eight standard toxicological endpoints:

- acute toxicity
- skin corrosion and irritation
- serious eye damage and irritation
- respiratory and skin sensitization
- germ cell mutagenicity
- carcinogenicity
- reproductive/developmental toxicity
- target organ toxicity resulting from repeated exposure

A

B

C

D

E

Least hazardous

Most hazardous

Hazard Classification

- Each physical or health hazard is a “hazard class” (e.g., Carcinogenicity is a hazard class)
- A “hazard class” may be sub-divided in the criteria into several “hazard categories” based on the degree of severity of the hazard
- Placing a chemical into a “hazard class” , and where necessary, a “hazard category”, is the concept of classification—determining not only the hazard, but also the severity of the effect



Tier 1 Overview

Chemical of interest has no OEL



Locate GHS hazard codes and categories in recommended databases



Compare hazard codes and categories with NIOSH criteria for each health endpoint



Assign band for each relevant health endpoint based on criteria



Assign a Tier 1 OEB for the chemical based on most protective endpoint band

Endpoint	Band	C	D	E
OEL Ranges	Particles	> 0.1 and ≤ 1 mg/m ³	> 0.01 ≤ 0.1 mg/m ³	≤ 0.01 mg/m ³
	Vapors	> 1 ≤ 10 ppm	> 0.1 ≤ 1 ppm	≤ 0.1 ppm
Acute Toxicity	GHS Hazard Category	3, 4	2	1
	GHS Hazard Statements	Harmful if swallowed. Harmful if inhaled. Harmful in contact with skin Toxic if swallowed. Toxic if inhaled. Toxic in contact with skin	Fatal if swallowed. Fatal if inhaled. Fatal in contact with skin.	Fatal if swallowed. Fatal if inhaled. Fatal in contact with skin.
	"H" Codes	H301, H302, H311, H332, H314, H315	H300, H330, H310	H300, H330, H310
Skin Corrosion/ Irritation	GHS Hazard Category	2		1A, 1B, 1C
	Skin corrosion/ irritation GHS Hazard statement	Causes skin irritation.		Causes severe skin burns and eye damage.
	Skin corrosion/ irritation "H" Code	H315		H314
Serious Eye Damage/ Eye Irritation	GHS Hazard Category	2A, 2B		1
	GHS Serious Eye Damage/Eye Irritation Hazard statement	Causes eye irritation Causes serious eye irritation		Causes serious eye damage
	Serious Eye Damage/ Eye Irritation "H" Codes	H319		H318

Endpoint	Band	C	D	E
OEL Ranges	Particles	> 0.1 and ≤ 1 mg/m ³	> 0.01 ≤ 0.1 mg/m ³	≤ 0.01 mg/m ³
	Vapors	> 1 ≤ 10 ppm	> 0.1 ≤ 1 ppm	≤ 0.1 ppm
Respiratory and Skin Sensitization	GHS Hazard Category	1B (skin)	1B (resp.) 1A (skin)	1A (resp.)
	GHS Respiratory and Skin Sensitization Hazard Statements	May cause an allergic skin reaction	May cause allergy or asthma symptoms or breathing difficulties if inhaled May cause an allergic skin reaction	May cause allergy or asthma symptoms or breathing difficulties if inhaled
	Respiratory and Skin Sensitization "H" Codes	H317	H334 H317	H334
Germ Cell Mutagenicity	GHS Hazard Category	2	1B	1A
	GHS Germ Cell Mutagenicity Hazard Statement	Suspected of causing genetic defects	May cause genetic defects	May cause genetic defects
	GHS Germ Cell Mutagenicity "H" Codes	H341	H340	H340
Carcinogenicity	GHS Hazard Category			2 1B 1A
	GHS Carcinogenicity Hazard statement			Suspected of causing cancer May cause cancer May cause cancer
	Carcinogenicity "H" Codes			H351, H350

Tier 1 Validation

Compared bands obtained from Tier 1 process for 744 chemicals with full shift OELs from the following authoritative bodies:

- NIOSH Recommended Exposure Limits (RELs)
- OSHA - Permissible Exposure Limits (PELs)
- ACGIH- Threshold Limit Values (TLVs)
- AIHA - Workplace Environmental Exposure Levels (WEELs)
- California OSHA Program (Cal/OSHA) - PELs
- German Maximale Arbeitsplatz-Konzentration (MAK)

** Greater than 80% of Tier 1 bands at least as protective as the OEL



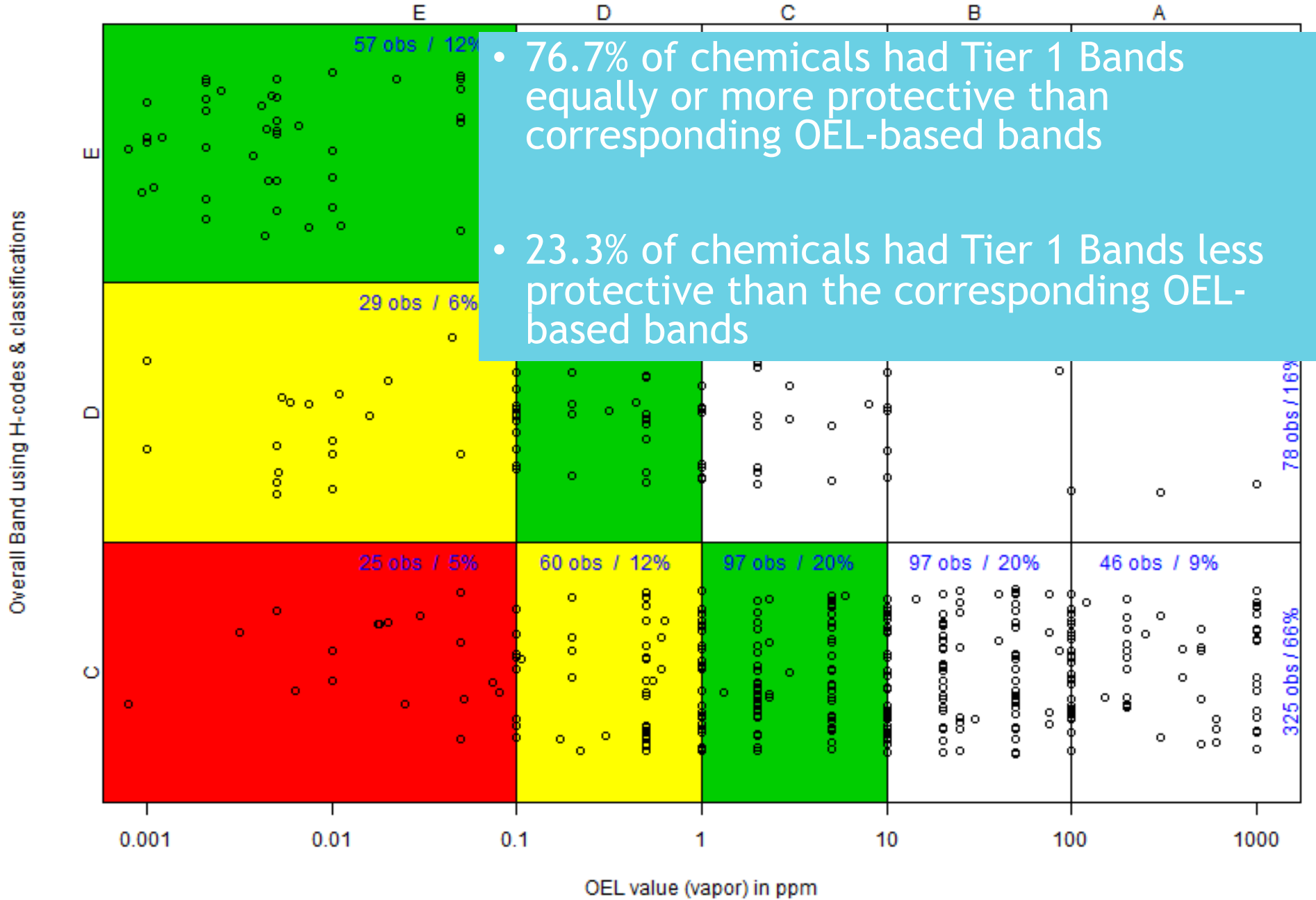
Tier 1 Validation Results

- What were the sources of the minimum full shift OEL used for validation of Tier 1?

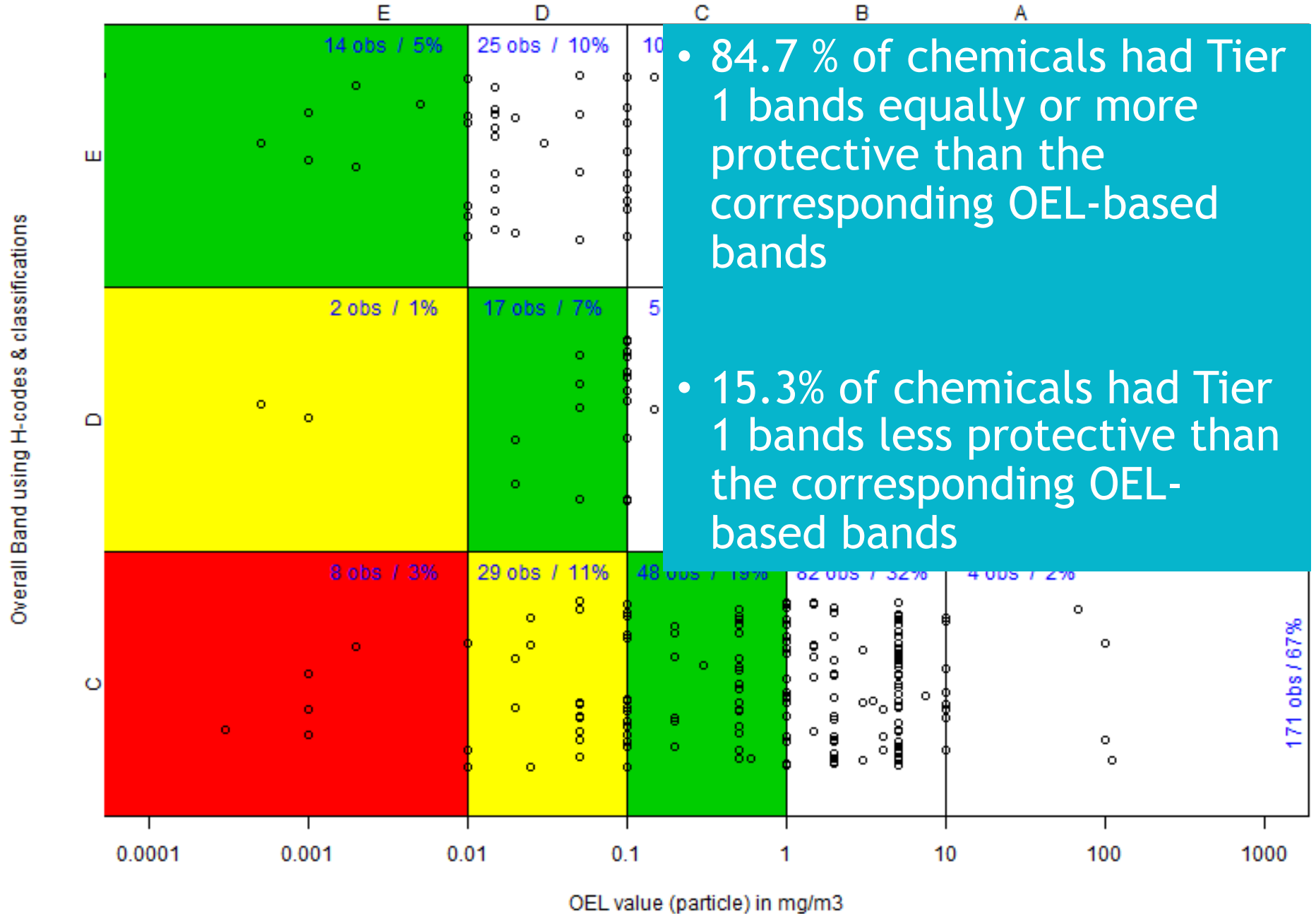
Source of minimum OEL	Frequency
TLV	117
MAK	109
WEEL	99
NIOSH REL	62
CAL PEL	30
OSHA PEL	6
2 sources	118
3 sources	134
4 sources	92
5 sources	37



VAPORS - Minimum OEL values vs. Overall Band (n=489)



PARTICLES - Minimum OEL values vs. Overall Band (n=255)

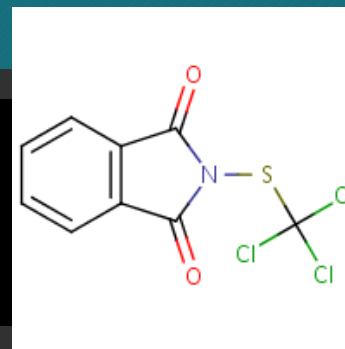


Tier 1 Validation -Thoughts

- The overall rate of Tier 1 bands being at least as protective as the OEL was 79.4% (combined vapor and particulate)
- Recommend always doing a Tier 2 assessment since about 20% of the time the Tier 1 band is not as protective as the OEL.
- Possible to skip the Tier 2 process if you get band E in Tier 1



Tier 1 Example: Folpet



- Can be formulated into liquid, wettable powder, and solid forms
- Applied by dipping, soaking, or spraying
- Used as a fungicide as well as paint additive, wood surface treatment, and high volume spray
- Has been known to cause irritation to eyes, skin, respiratory tract
- Workers involved in mixing, loading and applying folpet may be occupationally exposed
- Some qualitative and quantitative data exist, but...
- **No OEL exists**



Tier 1 Overview

Chemical of interest has no OEL



Locate GHS hazard codes and categories in recommended databases



Compare hazard codes and categories with NIOSH criteria for each health endpoint



Assign band for each relevant health endpoint based on criteria



Assign a Tier 1 OEB for the chemical based on most protective endpoint band

Reliable sources for Tier 1

- GESTIS

www.dguv.de/ifa/gestis-database

- ECHA Annex VI to CLP



Examples of Data

National Library of Medicine

NIH U.S. National Library of Medicine National Center for Biotechnology Information

Pubchem | OPEN CHEMISTRY DATABASE

Search Compounds

Compound Summary for CID 8607

Download Print Share Help

folpet

What's new in this version? [Go to previous version?](#)

Vendors Pharmacology Literature Patents Bioactivities

Also known as: Folpet, 133-07-3, Orthophaltan, PHALTAN, Phthaltan, Spolacid

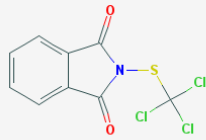
Molecular Formula: C ₉ H ₄ Cl ₃ NO ₂ S	Molecular Weight: 296.55756 g/mol	InChI Key: HKIOYBQGHSTUDB-UHFFFAOYSA-N	FDA UNII: X5NFK36917
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Contents

- 1 2D Structure
- 2 3D Conformer
- 3 Identification
- 4 Chemical and Physical Properties
- 5 Related Records
- 6 Chemical Vendors
- 7 Pharmacology and Biochemistry
- 8 Use and Manufacturing
- 9 Safety and Hazards
- 10 Toxicity

1 2D Structure

Search Download Get Image



The image shows the 2D chemical structure of folpet. It consists of a benzimidazole ring system. The benzimidazole ring has two carbonyl groups (C=O) at the 2 and 4 positions. The nitrogen atom at the 1 position is bonded to a sulfur atom, which is in turn bonded to three chlorine atoms (a trichloromethyl group).

Tier 1 Example: Folpet

Step 1: Locate GHS H-codes and categories from recommended databases

Search by name or CASN

IDENTIFICATION

Folpet
N-((Trichloromethyl) thio)-phthalamide

ZVG No:	490164
CAS No:	133-07-3
INDEX No:	613-045-00-1
EC No:	205-088-6

CHARACTERISATION

Tier 1 Example: Folpet

Step 1: Locate GHS H-codes and categories from recommended databases

REGULATIONS

[GHS Classification/Labelling](#) | [Old Classification](#) | [Workplace labelling](#) | [Water hazard class](#) | [Air quality control](#) | [Transport Regulations](#) | [Hazard Incident Ordinance](#) | [Further regulations](#) | [Medical check-ups](#)

Classification:
Acute toxicity, Category 4, inhalation; H332
Skin sensitisation, Category 1; H317
Eye irritation, Category 2; H319
Carcinogenicity, Category 2; H351
~~Hazardous to the aquatic environment, Acute Category 1; H400~~

Signal Word: "Warning"

Hazard Statement - H-phrases:
H332: Harmful if inhaled.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H351: Suspected of causing cancer.
H400: Very toxic to aquatic life.

Precautionary Statement - P-phrases:
P273: Avoid release to the environment.
P280: Wear protective gloves.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Manufacturer's specification by Sigma-Aldrich Group

Reference: 01221

The substance is listed in appendix VI, table 3.1 of CLP regulation.

Tier 1 Example: Folpet

Step 1 : Locate GHS H-codes and categories from recommended databases

Folpet CAS: 133-07-3

Health Endpoint	Hazard Code	Hazard Category	H-code source	Endpoint Band
Acute Toxicity	H332	4	GESTIS	
Skin Corrosion/Irritation				
Serious Eye Damage/ Eye Irritation	H319	2	GESTIS	
Respiratory and Skin Sensitization	H317	1	GESTIS	
Germ Cell Mutagenicity				
Carcinogenicity	H351	2	GESTIS	
Toxic to Reproduction				
Specific Target Organ Toxicity				



Tier 1 Overview

Chemical of interest has no OEL



Locate GHS hazard codes and categories in recommended databases



Compare hazard codes and categories with NIOSH criteria for each health endpoint



Assign band for each relevant health endpoint based on criteria



Assign a Tier 1 OEB for the chemical based on most protective endpoint band

Tier 1 Example: Folpet


Step 2: Determine corresponding band with NIOSH Tier 1 OEB Criteria Chart

Endpoint	Band	C	D	E
OEL Ranges	Particles	> 0.1 and ≤ 1 mg/m ³	> 0.01 \leq 0.1 mg/m ³	\leq 0.01 mg/m ³
	Vapors	> 1 \leq 10 ppm	> 0.1 \leq 1 ppm	\leq 0.1 ppm
Acute Toxicity	GHS Hazard Category	3, 4	2	1
	GHS Hazard Statements	Harmful if swallowed. Harmful if inhaled. Harmful in contact with skin Toxic if swallowed. Toxic if inhaled. Toxic in contact with skin.	Fatal if swallowed. Fatal if inhaled. Fatal in contact with skin.	Fatal if swallowed. Fatal if inhaled. Fatal in contact with skin.
	"H" Codes	H301, H302, H331, H332, H311, H312	H300, H330, H310	H300, H330, H310
Skin Corrosion/ Irritation	GHS Hazard Category	2		1A, 1B, 1C
	Skin corrosion / irritation GHS Hazard statement	Causes skin irritation.		Causes severe skin burns and eye damage.
	Skin corrosion / irritation "H" Code	H315		H314

Tier 1 Example: Folpet

Step 2: Determine corresponding band with NIOSH Tier 1 OEB Criteria Chart

Folpet CAS: 133-07-3

Health Endpoint	Hazard Code	Hazard Category	H-code source	Endpoint Band
Acute Toxicity	H332	4	GESTIS	C 
Skin Corrosion/Irritation				
Serious Eye Damage/ Eye Irritation	H319	2	GESTIS	
Respiratory and Skin Sensitization	H317	1	GESTIS	
Germ Cell Mutagenicity				
Carcinogenicity	H351	2	GESTIS	
Toxic to Reproduction				
Specific Target Organ Toxicity				



Tier 1 Overview

Chemical of interest has no OEL



Locate GHS hazard codes and categories in recommended databases



Compare hazard codes and categories with NIOSH criteria for each health endpoint



Assign band for each relevant health endpoint based on criteria



Assign a Tier 1 OEB for the chemical based on most protective endpoint band

Tier 1 Example: Folpet

Step 2: Determine corresponding band with NIOSH Tier 1 OEB Criteria Chart

Folpet CAS: 133-07-3

Health Endpoint	Hazard Code	Hazard Category	H-code source	Endpoint Band
Acute Toxicity	H332	4	GESTIS	C
Skin Corrosion/Irritation				
Serious Eye Damage/ Eye Irritation	H319	2	GESTIS	C
Respiratory and Skin Sensitization	H317	1	GESTIS	D
Germ Cell Mutagenicity				
Carcinogenicity	H351	2	GESTIS	E
Toxic to Reproduction				
Specific Target Organ Toxicity				



Tier 1 Overview

Chemical of interest has no OEL



Locate GHS hazard codes and categories in recommended databases



Compare hazard codes and categories with NIOSH criteria for each health endpoint



Assign band for each relevant health endpoint based on criteria



Assign a Tier 1 OEB for the chemical based on most protective endpoint band

Tier 1 Example: Folpet

Step 3: Select the most conservative band as the Tier 1 OEB

Folpet CAS: 133-07-3

Health Endpoint	Hazard Code	Hazard Category	H-code source	Endpoint Band
Acute Toxicity	H332	4	GESTIS	C
Skin Corrosion/				
Serious Eye Damage/ Eye Irritation	H319	2	GESTIS	C
Respiratory and Skin Sensitization		1	GESTIS	D
Germ Cell Mutagenicity				
Carcinogenicity	H351	2	GESTIS	E
Toxic to Reproduction				
Specific Target Organ Toxicity				

**Most protective band:
Band E**





Based upon the Tier 1 banding process,
the chemical should be in Band E

Tier 2 could be completed.



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Chemical XYZ				
Endpoint	Hazard Code	Hazard Category	H-code source	Endpoint Band
Acute Toxicity	H301	3	GESTIS	C
	H330	2	GESTIS	D
Skin Corrosion/Irritation	H314	1B	GESTIS	E
Serious Eye Damage/ Eye Irritation				
Respiratory and Skin Sensitization	H317	1	GESTIS	D
Germ Cell Mutagenicity				
Carcinogenicity				
Toxic to Reproduction				
Specific Target Organ Toxicity (single exposure)				
Specific Target Organ Toxicity (repeated exposure)				
Most Protective Band				



- Why is Respiratory and Skin Sensitization Band D, not Band C?
 - GESTIS labels the chemical as H317, Category 1
 - NIOSH Master Key distinguishes between Category 1a & 1b, so assume most protective Category (1a)



Chemical XYZ				
Endpoint	Hazard Code	Hazard Category	H-code source	Endpoint Band
Acute Toxicity	H301	3	GESTIS	C
	H330	2	GESTIS	D
Skin Corrosion/Irritation	H314	1B	GESTIS	E
Serious Eye Damage/ Eye Irritation	H317	2	GESTIS	D
Respiratory or Skin Sensitization	H317	2	GESTIS	D
Germ Cell Mutagenicity	H341	2	GESTIS	D
Carcinogenicity	H350	1B	GESTIS	E
Toxic to Reproduction				
Specific Target Organ Toxicity (single exposure)				
Specific Target Organ Toxicity (repeated exposure)				
Most Protective Band				E

Most protective band:
E



- Chemical XYZ = Dimethyl sulfate (CAS: 77-78-1)
- NIOSH REL: 0.1 ppm
- OSHA PEL: 1 ppm
- NIOSH Occupational Exposure Band E exposure range: ≤ 0.1 ppm



Tier 2

Tier 2 is an additional level of analysis used when:

- there are no GHS H codes
- the outcome of the Tier 1 analysis is incomplete
- Additional data for health potency of the chemical exists



Tier 2

- Tier 2 - Semi-Quantitative
 - Trained professional
 - Based on readily available secondary data from authoritative sources (government, professional health agencies, authoritative toxicological benchmarks)
 - Needs sufficient data to generate reliable OEB
 - Prescriptive analytical strategy to ensure consistency
 - Potential for chemicals to be moved from the Tier 1 OEB to a more or less protective OEB



How is decision logic organized?

Tier 1 and 2 is based on the findings for eight standard toxicological endpoints and/or health outcomes:

- acute toxicity
- skin corrosion and irritation
- serious eye damage and irritation
- respiratory and skin sensitization
- germ cell mutagenicity
- carcinogenicity
- reproductive/developmental toxicity
- target organ toxicity resulting from repeated exposure



Tier 2 Overview

Begin Tier 2 process



Search recommended databases for toxicity information



Compare qualitative and quantitative data to criteria



Assign band for each health endpoint based on criteria



Assign a Tier 2 OEB for the chemical based on most protective endpoint band

Tier 2 Banding Principles

- For 8 specified health endpoints, search authoritative databases for summary toxicity information
- Collate results for each endpoint
- Find a Total Determinant Score and/or Occupational Exposure Band (this is done automatically in the electronic spreadsheet)



Total Determinant Score

- **Determinant score** = weighted score indicating the presence/absence of data for a specific health endpoint.
- **Total determinant score (TDS)** = sum of weighted scores for each health endpoint. Overall score gives an indication of sufficiency of data for banding.
- **TDS \geq 30: sufficient data for banding in Tier 2**



Acute Toxicity

- Acute Toxicity - refer to effects that arise from single or short-term exposures - the effects themselves can be long-lasting
- Acute Toxicity Studies
 - Generally based on a single exposure with observation period
 - Clinical observations, gross effects, and mortality
- The Lethal Dose or Concentration is used most often as a criterion in banding approaches
 - LD50 is the *statistically* estimated dose associated with 50% mortality



NIOSH Tier 2 Acute Toxicity Criteria

Band		A	B	C	D	E
NIOSH banding criteria for acute toxicity	Oral toxicity (LD₅₀)	>2,000 mg/kg-bodyweight	>300 and ≤ 2,000 mg/kg-bodyweight	>50 and ≤ 300 mg/kg-bodyweight	>5 and ≤ 50 mg/kg-bodyweight	≤ 5 mg/kg-bodyweight
	Dermal toxicity (LD₅₀)	> 2,000 mg/kg-bodyweight	>1,000 and ≤ 2,000 mg/kg-bodyweight	>200 and ≤ 1,000 mg/kg-bodyweight	>50 and ≤ 200 mg/kg-bodyweight	≤ 5 mg/kg-bodyweight
	Inhalation gases (LC₅₀)	> 20,000 ppmV/4h	>2,500 and ≤ 20,000 ppmV/4h	>500 and ≤ 2,500 ppmV/4h	>100 and ≤ 500 ppmV/4h	≤ 100 ppmV/4h
	Inhalation vapors (LC₅₀)	> 20.0 mg/liter/4h	>10.0 and ≤ 20.0 mg/liter/4h	>2.0 and ≤ 10.0 mg/liter/4h	>0.5 and ≤ 2.0 mg/liter/4h	≤ 0.5 mg/liter/4h
	Inhalation dusts and mists (LC₅₀)	> 5.0 mg/liter/4h	>1.0 and ≤ 5.0 mg/liter/4h	>0.5 and ≤ 1.0 mg/liter/4h	>0.05 and ≤ 0.5 mg/liter/4h	≤ 0.05 mg/liter/4h



Sources

ENDPOINT		SOURCE OF INFORMATION	ACRONYM	WEBSITE
	Rank 2	Agency for Toxic Substances & Disease Registry	ATSDR	http://www.atsdr.cdc.gov/toxprofiles/index.asp
		U.S. EPA Integrated Risk Information System	IRIS	http://www.epa.gov/iris/
		Association of Occupational and Environmental Clinics	AOEC	http://www.aoec.org/
Skin sensitization	Rank 1	NIOSH Skin Notation Profiles	SK Profiles	http://www.cdc.gov/niosh/topics/skin/skin-notation_profiles.html
		European Chemicals Agency; Registration, Evaluation, Authorisation and Restriction of Chemicals	REACH	http://echa.europa.eu/web/guest
		Organization for Economic Co-operation and Development	OECD	http://www.oecd.org/
		International Programme on Chemical Safety	IPCS	http://www.inchem.org/
		National Toxicology Program Interagency Coordinating Committee on the Validation of Alternative Methods	ICCVAM	http://iccvam.niehs.nih.gov
	Rank 2	Hazardous Substance Data Bank	HSDB	http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB
Acute Toxicity	Ranks 1	National Library of Medicine ChemID Plus	ChemID plus	http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp
		U.S. EPA Superfund Chemical Data Matrix	U.S. SCDM	http://www.epa.gov/superfund/sites/npl/hrsres/tools/scdm.htm
		Pesticide Properties Database	PPDB	http://sitem.herts.ac.uk/aeru/ppdb/en/
		International Programme on Chemical Safety	IPCS	http://www.inchem.org/
	Rank 2	Hazardous Substance Data Bank	HSDB	http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB
		Agency for Toxic Substances & Disease Registry	ATSDR	http://www.atsdr.cdc.gov/toxprofiles/index.asp

Acute Toxicity (5 points possible)						
Accepted values		Rejected values				
Oral LD ₅₀ (mg/kg bodyweight)	Animal model	Oral LD ₅₀ (mg/kg bodyweight)	Animal model	Reason for Rejection	Source	Comments/Questions
600	mouse				ChemID	
1900	rat				ChemID	
Accepted values		Rejected values				
Dermal LD ₅₀ (mg/kg bodyweight)	Animal model	Dermal LD ₅₀ (mg/kg bodyweight)	Animal model	Reason for Rejection	Source	Comments/Questions
		4ml/kg	rabbit	units	ChemID	
Accepted values		Rejected values				
Inhalation Gas LC ₅₀ (ppmV/4h)	Animal model	Inhalation Gas LC ₅₀ (ppmV/4h)	Animal model	Reason for Rejection	Source	Comments/Questions
Accepted values		Rejected values				
Inhalation Vapor LC ₅₀ (mg/liter/4h)	Animal model	Inhalation Vapor LC ₅₀ (mg/liter/4h)	Animal model	Reason for Rejection	Source	Comments/Questions
10.8	mouse				ChemID	
Accepted values		Rejected values				
Inhalation Dust/Mist LC ₅₀ (mg/liter/4h)	Animal model	Inhalation Dust/Mist LC ₅₀ (mg/liter/4h)	Animal model	Reason for Rejection	Source	Comments/Questions

Tier 2 Validation

- Is the Tier 2 process consistent and specific to independent users?
- Do the Tier 2 banding criteria reflect toxicity as determined by an independent evaluation (e.g. OELs)?
- Do new users get the same Tier 2 bands as expert users?
- Do users get the same endpoint specific bands as other users?
- Are there any health effects that band more reliably than others?

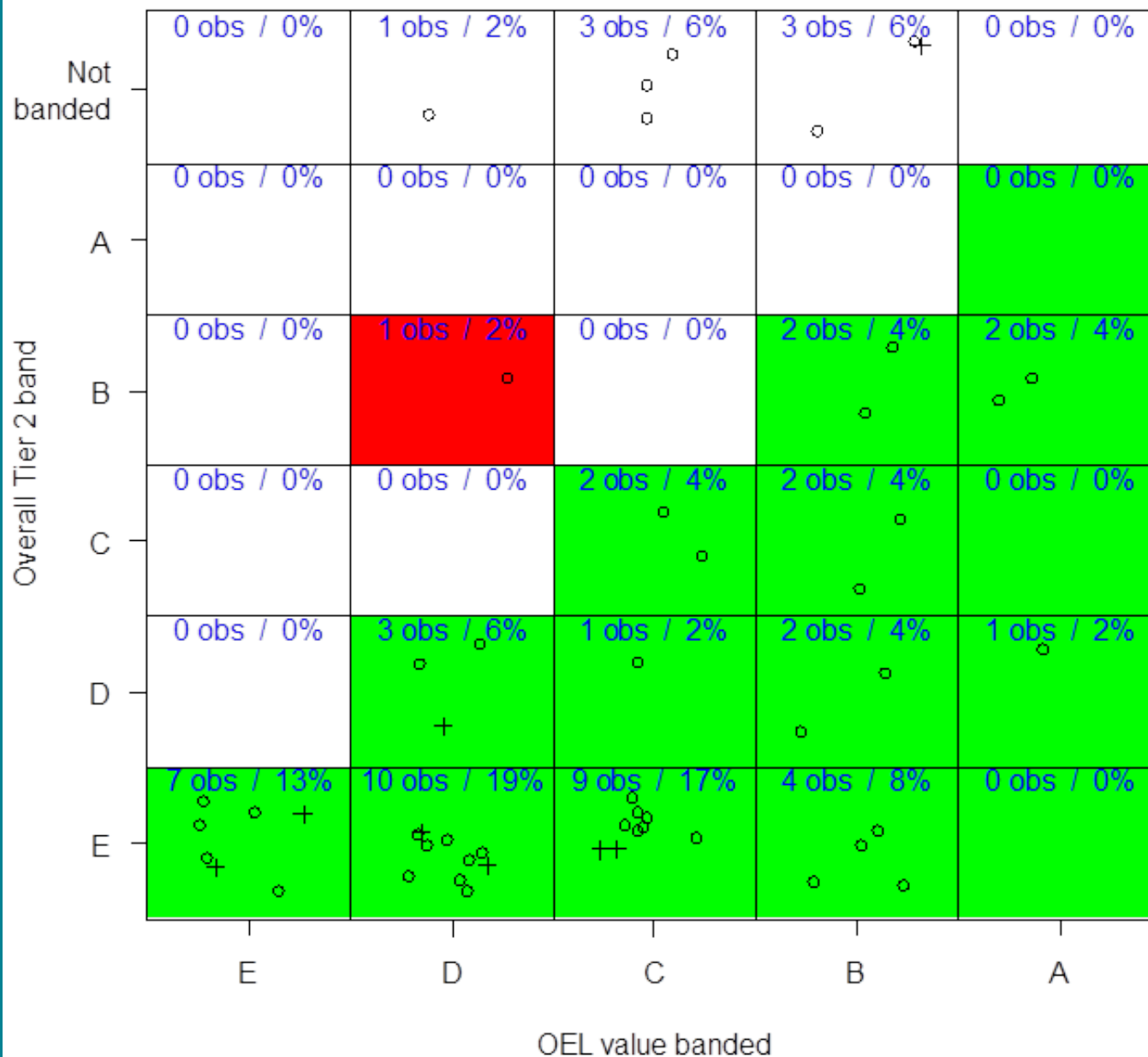


Tier 2 Validation - phase 1

- Two groups (Expert users and new users) completed Tier 2 process on 102 chemicals
- Comparisons of the chemicals with OELs to the OELs banded
- Used different scales and units for vapors (ppm) and particles (mg/m^3)
- Separately for NIOSH and both users



Minimum OEL values banded vs. NIOSH Overall Tier 2 Band
 (o = vapors, + = particles) (n=53)



Tier 2 Exercises

Phase	Number of People	Number of chemicals
May 2014 NIOSH volunteers	10	5
July 2014 Contract	12	112
June 2015 OEB Collaborative Team	27	3
September 2015 Contract	15	3

Lessons Learned

- Needed improved descriptions for some endpoints-
- Need to limit data trawling
- Toxicology primer necessary
- “Transferring” errors
- Source issues



Endpoint Agreement

Endpoint	Good Agreement?
Acute Toxicity	★
Skin Corrosion/Irritation	★
Serious Eye Damage/ Eye Irritation	★
Respiratory and Skin Sensitization	★
Germ Cell Mutagenicity	variability
Carcinogenicity	★
Toxic to Reproduction	variability
Specific Target Organ Toxicity	★
Overall	★

Next Steps

- Improve guidance on two endpoints
- Internal Review Complete
- Peer review and public comment
- Dissemination /Computer tools



Expected project outputs

- NIOSH guidance document
- OEB training class, blended -learning option
- Emergency response modifier
- Overall process, including the decision logic
- Tools to facilitate finding and evaluating hazard data and assign chemicals to hazard bands
- Electronic tools to help users create OEB online
- Education materials for H&S professionals, managers, emergency responders and workers



Select Health Endpoint Below

Acute Toxicity

	Hazard Code & Category
<input type="checkbox"/>	Code: 300, Category: 1
<input type="checkbox"/>	Code: 300, Category: 2
<input type="checkbox"/>	Code: 301, Category: 3
<input type="checkbox"/>	Code: 302, Category: 4
<input type="checkbox"/>	Code: 310, Category: 1
<input type="checkbox"/>	Code: 310, Category: 2
<input type="checkbox"/>	Code: 311, Category: 3
<input type="checkbox"/>	Code: 312, Category: 4
<input type="checkbox"/>	Code: 330, Category: 1
<input type="checkbox"/>	Code: 330, Category: 2
<input type="checkbox"/>	Code: 331, Category: 3
<input type="checkbox"/>	Code: 332, Category: 4

Skin Corrosion/Irritation

	Hazard Code & Category
<input type="radio"/>	Code: 314, Category: 1a
<input type="radio"/>	Code: 314, Category: 1b
<input type="radio"/>	Code: 314, Category: 1c
<input type="radio"/>	Code: 315, Category: 2

Serious Eye Damage/ Eye Irritation

	Hazard Code & Category
<input type="radio"/>	Code: 318, Category: 1
<input type="radio"/>	Code: 319, Category: 2a
<input type="radio"/>	Code: 319, Category: 2b

Respiratory and Skin Sensitization

	Hazard Code & Category
<input type="radio"/>	Code: 317, Category: 1a (skin)
<input type="radio"/>	Code: 317, Category: 1b (skin)
<input type="radio"/>	Code: 334, Category: 1a (resp.)
<input type="radio"/>	Code: 334, Category: 1b (resp.)

Germ Cell Mutagenicity

	Hazard Code & Category
<input type="radio"/>	Code: 340, Category: 1a
<input type="radio"/>	Code: 340, Category: 1b
<input type="radio"/>	Code: 341, Category: 2

Carcinogenicity

	Hazard Code & Category
<input type="radio"/>	Code: 350, Category: 1a
<input checked="" type="radio"/>	Code: 350, Category: 1b
<input type="radio"/>	Code: 351, Category: 2

Toxic to Reproduction

	Hazard Code & Category
<input type="radio"/>	Code: 360d, Category: 1a
<input type="radio"/>	Code: 360d, Category: 1b
<input type="radio"/>	Code: 360f, Category: 1a
<input type="radio"/>	Code: 360f, Category: 1b
<input type="radio"/>	Code: 360fd, Category: 1a
<input type="radio"/>	Code: 360fd, Category: 1b
<input type="radio"/>	Code: 361d, Category: 2
<input type="radio"/>	Code: 361f, Category: 2
<input type="radio"/>	Code: 361fd, Category: 2

Specific Target Organ Toxicity

	Hazard Code & Category
<input type="radio"/>	Code: 370, Category: 1
<input type="radio"/>	Code: 371, Category: 2
<input type="radio"/>	Code: 372, Category: 1
<input type="radio"/>	Code: 373, Category: 2

Physical State

Liquid/Vapor Particles

Calculate Tier 1 OEB

Looking Ahead

More than just an OEB...

- Identify potential health effects and target organs
- Identify health risks that impact health communication
- Inform implementation of control interventions
- Inform medical surveillance decisions
- Provide critical information quickly



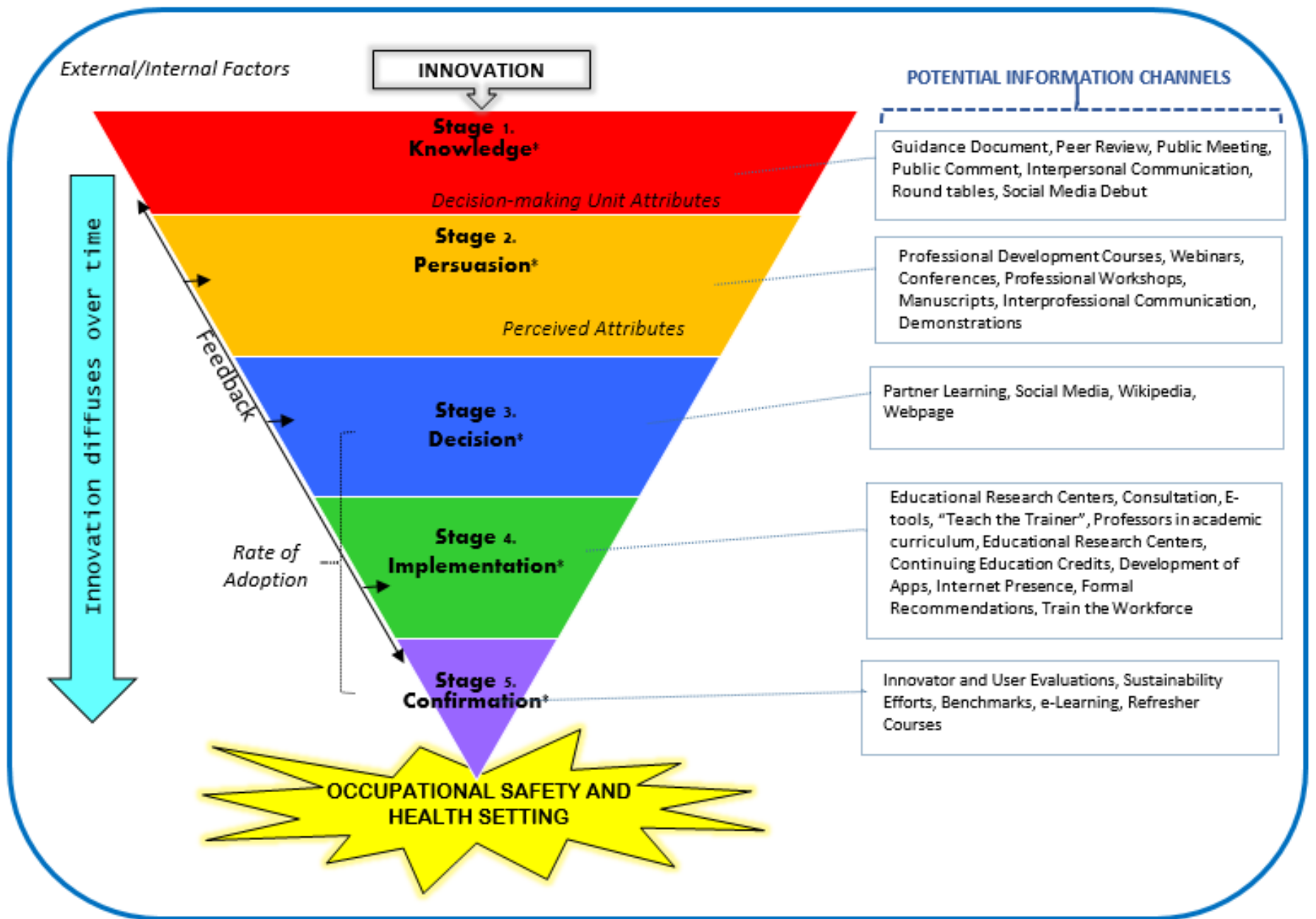


Figure 1. The Diffusion of Occupational Safety and Health Innovations Pyramid

Notes: *Adapted from the Innovation-Decision Process Theory. Concepts are modified from Rogers' (2003) *Diffusion of Innovations*.



CDC
Workplace
Safety and Health

NIOSH
National Institute for
Occupational Safety and Health