

# Occupational Exposure Bands (OEBs)

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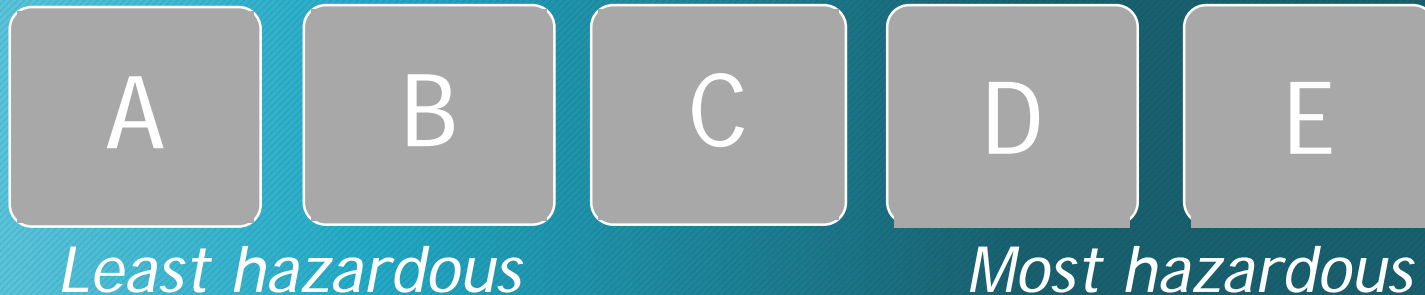
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# What is an Occupational Exposure Band (OEB) ?

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



# 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



<https://www.youtube.com/embed/oUY8vd4BaB8?rel=0&start=38&end=75&autoplay=0>



# 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 <sup>3</sup> 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 <sup>3</sup> dust >5 to 50 ppm vapor	Harmful on single exposure	Use local exhaust ventilation.
3	>0.01 to 0.1 mg/m <sup>3</sup> dust >0.5 to 5 ppm vapor	Severely irritating and corrosive	Enclose the process.
4	<0.01 mg/m <sup>3</sup> dust <0.5 ppm vapor	Very toxic on single exposure, reproductive hazard, sensitizer*	Seek expert advice

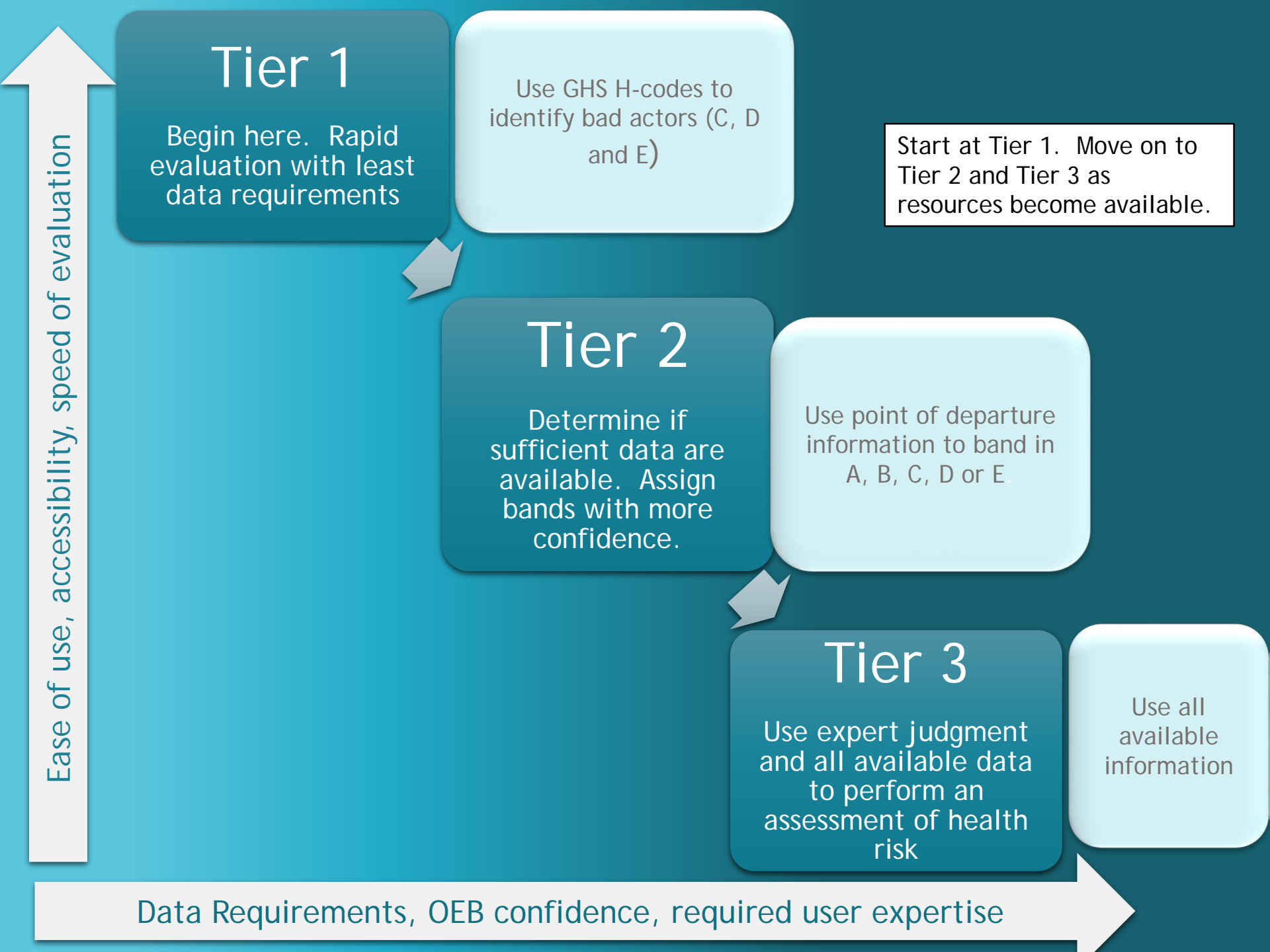
# Occupational Exposure Banding is different!

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



# Tools for the Occupational Hygienist





# Tier 1

Begin here. Rapid evaluation with least data requirements

Use GHS H-codes to identify bad actors (C, D and E)

Start at Tier 1. Move on to Tier 2 and Tier 3 as resources become available.

# Tier 2

Determine if sufficient data are available. Assign bands with more confidence.

Use point of departure information to band in A, B, C, D or E.

# Tier 3

Use expert judgment and all available data to perform an assessment of health risk

Use all available information

Data Requirements, OEB confidence, required user expertise

## 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

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

<b>Endpoint</b>	<b>Band</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>OEL Ranges</b>	<b>Particles</b>	> 0.1 and ≤ 1 mg/m <sup>3</sup>	> 0.01 ≤ 0.1 mg/m <sup>3</sup>	≤ 0.01 mg/m <sup>3</sup>
	<b>Vapors</b>	> 1 ≤ 10 ppm	> 0.1 ≤ 1 ppm	≤ 0.1 ppm
<b>Respiratory and Skin Sensitization</b>	<b>GHS Hazard Category</b>	1B (skin)	1B (resp.) 1A (skin)	1A (resp.)
	<b>GHS Respiratory and Skin Sensitization Hazard Statements</b>	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
	<b>Respiratory and Skin Sensitization "H" Codes</b>	H317	H314 H317	H334
<b>Germ Cell Mutagenicity</b>	<b>GHS Hazard Category</b>	2	1B	1A
	<b>GHS Germ Cell Mutagenicity Hazard Statement</b>	Suspected of causing genetic defects	May cause genetic defects	May cause genetic defects
	<b>GHS Germ Cell Mutagenicity "H" Codes</b>	H341	H340	H340
<b>Carcinogenicity</b>	<b>GHS Hazard Category</b>	2	1B 1A	2 1B 1A
	<b>GHS Carcinogenicity Hazard statement</b>	Suspected of causing cancer	May cause cancer	Suspected of causing cancer May cause cancer May cause cancer
	<b>Carcinogenicity "H" Codes</b>	H351	H350	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

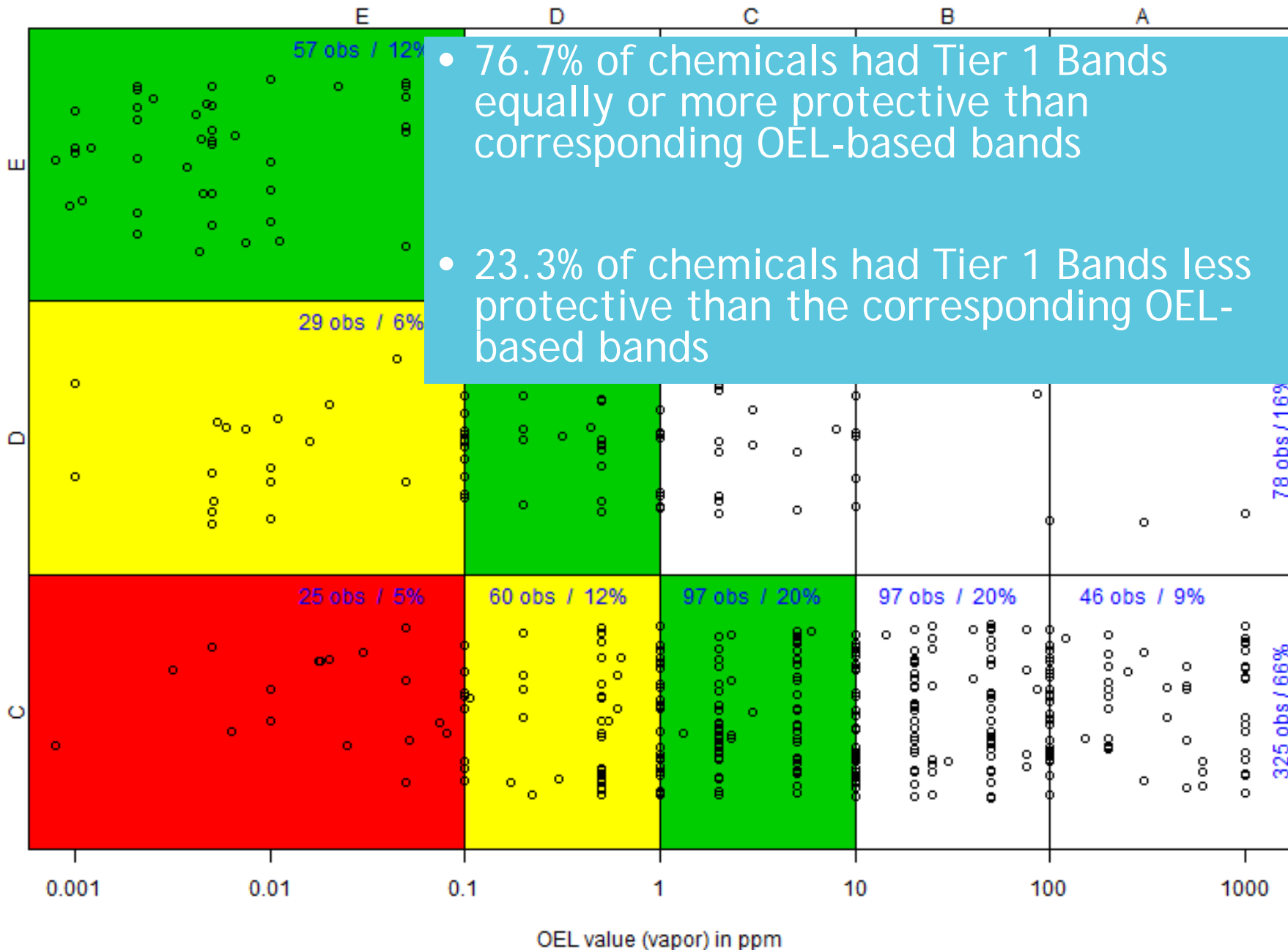
- What were the sources of the minimum full shift OEL used for validation of Tier 1?

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)

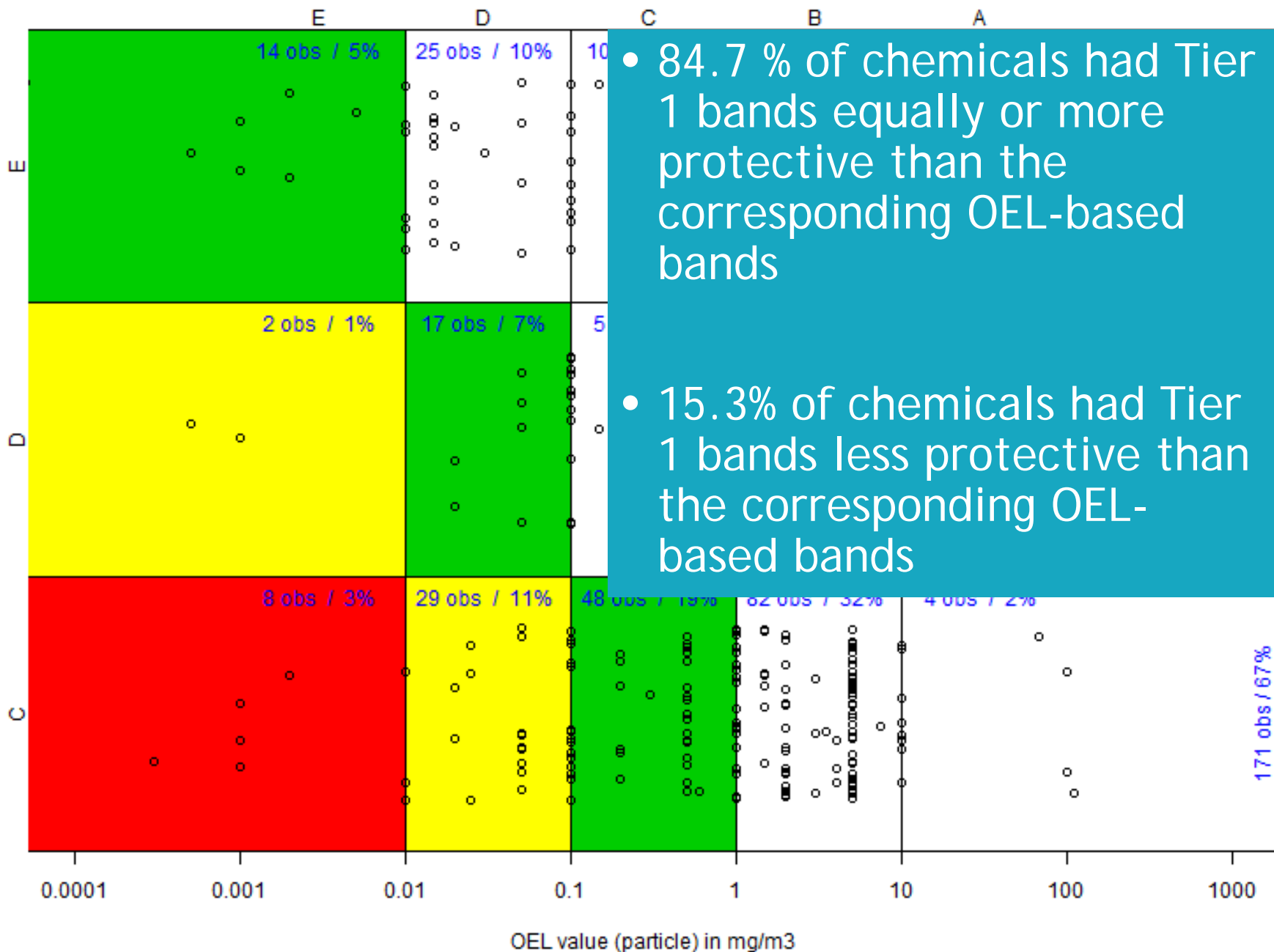
Overall Band using H-codes & classifications





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

Overall Band using H-codes & classifications



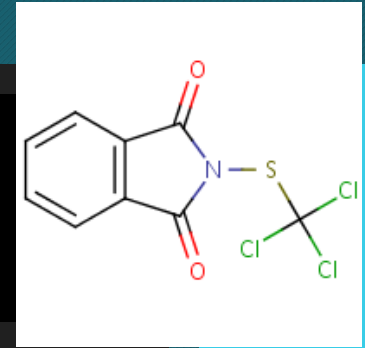
- 84.7 % of chemicals had Tier 1 bands equally or more protective than the corresponding OEL-based bands
- 15.3% of chemicals had Tier 1 bands less protective than the corresponding OEL-based bands

# 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](http://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


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



# Tier 1 Example: Folpet

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

The screenshot shows the GESTIS Substance Database interface. The search bar at the top contains the text 'Folpet'. A red arrow points from the search bar to a red-bordered box containing the text 'Search by name or CASN'. Below the search bar, there are three GHS hazard pictograms: a red diamond with a black exclamation mark, a red diamond with a black silhouette of a person, and a red diamond with a black tree and a dead animal. A red arrow points from the second pictogram to a red-bordered box containing the text 'Search by name or CASN'. Below the pictograms, there is a navigation menu with the following items: Identification | Characterisation | Formula | Toxicology / Ecotoxicology | Physical and chemical properties | Occupational health and first aid | Safe handling | Regulations | Literature register. The 'Characterisation' item is circled in red. Below the navigation menu, there is a section titled 'IDENTIFICATION' with a blue border. The text in this section is: Folpet, N-((Trichloromethyl) thio)-phthalamide. Below this, there is a table with the following data:

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

Below the table, there is a section titled 'CHARACTERISATION' with a blue border.

# 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 Inci](#)  
[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



# 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	<b>H332</b>	<b>4</b>	GESTIS	
Skin Corrosion/Irritation				
Serious Eye Damage/ Eye Irritation	<b>H319</b>	<b>2</b>	GESTIS	
Respiratory and Skin Sensitization	<b>H317</b>	<b>1</b>	GESTIS	
Germ Cell Mutagenicity				
Carcinogenicity	<b>H351</b>	<b>2</b>	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

<b>Endpoint</b>	<b>Band</b>	<b>C</b>	<b>D</b>	<b>E</b>
<b>OEL Ranges</b>	<b>Particles</b>	> 0.1 and ≤ 1 mg/m <sup>3</sup>	> 0.01 ≤ 0.1 mg/m <sup>3</sup>	≤ 0.01 mg/m <sup>3</sup>
	<b>Vapors</b>	> 1 ≤ 10 ppm	> 0.1 ≤ 1 ppm	≤ 0.1 ppm
<b>Acute Toxicity</b>	<b>GHS Hazard Category</b>	3, 4	2	1
	<b>GHS Hazard Statements</b>	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.
	<b>"H" Codes</b>	H301, H302, H331, H332, H311, H312	H300, H330, H310	H300, H330, H310
<b>Skin Corrosion/Irritation</b>	<b>GHS Hazard Category</b>	2		1A, 1B, 1C
	<b>Skin corrosion / irritation GHS Hazard statement</b>	Causes skin irritation.		Causes severe skin burns and eye damage.
	<b>Skin corrosion / irritation "H" Code</b>	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	<b>H332</b>	<b>4</b>	GESTIS	<b>C</b>
Skin Corrosion/Irritation				
Serious Eye Damage/ Eye Irritation	<b>H319</b>	<b>2</b>	GESTIS	<b>C</b>
Respiratory and Skin Sensitization	<b>H317</b>	<b>1</b>	GESTIS	<b>D</b>
Germ Cell Mutagenicity				
Carcinogenicity	<b>H351</b>	<b>2</b>	GESTIS	<b>E</b>
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


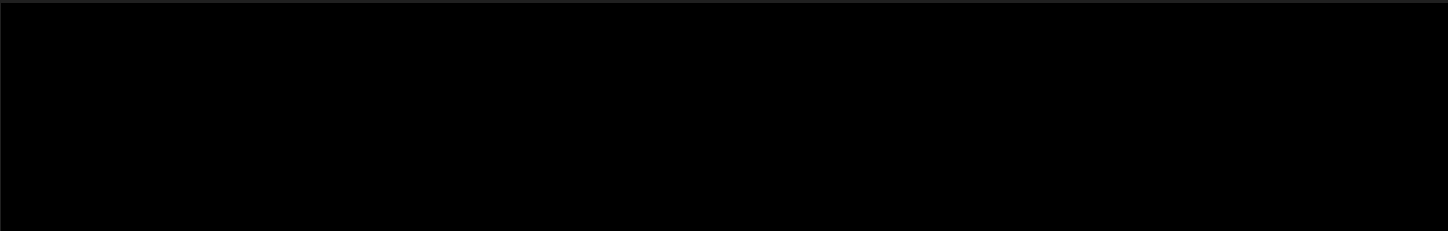
## Folpet CAS: 133-07-3

Health Endpoint	Hazard Code	Hazard Category	H-code source	Endpoint Band
Acute Toxicity	H332	4	GESTIS	C
Skin Corrosion/Irritation	H314	2	GESTIS	C
Serious Eye Damage/ Eye Irritation	H319	2	GESTIS	C
Respiratory and Skin Sensitization	H337	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.



Now it is your turn to  
band a chemical...

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# Tier 1: Try it on your own #1

- See page 3 of handout for GESTIS information
- Use the Tier 1 Criteria Overview (pages 1-2) and corresponding worksheet (page 4) to band the chemical in Tier 1
- Assume the chemical has no OEL



## 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)				
<b>Most Conservative Band</b>				



- 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	H332	2	GESTIS	D
Respiratory Tract Irritation	H332	2	GESTIS	D
Germ Cell Mutagenicity	H341	2	GESTIS	D
Carcinogenicity	H350	1B	GESTIS	E
Toxic to Reproduction	H360	2	GESTIS	D
Specific Target Organ Toxicity (single exposure)	<b>E</b>			
Specific Target Organ Toxicity (repeated exposure)				
<b>Most Conservative Band</b>				<b>E</b>

**Most conservative band:**

- Chemical XYZ = Dimethyl sulfate (CAS: 77-78-1)
- NIOSH REL: 0.1 ppm
- OSHA PEL: 1 ppm
- NIOSH Occupational Exposure Band E exposure range:  $\leq 0.1$  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, or an insufficient reflection of the health potency of the chemical





# 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	<b>Oral toxicity (LD<sub>50</sub>)</b>	>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
	<b>Dermal toxicity (LD<sub>50</sub>)</b>	> 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
	<b>Inhalation gases (LC<sub>50</sub>)</b>	> 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
	<b>Inhalation vapors (LC<sub>50</sub>)</b>	> 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
	<b>Inhalation dusts and mists (LC<sub>50</sub>)</b>	> 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	<a href="http://www.atsdr.cdc.gov/toxprofiles/index.asp">http://www.atsdr.cdc.gov/toxprofiles/index.asp</a>
		U.S. EPA Integrated Risk Information System	IRIS	<a href="http://www.epa.gov/iris/">http://www.epa.gov/iris/</a>
		Association of Occupational and Environmental Clinics	AOEC	<a href="http://www.aoec.org/">http://www.aoec.org/</a>
Skin sensitization	Rank 1	NIOSH Skin Notation Profiles	SK Profiles	<a href="http://www.cdc.gov/niosh/topics/skin/skin-notation_profiles.html">http://www.cdc.gov/niosh/topics/skin/skin-notation_profiles.html</a>
		European Chemicals Agency; Registration, Evaluation, Authorisation and Restriction of Chemicals	REACH	<a href="http://echa.europa.eu/web/guest">http://echa.europa.eu/web/guest</a>
		Organization for Economic Co-operation and Development	OECD	<a href="http://www.oecd.org/">http://www.oecd.org/</a>
		International Programme on Chemical Safety	IPCS	<a href="http://www.inchem.org/">http://www.inchem.org/</a>
		National Toxicology Program Interagency Coordinating Committee on the Validation of Alternative Methods	ICCVAM	<a href="http://iccvam.niehs.nih.gov">http://iccvam.niehs.nih.gov</a>
	Rank 2	Hazardous Substance Data Bank	HSDB	<a href="http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB">http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB</a>
Acute Toxicity	Ranks 1	National Library of Medicine ChemID Plus	ChemID plus	<a href="http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp">http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp</a>
		U.S. EPA Superfund Chemical Data Matrix	U.S. SCDM	<a href="http://www.epa.gov/superfund/sites/npl/hrsres/tools/scdm.htm">http://www.epa.gov/superfund/sites/npl/hrsres/tools/scdm.htm</a>
		Pesticide Properties Database	PPDB	<a href="http://sitem.herts.ac.uk/aeru/ppdb/en/">http://sitem.herts.ac.uk/aeru/ppdb/en/</a>
		International Programme on Chemical Safety	IPCS	<a href="http://www.inchem.org/">http://www.inchem.org/</a>
	Rank 2	Hazardous Substance Data Bank	HSDB	<a href="http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB">http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB</a>
		Agency for Toxic Substances & Disease Registry	ATSDR	<a href="http://www.atsdr.cdc.gov/toxprofiles/index.asp">http://www.atsdr.cdc.gov/toxprofiles/index.asp</a>



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

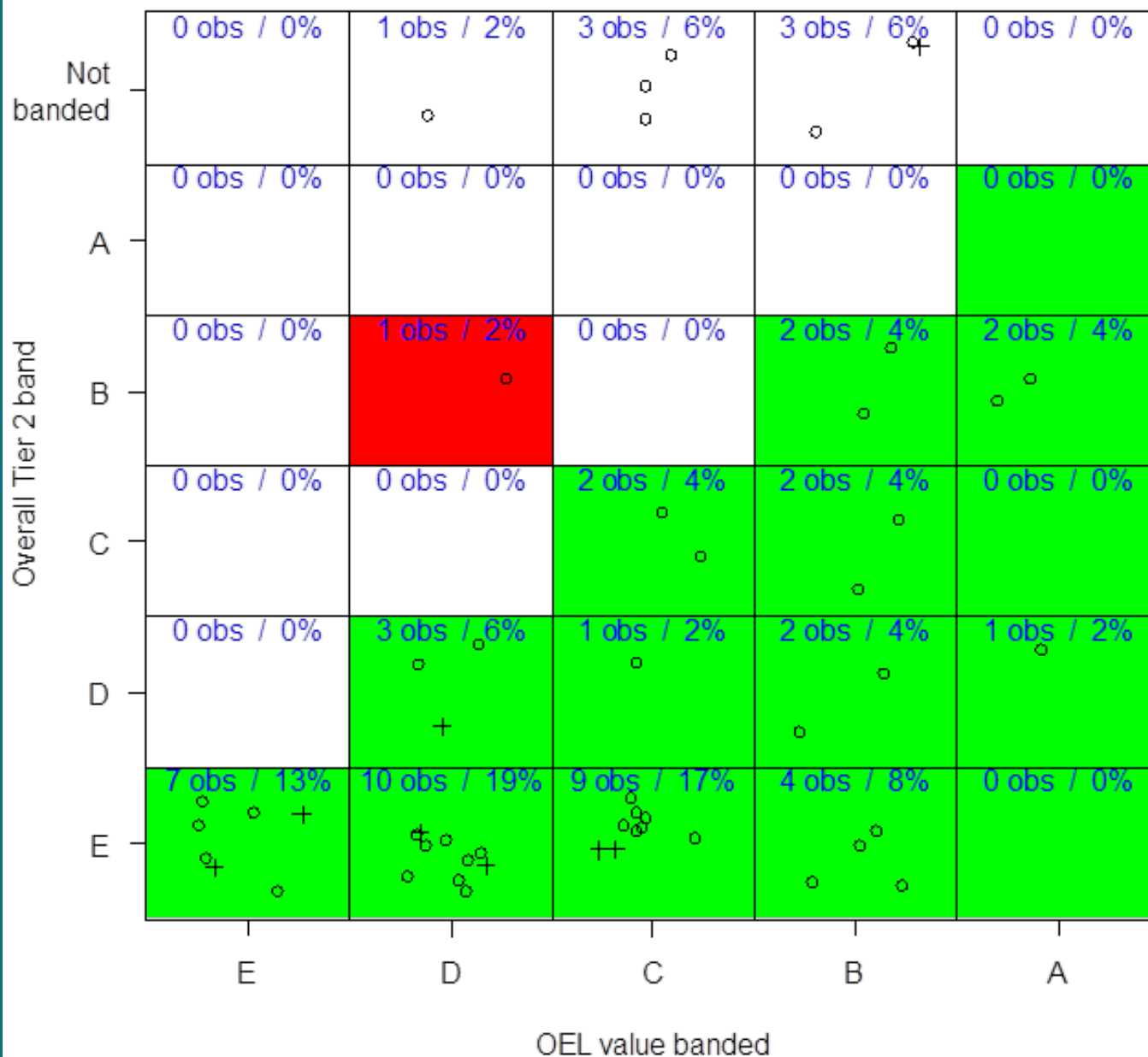


# Tier 2 Validation - phase 1

- 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<sup>3</sup>)
- 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	★
<b>Overall</b>	★

# 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

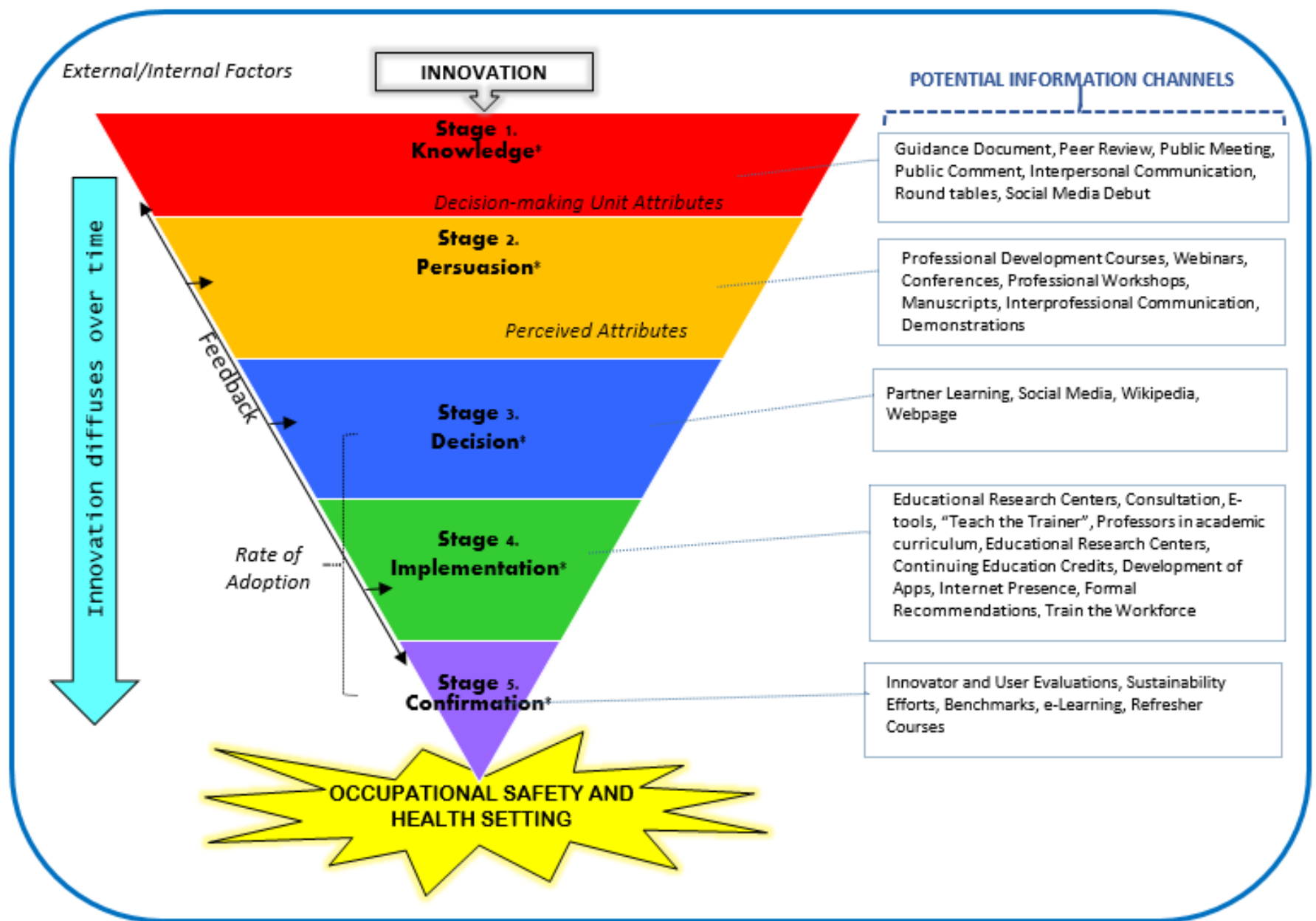
Calculate Tier 1 OEB

# Looking Ahead

# More than just an OEB...

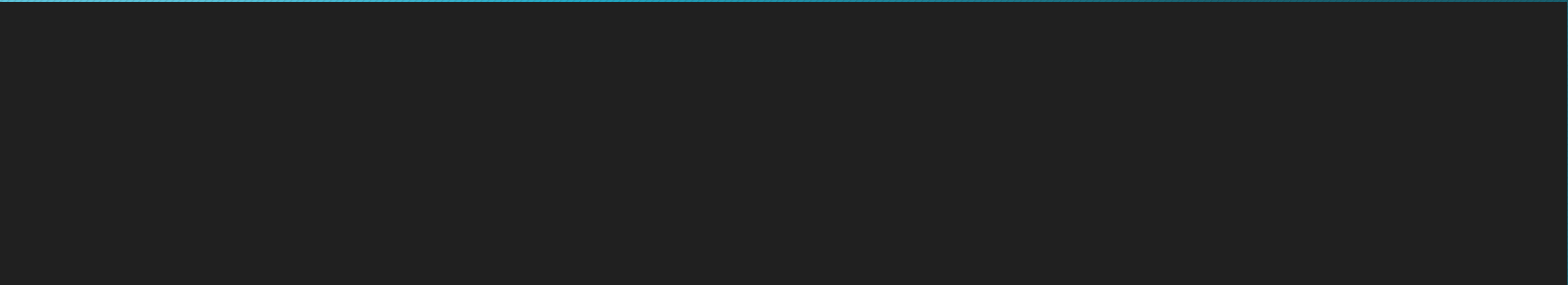
- Identify potential health effects and target organs
- Identify health risks that impact health communication
- Inform implementation of control interventions
- Inform medical surveillance decisions
- Provide critical information quickly





**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**