# **Occupational Exposure Banding:** What if there is no Occupational Limit? **AIHA Gulf Coast Local Section PDC**

John Baker, CIH FAIHA johnbaker1947@iCloud.com

April 22, 2022

# **Occupational Exposure Limits** There's a lot, but not enough

- chemicals regulated under TSCA.
- Yet only about 1,000 of them have been assigned government, consensus or peer-reviewed OELs.
- tobacco products, nuclear materials or munitions.
- registered substances, with thousands more added every day.
- Sources:
  - https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory

  - https://www.cas.org/cas-data

US EPA Toxic Substances Control Act (TSCA) Chemical Substances Inventory lists more than 86,000

• The 86,000 chemicals do NOT include: pesticides, foods and food additives, drugs, cosmetics, tobacco or

• The Chemical Abstracts Registry Service of the ACS has assigned CAS Numbers to more than 263 million

• <u>https://www.cdc.gov/niosh/docs/2019-132/pdfs/2019-132.pdf?id=10.26616/NIOSHPUB2019132</u>

# **Limitations on Limits OELs Not Always Understood**

- Time Weighted Average (TWA) Σ (Ci/Ti)/8
- Ceiling Value and Skin notations
- Why are non-enforceable OELs needed?
  - ACGIH Threshold Limit Value (See new ACGIH Data-Hub)
  - NIOSH Recommended Exposure Limit

Short Term Exposure Limit (STEL) 15 minutes - how many/how frequently

# **Limitations on Limits OELs Not Always Understood**

- Nuisance Dust ... or not?
- What Jurisdiction applies ... see OSHA Annotated List Z-1,2,3, Note on TLVs
  - <u>https://www.osha.gov/annotated-pels</u>
  - https://www.osha.gov/annotated-pels/table-z-1
  - https://www.osha.gov/annotated-pels/table-z-2
  - https://www.osha.gov/annotated-pels/table-z-3
  - <u>https://www.osha.gov/annotated-pels/note</u>

• Mixtures of Chemicals: OSHA reg does not specify similar toxicity or target organs, but should.

### Table Z-1: State PELs: California's nice, but what about Michigan, Oregon, etc. ? Note: the Cal/OSHA, PELs TLVs and RELs are only shown for Federal OSHA regulated chemicals in Table Z-1

Note: This table only includes occupational exposure limits (OELs) for substances listed in the OSHA Z-1 Table. OELs for hundreds of additional substances have been adopted by Cal/OSHA, NIOSH, and ACGIH. These organizations periodically make revisions to their OELs and so they should be consulted directly for their most current values and substances, as well as special notations such as for skin absorption. The TLVs® and BEIs® are copyrighted by ACGIH® and are not publicly available. However, they can be purchased in their entirety on the ACGIH<sup>®</sup> website. Permission must be requested from ACGIH<sup>®</sup> to reproduce the TLVs<sup>®</sup> and BEIs<sup>®</sup>. Click here for permission request form.

|                    |                  | OSHA An<br>*Go to |
|--------------------|------------------|-------------------|
|                    | Substance        |                   |
|                    | Acetaldehyde     | 7                 |
|                    | Acetic acid      | 6                 |
| os://www.acgih.org | Acetic anhydride | 1                 |
| NIOSH OEB teo      | chpdf ^          |                   |

#### nnotated Table Z-1<sup>(a)</sup>

#### to list of all footnotes

|                | ]                       | Regulatory Limits    |   |  | nded Limits                                     |  |
|----------------|-------------------------|----------------------|---|--|---|--|
|                | OSHA PEL <sup>(b)</sup> |                      | Cal/OSHA<br>PEL <sup>(f)</sup><br>(as of 10/2/2019) | <b>NIOSH REL<sup>(g)</sup></b><br>(as of 10/18/2019) | ACGIH <sup>®</sup> 2019<br>TLV <sup>® (h)</sup> |  |
| CAS No.<br>(c) | ppm <sup>(d)</sup>      | mg/m <sup>3(e)</sup> | 8-hour TWA<br>(ST) STEL<br>(C) Ceiling              | Up to 10-hour<br>TWA<br>(ST) STEL<br>(C) Ceiling     | 8-hour TWA<br>(ST) STEL<br>(C) Ceiling          |  |
| 75-07-0        | 200                     | 360                  | (C) 25 ppm  | Ca<br>See Appendix A<br>See Appendix C               | (C) 25 ppm                                      |  |
| 64-19-7        | 10                      | 25                   | 10 ppm<br>(ST) 15 ppm<br>(C) 40 ppm                 | 10 ppm<br>(ST) 15 ppm                                | 10 ppm<br>(ST) 15 ppm                           |  |
| 108-24-7       | 5                       | 20                   | (C) 5 ppm   | (C) 5 ppm  | 1 ppm<br>(ST) 3 ppm                             |  |

Show All



### Table Z-2: Wait, why are Benzene, Beryllium, Cadmium, etc. listed specially here?

Note: This table only includes occupational exposure limits (OELs) for substances listed in the OSHA Z-2 Table. OELs for hundreds of additional substances have been adopted by Cal/OSHA, NIOSH, and ACGIH. These organizations periodically make revisions to their OELs and so they should be consulted directly for their most current values and substances, as well as special notations such as for skin absorption. The TLVs<sup>®</sup> and BEIs<sup>®</sup> are copyrighted by ACGIH<sup>®</sup> and are not publicly available. However, they can be purchased in their entirety on the ACGIH<sup>®</sup> website at http://www.acgih.org/store/. Permission must be requested from ACGIH<sup>®</sup> to reproduce the TLVs<sup>®</sup> and BEIs<sup>®</sup>. Click here for permission request form.

#### Annotated OSHA Z-2 Table<sup>(a)</sup>

| Regulatory Limits  |                                      |  |                      |   |   |  | Recommended Limits                             |  |
|--|--------------------------------------|--|----------------------|---|---|--|--|--|
|  | 0-1/0544                             |  |                      |   |   |  |  |  |
| Substance  | 8-hour                               | 8-hour ceiling concer                  |                      | ximum peak above the acceptable PEL <sup>(c)</sup><br>(as of 10/2/2019) |   | <b>NIOSH REL<sup>(d)</sup></b><br>(as of 10/18/2019) | ACGIH <sup>®</sup> 2019<br>TLV <sup>®(e)</sup> |  |
|  | Time<br>Weighted<br>Average<br>(TWA) | Acceptable<br>Ceiling<br>Concentration | Concentration        | Maximum<br>Duration   | 8-hour TWAUp to 10-hour TWA(ST) STEL(ST) STEL(C) Ceiling(C) Ceiling           |  | 8-hour TWA<br>(ST) STEL<br>(C) Ceiling         |  |
| Benzene <sup>(f)</sup> (Z37.40-1969)                                 | 69) 10 ppm 25 ppm                    |  | 50 ppm 10 min        |   | See Annotated Table Z-1   |  |  |  |
| Beryllium and beryllium<br>compounds <sup>(i)</sup><br>(Z37.29-1970) | 2 µg/m <sup>3</sup>                  | 5 µg/m <sup>3</sup>                    | 25 μg/m <sup>3</sup> | 30 min  | 0.2 μg/m <sup>3</sup><br>(ST) 2 μg/m <sup>3</sup><br>(C) 25 μg/m <sup>3</sup> | Ca<br>See Appendix A                                 | 0.05 µg/m <sup>3</sup> (IHL)                   |  |
| Cadmium fume <sup>(g)</sup> (Z37.5-<br>1970)                         | 0.1<br>mg/m <sup>3</sup>             | 0.3 mg/m <sup>3</sup>                  |                      |   | See Annotated T   | able Z-1   |  |  |
|  | ~ ~                                  | 00 / 3                                 |                      |   |   |  |  |  |

#### \*Go to list of all footnotes

### Table Z-3: Wait, what are these silica limits for? And the mica Federal OSHA PEL is only in mppcf?

|  | Regulatory Lin  | nits   |  | Recommen             | nded Limits          |
|--|---|--|--|----------------------|----------------------|
|  | <b>Cal/OSHA</b><br><b>PEL<sup>(c)</sup></b><br><b>8-hour TWA</b><br>(as of 10/2/2019) | NIOSH REL <sup>(d)</sup><br>Up to 10-hour<br>TWA<br>(as of 10/18/2019) | ACGIH <sup>®</sup> 2019<br>TLV <sup>®(e)</sup><br>8-hour TWA |                      |                      |
| Substance  | mppcf <sup>(f)(g)</sup> mg/m <sup>3</sup>   |  | mg/m <sup>3</sup>  | mg/m <sup>3</sup>    | mg/m <sup>3</sup>    |
| Silica: Crystalline  |   |  |  |                      |                      |
| Quartz (Respirable) <sup>(I)</sup>   | 250 <sup>(h)</sup><br>(%SiO <sub>2</sub> +5)  | 10 mg/m <sup>3(k)</sup> (%SiO <sub>2</sub> +2)                         | See Annotated<br>Z-1   | See Annotated<br>Z-1 | See Annotated<br>Z-1 |
| Cristobalite <sup>(I)</sup> Use ½ the value calculated from the count or mass formulae for quartz. |   |  | See Annotated<br>Z-1   | See Annotated<br>Z-1 | See Annotated<br>Z-1 |
| Tridymite <sup>(I)</sup> Use ½ the value calculated from the formulae for quartz.                  |   |  | See Annotated<br>Z-1   | See Annotated<br>Z-1 | See Annotated<br>Z-1 |
| Amorphous, including natural diatomaceous<br>earth   | 20  | 80 mg/m <sup>3</sup><br>(%SiO <sub>2</sub> )                           | 6 (total)<br>3 (resp.)                                       | 6                    |                      |
| Silicates (less than 1% crystalline silica):   |   |  |  |                      |                      |
| lica   | 20  |  | 3 (resp.)  | 3 (resp.)            | 3 (resp.)            |

#### Annotated TABLE Z-3 Mineral Dusts<sup>(a)</sup>

#### \*Go to list of all footnotes

# **Limitations on Limits** OELs Not Always Used: UK Study on Small Businesses

- Relied on suppliers or personal experience for decisions on control measures
- Only 19% of almost 1200 respondents understood OELs
- Especially true for microbusinesses (< 5 employees)</li>
  - No OSH specialist in house
  - Measurements of workers' exposure expensive, not available, difficult to interpret and apply to micro business
  - Source: <u>https://www.cdc.gov/niosh/docs/2009-152/pdfs/2009-152.pdf</u>

# **TSCA Update: OELs from EPA Existing Chemical Exposure Limits (ECELs)**

- January 15, 2021, but an indicator of possible future actions.
- Methylene Chloride 1 ppm TWA
  - OSHA 25 ppm TWA, 125 ppm STEL
- longer than 8 hour shifts
  - $ECEL_n = ECELx (8/n)x(24-n/16)$

• January 19, 2017 Federal Register (82 FR 7464) Proposed Rule under TSCA Section 6(a) on commercial paint and coating removal was WITHDRAWN on

N-Methyl-Pyrrolidone 5 ppm TWA (20 mg/m<sup>3</sup>) and Brief-Scala reduction for

# Lack of OELs May Impose Limitations, too Why monitor if there's no PEL?

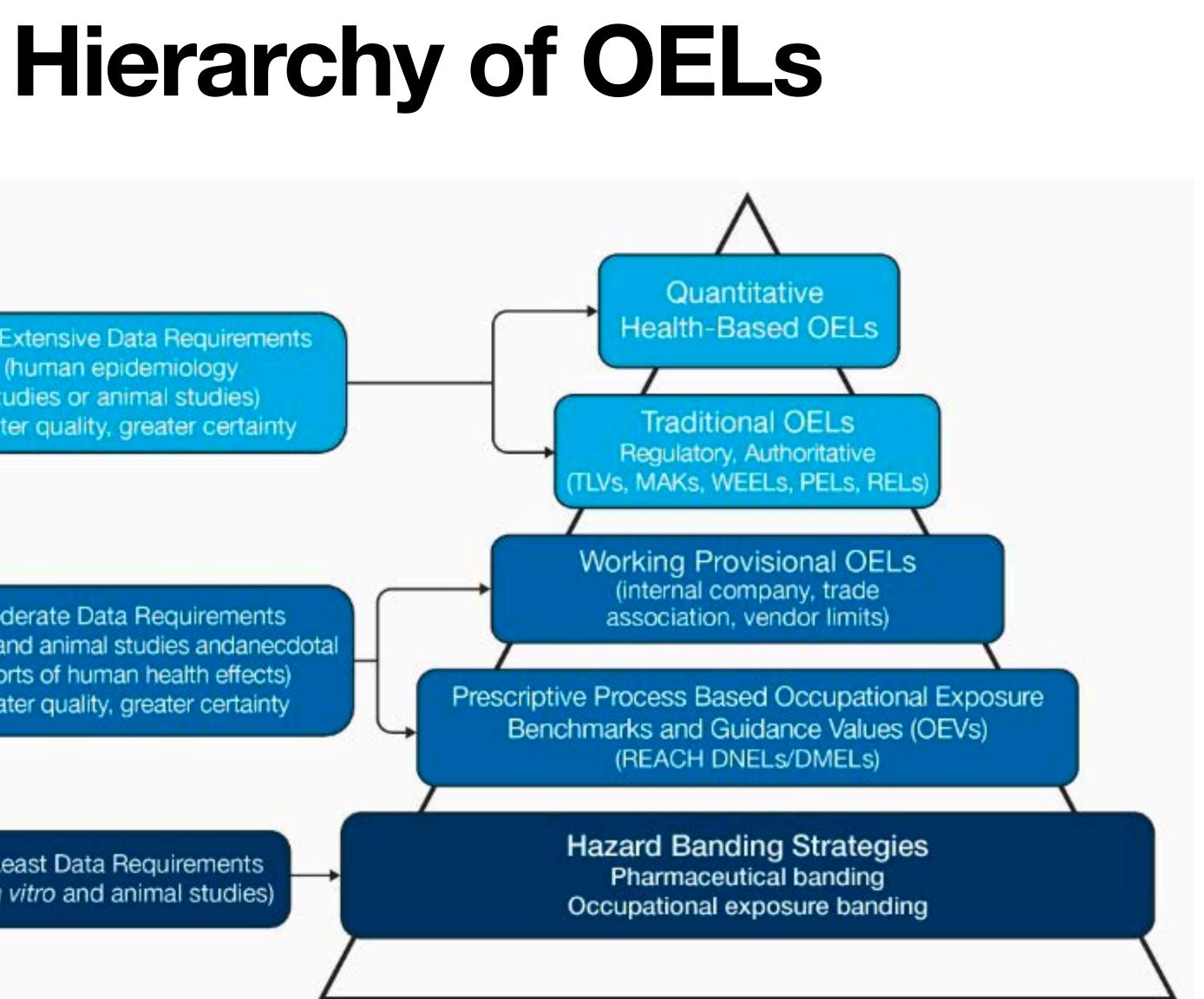
- Some organizations have asked, "Why monitor for a chemical if there is no PEL or other OEL to which to compare the results?"
- It's not that the millions of chemicals without a PEL or other OEL are safe.
- What does the Safety Data Sheet (SDS) say?
  - Section 8 of SDS: Exposure Controls/Personal Protection
  - Section 11 of SDS: Toxicological Information
  - Most products are mixtures, but these sections only list OELs and Tox data for individual ingredients, not usually for the mixture as a whole

Most Extensive Data Requirements (human epidemiology studies or animal studies) greater quality, greater certainty

Moderate Data Requirements (in vitro and animal studies and anecdotal reports of human health effects) greater quality, greater certainty

> Least Data Requirements (in vitro and animal studies)

Source: https://www.cdc.gov/niosh/topics/oeb/purpose.html



# **Occupational Exposure Banding Defined** aka Hazard Banding or Health Hazard Banding

- Process of assigning chemicals into categories ("bands") based on:
  - toxicological potency and
  - risk and type of adverse health effects from exposure
- Resulting in a range of airborne concentrations anticipated to protect worker health
- Related but NOT the same as Control Banding

# **Applications of Banding Concept** Pharmaceutical and Chemical Industry pioneered banding

- Active Pharmaceutical Ingredients were created, but had no OEL
- Toxicological, Physical and Chemical Properties affecting Health
- Grouped into categories requiring specific levels of controls (PB-ECL)
  - Conventional handling low potency PB-ECL category 1...1 mg/m<sup>3</sup>
  - No open handling for potent or toxic PB-ECL category  $3...10 \ \mu g/m^3$
  - Closed process/robotics extremely toxic PB-ECL category 5...0.1µg/m<sup>3</sup>

Source: Naumann et. al, (1996) Performance- Based Exposure Control Limits for Pharmaceutical Active Ingredients, AIHAJ, 57:1, 33-42.

# NIOSH expanded concept to industrial chemicals <a href="https://www.cdc.gov/niosh/topics/oeb/default.html">https://www.cdc.gov/niosh/topics/oeb/default.html</a>

- Intended to apply banding to a broader group of chemicals than previously
- Uses available, but often limited, toxicological information to set exposure levels for workers
- The airborne concentrations set can then be used as a target for exposure controls based on the specific situation
- Technical Guidance Document explains how in detail
  - <u>https://www.cdc.gov/niosh/docs/2019-132/default.html</u>
- NIOSH also developed an e-Tool to assist deriving OEBs

# AIHA & NIOSH EXPOSURE BANDING

- Vision Statements:
- professional practice.
- CPAG Champion: John Baker, johnbaker1947@icloud.com -



- AIHA in partnership with NIOSH is educating health & safety professionals on the importance of utilizing Occupational Exposure Banding (OEB) in their exposure risk assessments.

IH/OEHS and allied professionals, e.g., Product Stewards, Occupational Health Nurses and Doctors, etc., develop and actively use practical guidance for application of OEB in their



### AIHA OEB WEBSITE - WWW.AIHA.ORG/OEB

### 

### **Occupational Exp** What You Ne

Occupational exposure banding, also called hazard banding, health hazard banding, or exposure banding, is a process of assigning chemicals into bands or categories based on a chemical's toxicological potency and the risk of adverse health effects associated with exposure. The result of this process is called an occupational exposure band, or OEB, which is a range of exposure concentrations where worker health is anticipated to be protected.





|            |            | Catalyst Fi  | nd Consultants Job | Board Marketpla | ce Member Center |              | earch Join Now - |
|------------|------------|--------------|--------------------|-----------------|------------------|--------------|------------------|
| About AIHA | Membership | Get Involved | AIHA Universit     | y Events        | IH/OEHS Careers  | Publications | Public Resource  |

While OEBs are provisional, OELs are official, authoritative standards created by recognized occupational



# **AIHA OEB resources** Available for your use

- Technical Framework/Body of Knowledge
- Intro to OEB guidance
- Link to NIOSH e-Tool
- Link to CPAG OEB page
- OEB Virtual Conference Recordings
- 2 Microlearning Videos



grade smetic % 80 D



### Technical Framework

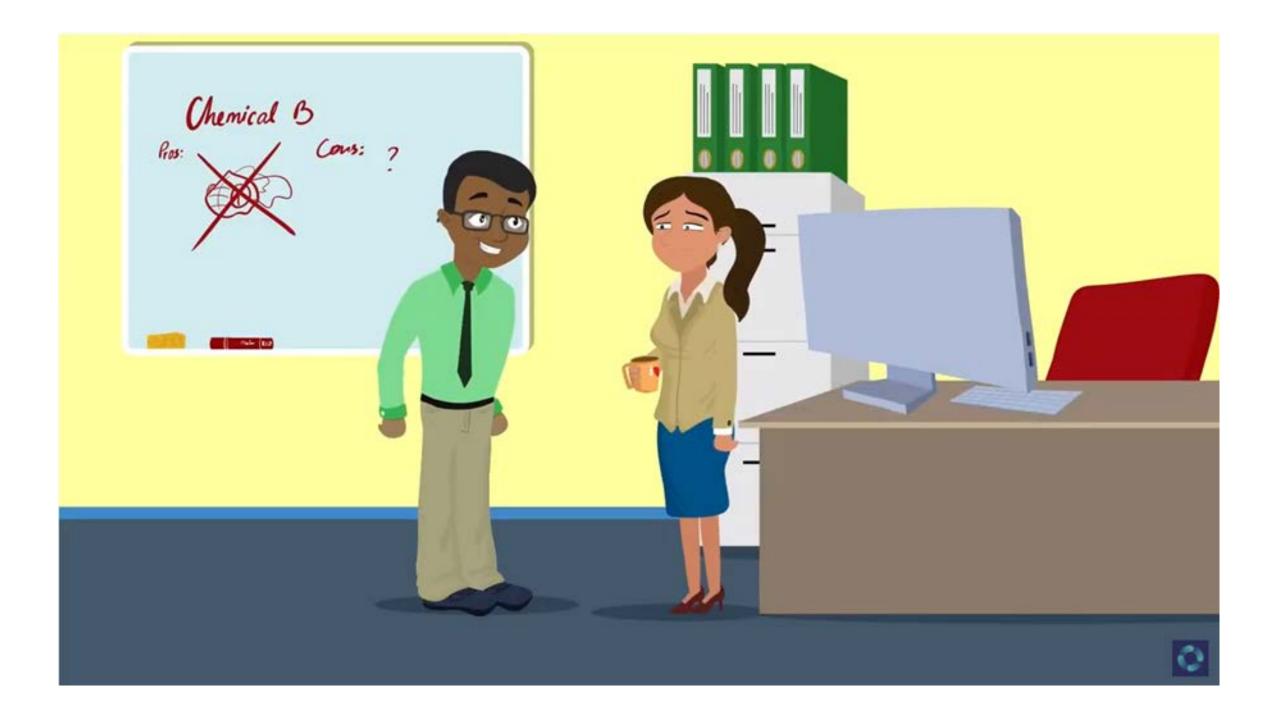
Occupational Exposure Banding Process



# WWW.AIHA.ORG/OEB







# QUESTIONS FOR THE GROUP

- Are you familiar with the principles of OEB?
- Have you personally used OEB in a professional setting?
- Have you seen either of the two OEB instructional videos?
- If you are familiar but have not used OEB what was the barrier?

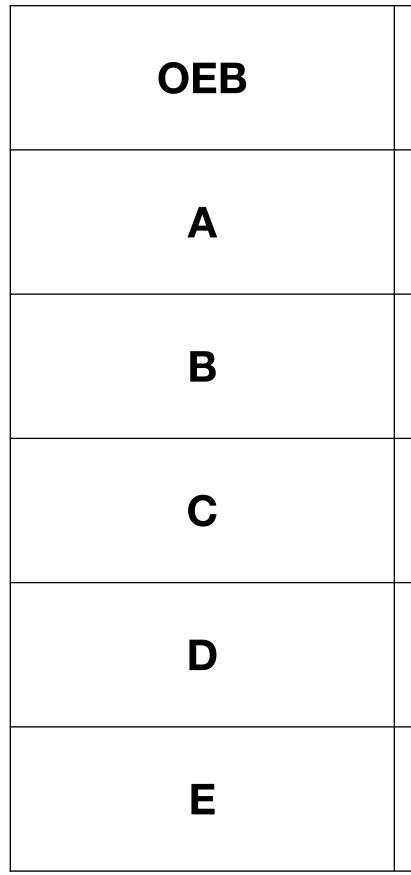


# What are Tier 1, Tier 2, and Tier 3? Levels of OEBs developed with less to more data

- Tier 1 uses GHS Hazard Codes ("H-codes") assigned to chemicals under the UNECE Globally Harmonized System for Classification and Labeling of Chemicals to place the chemicals in air concentrations called Bands C, D or E.
  - Typically Gestis, ECHA Annex VI or SDS data is used for Tier 1
- Tier 2 uses specific toxicological data from authoritative databases such as National Toxicology Program (NTP), International Agency for Research on Cancer (IARC), Health Canada, Agency for Toxic Substances and Disease Registry (ATSDR), EPA Integrated Risk Information System (IRIS), etc. to place the chemicals in air concentrations called Bands A, B, C, D or E.
- Tier 3 requires expert judgement to evaluate experimental data

#### The 5 Bands of NIOSH A В С D E **Recommended airborne concentrations decrease from A to E**

- Tier 1 C,D,E only
- Tier 2 A,B,C,D,E





| Dust/Particle<br>mg/m <sup>3</sup> | Gas/Vapor<br>ppm |
|------------------------------------|------------------|
| >10                                | >100             |
| >1 to 10                           | >10 to 100       |
| >0.1 to 1                          | >1 to 10         |
| >0.01 to 0.1                       | >0.1 to 1        |
| ≦0.01                              | ≦0.1             |

### **GHS H-Codes are used in Tier 1**

### **Hazard Class and Category**



### **Globally Harmonized System of Classification and Labelling of Chemicals (GHS)**

**Eighth revised edition** 





# Let's start with an SDS...Oh, wait... OSHA Hazard Communication Standard 29 CFR 1910.1200

- OSHA does not require H-codes on SDSs.
- Hazard statements and pictograms ARE harmonized.
- You need UN GHS "Purple Book" Annex 3 to cross-reference.
- Example:
  - Acute Toxicity, oral, category 1
  - Skull and Crossbones pictogram
  - "Fatal if swallowed" = H 300

# **Overview of Tier 1 Banding Process** Table 2-2 of NIOSH Guidance Doc. 2019-132

- Step 1. Chemical of Interest has no OEL
- Step 2. Locate GHS Hazard codes and categories in recommended databases
- Step 3. Compare hazard codes/categories for each NIOSH criteria of each health endpoint
- Step 4. Assign band to each relevant health endpoint based on criteria
- Step 5. Assign an OEB for the chemical based on the most protective endpoint band among C, D, E.

# Health endpoints used for NIOSH OEB GHS health hazard classes used (which ones are missing?)

- Carcinogenicity
- Reproductive and Developmental Toxicity
- Specific Target Organ Toxicity
   Repeated Exposure
- Genotoxicity

- Respiratory Sensitization
- Skin Sensitization
- Acute Toxicity/Lethality
- Skin Corrosion/Irritation
- Eye Damage/Corrosion

#### OFR 6-1001 Home

| About<br>Fier One     | + |
|-----------------------|---|
|                       | + |
| ier Two               |   |
|                       | + |
| Additional Resources  |   |
| Conversion Calculator |   |
| .og Off               |   |
| Related Information   |   |
| NIOSH Pocket Guide    |   |

NIOSH OEB Topic Page

### NIOSH Occupational Exposure Banding e-Tool

#### Overview

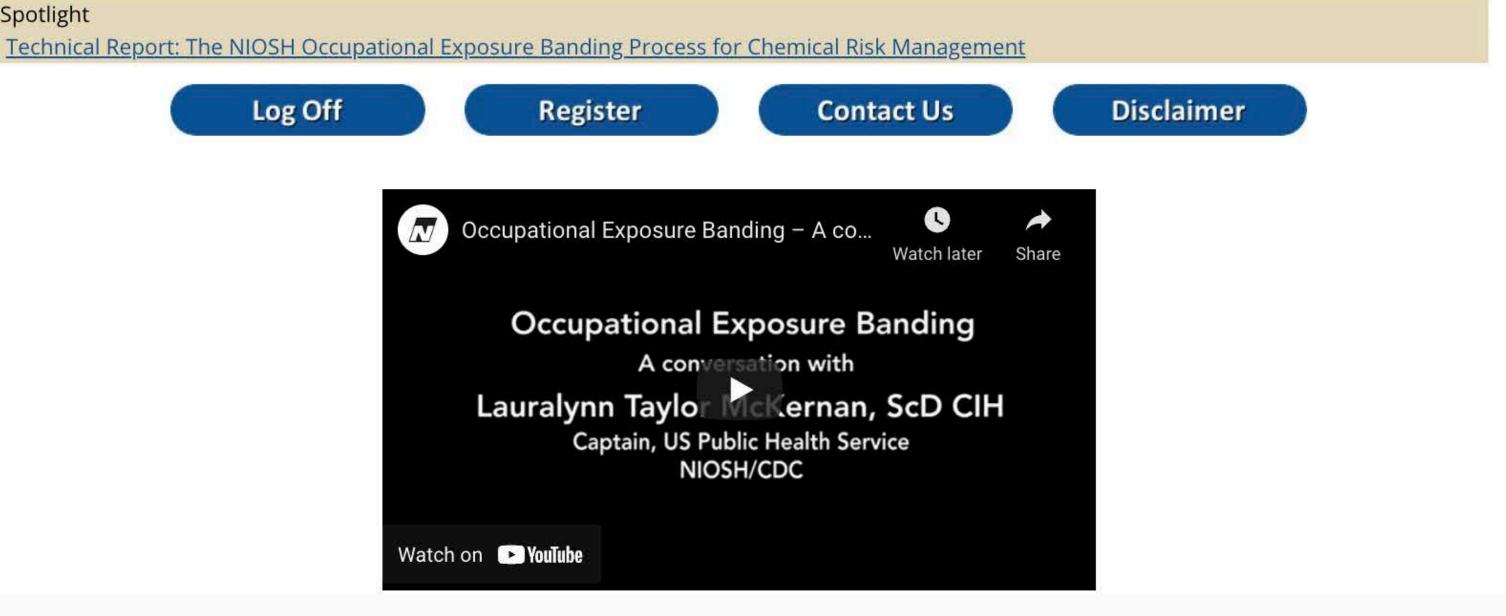
Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that is expected to protect worker health. For more information on occupational exposure banding please refer to the NIOSH occupational exposure banding topic page: occupational exposure banding.

The occupational exposure banding e-Tool is a supplementary online application that incorporates the occupational exposure banding process and allows users to apply toxicology and potency information to generate quantitative exposure guidance for chemicals. The Occupational Exposure Banding e-Tool should be used in concert with the Current Intelligence Bulletin (CIB). The CIB contains detailed instructions for searching for and choosing appropriate data for banding. This e-Tool is a supplementary tool meant to assist with Tier 1 and Tier 2 banding. To learn more click here: e-Tool

Spotlight

Log Off







| Negelyen Links                                      |   |  |  |  |  |
|---|---|--|--|--|--|
| Collected Links                                     | NIOSH Occup   | ational Exposure Banding e-T   |  |  |  |
| <ul> <li>Bookmarks</li> <li>Reading List</li> </ul> | OEB e-Tool Home > Tier One                              |  |  |  |  |
|   | A OEB e-Tool Home                                       |  |  |  |  |
|   | About   | Chemical Information<br>Please note that the following hazard of               |  |  |  |
|   | Tier One —  | H200's (physical hazards), H303, H305,<br>H362, and H400's (environmental haza |  |  |  |
|   | Overview  | of these codes, they will not contribute                                       |  |  |  |
|   | New Entry   | Chemical Information   |  |  |  |
|   | View/Edit Entry   | Chemical Name  |  |  |  |
|   | Recommended Sources                                     | CAS Number   |  |  |  |
|   | Tier Two +  | Physical State   |  |  |  |
|   | Additional Resources                                    | <ul><li>Vapor</li><li>Particles</li></ul>                                      |  |  |  |
|   | Conversion Calculator                                   | Vapor & Particles  |  |  |  |
|   | https://wwwn.cdc.gov/NIOSH-OEB/TierOne/Over<br>How to F | View<br>M 1488 PIT Master- Institute of Holding Workin                         |  |  |  |

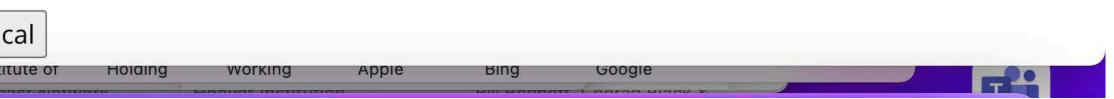
### ool (version 1.1)





### ion

codes will not be used for Tier 1 Banding: H313, H316, H320, H333, H335, H336, ards). If a chemical has been assigned any e to the Tier 1 band assignment.



#### A OEB e-Tool Home

| About                 |   |
|-----------------------|---|
| Tier One              | ÷ |
| Tier Two              | + |
| Additional Resources  |   |
| Conversion Calculator |   |
| Log Off               |   |
| Related Information   |   |

### **Tier One Update**

Please note that the following hazard codes will not be used for Tier 1 Banding: H200's (physical hazards), H303, H305, H313, H316, H320, H333, H335, H336, H362, and H400's (environmental hazards). If a chemical has been assigned any of these codes, they will not contribute to the Tier 1 band assignment.

| Carcinogenicity | Reproductive Tox | 5 |
|-----------------|------------------|---|
| Physical State  | Particles        |   |
| CAS Number      | 75-60-5          |   |
| Chemical Name   | Cacodylic acid   |   |

| Carcinogeni | city          |
|-------------|---------------|
| Select      | Hazard Catego |
|             |               |

| Chemical Inform | ation                 |              |                         |           |                 |                |                 |
|-----------------|-----------------------|--------------|-------------------------|-----------|-----------------|----------------|-----------------|
| Chemical Name   | Cacodylic acid        |              |                         |           |                 |                |                 |
| CAS Number      | 75-60-5               |              |                         |           |                 |                |                 |
| Physical State  | Particles             |              |                         |           |                 |                |                 |
| Carcinogenicity | Reproductive Tox STOT | Genotoxicity | Resp/Skin Sensitization | Acute Tox | Skin Corr/Irr   | Eye Damage/Irr |                 |
| Carcinogenicity | y                     |              |                         |           |                 |                | Clear Selection |
| Select          | Hazard Category       |              | Hazard Code             | Haza      | rd Statement    |                |                 |
| 0               | 1                     |              | 350                     | May c     | ause cancer     |                |                 |
| 0               | 1a                    |              | 350                     | May c     | ause cancer     |                |                 |
| 0               | 1b                    |              | 350                     | May c     | ause cancer     |                |                 |
| 0               | 2                     |              | 351                     | Suspe     | ected of causin | g cancer       |                 |

Update Tier One

**NIOSH Pocket Guide** 

NIOSH OEB Topic Page



Page last reviewed: September 21, 2021 Page last updated: September 21, 2021 Content source: National Institute for Occupational Safety and Health. Division of Science Integration.







### Tier 1 Example 1 Chloral Hydrate

Example of eTool Tier 1 Screen Shot summary from NIOSH 2019-132 Guidance Document

- Band of C based on:
  - Acute Toxicity Oral category 3,
  - Skin Irritation, category 2
  - Eye Irritation, category 2

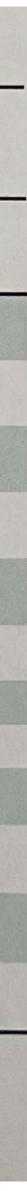
#### Table 2-2. Tier 1 example.

#### **Chemical Name: Chloral Hydrate**

CAS Number: 302-17-0

| Endpoint                           | Hazard<br>code | Hazard<br>category   | H-code<br>source  | Endpoint<br>band   |
|------------------------------------|----------------|--|---|--|
| Carcinogenicity                    | None           | _  | _   | -  |
| Reproductive toxicity              | None           |  |   |  |
| Specific target organ toxicity     | None           | —<br>—   | -   |  |
| Genotoxicity                       | None           |  | -   |  |
| Respiratory and skin sensitization | None           | _  |   | -  |
| Acute Toxicity                     |                |  |   | _  |
| Inhalation                         |                | <u> </u>   | _   | _  |
| Oral                               | H301           | Category 3   | GHS   | С  |
| Dermal                             | None           | -  | -   | -  |
| Skin corrosion/irritation          | H315           | Category 2   | GHS   | С  |
| Eye damage/irritation              | H319           | Category 2   | GHS   | С  |
| Most stringent band                |                |  |   | с  |
|                                    |                | And a share was a subscription of the second s | and the second se | the second s |

Notes:



### Tier 1 Example 2 Perfluorooctane Sulfonic Acid

Example of Tier 1 eTool Screen Shot Summary from NIOSH Guidance Document 2019-132

- Band of E based on:
  - Carcinogenicity category 1B
  - STOT-RE category 1
  - Skin Corrosion category 1B
- Bands of C and D for Acute Toxicity and Reproductive Toxicity were overridden, but useful to see in evaluation
- Tier 2 optional because its Band E

#### **Chemical Name: Perfluorooctane Sulfonic Acid**

#### **Chemical Name: Perfluorooctane Sulfonic Acid**

CAS number: 1763-23-1

| Endpoint  | Hazard<br>code | Hazard<br>category | H-code<br>source | Endpoint<br>band |
|---|----------------|--------------------|------------------|------------------|
| Carcinogenicity                                       | H351           | Category 2         | GHS              | E                |
| Reproductive toxicity                                 | H360D          | Category 1B        | GHS              | D                |
| Specific Target organ toxicity -<br>repeated exposure | H372           | Category 1         | GHS              | E                |
| Genotoxicity  |                |                    |                  |                  |
| Respiratory and skin<br>sensitization                 |                |                    |                  |                  |
| Acute toxicity  |                |                    |                  |                  |
| nhalation   | H332           | Category 4         | GHS              | с                |
| ral   | H302           | Category 4         | GHS              |                  |
| ermal   |                |                    |                  |                  |
| in corrosion/irritation                               | H314           | Category 1B        | GHS              | E                |
| e damage/irritation                                   |                |                    |                  |                  |
| st stringent band                                     |                |                    |                  | E                |

Result: Band E is assigned as a result of the Tier 1 evaluation. A Tier 2 evaluation is optional. Data Source: GESTIS: http://www.dguv.de/ifa/gestis-database



# **Overview of Tier 2 Banding Process** Figure 3.1 of OEB Guidance 2019-132

- Step 1. Begin Tier 2 process
- Step 2. Search recommended databases for toxicity information
- Step 3. Compare qualitative and quantitative data to NIOSH Tier 2 banding criteria
- Step 4. Assign band and Endpoint Determinant Score (EDS) for each NIOSH Tier 2 banding criteria
- Step 5. Assign a Tier 2 band for the chemical based on most protective endpoint band if the Total Determinant Score (TDS) is above 30 or if the overall band is E

A numerical scheme for data adequacy is used to evaluate chemical substances with different combinations of toxicological outcomes and available data, as shown in Table 3-4.

### Table 3-4. Assigned scores for the presence of toxicological endpoints encountered in the Tier 2 evaluation.

**Toxicological endpoint** 

### Carcinogenicity

Reproductive and Developmental Toxicity Specific Target Organ Toxicity-Repeated Ex Genotoxicity **Respiratory Sensitization Skin Sensitization** Acute Toxicity/Lethality Skin Corrosion/Irritation Eye Damage/Irritation Data Sufficiency/Total Determinant Score

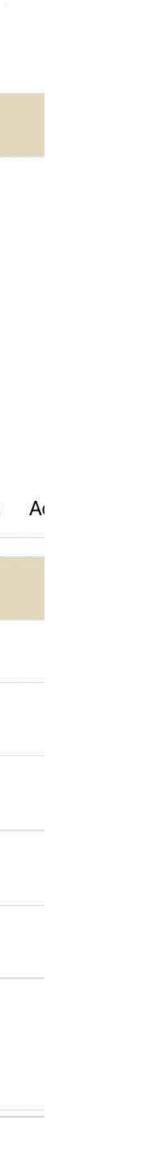
\*The minimum TDS criteria are waived if any of the endpoint bands are E. In that case, the chemical is assigned an overall band E, regardless of TDS.

|          | Endpoint determinant score ( <mark>EDS</mark> ) |
|----------|---|
|          | Qualitative = 20 or 30<br>Quantitative = 30     |
| /        | 30  |
| Exposure | 30  |
|          | 5   |
|          | 10  |
|          | 5   |
|          | 5   |
|          | 5   |
|          | 5   |
| (TDS)*   | 30/125  |

### Tier 2 Data Entry Example Bromodichloromethane STOT-RE Health Endpoint

- Rank 1 (preferred data source)
- Endpoint type
- Duration of exposure (issues?)
- Route of exposure
- Quantitative data entry
- Can add more source of info

#### Tier Two + **Chemical Information** Chemical Name Bromodichloromethane 75-27-4 CAS Number **Physical State** Vapor Particles Vapor & Particles 0 Reproductive Tox **STOT** Genotoxicity Sensitization(resp) Carcinogenicity Sensitization(skin) **Specific Target Organ Toxicity** Rank 1 **ATSDR:** Toxicological Profiles Source: $\sim$ NOAEL/LOAEL: NOAEL O LOAEL Duration: Oral, Dermal V Type: Input: 60 mg/kg-day



### **Example of Tier 2 NOAEL data**

**ATSDR tox profile of bromodichloromethane** 

- Useful for STOT-RE data entry
- Which data to select?
  - Exposure period
  - Route of entry
  - Endpoint effect
  - Other considerations?

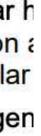
#### 2. HEALTH EFFECTS

#### 2-2. Levels of Significant Exposure to Bromodichloromethane – Inhala

| ure<br>eters | Doses<br>(ppm)     | Parameters<br>monitored | Endpoint                             | NOAEL<br>(ppm) |    | Serious<br>LOAEL<br>(ppm) | Effect   |
|--------------|--------------------|-------------------------|--------------------------------------|----------------|----|---------------------------|--|
|              |                    |                         |                                      |                |    |                           |  |
| /day<br>week | 1, 10,<br>30, 100, | LE, BW, OW,<br>HP       | Death                                |                |    | 30                        | 2/6, 1/6, 3/6 o<br>30, 100, and                |
|              | 150                |                         | Bd wt                                | 10             | 30 |                           | Decreased be                                   |
|              |                    |                         | Hepatic                              | 10             | 30 |                           | Centrilobular<br>degeneration<br>hepatocellula |
|              |                    |                         | Renal                                | 1              | 10 |                           | Tubular dege                                   |
|              |                    |                         | Ocular                               | 10             | 30 |                           | Mild eye irrita                                |
|              |                    |                         | Other noncancer<br>(urinary bladder) | 150            |    |                           |  |
| /day<br>week | 1, 10,<br>30, 100, | LE, BW, OW,<br>HP       | Death                                |                |    | 30                        | 2/6, 4/6, 6/6 o<br>150 ppm, res                |
|              | 150                |                         | Bd wt                                | 100            |    |                           |  |
|              |                    |                         | Hepatic                              | 1              | 10 |                           | Centrilobular<br>degeneration<br>hepatocellula |
|              |                    |                         | Renal                                | 1              | 10 |                           | Tubular dege                                   |
|              |                    |                         | Other noncancer                      | 150            |    |                           |  |







# **Tier 2 process is time consuming** Need to research available data for 9 health endpoints

- Rank 1 preferred databases may have large amounts of information, but need to be carefully studied
- The eTool requires certain data parameters for input
  - Example: Bromodichloromethane ATSDR tox profile
    - inhalation studies were not more than 29 days long
    - oral chronic studies ran as long as 2 years
    - neither of which is a selection in the eTool

### Completed Tier 2 Example 1 Cacodylic Acid Summary pdf from e-tool

- Carcinogenicity Weight of Evidence alone would have resulted in Band E
- Acute Oral Toxicity quantitative data (EDS = 5) would not have resulted in Band B if no other information had been available because need TDS of 30 or more.



| Chemical Name: cacodylic acid<br>CAS Number: 75-60-5 |   |   |        |                  |  |  |  |
|--|---|---|--------|------------------|--|--|--|
| Endpoint   | Source                                      | Data  | EDS    | Endpoint<br>Band |  |  |  |
| Carcinogenicity<br>Quant                             |   |   |        |                  |  |  |  |
| Carcinogenicity<br>WOE                               | IARC  | Group 2B (possibly carcinogenic to humans)                  | 30     | E                |  |  |  |
| Reproductive<br>Toxicity                             |   |   |        |                  |  |  |  |
| Target-Organ<br>Toxicity                             |   |   |        |                  |  |  |  |
| Genotoxicity<br>Toxicity                             |   |   |        |                  |  |  |  |
| Respiratory<br>Sensitization                         |   |   |        |                  |  |  |  |
| Skin Sensitization                                   |   |   |        |                  |  |  |  |
| Acute Toxicity                                       | National Library of Medicine<br>ChemID Plus | Rank: 1; Type: Oral LD50; Duration: 4.00<br>hrs; Input: 644 | 5      | В                |  |  |  |
| Skin Irritation                                      |   |   |        |                  |  |  |  |
| Eye Irritation                                       |   |   |        |                  |  |  |  |
| <b>Overall Recommend</b>                             | ed Band                                     |   | TDS=35 | E                |  |  |  |
| Notes  |   |   |        |                  |  |  |  |

### Completed Tier 2 Example 2 Benzo(k)Fluoranthene Summary pdf from eTool

- Carcinogenicity Quantitative results would be Band D but
- Carcinogenicity Weight of Evidence moved it to Band E
- Genotoxicity resulted in Band E also
- Total Band E TDS of 40 sufficient to score.

#### Selected Tier Two Entry Recommendation



| Chemical Name: I<br>CAS Number: 207 |                                       | hene  |        |                  |
|-------------------------------------|---------------------------------------|---|--------|------------------|
| Endpoint                            | Source                                | Data  | EDS    | Endpoint<br>Band |
| Carcinogenicity                     | California Slope<br>Factor            | 1.2 x 1 (mg/kg-day)-1                                   | 30     | D                |
| Quant                               | California<br>Inhalation Unit<br>Risk | 1.1 x 0.0001 (µg/m³)-¹                                  |        | D                |
| Carcinogenicity<br>WOE              | U.S. EPA IRIS                         | Group B2 (probable human carcinogen)                    | 30     | Е                |
| Reproductive<br>Toxicity            |                                       |   |        |                  |
| Target-Organ<br>Toxicity            |                                       |   |        |                  |
|                                     | NTP: Report on<br>Carcinogens         | Rank 1; Results: Positive                               | 5      | Е                |
| Respiratory<br>Sensitization        |                                       |   |        |                  |
| Skin<br>Sensitization               |                                       |   |        |                  |
| Acute Toxicity                      |                                       |   |        |                  |
| Skin Irritation                     | REACH                                 | Rank: 1; Results: Irritant with<br>unspecified severity | 5      | С                |
| Eye Irritation                      |                                       |   |        |                  |
| <b>Overall Recomm</b>               | ended Band                            |   | TDS=40 | E                |
| Notes                               |                                       |   |        |                  |



# **Benefits of e-Tool** Tier 1 and Tier 2

- Tier 1 is quick and easy using the e-Tool
- Tier 2 can be done manually, but the e-Tool provides
  - hyperlinks to Reference databases (kinda)
  - concise summary of endpoints and scores in the "Edit" screen

| Tier One Edit Entry ×           | +<br>NOSH-OEB/TierOne/E | dit                        |               |     |
|---------------------------------|-------------------------|----------------------------|---------------|-----|
| 🔄 Translate 📝 Big Data and Sens | Exposure Banding        | . 🗹 Communicating O        | Serving the   | Cha |
| About                           |                         | Tier One E                 | dit           |     |
| Tier One                        |                         | List of Existing Tier      | One Entries   |     |
| Overview                        |                         | Chemical Name              | <u>CAS</u>    | ١   |
| New Entry                       |                         | •<br>•                     | <u>Number</u> | I   |
| View/Edit Entry                 |                         | 2-butyl-1,2-               | 4299-         | 4   |
| Recommended Sources             |                         | benzisothiazolin-<br>3-one | 07-4          | I   |
| Tier Two                        | +                       | Acetyl chloride            | 75-36-5       | 1   |
| Additional Resources            |                         | >                          |               | l   |
| Conversion Calculator           |                         | Cacodylic acid             | 75-60-5       |     |
| Log Off                         |                         | n-Hexyllithium             | 21369-        |     |
|                                 |                         |                            | 64-2          | ł   |
| Related Information             |                         | quercetin                  | 117-39-<br>5  | 2   |
| NIOSH Pocket Guide              |                         |                            | J.,           | ł   |
| NIOSH OEB Topic Page            |                         | quercetin                  | 117-39-<br>5  |     |

|                     |                     |                         |             |               |                            |     |         |       | ~    |
|---------------------|---------------------|-------------------------|-------------|---------------|----------------------------|-----|---------|-------|------|
|                     |                     |                         |             |               |                            | ₫ ☆ |         | J     | :    |
| Chan 🗹 T            | otal Exposure He    |                         |             |               |                            |     | Other I | Bookm | arks |
|                     |                     | through safety and heal | th research |               | og Off                     |     |         |       |      |
|                     |                     |                         |             |               | <u>Print</u><br><u>PDF</u> |     |         |       |      |
| Vapor<br>Range      | Particles<br>Range  | Recommended<br>Band     |             |               |                            |     |         |       |      |
| ≤ 0.1<br>ppm        |                     | E                       | <u>Edit</u> | <u>Delete</u> | <u>Print</u><br><u>PDF</u> |     |         |       |      |
| ≤ 0.1<br>ppm        | ≤ 0.01<br>mg/m³     | E                       | <u>Edit</u> | <u>Delete</u> | Print<br>PDF               |     |         |       |      |
|                     | > 0.1 to 1<br>mg/m³ | C                       | <u>Edit</u> | <u>Delete</u> | Print<br>PDF               |     |         |       |      |
| ≤ 0.1<br>ppm        | ≤ 0.01<br>mg/m³     | E                       | <u>Edit</u> | <u>Delete</u> | Print<br>PDF               |     |         |       |      |
| > 1 to<br>10<br>ppm |                     | c                       | <u>Edit</u> | <u>Delete</u> | Print<br>PDF               |     |         |       |      |
| > 1 to<br>10<br>ppm |                     | C                       | <u>Edit</u> | <u>Delete</u> | Print<br>PDF               |     |         |       |      |

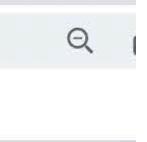
| $\leftarrow \rightarrow C$ $\triangleq$ wwwn.cdc.gov/NIOS | SH-OEB/TierTwo/Ed | lit                   |              |
|---|-------------------|-----------------------|--------------|
|   | Exposure Banding  | Communicating O       | . 🗹 Ser      |
| OFR 6-1001 Home > 116L IMO                                |                   |                       |              |
| A OEB e-Tool Home   |                   |                       |              |
| About   | -                 | Гier Two E            | dit          |
| Tier One  | +                 | List of Existing Tier | rwo Entri    |
| Tier Two  |                   | Chamical Nama         | CAS          |
| Overview  |                   | Chemical Name         | CAS<br>Numbe |
| New Entry   |                   | •                     |              |
| View/Edit Entry   |                   | acetyl Chloride       | 75-36-5      |
| Recommended Sources                                       |                   | Benzo (k)             | 207-08-      |
| Additional Resources                                      |                   | Fluoranthene          |              |
| Conversion Calculator                                     |                   | cacodylic acid        | 75-60-5      |
| Log Off   |                   | vincristine sulfate   | 2068-78      |
| Related Information                                       |                   |                       |              |
| NIOCH Decket Cuide  |                   |                       |              |

| ving th | e Chan |
|---------|--------|
|---------|--------|

Total Exposure He...  ${f V}$  VDH's Blade of Pe...



| ries |                |                    |                      |             |               | <u>Print</u><br>PDF |
|------|----------------|--------------------|----------------------|-------------|---------------|---------------------|
| er   | Vapor<br>Range | Particles<br>Range | Recommended<br>Band  |             |               |                     |
| 5    |                |                    | INSUFFICIENT<br>DATA | <u>Edit</u> | Delete        | Print<br>PDF        |
| 3-09 | ≤ 0.1<br>ppm   | ≤ 0.01<br>mg/m³    | E                    | <u>Edit</u> | <u>Delete</u> | Print<br>PDF        |
| 5    |                | ≤ 0.01<br>mg/m³    | E                    | <u>Edit</u> | <u>Delete</u> | Print<br>PDF        |
| 78-2 |                |                    |                      | <u>Edit</u> | Delete        | Print<br>PDF        |



C

# **NIOSH OEB Tier 3 - not an eTool process** Using Expert Judgment to Evaluate Experimental Data

- Searching the literature
- Selecting relevant studies
- Evaluating the studies
- Selecting a band
- Judging data sufficiency
- Assessing uncertainty

# **Special Issues in NIOSH OEB** More research needed...

- Special categories of aerosols: nanoparticles and fibers
- Impacts of physical form on OEB selection
- Banding mixtures of chemical substances

### Lessons Learned by NIOSH - so far It's a Process....

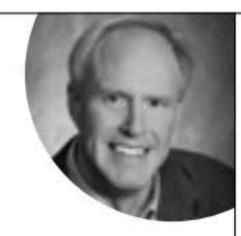
- Users want it short and sweet: how to video's not 156 page technical manual
  - But "the devil is in the details..."
- Toxicology terms don't mean the same thing to everyone
- Conducting a Tier 2 requires training
- Transcription errors from using other agencies' classifications
- Therefore the NIOSH OEB e-tool was created
- https://synergist.aiha.org/201603-the-niosh-decision-logic-for-oebs

# Upcoming activities by NIOSH Stay tuned...

- eTool update is awaiting a close look at OSHA proposed updates on the Hazard Communication rule and updates from GHS
- So far, none warrant revisions to the banding process guidance as of April 12, 2022.
- A companion document to the NIOSH Technical Report 2019-132 is in the works: Toxicological Endpoints and Banding Criteria Employed in the NIOSH Occupational Exposure Banding Process. (currently undergoing final updates to address peer reviewers' comments)

# **Occupational Exposure Banding: No More Excuses**

BY JOHN MULHAUSEN, AIHA PRESIDENT



JOHN MULHAUSEN, PhD, CIH, CSP, FAIHA, retired in 2018 from 3M where he worked for 31 years in a variety of global health and safety risk management roles, most recently as director of corporate safety and industrial hygiene. He can be reached at jrmulhausen@gmail.com.

Send feedback to synergist(daiha.org.

#### RESOURCES

AIHA: A Strategy for Assessing and Managing Occupational Exposures, Chapter 25, "Occupational Exposure and Control Banding," 4th ed. (2015).

AIHA: "Occupational Exposure Banding: What You Need to Know," bit.ly/aihaoeb.

AIHA: "Top 10 Imperatives for the AIHA Exposure Risk Management Process" bit.ly/aihauimperatives

January Synergist article (bit.ly/syn2201care) presented an example of two OEHS practitioners with similar backgrounds but different approaches to IH programs: Practitioner A pursues regulatory compliance by seeking to control exposures below OSHA's permissible exposure limits. while Practitioner B sets a goal of driving exposures below

ACGIH threshold limit values. The point of the simplistic example was to illustrate how standards of care—the minimum expected performance of a particular function—influence our interventions and help determine how protective our programs will be on the shop floor.

This month's column concerns what is intended for use with substances happens when we're dealing with with established hazard statements in the Globally Harmonized System of a substance that does not have an Classification and Labeling of Chem-OEL. We all know that this situation icals (GHS). For chemicals without is quite common: the gap between the number of chemicals in commerce appropriate GHS hazard statements, the e-Tool guides the user through a and those that have OELs is vast and structured "Tier 2" process of data getting larger every year. Fortunately, an effective approach exists for these collection and interpretation to assign substances, but distressingly few an appropriate OEB. The e-Tool is a remarkable achieve-OEHS professionals are taking advanment. It provides a freely available tage of it.

which are decades old. Refusing to use a tool because it isn't required by regulations reflects the mindset of Practitioner A. Do we really want to resign ourselves to practicing our profession with science that was state of the art in the 1960s?

"It's only for the most distinguished experts." This may have been true in the early days of occupational exposure banding, but the e-Tool has been designed for use by OEHS professionals without extensive toxicology knowledge. While a Tier 2 assessment can require several hours, this time is very well spent considering the alternative with substances that have no OELs is to throw up our hands and do nothing.

"I don't see it being done routinely in major organizations." This objection ignores the history of occupational exposure banding, which has been used for decades in the phar-

### No more excuses... February 2022 The Synergist President's Letter

- an effective approach exists for these substances, but distressingly few OEHS professionals are taking advantage of it."
- Excuses:
  - OSHA doesn't require it...
  - It's only for the most distinguished experts...
  - I don't see it being done routinely in major organizations...
- Our profession owes workers and communities better protection.
- We are best prepared and ethically obligated to make progress.

• AIHA President John Mulhausen stated regarding substances without an OEL, "Fortunately

# Thank you! Questions?