Updates from NIOSH: Proposed Chemical Carcinogen Policy and NIOSH Occupational Exposure Banding Process

Lauralynn McKernan
NIOSH
NIOSH Updates:

NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace

NIOSH Occupational Exposure Banding

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Why Update the Cancer Policy?

- Update the NIOSH process with current science
- Receive peer and public input on the NIOSH process
- Increase the transparency of the NIOSH process
Current Intelligence Bulletin

- Carcinogen classification
- Target risk level for carcinogen RELs
- Analytical feasibility and engineering achievability
Carcinogen Classification: History

- NIOSH used potential occupational carcinogen
- Some dissatisfaction with that terminology
- Carcinogen and RELs Policy Update Committee formed (interdivisional)
- Public meeting on issues on 12-12-11
- Draft document on web for public/peer review
- Public meeting on 12-17-13
- Currently – considering public and peer review comments before publishing final policies
Carcinogen Classification: Features

- Adopts NTP, EPA, and IARC cancer classifications for chemicals
- Evaluates occupational relevance in terms of exposure and applicability of the data
- Assigns Globally Harmonized System (GHS) category for hazard communication
Is occupational exposure to the chemical likely?

- YES
  - Is the chemical classification as carcinogen by NTP, EPA, or IARC?
    - YES
      - Evaluate occupational relevance of NTP, EPA, or IARC carcinogen data
    - NO
      - Is there other evidence of carcinogenicity?
        - YES
          - Is carcinogenicity occupationally relevant?
            - YES
              - Assign GHS category
              - Report as occupational carcinogen
            - NO
              - Report as not anticipated to be an occupational carcinogen
        - NO
          - Evaluate other health endpoints
          - Nominate for NTP classification
          - Evaluate using GHS criteria
          - Is carcinogenicity occupationally relevant?
Target Risk Level for Carcinogen RELs

- NIOSH conducts quantitative risk assessment using mathematical models to describe the exposure-response relationship.
- Estimates risk for a 45-year working lifetime.
- To set a REL, a target risk level is needed.
Target Risk Level for Carcinogen RELs

- This policy reaffirms 1 in 1000 target risk
- This represents a minimum level of protection. Controlling exposures to lower concentrations is recommended.
- RELs will be based on these risk levels and consideration of analytical feasibility.
Analytical Feasibility and Engineering Achievability

- “. . . Engineering controls . . . should be used to control occupational exposures to the fullest extent feasible.” [1988]

- “NIOSH RELs will be based upon risk evaluations . . . and on an assessment of what levels can be feasibly achieved by engineering controls and measured by analytical techniques.” [1995]
Analytical Feasibility and Engineering Achievability: Issues

- Current NIOSH RELs are not all health-based
- Many NIOSH RELs are based on analytical feasibility
- NIOSH has made some evaluations of engineering feasibility or achievability, but has not done a quantitative analysis of the technical feasibility of achieving RELs
Analytical Feasibility and Engineering Achievability

- NIOSH will no longer set RELs relying on an evaluation of engineering controls, but will make an effort to provide information on appropriate controls.

- Basis of NIOSH RELs
  - Health effects (quantitative risk assessment)
  - Analytical feasibility (measurement of chemical in the work environment)
For new RELs, NIOSH will distinguish between health-based and analytical feasibility-based RELs

- Health-based RELs = REL
- RELs based on analytical feasibility = REL_{AF}
**Health Basis**

What is the 1/1000 risk estimate?

**Analytical Method Feasibility**

Is there a validated analytical method to measure the substance?  
**NO**  
Conduct research to create a validated analytical method

**YES**

Can the validated analytical method measure the 1/1000 risk estimate?  
**NO**  
Adjust to the analytical Limit of Quantitation (LOQ) or Reliable Quantitation Limit (RQL)

**YES**  
Add AF Designation

**Engineering Achievability**

Provide recommendations* based upon hierarchy of controls including engineering controls (when available) within guidance document that contains REL

**Recommended Exposure Limit**

*Research on engineering controls will be conducted if such guidance does not yet exist.
Timeline

- Public meeting on December 17, 2013
- Received all public comments by February 13, 2014
- Received all peer review comments by March 14, 2014
- Currently reviewing comments and preparing final policies.
Carcinogen and RELs Policy Update Committee

- David Dankovic
- John Decker (OD)
- Charles Geraci
- Pius Joseph (HELD)
- Eileen Kuempel
- Thomas J. Lentz
- Qiang Ma (HELD)
- Kathleen MacMahon
- Lauralynn McKernan
- Paul Middendorf (OD)
- Rick Niemeier (ret.)
- Andrea Okun
- Faye Rice
- Teresa Schnorr (DSHEFS)
- Paul Schulte
- Christine Sofge
- Patricia Sullivan (DRDS)
- Mark Toraasson (OD)
- Ainsley Weston (DRDS)
- Ralph Zumwalde
Question:
What are some challenges of our profession?

Do we always have the OELs we need?
Chemicals in Commerce

New Occupational Exposure Limits

- Approximately 1,000 chemicals with authoritative OELs
  - NIOSH RELs
  - OSHA PELs
  - California PELs
  - TLVs
  - WEELs
  - MAKs
How do we handle all the new chemicals?

- Mechanism to quickly and accurately assign chemicals into “categories” or “bands” based on their health outcomes and potency considerations, is needed

- Occupational Exposure Bands (OEBs)
As more toxicological and epidemiological data becomes available, we move up the hierarchy of OELs using “Risk-based prioritizations”.

**Slide courtesy of ERAM working group**
OEB value

- NIOSH
  - Facilitates more rapid evaluation of health risk
  - Used with minimal data
    - Highlights areas where data are missing
  - Supports the definition 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
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

* Slide courtesy of OSHA
## Health Hazards

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<td>Carcinogenicity</td>
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<td>STOT – Single Exposure</td>
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<td>STOT – Repeated Exposure</td>
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</table>

*Slide courtesy of OSHA*
OEB toxicological endpoints are aligned with GHS classification and labeling system*

Important goal is to relate potency of each toxicological hazard-banding endpoint to GHS hazard statements and categories, when possible

*CLP 2008 1272
Overview of tier approach to OEBs

Tier 1 — Qualitative
Use GHS Hazard Statements to identify chemicals with potential for irreversible health effects at relatively low doses (Band D-E) or remain at default Band C Use GHS Hazard Categories to assign chemicals into Bands D or E or remain at default Band C

Tier 2 — Quantitative
Determine point of departure, factoring data availability, hierarchy, and quality to support assigning chemicals into alternate bands

Tier 3 — Weight of Evidence
Involves integration of all available data and determining the degree of conviction of the outcome
Framework for decision logic

- Tier 1: GHS hazard code or statement from SDS or the preferred GHS database (Annex VI, REACH, GESTIS, etc.)
  - **User**: H&S generalist; may overestimate risk
- Tier 2: quantitative data from authoritative sources
  - **User**: skilled industrial hygienist
- Tier 3: toxicological weight of evidence; determine the critical study from which a scientifically sound point of departure (POD) can be determined
  - **User**: toxicologist or experienced industrial hygienist
<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Band</th>
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<th>D</th>
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<td>Vapors</td>
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<td><strong>Acute Toxicity</strong></td>
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<td>“H” Codes</td>
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<td>H301, H302, H331, H332, H311, H312</td>
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<td>H300, H330, H310</td>
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<td>1A, 1B, 1C</td>
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<td>Skin corrosion/irritation GHS Hazard statement</td>
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<td>Causes skin irritation.</td>
<td>Causes severe skin burns and eye damage.</td>
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<td>H314</td>
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<td>GHS Hazard Category</td>
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<td>1A</td>
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<tr>
<td>GHS Germ Cell Mutagenicity</td>
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<td>May cause genetic defects</td>
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<td>Codes</td>
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<td>GHS Hazard Category</td>
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<td></td>
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<td>2</td>
<td>1B</td>
<td>1A</td>
</tr>
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<td>GHS Carcinogenicity Hazard</td>
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<td>Suspected of causing cancer</td>
<td>May cause cancer</td>
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<td>statement</td>
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<td>Carcinogenicity “H” Codes</td>
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<td>H351, H350</td>
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</tbody>
</table>

**DRAFT**
### Toxic to Reproduction

**GHS Hazard Category**
- 2
- 1B
- 1A

**GHS Reproduction Hazard Statement**
- Suspected human reproductive toxicant
- Known human reproductive toxicant
- Presumed human reproductive toxicant

**Reproduction “H” Codes**
- “Suspected of damaging fertility or the unborn child”—H361f, H361d, or H361fd
- “May damage fertility or the unborn child”—H360f, H360d, or H360fd

### Specific Target Organ Toxicity (Single Exposure)

**GHS Hazard Category**
- 2 (H371, H335, and H336)
- 1

**GHS Hazard Statement**
- May cause damage to organs
- May cause respiratory irritation
- May cause drowsiness or dizziness

**“H” Codes**
- H371, H335, H336
- H370

### Specific Target Organ Toxicity (Repeated Exposure)

**GHS Hazard Category**
- 2
- 1

**GHS Hazard Statement**
- May cause damage to organs through prolonged or repeated exposure

**“H” Codes**
- H373
- H372

---

**Endpoint** | **Band** | **C** | **D** | **E**
--- | --- | --- | --- | ---
**Particles** | GHS Hazard Category | 2 | 1B | 1A
**Vapors** | **GHS Reproduction Hazard Statement** | Suspected human reproductive toxicant | Known human reproductive toxicant | Presumed human reproductive toxicant
| **Reproduction “H” Codes** | “Suspected of damaging fertility or the unborn child”—H361f, H361d, or H361fd | “May damage fertility or the unborn child”—H360f, H360d, or H360fd | Known human reproductive toxicant.

---

**Endpoint** | **Band** | **C** | **D** | **E**
--- | --- | --- | --- | ---
**OEL Ranges** | **GHS Hazard Category** | 2 (H371, H335, and H336) | 1 | 1
| **GHS Hazard Statement** | May cause damage to organs | May cause respiratory irritation | May cause drowsiness or dizziness | Causes damage to organs
| **“H” Codes** | H371, H335, H336 | | H370 |
Tier 1

Chemical for OEB

Authoritative OEL available?
- yes
  - No OEB necessary
- no
  - Health statements available?
    - no
      - Band C default assigned
    - yes
      - D or E statement?
        - no
          - Band C default assigned
        - yes
          - Tier 2 process to assign band with greater confidence

Review available H categories

E Hazard categories?
- yes
  - Assign Band E
- no
  - D Hazard categories?
    - yes
      - Assign Band D
    - no
Examples of reliable data sources

* IUCLID 5: [http://iuclid.eu/](http://iuclid.eu/)
Tier 1 Example 2: Chemical XXY

* Used in ceramic glazes, chromium plating, and in colored glasses
* Has been known to cause severe irritation of the skin, nose, throat, and lungs; liver damage; and ulceration of the nasal septum
* Exposures occur in the vapor phase
* Interested because it is being used in new process

* Information Available includes:
  * SDS information
  * Peer reviewed studies
  * Internal industry

* No OEL exists
### Section 11: Toxicological Information

**Routes of Entry:** Absorbed through skin. Eye contact. Inhalation. Ingestion.

**Toxicity to Animals:** Acute oral toxicity (LD50): 800 mg/kg (Rat) (Calculated value for the mixture).

**Chronic Effects on Humans:**
CARCINOGENIC EFFECTS: Classified A1 (Confirmed for human.) by ACGIH. 1 (Proven for human.) by IARC. 1 MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. Mutagenic for bacteria and/or yeast. [Chromium Trioxide]. Contains material which may cause damage to the following organs: kidneys, liver, gastrointestinal tract, upper respiratory tract, skin, eyes.

**Other Toxic Effects on Humans:**
Very hazardous in case of skin contact (irritant), of ingestion, . Hazardous in case of skin contact (corrosive), of eye contact (corrosive), of inhalation (lung corrosive).

**Special Remarks on Toxicity to Animals:**
Lowest Published Lethal Dose LDL [Rat] - Route: Skin; Dose: 55 mg/kg.

**Special Remarks on Chronic Effects on Humans:**
May cause adverse reproductive effects (effects on fertility: fetotoxicity or post-implantation mortality) and birth defects. May affect genetic material (mutagenic). May cause cancer (tumorogenic). Epidemiological studies indicate long term exposure to dusts and mists at levels above the current PEL in chrome processing is associated with increases in respiratory tract cancer in man. (Chromium Trioxide)

**Special Remarks on Other Toxic Effects on Humans:**
Acute Potential Health Effects: Skin: Causes skin irritation and possible burns. Contact with broken skin may lead to formation of firmly margined "chrome sores." May cause allergic contact dermatitis. Dermal absorption of large amounts may affect behavior and may result in kidney failure. Eyes: Causes eye irritation. May cause severe damage including burns and
## Tier 1 - Chemical XXZ

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

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Hazard Code</th>
<th>Hazard Category</th>
<th>H-code source</th>
<th>Endpoint Band</th>
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<tbody>
<tr>
<td><strong>Acute Toxicity</strong></td>
<td>H330</td>
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<td>GESTIS</td>
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<tr>
<td><strong>Skin Corrosion/Irritation</strong></td>
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<td></td>
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<td></td>
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<tr>
<td><strong>Serious Eye Damage/ Eye Irritation</strong></td>
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<td><strong>Respiratory and Skin Sensitization</strong></td>
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<td>GESTIS</td>
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<td><strong>Germ Cell Mutagenicity</strong></td>
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<td>1B</td>
<td>GESTIS</td>
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<tr>
<td><strong>Carcinogenicity</strong></td>
<td>H350</td>
<td>1A</td>
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<td><strong>Toxic to Reproduction</strong></td>
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<tr>
<td><strong>Specific Target Organ Toxicity (single exposure)</strong></td>
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<td><strong>Specific Target Organ Toxicity (repeated exposure)</strong></td>
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**Step 2: Determine corresponding band with NIOSH Tier 1 OEB Criteria Chart**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Band</th>
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<th>D</th>
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<tr>
<td><strong>OEL Ranges</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Particles</strong></td>
<td></td>
<td>&gt; 0.1 and ≤ 1 mg/m³</td>
<td>&gt; 0.01 ≤ 0.1 mg/m³</td>
<td>≤ 0.01 mg/m³</td>
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<tr>
<td><strong>Vapors</strong></td>
<td></td>
<td>&gt; 1 ≤ 10 ppm</td>
<td>&gt; 0.1 ≤ 1 ppm</td>
<td>≤ 0.1 ppm</td>
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<tr>
<td><strong>Acute Toxicity</strong></td>
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<tr>
<td><strong>GHS Hazard Category</strong></td>
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<td>3, 4</td>
<td>2</td>
<td>1</td>
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<tr>
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<td>1A, 1B, 1C</td>
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<tr>
<td><strong>Skin corrosion/irritation GHS Hazard statement</strong></td>
<td></td>
<td>Causes skin irritation.</td>
<td>Causes severe skin burns and eye damage.</td>
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<tr>
<td><strong>Skin corrosion/irritation “H” Code</strong></td>
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<td>H315</td>
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## Tier 1- Chemical XXZ

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

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<td></td>
<td></td>
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<tr>
<td>Serious Eye Damage/ Eye Irritation</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Respiratory and Skin Sensitization</td>
<td>H334</td>
<td>1</td>
<td>GESTIS</td>
<td></td>
</tr>
<tr>
<td>Germ Cell Mutagenicity</td>
<td>H340</td>
<td>1B</td>
<td>GESTIS</td>
<td></td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>H350</td>
<td>1A</td>
<td>GESTIS</td>
<td></td>
</tr>
<tr>
<td>Toxic to Reproduction</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specific Target Organ Toxicity (single exposure)</td>
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<tr>
<td>Specific Target Organ Toxicity (repeated exposure)</td>
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</tr>
<tr>
<td>Endpoint</td>
<td>Band</td>
<td>C</td>
<td>D</td>
<td>E</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>---------------</td>
<td>---------------------------------</td>
<td>---------------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>OEL Ranges</td>
<td><strong>Particles</strong></td>
<td>&gt; 0.1 and ≤ 1 mg/m³</td>
<td>&gt; 0.01 &lt; 0.1 mg/m³</td>
<td>≤ 0.01 mg/m³</td>
</tr>
<tr>
<td></td>
<td><strong>Vapors</strong></td>
<td>&gt; 1 ≤ 10 ppm</td>
<td>&gt; 0.1 ≤ 1 ppm</td>
<td>≤ 0.1 ppm</td>
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<tr>
<td>Respiratory and Skin Sensitization</td>
<td>GHS Hazard Category</td>
<td>1B (skin)</td>
<td>1B (resp.)</td>
<td>1A (resp.)</td>
</tr>
<tr>
<td></td>
<td>GHS Respiratory and Skin Sensitization Hazard Statements</td>
<td>May cause an allergic skin reaction</td>
<td>May cause an allergic skin reaction</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled</td>
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<tr>
<td></td>
<td>Respiratory and Skin Sensitization “H” Codes</td>
<td>H334</td>
<td>H334</td>
<td>H334</td>
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<tr>
<td>Germ Cell Mutagenicity</td>
<td>GHS Hazard Category</td>
<td>1B</td>
<td>1B</td>
<td>1A</td>
</tr>
<tr>
<td></td>
<td>GHS Germ Cell Mutagenicity Hazard Statement</td>
<td>Suspected of causing genetic defects</td>
<td>May cause genetic defects</td>
<td>May cause genetic defects</td>
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<tr>
<td></td>
<td>GHS Germ Cell Mutagenicity “H” Codes</td>
<td>H341</td>
<td>H340</td>
<td>H340</td>
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<tr>
<td>Carcinogenicity</td>
<td>GHS Hazard Category</td>
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<td></td>
<td>Suspected of causing cancer</td>
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<td>GHS Carcinogenicity Hazard statement</td>
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<td>May cause cancer</td>
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<td>Carcinogenicity “H” Codes</td>
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<td>H351, H350</td>
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</tbody>
</table>
## Tier 1- Hazard Categories

### Chemical XXZ

*Step 3: Select the most conservative Band*

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Hazard Code</th>
<th>Hazard Category</th>
<th>H-code source</th>
<th>Endpoint Band</th>
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<tbody>
<tr>
<td>Acute Toxicity</td>
<td>H330</td>
<td>2</td>
<td>GESTIS</td>
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<tr>
<td>Skin Corrosion/Irritation</td>
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<td>H372</td>
<td>1</td>
<td>GESTIS</td>
<td>E</td>
</tr>
</tbody>
</table>

Exposure should be controlled to Band E < 0.1 ppm
Tier 2

Tier 1 Process results in Band C

Identify points of departure

Score data relevance

Establish Total Determinant Score (TDS)

Does TDS exceed threshold for minimum, quality dataset?

yes

Establish OEB

no

Data insufficient for OEB, “C” default band

TDS reflects the availability of qualitative info and/or quantitative data for each endpoint under consideration. Endpoint scores include data relevance and quality factors. TDS is the sum of the endpoint scores.
If you are too protective, the tool has no value for stakeholders.

Criteria Overview must be correct.
Randomly select chemicals by CAS number

- Run through Tier 2 process, derive OEB

- Determine if Total Determinant score is above threshold, if yes derive OEB

- Compare results of multiple users
Tier 2- Validation

- Plan– Host Virtual Workshop with multiple sessions
- Participants become familiar with NIOSH health hazard banding process, including Tier 2
- Participants will be randomly assigned chemicals
- Participants have “homework” to conduct Tier 2 process anonymously
- Results will be compared to NIOSH index for validation
- Inter-rater variability will also be assessed
We need volunteers!

Send me an email at: LMcKernan@cdc.gov to volunteer for the Validation Workshop. We will send materials on when, where and how to participate…
* NIOSH guidance
* Overall process, including the decision logic
* Tools to facilitate finding and evaluating hazard data and assign chemicals to hazard bands
* Education materials for H&S professionals, managers, emergency responders and workers
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