NIOSH OCCUPATIONAL EXPOSURE BANDING: A NEW TOOL FOR EVALUATING CHEMICAL HAZARDS

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NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

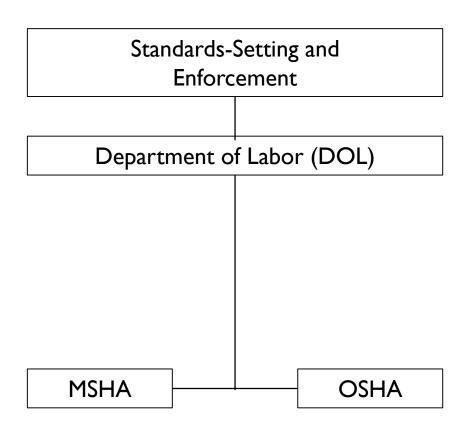
CENTERS FOR DISEASE CONTROL AND PREVENTION

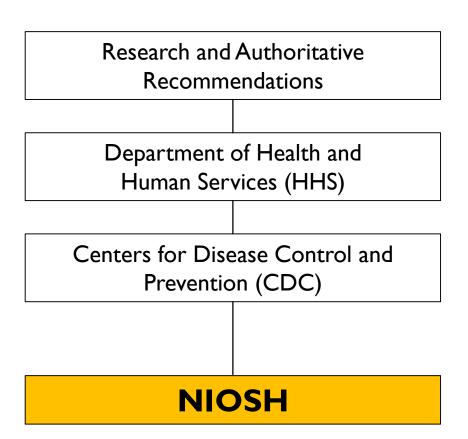


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OCCUPATIONAL SAFETY AND HEALTH ACT OF 1970







DOCUMENT OBJECTIVE

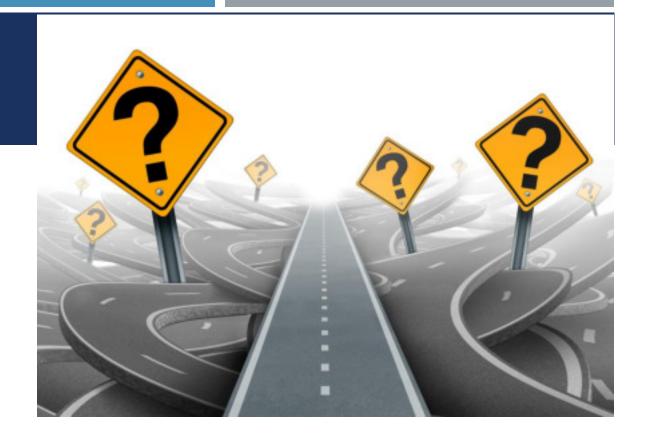
To create a consistent and documented process to characterize chemical hazards so timely and well-informed risk management decisions can be made for chemicals lacking OELs.





IMPORTANT POINT

An OEB is not meant to replace an OEL, rather it serves as a starting point to inform risk management decisions.





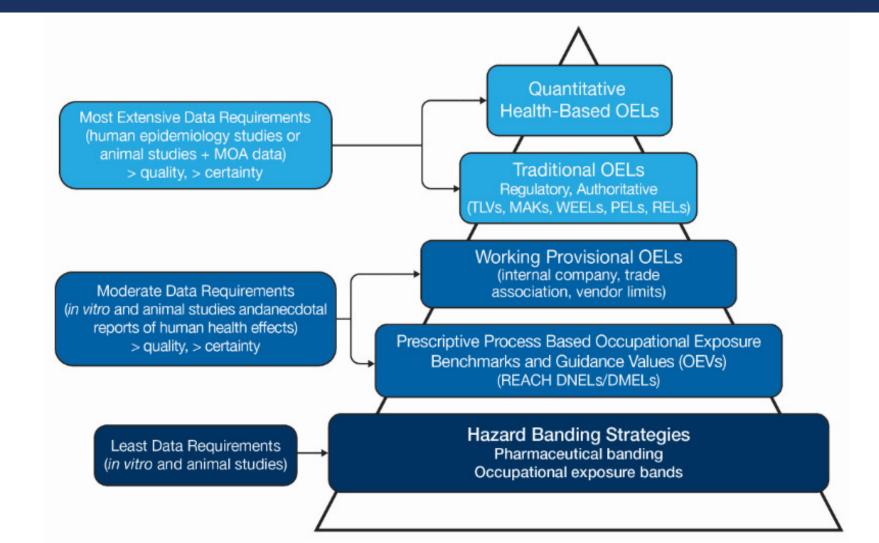
HISTORY

- One of the best ways to prevent and control occupational injuries, illnesses, and fatalities is to "design out" or minimize hazards and risks.
- NIOSH leads a national initiative called Prevention through Design (PtD).
- PtD encompasses all of the efforts to anticipate and design out hazards to workers in facilities, work methods and operations, processes, equipment, tools, products, new technologies, and the organization of work.
- The Occupational Exposure Banding Initiative emerged from this fundamental philosophy



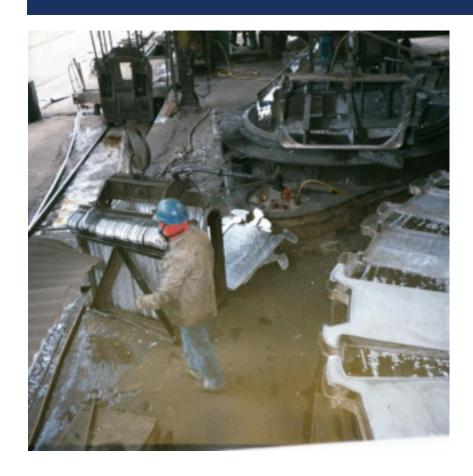


HIERARCHY OF OELS

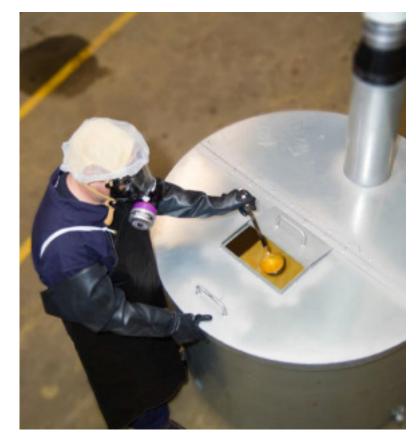




WHY DO WE NEED OEBs?



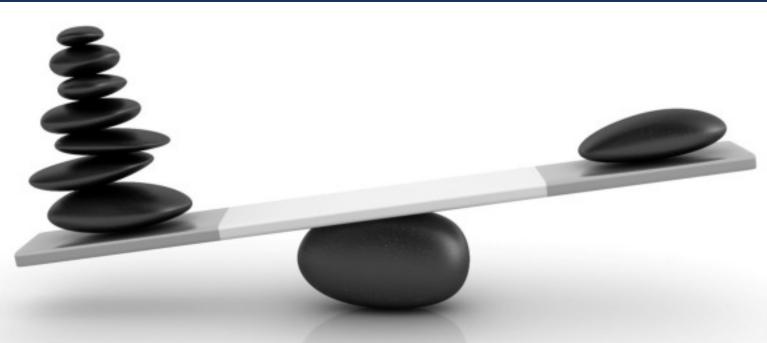






CHEMICALS IN COMMERCE

OCCUPATIONAL EXPOSURE LIMITS



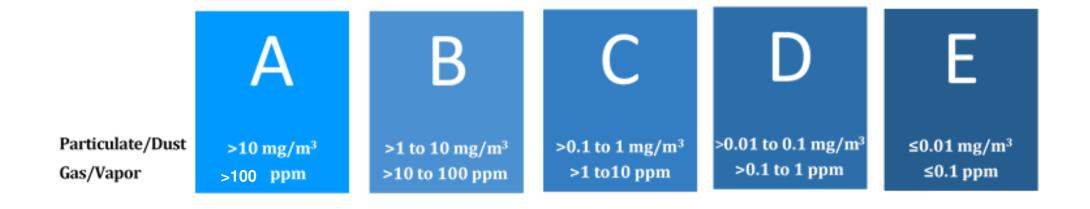
Approximately 85,000 chemicals in commerce.

Approximately 1,000 chemicals with authoritative OELs



WHAT IS OCCUPATIONAL EXPOSURE BANDING?

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





NIOSH OCCUPATIONAL EXPOSURE BANDS

Occupational Exposure Band	Airborne Target Range for Particulate Concentration (mg/m³)	Airborne Target Range for Gas or Vapor Concentration (ppm)
A	>10mg/m ³	>100 ppm
В	>I to I0 mg/m ³	>10 to 100 ppm
С	>0.1 to 1 mg/m ³	>I toI0 ppm
D	>0.01 to 0.1 mg/m ³	>0.1 to 1 ppm
E	≤0.01 mg/m ³	≤0.1 ppm



THE PROMISE OF OCCUPATIONAL EXPOSURE BANDING

- Facilitates more rapid evaluation of health risk
- Provides guidance for materials without OELs
- Highlights areas where data are missing
- Provides a screening tool for the development of RELs

- Identifies hazards to be evaluated for elimination or substitution
- Aligned with GHS for hazard communication
- Facilitates the application of Prevention through Design principles



IS THIS THE SAME AS CONTROL BANDING? NO.

- 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
- NIOSH has reviewed control banding strategies previously





OCCUPATIONAL EXPOSURE BANDING IS DIFFERENT!

- OEBs derived from <u>toxicology</u> and <u>potency</u>
- OEBs can be used to identify one of many control strategies

Assessment of hazard potential using Occupational Exposure Banding

Assignment of a health based OEB

Risk Management Strategies



TOOLS FOR THE OCCUPATIONAL HYGIENIST

GHS classifications

Hazard Communication

Exposure Monitoring

Medical Surveillance



Engineering Controls

PPE

Occupational Exposure Bands

OELS

Quantitative Risk Assessments



HOW IS THE PROCESS ORGANIZED?

Bands are assigned based on the findings for nine standard toxicological endpoints:

- I. Carcinogenicity
- 2. Reproductive toxicity
- 3. Specific target organ toxicity resulting from repeated exposure
- 4. Acute toxicity

- 5. Genotoxicity
- 6. Skin corrosion and irritation
- 7. Respiratory sensitization
- 8. Skin sensitization
- 9. Serious eye damage and irritation



Tier I —GHS Hazard Codes

User: Health and safety generalist

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

Tier 2— Secondary Data Sources

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—Expert Judgement

<u>User</u>: Toxicologist or experienced occupational hygienist

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



TIER 1 OVERVIEW



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TIER 1

- GHS hazard codes and categories provide the basis for Tier 1 criteria
- Relatively low data requirements
- Chemicals can be banded in bands C, D, and E
- Chemicals are assigned Tier 1 OEBs based on severity and reversibility of effects
- Tier 1 is useful as a screening tool, but Tier 2 is recommended if data and expertise are available



GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELING OF CHEMICALS

- GHS is a hazard classification system developed by the United Nations to standardize chemical regulations in different countries
 - Within GHS, each physical or health hazard is a hazard class (e.g., Carcinogenicity is a hazard class)
 - A hazard class may be sub-divided into several hazard categories based on the severity of the hazard
 - GHS uses alphanumeric hazard codes to represent these hazards



GHS CODES NOT USED IN BANDING

- H200 codes (physical hazards)
- H400 codes (ecological hazards)
- H303, H304, H305, H313, H316, H320, H333, H335, H336, H362
 - Not occupationally relevant, OR
 - Not sufficient to affect the result of Tier 1 banding



Chemical of interest has no OEL



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 I OEB for the chemical based on most protective endpoint band (C, D, or E)



TIER I Criteria		C	D	E
OEL Ranges	Particle	> 0.1 to < 1 milligrams per cubic meter of air (mg/m³)	$> 0.01 \text{ to} \le 0.1 \text{ mg/m}^3$	≤ 0.01 mg/m³
	Vapor	> 1 to ≤ 10 parts per million (ppm)	> 0.1 to <u><</u> 1 ppm	<u>≤</u> 0.1 ppm
Acute Toxicity		H301 Category 3 H302 Category 4	H300 Category 2	H300 Category I
		H331 Category 3 H332 Category 4 H311	H330 Category 2	H330 Category I
		Category 3 H312 Category 4	H310 Category 2	H310 Category I
Skin Corrosion/ Irritation		H315 Category 2		H314 Category I, IA, IB, or IC
Serious Eye Damage/ Eye irritation		H319 Category 2, 2A or 2B		H318 Category I
Respiratory and Skin		H317 Category 1B	H317 Category I or IA	
Sensitization			H334 Category IB	H334 Category I or IA
Genotoxicity			H341 Category 2	H340 Category I, IA or IB
Carcinogenicity				H350 Category I, IA, or IB H351 Category 2
Toxic to Reproduction		H361 (including H361f, H361d, and H361fd) Category 2	H360 (including H360f, H360d, and H360fd) Category IB	H360 (including H360f, H360d, and H360fd) Category I or IA
Specific Target Organ Toxicity		H371 Category 2 H373 Category 2	,	H370 Category I H372 Category I



TIER I Cr <mark>iteria</mark>		С	D	E	
OEL Ranges	Particle	> 0.1 to < 1 milligrams per cubic meter of air (mg/m³)	$> 0.01 \text{ to} \le 0.1 \text{ mg/m}^3$	≤ 0.01 mg/m³	
· · · · · · ·	Vapor	> 1 to ≤ 10 parts per million (ppm)	> 0.1 to <u><</u> 1 ppm	<u><</u> 0.1 ppm	
Acute Toxicity		H301 Category 3 H302 Category 4	H300 Category 2	H300 Category I	
		H331 Category 3 H332 Category 4	H330 Category 2	H330 Category I	
		H311 Category 3 H312 Category 4	H310 Category 2	H310 Category I	
Skin Corrosion/ Irritation		H315 Category 2		H314 Category I, IA, IB, or IC	
Serious Eye Damage/ Eye irritation		H319 Category 2, 2A or 2B		H318 Category I	
Respiratory and Skin		H317 Category 1B	H317 Category I or IA		
Sensitization			H334 Category IB	H334 Category I or IA	
Genotoxicity			H341 Category 2	H340 Category I, IA or IB	
Carcinogenicity				H350 Category I, IA, or IB H351 Category 2	
Toxic to Reproduction		H361 (including H361f, H361d, and H361fd) Category 2	H360 (including H360f, H360d, and H360fd) Category IB	H360 (including H360f, H360d, and H360fd) Category I or IA	
Specific Target Organ Toxicity		H371 Category 2 H373 Category 2		H370 Category I H372 Category I	



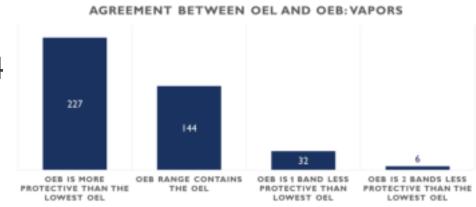
TIER I Criteria		С	D	E	
OEL Ranges	Particle	> 0.1 to < 1 milligrams per cubic meter of air (mg/m³)	$> 0.01 \text{ to} \le 0.1 \text{ mg/m}^3$	≤ 0.01 mg/m³	
	Vapor	> 1 to ≤ 10 parts per million (ppm)	> 0.1 to ≤ 1 ppm	<u>≤</u> 0.1 ppm	
Acute Toxicity		Category 3 H302 Category 4	H300 Category 2	H300 Category I	
		H331 Category 3 H332 Category 4	H330 Category 2	H330 Category I	
		H311 Category 3 H312 Category 4	H310 Category 2	H310 Category I	
Skin Corrosion/ Irritation		H315 Category 2		H314 Category I, IA, IB, or IC	
Serious Eye Damage/ Eye irritation		H319 Category 2, 2A or 2B		H318 Category I	
Respiratory a	nd Skin	H317 Category IB	H317 Category I or IA		
Sensitization S			H334 Category IB	H334 Category I or IA	
Genotoxicity			H341 Category 2	H340 Category I, IA or IB	
Carcinogenicity				H350 Category I, IA, or IB H351 Category 2	
Toxic to Reproduction		H361 (including H361f, H361d, and H361fd) Category 2	H360 (including H360f, H360d, and H360fd) Category IB	H360 (including H360f, H360d, and H360fd) Category I or IA	
Specific Target Organ Toxicity		H371 Category 2 H373 Category 2		H370 Category I H372 Category I	



TIER I EVALUATION

Compared bands obtained from Tier I 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 I bands at least as protective as the OEL



TIER 2 OVERVIEW



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TIER 2

Tier 2 is always recommended, but especially useful when:

- there are no GHS H codes
- the outcome of the Tier I analysis is incomplete, or an insufficient reflection of the health potency of the chemical



TIER 2

Tier 2 — Both Qualitative and Quantitative

- Some training in toxicology
- 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 I OEB to a more or less protective OEB



Begin Tier 2 process



Compare data to NIOSH criteria for each health endpoint and assign endpoint band and endpoint determinant score

Ensure that total determinant score is sufficient for banding

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



TIER 2 BANDING PROCESS

Search authoritative databases for summary toxicity information:

For 9 specified health endpoints, search authoritative databases for summary toxicity information

Combine information through a weighted score:

Find the weighted score (Total Determinant Score) and calculate the Occupational Exposure Band (this is done automatically in the e-Tool)











TOTAL DETERMINANT SCORE

- Endpoint determinant score (EDS) = 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 ≥ 30: sufficient data for banding in Tier 2

Example: a cancer inhalation unit risk value tells us a lot about the hazardous nature of a chemical, so the presence of that information corresponds to a EDS of 30. However, an LD50 value for the acute toxicity endpoint is only weighted as a EDS of 5.



TOTAL DETERMINANT SCORE

Health Endpoint	Endpoint Determinant Score (EDS)	
Skin Irritation/Corrosion	5	
Eye Irritation/Corrosion	5	
Skin Sensitization	5	
Acute Toxicity/Lethality (LD ₅₀ or LC ₅₀)	5	
Genotoxicity	5	
Respiratory Sensitization	10	
Systemic Target Organ Toxicity (STOT-RE)	30	
Reproductive and Developmental Toxicity	30	
Cancer Weight of Evidence Descriptor	20 or 30	
Cancer Quantitative Measures	30	
Data Sufficiency/Total Determinant Score (TDS)	30/125	



TIER 2 EVALUATION PROCESS

	Phase I	Phase 2	Phase 3	Phase 4	Phase 5
Purpose	To prototype training and conduct preliminary interrater reliability.	To conduct large scale banding effort and refine process.	To review endpoints results with interrater reliability.	To obtain additional data on Tier 2 endpoints to determine level of detail within endpoint descriptions.	To assess accuracy and usability across chemicals for additional chemicals.
Lessons learned	Some data source websites linked to another that had lesser quality.	Some endpoints such as skin sensitization needed more information.	Recruitment was easy, it was difficult to obtain completed information from reviewers. Learning curve was significant.	Confusion on TDS scoring in some cases.	Good agreement with endpoints based upon quantitative data.
Resulting OEB Methodology Improvements	Data sources curtailed to insure data quality	Materials with key sources were created. Skin sensitization endpoint documentation re-written.	Genotoxicity endpoint description was rewritten. Training on Tier 2 re-designed with example	TDS was streamlined and enhanced for clarity.	Endpoints based upon qualitative endpoints such as genotoxicity were further refined to aid in users finding information sources



TIER 2 EVALUATION

- Evaluations for interrater reliability and accuracy:
 - Compared user banding results across chemicals
 - Results: Overall good agreement among users. Some endpoints (especially those requiring scientific judgement) have variable results
 - Compared OEBs with existing OELs
 - Results: OEBs, in general, at least as protective as OELs



- Requires expertise in toxicology
- Requires intensive review and evaluation of primary data
- Is required when insufficient data for Tier 2 banding
- Completed when no detailed guidance is available



MORE THAN A BAND

Identify potential health effects and target organs



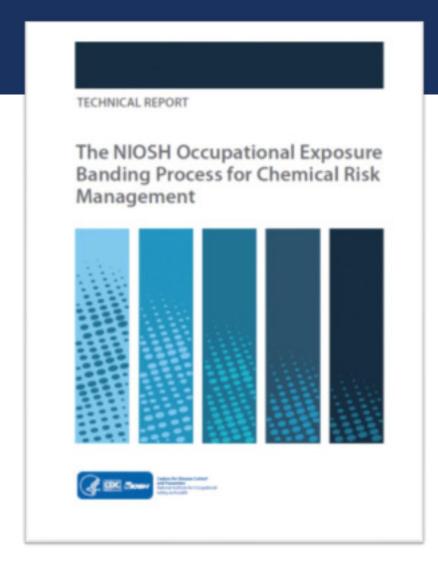
- Identify health risks to improve health communication
- Inform implementation of control interventions
- Inform medical surveillance decisions
- Provide critical information in a timely fashion



MORETHAN A BAND (CONT'D.)

 Innovative approach to provide guidance prescriptive enough to be used by small- and medium-sized establishments

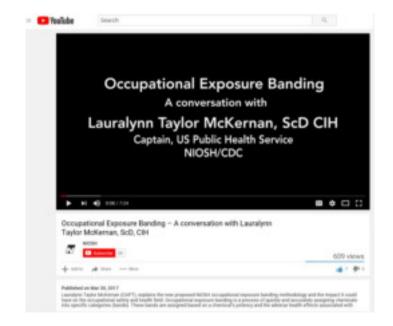
- Occupational Exposure Banding process to provide guidance for chemicals without OELs
- Accompanying electronic tool (e-Tool) also created



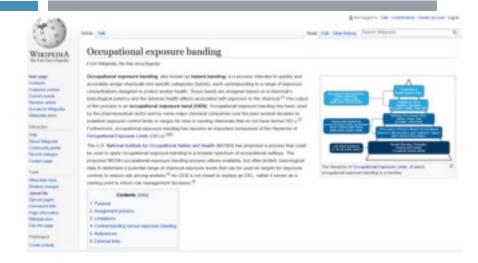


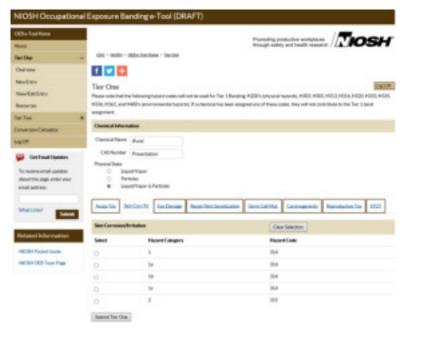
ADDITIONAL GUIDANCE











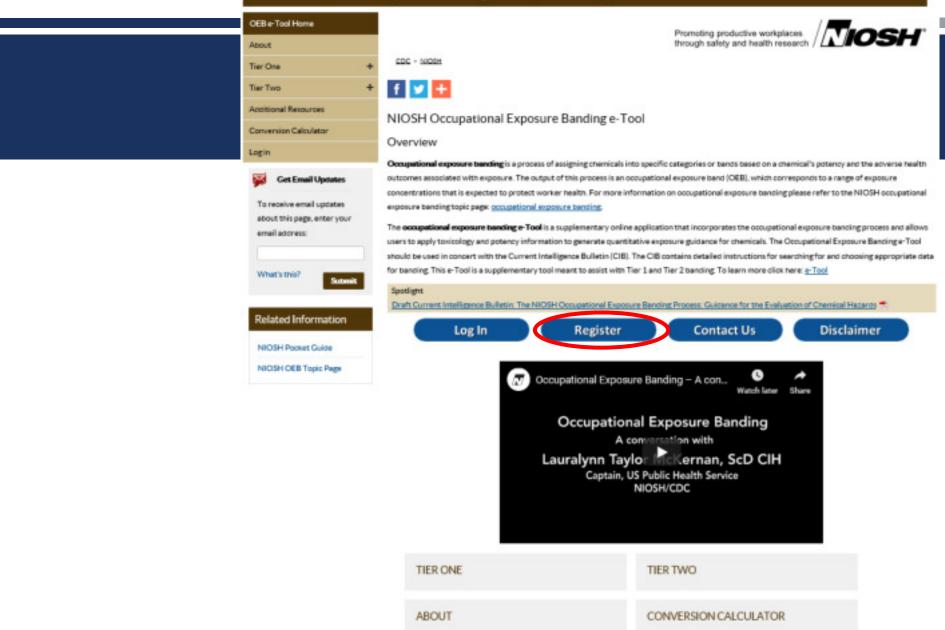


OCCUPATIONAL EXPOSURE BANDING E-TOOL



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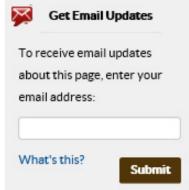
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Register

CDC > NIOSH

Create a new account.



Related Information

NIOSH Pocket Guide

NIOSH OEB Topic Page

Password

Confirm password

Must be 6 or more characters.

Must contain one uppercase character (A through Z)

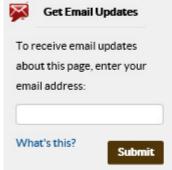
Must contain one lowercase character (a through z)

Must contain one number (0 through 9)

Must contain one symbol (such as \$, !, #, %)

By checking this box, you have read the Disclaimer.







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CDC > NIOSH > OEB e-Tool Home







About

The rate at which new chemicals are being introduced into commerce significantly outpaces occupational exposure limit (OEL) development, creating a need for risk guidance on thousands of chemicals that lack evidence-based exposure limits. 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 (Figure 1). Not to be confused with control banding (which gives guidance on control measures), the proposed NIOSH occupational exposure banding process uses available, but often limited, toxicological data to determine a potential range of exposure levels to chemicals to guide risk management decisions. For more information on occupational exposure banding please refer to the NIOSH occupational exposure banding topic page: Occupational Exposure Banding.



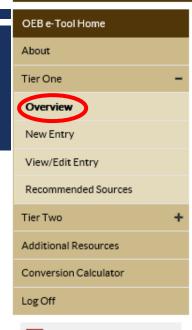
Figure 1: Occupational Exposure Bands (OEBs) define the range of exposures expected to be protective of worker health. The bands range from band A to band E. Band E represents the lowest range of exposure concentrations, while band A represents the highest range [McKernan et al. 2016].

To assist users of the occupational exposure banding process, an e-Tool has been developed. The NIOSH Occupational Exposure Banding e-Tool will allow users to apply toxicology and potency information to generate quantitative exposure guidance for chemicals. Users of the e-Tool are provided a series of screens which allow them to input toxicological information on nine different health endpoints related to exposure to the chemical that they are evaluating. The e-Tool provides links to publicly available databases and resources to aid the user in search of data. Once entered, the e-Tool compares the data to predefined NIOSH criteria and supplies an OEB that corresponds to a range of exposure concentrations. Ultimately, the e-Tool facilitates the use of the draft occupational exposure banding process and eliminates the need to go through the process manually.

Spotlight

Draft Current Intelligence Bulletin: The NIOSH Occupational Exposure Banding Process: Guidance for the Evaluation of Chemical Hazards 🏂









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CDC > NIOSH > OEB e-Tool Home > Tier One







Overview

Tier 1 produces a qualitative occupational exposure band (OEB) assignment based on Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Tier 1 involves assigning the OEB based on criteria aligned with specific GHS hazard codes and categories. Chemicals with potential to cause serious or irreversible health effects at relatively low doses warrant assigning band D or band E. Chemicals that are likely to cause reversible health effects at higher concentrations are categorized in band C. Bands A and B are not assigned in Tier 1. Tier 1 is intended to be used by individuals with basic toxicology knowledge.

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.



Tier 1 Resources

Basic instructions to use the Occupational Exposure Banding e-Tool for Tier 1.

CAS number. If the chemicial has an OEL listed in the NIOSH Pocket Guide, you will be redirected to the Pocket Guide entry.

Step 1: Enter chemical name and/or

Step 2: Select the physical state of the chemical.

This allows the tool to display the appropriate units for the expsoure range that corresponds to the OEB.

Step 5: Click "Submit Tier One."

A recommendation page will display the

information that was submitted, the Tier 1 OEB.

and the coresponding exposure range.

Step 3: Choose to auto fill data from **GESTIS Substance Database or enter** your own data.

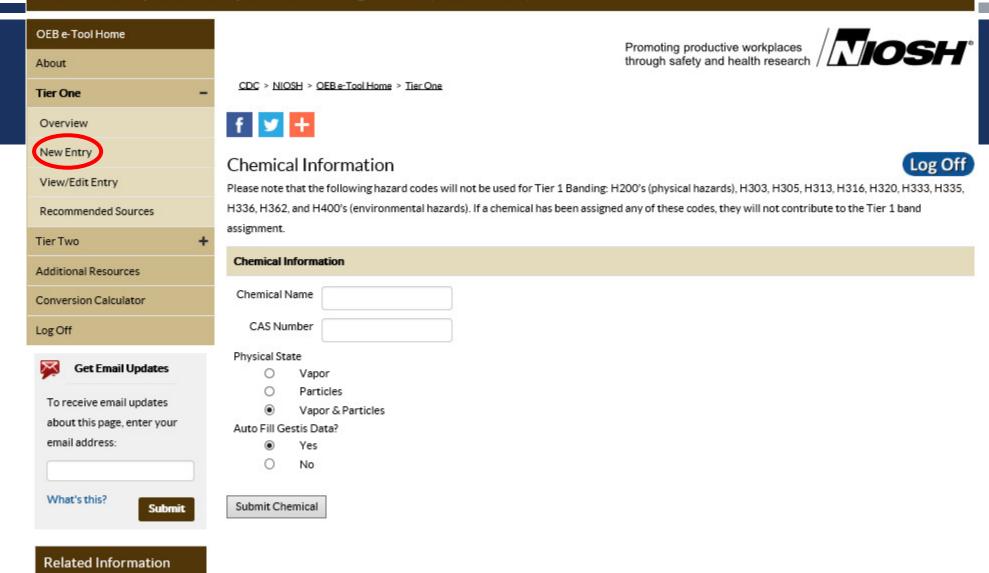
The e-Tool has been linked to the GESTIS Substance Database and the data can be autofilled for chemicals found in the GESTIS database. Users can also use Annex VI or safey data sheets (SDS) to find and enter H-codes and categories manually. Links are provided in the resources tab on the left navigation pane.

Step 4: If data is auto-filled move to Step 5. Otherwise enter GHS information into the e-Tool.

If the data was not auto-filled use Annex VI or SDS to enter data by clicking through the health endpoint tabs across the page to select the appropriate hazard code/category combination for each endpoint.

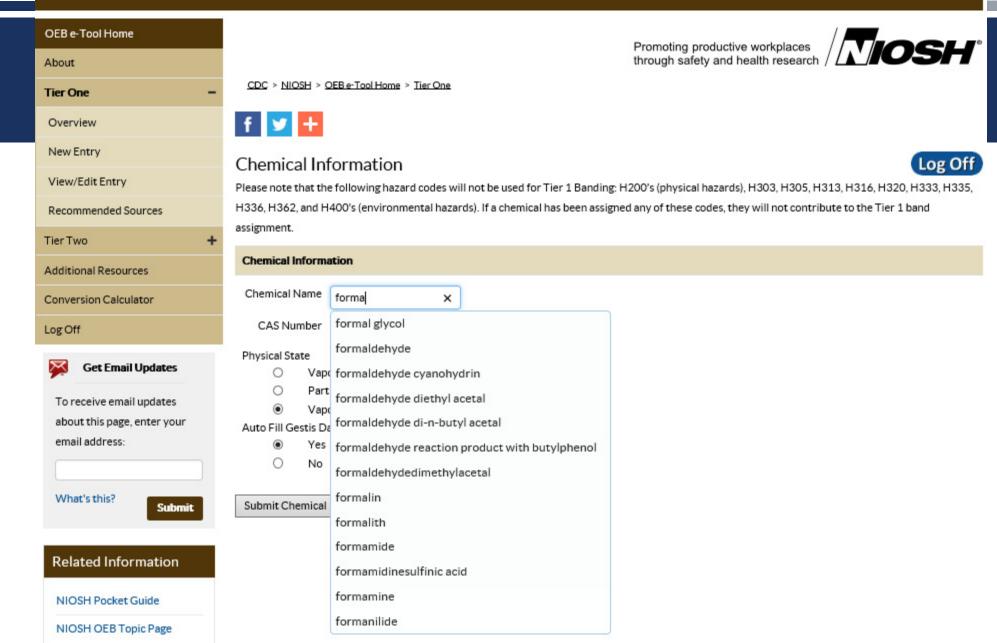
Step 6: Review results and edit entry if necessary.

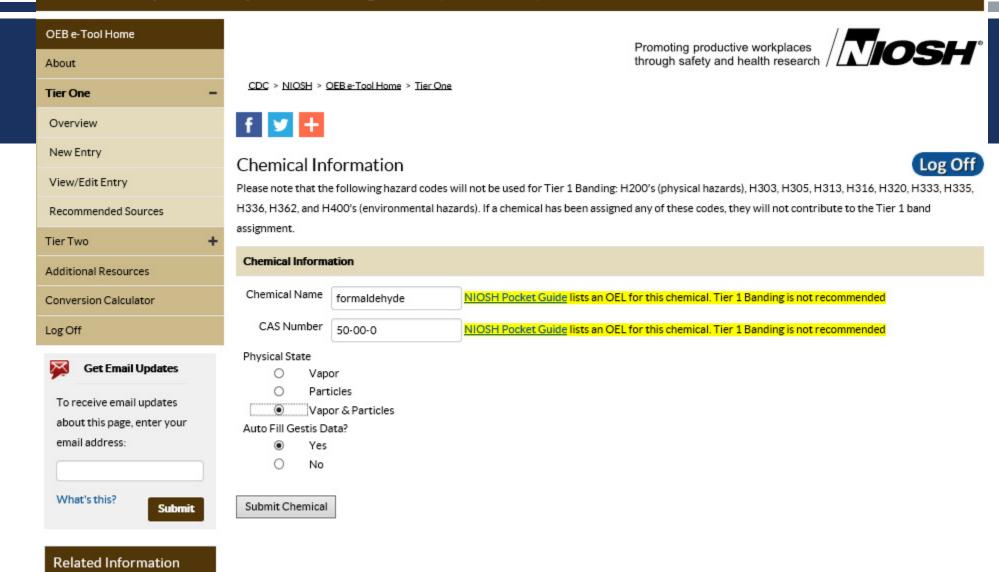
If everything is correct, the OEB can be applied. If not, select "Edit This Entry" in the yellow highlighted section on the bottom of the screen.



NIOSH Pocket Guide

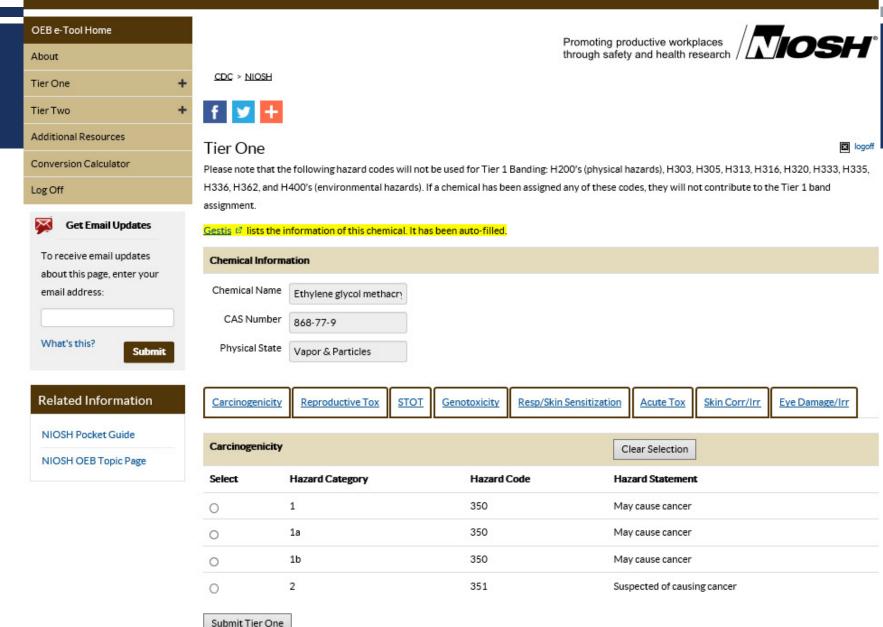
NIOSH OEB Topic Page

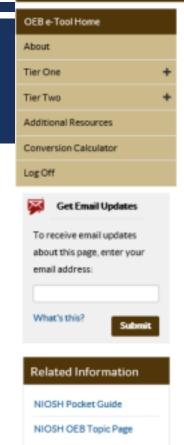




NIOSH Pocket Guide

NIOSH OEB Topic Page







CDC > NIOSH



Tier One Recommendation

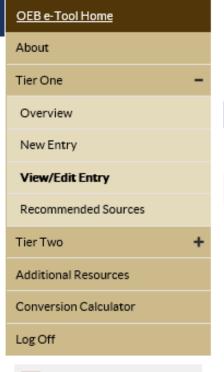


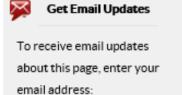
Endpoint		Hazard Code	Hazard Category	Endpoint Band
Acute Toxicity	Dermal			
	Oral			
	Inhalation			
Skin Corrosion/Irritation		315	2	С
Serious Eye Damage/ Eye Irritation		319	2	С
Respiratory and Skin Sensitization		317	1 (skin)	D
Germ Cell Mutag	enicity			
Carcinogenicity				
Reproductive Tox	ricity			
Specific Target O	rgan Toxicity			
Overall Recomm	ended Band			D

Please do not use the back button. Using the back button will result in multiple entries. Click the button below to make changes to data inputs.

Edit this Entry

Grey Box - No Data Entered





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CDC > NIOSH > OEB e-Tool Home > Tier One







Tier One Edit

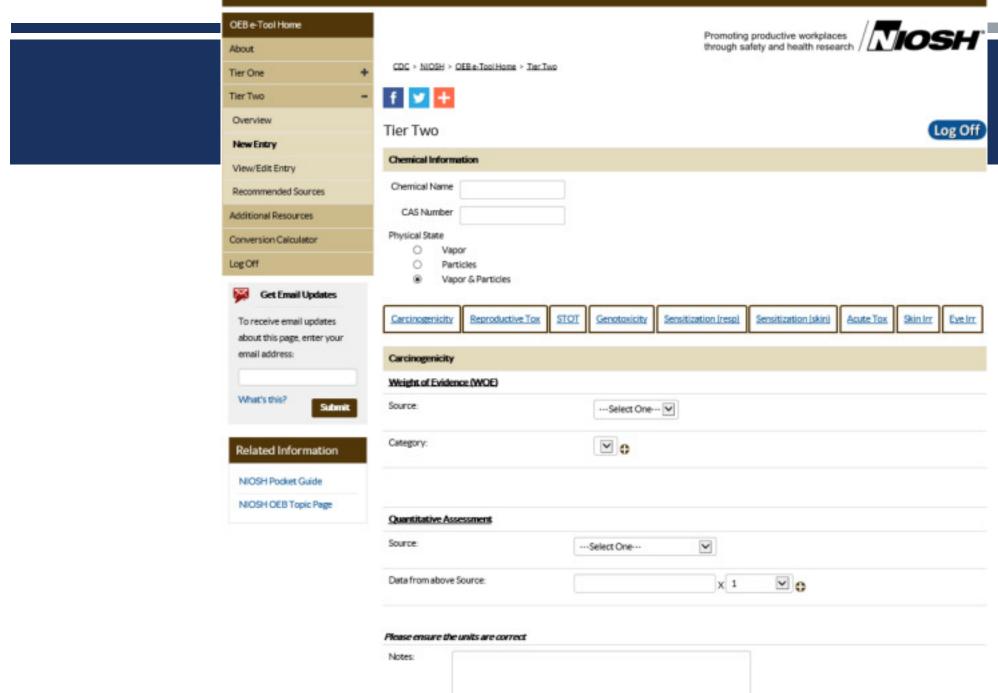


List of Existing Tier One Entries							Print PDF
Chemical Name +	CAS Number	Vapor Range	Particles Range	Recommended Band			
test rane 11	test rane 11	<= 0.1 ppm	<= 0.01 mg/m²	E	<u>Edit</u>	<u>Delete</u>	Print PDF
test rane 1	test rane 1	<= 0.1 ppm		E	Edit	<u>Delete</u>	Print PDE
test rane	all hands	<= 0.1 ppm		E	<u>Edit</u>	<u>Delete</u>	Print PDF
test 45	test 45	<= 0.1 ppm	<= 0.01 mg/m²	E	<u>Edit</u>	Delete	Print PDF
test 24		> 1 and < 10 ppm	> 0.1 and < 1 mg/m²	С	<u>Edit</u>	<u>Delete</u>	Print PDF
test 111	106-94-5	> 1 and < 10 ppm	> 0.1 and < 1 mg/m²	С	<u>Edit</u>	<u>Delete</u>	Print PDF
test 1 rane	test 1 rane	<= 0.1 ppm		E	Edit	<u>Delete</u>	Print PDE



Tier One Entry List

Chemical Name	CAS Number	Liquid Range	Particles Range	Recommended Band
Rane Test 1	1	> 1 and < 10 ppm		С
Rane Test 2	2		> 0.01 and < 0.1 mg/m²	D
Rane Test 3	3	<= 0.1 ppm	<= 0.01 mg/m³	E
Rane Test 4	4		> 0.1 and < 1 mg/m³	С
Rane Test 5	5	<= 0.1 ppm		E
Rane Test 6	6		<= 0.01 mg/m³	E
Rane Test 7	7	<= 0.1 ppm	<= 0.01 mg/m³	E
Rane Test 8	8	> 1 and < 10 ppm	> 0.1 and < 1 mg/m³	C



OEB E-TOOL LINK

https://wwwn.cdc.gov/niosh-oeb



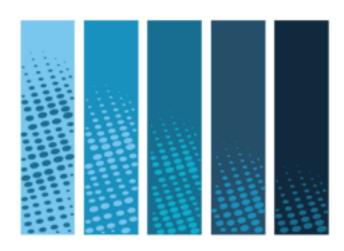
NEXT STEPS

- Dissemination of Document
- Launch of e-Tool
- AlHce PDC



TECHNICAL REPORT

The NIOSH Occupational Exposure Banding Process for Chemical Risk Management





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