

NIOSH Occupational Exposure Banding

Donna S. Heidel, CIH, FAIHA
National Practice Leader – Apex Companies, LLC
donna.heidel@apexcos.com



- Technical Director – National Practice Leader for Industrial Hygiene at Apex Companies, LLC
- Led the Prevention through Design (PtD) National Initiative at the Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH)
- Johnson & Johnson Worldwide Director of Industrial Hygiene and Toxicology
- Merck & Co, Inc.
- Masters of Science in Industrial Hygiene from Temple University
- American Board of Industrial Hygiene Certified Industrial Hygienist (CIH)
- Fellow in the American Industrial Hygiene Association (AIHA)
- AIHA Vice President



What is an occupational exposure band?

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



Higher Concentrations

Lower Concentrations

| Occupational exposure band | Airborne target range for dust or particle concentration (milligrams per cubic meter of air [mg/m ³]) | Airborne target range for gas or vapor concentration (parts per million [ppm]) |
|----------------------------|---|--|
| A | >10 | >100 |
| B | >1 to 10 | >10 to 100 |
| C | >0.1 to 1 | >1 to 10 |
| D | >0.01 to 0.1 | >0.1 to 1 |
| E | ≤0.01 | ≤0.1 |



Why do we need OEBs?



CHEMICALS IN COMMERCE

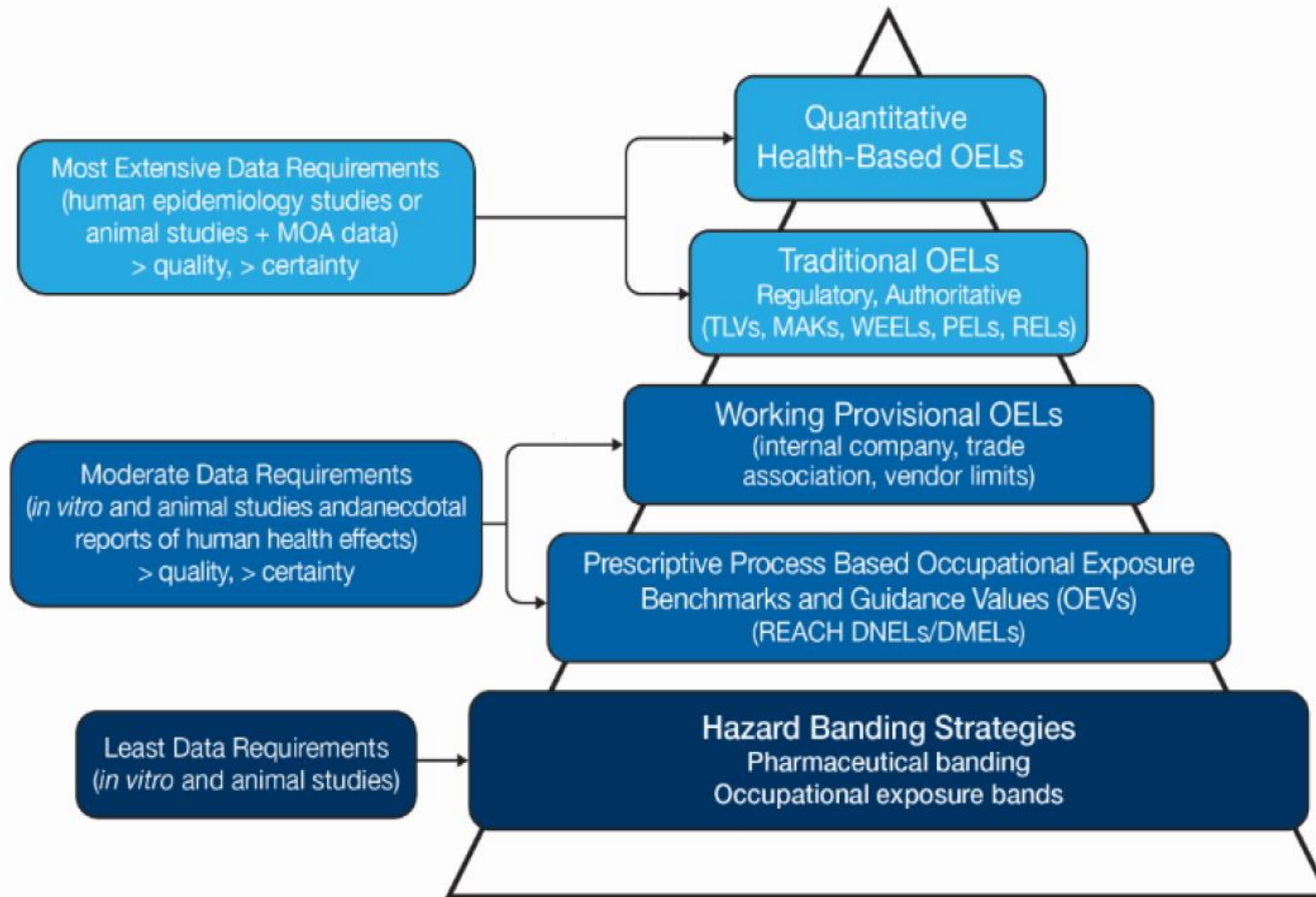
OCCUPATIONAL EXPOSURE LIMITS



- > 85,000 chemicals in EPA TSCA Chemical Substance Inventory

- Approximately 1,000 chemicals with authoritative OELs

OEBs on the hierarchy of OELs



Promise of occupational exposure banding

- Facilitates more rapid evaluation of health hazards
- Provides exposure guidance for materials without OELs
- Highlights areas where data are missing
- Provides a screening tool for the development of OELs
- Identifies hazards to be evaluated for elimination or substitution
- Aligned with GHS for Hazard Communication
- Facilitates the application of Prevention through Design principles for chemical agents



What data is used for occupational exposure banding?

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

- Acute toxicity
- Skin corrosion and irritation
- Serious eye damage and irritation
- Respiratory sensitization
- Skin sensitization
- Genotoxicity
- Carcinogenicity
- Reproductive / development toxicity
- Specific target organ toxicity resulting from repeated exposure



Three tiers

Tier 1 — Qualitative

User: Health and safety generalist

A Tier 1 evaluation utilizes GHS hazard statements and categories to identify chemicals that have the potential to cause irreversible health effects.

Today's goal

Tier 2 — Semiquantitative

User: Occupational hygienist

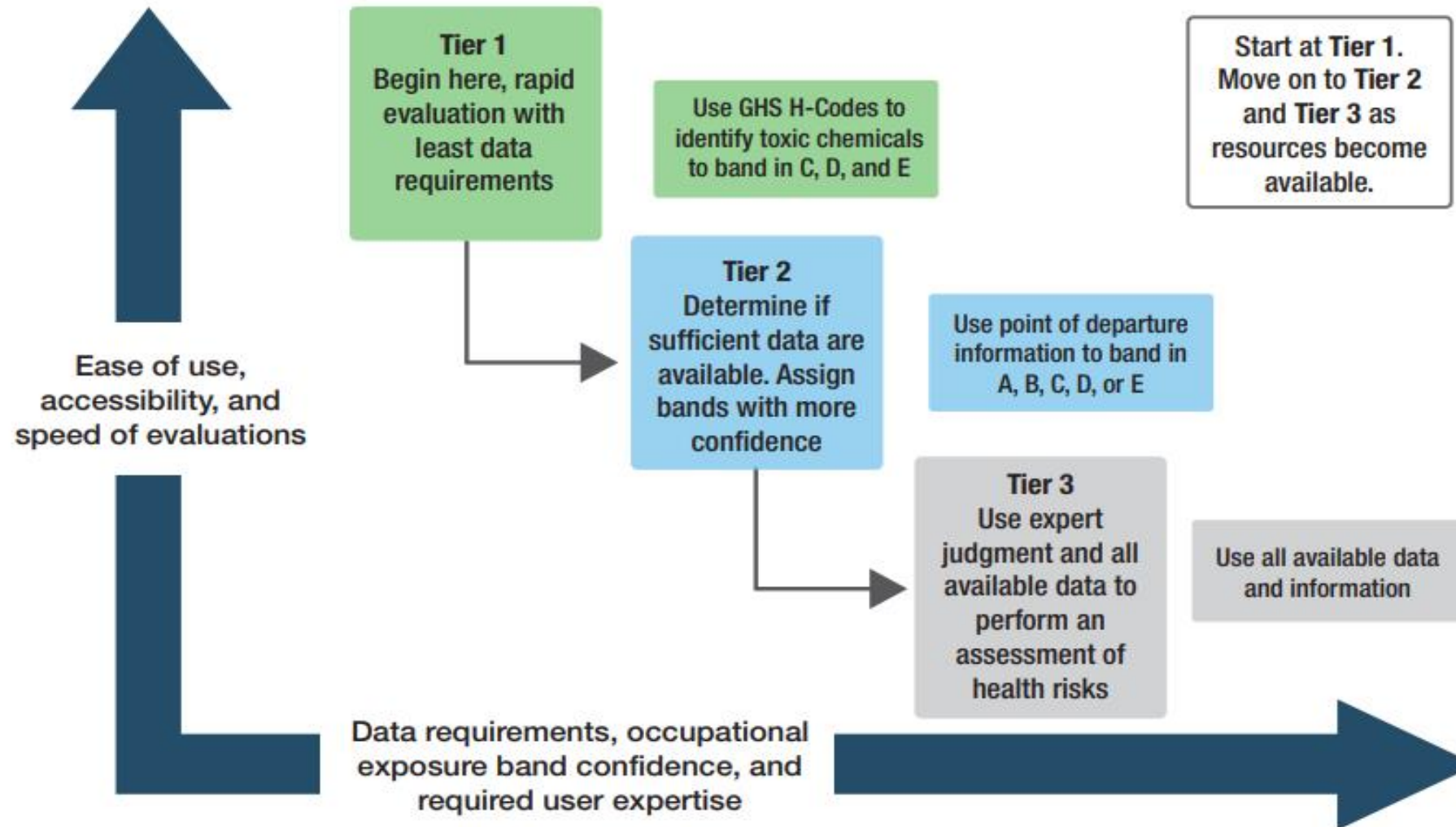
A Tier 2 evaluation based on point of departure data from reliable sources produces a more robust OEB than a Tier 1 evaluation. Data availability and quality are considered. Users of Tier 2 should be trained in the NIOSH process via the internet or in person.

Tier 3 — Expert Judgement

User: Toxicologist or experienced occupational hygienist

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

Use of the three tiers

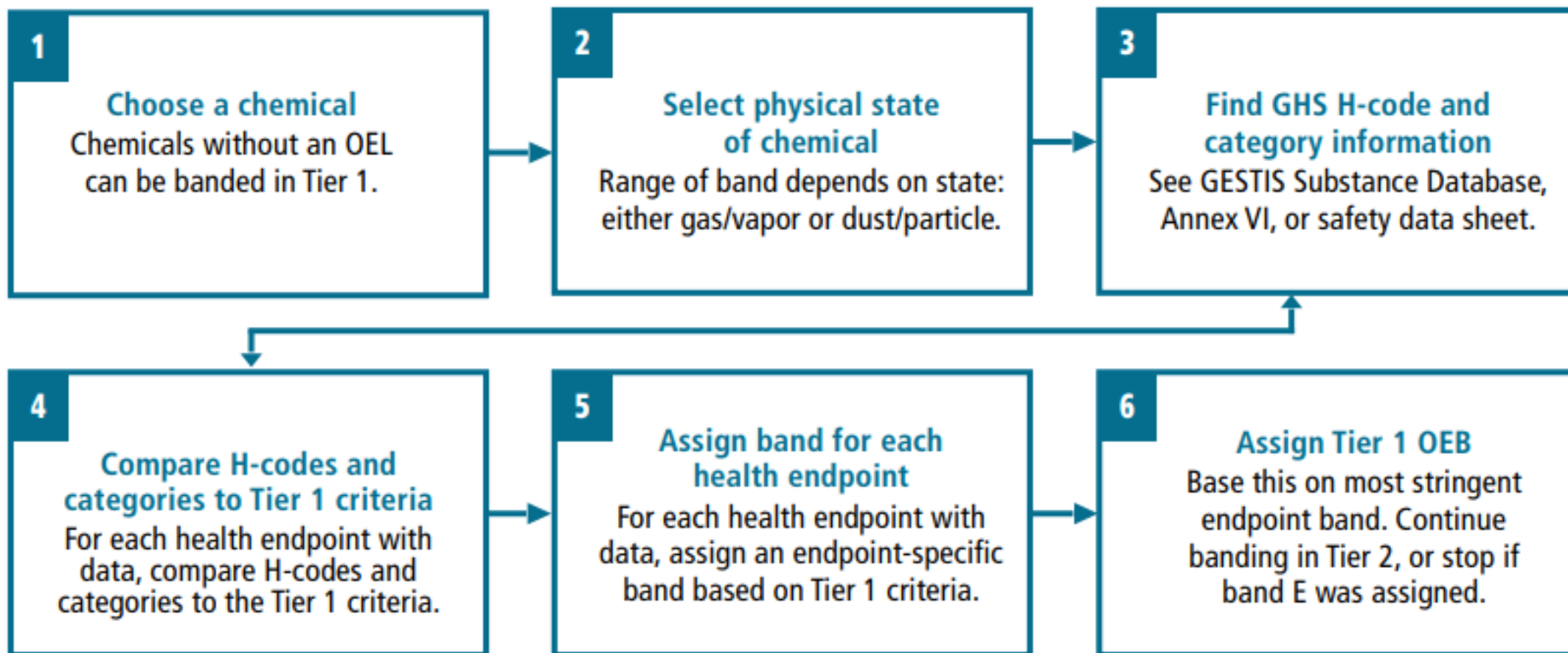


Tier 1 banding criteria

- GHS hazard codes and categories
- Chemicals can be banded into C, D and E
- Banding is based on severity and reversibility of effects



Tier 1 Overview



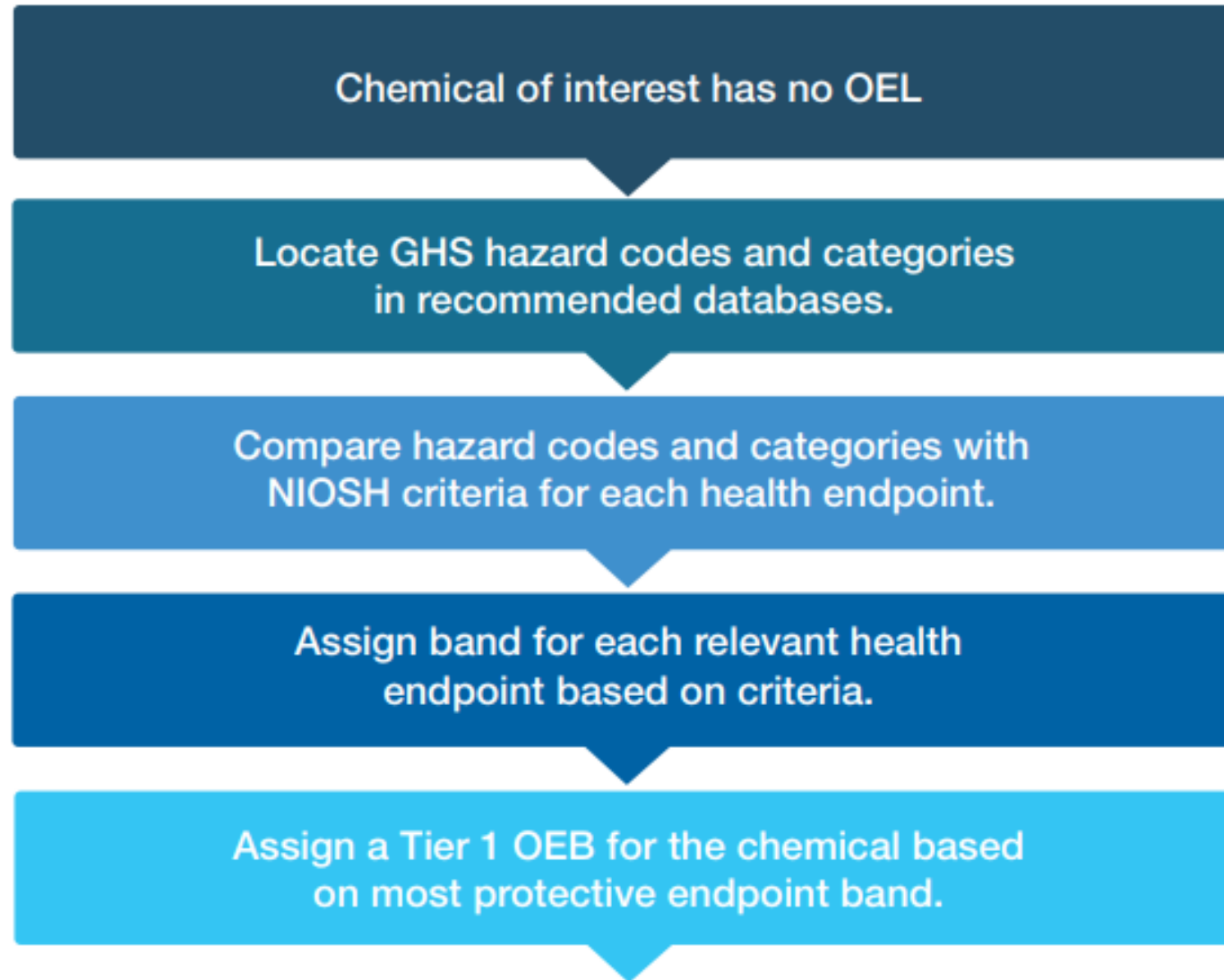
Tier 1 Codes and Categories

The following H-codes are not used for Tier 1 banding: H200s, H303, H304, H305, H331, H316, H320, H336, H362, and H400s

These codes are either not occupationally relevant or not sufficient for banding.

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

Tier 1 Process




Example – Chloral hydrate (CAS Number: 302-17-0)


1. Verify that an authoritative OEL has not been established
2. Identify the three-digit H-codes and hazard categories assigned to the chemical substance by GHS.
 - ECHA Annex VI to CLP
 - <https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp>
 - [GHS Annex VI Search Screen](#)
 - GESTIS database
 - <https://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp>
 - Updated OSHA-compliant SDSs
 - Use Annex VI and GESTIS as the initial resource




ECHA Annex VI search screen

 An agency of the European Union

Sign InEnglish (en)▼

 **ECHA**
EUROPEAN CHEMICALS AGENCY

About UsContact

Search the ECHA Website 

LEGISLATIONPUBLIC CONSULTATIONSINFORMATION ON CHEMICALSSUPPORT

ECHA > Search


Search


Please provide at least one keyword

Keywords

should match this exact phrase ▼

Publication Time

from: 24/09/2017 

to: 24/09/2019 

Results are displayed according to the range set in the above Publication Time.

Search

No results were found

Chloral hydrate harmonized classifications

DISCLAIMER:

This is an unofficial excel table containing the substances with harmonised classification and labelling up until the **13th Adaptation to Technical Progress**, i.e. Commission Regulation (EU) No 2018/1480 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (the CLP Regulation).

ECHA assumes no responsibility of any kind for your use of the data inter alia in the context of fulfilling the requirements of the relevant legal obligations. Please note that this document should be treated only for informative purposes not including commercial activities or reproduction

Updated on March 2019

| Index No | Chemical name | EC No | CAS No | Classification | Labelling | Specific Conc. Limits, M-factors and ATEs | Notes | ATP inserted/ATP Updated |
|--------------|---|-----------|----------|---|----------------------|---|-------|--------------------------|
| 605-014-00-6 | chloral hydrate; 2,2,2-trichloroethane-1,1-diol | 206-117-5 | 302-17-0 | Acute Tox. 3 * Skin Irrit. 2 Eye Irrit. 2 | H301 H315 H319 | GHS06 Dgr | | CLP00 |

| Classification | |
|----------------|------|
| Acute Tox. 3 * | H301 |
| Skin Irrit. 2 | H315 |
| Eye Irrit. 2 | H319 |

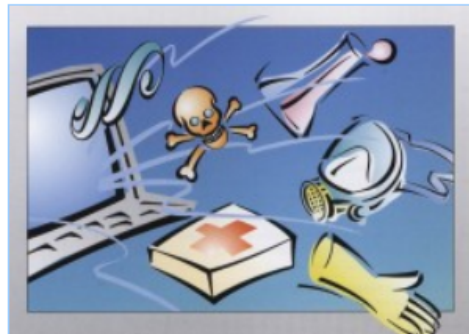




[Home](#) > [GESTIS](#) > [GESTIS Substance Database](#)

GESTIS Substance Database

Information system on hazardous substances of the German Social Accident Insurance



[open English version](#)

[open English mobile version](#)



Contents

The GESTIS Substance Database contains information for the safe handling of hazardous substances and other chemical substances at work, e.g. health effects, necessary protective measures and such in case of danger (incl. First Aid). Furthermore

Sample for inspection



[Exemplary substance data sheet](#)

For your comments



[Feedback](#)

Contact:



Dr Thomas Smola
Jutta Cramer
Amélia Veloso
Dr Caroline von Oppen

▶ [GESTIS Substance Database](#)

▶ [Tips & Tricks](#)

▶ [Frequently Asked Questions \(FAQs\)](#)

▶ [Linking](#)

▶ [Access Difficulties](#)

▶ [GESTIS Biological Agents Database](#)

▶ [GESTIS-Stoffenmanager®](#)

▶ [ISI information system for safety data sheets](#)

▶ [GESTIS - International limit values for chemical agents](#)


▶ [GESTIS DNEL list](#)

 Prev Hit Doc

 Next Hit Doc

 Prev Hit Match

 Next Hit Match

 Clear Highlights

Si

[GHS Classification/Labelling](#) | [Workplace labelling](#) | [Water hazard class](#) | [Air quality control](#) | [Transport Regulations](#) | [Seveso III](#) | [Technical rules](#) | [Regulations](#)

EUROPEAN GHS CLASSIFICATION AND LABELLING

Classification:

Acute toxicity, Category 3, oral; H301

Skin irritation, Category 2; H315

Eye irritation, Category 2; H319



Signal Word:

"Danger"

Hazard Statement - H-phrases:

H301: Toxic if swallowed.

H315: Causes skin irritation.

H319: Causes serious eye irritation.

Precautionary Statement - P-phrases:

P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.



Can I use an SDS?

Acute Tox 3 – H301
Skin Irritation 2 – H315
Eye Irritation 2 – H319

It depends...the attached SDS aligns with GESTIS and ECHA Annex 6.

However, another SDS, available on the web, did not include these three classifications.



Adobe Acrobat
Document

Chloral Hydrate SDS



SAFETY DATA SHEET Chloral hydrate

Page: 1 of 6

Revision: 04/11/2017

according to Regulation (EC) No. 1907/2006 as amended by (EC) No. 1272/2008

Section 1. Identification of the Substance/Mixture and of the Company/Undertaking

- 1.1 Product Code:** 21843
Product Name: Chloral hydrate
Synonyms: 2,2,2-Trichloro-1,1-ethanediol;
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant identified uses: For research use only, not for human or veterinary use.
- 1.3 Details of the Supplier of the Safety Data Sheet:**
Company Name: Cayman Chemical Company
1180 E. Ellsworth Rd.
Ann Arbor, MI 48108
Web site address: www.caymanchem.com
Information: Cayman Chemical Company +1 (734)971-3335
- 1.4 Emergency telephone number:**
Emergency Contact: CHEMTREC Within USA and Canada: +1 (800)424-9300
CHEMTREC Outside USA and Canada: +1 (703)527-3887

Section 2. Hazards Identification

- 2.1 Classification of the Substance or Mixture:**
Acute Toxicity: Oral, Category 3
Skin Corrosion/Irritation, Category 2
Serious Eye Damage/Eye Irritation, Category 2
- 2.2 Label Elements:**



GHS Signal Word: Danger

GHS Hazard Phrases:

H301: Toxic if swallowed.

H315: Causes skin irritation.

H319: Causes serious eye irritation.

Example – Chloral hydrate (CAS Number: 302-17-0) - continued

3. For chloral hydrate, the H-codes and categories are:
 - H315 – Skin Irritation 2
 - H319 – Eye Irritation 2
 - H301 – Acute Toxicity 3
4. Find the H-codes on the chart, and find the corresponding OEB at the top of the column.
5. If no H-codes are available for a particular endpoint, then that endpoint cannot be banded using Tier 1 – proceed to Tier 2.

NIOSH recommends that following Tier 1 banding, verify the band using Tier 2.



Tier 1 Codes and Categories

H315 – Skin Irritation 2
H319 – Eye Irritation 2
H301 – Acute Toxicity 3

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

Chloral Hydrate OEB C

Chemical Name: Chloral Hydrate

CAS Number: 302-17-0

| Endpoint | Hazard code | Hazard category | H-code source | Endpoint band |
|------------------------------------|-------------|-----------------|---------------|---------------|
| Carcinogenicity | None | — | — | — |
| Reproductive toxicity | None | — | — | — |
| Specific target organ toxicity | None | — | — | — |
| Genotoxicity | None | — | — | — |
| Respiratory and skin sensitization | None | — | — | — |
| Acute Toxicity | — | — | — | — |
| Inhalation | — | — | — | — |
| Oral | H301 | Category 3 | GHS | C |
| Dermal | None | — | — | — |
| Skin corrosion/irritation | H315 | Category 2 | GHS | C |
| Eye damage/irritation | H319 | Category 2 | GHS | C |
| Most stringent band | | | | C |

| Occupational exposure band | Airborne target range for dust or particle concentration (milligrams per cubic meter of air [mg/m ³]) | Airborne target range for gas or vapor concentration (parts per million [ppm]) |
|----------------------------|---|--|
| A | >10 | >100 |
| B | >1 to 10 | >10 to 100 |
| C | >0.1 to 1 | >1 to 10 |
| D | >0.01 to 0.1 | >0.1 to 1 |
| E | ≤0.01 | ≤0.1 |



- <https://wwwn.cdc.gov/Niosh-oeb/>
- Remdesivir - CAS



How accurate is the OEB Tier 1 process?

- NIOSH compared bands obtained from the Tier 1 process for 744 chemicals with full-shift OELs from the following authoritative bodies:
 - NIOSH Recommended Exposure Limits (RELs)
 - OSHA Permissible Exposure Limits (PELs)
 - ACGIH Threshold Limit Values (TLVs)
 - AIHA Workplace Environmental Exposure Values (WEELs)
 - California OSHA program (Cal/OSHA) PELs
 - German Maximale Arbeitsplatz-Konzentration (MAK)
- *Goal: greater than 80% of Tier 1 bands at least as protective as the OEL*
- Overall rate of Tier 1 bands, for vapors and particulates, being at least as protective as the OEL was 91.5%



OK - What do I do with an OEB?

- Qualitatively assess worker exposures
- Check with your lab – they may have a sampling and analytical method
- Consider use of surrogates or particle counters for solids
- For gases and vapors, apply the AIHA Mathematical Models for Estimating Occupational Exposure to Chemicals
 - https://online-ams.aiha.org/amsssa/ecssashop.show_product_detail?p_mode=detail&p_product_serno=889
- Based on your professional judgment, modeling, semi-quantitative exposure assessments with particle counters, and historical IH sampling data for the task or operation, identify additional controls that may be needed.



Tier 1 limitations

- The Tier 1 process is very conservative with regards to carcinogenicity – as it should be!
- Therefore, verify “D” and “E” bands that are based on these categories by using the Tier 2 process.
- Tier 2 process includes both qualitative (weight of evidence) and quantitative (slope factor, inhalation unit risks, or tumorigenic) data.
- Occasionally, a Tier 1 Band E classification can be reduced to Band D.
 - You must have the evidence!



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
 - Need sufficient data to generate reliable OEB
- Prescriptive analytical strategy to ensure consistency
- Potential for chemicals to be moved from the Tier 1 OEB to a more or less protective OEB



- 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 NIOSH e-Tool



Carcinogenicity databases



Endpoint and Total Determinant scores

- 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.
 - $TDS \geq 30$: sufficient data for banding in Tier 2
- Example:
 - Cancer inhalation unit risk value tells us a lot about the hazardous nature of a chemical, so the presence of that information corresponds to an EDS of 30.
 - However, an LD50 value for the acute toxicity endpoint is only weighted as an 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 example – sources of data for carcinogenicity endpoint

| Endpoint | Rank | Source of Information | Acronym |
|-----------------|------|---|---------|
| Carcinogenicity | 1 | National Toxicology Program 14th Report on Carcinogens (2016) | NTP RoC |
| | | US EPA Integrated Risk Information System | IRIS |
| | | International Agency for Research on Cancer | IARC |
| | | Health Canada | HC |
| | | California Office of Environmental Health Hazard Assessment | OEHHA |



Carcinogenicity

- Qualitative
 - Weight of Evidence (WOE) descriptors (NTP, IARC, EPA IRIS)
 - Classifications/phrases (i.e. "Group C: possible human carcinogen")
- Quantitative
 - Slope Factor (SF), Inhalation Unit Risk (IUR), or Tumorigenic Dose or Concentration with a 5% increase in incidence of mortality due to tumors (TD_{05} or TC_{05})
 - Numerical values (i.e. $IUR = 0.01 (\mu g/m^3)^{-1}$)
- Quantitative classification takes precedence



Example Tier 2

- Benzo(k)fluoranthene
- CAS 207-08-9

| Endpoint | Rank | Source of Information | Acronym |
|-----------------|------|---|---------|
| Carcinogenicity | 1 | National Toxicology Program 14th Report on Carcinogens (2016) | NTP RoC |
| | | US EPA Integrated Risk Information System | IRIS |
| | | International Agency for Research on Cancer | IARC |
| | | Health Canada | HC |
| | | California Office of Environmental Health Hazard Assessment | OEHHA |





About the Report on Carcinogens

14th Report on Carcinogens

RoC Process & Listing Criteria

RoC Handbook

Completed Scientific Reviews

Substances Under Evaluation

Substances Under Consideration

Nominate a Substance

Contact Us

14th Report on Carcinogens (RoC)



https://ntp.niehs.nih.gov/go/roc14

U.S. Department of Health and Human Services released the 14th Report on Carcinogens on November 3, 2016. The RoC is a congressionally mandated, science-based, public health document that NTP prepares for the [HHS Secretary](#). This **cumulative report** currently includes 248 listings of agents, substances, mixtures, and exposure circumstances that are known or reasonably anticipated to cause cancer in humans.

- [Press Release](#)
- [Complete Report on Carcinogens](#)
- [Fact Sheet on the 14th RoC](#)
- [Federal Register notice](#)



New Listings

Cobalt and Cobalt Compounds that Release Cobalt Ions In Vivo

- [Substance Profile](#)
- [Fact Sheet](#)
- [Scientific Review](#)

Epstein-Barr Virus

- [Substance Profile](#)
- [Fact Sheet - Five Viruses](#)
- [Scientific Review](#)

Human Immunodeficiency Virus Type 1

- [Substance Profile](#)
- [Fact Sheet - Five Viruses](#)

Kaposi Sarcoma-Associated Herpesvirus

- [Substance Profile](#)
- [Fact Sheet - Five Viruses](#)
- [Scientific Review](#)

Merkel Cell Polyomavirus

- [Substance Profile](#)
- [Fact Sheet - Five Viruses](#)
- [Scientific Review](#)

Trichloroethylene

- [Substance Profile](#)
- [Fact Sheet](#)
- [Scientific Review](#)

Polycyclic Aromatic Hydrocarbons: 15 Listings

Reasonably anticipated to be human carcinogens

Also known as PAHs or polynuclear aromatic hydrocarbons

The term “polycyclic aromatic hydrocarbon” (PAH) commonly refers to a large class of organic compounds that contain carbon and hydrogen and consist of two or more fused aromatic rings. Fifteen individual PAHs (not the entire class) are listed separately in the Report on Carcinogens as *reasonably anticipated to be a human carcinogen*:

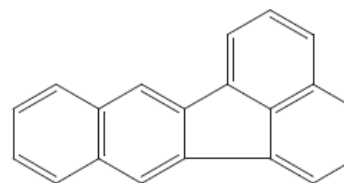
- Benz[*a*]anthracene, benzo[*b*]fluoranthene, benzo[*j*]-fluoranthene, benzo[*a*]pyrene, dibenz[*a,h*]acridine, dibenz[*a,j*]acridine, dibenz[*a,h*]anthracene, 7*H*-dibenzo[*c,g*]-carbazole, dibenzo[*a,h*]pyrene, dibenzo[*a,i*]pyrene, and indeno[1,2,3-*cd*]pyrene were first listed in the *Second Annual Report on Carcinogens* (1981).
- Benzo[*k*]fluoranthene, dibenzo[*a,e*]pyrene, dibenzo[*a,l*]pyrene, and 5-methylchrysene were first listed in the *Fifth Annual Report on Carcinogens* (1989).

The chemical structures of the 15 listed PAHs are shown below. Evidence for their carcinogenicity from studies in experimental animals is then discussed separately for each PAH. However, most of the information on mechanisms of carcinogenesis, cancer studies in hu-

Benzo[*k*]fluoranthene

CAS No. 207-08-9

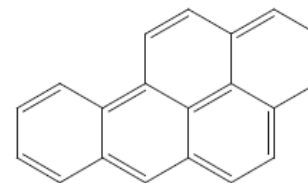
Also known as B[*k*]F



Benzo[*a*]pyrene

CAS No. 50-32-8

Also known as B[*a*]P



Dibenz[*a,h*]acridine

NIOSH Criteria

Table 3-7: Criteria for Carcinogenicity Toxicity (Qualitative Analysis)

| Classification | Endpoint Band | Endpoint Determinant Score |
|---|----------------|----------------------------|
| National Toxicology Program Report on Carcinogens | | |
| <i>Known to be human carcinogen</i> | E | 30 |
| <i>Reasonably anticipated to be human carcinogen</i> | E | 30 |
| <i>Group B2 (probable human carcinogen)</i> | E | 30 |
| <i>Likely to be carcinogenic to humans</i> | E | 30 |
| <i>Group C (possible human carcinogen)</i> | D | 20 |
| <i>Suggestive evidence of carcinogenic potential</i> | D | 20 |
| <i>Group D (not classifiable as to human carcinogenicity)</i> | <i>No band</i> | 0 |
| <i>Data are inadequate for an assessment of carcinogenic potential</i> | <i>No band</i> | 0 |
| <i>Group E (evidence of non-carcinogenicity for humans)</i> | A | 30 |
| <i>Not likely to be carcinogenic to humans</i> | A | 30 |
| International Agency for Research on Cancer | | |
| <i>Group 1 (carcinogenic to humans)</i> | E | 30 |
| <i>Group 2A (probably carcinogenic to humans)</i> | E | 30 |
| <i>Group 2B (possibly carcinogenic to humans)</i> | E | 30 |
| <i>Group 3 (not classifiable as to its carcinogenicity to humans)</i> | <i>No band</i> | 0 |
| <i>Group 4 (probably not carcinogenic to humans)</i> | A | 30 |
| State of California Office of Environmental Health Hazard Assessment | | |
| <i>Type of toxicity = cancer</i> | E | 30 |

| Carcinogenicity (20 or 30 points possible) | | | | | |
|---|---------------|---------------|---------------|---------------|---|
| | Band A | Band B | Band C | Band D | Band E |
| NTP/EPA/IARC/Canada/California (QUALITATIVE) | | | | | NTP Reasonably anticipated to be human carcinogen |
| EPA IRIS Slope Factor | | | | | |
| EPA IRIS Inhalation Unit Risk | | | | | |
| Health Canada TD05 | | | | | |
| Health Canada TC05 | | | | | |
| California Slope Factor | | | | | |
| California Inhalation Unit Risk | | | | | |



Benzo[k]fluoranthene



CAS Number

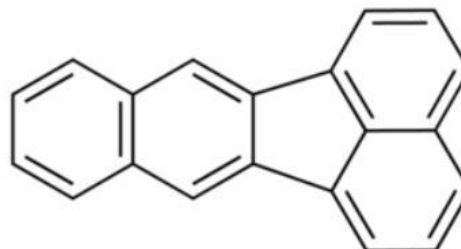
207-08-9

Synonym(s)

8,9-Benzfluoranthene; Dibenzo(B,JK)fluorene

Occurrence(s)/Use(s)

Product of combustion; component of tobacco smoke



Cancer Potency Information

Inhalation Unit Risk (µg/cubic meter)-1: 1.1 E-4

Inhalation Slope Factor (mg/kg-day)-1: 3.9 E-1

Oral Slope Factor (mg/kg-day)-1: 1.2 E+0



OEHHHA

- [About OEHHHA](#)
- [Biomonitoring](#)
- [Calendar](#)
- [Climate Change](#)
- [Comment Periods, Meetings](#)
- [DVBE and Small Business](#)
- [Emergency Response](#)
- [Fact Sheets](#)
- [Green Chemistry](#)
- [Jobs](#)
- [Join the Listserv \(Email\)](#)
- [Naturally Occurring Lead](#)
- [OEHHHA Chemical Database](#)
- [Press Releases](#)
- [Public Information](#)
- [Public Record Act Request](#)



Contact Us

Join
Fac

NIOSH QUANTITATIVE CANCER CRITERIA

SF: $1.2 \text{ (mg/kg day)}^{-1}$

IUR: $1.1 \times 10^{-4} \text{ (ug/m}^3\text{)}^{-1}$

| Band | C | D | E |
|-----------------------------|---|---|--|
| <i>Slope factor (oral)</i> | $< 0.01 \text{ (mg/kg-day)}^{-1}$ | $\geq 0.01 \text{ to } < 10 \text{ (mg/kg-day)}^{-1}$ | $\geq 10 \text{ (mg/kg-day)}^{-1}$ |
| <i>Inhalation unit risk</i> | $< 3 \times 10^{-6} \text{ (ug/m}^3\text{)}^{-1}$ | $\geq 3 \times 10^{-6} \text{ to } < 0.01 \text{ (ug/m}^3\text{)}^{-1}$ | $\geq 0.01 \text{ (ug/m}^3\text{)}^{-1}$ |
| TD_{05} | $> 5 \text{ mg/kg-day}$ | $> 0.005 \text{ to } \leq 5 \text{ mg/kg-day}$ | $\leq 0.005 \text{ mg/kg-day}$ |
| TC_{05} | $> 1.67 \times 10^4 \text{ ug/m}^3$ | $> 5 \text{ to } \leq 1.67 \times 10^4 \text{ ug/m}^3$ | $\leq 5 \text{ ug/m}^3$ |



Summary of benzo(k)fluoranthene carcinogenicity

- Qualitative (WOE): band E
- Quantitative (IUR): band D

Quantitative data takes precedence over qualitative; therefore,

Tier 2 Carcinogenicity = band D
EDS = 30



But...we need to continue the process with the remaining endpoints

| Chemical Name: Benzo (k) fluoranthene CAS: 207-08-9 | | | |
|--|--|-------|---------------|
| Endpoint | Data | EDS | Endpoint Band |
| Acute Toxicity | Source: | | |
| Skin Corrosion/Irritation | Irritation, severity unspecified Source: REACH | 5 | C |
| Serious Eye Damage/ Eye Irritation | Irr., photosensitivity severity unspecified Source: HSDB | 5 | C |
| Respiratory Sensitization | Source: | | |
| Skin Sensitization | Source: | | |
| Genotoxicity | 1 positive result Source: NTP | 5 | E |
| Carcinogenicity | 1.2 (mg/kg day) ⁻¹ Source: California Slope Factor | 30 | D |
| Reproductive Toxicity | Source: | | |
| Specific Target Organ Toxicity | Source: | | |
| OVERALL Tier 2 BAND | | TDS = | |



Final tier 2 OEB for benzo(k)fluoranthene

| Chemical Name: Benzo (k) fluoranthene CAS: 207-08-9 | | | |
|--|---|-----|---------------|
| Endpoint | Data | EDS | Endpoint Band |
| Acute Toxicity | Source: | | |
| Skin Corrosion/Irritation | Irritation, severity unspecified Source: REACH | 5 | C |
| Serious Eye Damage/ Eye Irritation | Irr., photosensitivity severity unspecified | 5 | C |
| Respiratory Sensitization | | | |
| Skin Sensitization | | | |
| Genotoxicity | Source: NTP | 5 | E |
| Carcinogenicity | 1.2 (mg/kg day) ⁻¹ | 30 | D |

TDS=45
TDS>30
Data sufficiency reached

Final Tier 2 band for benzo (k) fluoranthene is **Band E**, on the basis of genotoxicity

| | | |
|---------------------|----------|--|
| OVERALL Tier 2 BAND | TDS = 45 | |
|---------------------|----------|--|



Tier 3 banding process

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



NIOSH Technical Report and e-Tool

- Process Overview
 - <https://www.cdc.gov/niosh/topics/oeb/default.html>
- Technical Report
 - <https://www.cdc.gov/niosh/docs/2019-132/default.html>
- e-Tool
 - <https://wwwn.cdc.gov/Niosh-oeb/>



Questions and Discussion

