

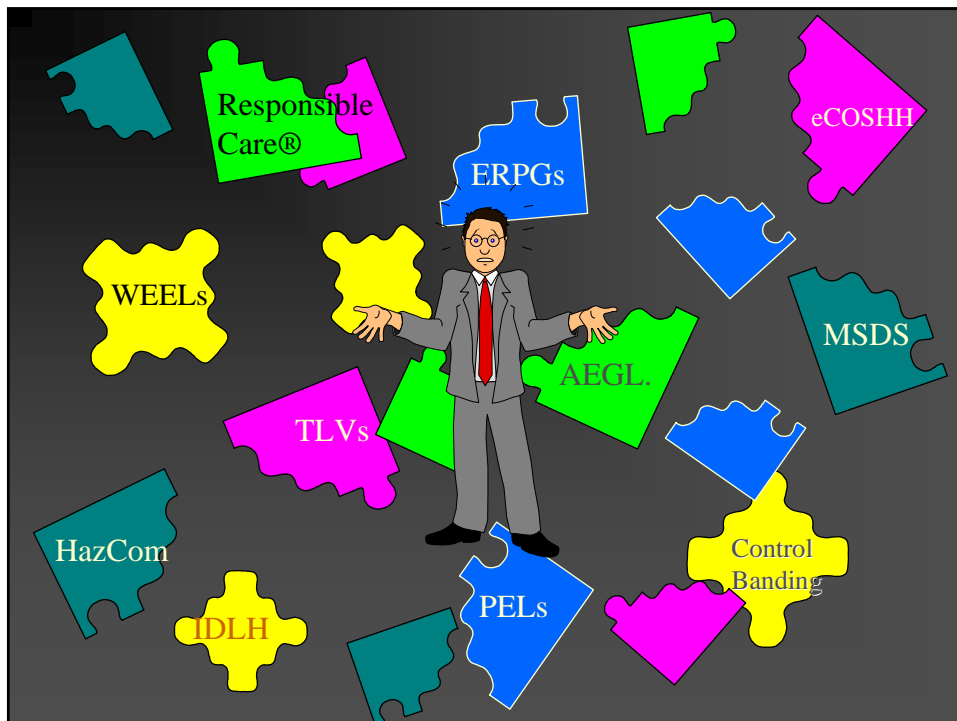


SETTING GLOBAL ENVIRONMENTAL HEALTH & SAFETY STANDARDS

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Global Industrial Hygiene Expertise Center
The Dow Chemical Company



Friday, January 25, 2008



Discussion Today: Setting Global Standards

- Perspective
 - Just how big is the 2nd largest “Global Chemical Company”?
 - Global Standard of Care:
 - Dow Internal Global EH&S Standards – IH Standards
- Global risk assessment and management strategies in Dow
 - Qualitative Exposure Assessment in Dow
 - OELs and Exposure Monitoring
 - Performance-Based Exposure Limits
- REACH: Impacts on our products and exposure assessment
 - DNELs and OELs



Global EH&S in a Global Chemical Company

- The largest chemical company in the US, and #2 worldwide (ahead of ExxonMobil and behind BASF)
- Plastics, chemicals, and agricultural products
- > 3,000 products
- > 175 countries
- ~43,000 people worldwide



A Global Company Striving to Be Globally Responsible



The ISSUES in Providing a “Global Standard of Care”

- Global Economy → Global Products → Global Transport → Global Companies
- Responsible Care® Principles → Global Standard of Care for workers, communities and the environment:
 - Standard of Care → Cradle to Grave for Products
 - Community
 - Environment
 - Exposures from transport, spills, releases, emissions
 - Exposures to products through consumer use
 - Workers
 - Global workforce of manufacturer
 - Toll manufacturers and formulators
 - End-users of products that are raw materials and intermediates in others' products

DO YOU WORK GLOBALLY?

Providing a Global Standard of Care: Occupational Risk Management (ORM)

- Global Standards for Risk Assessment and Risk Management by IHs
 - OEHS Professionals participate with NGOs, legislators and regulators to develop standards
 - >50 Dow GLOBAL EH&S Standards: Expect 100% compliance within Dow facilities
 - 17 Industrial Hygiene focused Global Standards
 - Responsible Care® Standards for Products: Expect 100% compliance for all users of our products
 - EH&S Metrics for compliance, injury/illness, releases to environment
- Exposure Assessment Issues
 - OELs and Hazard Evaluations
 - Monitoring Methods
 - Standardized Exposure Control Strategies → PB-ECLs

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Global EH&S Standards

A. Identification and Evaluation of Hazards Requirements
 B. Organizational and Individual Expectation Requirements
 C. Operational Controls and Task Procedures Requirements

- [ODMS / EH&S Requirement Applicability Tool](#) (Determine which requirements apply to your organization.)
- [Safety & Health Model Practices Archive](#)

A. Identification and Evaluation of Hazards Requirements	
Job Safety Analysis	Pre-Task Analysis Note: A global standard / requirements are not planned. Guidance and model practices are available in the Safety & Health Model Practices Archive
	Procedure Implementation Analysis (PIA)
	Guidelines for Safety on Non-Dow Premises [Word, size 80KB]
Exposure Assessment	Global Occupational Exposure Assessment Standard
	Global Occupational Exposure Limit (OEL) Standard
	Occupational Exposure Database
	Global Biosafety Standard
Health Assessment	Health Assessment Standard

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B: Organizational and Individual Expectation

Behavior Based Performance	Behavior-Based Performance Work Process
Individual Behavior Expectations	Examples of General Rules Standards: <ul style="list-style-type: none"> • Midland Scroll to Safety Rule Books • Freeport • Fort Saskatchewan [Word, size 106KB] Guidance and model practices are available in the Safety & Health Model Practices Archive
Employee Participation	Guidance and model practices are available in the Safety & Health Model Practices Archive
Hazard Awareness	Global Hazard Awareness Standard Compliance Date: April 2009
Health Care	Health Care Services Delivery Web <ul style="list-style-type: none"> • Clinical Services Process • Site Health Services Contact List
Preventive Health Services	Preventive Health Services Delivery Web

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C: Operational Controls and Task Procedures

- Biosafety and Bloodborne Pathogens
- Confined Space Entry
- Decontamination
- Electrical Safe Work
- Emergency Response Guidelines and Planning for Loss Prevention
- Equipment
- Ergonomics
- Excavations
- Fall Prevention / Elevated Work
- Hazard Awareness, MSDSs, Responsible Care communication
- Hot Work
- Hydroblasting and Pressure Washing
- Indoor Air Quality
- Laboratory Fume Hoods
- Line and Equipment Opening
- Lockout and Red Tag / Isolation of Energy Sources
- Hearing Conservation
- Permit System / Safe Work Permit
- Personal Protective Equipment
- Radiation (Ionizing & Nonionizing)
- Regulatory Advocacy & Technical Support
- Respiratory Protection
- Safe Operation of Motor Vehicles And Motorized Handling Equipment
- Thermal Stress (Heat/Cold)
- Ventilation

Global Exposure Assessment Std: Requirements

Occupational Exposure Assessment - Scope and Applicability - (ODMS Element 06.05.A.02)

Exposure Assessment Standard - Start Page	Global E-18 - 06.05 - Employee Health and Safety Standards - Occupational Exposure Assessment - Requirements
Scope and Applicability	
Requirements	Exposure Assessment Requirements
Requirements	1. Qualitative Exposure Assessments (QEAs) shall be conducted to evaluate worker exposures to chemical, physical, biological and ergonomic hazards with potential health significance in the workplace.
Training	2. QEAs shall be conducted using the Dow QEA process and will be used to establish priorities for quantitative assessments (e.g. air monitoring), training, health surveillance and exposure control activities.
Compliance Verification	3. QEAs shall be updated annually and when there are changes that may significantly impact employee exposures.
Self-Assessment	4. Based on QEA results and other exposure information, work environments shall be quantitatively assessed for potential health hazards. An approved Quantitative Exposure Assessment Plan shall be used to collect exposure data for correlation with safety / medical information and to evaluate compliance with occupational exposure limits.
Auditing	5. A system shall be established to ensure data quality, including the use of validated quantitative exposure assessment techniques.
Documentation and Recordkeeping	6. Procedures shall be established for the timely documentation and communication of findings from qualitative and quantitative exposure assessments to employees and their supervision.
Implementation Guide	7. Data management systems shall be used to organize, store and retrieve qualitative and quantitative exposure data as well as work history data. Quantitative exposure assessment data shall be communicated in reports (see report requirements).
Process and Programs	8. A member of the Industrial Hygiene Expertise Center or their designee shall review Qualitative Exposure Assessment, Quantitative Exposure Assessment Plans, and Exposure Assessment Reports.
Tasks and Procedures	
Roles and Responsibilities	
Tools	
Frequently Asked Questions	
Definitions and Acronyms	
Revision History	
Correspondence	

Global OEL Std: Requirements

06.05.A.02 Occupational Exposure Limit Standard

Occupational Exposure Limits (OELs) Home	Occupational Exposure Limits (OELs) - Requirements
Scope & Applicability	A printable page is available.
Requirements	These requirements have been developed for use with the global requirements for Exposure Assessment (06.05.A.02):
Process & Procedures	1. The IHG Review Board shall establish IHGs, BEGs, & EEPGs for chemical, biological and physical agents for which recent toxicological or other pertinent information suggests that existing guidelines or requirements may not be appropriate.
Documentation	2. These exposure limits shall be established by Dow health professionals serving on the Dow IHG Review Board for certain chemical, biological, or physical agents handled within or produced by The Dow Chemical Company. The Dow IHG Review Board shall consist of an EH&S representative in a management/leadership role from each of the following functions: <ul style="list-style-type: none"> o EH&S Product Safety o Industrial Hygiene Expertise o Health Services Expertise o Regulatory Affairs o EH&S Legal o Toxicology
Recordkeeping	3. The business supporting the development of an IHG shall establish a business Health Team to assist in the review of hazard data and propose an IHG value. For non-Dow products, the BOL is the molecule "owner", and for Dow products, the GPL is the molecule "owner".
Training/Knowledge/Skills	4. Dow IHGs, ACGH TLVs® and AIHA WEELs® shall be included on Dow's Material Safety Data Sheets (MSDSs) along with applicable National (country-specific) regulatory occupational exposure limits as a part of the company's Global Hazard Awareness Requirements and Responsible Care® product stewardship responsibilities.
Tools, Templates & Checklists	5. The IHG development process at The Dow Chemical Company shall be led by the Occupational Exposure Limits Technical Focal Point. The role designee shall be determined by Dow's Global Industrial Hygiene Expertise Center.
Appendices	
Print Page	

Globally

35 Certified IHs
>2000 EH&S Professionals

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Global EH&S Standards

Areas of Dow IH Technical Expertise – EH&S Standards

- Exposure Assessment & Risk Assessment Modeling/Design
- Exposure Monitoring –
 - Dow workers or Customers
 - Methods Development
- Occupational Exposure Limits and Control Bands
- BioSafety & Biotechnology
- Hazard Awareness, MSDSs, Responsible Care communication
- Regulatory Advocacy & Technical Support
- Ventilation
- Respiratory Protection
- Personal Protective Equipment
- Indoor Air Quality
- Radiation
- Training Resources
- Noise & Hearing Conservation
- Thermal Stress Prevention
- Ergonomics
- Auditing
- Emergency Response Guidelines and Planning

Global Risk Assessment & Management Standard?

- More global regulations require some form of documented risk assessment
- How do you assess, and then mitigate, risks of handling chemicals?
 - Differences country to country
 - Differences state to state
 - Shipping, import, & export differences globally
 - Hazard communication differences
 - Enforcement differences

Industrial Hygiene Value =

- Anticipate the Hazards of 'Exposures'
- Recognize the Risks of that 'Exposure'
- Control the Risks of potential 'Exposure'



Focus Today

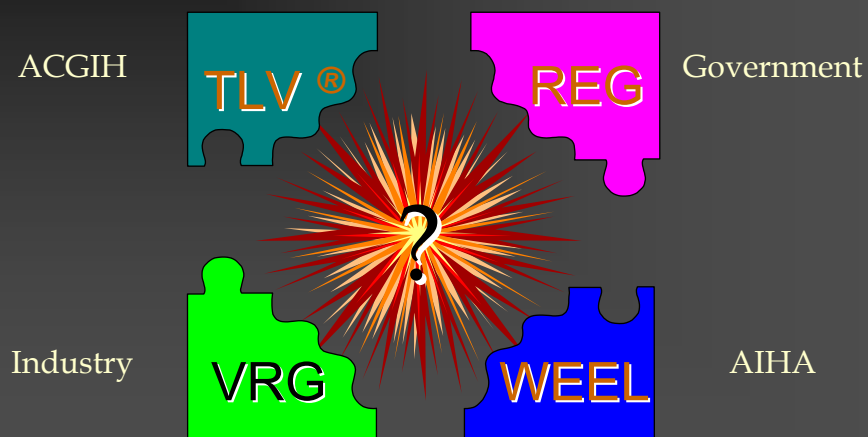
- Assessing hazards and risks from exposures to chemicals in a globally responsible way
Defer control strategies to another time!
- Hazard and Risk Assessment Strategies
 - Setting OELs vs. lack of OELs
 - Setting PB-ECLs
- Product Guidance Sheets

Guideline vs. Regulation?

OELs

- **Regulatory** - Set and enforced by government agencies
 - e.g. OSHA PEL, MSHA PEL
- **Authoritative** - Set and recommended by credible organizations
 - e.g. ACGIH TLV, AIHA WEEL
- **Internal** - Devised by organizations for internal use and/or recommendation
 - e.g. Company Exposure Guideline
- **Working** - Informal limit established in order to resolve an exposure assessment. Typically based on sparse toxicity data.

Completing the OEL Puzzle:



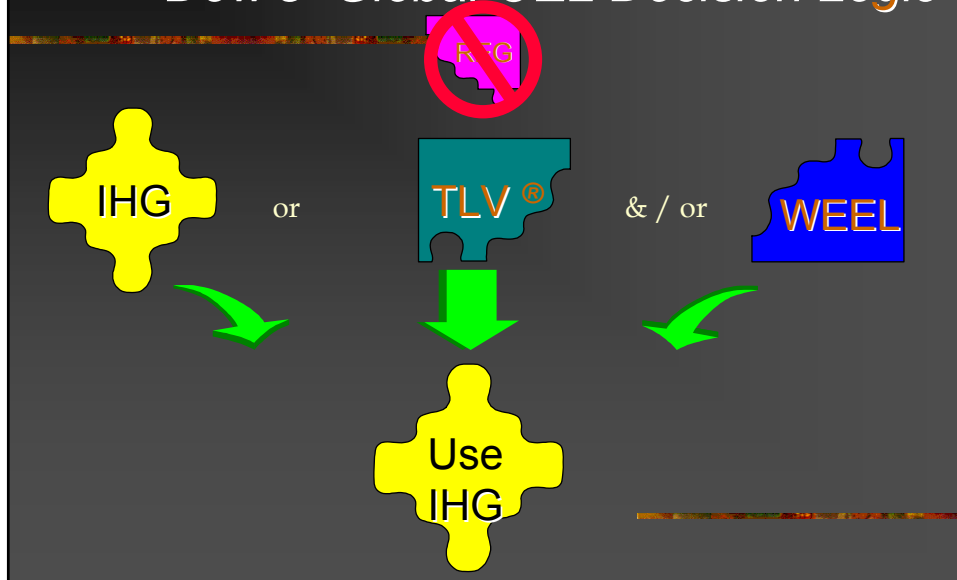
Industrial Hygiene Guidelines



The Dow IHG Process



Dow's "Global OEL Decision Logic"



Global Risk-Based Approach

- Many small and medium-size companies use available information to estimate hazards and risk management strategies
 - OELs, if any
 - NFPA or HMIS ratings
 - EU "R" and S phrases
 - Families of Chemicals or by analogy to "known" materials
 - Current 'risk assessments' done by agencies leveraged and recalculated for OELs (e.g. OEHHA/HESIS and US EPA)
 - DNELS – use only a NOAEL/LOAEL 'uncertainty factor' algorithm for community and worker OELs

Regulatory OELs

- Many regulatory agencies adopt TLVs®
- EU Annex I augmented by:
 - Country and State-specific Regulatory OELs
 - REACH DNELs ** - Process just announced!
- USA Federal PELs augmented by:
 - USA State OSHA PELs ** - some hope here!
- NCELS (EPA) – come and go based on SNURs and PMNs
- Proposal to adopt NIOSH RELs for MSHA (by legislative change)

** More info later

Guideline OELs – Can't use in the EU

- NIOSH RELs – current focus elsewhere due to lack of PEL-setting by OSHA and budgetary restraints
- MAK – functioning as usual
- TLV® – organization under duress due to lawsuits
- DECOS – no longer will set guidelines due to resources – defer to DNELs/DMELs and EU Annex I OELs
- WEEL – functioning as usual, all volunteers and resources limited



Challenges Setting OELs

Setting OELs: Challenges

- **Prioritization** of substances needing OELs
 - **Diversity** of committee membership
 - **Availability of data**
 - **Perception** of committee setting OELs
 - **Resources** time, data, and finance
 - **“Harmonization”** of OELs
-

OELs: Challenges of the Future

- Leveraging information with other OEL-setting bodies
 - Reference and data sharing
 - Stakeholder involvement and input
 - Monitoring Methods
 - Validation of “Banding” models
- “Weight of Evidence” approach vs. NOAEL algorithms (EU DNELs)

REACH DNELs and DMELs

- **DNEL:**
 - The Derived No-Effect Level (DNEL) is defined in Annex 1 of REACH as the level of exposure above which humans should not be exposed.
 - Manufacturers and importers are required to calculate DNELs as part of their Chemical Safety Assessment (CSA) for any chemicals used in quantities of 10 tons or more per year.
 - The DNEL is to be published in the manufacturer’s Chemical Safety Report and, for hazard communication, in an extended Safety Data Sheet.
- **DMEL:**
 - Derived Minimum Effect Level (DMEL), based on some concept of acceptable or negligible risk, (such as the “Threshold of Toxicological Concern”)
 - Continued question: “Should such materials automatically be banned because they cannot be adequately controlled?”

EU Indicative Occupational Exposure Limits (IOELs) versus DNELs

- May use an EU “IOEL” in place of developing a DNEL, or the derivation of a DNEL when there is already an IOEL, has to be documented in the registrant’s Chemical Safety Report
- IOEL- values are health-based, non-binding values, derived from the most recent scientific data available and taking into account the availability of measurement techniques.
 - Since they do not consider ‘technical or economic feasibility’ they are considered ‘health based’

EU Binding Occupational Exposure Limit (BOEL) versus DNELs

- BOELs reflect socio-economic and technical feasibility factors in addition to health-based toxicological information taken into account when establishing IOELs.
 - BOELs have been set for 4 substances.
- When a BOEL exists the registrant **cannot use it in place of a DNEL** without an evaluation of the scientific background for setting the BOEL **to eliminate** the impact of technical and socio-economic feasibility.
- Consequently, information and toxicological evaluations of health effects used for setting the BOEL may, as for IOELs, be used and taken into account in deriving the DNEL.

EU National Occupational Exposure Limits versus DNELs

- Member States may set national OELs for other substances than those included in Community legislation
 - Various approaches may be used;
 - in some cases the OELs are purely health based values and in other cases they may take into account feasibility factors.
 - A registrant cannot use a national OEL in place of a DNEL without an evaluation of the scientific background for setting the national OEL.
 - In cases where toxicological information and evaluations of health effects used for setting the national OEL are documented and available, this may, as for IOELs, be used and taken into account in **deriving the DNEL**.

Summary of Remaining Issues EU DNELs

- Currently under this guidance, companies are prohibited from using:
 - company internal OELs
 - OELs developed by non EU standard-setting organizations (e.g. TLV, MAK, DECOS, etc.), or
 - creating OELs for new compounds going forward

These OELs can not be used

- even when the values were set using the same methodologies as the IOELs,
- even when the toxicological bases for the OELs are current

OELs: More Challenges of the Future

- Continued international collaboration of OEL-setting bodies, governments and industry towards “Harmonization” of OELs
- Improving science-based setting of OELs
 - Evaluation of “Performance-based Banding”
 - Use of “cardinal numbers” in setting limits where data set is brief
- Extended workshifts (10 - 12 - 16 hours) WEEL Committee 2008
- Dermal and Respiratory Sensitization (R-SEN and D-SEN)
- Tox and Human Data generation and availability

A Simple Global Matrix

FOR TOXICOLOGICAL CATEGORIZATION OF
MATERIALS WHERE R-PHRASES ARE NOT AVAILABLE
IN THE CONTROL-BANDING PROCESS

Topic Discussions

- Sources of Health Hazard Ratings (Limited Comparison)
 - EU Risk Phrases – the e-COSHH essential
 - HMIS vs. NFPA
 - Acute vs. Chronic Hazards / Risks
 - Converting Safety Data Sheet (SDS) Hazard Phrases to Risk Phrases
- Simple Matrix to Convert SDS Health Hazards to Risk
- Assigning Controls to manage risks
- Assigning PPE to manage risks

Categorizing Health Hazards to Risks

- EU Risk Phrases
 - Categorizes chemicals that are “DANGEROUS”
- ☒ NFPA Standard 704
 - Identification of Fire Hazards of Materials
 - Acute effects only
- ☒ HMIS®
 - HMIS® is not intended for emergency circumstances
 - Identifies risk category with ‘*’ for chronic effects
- ? SDS hazards → Risk?
 - Detailed compilation of hazards



Consider These Limitations

- R-Phrases –
 - Some countries do not have knowledge of R-phrases
 - Does not assign phrases to chemicals considered “not dangerous”
- NFPA designated for acute effects or “fire hazard” situations
 - Not specific .. can’t use the designation
 - Chronic hazards needed
 - Not readily accessible on SDS
- HMIS categories identify risks
 - Can’t use the designation #, & target organ effects may not be listed
 - Not on SDS
- SDSs
 - Expertise required to determine the “RISK”
 - Statements are far from standardized

Health Hazard Risks Considered for Control Banding

- | | | | |
|--|--|--|---|
| <input type="checkbox"/> R20 | <input type="checkbox"/> R26/28 | <input checked="" type="checkbox"/> R42/43 | <input type="checkbox"/> R48/25 |
| <input type="checkbox"/> R20/21 | <input type="checkbox"/> R27 | <input type="checkbox"/> R43 | <input type="checkbox"/> R49 |
| <input type="checkbox"/> R20/21/22 | <input type="checkbox"/> R27/28 | <input type="checkbox"/> R45 | <input type="checkbox"/> R60 |
| <input checked="" type="checkbox"/> R20/22 | <input type="checkbox"/> R28 | <input type="checkbox"/> R46 | <input type="checkbox"/> R61 |
| <input type="checkbox"/> R21 | <input type="checkbox"/> R34 | <input type="checkbox"/> R48/20 | <input type="checkbox"/> R62 |
| <input type="checkbox"/> R21/22 | <input type="checkbox"/> R35 | <input type="checkbox"/> R48/20/21 | <input type="checkbox"/> R63 |
| <input type="checkbox"/> R22 | <input type="checkbox"/> R36 | <input type="checkbox"/> R48/20/21/22 | <input type="checkbox"/> R64 |
| <input type="checkbox"/> R23 | <input type="checkbox"/> R36/37 | <input type="checkbox"/> R48/20/22 | <input type="checkbox"/> R65 |
| <input type="checkbox"/> R23/24 | <input type="checkbox"/> R36/37/38 | <input type="checkbox"/> R48/21 | <input type="checkbox"/> R66 |
| <input type="checkbox"/> R23/24/25 | <input type="checkbox"/> R36/38 | <input type="checkbox"/> R48/21/22 | <input type="checkbox"/> R67 |
| <input type="checkbox"/> R23/25 | <input type="checkbox"/> R37 | <input type="checkbox"/> R48/22 | <input type="checkbox"/> R68 Muta cat 3 |
| <input type="checkbox"/> R24 | <input checked="" type="checkbox"/> R37/38 | <input type="checkbox"/> R48/23 | |
| <input type="checkbox"/> R24/25 | <input type="checkbox"/> R38 | <input type="checkbox"/> R48/23/24 | |
| <input type="checkbox"/> R25 | <input type="checkbox"/> R40 Carc cat 3 | <input type="checkbox"/> R48/23/24/25 | |
| <input type="checkbox"/> R26 | <input type="checkbox"/> R40 Muta cat 3 | <input type="checkbox"/> R48/23/25 | |
| <input type="checkbox"/> R26/27 | <input checked="" type="checkbox"/> R41 | <input type="checkbox"/> R48/24 | |
| <input type="checkbox"/> R26/27/28 | <input type="checkbox"/> R42 | <input type="checkbox"/> R48/24/25 | |

None of the above R-phrases apply.

If you wish to see a full description of what the R-phrases mean click [here](#)

<<Back 

Some Countries Don't Use R-Phrases

- How can employers and workers convert hazard phrases from SDSs into “Risk Phrases”?



International Mandate

- An international mandate to harmonize was adopted at the United Nations Conference on the Environment and Development (UNCED) in 1992 in Brazil:
 - *A globally-harmonized hazard classification and compatible labeling system, including material safety data sheets and easily understandable symbols, should be available, if feasible, by the year 2000.*

What should be done until this effort is reality?

Need a simplified matrix!

Health Hazards to Consider:

- Acute Toxicity
- Skin Corrosion/Irritation
- Serious Eye Damage/Eye Irritation
- Respiratory or Skin Sensitization
- Germ Cell Mutagenicity
- Carcinogenicity
- Reproductive Toxicity
- Target Organ Systemic Toxicity – Single & Repeated Dose

WEEL Banding Matrix - Validation

Criterion	A	B	C	D	E
Acute toxicity (Rat oral LD50)	>2,000 mg/kg	300-2,000 mg/kg	50-300 mg/kg	5-50 mg/kg	<5 mg/kg
Acute toxicity (Rat inhalation LC50)	>10,000 ppm	>10,000 ppm	1000-10,000 ppm	100-1000 ppm	1-100 ppm
Sensory irritation (RD50)	>3,000 ppm	>3,000 ppm	300-3000 ppm	30-300 ppm	1-30 ppm
Skin or eye irritation	mild to moderate	moderate to severe	severe to corrosive	corrosive	corrosive
Irritation threshold (ppm)	>1000	100-1000	10-100	1-Oct	<1
Target organ toxicity NOEL	>1000 ppm >100 mg/kg/d	>1000 ppm 10-100 mg/kg/d	100-1000 ppm 1-10 mg/kg/d	10-100 ppm 0.1-1 mg/kg/d	1-10 ppm <0.1 mg/kg/d
Severity of target organ toxicity	severity of the toxicity can push the above NOEL into a higher cell				
Repro/dev tox NOEL	>300 mg/kg/d	30-300 mg/kg/d	3-30 mg/kg/d	0.3-3 mg/kg/d	<0.3 mg/kg/d
Reproductive toxicity	severity of the toxicity can push the above NOEL into a higher cell				
Developmental toxicity	severity of the toxicity can push the above NOEL into a higher cell				
Genetox	negative	equivocal	likely / limited or based on <i>in vitro</i>	positive WOE including <i>in vivo</i>	positive WOE and potent
Cancer dose	>300 mg/kg/d	30-300 mg/kg/d	3-30 mg/kg/d	0.3-3 mg/kg/d	<0.3 mg/kg/d
Carcinogenicity potential	severity of the toxicity can push the above NOEL into a higher cell				
Warning properties / odor	good	good	fair to none	poor to none	poor to none
WEEL range (mcg/m3 and ppm)	≥1000	≥100, <1000	≥10, <100	≥1, <10	<1
Skin notation	No	Yes	Sensitization notation	No	Yes



Simplified Matrix

SDS Phrases vs. R-Phrases

Until a global harmonized R-Phrase system is available, could categorize SDS statements according to:

- **Not Dangerous / Hazardous**
 - **Harmful: Caution**
 - **Toxic: Warning**
 - **Very Toxic: Dangerous**
-

Harmful: Caution

R-Phrases	Statement
R20	Harmful by inhalation
R20/21	Harmful by inhalation and in contact with skin
R20/21/22	Harmful by inhalation, in contact with skin and if swallowed
R20/22	Harmful by inhalation and if swallowed
R21	Harmful in contact with skin
R21/22	Harmful in contact with skin and if swallowed
R22	Harmful if swallowed
R36	Irritating to eyes
R36/37	Irritating to eyes and respiratory system
R36/37/38	Irritating to eyes, respiratory system and skin
R36/38	Irritating to eyes and skin
R37	Irritating to respiratory system
R37/38	Irritating to respiratory system and skin
R38	Irritating to skin
R65	Harmful: may cause lung damage if swallowed
R66	Repeated exposure may cause skin dryness or cracking
R67	Vapours may cause drowsiness and dizziness
R68	Possible risk of irreversible effects
R68/20	Harmful: possible risk of irreversible effects through inhalation
R68/20/21	Harmful: possible risk of irreversible effects through inhalation and in contact with skin
R68/20/21/22	Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed
R68/20/22	Harmful: possible risk of irreversible effects through inhalation and if swallowed
R68/21	Harmful: possible risk of irreversible effects in contact with skin
R68/21/22	Harmful: possible risk of irreversible effects in contact with skin and if swallowed
R68/22	Harmful: possible risk of irreversible effects if swallowed

Toxic: Warning

R-Phrases	Statement
R23	Toxic by inhalation
R23/24	Toxic by inhalation and in contact with skin
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed
R23/25	Toxic by inhalation and if swallowed
R24	Toxic in contact with skin
R24/25	Toxic in contact with skin and if swallowed
R25	Toxic if swallowed
R33	Danger of cumulative effects
R34	Causes burns
R40	Limited evidence of a carcinogenic effect
R41	Risk of serious damage to eyes
R42	May cause sensitization by inhalation
R43	May cause sensitization by skin contact
R42/43	May cause sensitization by inhalation and skin contact
R60	May impair fertility
R61	May cause harm to the unborn child
R62	Possible risk of impaired fertility
R63	Possible risk of harm to the unborn child
R64	May cause harm to breast-fed babies

Very Toxic: Dangerous Including Long-Term Effects

R-Phrases	Statements
R26	Very toxic by inhalation
R26/27	Very toxic by inhalation and in contact with skin
R26/27/28	Very toxic by inhalation, in contact with skin and if swallowed
R26/28	Very toxic by inhalation and if swallowed
R27	Very toxic in contact with skin
R27/28	Very toxic in contact with skin and if swallowed
R28	Very toxic if swallowed
R30	Can become highly flammable in use
R32	Contact with acids liberates very toxic gas
R35	Causes severe burns
R39/23	Toxic: danger of very serious irreversible effects through inhalation
R39/23/24	Toxic: danger of very serious irreversible effects through inhalation and in contact with skin
R39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed
R39/23/25	Toxic: danger of very serious irreversible effects through inhalation and if swallowed
R39/24	Toxic: danger of very serious irreversible effects in contact with skin
R39/24/25	Toxic: danger of very serious irreversible effects in contact with skin and if swallowed
R39/25	Toxic: danger of very serious irreversible effects if swallowed
R39/26	Very Toxic: danger of very serious irreversible effects through inhalation
R39/26/27	Very Toxic: danger of very serious irreversible effects through inhalation and in contact with skin
R39/26/27/28	Very Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed
R39/26/28	Very Toxic: danger of very serious irreversible effects through inhalation and if swallowed
R39/27	Very Toxic: danger of very serious irreversible effects in contact with skin
R39/27/28	Very Toxic: danger of very serious irreversible effects in contact with skin and if swallowed
R39/28	Very Toxic: danger of very serious irreversible effects if swallowed

Very Toxic: Dangerous Including Long-Term Effects

R45	May cause cancer
R46	May cause heritable genetic damage
R48	Danger of serious damage to health by prolonged exposure
R48/20	Harmful: danger of serious damage to health by prolonged exposure through inhalation
R48/20/21	Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin
R48/20/21/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed
R48/20/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed
R48/21	Harmful: danger of serious damage to health by prolonged exposure in contact with skin
R48/21/22	Harmful: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed
R48/22	Harmful: danger of serious damage to health by prolonged exposure if swallowed
R48/23	Toxic: danger of serious damage to health by prolonged exposure through inhalation
R48/23/24	Toxic: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin
R48/23/24/25	Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed
R48/23/25	Toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed
R48/24	Toxic: danger of serious damage to health by prolonged exposure in contact with skin
R48/24/25	Toxic: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed
R48/25	Toxic: danger of serious damage to health by prolonged exposure if swallowed
R49	May cause cancer by inhalation



PB-ECLs Performance-Based - Exposure Control Levels

QEA Basics – Current Process

- List of chemicals with potential for exposure
 - Assign “hazard class” from OEL or tox properties (R-phrases or SDS statements)
 - Determine the Degree of Exposure
 - Determine the Duration or Frequency of Exposure

 - Focus on Priority 1, 2, and 3 for exposure control
-

Building the Matrix: Negligible Effects

Acute Effects				Exposure Limit		
Oral	4 Hr.	4 Hr.	Skin	OEL	OEL	
LD50- Rats	Inhalation LC50- Rats (Vapor)	Inhalation LC50- Rats (Aerosol)	LD50- Rabbits	PPM (vapor)	(mg/m3) (dust)	
(Mg/Kg)	(Mg/m3)	(Mg/m3)	(Mg/Kg)			
				500-999	(5-10)	<p><i>NEGLECTIBLE Effect</i></p> <p>no danger classification present</p> <p>no symbol or R phrases assigned</p>

Building the Matrix: Low Effects

Acute Effects				Exposure Limit		
Oral	4 Hr.	4 Hr.	Skin	OEL	OEL	
LD50- Rats	Inhalation LC50- Rats (Vapor)	Inhalation LC50- Rats (Aerosol)	LD50- Rabbits	PPM (vapor)	(mg/m3) (dust)	
(Mg/Kg)	(Mg/m3)	(Mg/m3)	(Mg/Kg)			
>2000	>20,000	>5000	>2000	50-499	(1-4.9)	<p><i>LOW Effect</i></p> <p>Symbols</p> <p>Xi: irritating (except sensitizing agent)</p> <p>R phrases</p> <p>R36 irritating to eyes</p> <p>R37 irritating to the respiratory system</p> <p>R38 irritation to skin</p>

Building the Matrix: Moderate Effects

Acute Effects		Exposure Limit				
Oral LD50- Rats (Mg/Kg)	4 Hr. Inhalation LC50- Rats (Vapor) (Mg/m3)	4 Hr. Inhalation LC50- Rats (Aerosol) (Mg/m3)	Skin LD50- Rabbits (Mg/Kg)	OEL PPM (vapor)	OEL (mg/m3) (dust)	
200 - 2000	2000 - 20,000	1000 - 5000	400 - 2000	10 - 49	(0.1-0.9)	<p style="text-align: center;"><i>MODERATE Effect</i></p> <p>Symbols</p> <p>Xn: harmful</p> <p>C: Corrosive</p> <p>R phrases</p> <p>R20 harmful by inhalation</p> <p>R21 harmful in contact with skin</p> <p>R22 harmful if swallowed</p> <p>R33 danger of cumulative effects</p> <p>R34 causes burns</p> <p>R40 possible risks of irreversible effect</p> <p>R41 risk of serious damage to eyes</p> <p>R42 may cause sensitization by inhalation (Xi)</p> <p>R43 may cause sensitization by skin contact (Xi)</p> <p>R62 possible risk of impaired fertility</p> <p>R63 possible risk of harm to the unborn child</p> <p>R64 may cause harm to breast fed babies</p>

Building the Matrix: Serious Effects

Oral LD50- Rats (Mg/Kg)	4 Hr. Inhalation LC50- Rats (Vapor) (Mg/m3)	4 Hr. Inhalation LC50- Rats (Aerosol) (Mg/m3)	Skin LD50- Rabbits (Mg/Kg)	OEL PPM (vapor)	OEL (mg/m3) (dust)	
<200	<2000	<1000	< 400	<10	(<0.1)	<p style="text-align: center;"><i>SERIOUS Effect</i></p> <p>Symbols</p> <p>T: toxic</p> <p>T+ very toxic</p> <p>R phrases</p> <p>R23 toxic by inhalation</p> <p>R24 toxic in contact with skin</p> <p>R25 toxic if swallowed</p> <p>R26 very toxic by inhalation</p> <p>R27 very toxic in contact with skin</p> <p>R28 very toxic if swallowed</p> <p>R30 causes serious burns</p> <p>R31 danger of very serious irreversible effects</p> <p>R32 may cause cancer</p> <p>R34 may cause heritable genetic damage</p> <p>R35 danger of serious damage to health by prolonged exposure</p> <p>R36 may cause cancer by inhalation</p> <p>R37 may impair fertility</p> <p>R38 may cause harm to the unborn child</p>

Within Dow – With or Without an OEL

- Priority 1 – Not allowed to continue working____Stop work to assess exposures and remediate as appropriate
- Priority 2 – Baseline monitoring.... adjust exposures with PPE, Controls, etc. and ongoing monitoring
- Priority 3 – Baseline monitoring to ensure compliance with OEL
- Priority 4 – QEA validates risk to worker is low... baseline monitoring
- Priority 5 – QEA validates risk to worker is negligible... no further action needed unless exposure potential changes

Within Dow – With or Without an OEL

What concentration do we target for monitoring without an OEL?

Dow Rule: No OEL → No Monitoring

■ Current Approach:

- Designate a “Hazard Class” based on the R-phrases, MSDS phrases, and typical tox endpoints
- Design to control concentrations within ‘order of magnitude’ concentration ranges [band] based on:
 - Hazards
 - Quantity
 - Temperature of process
 - Volatility/dustiness
 - Frequency and Duration of exposure

Generic CONTROL BANDING: Risk Assessment and Management

Health Hazard	Exposure Potential	Generic Risk Assessment	Control Approach (risk management)
Substances allocated to hazard group using Std. phrases	Substances allocated a dustiness or volatility band and a band for the scale of use	Combination of health hazard and exposure potential factors determine desired level of control	Type of approach needed to achieve adequate control



e-COSHH Essentials – Hazard Bands

Potential for harm

Least Hazardous \longrightarrow Most Hazardous

A	B	C	D	E
Skin, eye irritants; unclassified	Harmful on single exposure	Toxic, corrosive, etc.	Very toxic, toxic to reproduction	Asthma, cancer, genetic damage
R36 R38 No R	R20 R21 R22	R23, 24, 25 R34, 35 R37 R41, R43 R48/20/21/22	R26, 27, 28 R40 carc. R48/23/24/25 R60, 61, 62, 63	R42, R43,R45, R49 R46, R68
1 to 10 mg/m ³ dust 50 to 500 ppm vapour	0.1 to 1 mg/m ³ dust 5 to 50 ppm vapour	0.01 to 0.1 mg/m ³ dust 0.5 to 5ppm vapour	<0.01 mg/m ³ dust <0.5 ppm vapour	
S – causes harm in contact with skin and/or eyes				

Assigning PPE – The Global Matrix

Hazard	EU Risk Phrase	SDS Tox Description	PPE Assignment Prior to Risk Assessment
High / Danger	4; T; T+		
Carcinogenicity	R45 may cause cancer		Protect appropriate route of exposure with respirator or other PPE and engineering controls
Mutagenicity	R46 may cause heritable genetic damage		
Subchronic & Chronic	R48 danger of serious damage to health by prolonged exposure		
Carcinogenicity	R49 may cause cancer by inhalation		
Reproductive	R60 may impair fertility		
Developmental	R61 may cause harm to the unborn child		
Eye	R35 causes serious burns; R39 danger of very serious irreversible effects	Corrosive; Impairment of vision; blindness; - Splash Potential - Particles that could get under glasses - Working in areas with overhead splash potential	Chemical Goggles - no option
Skin Contact	R24 toxic in contact with skin; R27 very toxic in contact with skin; R35 causes serious burns	Short, single exposure may cause severe burns; prolonged repeated exposure may cause severe burns	Face shield; Protective gloves; Full skin coverage with appropriate barrier material
Inhalation	R23 toxic by inhalation; R26 very toxic by inhalation;	Excessive concentrations readily attainable & may cause death; single brief exposure may cause death (LC50 1-hr < 200 ppm or < 2 mg/liter	Appropriate respirator mandatory unless complete containment is verified for all aspects of the operation.. With no chance of release or emission
Skin Absorption	R39 danger of very serious irreversible effects	May be fatal if absorbed through the skin; LD50 < 200 mg/kg	All skin and mucous membranes protected with appropriate barrier PPE including but not limited to goggles, full hooded impervious suit, face shield; shoe coverings; etc.
Ingestion	R25 toxic if swallowed; R28 very toxic if swallowed	LC50 < 50 mg/kg; Single dose oral toxicity high or very high, severe burns of the mouth	Policy enforced for personal hygiene and no eating, smoking etc. plus decontamination of PPE prior to removal.

Hazard	EU Risk Phrase	SDS Tox Description	PPE Assignment Prior to Risk Assessment
Moderate/ Warning	3; Xn: harmful; C: Corrosive		
Long-Term Effects (Subchronic & Chronic)	R40 possible risks of irreversible effect		Protect appropriate route of exposure with respirator or other PPE and engineering controls
Reproductive	R62 possible risk of impaired fertility		
Developmental	R63 possible risk of harm to the unborn child		
Subchronic & Chronic	R64 may cause harm to breast fed babies		
Eye	R39 danger of very serious irreversible effects; R41 risk of serious damage to eyes	Moderate or severe irritation; some irreversible damage possible	Chemical Goggles - no option
Skin Contact	R21 harmful in contact with skin; R-43; R34 causes burns	Severe irritation; prolonged or repeated exposure may cause skin burns; allergic skin reaction in humans	Protective gloves; Skin coverage with appropriate barrier material based on potential for contact with the chemical; optional Face shield
Inhalation	R20 harmful by inhalation; R-45 (Cancer); R42 may cause sensitization by inhalation (Xi)	Excessive concentrations readily attainable & may cause death; single brief exposure may cause death	Appropriate respirator mandatory unless complete containment is verified for all aspects of the operation. Risk assessment of practices and engineering controls required to remove the respirator requirement.
Skin Absorption	R33 danger of cumulative effects; R43 may cause sensitization by skin contact (Xi)	A single prolonged exposure may cause absorption in harmful amounts; repeated exposure could cause death.	All skin and mucous membranes with potential for exposure protected with appropriate barrier PPE; Risk assessment required of practices & engineering controls to remove the minimum PPE requirement.
Ingestion	R22 harmful if swallowed	Single dose or toxicity LC50 > 50 mg/kg < 500 mg/kg	Policy enforced for personal hygiene and no eating, smoking etc. plus decontamination of PPE prior to removal.

Caution - Harmful

Hazard	EU Risk Phrase	SDS Tox Description	PPE Assignment Prior to Risk Assessment
Low / Caution	2; Xi: irritating (except. sensitizing agent: => 3)		
Eye	R36 irritating to eyes; R41 risk of serious damage to eyes	Corrosive; Impairment of vision; blindness; - Projectiles - General protection	Chemical Goggles - no option
Skin Contact	R38 irritation to skin	Short, single exposure may cause severe burns; prolonged repeated exposure ay cause severe burns	Face shield; Protective gloves; Full skin coverage with appropriate light-weight barrier material
Inhalation	R37 irritating to the respiratory system	Excessive concentrations readily attainable & may cause death; single brief exposure may cause death (LC50 1-hr < 200 ppm or < 2 mg/liter	Appropriate respirator mandatory unless complete containment is verified for all aspects of the operation.. With no chance of release or emission
Skin Absorption	R21-Harmful in contact with skin	May be fatal if absorbed through the skin; LD50 < 200 mg/kg	All skin and mucous membranes protected with appropriate light weight barrier PPE
Ingestion	R-22 Harmful if swallowed	LC50 < 50 mg/kg; Single dose oral toxicity high or very high, severe burns of the mouth	Policy enforced for personal hygiene and no eating, smoking etc. plus decontamination of PPE prior to removal.

Hazard	EU Risk Phrase	SDS Tox Description	PPE Assignment Prior to Risk Assessment
Negligible / Precautionary	1		
Eye	N/A	No corneal injury; slight transient irritation; essentially non-irritating	Safety Glasses
Skin Contact	N/A	Slight transient irritation; essentially non-irritating	Lab coat or uniform; Light barrier gloves
Inhalation	N/A	No adverse effects. not likely to be hazardous; dust may cause irritation; exposure to vapors unlikely	None
Skin Absorption	N/A	LD50 >2000 mg/kg	Lab coat or uniform; Light barrier gloves
Ingestion	N/A	LD50 >2000 mg/kg	Policy enforced for personal hygiene and no eating, smoking etc. plus decontamination of PPE prior to removal.

Non-hazardous..... determination must be archived!

**Typical Classifications of
Acute Physical & Toxicological Hazards*
(SDS → Risk Categories)**

Signal Words	Danger (High)	Warning (Moderate)	Caution (Low)	Not Classified as Dangerous
Hazard				
Flammability	Flashpoint < 20°F Extremely flammable liquid and vapor	20°F ≤ F.P. < 100°F Flammable liquid and vapor. Flammable Solid.	100°F ≤ F.P. < 200°F Combustible liquid and vapor.	Flashpoint ≥ 200°F
Reactivity	Ready detonation or explosive decomposition at normal temperature and pressure	Normally unstable. Detonation possible with strong initiation. Violent reaction with water.	Unstable at elevated temperatures and pressures. Reacts nonviolently with water.	Essentially nonreactive
Skin Absorption	LD ₅₀ ≤ 200mg/kg May be fatal if absorbed through skin.	200 < LD ₅₀ ≤ 1000 mg/kg A single prolonged exposure may cause absorption in harmful amounts; repeated exposure could cause death	1000 < LD ₅₀ ≤ 2000 mg/kg Repeated exposure may result in absorption of harmful amounts even though LD ₅₀ may be unknown or is > 2000 mg/kg.	LD ₅₀ > 2000 mg/kg
Inhalation	LC ₅₀ ≤ 200 ppm or ≤ 2mg/liter for 1 hr. Excessive concentrations readily attainable and may cause death; single brief exposure may cause death	200 < LC ₅₀ ≤ 2000 ppm, or 2 < LC ₅₀ ≤ 20 mg/liter for 1 hr. Excessive concentrations readily attainable and may cause death; single brief exposure may cause death	LC ₅₀ ≥ 2000 ppm, or > 20 mg/liter for 1 hr. Could be hazardous on single exposure; simple asphyxia; may cause irritation to upper respiratory tract/lungs/eyes; prolonged excessive exposure may cause adverse effects.	LC ₅₀ > 2000 ppm, or > 20 mg/liter No acute effects, or only at high concentrations; may cause minor respiratory irritation
Ingestion	LC ₅₀ ≤ 50 mg/kg Single dose oral toxicity high or very high; severe burns of mouth.	50 < LD ₅₀ ≤ 500 mg/kg Single dose oral toxicity moderate or moderate to high.	500 < LD ₅₀ ≤ 2000 mg/kg Single dose oral toxicity low or low to moderate.	LD ₅₀ > 2000 mg/kg
Eye/Skin Contact				
Eye	Impairment of vision; blindness; corrosive. Short, single exposure may cause severe burns; prolonged, repeated exposure may cause severe burns	Moderate or severe irritation, injury. Severe irritation; prolonged or repeated exposure may cause skin burns; allergic skin reaction in humans.	Slight irritation; slight corneal injury. Slight to moderate irritation, even a burn on single, prolonged, or repeated exposure; allergic skin reaction in susceptible individuals	No contact injury; slight irritation; moderate, severe irritation
Skin				

Control Bands: **D** **C** **B** **A**

PB-ECL Summary

- In order to assign control bands, hazards must be converted to “risk”
- Need to globally harmonize this process
- During the “gap period”, need a simplified matrix to apply control bands
 - Based on SDS phrases or tox endpoints