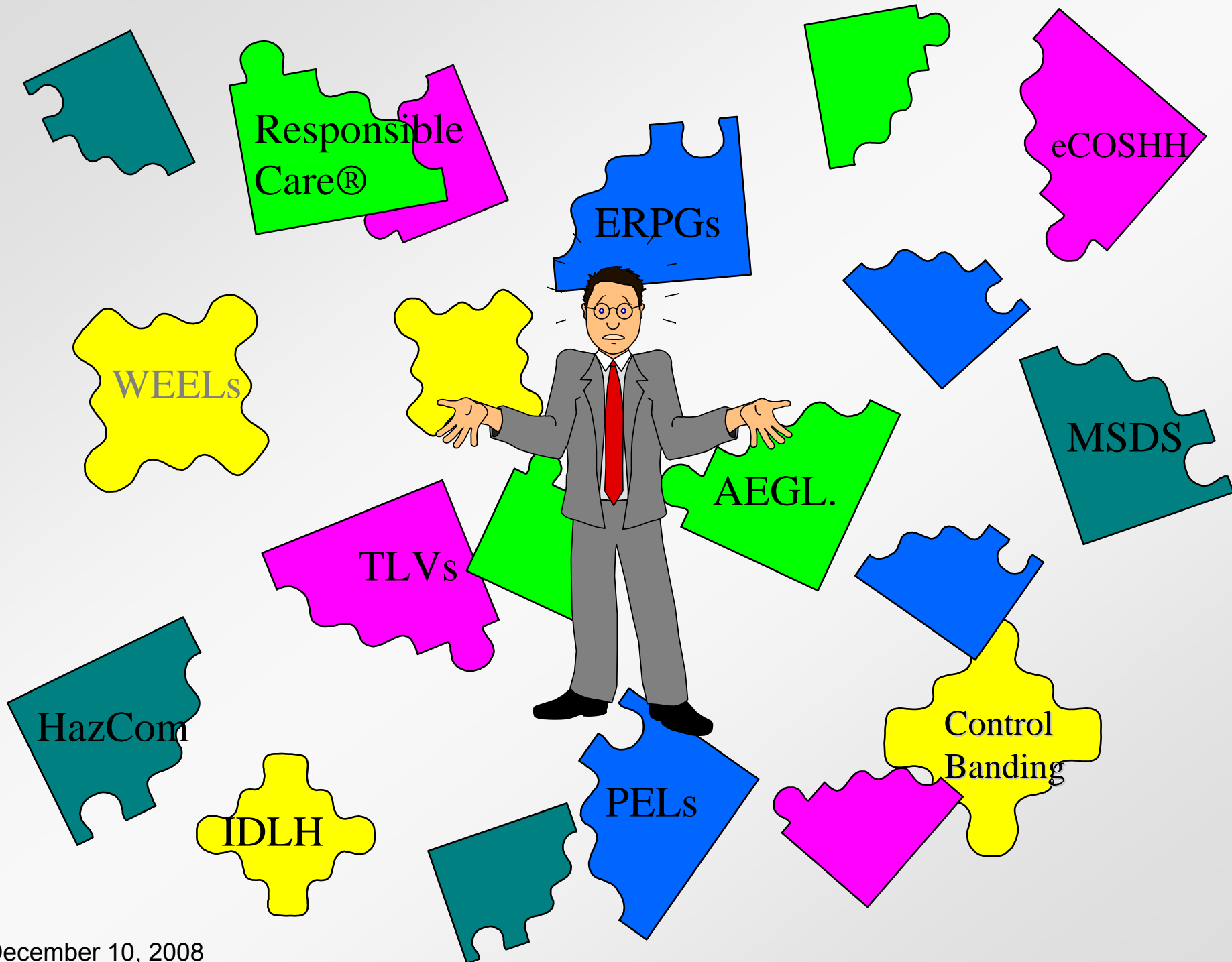




SETTING GLOBAL ENVIRONMENTAL HEALTH & SAFETY STANDARDS

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The Dow Chemical Company



Responsible
Care®

ERPGs

eCOSHH

WEELS

MSDS

AEGL.

TLVs

HazCom

Control
Banding

IDLH

PELs

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

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
- Exposure Assessment Issues
 - OELs and Hazard Evaluations
 - Monitoring Methods
 - Standardized Exposure Control Strategies → PB-ECLs

Globally

35 Certified IHs
>2000 EH&S Professionals

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

Focus Today

- Assessing hazards and risks from chemicals in a globally responsible way
- Hazard and Risk Assessment Strategies
 - Setting 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.

OELs

- OELs are set for a variety of reasons but primarily to:
 - Perform a **standardized hazard assessment** of a material (using standard tox & medical endpoints)
 - Communicate a relatively **safe target concentration** vs. time interval for employees from the hazard assessment which can be verified quantitatively for compliance
 - Thus **provide a target control approach** to ensure employees are not overexposed

Global Risk-Based Approach

- Many 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

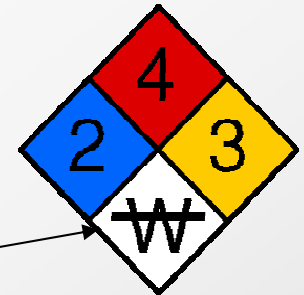
Topic Discussions

- 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.

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/m ³ 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

Toxic⁺: Danger

R-Phrases	Statement
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

Toxic⁺: Danger

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

Negligible Effects

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)			
>4000	>40,000	>10,000	>5000	500-999	(5-10)	<p><i>NEGLIGIBLE Effect</i></p> <p>no danger classification present</p> <p>no symbol or R phrases assigned</p>

Low Hazards and Effects

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)	<i>LOW Effect</i>
						Symbols
						Xi: irritating (except sensitizing agent)
						R phrases
						R36 irritating to eyes
						R37 irritating to the respiratory system
						R38 irritation to skin

Building the Matrix: Moderate 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	2000 - 20,000	1000 - 5000	400 - 2000	10 - 49	(0.1-0.9)	<p><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 style="padding-left: 20px;">T : toxic</p> <p style="padding-left: 20px;">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>R35 causes serious burns</p> <p>R39 danger of very serious irreversible effects</p> <p>R45 may cause cancer</p> <p>R46 may cause heritable genetic damage</p> <p>R48 danger of serious damage to health by prolonged exposure</p> <p>R49 may cause cancer by inhalation</p> <p>R60 may impair fertility</p> <p>R61 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

<p>Health Hazard +</p>	<p>Exposure Potential</p> <p style="text-align: right;">➔</p>	<p>Generic Risk Assessment</p> <p style="text-align: right;">➔</p>	<p>Control Approach (risk management)</p>
<p>Substances allocated to hazard group using Std. phrases</p>	<p>Substances allocated a dustiness or volatility band and a band for the scale of use</p>	<p>Combination of health hazard and exposure potential factors determine desired level of control</p>	<p>Type of approach needed to achieve adequate control</p>

e-COSHH Essentials – Hazard Bands

Potential for harm

Least Hazardous
Hazardous

Most

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		
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.
Decomposition	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; <ul style="list-style-type: none"> · 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!

Signal Words Hazard	Danger (High)	Warning (Moderate)	Caution (Low)	Not Classified as Dangerous
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 adverse effects; not likely to be hazardous; dust may cause irritation; exposure to vapors unlikely.
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.	Moderate or severe irritation, injury.	Slight irritation; slight corneal injury.	No corneal injury; slight, transient irritation.
Skin	Short, single exposure may cause severe burns; prolonged, repeated exposure may cause severe burns	Severe irritation; prolonged or repeated exposure may cause skin burns; allergic skin reaction in humans.	Slight to moderate irritation, even a burn on single, prolonged, or repeated exposure; allergic skin reaction in susceptible individuals	Essentially nonirritating

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

And for Product Guidance.....

PB-ECL Control Guidance Sheets
for End-Users

Control Banding Guidance



Control Guidance Sheet 301

Controlling Exposures to Isothiazoline Formulations

General Guidance for Safe Handling

Containment **301**

This guidance sheet is intended to provide best practice advice. It is designed to help employers, including the self-employed and small businesses, address potentially hazardous conditions in the workplace. The recommendations are intended to provide information for identifying specific hazardous substances or work activities and simple precautions for minimizing risks to workers. This guidance was developed by The Dow Chemical Company through evaluation of specific work environments and industry sectors.

Obtain (Material) Safety Data Sheets from your product supplier. Use the information on these sheets to identify the hazards associated with specific chemicals and to explore the possibility of using safer substitutes. If several products are equally efficacious try to use the least hazardous product(s).

All employees exposed or liable to be exposed to a substance which may cause adverse health effects during "normal" use should be under suitable health surveillance. The extent and detail of the health surveillance should be related to the degree of risk identified during an assessment. An occupational health professional should be consulted to determine the degree of risk and level of surveillance. Health surveillance should include the maintenance of a health record in a suitable form for each exposed individual. This guidance sheet can be used as part of the approach to control potential adverse health effects from inhalation of vapours.

Local ventilation is the recommended approach accompanied by use of appropriate protective equipment.

See COSHH Essential Control Guidance Sheets 400 (www.coshh-essentials.org.uk/assets/files/G400.pdf) and 402 (www.coshh-essentials.org.uk/assets/files/G402.pdf).

This guidance sheet is currently in DRAFT form awaiting review and approval. Please do not quote, cite, or distribute.

Workplace and access

- Isothiazoline formulations are classified in 'Hazard Class C', based on hazards, and therefore emissions and worker exposures should be controlled between 0.5 and 5 ppm vapor eq. (____ - ____ mg/m³) total aerosol/particles for the active ingredient.
- Ensure that only trained workers have access to isothiazoline formulations throughout any process. Training should include information about potential hazards, methods to control these hazards, and proper handling procedures for all products containing isothiazoline formulations.
- Do not remove labels from isothiazoline containers. Re-label transfer containers with the hazards and warnings from the original label.
- Limit access to the work areas where isothiazoline aerosol/particles might be present.
- Identify all potential employee exposure points to isothiazoline, including inhalation of aerosol droplets/particles or skin and eye contact.
- Personal protective equipment and local exhaust engineering controls are an important part of preventing health effects in workers.
- Develop your local spill cleanup plan and train workers for spill response.
- Keep an isothiazoline spill cleanup kit or station outside of the area where the formulations are used or stored to allow access if a spill occurs.

Design and equipment

- Keep the area well ventilated – 12 air changes per hour with a once-through draft in all areas.
- Use engineering controls to limit aerosol/particle exposures at or near the area where the solution is applied by drawing any vapor or droplets down and away from worker breathing zones.
- Do not use local exhaust ventilation designed to pull aerosol/particles upwards.
- Keep isothiazoline containers closed when not in use.
- Never allow isothiazoline formulations to make contact with the skin.
- Have hand-washing facilities readily available for decontamination after working with isothiazoline formulations, preferably near the work area and another near the exit.
- Place emergency eye wash and deluge shower stations in close vicinity of the work area where isothiazoline is used.
- Contain spills of isothiazoline formulations after the proper personal protective equipment and respirators are put on.

Control Guidance Sheet 301

Procedures

- Never enter an area where a spill has occurred without the proper personal protective equipment (PPE) and training.
- Safely dispose of all products you no longer need.
- Store products containing chemicals securely in a cool, dry, dark place, capable of containing spills.
- Clean up spills immediately following an emergency spill cleanup plan. Absorb liquids with the materials provided in the spill cleanup kit and follow your spill cleanup and disposal procedures.
- Always check the air exhaust or local ventilation with filter strips regularly to assure proper operation.
- Store isothiazoline containers so their labels face forward and store containers below eye level to avoid splashing in eyes.
- Never stand near open equipment or open application activities of isothiazoline formulations without proper PPE, including gloves, splash goggles and rubber boots.
- Wash or shower if skin is exposed to isothiazoline formulations. Flush eyes if contacted with isothiazoline formulations.

Cleaning and housekeeping

- Keep the work area clean and well organized.
- Clean up spills promptly – practice how to do this at least twice per year.
- Dispose of empty containers and wastes safely.
- Wear appropriate PPE when cleaning up a spill.

Special care

Brief skin contact with isothiazoline solutions may cause severe allergic skin irritation (itchiness, itching, rashes) or severe burns. Contact with the eyes causes severe damage to the cornea which may result in blindness. Isothiazoline solution mists are irritating to the nose, throat and lungs.

Personal Protective Equipment (PPE)

- Follow the instructions on product labels and/or safety data sheets.
- Ask your safety-clothing supplier to help you purchase the appropriate PPE.
- Make sure you know how to check that PPE fits correctly. Seek advice from your Safety Manager or supplier.
- Wear protective gloves - single-use nitrile gloves are acceptable. Natural rubber latex gloves are not recommended due to potential latex allergies.
- Dispose of single-use gloves every time you take them off.
- Skin creams are important for skin protection and help in washing contamination from the skin. These are not barrier creams, and do not protect the skin from isothiazoline exposures. After work, creams help to replace skin oils.

Training

- Show your workers this sheet and make certain that they understand it.
- Instruct workers about the hazards of isothiazolines. See product labels or the (Material) Safety Data Sheet from your product supplier.
- Make certain everyone wears the required PPE, special attention to goggles and gloves is important.
- Make certain everyone knows how to clean up spills promptly and safely according to your emergency spill cleanup plan.

Supervision

- Check that ventilation is working properly and that PPE is being used correctly.
- Ensure that employees see a health care professional if they develop skin or eye irritation symptoms.

Further information

- Consult the supplier's (Material) Safety Data Sheet for further information or contact phone numbers for emergency information. Additional information can be obtained from the NIOSH toll-free number 1-800-35-NIOSH (1-800-235-4874) within the U.S. or 313-533-3333 outside the U.S., or access the web site at http://www.cdc.gov/niosh/topic_nit.html

Employee checklist

- Check that your Personal Protective Equipment (PPE) works properly every time you put it on.
- Use, maintain and store your PPE in accordance with instructions.
- If you encounter any problems, tell your supervisor. Don't just carry on working.
- Wash your hands after use, and before and after eating, drinking, smoking and using the toilet.
- Never clean your hands with concentrated cleaning products or solvents.
- Clean up spills immediately. Wear the appropriate PPE. Use absorbent granules for spills and put them in a lidded waste container.
- Always follow the standard operating procedures.
- Report skin soreness and itching, nausea, blistering (dermatitis), or irritation to the eye immediately to your supervisor and a designated health care professional.

Questions?

