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HUMAN HEALTH RISK ASSESSMENT


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RISK ASSESSMENT METHODOLOGY

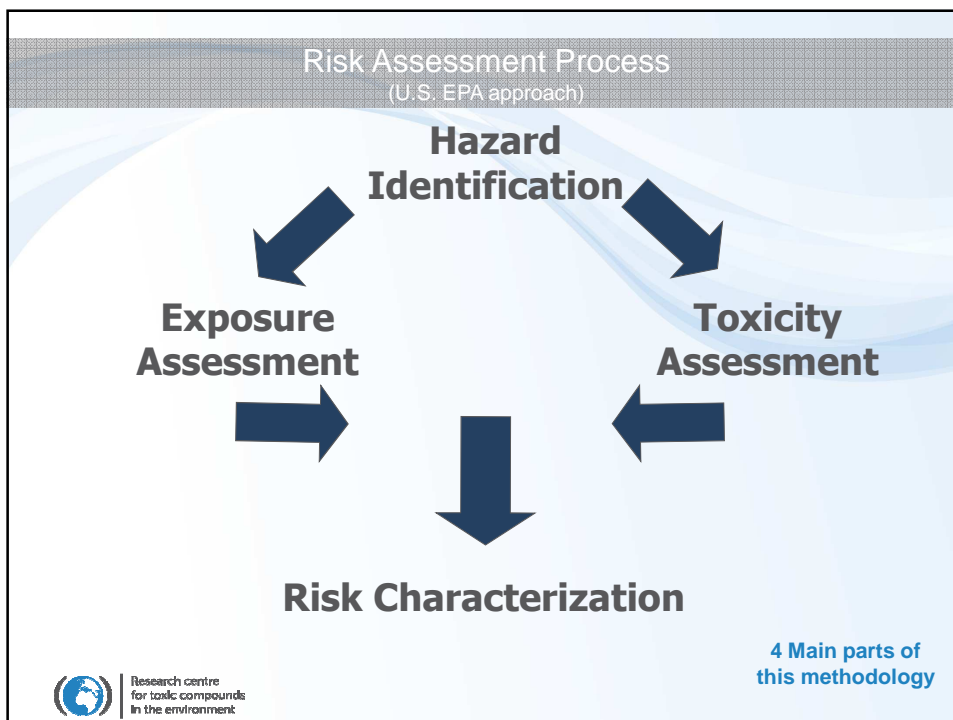
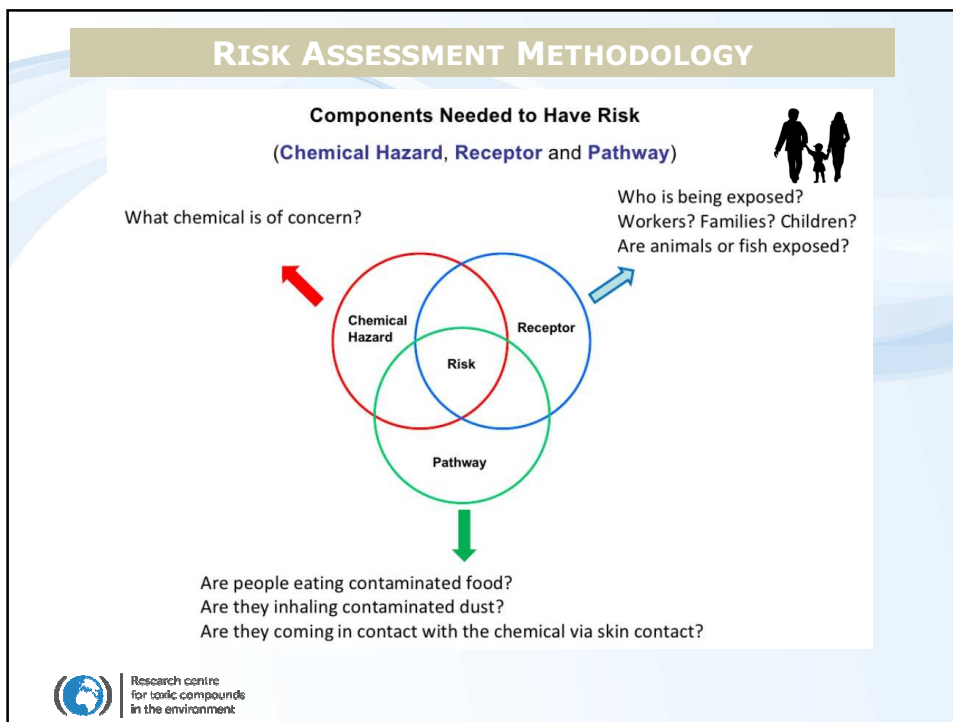
Human health risk assessment is the **PROCESS to estimate** the probability of adverse health effects in humans who may be exposed to chemicals in contaminated environmental media

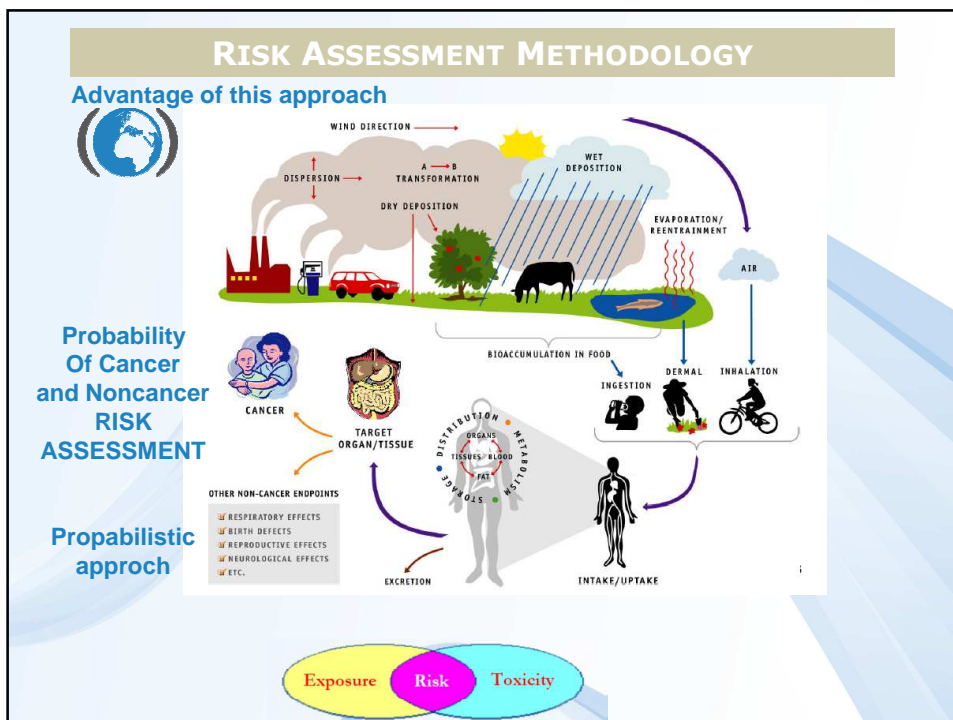
- food, drinking water, sediments, soil, air - inhalation....),
- for actual time or in the future (prospective estimation) or retrospective assessment (in the past...).

WHY we are doing RA?
– We must interpret all measured Concentrations - **CONTAMINATION**



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Step 1: Hazard Identification

The first step in the RA is the Hazard identification. The hazard identification defines the problem, explicitly identifies the components like:

- **Collected database about chemical concentration**
 - obtained by sampling
 - Or by modeling work
- **Info about toxicity of these chemicals**
- **Develop model of how chemical may move through environment**
 - **Conceptual Site Model** is used to organize information regarding chemicals and potential transport to organisms



AFCEE, 2002



© Vermont DPS, 2000

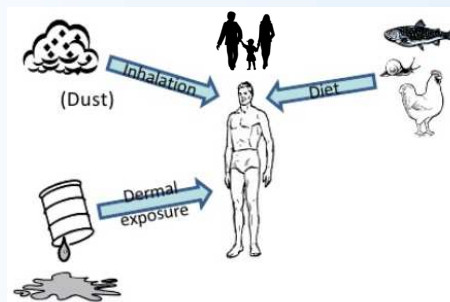
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Step 2: Exposure Assessment

The exposure assessment attempts to quantify the exposure of the receptor (selected population) to chemicals via a given pathway. The daily intake of a contaminant via individual pathways can then be summed to estimate the total daily intake TDI (mg/kg/day).

Exposure via individual exposure pathways can be calculated using contaminant concentrations in environmental samples (water, diet, sediments, soils, air..) and human behavior information (=exposure parameters = from exposure surveys).

Alternatively, total exposure (POPs,...) can be estimated by collecting human tissue samples for chemical analysis (i.e., blood and breast milk samples).



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Step 2: Exposure Assessment



- **Who is Exposed?**
 - Adult, Child, Special Populations
- **How Are They Exposed?**
 - Ingestion, Inhalation, Skin Contact
- **What is the Concentration of Chemical to Which They are Exposed?**
 - ppm in Water or Soil
- **How Often Are They Exposed?**
 - Days per year, Number of years

Prediction
of Exposure
scenarios



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Putting it all together. . . – exposure parameters

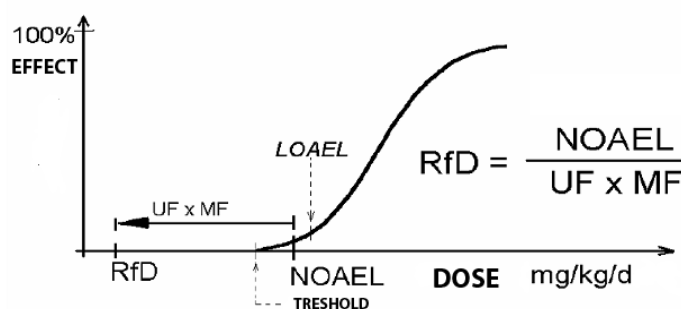
$$\text{Intake Dose } CDI (\text{mg/kg} - \text{day}) = \frac{C \times CR \times EF \times ED}{BW \times AT}$$

- Intake Equation for Drinking Water Example
 - C= Chemical Concentration (Obtain from sampling)
 - CR= Contact Rate (2 liters water/day)
 - EF= Exposure Frequency (350 days/year)
 - ED= Exposure Duration (30 years)
 - BW=Body Weight (70 kg.)
 - AT= Averaging Time (10,950 days)



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Step 3: Toxicity assessment / Dose-Response Curve relationship



The toxicity assessment attempts

- to quantify the sensitivity of the receptor to the chemical hazard (STRESOR).
- to use Dose/response relationship

Dose – Chemical concentration per unit body weight



Response – Level of measured adverse effect

- to quantify the Reference Dose – Chemical concentration per unit body weight without significant biolog. effects (<http://www.epa.gov/iris/rfd.htm>)



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Uncertainty Factors (UFs): (conditions for using of UF and MF)

- Use a 10-fold factor when extrapolating from valid experimental results in studies using prolonged exposure to average healthy humans. This factor is intended to account for the variation in sensitivity among the members of the human population and is referenced as "10H".
- Use an additional 10-fold factor when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. This factor is intended to account for the uncertainty involved in extrapolating from animal data to humans and is referenced as "10A".
- Use an additional 10-fold factor when extrapolating from less than chronic results on experimental animals when there are no useful long-term human data. This factor is intended to account for the uncertainty involved in extrapolating from less than chronic NOAELs to chronic NOAELs and is referenced as "10S".
- Use an additional 10-fold factor when deriving an RfD from a LOAEL, instead of a NOAEL. This factor is intended to account for the uncertainty involved in extrapolating from LOAELs to NOAELs and is referenced as "10L".

Modifying Factor (MF):

Use professional judgment to determine the MF, which is an additional uncertainty factor that is greater than zero and less than or equal to 10. The magnitude of the MF depends upon the professional assessment of scientific uncertainties of the study and data base not explicitly treated above; e.g., the completeness of the overall data base and the number of species tested. The default value for the MF is 1.

<http://www.epa.gov/iris/rfd.htm>



RISK ASSESSMENT METHODOLOGY – noncancer risk

[C] concentrations

Noncancer

Exposure scenario models

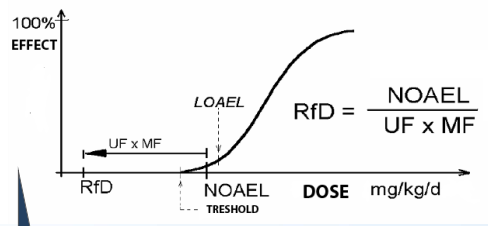
RISK = CDI / RfD

RISK > 1 Significant risk

Internal dose
Chronic Daily Intake



- Chemical 1
- Chemical 2
- Chemical 3
- ...
-
-

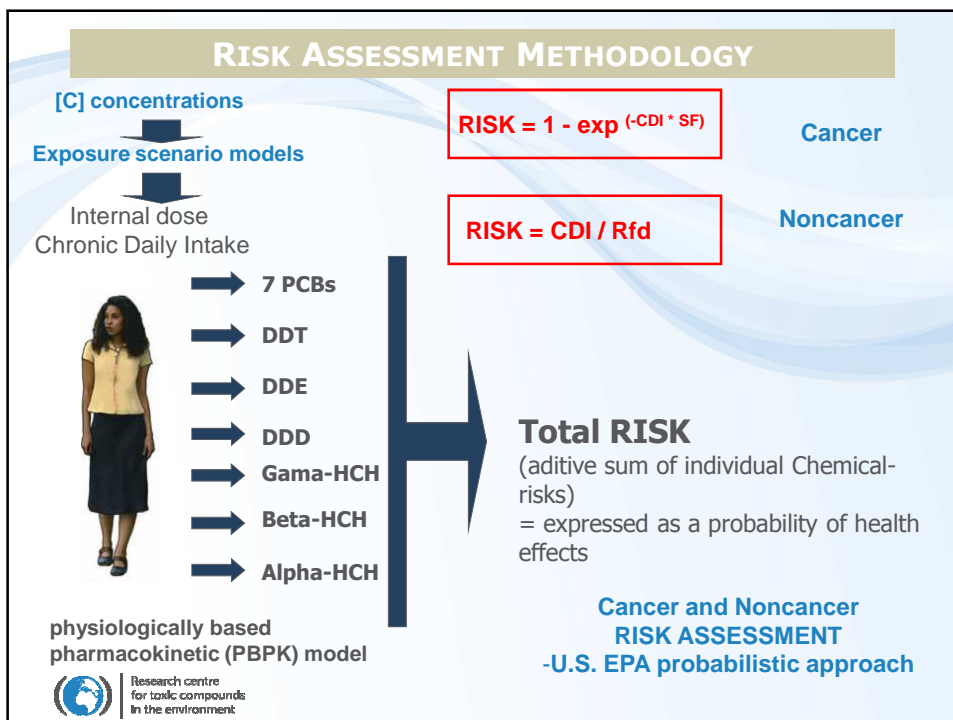
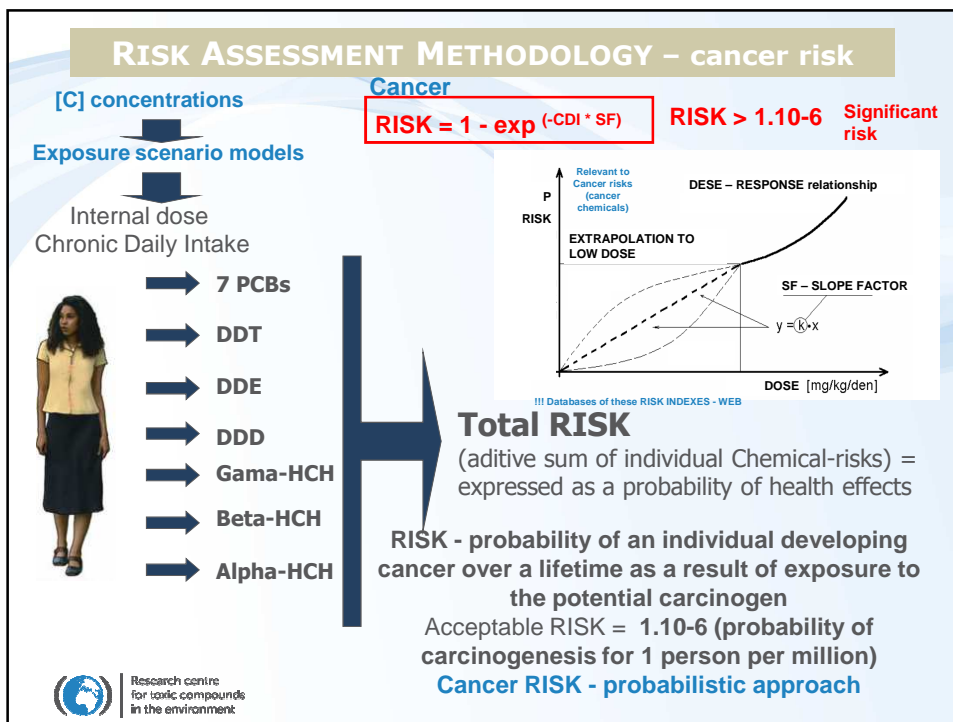


Total RISK
(aditive sum of individual Chemical-risks)

Noncancer RISK ASSESSMENT
RfD – reflect the worst type of health outcomes from this chemical

RfD = TDI Tolerable daily intake
(RfD is only for noncancer chemicals!!)





Step 4: Risk Characterization

The risk characterization combines the information obtained on toxicity with the calculated exposure to provide an estimate of risk.

Purdue 1997

Noncancer $RISK = CDI / RfD$ $RISK > 1$ Significant risk
Cancer $RISK = 1 - \exp(-CDI \cdot SF)$ $RISK > 1.10^{-6}$ Significant risk

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RISK ASSESSMENT METHODOLOGY

Spatial distribution of these both RISKS

Cancer

$RISK = 1 - \exp(-CDI \cdot SF)$

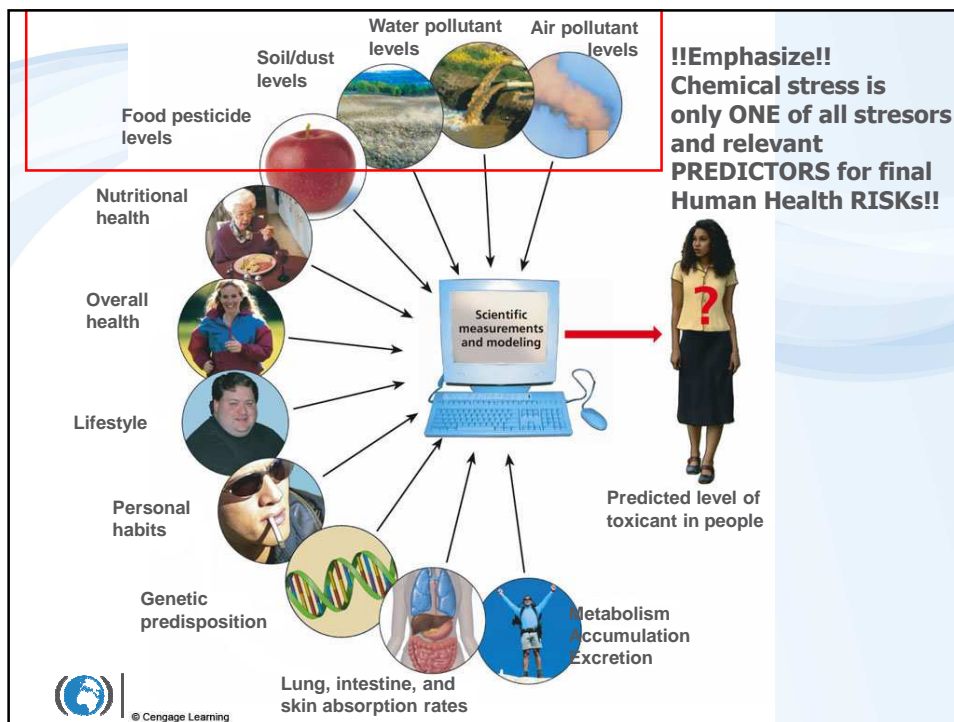
Noncancer

$RISK = CDI / RfD$

Total RISK
 (sum of individual Chemical-risks)
 All chemicals Together = expressed as a probability of health effects

Advantage –
 This RA allow us to realize the Exposure scenario models in future

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RISK ASSESSMENT METHODOLOGY

Detail description of Risk assessment method:

1) TGD - Technical Guidance Document on Risk Assessment

EC (European Commission 2003):

EC (European Commission 2003): Technical Guidance Document on Risk Assessment (Edition 2). Part II. Chapter 2 Risk Assessment for Human Health. (EUR 20418 EN/1).

http://ecb.jrc.ec.europa.eu/home.php?CONTENU=DOCUMENTS/TECHNICAL_GUIDANCE_DOCUMENT/EDITION_2/, Institute for Health and Consumer Protection. European Chemicals Bureau.

2) Quantitative Environmental Risk Analysis for Human Health – detail description of Risk assessment method with many exercises - case studies. (Robert A. Fjeld et al., 2007)

Robert A. Fjeld; Norman A. Eisenberg; Compton, K. L. Eds.) (2007): Quantitative Environmental Risk Analysis for Human Health. Chapter 9 Exposure Assessment, chapter 10 Basic Human Toxicology, chapter 11 Dose–Response and Risk Characterization, (pp 199-314). John Wiley & Sons, Inc. Hoboken, New Jersey.

3) Risk Assessment Guidance for Superfund, (U.S. EPA)

[Part A](#) (1989) [Part B](#) (1991) [Part C](#) (1991) [Part D](#) (2001) [Part E](#) (2004) [Part F](#) (2009)



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RISK ASSESSMENT METHODOLOGY

Where we can get these informations
SOURCES ? DATABASES?

**Source of important toxicological indexes:
RfD, Slope Factor...**

<http://www.epa.gov/reg3hwmd/risk/index.htm>

(CAS, chemicals..)

<http://www.epa.gov/iris>

example:
309-00-2

Substance	Milestone	Estimated Start Date
Propionaldehyde	External Peer Review	3/5/2008
2-Hexanone	External Peer Review	2/28/2008
Thallium	External Peer Review	2/15/2008

http://toxnet.nlm.nih.gov/

TOXNET - Windows Internet Explorer

http://toxnet.nlm.nih.gov/

Soubor Úpravy Zobrazit Obíbené položky Nástroje nápověda

Quinolone slope factor - Vyhle... US EPA Site Help & Tools | IRIS | US EPA EPA: Substance Registry Sys... TOXNET

United States National Library of Medicine **TOXNET** Toxicology Data Network

TOXNET PDA Access SIS Home About Us Site Map & Search Contact Us

Env. Health & Toxicology TOXNET

TOXNET - Databases on toxicology, hazardous chemicals, environmental health, and toxic releases.

Select Database

- ChemIDplus
- HSDB
- TOXLINE
- CCRIS
- DART
- GENETOX
- IRIS
- ITER
- LactMed
- Multi-Database
- TRI
- Haz-Map
- Household Products
- TOXMAP

Search All Databases

Enter term(s) to search all databases.

(e.g. asthma air pollution, ibuprofen fever, vinyl chloride)

Search Clear Help

TOXNET Search Options

- Search all databases: Enter term(s) in box above
- Search a specific database: Click database at left
- Database description: Click on the [?]

Env. Health & Toxicology

Portal to environmental health and toxicology resources

Support Pages

- Help
- TOXNET FAQ
- TOXNET Update Status
- Fact Sheet
- Database Description
- Training Manuals
- News

Additional Resource

http://www.inchem.org/

IPCS INCHEM - Windows Internet Explorer

http://www.inchem.org/

Soubor Úpravy Zobrazit Obíbené položky Nástroje nápověda

Chloranil (CCSC)

IPCS International Programme on Chemical Safety

INCHEM

Chemical Safety Information from Intergovernmental Organizations

Search options:

Full-text Search

Example: kofein 14201 201

Search

Chemical Identity Search

CAS Number

Example: 100-88-3

OR

Chemical Name or Synonym

Example: Toluene

Search

Advanced Search

Rapid access to internationally peer reviewed information on chemicals commonly used throughout the world, which may also occur as contaminants in the environment and food. It consolidates information from a number of intergovernmental organizations whose goal it is to assist in the sound management of chemicals.

Browse content using links below:

- Concise International Chemical Assessment Documents (CICADs)
- Environmental Health Criteria (EHC) Monographs
- Harmonization Project Publications
- Health and Safety Guides (HSGs)

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Thank you for your attention



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