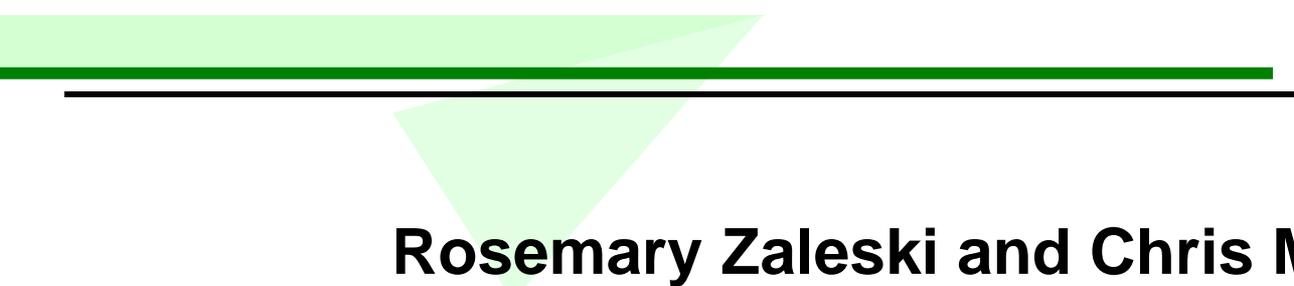


European Centre for Ecotoxicology and Toxicology of Chemicals Targeted Risk Assessment (ECETOC TRA) Tool



Rosemary Zaleski and Chris Money

On behalf of the ECETOC TRA Task Force

September 2008

Outline

- **ECETOC TRA:**

- /// Background on REACH

- /// Overview of ECETOC TRA

- Background

- Worker, Consumer, and Environmental modules

- Including current status and future plans for tool improvement

- **Another initiative of interest: HESI mixtures activity**

Registration, Evaluation and Authorization of Chemicals (REACH) - Introduction

- /// **All pre-REACH existing chemicals in commerce manufactured or imported at ≥ 1 ton per year must be registered**

- /// **For substances classified as dangerous, an exposure assessment and risk characterization is required for each end-use of each product (evaluation)**
 - All life cycle stages
 - Human direct use – worker and consumer
 - Human indirect – environmental emissions
 - Ecological receptors – environmental emissions
 - Include mitigation measures if needed

- /// **European Commission estimates:**
 - 30,000 substances to be registered
 - 5,000 – 6,000 substances to be evaluated

REACH - Timeline

Registration Dossiers including safety assessments to be completed by:

- 2010 for all substances manufactured/imported at \geq 1000 t/yr, and some lower tonnages depending upon classification
- 2013 for substances M/I at \geq 100 t/yr
- 2018 for substances M/I at \geq 1 t/yr

ECETOC Background

- **European Centre for Ecotoxicology and Toxicology of Chemicals**
 - /// Is a scientific, non-profit making, non-commercial trade association with a mission to act as an independent, credible, peer-reviewed technical resource to all concerned with the identification of research needs and provision of scientific rationale for the assessment of health effects and environmental impact
 - /// Membership consists of companies who manufacture or use chemicals
- **Goal: scientific-based pragmatic approach to efficiently and consistently screen chemicals based upon risk potential**

ECETOC Targeted Risk Assessment Tool Overview

- **Web-based, access and documentation on (www.ecetoc.org)**
- **Intentionally conservative assumptions to prevent false negatives**
- **Risk-based, tiered approach**
- **Tool evaluates uses and identifies handling procedures associated with safe use**
- **Covers worker, consumer and environmental exposures**
- **ECETOC currently making improvements based upon input from the European Chemical Agency and other stakeholders**

ECETOC TRA - Background

- **Core TRA concepts developed during 2002/3**
 - /// Presentations made at various scientific meetings
- **Early web-versions available in 4Q/03. Final version posted 2Q/04. TRA report published 1Q/04 (220+pp)-on www.ecetoc.org**
- **Subsequent to 2004, 1500+ registered users**
 - /// Evaluation by various industry and regulatory bodies
 - /// Chem. Safety Assessment (CSA) Tech. Guidance Doc. has endorsed the worker part of the TRA as a 'first line Tier 1 tool' for REACH
- **TRA Task Force 're-constituted' end Nov 2006 with the aim of identifying necessary science improvements and translating these into related Information Technology improvements**
- **Commission REACH-IT project foresees the TRA as serving a key role in the CSA/CSR IT tool**

Core Operating Philosophy for the TRA

- **A simple tiered process for determining which circumstances of use (Exposure Scenarios) constitute a concern or not**
 - /// **Expectation that the tool incorporates a certain inherent conservatism i.e. No false negatives**
 - /// **Implies suitable level of verifications of integrated proposals against a range of examples**
- **Examines the conditions arising from reasonable foreseeable use (following recommended Risk Mitigation Measures (RMMs)) and not 'worst case' extremes**
- **The TRA covers a range of conditions that can be expected to be required for the responsible stewardship of products**
- **Limited iteration at Tier 1 i.e. 'deferring' considerations that require professional judgements to be made until Tier 2**
- **Ensuring that the tool is accessible to non-experts but demands technical understanding consistent with 'responsible supply' of chemicals**
- **Maintaining transparency in the development and operation of the TRA tool**
- **Ensuring that the core principles on which the tool operates have wide applicability and are based on robust science**
 - /// **Adequate verification of new concepts**

ECETOC TRA - Worker

- **Based upon the Estimation and Assessment of Substance Exposure (EASE) model**
 - /// Established UK Health and Safety Executive occupational exposure model
 - /// Categorizes exposure based upon historical data in the UK's National Exposures Database
 - /// Exposure predicted based upon conditions of use and physical-chemical properties

ECETOC TRA - Consumer

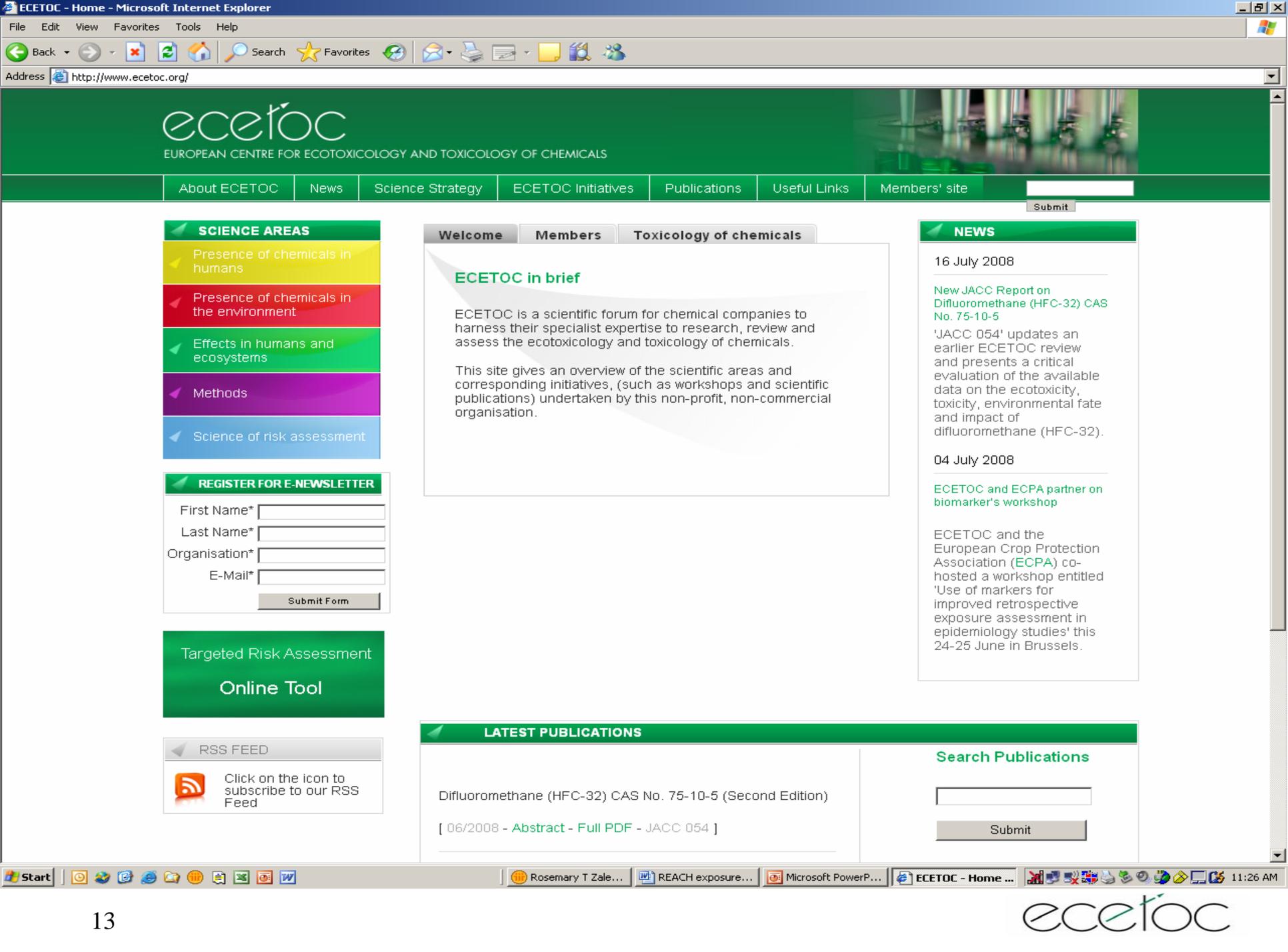
- **Simple linear equations**
- **Product-type based assessment**
 - /// Inhalation, dermal and oral routes and aggregate as appropriate
 - /// No risk mitigation measures in place (consistent with REACH consumer guidance)
 - /// Screening – assumes, for example, 100% substance in a product is released to air for inhalation exposure
 - does not consider physical-chemical properties

ECETOC TRA - Environment

- **Current web version very simplified, undergoing update**
- **Update is based upon a spreadsheet version of the European Union Substance Evaluation System (EUSES) multimedia model**

ECETOC TRA Walk-Through

- **Next few slides run through a test case example using the web-based TRA tool**
- **Note that the tool is in the process of being updated, and improvements to-date are not incorporated in the web version**
- **Slides provided to present an idea of:**
 - /// how the tool works
 - /// tool input
 - /// tool output



Submit

SCIENCE AREAS

- Presence of chemicals in humans
- Presence of chemicals in the environment
- Effects in humans and ecosystems
- Methods
- Science of risk assessment

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Targeted Risk Assessment

Online Tool

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Welcome | Members | Toxicology of chemicals

ECETOC in brief

ECETOC is a scientific forum for chemical companies to harness their specialist expertise to research, review and assess the ecotoxicology and toxicology of chemicals.

This site gives an overview of the scientific areas and corresponding initiatives, (such as workshops and scientific publications) undertaken by this non-profit, non-commercial organisation.

NEWS

16 July 2008

[New JACC Report on Difluoromethane \(HFC-32\) CAS No. 75-10-5](#)

'JACC 054' updates an earlier ECETOC review and presents a critical evaluation of the available data on the ecotoxicity, toxicity, environmental fate and impact of difluoromethane (HFC-32).

04 July 2008

[ECETOC and ECPA partner on biomarker's workshop](#)

ECETOC and the European Crop Protection Association (ECPA) co-hosted a workshop entitled 'Use of markers for improved retrospective exposure assessment in epidemiology studies' this 24-25 June in Brussels.

LATEST PUBLICATIONS

Difluoromethane (HFC-32) CAS No. 75-10-5 (Second Edition)

[06/2008 - [Abstract](#) - [Full PDF](#) - [JACC 054](#)]

Search Publications

Ecetoc - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <https://www.ecetoc-tra.org/index.asp>

--- THIS TOOL IS UNDER DEVELOPMENT AND IS NOT A FINAL VERSION ---
 --- THIS SITE WILL SHORTLY BE UPDATED TO REFLECT DIFFERENCES BETWEEN IT AND THE PUBLISHED FINAL TRA REPORT ---

ecetoc - Targeted Risk Assessment

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Welcome to the ECETOC Targeted Risk Assessment Web Tool

Introduction

This web-based system is the initial electronic implementation of the proposals from an [ECETOC](#) Task Force on Targeted Risk Assessment * which was formed to propose a Risk Assessment process within the context of the EU's New Chemicals Policy. It contains elements for both human health and environmental risk assessment.

It is not intended to be a complete working model, but a demonstration of the practicability and functionality of the ECETOC Tiered Risk Assessment approach, Tier 0 to Tier 1, resulting in a Chemical Safety Report. As such, not all the functionality is enabled (links to other models) and some options are not yet available. It is intended to develop the tool progressively and use it in a validation exercise.

The basic principles and flow of the Tiered and Targeted Risk Assessment approach are given in a brief description of the process.

▸ [Basic Principles of Targeted Risk Assessment](#)

Instructions for data input and risk assessment.

- The RA Web Tool is designed so that it takes the user through a series of the logic steps for the tiers of the risk assessment. It is transparent to the user what has happened at each stage of the process, as a screen builds showing the data / results so far.
- Data entry is simple with drop down and selection boxes wherever possible.
- Instruction for each stage is (will be) available.
- Please use the tool to enter data and give feed back to the Task Force on any aspect. An email link is provided.

Data input requirements

To see a list of what data will be required for each stage of the risk assessment process [click here](#).

Confidentiality

Access to the site is by username and password. Data entered into this web tool is stored within a record on a server. The record is defined by the chemical name and the organisation that entered the data. Unless the "Confidential Data" check box on the [chemical data entry screen](#) is selected all users with access to the site can see the final report. However, users from other organisations will not be able to modify the record. Records that are checked as confidential will only be available to the person who input the data and to members of the same organisation. ECETOC cannot be held responsible for any accidental violation of confidentiality resulting from system faults.

What information is stored?

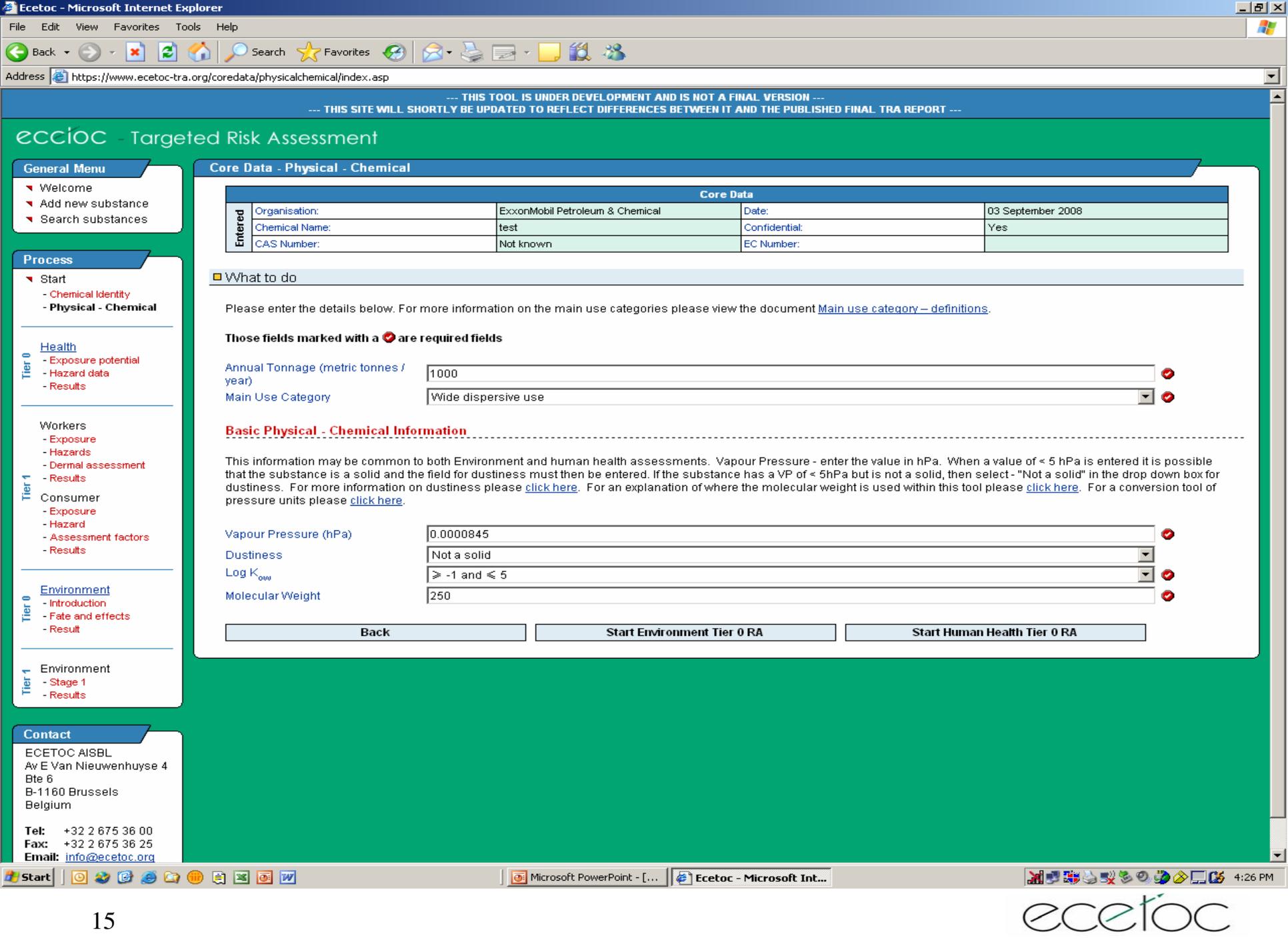
The entered data, calculations and results are stored in a central database. If deleted, the information is removed completely from the database. A backup of the database is kept for up to three months so it will take that amount of time before the data is completely removed from the system. ECETOC cannot be held responsible for any accidental deletion of data as a result of system faults.

Members

Members of the ECETOC Task Force on Targeted Risk Assessment are:

<ul style="list-style-type: none"> ▸ T. Feijtel (Procter and Gamble)¹ ▸ G. Boeije (Procter and Gamble) ▸ M. Comber (ExxonMobil) 	<ul style="list-style-type: none"> ▸ P. Koundakjian, (Eurofer) ▸ S. Lanz (BASF) ▸ A. Lecloux (Eurochlor)
---	---

Start | Microsoft PowerPoint - [...] | Ecetoc - Microsoft Int... | 4:23 PM



eccioc - Targeted Risk Assessment

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Contact

ECETOC AISBL
 Av E Van Nieuwenhuysse 4
 Bte 6
 B-1160 Brussels
 Belgium

Tel: +32 2 675 36 00
Fax: +32 2 675 36 25
Email: info@ecetoc.org

Core Data - Physical - Chemical

Core Data				
Entered	Organisation:	ExxonMobil Petroleum & Chemical	Date:	03 September 2008
	Chemical Name:	test	Confidential:	Yes
	CAS Number:	Not known	EC Number:	

What to do

Please enter the details below. For more information on the main use categories please view the document [Main use category - definitions](#).

Those fields marked with a  are required fields

Annual Tonnage (metric tonnes / year) 

Main Use Category 

Basic Physical - Chemical Information

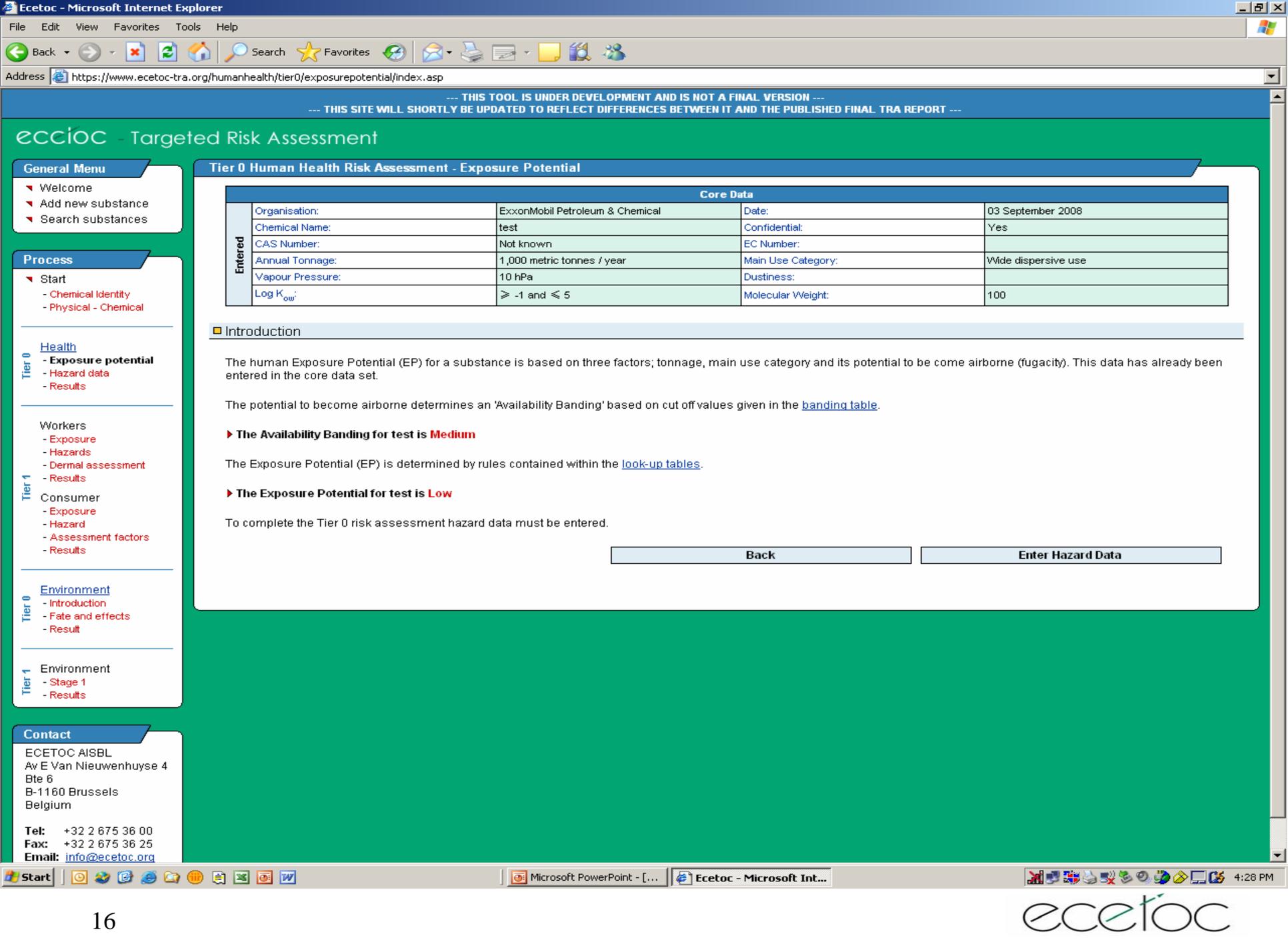
This information may be common to both Environment and human health assessments. Vapour Pressure - enter the value in hPa. When a value of < 5 hPa is entered it is possible that the substance is a solid and the field for dustiness must then be entered. If the substance has a VP of < 5hPa but is not a solid, then select - "Not a solid" in the drop down box for dustiness. For more information on dustiness please [click here](#). For an explanation of where the molecular weight is used within this tool please [click here](#). For a conversion tool of pressure units please [click here](#).

Vapour Pressure (hPa) 

Dustiness 

Log K_{ow} 

Molecular Weight 



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ECETOC AISBL
 Av E Van Nieuwenhuysse 4
 Bte 6
 B-1160 Brussels
 Belgium

Tel: +32 2 675 36 00
 Fax: +32 2 675 36 25
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Tier 0 Human Health Risk Assessment - Exposure Potential

Core Data				
Entered	Organisation:	ExxonMobil Petroleum & Chemical	Date:	03 September 2008
	Chemical Name:	test	Confidential:	Yes
	CAS Number:	Not known	EC Number:	
	Annual Tonnage:	1,000 metric tonnes / year	Main Use Category:	Wide dispersive use
	Vapour Pressure:	10 hPa	Dustiness:	
	Log K _{ow} :	≥ -1 and ≤ 5	Molecular Weight:	100

Introduction

The human Exposure Potential (EP) for a substance is based on three factors; tonnage, main use category and its potential to be come airborne (fugacity). This data has already been entered in the core data set.

The potential to become airborne determines an 'Availability Banding' based on cut off values given in the [banding table](#).

► **The Availability Banding for test is Medium**

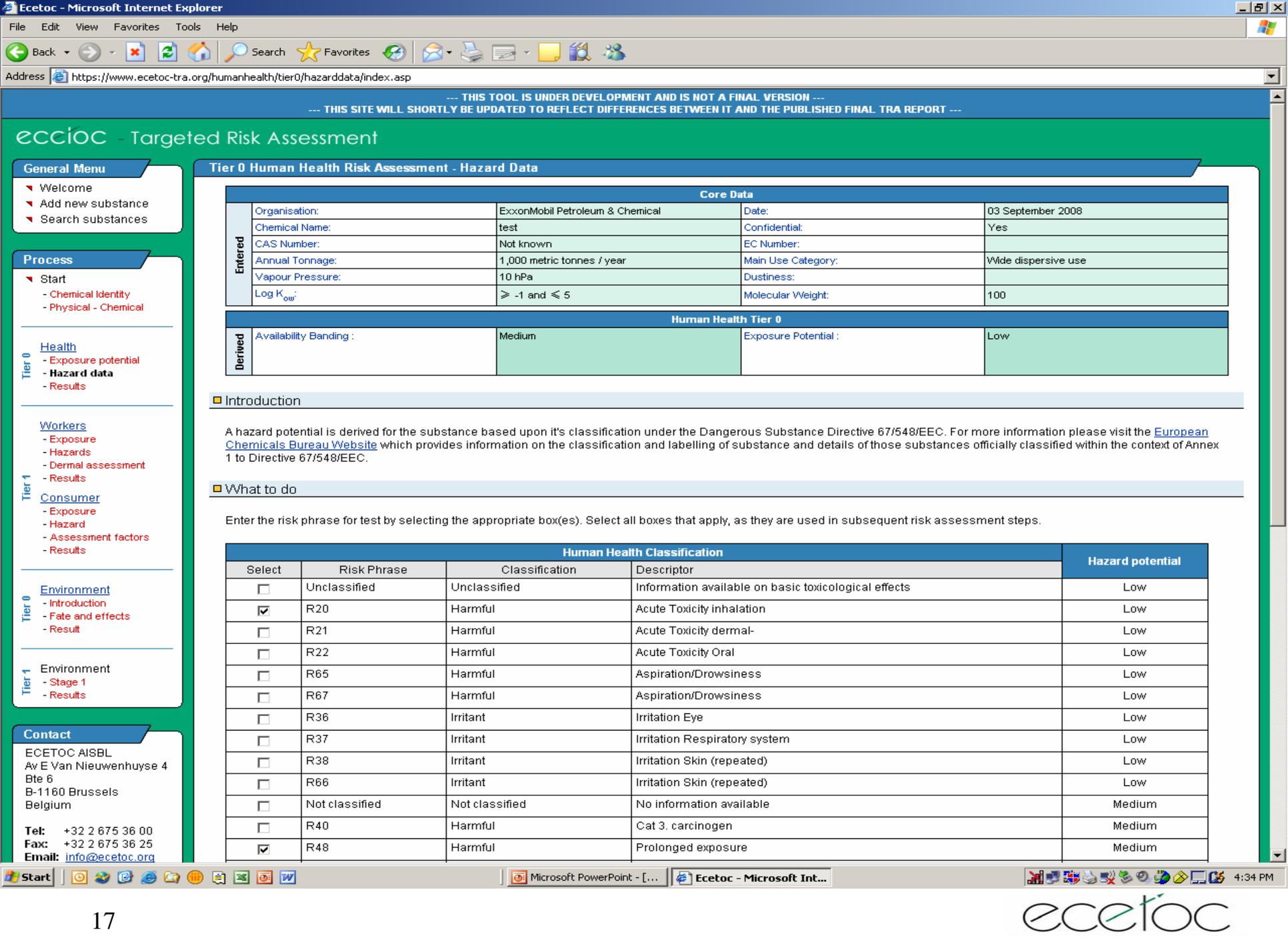
The Exposure Potential (EP) is determined by rules contained within the [look-up tables](#).

► **The Exposure Potential for test is Low**

To complete the Tier 0 risk assessment hazard data must be entered.

[Back](#)

[Enter Hazard Data](#)



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 Av E Van Nieuwenhuysse 4
 Bte 6
 B-1160 Brussels
 Belgium
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Tier 0 Human Health Risk Assessment - Hazard Data

Core Data				
Entered	Organisation:	ExxonMobil Petroleum & Chemical	Date:	03 September 2008
	Chemical Name:	test	Confidential:	Yes
	CAS Number:	Not known	EC Number:	
	Annual Tonnage:	1,000 metric tonnes / year	Main Use Category:	Wide dispersive use
	Vapour Pressure:	10 hPa	Dustiness:	
	Log K _{ow} :	≥ -1 and ≤ 5	Molecular Weight:	100

Human Health Tier 0				
Derived	Availability Banding :	Medium	Exposure Potential :	Low

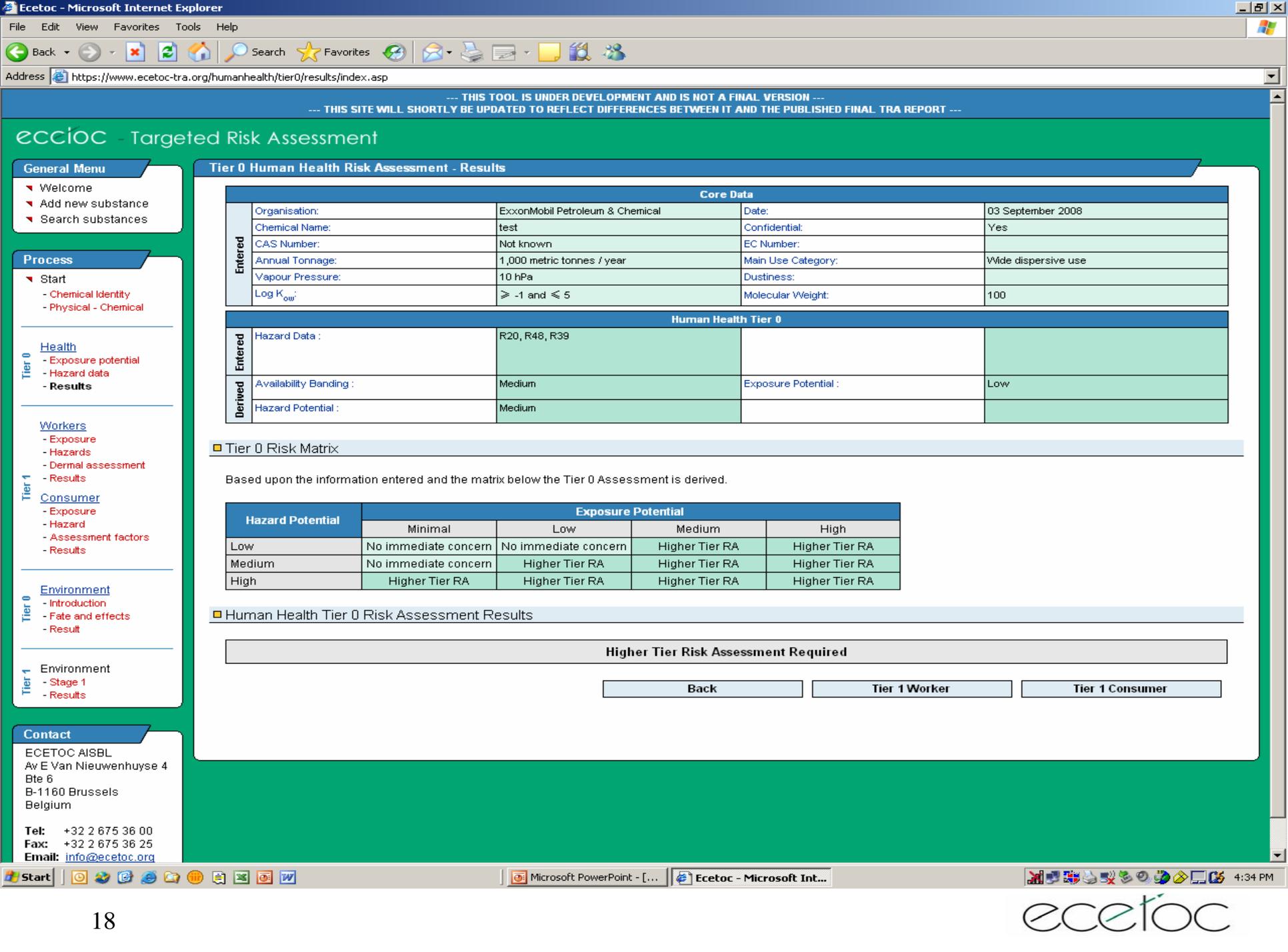
Introduction

A hazard potential is derived for the substance based upon its classification under the Dangerous Substance Directive 67/548/EEC. For more information please visit the [European Chemicals Bureau Website](#) which provides information on the classification and labelling of substance and details of those substances officially classified within the context of Annex 1 to Directive 67/548/EEC.

What to do

Enter the risk phrase for test by selecting the appropriate box(es). Select all boxes that apply, as they are used in subsequent risk assessment steps.

Human Health Classification				Hazard potential
Select	Risk Phrase	Classification	Descriptor	
<input type="checkbox"/>	Unclassified	Unclassified	Information available on basic toxicological effects	Low
<input checked="" type="checkbox"/>	R20	Harmful	Acute Toxicity inhalation	Low
<input type="checkbox"/>	R21	Harmful	Acute Toxicity dermal-	Low
<input type="checkbox"/>	R22	Harmful	Acute Toxicity Oral	Low
<input type="checkbox"/>	R65	Harmful	Aspiration/Drowsiness	Low
<input type="checkbox"/>	R67	Harmful	Aspiration/Drowsiness	Low
<input type="checkbox"/>	R36	Irritant	Irritation Eye	Low
<input type="checkbox"/>	R37	Irritant	Irritation Respiratory system	Low
<input type="checkbox"/>	R38	Irritant	Irritation Skin (repeated)	Low
<input type="checkbox"/>	R66	Irritant	Irritation Skin (repeated)	Low
<input type="checkbox"/>	Not classified	Not classified	No information available	Medium
<input type="checkbox"/>	R40	Harmful	Cat 3. carcinogen	Medium
<input checked="" type="checkbox"/>	R48	Harmful	Prolonged exposure	Medium



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Contact

ECETOC AISBL
 Av E Van Nieuwenhuysse 4
 Bte 6
 B-1160 Brussels
 Belgium

Tel: +32 2 675 36 00
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Tier 0 Human Health Risk Assessment - Results

Core Data				
Entered	Organisation:	ExxonMobil Petroleum & Chemical	Date:	03 September 2008
	Chemical Name:	test	Confidential:	Yes
	CAS Number:	Not known	EC Number:	
	Annual Tonnage:	1,000 metric tonnes / year	Main Use Category:	Wide dispersive use
	Vapour Pressure:	10 hPa	Dustiness:	
	Log K _{ow} :	≥ -1 and ≤ 5	Molecular Weight:	100

Human Health Tier 0			
Entered	Hazard Data :	R20, R48, R39	
	Availability Banding :	Medium	Exposure Potential :
Derived	Hazard Potential :	Medium	

Tier 0 Risk Matrix

Based upon the information entered and the matrix below the Tier 0 Assessment is derived.

Hazard Potential	Exposure Potential			
	Minimal	Low	Medium	High
Low	No immediate concern	No immediate concern	Higher Tier RA	Higher Tier RA
Medium	No immediate concern	Higher Tier RA	Higher Tier RA	Higher Tier RA
High	Higher Tier RA	Higher Tier RA	Higher Tier RA	Higher Tier RA

Human Health Tier 0 Risk Assessment Results

Higher Tier Risk Assessment Required

-

On site uses

Select	Generic Exposure Scenario	Duration of Activity	LEV Present?	Dermal Exposure Likely?
<input checked="" type="checkbox"/>	Use in a closed continuous process	> 4 hours	<input type="checkbox"/>	No
<input checked="" type="checkbox"/>	Use in a continuous process (with process sampling)	> 4 hours	<input type="checkbox"/>	No
<input checked="" type="checkbox"/>	Use in a closed batch process i.e. where no opportunity for breaching arises, including product transfers and sampling	> 4 hours	<input type="checkbox"/>	No
<input checked="" type="checkbox"/>	Use in a batch or other process (including related process stages, e.g. filtration, drying) where opportunities for exposure arise (e.g. sampling, dis/charging of materials)	> 4 hours	<input type="checkbox"/>	Yes

Non-dispersive

Select	Generic Exposure Scenario	Duration of Activity	LEV Present?	Dermal Exposure Likely?
<input checked="" type="checkbox"/>	Use in a closed continuous process	> 4 hours	<input type="checkbox"/>	No
<input checked="" type="checkbox"/>	Use in a continuous process	> 4 hours	<input type="checkbox"/>	No
<input checked="" type="checkbox"/>	Use in a closed batch process i.e. where no opportunity for breaching arises, including product transfers and sampling	> 4 hours	<input type="checkbox"/>	No
<input checked="" type="checkbox"/>	Use in a batch process including chemical reactions and/or the formulation by mixing, blending or calendaring of liquid and solid-based products	> 4 hours	<input type="checkbox"/>	Yes
<input checked="" type="checkbox"/>	Spraying of the substance or preparations containing the substance in industrial applications e.g. coatings	> 4 hours	<input type="checkbox"/>	Yes
<input checked="" type="checkbox"/>	Dis/charging the substance (or preparations containing the substance) to/from vessels	> 4 hours	<input type="checkbox"/>	Yes
<input checked="" type="checkbox"/>	Filling containers with the substance or its preparations	> 4 hours	<input type="checkbox"/>	No
<input checked="" type="checkbox"/>	Roller application or brushing of adhesives and other surface coatings	> 4 hours	<input type="checkbox"/>	Yes
<input checked="" type="checkbox"/>	Use as a blowing agent in the manufacture of foams, etc	> 4 hours	<input type="checkbox"/>	No
<input checked="" type="checkbox"/>	Use for coating/treatment of articles, etc (including cleaning), by dipping or pouring	> 4 hours	<input type="checkbox"/>	Yes
<input checked="" type="checkbox"/>	Production of products or articles from substance by compression, tableting or pelletisation	> 4 hours	<input type="checkbox"/>	Yes
<input checked="" type="checkbox"/>	Use as a laboratory reagent	> 4 hours	<input type="checkbox"/>	No
<input checked="" type="checkbox"/>	Use as a fuel	> 4 hours	<input type="checkbox"/>	No
<input checked="" type="checkbox"/>	Use as a lubricant (including metal working fluids)	> 4 hours	<input type="checkbox"/>	Yes

Wide dispersive

Select	Generic Exposure Scenario	Duration of Activity	LEV Present?	Dermal Exposure Likely?
<input checked="" type="checkbox"/>	Use for the formulation of liquid and solid-based products by mixing, blending or calendaring	> 4 hours	<input type="checkbox"/>	Yes
<input checked="" type="checkbox"/>	Spraying of the substance or preparations containing the substance e.g. paints and coatings	> 4 hours	<input type="checkbox"/>	Yes

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ECETOC AISBL
 Av E Van Nieuwenhuysse 4
 Bte 6
 B-1160 Brussels
 Belgium

Tel: +32 2 675 36 00
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Tier 1 Human Health Worker Exposure Assessment

Entered	Exposure Scenarios Evaluated							
	Type	Scenario	Duration of Activity	LEV Y/N	Estimated Exposure ppm	Margin of Exposure (OEL or GLEV) / Exposure	Assessment Factor	Further Assessment Required
		OEL	100 ppm					
Scenarios	On-site uses	Closed continuous	> 4 hours	No	0.010	10,000.000	2	No
	On-site uses	Continuous	> 4 hours	No	10.000	10.000	2	No
	On-site uses	Closed batch	> 4 hours	No	25.000	4.000	2	No
	On-site uses	Batch or other	> 4 hours	No	100.000	1.000	2	Yes
	Non-dispersive	Closed continuous	> 4 hours	No	0.010	10,000.000	2	No
	Non-dispersive	Continuous	> 4 hours	No	10.000	10.000	2	No
	Non-dispersive	Closed batch	> 4 hours	No	25.000	4.000	2	No
	Non-dispersive	Mixing, blending or calendering	> 4 hours	No	50.000	2.000	2	No
	Non-dispersive	Spraying	> 4 hours	No	500.000	0.200	2	Yes
	Non-dispersive	Discharging	> 4 hours	No	50.000	2.000	2	No
	Non-dispersive	Filling	> 4 hours	No	100.000	1.000	2	Yes
	Non-dispersive	Roller application or brushing	> 4 hours	No	500.000	0.200	2	Yes
	Non-dispersive	Blowing	> 4 hours	No	20.000	5.000	2	No
	Non-dispersive	Dipping or pouring	> 4 hours	No	100.000	1.000	2	Yes
	Non-dispersive	Compression, tableting or pelletisation	> 4 hours	No	100.000	1.000	2	Yes
	Non-dispersive	Laboratory reagent	> 4 hours	No	10.000	10.000	2	No
	Non-dispersive	Fuel	> 4 hours	No	10.000	10.000	2	No
	Non-dispersive	Lubricant	> 4 hours	No	500.000	0.200	2	Yes
	Wide dispersive	Mixing, blending or calendering	> 4 hours	No	100.000	1.000	2	Yes
	Wide dispersive	Spraying	> 4 hours	No	500.000	0.200	2	Yes
	Wide dispersive	Discharging	> 4 hours	No	50.000	2.000	2	No
	Wide dispersive	Filling	> 4 hours	No	100.000	1.000	2	Yes
	Wide dispersive	Roller application or brushing	> 4 hours	No	100.000	1.000	2	Yes
	Wide dispersive	Dipping or pouring	> 4 hours	No	100.000	1.000	2	Yes
	Wide dispersive	Compression, tableting or pelletisation	> 4 hours	No	100.000	1.000	2	Yes
	Wide dispersive	Laboratory reagent	> 4 hours	No	10.000	10.000	2	No
	Wide dispersive	Fuel	> 4 hours	No	10.000	10.000	2	No
	Wide dispersive	Lubricant	> 4 hours	No	500.000	0.200	2	Yes

Dermal risks are only evaluated for scenarios that might give rise to significant dermal contact. It is not done for those substances which have a high hydrophilicity (log P<-1) or a high molecular weight (>1000), consistent with the advice contained within the revised Technical Guidance documents (Revised TGD)

The estimated dermal applied dose for each scenario is determined by multiplying the EASE dermal output with the assumed dermal contact area (varying with scenarios). Values / assumptions can be viewed in the table of [EASE dermal outputs](#) by scenario. It is assumed no personal protection is in use.

A Generic Dermal Exposure Value is derived for volatiles from either the generic or entered Exposure Value for Volatiles (ppm) or generic or entered Exposure Value for Solids



Wide dispersive	Mixing, blending or calendaring	> 4 hours	No	100.000	1.000	2	Yes
Wide dispersive	Spraying	> 4 hours	No	500.000	0.200	2	Yes
Wide dispersive	Discharging	> 4 hours	No	50.000	2.000	2	No
Wide dispersive	Filling	> 4 hours	No	100.000	1.000	2	Yes
Wide dispersive	Roller application or brushing	> 4 hours	No	100.000	1.000	2	Yes
Wide dispersive	Dipping or pouring	> 4 hours	No	100.000	1.000	2	Yes
Wide dispersive	Compression, tableting or pelletisation	> 4 hours	No	100.000	1.000	2	Yes
Wide dispersive	Laboratory reagent	> 4 hours	No	10.000	10.000	2	No
Wide dispersive	Fuel	> 4 hours	No	10.000	10.000	2	No
Wide dispersive	Lubricant	> 4 hours	No	500.000	0.200	2	Yes

Potential Systemic Effects Arising from Dermal Exposures							
Type	Scenario	Duration of Activity	LEV Y/H	Estimated Exposure mg/kg/day	Margin of Exposure GDEV or DDEV / Exposure	Assessment Factor	Further Assessment Required
On-site uses	Batch or other	> 4 hours	No	0.69	84.5058520302531	2	No
Non-dispersive	Mixing, blending or calendaring	> 4 hours	No	6.86	8.49985975231408	2	No
Non-dispersive	Spraying	> 4 hours	No	107.14	0.544232199933494	2	Yes
Non-dispersive	Dis/charging	> 4 hours	No	6.86	8.49985975231408	2	No
Non-dispersive	Roller application or brushing	> 4 hours	No	13.71	4.25302975206963	2	No
Non-dispersive	Dipping or pouring	> 4 hours	No	6.86	8.49985975231408	2	No
Non-dispersive	Compression, tableting or pelletisation	> 4 hours	No	6.86	8.49985975231408	2	No
Non-dispersive	Lubricant	> 4 hours	No	68.57	0.850357851843001	2	Yes
Wide dispersive	Mixing, blending or calendaring	> 4 hours	No	1	58.3090379008746	2	No
Wide dispersive	Spraying	> 4 hours	No	1	58.3090379008746	2	No
Wide dispersive	Discharging	> 4 hours	No	1	58.3090379008746	2	No
Wide dispersive	Roller application or brushing	> 4 hours	No	1	58.3090379008746	2	No
Wide dispersive	Dipping or pouring	> 4 hours	No	1	58.3090379008746	2	No
Wide dispersive	Lubricant	> 4 hours	No	1	58.3090379008746	2	No

Dermal Sensitisation Scenarios

No dermal risks were calculated for this material because no worker exposure scenarios were identified with dermal exposures.

Local Dermal Effects

▶ No local dermal effects.

ECETOC AISBL
 Av E Van Nieuwenhuysse 4
 Bte 6
 B-1160 Brussels
 Belgium

 Tel: +32 2 675 36 00
 Fax: +32 2 675 36 25
 Email: info@ecetoc.org

Select each relevant Consumer Product Use Category for the chemical. To override the defaults of the most critical aspects of the exposure assessment, enter the appropriate data in the box(es) provided. Note that some routes of exposure are not relevant for some applications and therefore it is not possible to enter any data. Results of the subsequent calculation are displayed on the next page.

Select	Consumer Product Use Category	Product Ingredient*	Dermal Contact Area of Article / Product with Skin (cm ²)	Oral Contact Area with Mouth (cm ²)	Inhalation Amount of Substance used per Application (g)
<input checked="" type="checkbox"/>	Adhesives, binding agents and sealants	<input type="text" value="0.3"/>	<input type="text" value="30"/>	<input type="text" value="5"/>	<input type="text" value="5"/>
<input checked="" type="checkbox"/>	Artists supplies and craft/hobby materials	<input type="text" value="0.5"/>	<input type="text" value="50"/>	<input type="text" value="50"/>	
<input checked="" type="checkbox"/>	Automotive care products	<input type="text" value="0.5"/>	<input type="text" value="100"/>		
<input checked="" type="checkbox"/>	Construction materials	<input type="text" value="0.2"/>	<input type="text" value="240"/>		<input type="text" value="10"/>
<input checked="" type="checkbox"/>	Electrical and electronic products	<input type="text" value="0.2"/>	<input type="text" value="30"/>		
<input checked="" type="checkbox"/>	Fabrics, textiles and apparel	<input type="text" value="0.2"/>	<input type="text" value="1200"/>	<input type="text" value="30"/>	
<input checked="" type="checkbox"/>	Glass and ceramic products	<input type="text" value="0.2"/>	<input type="text" value="420"/>		
<input checked="" type="checkbox"/>	Lawn and garden products (non-pesticide/herbicide)	<input type="text" value="0.5"/>	<input type="text" value="100"/>	<input type="text" value="15"/>	
<input checked="" type="checkbox"/>	Leather products	<input type="text" value="0.1"/>	<input type="text" value="640"/>		
<input checked="" type="checkbox"/>	Lubricants, greases, fuel and fuel additives	<input type="text" value="1"/>	<input type="text" value="50"/>		
<input checked="" type="checkbox"/>	Metal products	<input type="text" value="1"/>	<input type="text" value="50"/>		
<input checked="" type="checkbox"/>	Paintings and coatings	<input type="text" value="0.3"/>	<input type="text" value="240"/>		<input type="text" value="20"/>
<input checked="" type="checkbox"/>	Paper products	<input type="text" value="0.1"/>	<input type="text" value="50"/>	<input type="text" value="50"/>	
<input type="checkbox"/>	Photographic & reprographic products	<input type="text" value="0.1"/>	<input type="text" value="30"/>		
<input type="checkbox"/>	Plastic products	<input type="text" value="0.5"/>	<input type="text" value="400"/>	<input type="text" value="50"/>	
<input type="checkbox"/>	Polishes	<input type="text" value="0.5"/>	<input type="text" value="120"/>		<input type="text" value="15"/>
<input type="checkbox"/>	Rubber products	<input type="text" value="0.05"/>	<input type="text" value="480"/>		
<input type="checkbox"/>	Soaps and detergents (washing & cleaning agents)	<input type="text" value="0.2"/>	<input type="text" value="840"/>	<input type="text" value="1000"/>	<input type="text" value="10"/>
<input type="checkbox"/>	Wood and wood furniture	<input type="text" value="0.3"/>	<input type="text" value="420"/>	<input type="text" value="100"/>	<input type="text" value="10"/>

* fraction of substance in product / article

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Contact
 ECETOC AISBL
 Av E Van Nieuwenhuysse 4
 Bte 6
 B-1160 Brussels
 Belgium
Tel: +32 2 675 36 00
Fax: +32 2 675 36 25
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Is data available for rat or mouse repeat dose toxicity for test?

If **no data** is available a conservative Generic Lo Effect Value (GLEV) will be determined dependant upon the hazard classification entered into the Tier 0 Assessment. Values are:

Hazard Category	Generic Low Effect Value Oral (mg/kg/day)	Generic Low Effect Value Dermal (mg/kg/day)	Generic Low Effect Value Inhalation (mg/kg/day)
Low	50	100	250
Medium	5	10	25
High	0.5	1	2.5

For a description of the process and more information on these values see - [The basis of Generic Low Effect Values](#).

If repeat dose toxicity data are **available**, enter them into the form below

Assumptions and approach

For simplicity and conservatism at the Tier 1 level :-

- ▶ Only rat or mouse data are selectable. This does not preclude the use of other species, but rather that they should be considered in a Tier 2 risk assessment.
- ▶ 100% absorption is assumed for all routes of exposure. Consequently, an oral or dermal dose yields the same systemic dose. For inhalation data, the data are converted to a systemic dose in mg/kg/day.
- ▶ No account is made to differentiate between local and systemic effects. (This is a gross simplification and is conservative, as local effects will not lead to systemic toxicity) and lower Assessment Factors are proposed for local effects.
- ▶ Assessment Factors are applied dependent upon the available information based upon ECETOC Technical Report No. 86.

What to do

Enter data for each Route of Exposure where information is available. A calculated or inferred value will be automatically generated for a route where there is no information is available.

Route of Exposure	Study Duration	Species	Actual Value*		Dosed Days / Week	Dosed Hours / Day
			Enter one column only			
			NOEL	LOEL		
Oral	28 days	Rat				
Dermal	28 days	Rat	1000		2	
Inhalation	28 days	Rat	1000		2	2

* Oral & Dermal Actual Values are measured in mg/kg/day. The following formula are used to convert from inhalation studies with values in mg/m³ to a systemic dose in mg/kg bw.

Rat	$0.04 \times H \times \text{NOAEC or LOEC} \text{ [mg/m}^3\text{]}$
Mouse	$0.05 \times H \times \text{NOAEC or LOEC} \text{ [mg/m}^3\text{]}$

For an explanation on how these values are derived click [here](#).

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Contact

ECETOC AISBL
 Av E Van Nieuwenhuysse 4
 Bte 6
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 Belgium

Tel: +32 2 675 36 00
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Entered	Low/No Effects Values Used in this Assessment						
	Type	Value	Units	Determination or No.Low Values	Calculated		
	Dermal	1000	mg/kg/day	NOAEL	No		
	Oral	80	mg/kg/day	NOAEL	Yes		
	Inhalation	80	mg/kg/day	NOAEL	No		
Derived	Consumer Product Use Categories						
	Product Use	Route of Exposure Assessed	Surrogate of Exposure mg/kg/day	Margin of Exposure Effect / Exposure	Assessment Factor	Further Assessment Required?	
	Adhesives, binding agents and sealants	Dermal	0.0005	2133333	420	No	
		Oral	0.0001	640000	420	No	
		Inhalation	0.0094	8533	1260	No	
		Total **	0.01	8025	420	No	
	Artists supplies and craft/hobby materials	Dermal	0.0017	576000	420	No	
		Oral	0.0006	128000	420	No	
		Total **	0.0024	33882	420	No	
	Automotive care products	Dermal	0.0005	1920000	420	No	
	Construction materials	Dermal	0	60000000	420	No	
		Inhalation	0.6667	120	1260	Yes	
		Total **	0.6667	120	420	Yes	
	Electrical and electronic products	Dermal	0	24000000	420	No	
		Fabrics, textiles and apparel	Dermal	0.0013	750000	420	No
			Oral	0.001	80000	420	No
		Total **	0.0023	34286	420	No	
	Glass and ceramic products	Dermal	0.0001	17142857	420	No	
		Lawn and garden products (non-pesticide/herbicide)	Dermal	0.0026	384000	420	No
			Oral	0.0019	42667	420	No
	Total **		0.0045	17860	420	No	
	Leather products	Dermal	0.0027	375000	420	No	
	Lubricants, greases, fuel and fuel additives	Dermal	0.0013	768000	420	No	
	Metal products	Dermal	0	57600000	420	No	
		Paintings and coatings	Dermal	0.0002	5000000	420	No
			Inhalation	0.075	1067	1260	Yes
	Total **		0.0752	1064	420	No	
	Paper products	Dermal	0.0002	5760000	420	No	
		Oral	0.0017	48000	420	No	
		Total **	0.0018	43472	420	No	

** The Margin of Exposure for the total potential exposure via any one consumer use scenario is calculated using the lowest value of the NOAEL / GLEV's used.

Consumer Dermal Exposure Assessment

Ecetoc - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <https://www.ecetoc-tra.org/environment/tier0/fateandeffects/index.asp>

--- THIS TOOL IS UNDER DEVELOPMENT AND IS NOT A FINAL VERSION ---
 --- THIS SITE WILL SHORTLY BE UPDATED TO REFLECT DIFFERENCES BETWEEN IT AND THE PUBLISHED FINAL TRA REPORT ---

eccioc - Targeted Risk Assessment

General Menu

- ▼ Welcome
- ▼ Add new substance
- ▼ Search substances

Process

- ▼ Start
 - Chemical Identity
 - Physical - Chemical

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[Workers](#)

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- Hazards
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Tier 1

[Consumer](#)

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Tier 0

[Environment](#)

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- **Fate and effects**
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Tier 1

[Environment](#)

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Environment Tier 0 Risk Assessment - Fate and effects

Core Data				
Entered	Organisation:	ExxonMobil Petroleum & Chemical	Date:	03 September 2008
	Chemical Name:	test	Confidential:	Yes
	CAS Number:	Not known	EC Number:	
	Annual Tonnage:	1,000 metric tonnes / year	Main Use Category:	Wide dispersive use
	Vapour Pressure:	10 hPa	Dustiness:	
	Log K _{ow} :	≥ -1 and ≤ 5	Molecular Weight:	100

■ **Environment Exposure Potential**

To obtain the exposure potential the following additional information is required. Firstly, unless the use scenario is "wide dispersive use" (assumed number of release days is 365), the number of days over a year when the chemical is considered to be released to the environment is required. Secondly the chemical needs to be assigned one of the following two classes; either readily biodegradable or not biodegradable. (NB an alternative to biodegradation based on immobilisation of the substance in environmental compartments is being developed for inorganic substances).

Those fields marked with a ❗ are required fields

Biodegradation ❗

■ **Environment Hazard Potential**

Select the row that best describes the available information on the substance. This information is used to derive the hazard potential for the various environmental compartments (water, soil, sediment).

	EU Classification	GHS Classification		Description	Available Information	Tier 0 PNEC
<input type="radio"/>	R50	Acute class 1	Chronic class 1	Very Toxic	Acute Toxicity < 1 mg/l	0.1 µg/l
<input checked="" type="radio"/>	R51 or R51/53	Acute class 2	Chronic class 2	Toxic	Acute Toxicity 1 - 10mg/l	1 µg/l
<input type="radio"/>	R52 or R52/53	Acute class 3	Chronic class 3	Harmful	Acute Toxicity 10 - 100mg/l	10 µg/l
<input type="radio"/>	No risk phrase based on data	No Classification based on data	Chronic class 4	Minimal	Acute Toxicity > 100mg/l	100 µg/l

Contact

ECETOC AISBL
 Av E Van Nieuwenhuyse 4
 Bte 6
 B-1160 Brussels
 Belgium

Tel: +32 2 675 36 00
Fax: +32 2 675 36 25
Email: info@ecetoc.org

CCIOC - Targeted Risk Assessment

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Contact

CETOC AISBL
 v E Van Nieuwenhuysse 4
 ete 6
 -1160 Brussels
 elgium

tel: +32 2 675 36 00
 fax: +32 2 675 36 25
 mail: info@ecetoc.org

Tier 0 Environmental Assessment - Results

Core Data				
Entered	Organisation:	ExxonMobil Petroleum & Chemical	Date:	03 September 2008
	Chemical Name:	test	Confidential:	Yes
	CAS Number:	Not known	EC Number:	
	Annual Tonnage:	1,000 metric tonnes / year	Main Use Category:	Wide dispersive use
	Vapour Pressure:	10 hPa	Dustiness:	
	Log K _{ow} :	≥ -1 and ≤ 5	Molecular Weight:	100

Environment Tier 0				
Entered	Biodegradation:	Not readily biodegradable		
	Tier 0 PNEC:	1 µg/l		

Environment Tier 0 Results

The decision on whether or not further risk assessment is necessary is based on the exposure potential and hazard potential. From the EUSES 1.0 analysis (this will be replaced with EUSES 2.0 when it becomes available), the tonnage that would give rise to the worst case (i.e. highest PEC/PNEC) for the substance is calculated and compared to the tonnage released (assessed on a daily basis).

Further risk assessment required. PEC / PNEC > 10

Back

Tier 1

Science & Functionality Needs Scoped

The TRA Task Force has now

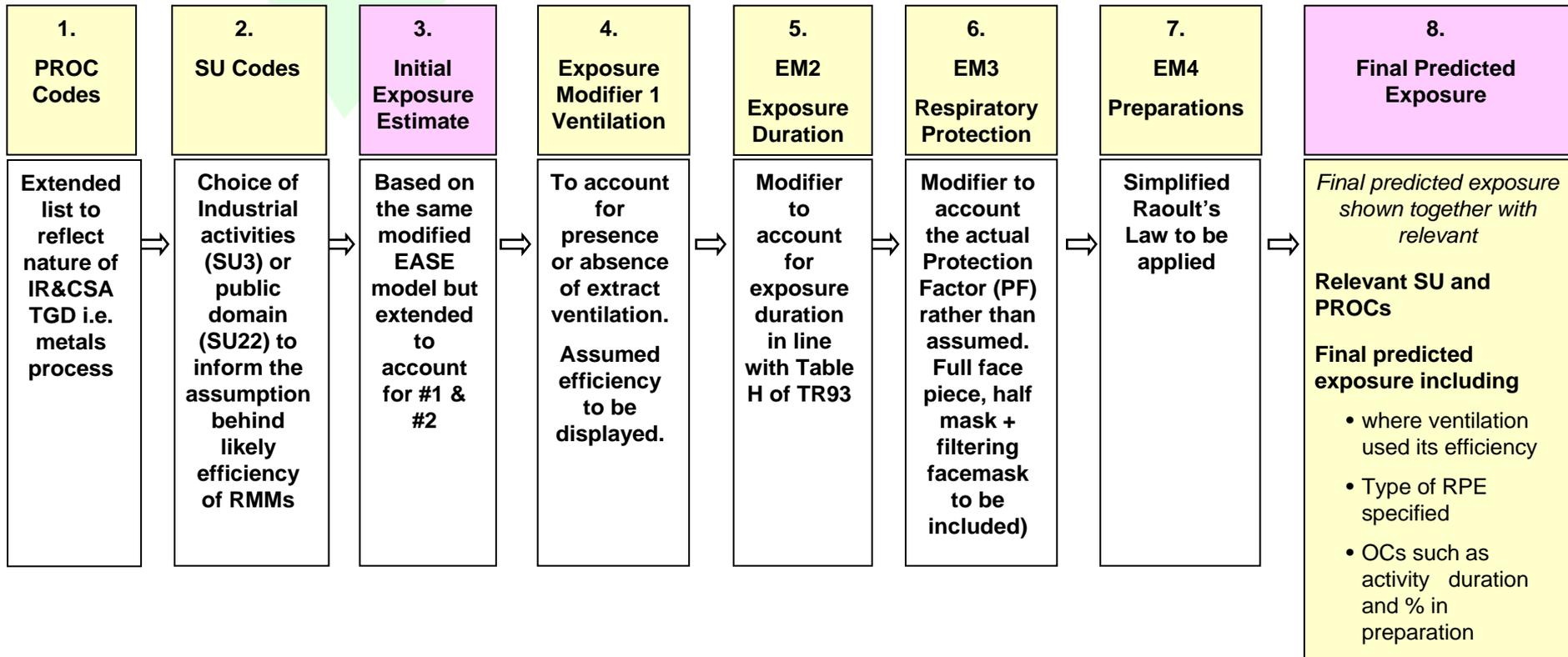
- /// Identified potential improvements (science, workability and functionality) arising from user comments and operating experiences
- /// Considered content and outcome and impact of REACH Implementation Projects
- /// Accounted for comments on the TRA received
- /// Undertaken an analysis of value/merits of each proposal
- /// Tried to predict/account for the anticipated direction/format of REACH IT platform (and supporting concepts)

ECETOC TRA – Improvement Plans

- **Worker:**

- /// Workflows to be re-ordered to be consistent with REACH expectations (initial prediction followed by ability to add exposure modifiers (change in operational conditions or RMMs) ex. default 8 hrs no ventilation, can use LEV etc.
- /// To be expanded to cover all REACH process categories
- /// Exposure predictions further refined to discriminate between industrial and professional
- /// Outputs will reflect all primary determinants, still based upon EASE coupled with consensus around what constitutes typical worst case

Schematic for Updated TRA



ECETOC TRA – Improvement Plans

- **Consumer:**

- /// Improvements identified in conjunction with key REACH stakeholders (e.g., RIVM, ECHA)
- /// Serves as a tiered entry to CONSEXPO (higher tier consumer exposure model)
- /// Will align with REACH expectations
- /// Additional scenarios
- /// Refinement and enhanced documentation of scenario defaults

ECETOC TRA – Improvement Plans

- **Environment:**

- /// ECETOC Task Force developed and validating a spreadsheet version of EUSES, now in final stages of testing
- /// Aligned with REACH expectations

Summary

- **TRA v2 retains the same philosophy as v1 while including enhancements that reflect user feedback**
 - /// ECETOC has tried to retain 'user friendliness' e.g. access by DUs as well as use by specialist groups
 - /// Enhancing transparency as an output of the tool itself (together with an Addendum to original report TR93)
 - /// Maintaining alignment with expectations of the CSA TGD
- **ECETOC anticipates having:**
 - /// A web and/or Excel-based version of individual components (worker, consumer, environmental) available by mid 4Q/08 for ECETOC member companies to review
 - /// An integrated TRA tool (worker, consumer, environment supported by integrated data entry/output planned for 1Q/09)
 - /// Public release est. 2Q/09
 - A stand-alone exposure estimation tool
 - To be integrated with REACH-IT tools

International Life Sciences Institute
Health and Environmental Sciences Institute
Risk Assessment Methodology (RAM)
Technical Committee

Project on Risk Assessment of Chemical Mixtures

Rosemary Zaleski- ExxonMobil Biomedical Sciences, Inc.

Michelle Embry – Health and Environmental Sciences Inst.



Mixtures Project Participation

INDUSTRY

Bayer CropScience
The Coca-Cola Company
The Dow Chemical Company
Dow Corning
ExxonMobil Biomed. Sciences, Inc.
Pfizer, Inc.
The Procter & Gamble Company
Rohm and Haas Company
Syngenta Ltd.

GVT/ACADEMIA/OTHER

Centers for Disease Control, ATSDR
Colorado State University
Imperial College London
U.S. Food and Drug Administration
University of Guelph
U.S. Environmental Protection Agency

Mixtures Project: History

- Initiated in 2005 as part of RAM
- Aims to develop a decision-framework to advance and improve mixtures risk assessment methodology
- Current project focused at present on the potential application of a threshold of toxicological concern (TTC) approach to mixtures risk assessment as a critical "decision point."

Mixtures Project: Objective

How to prioritize those environmental chemical mixtures that should be subject to in-depth risk assessment and those that are expected to be of lesser concern?

Examine the applicability of the Toxicological Threshold of Concern (TTC) concept to chemical mixtures as a screening-level, prioritization approach

- TTC proposes that a de minimis value can be identified for many chemicals based on SAR

Focus is on low-level exposures (individual chemical levels at or below low-observed or no-observed effect levels)

Project Plan and Scope of Work

Goal: Develop a framework for applying the TTC concept to determine if a mixture requires further assessment

- Perform a review/analysis of available synergy literature
- Analyze/review different methodologies used to calculate/determine synergy
- Define the steps of a TTC screening tool
- Develop criteria for case studies to test the TTC approach
- Select and perform case studies to illustrate the TTC approach
- Integrate findings to support, modify, or reject the TTC screening tool
- If outcome supports the approach, develop step-by-step process to integrate into the IPCS framework currently under development