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Speakers





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Presentation Outline



Chemical Risk Assessment

- Understanding Risk Assessment
- ICCA Global Product Strategy (GPS)
- Dose-Response Analysis (Toxic Effects with Threshold)
- Derivation of Reference Value (DNEL, PNEC)
- Understanding Risk Characterization
- GPS Safety Summary (GPS SS)
- Stepwise Chemical Risk Assessment
 - Information available required and needed
 - Hazard Assessment (Data requirement & DNEL Setting)
 - Exposure Assessment (Occupation exposure)
 - Risk Assessment (Risk characterization ratio)





Understanding Risk Assessment

Risk = Hazard × Exposure

Risk: Probability of <u>Adverse Effects</u> resulting from a given exposure

Hazard: Intrinsic properties causing <u>Adverse Effects</u>

Even if the substance has a High hazard, Low exposure can minimize the risk
Even if the substance has a Low hazard, High exposure may cause high risk

It is important to **assess the "risk"** by substance in use





Understanding Hazard Assessment



GHS (Globally Harmonized System of Classification and Labelling of Chemicals)
 "The Purple Book" Latest Edition: 9th Revised Edition, Issued year: 2021
 Thai Regulations: 3rd Revised Edition, Issued year: 2009





• **GHS Hazard Classification**

2. Physical hazards		GHS Hazard Category (8th Revision Edition, 2019)					
2.1 Explosives	Unstable explosive	Division 1.1	Division 1.2 Category 1A	Division 1.3 Category 1A	Division 1.4 Category 1B	Division 1.5 Category 2	Division 1.6
2.2 Flammable gases	Category IA (Flammable gas)	Category IA (Pyrophoric gas)	(Chemically unstable gas) A	(Chemically unstable gas) B	(Flammable gas)	(Flammable gas)	
2.3.1 Aerosols	Category I (Aerosols) Category I	Category 2 (Aerosols) Category 2	Category 3 (Aerosols) Category 3				
2.3.2 Chemicals under Pressure	(Chemicals under pressure)	(Chemicals under pressure)	(Chemicals under pressure)				
2.4 Oxidizing gases	Category I						
2.5 Gases under pressure	Compressed gas	Liquefied gas	Refrigerated liquefied gas	Dissolved gas			
2.6 Flammable liquids	Category I	Category 2	Category 3	Category 4			
2.7 Flammable solids	Category I	Category 2					
2.8 Self-reactive substances and mixture	Туре А	Туре В	Туре С	Туре D	Туре Е	Type F	Type G
2.9 Pyrophoric liquids	Category I						
2.10 Pyrophoric solids	Category I						
2.11 Self-heating substances and mixture	Category I	Category 2					
2.12 Substances and mixtures, which in contact with water, emit flammable							
gases	Category I	Category 2	Category 3				
2.13 Oxidizing liquids	Category I	Category 2	Category 3				
2.14 Oxidizing solids	Category I	Category 2	Category 3				
2.15 Organic peroxides	Туре А	Туре В	Туре С	Туре D	Туре Е	Type F	Type G
2.16 Corrosive to metals	Category I						
2.17 Desensitized explosives	Category I	Category 2	Category 3	Category 4			

GHS (Globally Harmonized System of Classification and Labelling of Chemicals) Hazard Classification above is based on 8th Revised Edition, Issued year: 2019





• **GHS Hazard Classification**

3. Health hazards	Gŀ	IS Hazard Cate	egory (8th Revis	sion Edition, 201	9)
3.I Acute toxicity (Oral/Dermal/Inhalation)	Category I	Category 2	Category 3	Category 4	Category 5
3.2 Skin corrosion/irritation	Category I (IA/IB/IC)	Category 2	Category 3		
3.3 Serious eye damage/eye irritation	Category I	Category 2/2A	Category 2B		
3.4 Respiratory/skin sensitization	Category I	Category IA	Category IB		
3.5 Germ cell mutagenicity	Category I (IA/IB)	Category 2			
3.6 Carcinogenicity	Category I (IA/IB)	Category 2			
			Effects on or via	Effects on or via	
3.7 Reproductive toxicity	Category I (IA/IB)	Category 2	lactation	lactation	
3.8 Specific target organ toxicity - Single exposure	Category I	Category 2	Category 3		
3.9 Specific target organ toxicity - Repeated expo	Category I	Category 2			
3.10 Aspiration hazard	Category I	Category 2			
4. Environmental hazards	Gł	IS Hazard Cate	egory (8th Revis	sion Edition, 201	9)
4.1 Hazardous to the aquatic environment					
- Short-term (Acute)	Acute I	Acute 2	Acute 3		
- Long-term (Chronic)	Chronic I	Chronic 2	Chronic 3	Chronic 4	
4.2 Hazard to the ozone layer	Category I				

GHS (Globally Harmonized System of Classification and Labelling of Chemicals) Hazard Classification above is based on 8th Revised Edition, Issued year: 2019







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Global Product Strategy (GPS)

ICCA Guidance on Chemical Risk Assessment





Download: https://icca-chem.org/resources/global-product-strategy-icca-guidance-on-chemical-risk-assessment/ **Source: ICCA, Global Product Strategy ICCA Guidance on Chemical Risk Assessment, 2nd Edition 2011**



GPS Chemical Risk Assessment Process





Download: https://icca-chem.org/resources/global-product-strategy-icca-guidance-on-chemical-risk-assessment/ **Source: ICCA, Global Product Strategy ICCA Guidance on Chemical Risk Assessment, 2nd Edition 2011**





• Dose-Response Analysis (Toxic Effects with Threshold)



Source: GHS & CRA Expert, Mutsuo Wada san, JCDB Limited.





• Derivation of Reference Value (DNEL, PNEC)

DNEL=NOAEL or LOAEL/ AFs

...for human

Example of AFs (ref. REACH guidance)

LOAEL : Lowest Observed Adverse Effect Level

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r8_en.pdf?vers=20_08_08

Interspecies (rats)	10	Effect correction (LOAEL \rightarrow NOAEL)		10
Intraspecies	10* Exposure duration	-	Sub-acute(28d)→Sub-chronic(90d)	3
		Exposure	Sub-acute(28d)→Chronic(1.5-2y)	6
			Sub-chronic(90d) \rightarrow Chronic(1.5-2y)	2

To derive AFs, any relevant factors multiplied

* use 5 for worker

■ PNEC=L(E)C₅₀ or NOEC/ AFs

...for environment

Example of AFs (ref. REACH guidance)

L(E)C50: 50% Lethal (Effect) Concentration

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r10_en.pdf?vers=20_08_08

At least one short-term L(E)C50	1000	Two long-term results	50
One long-term EC10 or NOEC	100	Long-term results from at least three species	10





Understanding Risk Assessment



NOAEL	10 mg/kg/day	NOAEL	10 mg/kg/day
Estimated exposure dose	1 mg/kg/day	Estimated exposure dose	30 mg/kg/day

Source: Risk Assessment on Chemicals for Better Understanding, NITE, Japan





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Understanding Risk Characterization

1) Risk Characterization Ratio (RCR)

- Human Health (Threshold or nonthreshold effect)
 - RCR = EXPOSURE / DNEL
 - RCR = EXPOSURE / DMEL
- Environmental
 - RCR = PEC / PNEC

RCR ≥ 1 Risk is high Detailed assessment and RMMs required RCR < 1 Risk is controlled No further action required

2) Margin of Exposure (MoE)

- MOE = <u>NOAEL or NOAEC</u> Exposure
 - If MOS > Overall Assessment Factor
 - \rightarrow No concern
 - If MOS < Overall Assessment Factor</p>

 \rightarrow Concern

MOE > 100 No concerns MOE < 100 Concern Refine analysis or control exposures MOE < 1 Cause for high concern Direct measures needed



GPS Safety Summary (GPS SS)



Recommended Elements of GPS Safety Summary

Recommended elements of GPS Safety Summary

- Chemical identity (or category description)
- Uses applications, functions
- Physical / chemical properties
- Health effects
- Environmental fate and potential effects
- Exposure exposure potential
- Risk management recommended measures
- First-aid measures
- Fire-fighting measures
- Accidental release measures
- Disposal consideration
- Handling and storage

Optional elements of GPS Safety Summary

- Benefits of chemical
- Special considerations
- Production
- Findings by agencies / scientific organizations
- Regulatory compliance
- Sources for additional information
- Conclusion statement
- Contact information

Source: ICCA (International Council of Chemical Associations) Guidance on Chemical Risk Assessment, 2nd Edition -2011





Overview of CRA & CRM



Source: Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.12: Use Description





• Use Descriptor Category

Use descriptor category	Related key element(s)
Life cycle stage (LCS)	Life cycle stage
Sector of use (SU)	Market description (sector of economy where the use takes place)
Product category (PC)	Market description (type of product), Contributing activities (consumers)
Process category (PROC)	Contributing activities (workers)
Environmental release category (ERC)	Contributing activities (environment)
Article category (AC)	Market description (type of article), Contributing activities (service life)
Technical function (TF)	Technical function of the substance

Source: Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.12: Use Description



Information: Available – required/needed





Source: Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.12: Use Description

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Information:



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Available – required/needed

• The concepts of use/contributing activity and exposure scenario/contributing scenario



Source: Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.12: Use Description





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• Example of Descriptor of Use

Life U cycle na stage	Use name	Further description of use	Market description	Contributing activity (CA) name	C A descriptor	Other information
Use at Us industrial ve site cl pr	Jse of vehicle cleaning product	Spraying and rinsing of cleaning product at car manufacturing lines (largely automated process – mainly open – ambient temperature)	PC35, SU17	Automated water based washing of large articles – Indoor use Transfer of products with manual coupling/decoupling Spraying and rinsing of a diluted cleaning product (automated process; open systems)	ERC4 PROC8b PROC7	Technical function of substance in this use: surfactant Tonnage per use: 100 t/y (Total EU tonnage for this use) Use specific regulatory status: no Limited number of sites for this use: no Subsequent service life relevant to this use: no





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• Example of Descriptor of Use

Life cycle stage	Use name	Further description of use	Market description	Contributing activity name	Contributi ng activity descriptor	Other information
Widespre ad use by professio	Professio nal use of	Regular cleaning of equipment. Manual spraying and wiping using long-bandle tool	PC35	Application of solvent borne or water-borne products; Indoor use	ERC8a	Technical function of substance in this use: solvent; Tonnage per use: 100 t/y
workers surface	surface	using long-handle tool		Manual spraying	PROC11	(Total EU tonnage for this use)
	products			Wiping	PROC10	Limited number of sites for this use: no
						Subsequent service life relevant to this use: no
						Supplied as a mixture



Information:





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Life Cycle Stage vs Occupational Health and Safety Management Systems

Life cycle stage	Occupational health and safety management system	Example
Use at industrial site	Advanced (`industrial conditions' or similar)	Use of substance as intermediate in manufacturing process
	Basic (`professional conditions')	Contractors working in an industrial site on cleaning tasks
Widespread use by professional workers	Advanced (`industrial conditions' or similar)	Application of biocidal products by specialised companies
	Basic ('professional conditions')	Self-employed painter painting in private households





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• Descriptor List for Life cycle stages

Code	Name
М	Manufacture
F	Formulation or re-packing
IS	Use at industrial sites
PW	Widespread use by professional workers
С	Consumer use
SL	Service life





Descriptor List for Sector of Uses (SU)

Code	Name	NACE codes
SU1	Agriculture, forestry, fishery	А
SU2a	Mining, (without offshore industries)	В
SU2b	Offshore industries	B 6
SU4	Manufacture of food products	C 10,11
SU5	Manufacture of textiles, leather, fur	C 13-15
SU6a	Manufacture of wood and wood products	C 16
SU6b	Manufacture of pulp, paper and paper products	C 17
SU7	Printing and reproduction of recorded media	C 18
SU8	Manufacture of bulk, large scale chemicals (including petroleum products)	C 19.2+20.1
SU9	Manufacture of fine chemicals	C 20.2-20.6
SU11	Manufacture of rubber products	C 22.1
SU12	Manufacture of plastics products, including compounding and conversion	C 22.2
SU13	Manufacture of other non-metallic mineral products, e.g. plasters, cement	C 23
SU14	Manufacture of basic metals, including alloys	C 24
SU15	Manufacture of fabricated metal products, except machinery and equipment	C 25

Code	Name	NACE codes
SU16	Manufacture of computer, electronic and optical products, electrical equipment	C 26-27
SU17	General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment	C 28-30,33
SU18	Manufacture of furniture	C 31
SU19	Building and construction work	F
SU20	Health services	Q 86
SU23	Electricity, steam, gas water supply and sewage treatment	D 35, D36-37
SU24	Scientific research and development	M72
SU0	Other	

Source: Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.12: Use Description





Descriptor List for Chemical Products Categories (PC)

Code	Name	Explanation and examples	Code	Name	Explanation and examples	
PC1	Adhesives, sealants		PC12	Fertilizers		
PC2	Adsorbents		PC13	Fuels		
PC3	Air care products		PC14	Metal surface treatment products	This covers substances permanently binding with the metal surface.	
PC4	Anti-Freeze and de-icing products				It includes e.g. galvanic and electroplating products.	
PC7	Base metals and alloys		PC15	Non-metal-surface treatment products	It includes e.g. example	
PC8	Biocidal products	iocidal products Includes e.g. disinfectant			painting.	
	Note that the category refers to types of products, not to the		PC16	Heat transfer fluids		
		technical function of the substance. PC 35 should be assigned to disinfectants being used as a component in a cleaning product.	PC17	Hydraulic fluids		
			PC18	Ink and toners		
PC9a	Coatings and paints, thinners, paint removers		PC19	Removed from PC list and relocated in the technical function list (Table R.12- 15) ²⁴ .		
PC9b	Fillers, putties, plasters, modelling clay		PC20	Processing aids such as pH-regulators, flocculants,	This category covers processing	
PC9c	Finger paints			precipitants, neutralization agents	aids used in the chemical industry.	
PC11	Explosives		PC21	Laboratory chemicals	/4	

Source: Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.12: Use Description





Descriptor List for Chemical Products Categories (PC)

Code	Name	Explanation and examples	Code	Name	Explanation and examples
PC23	Leather treatment products	This category includes dyes, finishing, impregnation and care products.	PC34	Textile dyes, and impregnating products	This category includes e.g. bleaches and other processing aids.
PC24	Lubricants, greases, release products		PC35	Washing and cleaning products	This category includes water and solvent based products.
PC25	Metal working fluids		PC36	Water softeners	
PC26	Paper and board treatment products	This category includes e.g. bleaches, dye, finishing, impregnation products and other	PC37	Water treatment chemicals	
		processing aids.	PC38	Welding and soldering products, flux products	
PC27	Plant protection products		PC39	Cosmetics, personal care products	This category includes products
PC28	Perfumes, fragrances				Regulation (EU Regulation 1223/2009) and other
PC29	Pharmaceuticals				personal care products. It includes products such as. toothpaste, deodorants, etc.
PC30	Photo-chemicals		PC40	Extraction agents	
PC31	Polishes and wax blends		PC41	Oil and gas exploration or production products	
PC32	Polymer preparations and compounds		PC42	Electrolytes for batteries	Mixtures (liquids or pastes)
PC33	Semiconductors				in batteries.
Sour	ce : Guidance on Information Regu	irements and	PCO	Other	

Chemical Safety Assessment: Chapter R.12: Use Description





Descriptor List for Process Categories (PROC)

Code	Name	Explanations and examples	Code	Name	Explanations and examples
PROC1	Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.	Describes the general nature of processes taking place in sectors where the manufacture of substances or production of mixtures takes place or processes with closed process conditions as applied in chemical industry ²⁵ . The closed transfers inherent to the process including closed sampling are included. Open transfers to charge/discharge the system are not included.	PROC4	Chemical production where opportunity for exposure arises	Describes the general nature of processes taking place in sectors where the manufacture of substances or production of mixtures takes place (processes where the nature of the design does not exclude exposure). The closed transfers inherent to the process including closed sampling are included. Open transfers to charge/discharge the system are not included.
			PROC5	Mixing or blending in batch processes	Covers mixing or blending of solid or liquid materials in the context of manufacturing or
PROC2	Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions Describes the general nature of processes taking place in sectors where the manufacture of substances or production of mixtures takes place (continuous processes that involve limited manual interventions), or processes with equivalent closed process conditions as applied in chemical industry. The closed transfers inherent to the process including closed sampling are included. Open transfers to charge/discharge the system are not included.			formulating sectors, as well as upon end use. Charging/discharging of the blending vessel and sampling are considered separate activities and are not included in this PROC.	
		The closed transfers inherent to the process including closed sampling are included. Open transfers to charge/discharge the system are not included.	PROC6	Calendering operations	Processing of large surfaces at elevated temperature e.g. calendering of textile, rubber or paper
			PROC7	Industrial spraying	Air dispersive techniques i.e. dispersion into air (= atomization) by e.g. pressurized air, hydraulic
PROC3	Manufacture or formulation in the	Describes the general nature of processes taking place in sectors where the manufacture of			pressure or centrifugation, applicable for liquids and powders. Spraving for surface coating, adhesives
	closed batch processes	(batch processes that involve limited manual interventions) or processes with closed process			polishes/cleaners, air care products, blasting.
	with occasional controlled exposure or processes with equivalent containment condition	conditions as applied in chemical industry. The closed transfers inherent to the process including closed sampling are included. Open transfers to charge/discharge are not included.			The reference to 'industrial' means that workers involved have received specific task training, follow operating procedures and act under supervision. Where engineering controls are in place, they are also operated by trained personnel and regularly maintained according to procedures. It is not meant that the activity can only take place at industrial sites.
Source	· Guidanco on Info	rmation Poquiromonts and			

Chemical Safety Assessment: Chapter R.12: Use Description





Descriptor List for Process Categories (PROC)

Code	Name	Explanations and examples	Code	Name	Explanations and examples
PROC8a	Transfer of substance or mixture (charging and discharging) at non- dedicated facilities ²⁶	Covers general transferring operations of large quantities of chemicals from/to vessels, containers, installations or machinery without dedicated engineering controls in place for reducing exposure. Transfer includes loading, filling, dumping, bagging and weighing.	PROC11	Non industrial spraying	Air dispersive techniques i.e. dispersion into air (= atomization) by e.g. pressurized air, hydraulic pressure or centrifugation, applicable for liquids and powders. Includes spraying of substances/mixtures for surface coating, adhesives, polishes/cleaners, air care products, blasting. The reference to `non-industrial' is to differentiate where conditions mentioned in PROC7 cannot be
PROC8b	Transfer of substance or mixture (charging and discharging) at dedicated facilities ²⁶	fer of substance or re (charging and arging) at dedicated es ²⁶ Covers general transferring operations from/to vessels or containers with provision of dedicated engineering controls in place for reducing exposure: it addresses operations where material transfers are undertaken at locations that are specifically			met. It is not meant that the activity can only take place at non-industrial sites.
		designed and operated for the transfer of larger quantities (tens of kilos and higher) of chemicals and where the exposure is primarily related to the un-coupling/coupling activity rather than the transfer itself. Such situations include tanker loading bays and drum filling.	PROC12	Use of blowing agents in manufacture of foam	Use of substances to facilitate the process of production of foams by forming gas bubbles in a liquid mixture. It can be either a continuous or a batch process.
		Transfer includes loading, filling, dumping, bagging.	PROC13	Treatment of articles by	Treatment of articles by dipping, pouring,
PROC9	Transfer of substance or mixture into small containers (dedicated spillage.			apping and poaring	substances; Includes handling of treated objects (e.g. from/to treatment basin, after drying, plating). The service life of the article after the treatment needs to be reported separately.
	weighing)	This PROC can also be used to cover sampling operations.	PROC14	Tabletting, compression, extrusion, pelletisation,	This covers processing of mixtures and/or substances into a defined shape for further use.
PROC10	Roller application or	This includes application of paints, coatings, removers, adhesives or cleaning agents to surfaces		granulation	
	brushing removers, adhesives or cleaning agents to surfaces with potential exposure arising from splashes. This PROC can also be assigned to tasks such as cleaning of surfaces using long-handle tools.		PROC15	Use as laboratory reagent	Use of substances at small scale in laboratories (less than or equal to 1 l or 1 kg present at workplace). Larger operations in laboratories and R+D installations should be treated as industrial processes
Source	: Guidance on Info	rmation Requirements and			This includes the use in quality control processes.

Source: Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.12: Use Description





Descriptor List for Process Categories (PROC)

Code	Name	Explanations and examples	Code	Name	Explanations and examples
PROC16	Use of fuels	Covers the use of (solid and liquid) fuel (including additives), including transfers via the closed system, where limited exposure to the product in its unburned form is expected. Assignment of PROC 8 or PROC 9 not needed in this case. The exposure to exhaust gases is not covered.	PROC22	Manufacturing and processing of minerals and/or metals at substantially elevated temperature	Describes the general nature of processes taking place at smelters, furnaces, refineries, ovens, excluding casting, tapping and drossing operations. When the temperature has decreased, the handling of the cool material can be covered by PROC21 or PROC26.
PROC17	Lubrication at high energy conditions in metal working operations	Covers metal working processes where the lubricants are exposed to high temperature and friction e.g. metal rolling/forming processes, drilling and grinding, etc. Transfers for refilling or discharging from/to reservoirs are not covered.	PROC23	Open processing and transfer operations at substantially elevated temperature	Describes certain processes taking place at smelters, furnaces and ovens: casting, tapping and drossing operations. Covers also hot dip galvanising raking of melted
PROC18	General greasing /lubrication at high kinetic energy conditions	Use of lubricant or greasing agents in high kinetic energy conditions, including manual application. It does not refer to any filling operation.			solids in paving and water granulation. When the temperature has decreased, the handling of the cold material can be covered by PROC21 or PROC26.
PROC19	Manual activities involving hand contact	Addresses tasks, where exposure of hands and forearms can be expected; no dedicated tools or specific exposure controls other than PPE can be put in place. Examples are manual mixing of cement and plasters in construction works or mixing of hair dyes and bleaches.	PROC24	High (mechanical) energy work-up of substances bound in /on materials and/or articles	Substantial thermal or kinetic energy applied to substance by e.g. hot rolling/forming, grinding, mechanical cutting, drilling or sanding, stripping.
PROC20	Use of functional fluids in small devices	Includes the filling and emptying of systems containing functional fluids (including transfers via	PROC25	Other hot work operations with metals	Welding, soldering, gouging, brazing, flame cutting.
		the closed system) e.g. heat and pressure transfer fluids; takes place on routine basis Example: charging and discharging of motor and engine oils, brake fluids, home appliances. Assignment of PROCs 8-9 not needed in this case.	Source Chemic	: Guidance on Infor al Safety Assessme	mation Requirements and ent: Chapter R.12: Use Description
PROC21	Low energy manipulation and handling of substances bound in/on materials or articles	Cover activities such as manual cutting, cold rolling or assembly/disassembly of material/article. It can also be used for handling/transfer of massive (metal) objects.			28





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• Descriptor List for Process Categories (PROC)

Code	Name	Explanations and examples
PROC26	Handling of solid inorganic substances at ambient temperature	Transfer and handling of ores, concentrates, metals and other inorganic substances in solid (but not massive) potentially dusty form. Assignment of PROC8a, PROC8b or PROC9 not needed in this case. The handling of massive objects should be addressed with PROC21.
PROC27a	Production of metal powders (hot processes)	Production of metal powders by hot metallurgical processes (atomisation, dry dispersion).
PROC27b	Production of metal powders (wet processes)	Production of metal powders by wet metallurgical processes (electrolysis, wet dispersion).
PROC28	Manual maintenance (cleaning and repair) of machinery	 Covers maintenance activities for uses where the maintenance is not already included in any of the other process categories. The category covers for example: activities when closed systems are opened and potentially entered for cleaning generally dedicated/separate cleaning tasks conducted on a shift or less frequent basis (e.g. between individual production batches) removal of splashes around the machinery removal of filters or material from filters cleaning of floors that are not directly around the machinery, but still need cleaning for instance because of dust deposition when handling a dusty product
PROC0	Other	

Source: Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.12: Use Description





• Descriptor List for Environmental Release Categories (ERC)

Code	Name	Explanation and examples	Code	Name	Explanation and examples		
ERC1	Manufacture of the substance		ERC5 Use at industrial site leading to inclusion into/onto article The substance or its transformation pincluded into or onto article Examples: Use of binding agent and propaints and coatings or adhesives Use of dyes in textile fabrics and Use of plasticisers, pigments or article matrix or coatings on article Covers also uses where the substa article after having previously been	The substance or its transformation products are included into or onto article Examples:			
ERC2	Formulation into mixture	 Applies to uses in all types of formulating industries; substance is mixed (blended) into (chemical) mixtures Examples: formulation of paints, household cleaners, lubricants, fuels, bulk chemicals for industrial uses etc. 					
ERC3	Formulation into solid matrix	Applies to uses in formulating industries; substance is mixed (blended) in order to be physically or chemically bound into or onto a solid matrix Example:	ERC6a	Use of intermediate	aid (e.g. heat stabilisers in plastic processing). The substance is used in order to manufacture another substance		
		 formulation of stabilisers into master-batches for production of polymer pellets 			Examples: • Use of chemical building blocks (feedstock) in the second s		
ERC4	Use of non-reactive processing aid at industrial site (no	Examples: • Chemical processing where the substance is used as solvent for crystallisation			synthesis of agrochemicals, pharmaceuticals etc.Use of cyclopentanone in the synthesis of cyclopentanol		
	article)	 Production activities where the substance is used as a cleaning agent (solvent or surfactant) Polymer moulding/casting where the substance is used as anti-set off agent 	ERC6b	Use of reactive processing aid at industrial site (no inclusion into or onto	The substance or its transformation product(s) are not included into or onto article; substance reacts on use Examples:		
				article)	 Use of bleaching agents in textile and paper industry Use of catalysts 		

Source: Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.12: Use Description





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• Descriptor List for Environmental Release Categories (ERC)

Code	Name	Explanation and examples		Code	Name	Explanation and examples
ERC6c	Use of monomer in polymerisation processes at industrial site (inclusion or not into/onto article)	 The substance is used as monomer in the production of polymers (resins, plastics (thermoplastics)) Examples: Use of vinyl chloride monomer in the production of PVC. Use of monomers in production of resins 	f	ERC8a	Widespread use of non- reactive processing aid (no inclusion into or onto article, indoor)	Applies to uses by the public at large or by professional workers Use (usually) results in release into air or the sewage system Examples: • Down the drain product like e.g. Use of detergents in fabric washing, use of machine wash liquids and
ERC6d	ERC6dUse of reactive process regulators in polymerisation processes at industrial site (inclusion or not into/onto article)The substance is used as process regulator (e.g. cross- polymeris) for polymerisation process - production of resins, thermosets, rubbers, polymers Examples: • Use of styrene in polyester production • Use of vulcanization agents in the production of rubbers • Use of catalystsERC7Use of functional fluid at industrial siteThe substance is used as functional fluid and does not get in contact with products; substance is contained during the use. Examples: • Use of engine and machine oils • Use of fluids in hydraulic systems and heat transfer systems Does not cover the case where a substance/mixture is an integral part of an article (e.g. batteries) Does not cover uses where • substances are used as processing aids or reactants				 lavatory cleaners, use of automotive and bicycle care products (polishes, lubricants, de-icers) Use of solvents in paints and adhesives Use of fragrances and aerosol propellants in air fresheners. 	
			ERC8b	Widespread use of reactive processing aid (no inclusion into or onto article, indoor)	Applies to uses by the public at large or by professional workers Example: • Use of sodium bypochlorite in lavatory cleaners	
ERC7					bleaching agents in fabric washing products, hydrogen peroxide in dental care products.	
			ERC8c	Widespread use leading to inclusion into/onto article (indoor)	 Applies to uses by the public at large or by professional workers; substance or its transformation products will be physically or chemically bound into or onto article Examples: Use of binding agent or process regulators in paints and coatings or adhesives Use of dyes during dyeing of textile fabrics 	
		 In chemical processes (see ERC 6a to 6d) articles are treated with processing aids (e.g. metal part cleaning or textile cleaning) (see ERC 4) 				





• Descriptor List for Environmental Release Categories (ERC)

Code	Name	Explanation and examples	С	Code	Name	Explanation and examples				
ERC8d	Widespread use of non- reactive processing aid (no inclusion into or onto article, outdoor)	 Applies to uses by the public at large or by professional workers Examples: Use of automotive and bicycle care products (polishes, greases de-icers, detergents), use of highly volatile solvents in paints and adhesives 	E	ERC9b ERC10a ERC10b	ERC9b	ERC9b	ERC9b \	ERC9b Wide funct	Widespread use of functional fluid (outdoor)	Applies to uses by the public at large or by professional workers; substance is used as functional fluid and does not get in contact with products; substance is contained during the use Examples: Motor oils Break fluids in automotive brake systems Fluide/gasee is air conditioning systems
ERC8e	Widespread use of reactive processing aid (no inclusion into or onto	Applies to uses by the public at large or by professional workers				Does not cover the case where a substance/mixture is an integral part of an article (e.g. batteries)				
	article, outdoor)	 use of sodium hypochlorite or hydrogen peroxide for surface cleaning (building materials) 	EI		ERC10a	RC10a Widespread use articles with low (outdoor)	Widespread use of articles with low release (outdoor)	Applies to the use of articles by the public at large or by professional workers where there is no intended release of the registered substance and where the conditions of use do not promote releases.		
ERC8f	Widespread use leading to inclusion into/onto article (outdoor)	Applies to uses by the public at large or by professional workers; substance or its transformation products will be physically or chemically bound into or onto article Example: • Use of binding agent or process regulators in paints					 Example: Service life of metal, wooden and plastic construction and building materials (gutters, drains, frames, etc.) Automotive batteries 			
ERC9a	Widespread use of functional fluid (indoor)	 Applies to uses by the public at large or by professional workers; substance is used as functional fluid and does not get in contact with products; substance is contained during the use Example: Use of substance in oil-based electric heaters Does not cover the case where a substance/mixture is an integral part of an article (e.g. batteries) 	E		Widespread use of articles with high or intended release (outdoor)	Applies to the use of articles by the public at large or by professional workers where the registered substance is intended to be released or where the conditions of use promote releases. Also applies to processing by the public at large or by professional workers where the substances included into or onto articles are released (intended or not) from/with the article matrix as a result of processing. Examples: • Service life of tyres and brake pads in trucks or cars				
						 Substances released from articles during work at elevated temperature 				

Source: Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.12: Use Description





• Descriptor List for Environmental Release Categories (ERC)

Code	Name	Explanation and examples	Code	Name	Explanation and examples
ERC11a	Widespread use of articles with low release (indoor)	 Applies to the use of articles by the public at large or by professional workers where there is no intended release of the registered substance and where the conditions of use do not promote releases Examples: Non-volatile substances in flooring, furniture, toys, construction materials, curtains, footwear, leather products, paper and cardboard products (magazines, books, news paper and packaging paper), electronic equipment (casing) 	ERC12b	Processing of articles at industrial sites with high release	 Applies to uses at industrial sites where the substances included into or onto articles are released (intended or not) from/with the article matrix as a result of processing by workers; release is high Examples: Substances released from articles during sanding operations or paint stripping by shot-blasting (high amounts of dust expected) Substances released from articles during processes at elevated temperature
ERC11b	Widespread use of articles with high or intended release (indoor)	 Applies to the use of articles by the public at large or by professional workers where the registered substance is intended to be released or where the conditions of use promote releases. Also applies to processing by the public at large or by professional workers where the substances included into or onto articles are released (intended or not) from/with the article matrix as a result of processing. Examples: Substances released from fabrics, textiles (clothing, floor rugs) during washing Fragrance in scented articles (toys, papers, sanitary towels,) 	ERC12c Source:	Use of articles at industrial sites with low release Guidance on Info	Applies to uses of articles at industrial sites where the substances included into or onto articles are not intended to be released and where the conditions of use do not promote release. Examples: Machinery at industrial sites Note: where an article is used at industrial sites but also in the same conditions by professional workers or consumers (e.g. pens, plates, mobile phones) there is no need to report that use with an ERC12c. That use can be reported with the ERC categories corresponding to widespread use of articles.
ERC12a	Processing of articles at industrial sites with low release	 Applies to uses at industrial sites where the substances included into or onto articles are released (intended or not) from/with the article matrix as a result of processing by workers; release remains low Examples: Cutting of textile, cutting, machining or grinding of metal or polymers in engineering industries 	Chemica	al Safety Assessm	nent: Chapter R.12: Use Description





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Code	Name	Suitable TARIC chapters	Explanation and examples
Categori	es of complex articles		
AC1	Vehicles	86-89	
AC1a	Vehicles covered by End of Life Vehicles (ELV) directive		e.g. personal vehicles, delivery vans
AC1b	Other vehicles		e.g. boat, train, metro, planes
AC2	Machinery, mechanical appliances, electrical/electronic articles	84/85	
AC2a	Machinery, mechanical appliances, electrical/electronic articles covered by the Waste Electrical and Electronic Equipment (WEEE) directive		e.g. refrigerators, washing machines, vacuum cleaners, computers, telephones, drills, saws, smoke detectors, thermostats, radiators
AC2b	Other machinery, mechanical appliances, electrical/electronic articles		e.g. large-scale stationary industrial tools
AC3	Electrical batteries and accumulators	8506/07	

Code	Name	Suitable TARIC chapters	Explanation and examples
Materia	-based categories of articles		
AC4	Stone, plaster, cement, glass and ceramic articles	68/69/ 70	
AC4a	Stone, plaster, cement, glass and ceramic articles: Large surface area articles		Construction and building materials e.g. floor coverings, isolation articles
AC4b	Stone, plaster, cement, glass and ceramic articles: Toys intended for children's use (and child dedicated articles)		
AC4c	Stone, plaster, cement, glass and ceramic articles: Packaging (excluding food packaging)		
AC4d	Stone, plaster, cement, glass and ceramic articles: Articles intended for food contact		e.g. dinner ware, drinking glasses, pots, pans, food storage containers
AC4e	Stone, plaster, cement, glass and ceramic articles: Furniture & furnishings		
AC4f	Stone, plaster, cement, glass and ceramic articles: Articles with intense direct dermal contact during normal use		e.g. jewellery
AC4g	Other articles made of stone, plaster, cement, glass or ceramic		





Code	Name	Suitable TARIC chapters	Explanation and examples
AC5	Fabrics, textiles and apparel	50-63 , 94/95	
AC5a	Fabrics, textiles and apparel: Large surface area articles		Construction and building materials e.g. floor or wall materials: carpets, rugs, tapestries
AC5b	Fabrics, textiles and apparel: Toys intended for children's use (and child dedicated articles)		e.g. stuffed toys, blankets, comfort objects
AC5c	Fabrics, textiles and apparel: Packaging (excluding food packaging)		
AC5d	Fabrics, textiles and apparel: Articles intended for food contact		
AC5e	Fabrics, textiles and apparel: Furniture & furnishings, including furniture coverings		e.g. sofa cover, car seat cover, fabric chair, hammock
AC5f	Fabrics, textiles and apparel: Articles with intense direct dermal contact during normal use		e.g. clothing, shirts, pants, shorts
AC5g	Fabrics, textiles and apparel: Articles with intense direct dermal contact during normal use: bedding and mattresses		e.g. blankets, sheets
AC5h	Other articles made of fabrics, textiles and apparel		

Code	Name	Suitable TARIC chapters	Explanation and examples
AC6	Leather articles	41-42 , 64, 94	
AC6a	Leather articles: Large surface area articles		Construction and building materials
AC6b	Leather articles: Toys intended for children's use (and child dedicated articles)		
AC6c	Leather articles: Packaging (excluding food packaging)		
AC6d	Leather articles: Articles intended for food contact		
AC6e	Leather articles: Furniture & furnishings, including furniture coverings		e.g. sofa, car seat, chair
AC6f	Leather articles: Articles with intense direct dermal contact during normal use		e.g. clothing such as jackets, shoes, or gloves
AC6g	Other leather articles		e.g. domestic articles such as decoration articles, leather boxes





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Code	Name	Suitable TARIC chapters	Explanation and examples
AC7	Metal articles	71, 73- 83 , 95	
AC7a	Metal articles: Large surface area articles		Construction and building materials e.g. roof sheets, pipes,
AC7b	Metal articles: Toys intended for children's use (and child dedicated articles)		
AC7c	Metal articles: Packaging (excluding food packaging)		
AC7d	Metal articles: Articles intended for food contact		e.g. packaging containers, metal tins, knifes, cooking pots
AC7e	Metal articles: Furniture & furnishings		e.g. outdoor furniture, benches, tables
AC7f	Metal articles: Articles with intense direct dermal contact during normal use		e.g. handles, jewellery
AC7g	Other metal articles		

Code	Name	Suitable TARIC chapters	Explanation and examples
AC8	Paper articles	48-49	includes paperboard, cardboard
AC8a	Paper articles: Large surface area articles		Construction and building materials e.g. insulation panels, wall papers
AC8b	Paper articles: Toys intended for children's use (and child dedicated articles)		
AC8c	Paper articles: Packaging (excluding food packaging)		
AC8d	Paper articles: Articles intended for food contact		
AC8e	Paper articles: Furniture & furnishings		
AC8f1	Paper articles: Articles with intense direct dermal contact during normal use: personal hygiene articles		e.g. nappies, feminine hygiene products, adult incontinence products, tissues, towels, toilet paper
AC8f2	Paper articles: Articles with intense direct dermal contact during normal use: printed articles with dermal contact in normal conditions of use		e.g. newspapers, books, magazines, printed photographs
AC8g	Other paper articles		e.g. lampshades, paper lanterns





Code	Name	Suitable TARIC chapters	Explanation and examples
AC10	Rubber articles	40 , 64, 95	Includes foam materials
AC10a	Rubber articles: Large surface area articles		Construction and building materials e.g. flooring
AC10b	Rubber articles: Toys intended for children's use (and child dedicated articles)		e.g. baby bottle nipples, soothers
AC10c	Rubber articles: Packaging (excluding food packaging)		
AC10d	Rubber articles: Articles intended for food contact		
AC10e	Rubber articles: Furniture & furnishings, including furniture coverings		
AC10f	Rubber articles: Articles with intense direct dermal contact during normal use		e.g. gloves, boots, clothing, rubber handles, gear lever, steering wheels
AC10g	Other rubber articles		

Code	Name	Suitable TARIC chapters	Explanation and examples
AC11	Wood articles	44 , 94/95	
AC11a	Wood articles: Large surface area articles		Construction and building materials e.g. floor, claddings
AC11b	Wood articles: Toys intended for children's use (and child dedicated articles)		
AC11c	Wood articles: Packaging (excluding food packaging)		
AC11d	Wood articles: Articles intended for food contact		
AC11e	Wood articles: Furniture & furnishings		
AC11f	Wood articles: Articles with intense direct dermal contact during normal use		e.g. handles, pencils
AC11g	Other wood articles		





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Code	Name	Suitable TARIC chapters	Explanation and examples
AC13	Plastic articles	39 , 94/95, 85/86	includes foam materials
AC13a	Plastic articles: Large surface area articles		Construction and building materials e.g. flooring, insulation
AC13b	Plastic articles: Toys intended for children's use (and child dedicated articles)		includes baby-bottles
AC13c	Plastic articles: Packaging (excluding food packaging)		
AC13d	Plastic articles: Articles intended for food contact		e.g. plastic dinner ware, food storage
AC13e	Plastic articles: Furniture & furnishings, including furniture coverings		
AC13f	Plastic articles: Articles with intense direct dermal contact during normal use		e.g. handles, ball pens
AC13g	Other plastic articles		
AC0	Other		



Hazard Assessment

(Data Requirement)



Hazard Assessment Data Requirement

Main Issues	Details		
1. Identity of the Substance and Physical and Chemical Properties			
1.1 Name and other identifiers of the substance	Chemical Name, CAS Number, EC Number, EC Name, IUPAC Name, Molecular formula, Molecular weight range, Synonyms, Structural formula		
1.2 Composition of the substance	Name, Description, Degree of impurity,		
1.3 Physico-chemical properties	Physical state at 20°C and 101.3 kPa, Melting/freezing point, Boiling point, Vapour pressure, Water solubility, Partition coefficient n-octanol/water (log POW), Flashpoint, Auto Flammability, Reactivity, Density		
2. Harmonized Classification and Labelli	ng		
2.1 GHS Classification	Hazard Class & Category Code(s), Hazard Statement Code(s), Pictogram & Signal Word Code(s), Supplement Hazard Statement Code (if any), Spec. Concentration Limits, M-factors		
2.2 EU Annex I Classification (if required)	Classification, Labelling, Concentration Limits		



Hazard Assessment

(Data Requirement)



Hazard Assessment Data Requirement

Main Issues	Details
3. Environmental Fate Properties	
4. Human Health Hazard Assessment	
5. Environmental Hazard Assessment	
6. Conclusion on the SVHC Properties	
6.1 PBT, vPvB Assessment	Consider its properties according to GHS classification
5.2 CMR Assessment Consider its properties according to GHS classification	
6.3 Substances of equivalent level of concern assessment	Consider its properties according to GHS classification



Hazard Assessment (DNEL Setting)



• Overview of derivation of reference DNELs for workers and general population (adults and children)

Point of departure for DNEL derivation by all routes for Diglyme (DuPont, 1989)

Rat 2-week Inhalation NOAEC in mg/m ³ (testicular				
toxicity)	167			
Dosing regime	6 h/d, 5 d/wk, 2 wk			
Inhalation absorption percentage	100 %			
Derivation of Refere	nce DNELs	·		
		CENEDAL		
	WORKERS	POPULATION		
Assessment Factors				
Interspecies, Allometric scaling	-	-		
Interspecies, remaining differences	2.5	2.5		
Intraspecies	5	10		
Subacute to chronic	4	4		
Hours/day	8	24		
Days/week	5	7		

Source: Application for authorisation: DNEL setting for reprotoxic properties of Diglyme (ECHA)



Hazard Assessment (DNEL Setting)



• Overview of derivation of reference DNELs for workers and general population (adults and children)

INHALATION	-	
Absorption percentage	100%	100%
Correction for exposure regime	6/8	6/24 x 5/7
Breathing rate for workers light activity vs rest	6.7/10	
NOAEC (corrected)	83.9	29.8
Reference DNEL INHALATION in mg/m ³	1.68	0.30
DERMAL		
Absorption percentage	100%	100%
Correction for exposure regime	6/8	6/8 x 5/7
Standard respiratory volume in m³/kg bw/day	0.384	0.384
NOAEL (corrected)	48.1	34.4
Reference DNEL DERMAL in mg/kg/day	0.24	0.09
ORAL		
Absorption percentage	100%	100%
Correction for exposure regime	6/8	6/8 x 5/7
Standard respiratory volume in m³/kg bw/day	0.384	0.384
NOAEL (corrected)	48.1	34.4
Reference DNEL ORAL in mg/kg/day	0.24	0.09

Source: Application for authorisation: DNEL setting for reprotoxic properties of Diglyme (ECHA)





- Occupational Exposure Estimation
 - Types and routes of exposure (Inhalation/dermal/oral exposure)
 - Determinants of occupational exposure
 - Exposure assessment with measurements and modelling approaches
 - Core information requirements
 - Use and selection of measured data
 - ECETOC TRA
 - Higher Tier Exposure Assessment





- Determinants of Occupational Exposure
 - where is the substance used? (including description of processes, activities and products);
 - characteristics of the substance: physical state, vapour pressure, dustiness (e.g. powder, pellets);
 - the composition of mixtures (preparations) and articles (including approximate percentages);
 - possible hazardous impurities in the substance;
 - how is the substance used? (including description of work activities/tasks leading to exposure, quantities used);
 - approximate percentage in process materials and finished products;

Source: Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.14: Occupational exposure estimation





• Determinants of Occupational Exposure

- the nature of exposure, i.e. the operational conditions (including type and approximate frequency and duration of tasks, duration and frequency of exposures);
- what risk management measures (technical/personal) are (to be) used when the activities are carried out?; this includes information to show that any personal protective equipment (PPE) recommended is suitable, well-fitted and maintained, and is used as a last resort (i.e. other control options are used to the extent possible);
- recommendations regarding appropriate management systems to ensure that the measures to limit or prevent exposure are correctly applied (e.g. duration of exposure is minimised and PPE is used correctly).





- Core Information requirements for modelling approaches
 - physical state of the substance/
 - physical state of the product handled
 - vapour pressure (for liquids)/
 - different levels of "dustiness" (for solids)
 - the concentration of the substance in the mixture
 - the level of containment
 - efficiency of local exhaust ventilation (LEV)
 - duration of activity
 - what is done with the substance, covering parameters related to: energy exerted on the substance or product, surface area of source in contact with air, if very limited amounts handled.





• ECETOC TRA (Targeted Risk Assessment) – Input Data

Vapor Pressure and Dustiness

Table R.14-4: General fugacity table

Vapour pressure (kPa)	Dustiness	Fugacity
>=0.00001- <0.5	Low	Low
0.5 to 10	Medium	Medium
>10	High	High

Table R.14-6: Fugacity classifications for process temperature / melting point relations (PROCs 22-25 (metals) only)

Process temperature* in relation to melting point	Fugacity
process temp < melting point	low
process temp ≈ melting point	moderate
process temp > melting point	high
* In drilling or "abrasion" techniques	(e.g. grinding) the temperature

* In drilling or "abrasion" techniques (e.g. grinding) the temperature of the "tool-material contact area" may be used instead of the process temperature.

Table R.14-5: Help on fugacity selection criteria

General description	Relative dustiness potential	Typical materials	TRA Selection Value								
Not dusty	1	Plastic granules ^a , pelleted fertilisers	Low								
Slightly dusty	10 - 100 times dustier	Dry garden peat, sugar, salt	Low /Medium ^c								
Dusty	100 - 1,000 times dustier	Talc, graphite	Medium								
Very/extremely dusty	More than 1,000 times dustier	Cement dust, milled powders, plaster, flour, lyophilised powders, (process fumes ^b)	High								
^a Exposures to materials where a substance is contained and bound in a matrix (e.g. pigment within a plastic, filler within paint) should also be included in this category. Although the real exposure is actually determined by a combination of physical form and the bioavailability of the substance within the matrix, because the bioavailability is very low under such circumstances this will result in a low exposure potential.											
^b Process fumes (e.g. rub category if exposures to su	^b Process fumes (e.g. rubber, welding, soldering) behave like gases and would be considered within this category if exposures to such complex mixtures are considered in any risk assessment.										

 $^{\circ}\,$ The user may choose between low and medium fugacity





- ECETOC TRA (Targeted Risk Assessment) Input Data
 - Process Categories (PROCs): The parameters that provide options for iteration (alternative Operational Conditions or Risk Management Measures)
 - Operational conditions
 - Industrial or professional activity
 - Activity taking place indoors or outdoors
 - Duration of the activity
 - Percentage of substance used (if used in a mixture)
 - Risk Management Measures
 - Presence of Local Exhaust Ventilation (LEV)
 - Use of Personal Protective Equipment (Respirators/Gloves)





• ECETOC TRA (Targeted Risk Assessment) – Input Data

Operational Conditions

- Impact of working outdoor: A default reduction of the basic estimate for working outdoors is calculated by multiplying the basic estimate by a factor of 0.7. In other words: the outdoor exposure is 70% of the indoor exposure if all else is the same.
- Limited exposure duration

Duration of activity	Exposure modifying factor
> 4 hours	1
1 - 4 hours	0.6
15 min - 1 hour	0.2
< 15 min	0.1

Table R.14-7: Modifiers for duration of activity

Source: Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.14: Occupational exposure estimation





- ECETOC TRA (Targeted Risk Assessment) Input Data Operational Conditions
 - Impact of percentage of substance used in a mixture

Table R.14-8: Influence of the con	ncentration in mixtures
------------------------------------	-------------------------

Concentration in mixture (w/w)	Exposure modifying factor
Not in a mixture	1
> 25% *	1
5 – 25%	0.6
1 – 5%	0.2
< 1 %	0.1

Remark: * Highest concentration in 1999/45/EC the EU Dangerous Preparations Directive

Source: Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.14: Occupational exposure estimation





• ECETOC TRA (Targeted Risk Assessment) – Input Data

Risk Management Measures

Presence of Local Exhaust Ventilation (LEV)

Table 1: Treatment of different forms of general ventilation within the TRA

Type of general ventilation	Application	Ventilation effectiveness (modifier to initial inhalation estimate)
'Basic' general ventilation is assumed in the base TRAv1 and TRAv2 estimates	 Corresponds to: Basic natural ventilation (i.e. normal GV arising from incidental activities within a workplace) Typically 1-3 air exchange per hour 	0% (1.0 x)
'Good' general ventilation is not assumed in the TRA estimates and can be applied as an exposure modifier for indoor activities (exposure reduction consistent with 'use outdoors')	 Corresponds to: Good natural (e.g. intentional opening of doors and windows) and/or 'non-engineered' mechanical ventilation Typically 3-5 air exchange per hour TRA does not support use in combination with 'use outdoors' 	30% (0.7 x)
Enhanced general ventilation	 Corresponds to: Engineered mechanical ventilation for the workplace At least 5-10 air exchanges per hour TRA does not support use in combination with 'use outdoors' TRA does not support use in combination with LEV for professional settings 	70% (0.3 x)

Source: ECETOC TRA version 3 Background and Rationale for Improvements





• ECETOC TRA (Targeted Risk Assessment) – Input Data

Risk Management Measures

- Use of Personal Protection (Gloves)

Table 7: Exposure control efficiencies for different dermal protection strategies

Dermal Protection Characteristics	Indicated Efficiency %	Affected User Groups
a. Any glove / gauntlet without permeation data and without employee training	0	
 B. Gloves with available permeation data indicating that the material of construction offers good protection for the substance 	80	 Applies to both industrial and professional users
 c. Chemically resistant gloves (i.e. as #b above) with 'basic' employee training 	90	
d. Chemically resistant gloves in combination with specific activity training (e.g. procedures for glove removal and disposal) for tasks where dermal exposure can be expected to occur	95	Industrial users only





• Output of ECETOC TRA (Worker exposure estimation)

Table R.14-9: Output of ECETOC TRA worker exposure estimation

Worker Exposure report for	Exposure Estimate
Substance ABC (CAS NO. 00-00-1)	(Units ppm)
Medium fugacity	
Exposure scenario (Roller painting)	
Process Category 10 - Roller application or brushing	
Public Domain (Professional) activity	
Initial Exposure Estimate	100
Exposure modifiers	
The activity takes place Indoors	
Ventilation is present with an assumed efficiency of 80%	20
The maximum duration of the activity is 1 - 4 hours	12
Respiratory Protection with a minimum efficiency of	1.2
90% is used	
Is this substance part of a mixture? Yes at 5 – 25% w/w	
Assessment factor applied is 0.6	0.72
The Inhalation Exposure Estimate for this Exposure	0.72 ppm
Scenario is	
Dermal exposures may arise from this Exposure Scenario	960 (sq cm)
and, assuming a maximal exposed skin area	
Dermal exposures are estimated at	1.37 mg/kg/day

Source: Guidance on Information Requirements and Chemical Safety Assessment: Chapter R.14: Occupational exposure estimation





• ECETOC TRA (Targeted Risk Assessment) – Sample Screens

- Part I. Overview of the user interface

	B	С	D	E	F	G	Н	1		J	C
1											
2					ECET	OC TARGETED	RISK ASSESSMENT	T MODEL			
3											
4	General workflow:										
5											
6	STEP 1	Identificati	on of substance, use a	nd assessment			Step 1 - Identification				
7	SIEP 2	Input of ph	ysical-chemical paramo	eters			Step 2 - PC data				
8	31EP 3	Set-up ass	essments (select one o	r more):							
9			a	Human Health - Workers			Step 3a - worker asses	ssement			
10			ь	Human Health - Consumer	s		Step 3b - consumer as	sessment			
12	STEP 4	S	c an anti-anti-un ta alataka	Environmental			Step Sc - environments	al assessment			
13		Sare asses	sment set-up to datab	ase or load from databas	e						
14	Please note that this tool is provided for your personal use	onlu. It should n	ot be copied or forwar	ded to third parties.The	tool has been subjected to thor	ouah testina. Despite	this. ECETOC does not a	uarantee that the ECE	TOC TRA tool wo	orks error-free. The	tool contains :
	has been provided by third parties. ECETOC is making this	tool available fo	r users to aid them in t	he risk assessment of the	ir materials. ECETOC offers no	warranty either to the	reliability of the tool and o	of the provided inform	ation or to the co	nclusions or assum	ptions made by
	of the use of this tool or the use of such information. All us	age is at the disc	retion of the user and B	ECETOC is not liable for	any consequences resulting from	n such use.					1
15											
16											
17	Operation mode:				Entry guidance:		Mandatory entries	5			
18	manual/batch (m/b) automatically set by system	Ь					Uptional entries				
19	Manual										
20	Manual:			Read				Clear	1	Class is not and out	tout data
21	Read EUELOU substance from database	2N/A		nceu	Read substance into from (Due and definite the least d	data base (for manual i ata face ata interfector	input via interfacej Genteut electro interface)	- Court		Imports ONE sub-	stance in datas
22	Easter Substance Number retrieved	2		Run	Sous on noder with the input di	ata rrom the interface htshace	(output also on interface)	Impo	rt substance	"Import" (TRAv3	format) into fi
24	to be saved as Ecetor Substance Number	-		Save	save as new substance in d	acabase	·i	ConsTest			Exportss
		-								Export	cell left in
25	Batch:	_			-					and the second	datasheet
26	Ecetoc Substance Number being processed	2		Run betch	Run model using batch mod	de from database. Fro	m substance #	2		to substance #	
	Batch mode extends the number of scenarios per substance from 15 to 50. Entries need to be in the				-						
	datasheets (direct entries on datasheets or from user			Run batch - Human he	alth					Note: Advanced m	ode shows me
	interface by the Save function). The release					Select Standard or /	Advanced version of the	Advas	ced	and below. It is als	so required to
	estimation for the environment is also extended			Run batch - Environm	ent	batch mode				ecotoxicological o	data inputs in t
	Deyond ERUs and SPERUs to three additional "TIER II" approaches									scaling informatio	n to support e
27	a approaches.										
28	Identification of Substance										

Source: User Guide for the TRA integrated tool – TRAM, version 3.1





• ECETOC TRA (Targeted Risk Assessment) – Sample Screens

- Part II. Identification of substance

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28		Identification of Substance								
29										
30	:	SUBSTANCE (USE A UNIQUE NAME FOR EACH SUBSTANCE)		Test_1 for user guide			Identification of use	Use as an example		
31		General description/name					Assesment identifier	Test_example_version1	=	
32		CAS no.		1111-22-3			Assesment date	23Dec2011		
33		EC no.					Comments	Demo for user guide		

- Part III. General physico-chemical data







• ECETOC TRA (Targeted Risk Assessment) – Sample Screens

- Part IV. Worker exposure entry fields

		100 / × × 10010 (u	Giudi	9											
	A	В	С	D	E	F	G	Н	1	J	к	L	M		=
53		Human Health Assessment - Vorkers													*
				Process Category	Type of setting (PROC 7 and 22 always industrial, PROC 11 and 20	ls substance a solid?	Dustiness of solids OR VP of volatiles (Pa) at process temperature (clear entries if you change column F to	Duration of activity	Use of ventilation ? (addresses outdoor use, LEV and	Use of respiratory protection and, if so, minimum	Substance in preparation? (applies to inhalation and		Consider LEV for dermal exposure? (conservative		
54	No.	Scenario name		(PROC)	always professional)	(yes/no)	"No")	[hours/day]	general ventilation)	efficiency ?	dermal for volatiles and solids)	Dermal PPE / Gloves	default is "No")	- C	-
55 56 57	1 2 3			PROC 2 PROC 3	industrial professional industrial	No Yes	high	>4 hours (default >4 hours (default >4 hours (default	Indoors Indoors with LEV Indoors with good general	No No	>252 >252	no Gloves APF 5 Gloves APF 10			
58	4			PROC 4	professional	No		1 - 4 hours	Indoors with enhanced general ventilation	No	>25%	No			8
59	5			PROC 5	industrial	No	100	>4 hours (default	Indoors with LEV and enhanced general ventilation	No	5-25%	Gloves APF 20	Yes		
60	6			PROC 6	professional	No		>4 hours (default	Indoors with LEV	No	5-253	No			Π
61	7			PROC 7	industrial	No		>4 hours (default	enhanced general ventilation	952	5-25%	No			
62	8			PROC 84	professional	No		>4 hours (default	Indoors with LEV	No	5-253	No			
64	10			PROC 9	professional	No		>4 hours (default	Indoors with LEV	No	5-252	No			
65	11			PROC 10	industrial	No		>4 hours (default	videors with LEV	No	5-252	No			
66	12			PROC 11	professional	No		>4 hours (default	Indoors with LEV and good general ventilation	902	5-252	No			
67	13			PROC 12	industrial	No		>4 hours (default	Indoors with LEV	No	5-252	No			
68	14			PROC 13	professional	No		>4 hours (default	Indoors with LEV	No	5-254	No			
70 71	15	for debugging scenario no.	1		industrial	no		74 Bours (derault	INDOORS WITH LEV	no	5-234	Ro			
72		PROC glossary (text descriptions for refer	ence):	4 - Use in batch and oth	her process (synthesis) (where opportunity for	exposure arises								
73 74															
75		Manual entry of indicative reference values				Basis of reference value:									
76		Reference value lontg-term inhalation - workers			mq.kq ^{.1} dəy ^{.1}		OR	1.00E+01	mg.m ⁻⁸ (8-hour average)						
77		Reference value long-term dermal - workers		5.00E+00	mq.kq ^{.1} dəy ^{.1}										
78		Reference value short-term inhalation - workers						2.00E+01	mg.m ⁻¹ (15-minute average)						
79		Reference value long-term local dermal - workers			u.a.cm-2										





• ECETOC TRA (Targeted Risk Assessment) – Sample Screens

- Part V. Consumer exposure in the "Interface" sheet

	A B	С	D	E	F	G	Н	1	J	K	L
80	Human Health Assessment - Consumer										
81				NUALLY CLEAR CELLS	IF YOU MADE CHANGE	ES TO THE PC/AC, I	RODUCT/ARTICLE	CATEGORY, OR SUBCATEGOR			
82 1	Jo. Scenario name	(Remark: if "!" => edit in sub-	Product / Article category	PC / AC sub-category (optional for calculating subcat outcomes)	For PC only: Is product a spray?	Amount of product used per application (q)	Product ingredient fraction by weight (value must be: 0 < Ivalue1 > 1)	Skin surface area - dermal	Skin surface area - oral	Transfer factor ingestion (unitless - value must be: 0 < [value] > 1)	Transfer factor dermal (unitless - value must be: 0 < [value] > 1])
83	1		PC1_Adhesives_sealants	Glues, hobby use		5	0.2		1: some fingertips		0.1
83 84 85 86 87 88 88 83 90 91 90 91 92 93 93 94 95 96	1 2 3 4 5 6 7 8 8 9 10 11 12 12 13 14	ŗ	PC1_Adhesires_scalants PC1_Adhesires_scalants PC1_Adhesires_scalants PC3_Air_care_products PC3_Contings_paints_t Linners remores PC33_Contings_paints_t Linners remores PC33_Contings_paints_t Linners remores PC33_Contings_paints_t Linners remores PC1_Adhesires_scalants	Glues DIY-ese (carpet due, tile due, wood Glue from spray Sealants PCL_newl	yes 80 yes 12	500 1 50 10 5 5000 1000 500	0.3 0.4 0.2 0.3 0.4 0.2 0.4 0.2 0.1	2: inside hands / one hand / pale 2: inside hands / one hand / pale	n of hands 1: some fingertips 2: fingers one hand	0.2	
97	15		.	1							
98 99	for debugging scenario no.	1	Greate or edit new subcategory					-			
100	PC glossary (R12 incl. text descriptions for	referenc	PC 20 Products such as ph-requ	lators, flocculants, precipitants,	neutralization agents			4			
101	AC glossary (R12 incl. text descriptions for	referen	AC 3-2 Electrical batteries and a	ccumulators;]			
102											
103											
104	Manual entry of indicative reference values				Basis of reference value						
105	reference value inhalation - consumer		5.00E+00	mg.m ^{.9}	DNEL	OR		mg kgʻ ¹ dayʻ ¹			
106	reference value dermal - consumer		1.00E+00	mg kgʻ ¹ dayʻ ¹	DNEL						
107	reference value oral - consumer		5.00E-01	mg kgʻ ¹ dayʻ ¹	DNEL						
108											
103											





• ECETOC TRA (Targeted Risk Assessment) – Sample Screens

- Part VI. Environmental exposure assessment input

Microsoft Excel - ecetocTRAM.x	ls										
Be sat yen poer fyrnat	Iools Rata Inc.	dow (seip gost) - (* -) 🥹 3	ocTRAM gomocTA E + 21 21 10	AM goetocTR	AM goetocTRJ	entocTRAM goes	B Z J		11 aug m	Tipe a substant for the 201 DR. UR 1 (100 · _ θ >] · Δ · Δ ·]
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Source: User Guide for the TRA integrated tool – TRAM, version 3.1





ECETOC TRA (Targeted Risk Assessment) – Sample Screens – Worker output fields in the user interface

Long-term Inhalative	Long-term				
Exposure Estimate (ppm	Inhalative	Long-term Dermal	Short-term Inhalative	Local Dermal	
for volatiles) / (mg/m3	Exposure Estimate	Exposure Estimate	Exposure Estimate	Exposure Estimate	Notes/comments on
for solids)	(mg/m3)	(mg/kg/day)	(mg/m3)	(µg/cm2)	exposure estimates:
1.00E+00	4.17E+00	2.74E-01	1.67E+01	4.00E+01	
5.00E+00	2.08E+01	6.86E-02	8.33E+01	1.00E+01	
					LEV efficiency inhalation
					[%]: 90, LEV efficiency
1.00E+00	4.17E+00	6.86E-03	1.67E+01	1.00E+00	demal [%]: 90,
					LEV efficiency inhalation
					[%]: 80, LEV efficiency
4.00E+00	1.67E+01	2.74E-02	6.67E+01	4.00E+00	demal [%]: 80,
					LEV efficiency inhalation
					[%]: 90, LEV efficiency
1.50E-04	6.25E-04	6.86E-05	2.50E-02	1.00E-02	demal [%]: 90,
					Note that the TRA
					predicts vapour phase
					exposure; exposure by
					aerosols is not taken into
					account; if aerosol
					formation is relevant,
					refer to other information
2.50E+02	1.04E+03	4.29E+01	4.17E+03	2.00E+03	or models.
					Note that the TRA
					predicts vapour phase
					exposure; exposure by
					aerosols is not taken into
					account; if aerosol
					formation is relevant,
					refer to other information
2.50E+02	1.04E+03	4.29E+01	4.17E+03	2.00E+03	or models.
					Note that the TRA
					predicts vapour phase
					exposure; exposure by
					aerosols is not taken into
					account; if aerosol
					formation is relevant,
					refer to other information
1.75E+02	7.29E+02	4.29E+01	2.92E+03	2.00E+03	or models.

Risk	Risk		Risk	Risk
Characterisation	Characterisation	Risk Characterisation	Characterisation	Characterisation
Ratio - Long-term	Ratio -Long-term	Ratio - Long-term	Ratio - Short-term	Ratio - Local
Inhalation	Dermal	Total Exposure	Inhalation	Dermal
4.17E-01	5.49E-02	4.72E-01	8.33E-01	4.00E-01
2.08E+00	1.37E-02	2.10E+00	4.17E+00	1.00E-01
4.17E-01	1.37E-03	4.18E-01	8.33E-01	1.00E-02
1.67E+00	5.49E-03	1.67E+00	3.33E+00	4.00E-02
6.25E-05	1.37E-05	7.62E-05	1.25E-03	1.00E-04
1.04E+02	8.57E+00	1.13E+02	2.08E+02	2.00E+01
1.041+02	8.57E+00	1.136+02	2.08E+02	2.00E+01
7 205-01	0.575.00	0 455.04	1 465-00	2.005.01
7.296+01	8.57E+00	8.15E+01	1.46E+02	2.002+01

Source: User Guide for the TRA integrated tool – TRAM, version 3.1





• ECETOC TRA (Targeted Risk Assessment) – Sample Screens

- Consumer output fields for Product Subcategory in the user interface

OUTPUT BY PRODUCT SUBCATEGORY

Inhalation exposure	Dermal exposure (mg.kg-	Oral exposure	Inhalation exposure
(mg.kg-1.d-1)	1.day-1)	(mg.kg-1.day-1)	(mg.m-3)
1.34E-01	0.00E+00		1.47E+00
5.53E+00	0.00E+00		4.04E+01
5.38E-01	0.00E+00		5.88E+00
1.34E+00	0.00E+00		1.47E+01
2.02E-01	1.78E+01	7.42E-01	2.21E+00

	Risk	Risk	Risk
Risk Characterisation	Characterisation	Characterisation	Characterisation
Ratio - Inhalation	Ratio - Dermal	Ratio - Oral	Ratio - Total
1.34E-02	0.00E+00		1.34E-02
5.53E-01	0.00E+00		5.53E-01
5.38E-02	0.00E+00		5.38E-02
1.34E-01	0.00E+00		1.34E-01
2.02E-02	1.78E+00	7.42E-01	1.88E+00





• ECETOC TRA (Targeted Risk Assessment) – Sample Screens

- Environmental output fields in the user interface

PBC in STP (mg.L.')	PEC for local freshwater (mg L)	FEC for local frecheratur rediment	PEC for facal coll ing signal?	PEC for local matina watar (mg1 ⁻)	PEC for local marine pediments (mgRg _{en} -)	Tetal daily intake man via the environment local img kg, ²¹⁷)	RCR in STP	R.CR fair local freshwater	RCR for local freshwater sediment	RCR for local terrestrial environment	RCR for Incal marine water	PCR feriocal marine sediments	RCR for humans via the environment	Maafe in STP (kg day')	Mzafe freshwater (kg.day.)	Miade frachwater sediments (kg day)	ldsafe terrestrial (kg.day ⁻)	Maafe marine water (log day ')	Maafe marine sediments (kg day')	Nizafe homans Gig day ()
2.965102	2.948401	6,758401	\$.501+00	2.555400	6,758400	2.255400	2.328+02	2.955+02	4.046+00	5.545-01	2.961+03	4.048-01	5.528-03	4.758101	0.076+01	2:305+02	1.775404	3.375-00	2.485+04	2/835-04
1335.04	5.520.05	2.916.02	1111111	1.005.03	1.101.01	2 6 2 5 0 5	0.688-85	Nearest	3 3 56 53	1408.45	1.002+00	1-110-01	1.1100.01	078401	1.126400.	A GREEKE	1.458661	5476-01	4,045005	2-586-01
2,718-02	1.156-02	3.636-02	2.436-92	3,298-03	3.728-05	3.445-03	1,936-82	1.156-03	3,705-03	4.905-93	1.255+00	1.710-51	0.416-04	2.048400	4.996-01	1 225+01	1.375-01	4.555-02	3,205+02	6.526+01
2.476+00	2.578.02	7.516-01	2.965.92	2.575.02	7.595-02	5.975-03	1.768+00	2.571+00	0.505-02	4-146-03	2.578+01	1-101-01	1-705-03	2-548+00	1.956+00	3-458-02	1.026-01	11118-03	3-458-01	2-936-93
4.244-03	3.036-02	3-936-02	2,486-02	1.035-03	3:066-03	3.951-03	5.505-07	3.035-03	1.405-03	8.335-03	1.035+00	1.411-04	5.405-04	3-428403	4.075403	3.595403	1.226-01	4,835,600	3.555404	5.325+03
4.495-01	5-176-03	3.626-03	1,276.02	5.535-03	31636-02	3.3.98-03	1 215 91	5-475-01	7.456.01	1716.01	5.535+00	7110100	8-246-04	1.426403	0.025402	111202401	1,205405	8-228401	0.031001	5-505405
3.952+02	2.968401	8.755403	3,601+07	2.958409	0.755405	2,252+00	2.120+92	2.958402	4.041+00	5.648-01	2.962+03	4.041-01	5.525-01	4.756+01	3.575403	2.466+03	1.775404	5.575+00	2.465+04	3.052+04
3.155.01	8.926.01	3.916.02	1.376.03	5.006.03	3,365.03	1.416-01	9.665-05	9.926-02	1.156.01	8.785.01	1.007+00	3-175-04	6.196.03	5.676403	5.528+0011	5.055403	3.265+02	6.478-03	8.015+01	8.588402
2.715-02	1.255-02	3.696-02	2.418-02	1.268-03	3.925-03	3.441-03	1.995-92	3.258-03	3.006-03	4,005-01	1.261+00	4-710-04	0.415-04	2.048400	4.891-01	5,225+03	1.071+01	4,358-02	3.205+02	6.525+01
2.878400	2.576-03	7.596-01	2.981-02	2,578-02	7.896.03	5.978-02	1.768400	2.578+00	1.105-02	1.905-01	3.575+01	1.505.01	1.706-01	3.848+00	1.955+00	5.235403	1.015+01	1.955-01	1:135+01	2.935401
4,948-03	3,014-02	3,938-92	2.485-02	3.056-03	1,096-01	5.858-03	3.936-03	3,034-01	1,408-03	4,116-03	1.016+00	2.418-04	5.408-04	3.428403	4.876+01	3.555403	1.228+03	4,855400	2.558404	9.826403
4.496-01	6.676-02	1.626-01	2.278.02	5.516.01	1.618-02	1.191.01	1.215-01	5,475-03	7,455.05	3.785.01	5.515+00	7.531.04	8.265.05	1.425+01	8.325+02	5.10fe01	1.205+01	8.125+01	6.018405	6.50E+05
2.986402	2/984902	8/146403	3.505+03	21966400	8-166400	2.256600	2.126+02	2.956+02	4.045+00	5.448-01	2.955+01	3.245-01	51528-03	3-734402	11076601	21426407	1778003	0.578900	2.485404	1.035475
1.151-01	9.926.05	21846-02	2.276.02	1.036-01	2.965.01	2.616.01	9.555.05	9.926.02	1-156-01	3.785-05	1.005+00	1.176.01	0.195-04	C.678405	5.525400	4.045402	1.455402	5.478-01	0.015405	8.588402
2.735-02	1 1953	3.638-92	2,326.02	3.246-01	1/7/16-01	2.485-01	1.935-02	10101-01	1.706-01	0.028-03	1 255+00	1 125-00	8.418-04	2.048400	4-1515-01	5.725407	2100607	4.191-01	5.202402	8.57(+01)



Risk Assessment (Risk Characterization Ratio)



• Calculation of Risk Characterization Ratio (RCR) for human health

RCR = EXPOSURE / DNEL

If Exposure < DNEL \rightarrow Risk is adequately controlled If Exposure > DNEL \rightarrow Risk is NOT adequately controlled

RCR ≥ 1: Risk is high: detailed assessment and risk reduction measures required

RCR < 1: Risk is controlled: No further action required





Questions & Answers

Mr. Chalermsak Karnchanawarin & Mr. Napatr Kunachitpimol

Responsible Care[®] Management Committee of Thailand (RCMCT) Chemical Industry Club (CIC), The Federation of Thai Industries (FTI)





