Human Health assessment

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Kiev, 22-24 May 2018

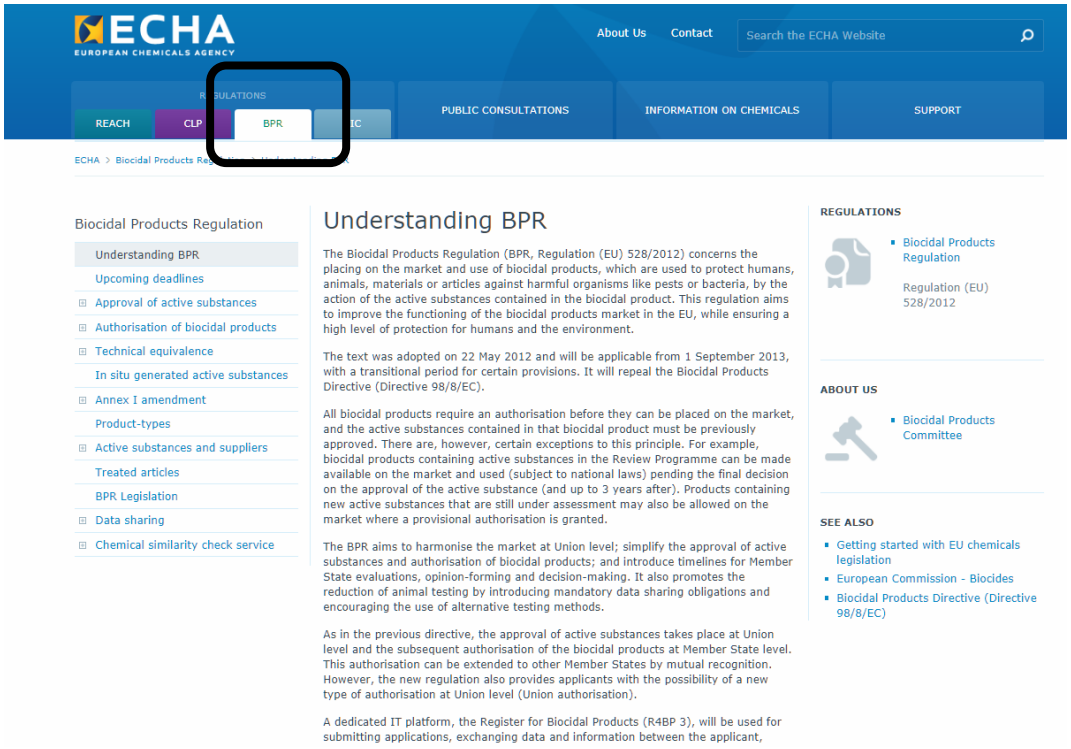
What information is available and where to find it

Guidance document

ECHA website

What is available on the ECHA website?

- Information on Biocidal Product Regulation 528/2012, including former legislations in place under the Biocidal Product Directive.
- Guidance on the process to be followed either for the approval of an a.s. or the authorization of a b.p. (*i.e.*, Guidance on Technical equivalence and Chemical similarity, data sharing and alternative suppliers).
- Old and new guidance documents to be used for the active substances and biocidal products assessment.
- IT-Tools: how to prepare a IUCLID dossier and submit a dossier by R4BP 3
- Information on how the provisions for nanomaterials match with the requirements in the Biocidal Products Regulation
- Treated article under BPR: the Regulation sets the rules for the use of treated articles with or incorporating biocidal products.



https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr

Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C)

Version 2.1 February 2017

Guidance

- Identify your obligations
- Consultation Procedure
- Guidance Documents
- Guidance in a Nutshell
- Practical Guides
- Formats and templates

Guidance on biocides legislation

Guidance on REACH | Guidance on CLP | Guidance on BPR | Guidance on PIC

The ECHA Guidance on biocides legislation describes how to fulfil the information requirements set by the **Biocidal Products Regulation**, Regulation (EU) 528/2012) (BPR) and how to perform the required assessments. It also explains the guiding principles for the evaluation of the applications to be performed by the authorities.

In addition to the BPR guidance, Biocidal Products Directive (BPD) guidance and other related documents are still considered applicable for new submissions under the BPR in the areas where

Related links

- Biocides competent authorities meetings documents
- Biocidal Products

Volume III Human health

Part A: Information Requirements

Parts B+C: Assessment and Evaluation

Reference name:	Guidance on the BPR: Volume III Human Health, Assessment + Evaluation (Parts B+C)
Description:	This Guidance provides technical advice on how to perform the hazard and exposure assessment and risk characterisation for biocidal active substances and products with respect to human health risk assessment and evaluation. download full PDF document (11/12/2017)
Additional information on the ECHA website	Biocides Human Health Exposure Methodology

ECHA website: http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation

Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C)

Version 2.1 February 2017

The Guidance provides **technical support** for performing the hazard and **exposure assessment** and **risk characterization** for biocidal active substances and products with respect to human health risk assessment and evaluation

The Guidance…

- is based on the previous **TNsG** used for the implementation of the BPD (TNsG 2007);
- consists of a written part (the present document), as well as a computerized database (**BEAT**) of exposure data (largely for occupational settings), and the consumer exposure model **ConsExpo** (both downloadable);
- **excel database** on use patterns is embedded in the written report.

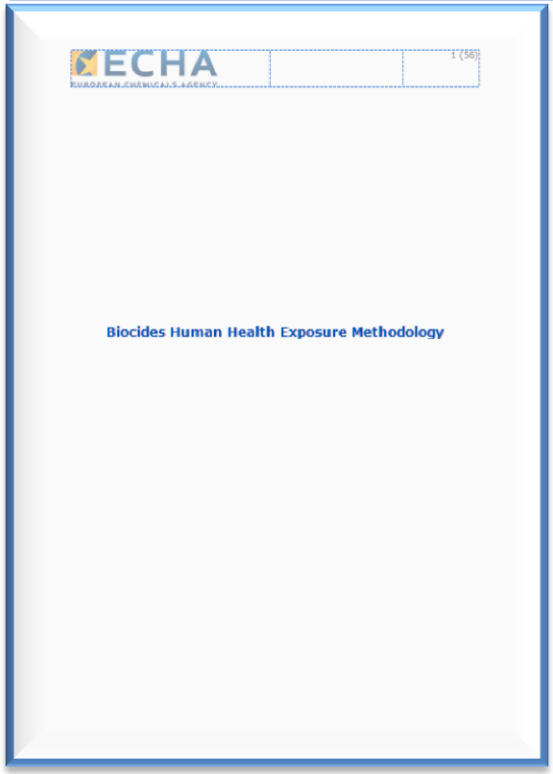
Guidance presents a tiered approach for conducting exposure assessment with refinement options to be chosen using higher tier methodologies when needed.

The guidance provides the general principles of the exposure assessment by identifying:

- **potential users** of biocides;
- **primary** and **secondary exposure scenarios**, and the pathways of exposure;
- **information** to be provided for developing an exposure scenario;
- **methods of application** and **tasks** where biocidal products can be used;
- **Personal protective equipment** and **control measures** to be set for controlling and limiting exposure to biocides.

Moreover, the guidance document sets criteria for the quality assessment of exposure data coming from survey and study reports.

Biocides Human Health Exposure Methodology (BHHEM)



The BHHEM collects information and details of a number of exposure models:

- ConsExpo;
- SprayExpo model developed for predicting aerosol exposure during spraying;
- US-EPA screening models:
  - E-FAST for estimating of the concentrations of chemicals released to air, surface water, landfills, and from consumer products;
  - ChemSTEER for estimating occupational inhalation and dermal exposure;
- US-EPA Higher tier models:
  - Multi-Chamber Concentration and Exposure Model;
  - Wall Paint Exposure Assessment Model (WPEM);
- Office of Pesticide Programs SOPs;
- US Aggregate exposure models: newly emerging exposure models are set up to accommodate aggregated residential exposure scenarios, containing multiple sources of a chemical;
- EUROPOEM: constructed a generic database of monitored operator exposure studies on plant protection products in Europe.

Ad hoc Working Group - Human Exposure

Under the BPR

Fourteen endorsed position papers on specific topics

Recommendations of the Ad hoc Working Group on Human Exposure

The Ad hoc Working Group on Human Exposure prepares recommendations on issues concerning human exposure related matters for which a harmonised approach is desirable.

- Recommendation 1 - Hand disinfection PT1 [PDF]
- Recommendation 2 - Mopping and wiping time PT2 [PDF]
- Recommendation 3 - Spraying models low pressure downward uses PT18 [PDF]
  - Annex - Studies with spraying applications PT18 [XLS]
- Recommendation 4 - Cleaning spray equipment PT21 [PDF]
- Recommendation 5 - Toddler scenario PT21 [PDF]
- Recommendation 6 - Methods and models – version 3 [PDF]
- Recommendation 7 - Professional exposure PT13 [PDF]
- Recommendation 8 - Consumers protection factor from clothing [PDF]
- Recommendation 9 - Professional hand disinfection in hospitals [PDF]
  - Annex - Inhalation exposure calculation ConsExpo [XLS]
- Recommendation 10 – Paints non-professional application by brushing and rolling [PDF]
- Recommendation 11 - Proposal for harmonisation PT19 assessment - version 2.1 [PDF]
- Recommendation 12 - Default values for indoor Transfer Coefficient [PDF]
- Recommendation 13 - Teat Disinfection Products for Veterinary Hygiene (PT3) [PDF]
- Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products [PDF]

https://echa.europa.eu/view-article/-/journal_content/title/recommendations-of-the-ad-hoc-working-group-on-human-exposure

Under the BPD

Eighteen endorsed position papers on specific topics

HEEG opinions

The Human Exposure Expert Group (HEEG) prepared opinions in the context of the BPD in order to provide guidelines towards a harmonised approach to biocide exposure assessment for industry and competent authorities.

However, in the absence of more recent references (e.g. recommendations of the BPC Ad hoc Working Group on Human Exposure), the HEEG opinions listed below can still be used in the framework of the BPR, notwithstanding the references to the BPD and without prejudice to the scientific content.

- HEEG opinion 1 - Mixing loading model 7 alternatives [PDF]
  - Annex – Calculator for RISKOFDERM Dermal Model [XLS]
    Please enable Excel macros to use the file
- HEEG opinion 2 - Potential & Actual Hand Exposure [PDF]
- HEEG opinion 3 - Use of ConsExpo for the Exposure Assessment for Professional Users [PDF]
- HEEG opinion 4 - Amendment of TNsG on Human exposure to biocidal products Antifouling painting model [PDF]
- HEEG opinion 5- Human exposure assessment to biocidal products used in metalworking fluids (PT13) [PDF]
  This HEEG opinion has been replaced by Recommendation 7 of the Ad hoc Working Group on Human Exposure
  - Recommendation 7 – Professional exposure PT13 [PDF]
- HEEG opinion 6 - Harmonising the use of new and old versions of the TNsG on human exposure and of BEAT [PDF]
- HEEG opinion 7 - Choice of secondary exposure parameters for PTs 2, 3 and 4 [PDF]
- HEEG opinion 8 - Defaults and appropriate models to assess human exposure for dipping processes (PT 8) [PDF]
- HEEG opinion 9 - Default protection factors for protective clothing and gloves [PDF]
- HEEG opinion 10 - Harmonising the number of manipulations in the assessment of rodenticides (anticoagulants) [PDF]
- HEEG opinion 11 - Exposure model Primary exposure scenario - washing out of a brush which has been used to apply a paint [PDF]
  - Annex - General exposure calculator for washing out of brushes [XLS]
- HEEG opinion 12 - Harmonised approach for the assessment of rodenticides (anticoagulants) [PDF]
- HEEG opinion 13 - Assessment of inhalation exposure of volatilised biocide active substance [PDF]
- HEEG opinion 14 - An approach to identification of worst-case human exposure scenario for PT6 [PDF]
- HEEG opinion 15 - On the paper by Links et al. 2007 on occupational exposure during application and removal of antifouling paints [PDF]
- HEEG opinion 16 - Biocidal products: model for dipping of hands/forearms in a diluted solution [PDF]
- HEEG opinion 18 - For exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping [PDF]

http://echa.europa.eu/web/guest/view-article/-/journal_content/title/support-biocides-heeg-opinions

Technical Agreements for Biocides (TAB)

The Technical Agreements for Biocides (TAB) is an **information document** that intends to provide the agreements of the WGs in a concise format.
The TAB is intended to **cover the technical and scientific WG agreements** that have general relevance and to create a general database of questions where an agreement has already been reached.

The **main sources** for the TAB are the **adopted minutes of the WGs** and **Technical Meetings (TMs)**, as well as the Manual of Technical Agreements of the Biocides Technical Meeting (MOTA). In all cases, a reference is given to the WG meeting or TM where the agreement was reached.

https://echa.europa.eu/documents/10162/20733977/technical_agreements_for_biocides_en.pdf/4280fdc4-dfb0-405e-898e-70f3cdf62ce2

Ad hoc Working Group - Assessment of Residue Transfer to Food (ARTFood)

ARTFood supports the BPC and its WGs (especially the Working Group on Human Health) with issues related to human exposure to biocides through food, including among others:

- **Assessment of biocidal residue transfer to food** (include drafting, amending and revising guidance documents)
- **Contribution to guidance documents** related to dietary risk assessment and the maximum residue limits (MRLs) set for biocides prepared by other relevant bodies such as the European Medicines Agency (EMA) and the European Food Safety Authority (EFSA)
- **Contribution to general issues** relating to the assessment of risks posed by direct or indirect food exposure to biocides
- **Implementation of relevant guidance documents**

- **Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products** (S-CIRCABC – restricted access)
- **Draft Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses** (ECHA web-site)
- **Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses** (S-CIRCABC – restricted access)

https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/assessment-of-residue-transfer-to-food

Introduction on exposure assessment of biocidal products

Risk Assessment - General principles (BPR definitions)

- **Hazard identification**

The identification of the adverse effects which a biocidal product has an inherent capacity to cause.

- **Dose (concentration) — response (effect) assessment**

The estimate of the relationship between the dose, or level of exposure, of an active substance or substance of concern in a biocidal product and the incidence and severity of an effect.

- **Exposure assessment**

The determination of the emissions, pathways and rates of movement of an active substance or a substance of concern in a biocidal product and its transformation or degradation in order to estimate the concentration/doses to which human populations, animals or environmental compartments are or may be exposed.

- **Risk characterisation**

The estimation of the incidence and severity of the adverse effects likely to occur in a human population, animals or environmental compartments due to actual or predicted exposure to any active substance or substance of concern in a biocidal product. This may include ‘risk estimation’, i.e. the quantification of that likelihood.

BPR - risk assessment for a biocidal product should be carried out before placing on the European Market.
For the purpose of the R.A., a safe use of the biocidal product (b.p.) containing the active substance (a.s.) should be demonstrated.

The **risk assessment** for humans compares the toxic effects of the substance with a predicted dose.

The **estimation of human exposure** is a fundamental element of the risk assessment process and requires quantification of the levels of exposure for both users of the biocidal product and others who may be exposed following its use.

Exposure assessment needs to be performed for the expected exposure situations including exposure to treated articles.

Exposure Assessment - General Principles

The fundamental concept underlying the approach for human exposure assessment is the need to **establish the full range of human exposure situations** that could occur from the use of a b.p. and to **consider all routes of exposure**.

Therefore, the **exposure assessment process requires** determination of:

- **the patterns of use** (mixing and loading, application, post-application);
- **identification of the exposed population** (workers, professional users, children);
- **establishing the pathways of exposure** (dermal, inhalation and/or oral route); and
- **quantification of potential chemical intake** (mg/kg bw/d).

Exposure Assessment is a tiered approach process

In the **first Tier**, the exposure assessment is based on realistic "worst case" where assumptions and model calculations used refer to default values.

- The risk assessment based on these assumptions concludes that the product is "**not of concern**" → the risk assessment can be stopped and no further refinement of the exposure estimate is required.
- The risk assessment concludes that the product is "**of concern**" → the assessment should be refined using additional data and/or reasoned arguments based on expert judgment to allow a more informed decision.

The **second Tier** is more complex and requires further specific data and/or reasoned arguments to produce a more **refined** exposure assessment. The same exposure models as in Tier 1 are used but specific data on time budgets; transfer factors and the effects of exposure reduction measures (e.g. personal protective equipment) may be used to modify the exposure assessment.

However, the use of PPE by consumers should only be considered in very limited situations e.g. where gloves are to be supplied with the product.

The **third Tier** requires a detailed level of information from surveys or studies with the actual product or with a surrogate.

Users of Biocides

Professional users

- **Industrial users** – people involved in manufacturing, handling and/or packaging of actives or products in industry;
- **Professional users** – people using end-products outside industry.

"Professional users" are people …

- coming into contact with the biocidal product as a consequence of their professional life;
- subjecting to national worker protection legislation and has risk control measures including the use of Personal Protective Equipment (PPE).

Non-professional users (consumers)

The consumer is a member of the general public who may primarily be exposed to biocides by using a consumer product.

Non-professional users…

- Do not take informed measures to control exposure and follow exactly the instructions for using the biocidal product.
- Have pattern of use expected to show a low frequency and/or duration of use.
- Have very limited use of PPE to control exposure. Consumers will not normally use PPE unless it is recommended by the manufacturer and provided with the product. As a result only typical clothing should be assumed when carrying out consumer exposure assessments.

Primary and secondary exposure scenarios

IMPORTANT

- The **user** of a product may be subject to both primary and secondary exposure;
- the **non-user or bystander** will only experience secondary exposure.

Primary exposures are invariably higher than secondary exposures, however, some specific subgroups of the population may experience higher secondary exposures because of their specific behaviour (e.g., children crawling on a treated carpet).

Routes of exposure

Human exposure occurs through any or all of three potential exposure routes: inhalation, dermal contact and ingestion.

Second step in the exposure assessment process is…

- to determine the probability for a biocides to enter in the body by inhalation, by absorption through the skin, or by ingestion.

If in the second step it is indicated that exposure via one or more of the pathways does not occur, no further assessment is needed for that route of exposure and the conclusion can be mentioned in the risk assessment phase.

If one or more routes of exposure have been identified, then each route of exposure requires a quantitative exposure assessment.

Dermal exposure

Exposure of and via the skin is usually a significant aspect of human exposure to biocides and can be subdivided into **potential** or **actual dermal exposure**.

- **Potential dermal exposure:** the amount of chemical deposits on the clothes or gloves and on exposed skin over a defined period of time. It is commonly expressed in terms of amount of biocide product that deposits per unit time (mg/min) or task (mg/cycle).
- **Actual dermal exposure:** an estimate of the amount of contamination that actually reaches the skin. It is dependent on the effectiveness of clothing and can be also expressed as a weight of biocide product on skin (mg on skin).

For the assessment of dermal exposure (professional and non-professional) it is estimated that the calculated external dose (mg/min x duration of exposure resulting in mg per person) will **stay on the skin for the whole shift** or even longer, since it is generally **not possible to rely on cleaning habits** as a reducing factor.

Inhalation exposure

Inhalation exposure is usually derived from the airborne concentration in the breathing zone of the exposed individual.

The exposure refers to the **active substance** or to the **product in use** and is expressed as mg/m^3 as a time weighted average concentration over a stipulated period of time.

- **Potential exposure:** by its nature this concentration represents an assessment of potential exposure.
- **Actual exposure:** if respiratory protection is used, actual exposure is calculated takinge into account the effectiveness of the protection measures.

Ingestion exposure

It refers to **the amount entering into the mouth** other than the amount of chemical which is inhaled. **It is usually assumed that ingestion exposure in workplaces does not occur when good hygiene is applyed.**

Systemic exposure

The estimates of exposure, via the three routes, refer to external exposure concerning:

- the amount of the substance ingested,
- the amount in contact with the skin, and/or
- the amount inhaled.

Systemic exposure level is expressed in terms of mg/kg bw/d or mg/m^3

Patterns of use

Pattern of use collects a number of information to be used for the development of exposure scenarios. The exposure scenarios are then evaluated to derive quantitative exposure levels.

Some **information on the use pattern** are required for building the exposure scenarios.

This information includes…

- Information on the product (physical state, concentration, vapour pressure);
- Where and how the product will be used (location, method of application);
- By whom the product will be used (primary exposure);
- Tasks, frequency and duration for each stage of use;
- Expected exposure controls;
- Who else may be exposed (secondary exposure).

Variation of frequency and duration

The frequency and duration of a task are major determinants influencing the level of exposure.

FREQUENCY: it is variable and is critical in deciding whether the exposure is **chronic** or **acute** for risk characterization purposes. It should be expressed as events per day (with precision as to how many days per year the user of biocides is exposed).

DURATION: it should be expressed as minutes or hours per day.

Methods of application and tasks

Primary exposure is experienced by professionals and non-professionals (consumers) who use/apply a biocidal product.

It is related to the task and the overall exposure scenario will consist of a series of tasks that can be allocated to three distinct phases of use:

- **Mixing & loading** Include the tasks involved in delivery and handling of bulk ready-for-use and concentrate products, dilution of concentrates and/or the introduction of product to the application apparatus/system;

- **Application** Involves all uses of biocidal products, including application by hand, by hand-held tool, by dipping, by spraying, handling treated articles, and in machining. This phase of use can lead to the exposure of people who are present during the product application (secondary exposure);

- **Post-application** Includes exposure through separately cleaning and maintaining process equipment and tools. Secondary exposure is also included in the post-application phase.

Information requirements

Annex II of BPR
Information required **to support the approval of an a.s.**

core data set
additional data set

L 167/52 EN Official Journal of the European Union 27.6.2012

ANNEX II

INFORMATION REQUIREMENTS FOR ACTIVE SUBSTANCES

1. This Annex sets out the information requirements for the preparation of the dossier referred to in point (a) of Article 6(1).

2. The data elements set down in this Annex comprise a Core Data Set (CDS) and an Additional Data Set (ADS). The data elements belonging to the CDS are considered as the basic data which should, in principle, be provided for all active substances. However, in some cases the physical or chemical properties of the substance may mean that it is impossible or unnecessary to provide specific data elements belonging to the CDS.

With regard to the ADS, the data elements to be provided for a specific active substance shall be determined by considering each of the ADS data elements indicated in this Annex taking into account, inter alia, the physical and chemical properties of the substance, existing data, information which is part of the CDS and the types of products in which the active substance will be used and the exposure patterns related to these uses.

Annex III of BPR
Information required to support the authorization of a b.p.

core data set
additional data set

27.6.2012 EN Official Journal of the European Union L 167/81

ANNEX III

INFORMATION REQUIREMENTS FOR BIOCIDAL PRODUCTS

1. This Annex sets out the information requirements that shall be included in the dossier for the biocidal product accompanying an application for the approval of an active substance in accordance with point (b) of Article 6(1) and the dossier accompanying an application for the authorisation of a biocidal product in accordance with point (a) of Article 20(1).

2. The data elements set down in this Annex comprise a Core Data Set (CDS) and an Additional Data Set (ADS). The data elements belonging to the CDS are considered as the basic data which should, in principle, be provided for all biocidal products.

With regard to the ADS, the data elements to be provided for a specific biocidal product shall be determined by considering each of the ADS data elements indicated in this Annex taking into account, inter alia, the physical and chemical properties of the product, existing data, information which is part of the CDS and the types of products and the exposure patterns related to these uses.

Information requirements

The information requirements are two-tiered:

I. The **core data set** (CDS) is mandatory for all product-types. This information always has to be submitted, unless the rules for adaptation of standard information are applicable.

II. The **additional data set** (ADS) might be required to perform the risk assessment under the following conditions:

a. ADS information on physical chemical properties, methods of detection and identification and on the toxicological profile is required **depending on the intrinsic properties** of the active substance or the biocidal product.

b. ADS information on the ecotoxicological properties and the environmental fate and behaviour of the active substance or biocidal product is required **depending on the product-type**, i.e. the foreseen use and route of exposure.

c. ADS information on the ecotoxicological properties and the environmental fate and behaviour might be required to **refine the initial risk assessment**.

For the active substance approval, specific information on the **intended uses** and the **exposure pattern** of the biocidal product is indicated under Section 7 (Annex II – BPR).

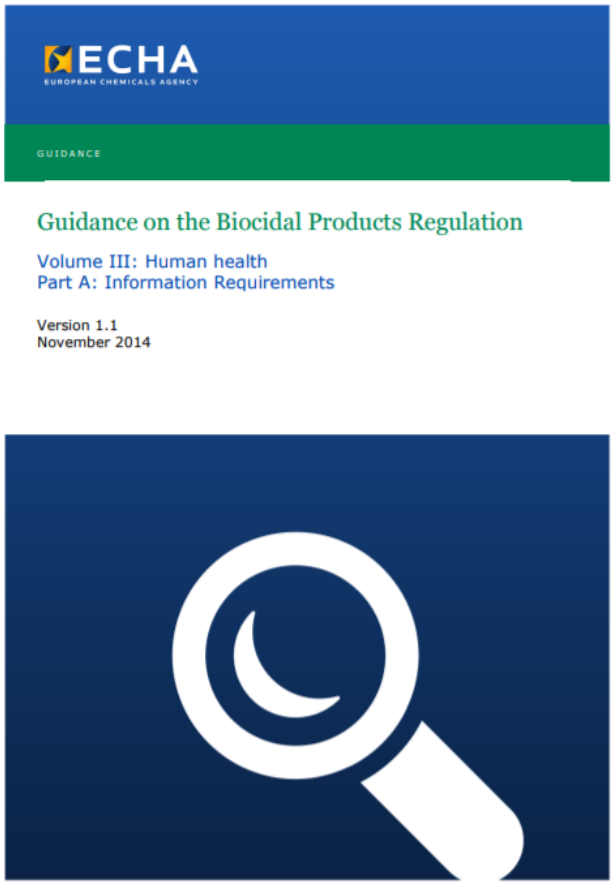
7.	INTENDED USES AND EXPOSURE
7.1.	Field of use(s) envisaged for biocidal products and, where appropriate, treated articles
7.2.	Product-type(s)
7.3.	Detailed description of the intended use pattern(s) including in treated articles
7.4.	Users e.g. industrial, trained professional, professional or general public (non-professional)
7.5.	Likely tonnage to be placed on the market per year and, where relevant, for the envisaged major use categories

7.6.	Exposure data in conformity with Annex VI to this Regulation
7.6.1.	Information on human exposure associated with the intended uses and disposal of the active substance
7.6.2.	Information on environmental exposure associated with the intended uses and disposal of the active substance
7.6.3.	Information on exposure of food- producing animals and food and feeding stuffs associated with the intended uses of the active substance
7.6.4.	Information on exposure from treated articles including leaching data (either laboratory studies or model data)

For the product authorization, specific information on **intended uses** and **exposure pattern** is indicated under Section 7 (Annex III – BPR).

7.	INTENDED USES AND EXPOSURE
7.1.	Field(s) of use envisaged for biocidal products and, where appropriate, treated articles
7.2.	Product-type
7.3.	Detailed description of intended use pattern(s) for biocidal products and, where appropriate, treated articles
7.4.	User e.g. industrial, trained professional, professional or general public (non-professional)
7.5.	Likely tonnage to be placed on the market per year and, where relevant, for different use categories
7.6.	Method of application and a description of this method
7.7.	Application rate and, if appropriate, the final concentration of the biocidal product and active substance in a treated article or in the system in which the product is to be used, e.g. cooling water, surface water, water used for heating purposes
7.8.	Number and timing of applications, and where relevant, any particular information relating to geographical location or climatic variations including necessary waiting periods, clearance times, withdrawal periods or other precautions to protect human health, animal health and the environment
7.9.	Proposed instructions for use
7.10.	Exposure data in conformity with Annex VI to this Regulation
7.10.1.	Information on human exposure associated with production and formulation, proposed/expected uses and disposal
7.10.2.	Information on environmental exposure associated with production and formulation, proposed/expected uses and disposal
7.10.3.	Information on exposure from treated articles including leaching data (either laboratory studies or model data)
7.10.4.	Information regarding other products that the product is likely to be used together with, in particular the identity of the active substances in these products, if relevant, and the likelihood of any interactions

Guidance on information requirements



For the Human Health assessment the information requirements are reported in the relevant BPR Guidance where they are divided into two parts:

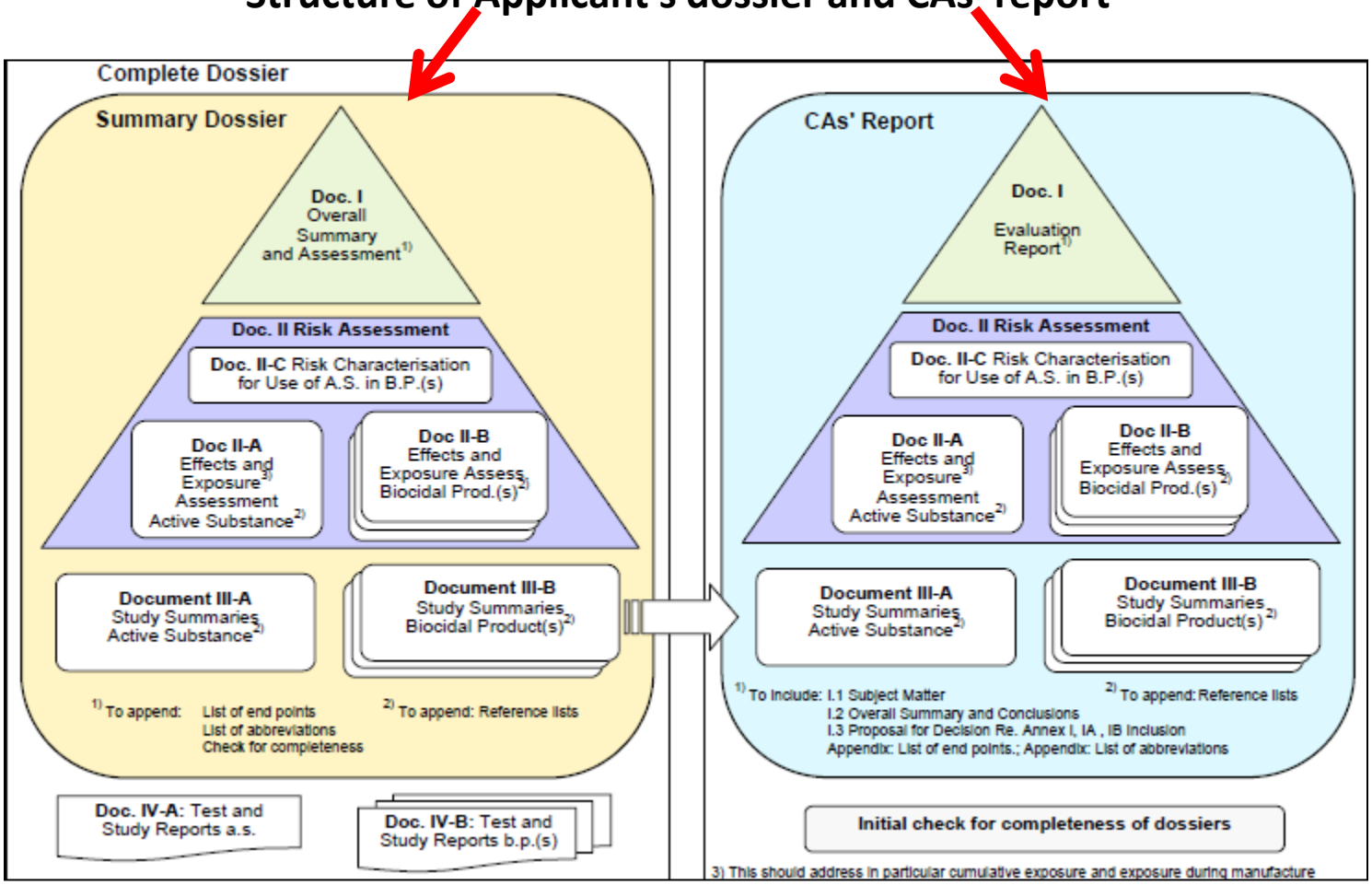
1. The CDS and ADS for active substances in Chapter II;

2. the CDS and ADS for biocidal products in Chapter III.

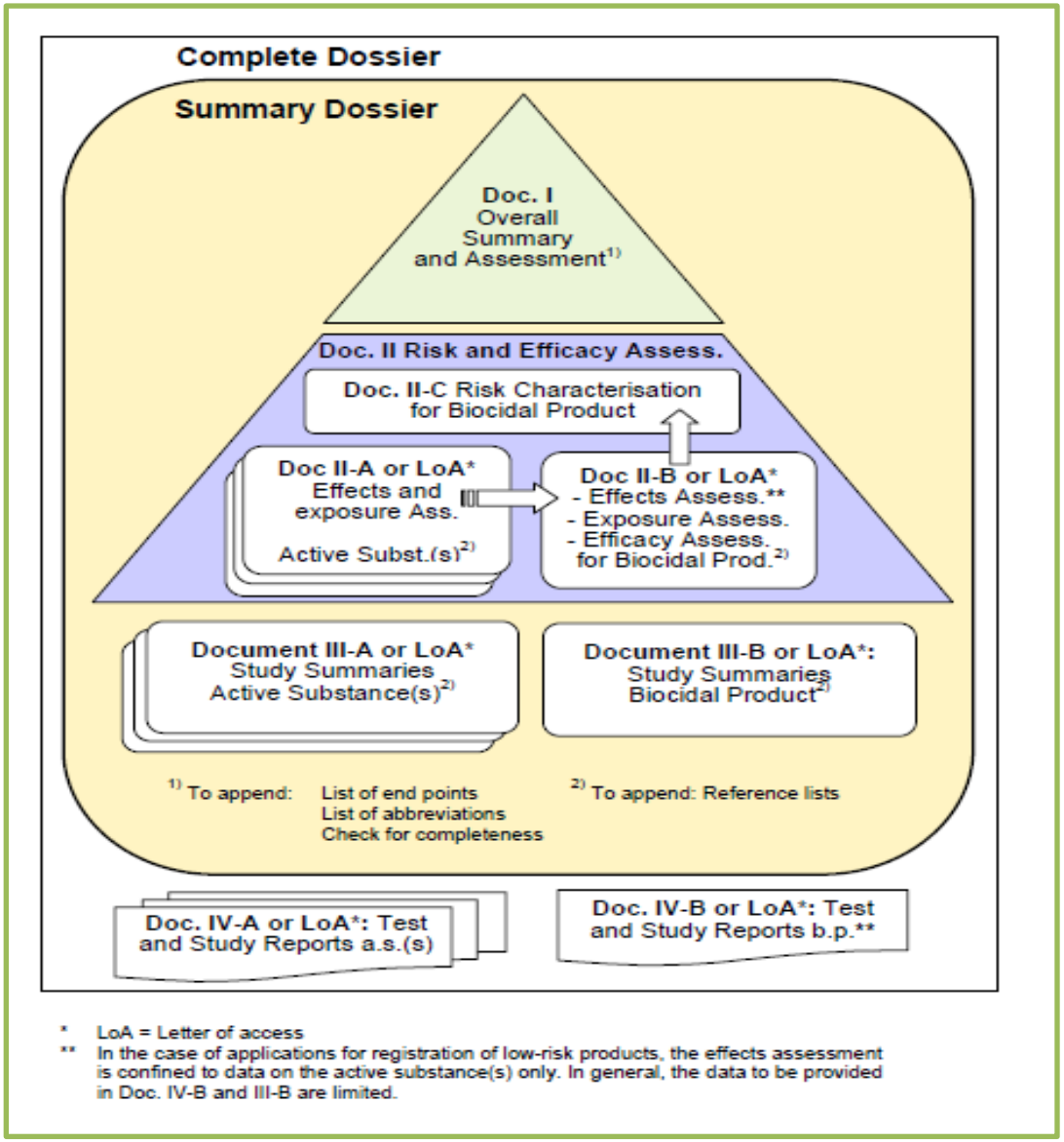
The CDS together with the ADS represent the complete set of information on the basis of which an overall and adequate risk assessment can be carried out.

Dossier structure according to BPD

Structure of Applicant's dossier and CAs' report



Structure of the dossier to be submitted for the product authorization



* LoA = Letter of access

** In the case of applications for registration of low-risk products, the effects assessment is confined to data on the active substance(s) only. In general, the data to be provided in Doc. IV-B and III-B are limited.

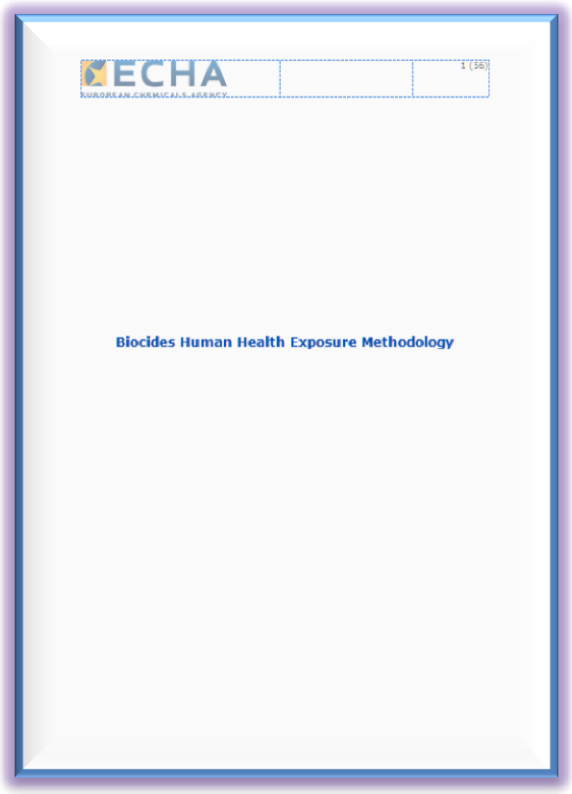
Exposure Assessment Models

MODELS AND TOOLS AVAILABLE

- **ConsExpo 4.1 Model**: consumer exposure assessment;
- **BEAT Model**: Bayesian statistics and probabilistic modelling mainly for industrial workers;
- **Technical Notes for Guidance on Human Exposure to Biocidal Products**: collections of models for Annex I inclusion and product authorization;
- **RISKOFDERM Model**: only dermal exposure is dealt with.

Elements to be considered in the exposure assessment

- **Relevant routes**: inhalation, dermal and oral
- **Time frame of the task** (acute and chronic exposure)
- **Exposure determinants** (air exchange rate; body weight; room size)
- **Risk management options**



BHHEM provides detailed information on the «Computer based & Mathematical data models»…

- Bayesian Exposure Assessment Toolkit (BEAT model)
- ConsExpo
- Emission Tool (RIVM)
- Stoffenmanager Tool
- RISKOFDERM TOOL
- ART (Advanced REACH Tool)
- EMKG-Expo Tool
- EASE (model implemented in EUSES) (inhalation)
- AOEM
- SprayExpo model
- EUROPOEM
- Models of the US-EPA Office for Pollution Prevention and Toxics
- US Aggregate exposure models

Mathematical models allow the exposure estimate by means of algoritms and integrated database

ConsExpo Model

ConsExpo is a computer program that was developed to assist in the exposure assessment of compounds in non-food consumer products.

ConsExpo offers a number of generally applicable exposure models and a database with data on exposure factors for a broad set of **consumer products**.

ConsExpo is a software implements generic, multi-tier models for inhalation, oral, and dermal routes of exposure.

ConsExpo includes a database with compiled data and suggested defaults on exposure scenarios and exposure factors for different product groups.

ConsExpo Model: consumer exposure assessment

Who is **"consumer"**?
A member of the general public who may be of any age, either sex, and in any stage of health exposed to a substance by using products

Consumer product

- *is a product that can be* purchased from retail outlets by members of the general public.
- can be the substance itself, or a preparation, or an article containing the substance.

Consumer exposure

is of importance because the possible tool for exposure control are extremely limited and cannot normally be monitored, or enforced beyond the point of sale of the products.

ConsExpo Fact sheets

Details and default values of exposure scenarios are fully provided by the following documents:

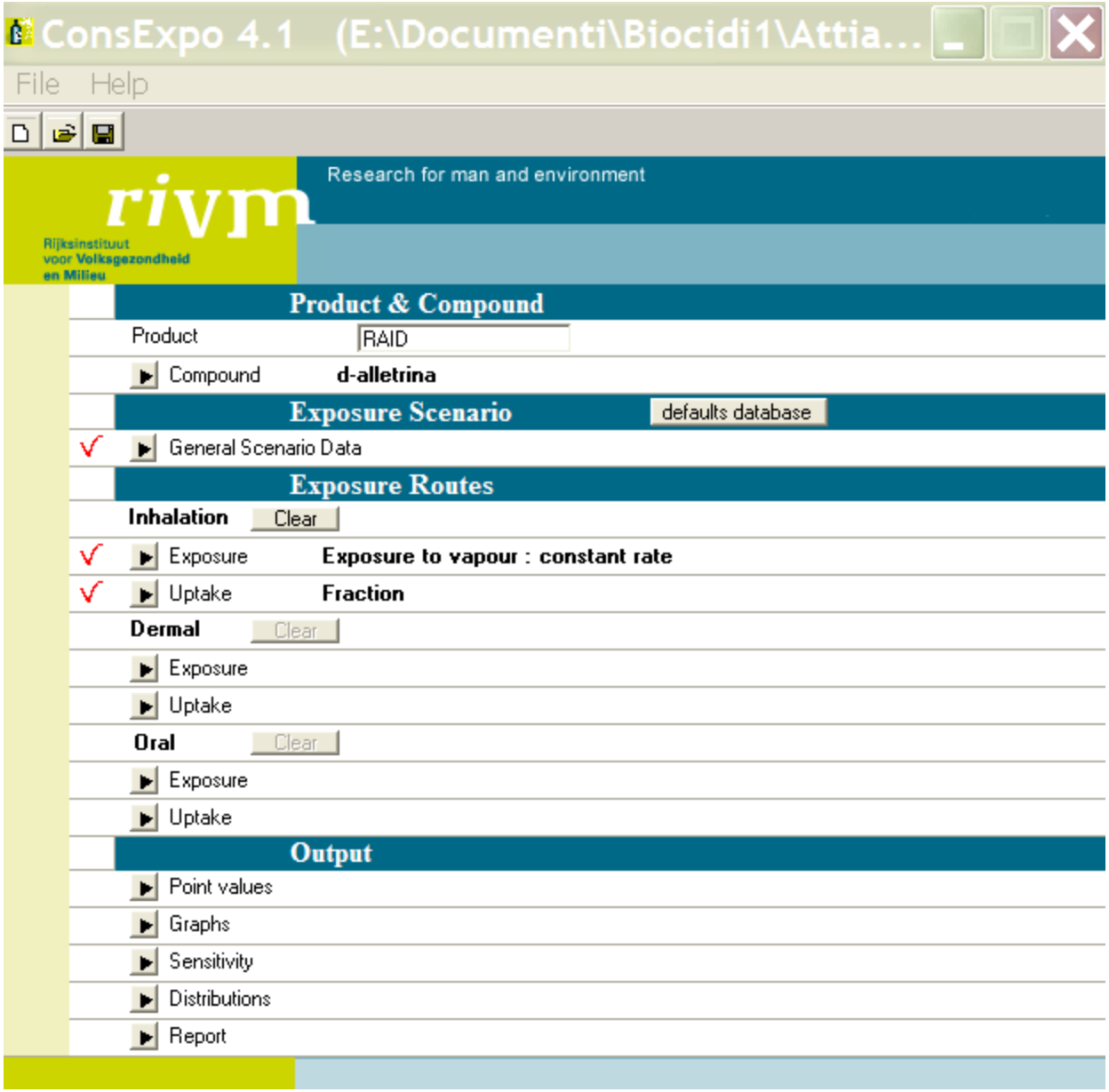
- **General Fact Sheet**
- **Children's Toys Fact Sheet**
- **Cleaning Products Fact Sheet**
- **Cosmetics Fact Sheet**
- **Disinfectants Products Fact Sheet**
- **Do-it-Yourself Products Fact Sheet**
- **Paints Products Fact Sheet**
- **Pest Control Products Fact Sheet**

The information for each main category is described in a specific fact sheets. The same information are included in the computerized programme downloaded from the RIVM web site: **http://www.rivm.nl/en/healthanddisease/productsafety/ConsExpo.jsp**

ConsExpo Fact sheets

The fact sheets are 'living documents' giving information that is important for the consistent estimation and assessment of the exposure to, and the uptake of, substances from consumer products while using ConsExpo.

Information about exposure to chemical substances is grouped into certain product or exposure categories and default parameters are given.
The fact sheet gives **general background information** but also it quantifies exposure parameters which, together with an exposure scenario, or a combination of the various exposure scenarios, produce a quantitative estimate of the exposure.


ConsExpo 4.1 (E:\Documenti\Biocidi1\Attia...
File Help
rivm
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Product & Compound
Product RAID
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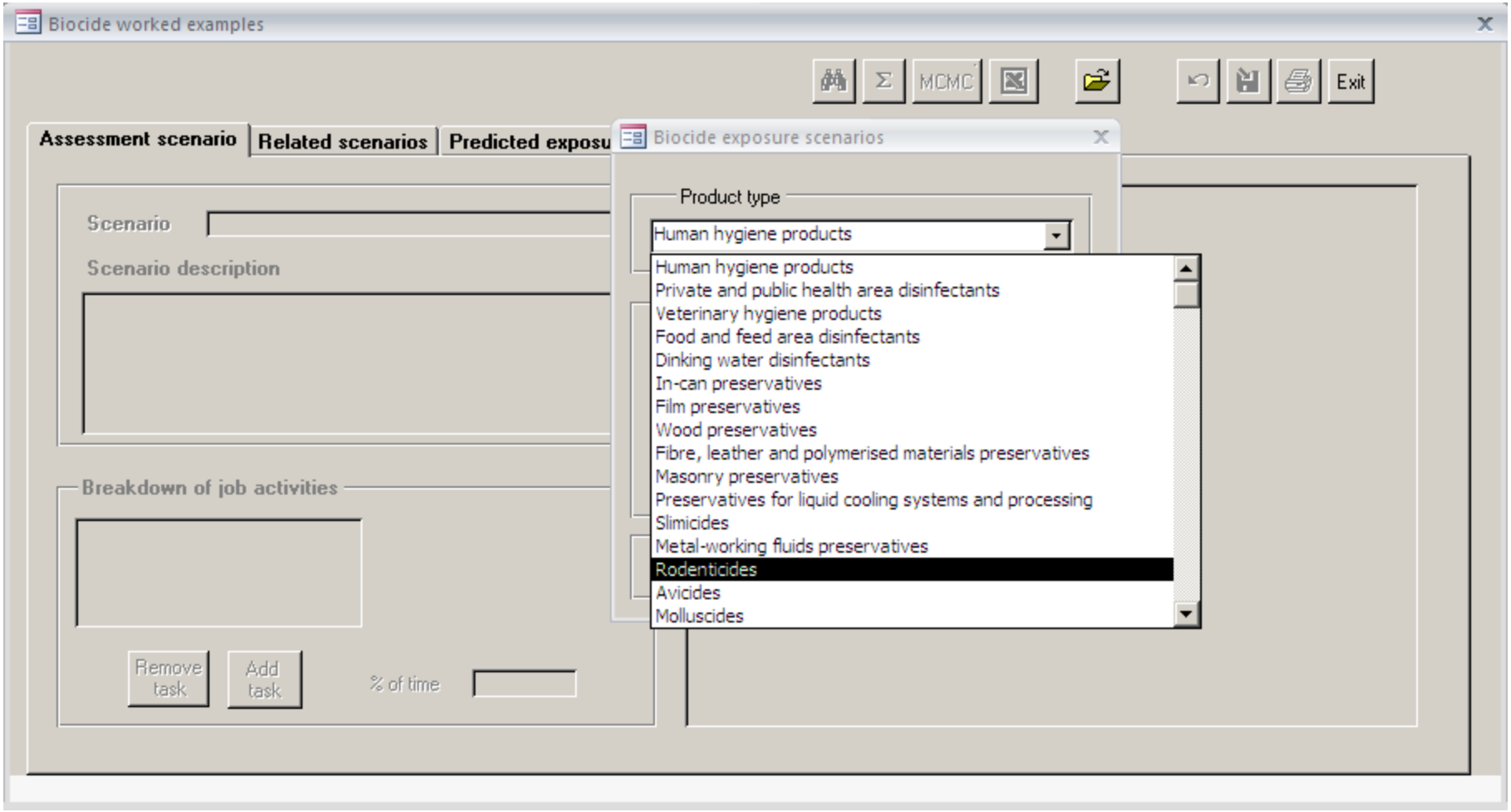
Exposure Scenario
defaults database
General Scenario Data
Exposure Routes
Inhalation Clear
Exposure Exposure to vapour : constant rate
Uptake Fraction
Dermal Clear
Exposure
Uptake
Oral Clear
Exposure
Uptake
Output
Point values
Graphs
Sensitivity
Distributions
Report

BEAT: Bayesian Exposure Assessment Tool

The **Bayesian Exposure Assessment Toolkit (BEAT)** consists of a number of integrated databases, search algorithms and statistical routines designed to assist exposure assessments for **professional use scenarios**.

BEAT provides probabilistic, task-based predictions for potential body and hand exposures based upon analogy with measured exposure data.

To assess an exposure scenario, the user provides information on the tasks performed by the worker, control measures and the physico-chemical properties of the product being used.


Biocide worked examples
Σ
MCMC
Exit
Assessment scenario
Related scenarios
Predicted exposu
Biocide exposure scenarios
Scenario
Scenario description
Product type
Human hygiene products
Human hygiene products
Private and public health area disinfectants
Veterinary hygiene products
Food and feed area disinfectants
Dinking water disinfectants
In-can preservatives
Film preservatives
Wood preservatives
Fibre, leather and polymerised materials preservatives
Masonry preservatives
Preservatives for liquid cooling systems and processing
Slimicides
Metal-working fluids preservatives
Rodenticides
Avicides
Molluscides
Breakdown of job activities
Remove task
Add task
% of time

Technical Notes for Guidance (TNsG) on Human Exposure to Biocidal Products

TNsG on Human Exposure collect generic exposure data measured from similar operations utilizing similar biocidal products.

The measured data…

- are collected from exposure surveys of workers or for consumers from simulation studies using analogous products;
- are used to develop simple (generic) database exposure models for particular product types and specific use scenarios.

Technical Notes for Guidance (TNsG) on Human Exposure to Biocidal Products

Generic exposure modelling is a useful **regulatory tool** because of its ability to predict the likely levels of occupational exposure of biocide users and to estimate the effect of changes in conditions of use on exposure.

Where representative generic data and a suitable model exist, modeling is the initial, and often the only, basis for the exposure assessment.

Generic exposure models may also be used instead of, or as well as, exposure data for the specific product if there is significant uncertainty associated with the quality and/or quantity of these data.

RISKOFDERM

RISKOFDERM…

- ✓ is an excel factsheet for estimating the dermal exposure levels in different tasks
- ✓ provides information on which risk control measures to put in place as to reduce potential risk from use of chemicals
- ✓ is intended for industrial and professional users, only
- ✓ was developed as a part of a European Research project attended by 11 Member States

RISKOFDERM

History…

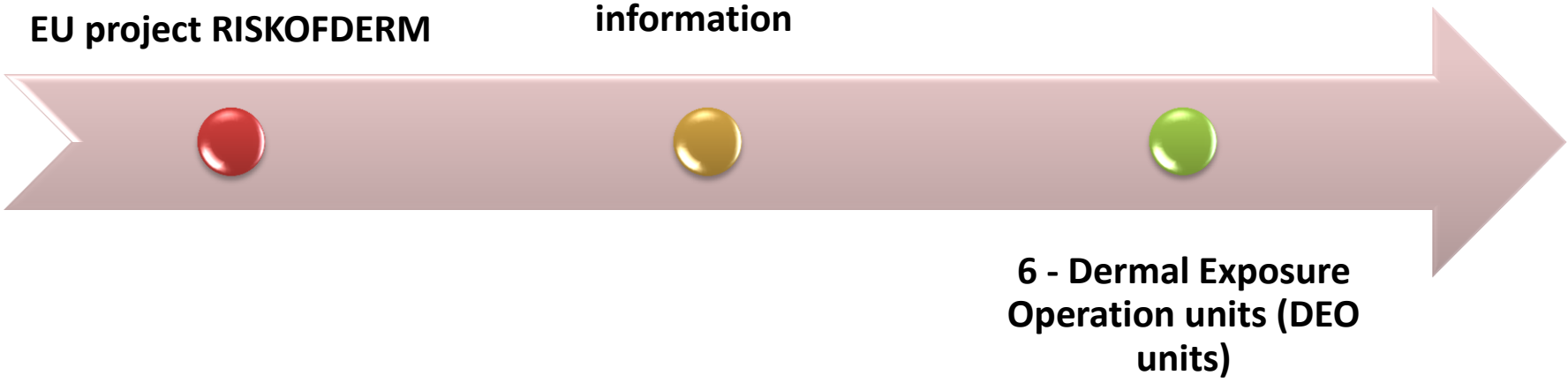
The model was built up by analyzing the main determinants of dermal hazard and dermal exposure (van Hemmen et al., 2003).

The results were combined in the form of a **decision-tree** that leads the user of the model through a number of questions on the exposure situation.

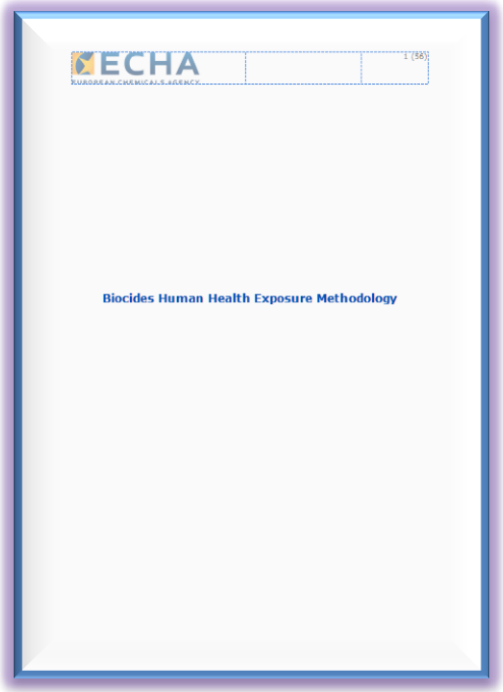
The model **identify model identifies six generic categories** of the exposure the exposure situations called Dermal Exposure Operational (DEO) units.

The majority of data that have been used to assign default potential exposure rates to the DEO units were collected specifically as a part of the project (Warren et al., 2006).

RISKOFDERM



- Handling of contaminated objects
- Manual dispersion of products
- Dispersion of products with a hand held tool
- Spray application of products
- Immersion
- Treatment of solid objects



BHHEM provides detailed information on the «Generic Models Algorithms for Primary & Secondary Exposure Assessment»…

- Inhalation exposure
- Dermal exposure to a non-volatile active substance
- Dermal exposure to a volatile active substance
- Evaporation time
- Oral exposure

A substance is released as a gas, vapour or airborne particulate into a room inhalation can be estimated by calculation of the concentration in the inhaled air (C_{inh}) after using an amount Q_{prod} of the product:

An example…

(mg/m^3) *Equation 1*

	concentration in inhaled air	mg/m³	
	unt of undiluted product used	mg	
FC_{prod}	Weight fraction of active substance in the product		
V_{room}	Volume of the room (living room)	m³	

The resulting inhalation intake of the active substance might be calculated as:

$$A_{inh} = \frac{F_{resp} \times C_{inh} \times Q_{inh} \times T_{contact}}{BW} \times N_{event} \quad (mg/kgBW/day)$$ *Equation 2*

A_{inh}	Amount of active substance inhaled/respired		mg/kg BW/d
F_{resp}	Inhalable or respirable fraction of product		(Default : 1)
C_{inh}	Average concentration in inhaled air		mg/m³
Q_{inh}	Ventilation rate of adult		m³/hour (Default: 0.021 m³/min; 1.25 m³/h)
$T_{contact}$	Duration of exposure		hours
N_{event}	Number of events		(usually per day)
BW	Body weight	Kg	

Case studies: examples of active substances and biocidal products evaluation

Active substance "*XX*" approved as Wood Preservative (PT8)

Selection of representative scenarios

Information on **XX** to be taken into account:

✓used as wood preservative for preventive treatments;

✓used for industrial application in treatment plant installations;

✓used for constructional timbers in Hazard Classes 1 to 4A (according to ISO draft standard).

Use Classes according to the ISO draft standard

Table 5.1
Use Classes according to the ISO draft standard 'An international framework for classifying wood products durability based on use classes'

Class	Service Conditions		Typical Uses	Biological Agents		
1	Interior, dry		Framing, roof timbers	Insects	A	wood boring beetles
					B	as A + termites
2	Interior, damp		Framing, roof timbers	As # 1	A	+ decay + mould [allergic potential]
					B	+ termites
3	A	Protected exterior	Exterior joinery	As # 2 + disfiguring fungi		
	B	Unprotected exterior	Deck boards	As # 2		
4	A	In-ground	Fence posts	As # 3 + soft rot		
	B	In-ground, severe, fresh water	Cooling tower	As # 3		
5	Marine		Piles	As # 4	A	Teridinids + Limnoria
					B	creosote tolerant Limnoria
					C	Sphaeroma, Pholads

Intended uses

Product Type	Field of use envisaged (Hazard class)	Likely concentrations at which a.s. will be used (w/w %)
PT 8; Wood Preservatives	Used in wood protection as a fungicide/insecticide	from 0.3% to 1.8%

Treatment processes

Wood preservative products based on XX are only used in industrial wood preservative facilities and is not used by professional workers outside the industrial facilities . The XX-based products are used as wood preservative in the following treatment applications:

- ✓ Dipping process (including the Mixing and loading phase) and;
- ✓ Vacuum pressure process

Dipping treatment

✓Mixing and loading

The active substance is supplied by tanker as a concentrate with approximately one delivery per week. It is delivered to the holding tank by transfer pipes and is a closed system. The concentrate is then diluted as appropriate in the process plant to give a solution to be use for preservation of the wood. All workers wear gloves, coveralls, and foot protection and are trained in the use of the equipment.

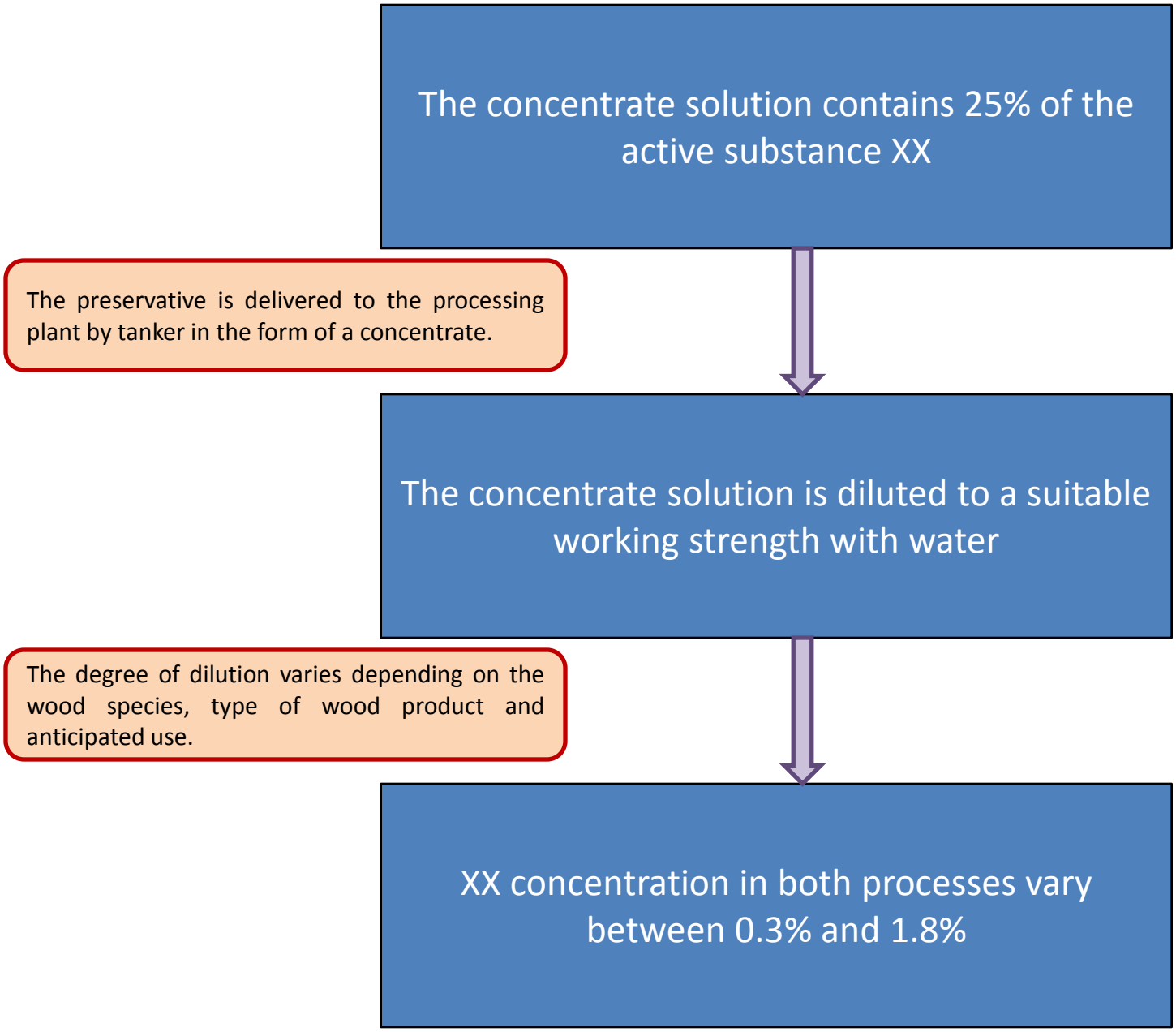
✓Dipping

Dipping treatment is a batch process with continuous treatment. A pack or single piece of wood is submerged into a dipping tank filled with a solution containing the wood preservative. Packs of wood are loaded on automatic equipment (e.g. hydraulic elevator) and lowered into a dipping tank. The period of time that the wood is submerged varies from a few minutes to an hour depending on anticipated use of the wood. At the end of treatment, the wood is held over the dipping vat for up to an hour to allow the excess preservative to drain. Drips are collected and recycled. The treated wood is then removed for storage. The dipping facilities are enclosed, and are equipped with vapour trapping and air emission control.

Vacuum pressure treatment

✓Vacuum pressure is a process used to apply wood preservative by overcoming the resistance of the wood to deep penetration using pressure. The treatment is carried out in cylindrical airtight steel pressure/vacuum vessels. The operations are carried out on a cyclical basis.

The untreated wood is loaded onto small rails or tramcars that are pushed into the cylinder using forklifts or other mechanical means. The cylinder door is sealed via a pressure tight door, either manually with bolts or hydraulically, and a vacuum applied to remove most of the air from the cylinder and the wood cells. The preservative solution is then pumped into the cylinder and the pressure raised. The total treatment time varies depending on species of wood and the commodity being treated, but in all instances the treating process remains a closed system. At the end of the treatment time, the pressure is released and the excess solution removed, typically by pumping, and recycled. A final vacuum may be applied to remove excess preservative that would otherwise drip from the wood. The treated wood is then unloaded and stored.


The concentrate solution contains 25% of the active substance XX
The preservative is delivered to the processing plant by tanker in the form of a concentrate.
The concentrate solution is diluted to a suitable working strength with water
The degree of dilution varies depending on the wood species, type of wood product and anticipated use.
XX concentration in both processes vary between 0.3% and 1.8%

Human exposure assessment

Main pathways of human exposure to the active ingredient from use of the product

Exposure path	Industrial use	Professional use	General public	Via the environment
Inhalation	YES	YES	MINIMAL	NO
Dermal	YES	YES	MINIMAL	NO
Oral	NO	NO	YES (INFANT)	NO

Industrial/professional users

Relevant exposure paths

- ✓ dermal and inhalation

Primary exposure

mainly via the dermal route as a result of direct contact with the surface of treated timber and through contact with equipment, contaminated process plants as well as contaminated overalls and gloves.

Secondary (indirect) exposure

after the actual use or application of the biocidal product.

Non-relevant exposure paths

- ✓ ingestion

Consumers

Relevant exposure paths

Secondary exposure

from contact with treated timber/wood; e.g. adults using preserved timber in construction, children playing on preserved timber structures and infants chewing preserved timber off-cuts.

Non-relevant exposure paths

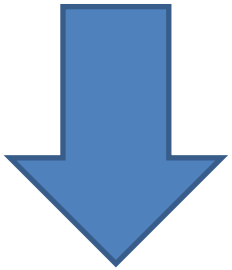
Secondary exposure

The treated wood is not placed on the market until it is dry. Therefore exposure through touching of treated wet surfaces is considered to be an unlikely exposure scenario .

It is not expected the use of DDAC-based products on wood, which is likely to come into prolonged direct contact with foodstuffs or feedstuffs.

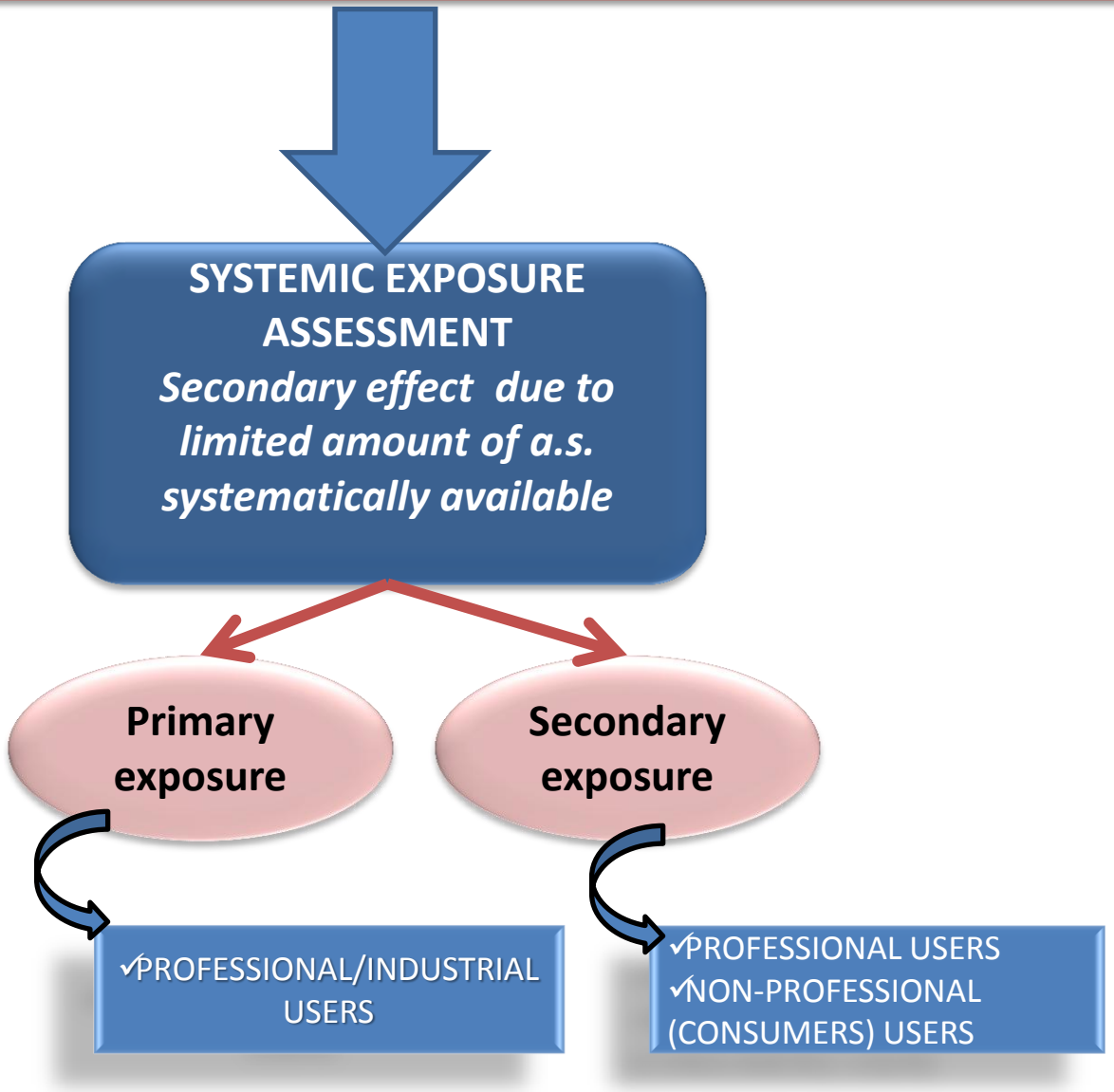
Indirect exposure via the environment is considered not relevant based upon the rapid environmental degradation of the active substance.

HUMAN HEALTH EXPOSURE



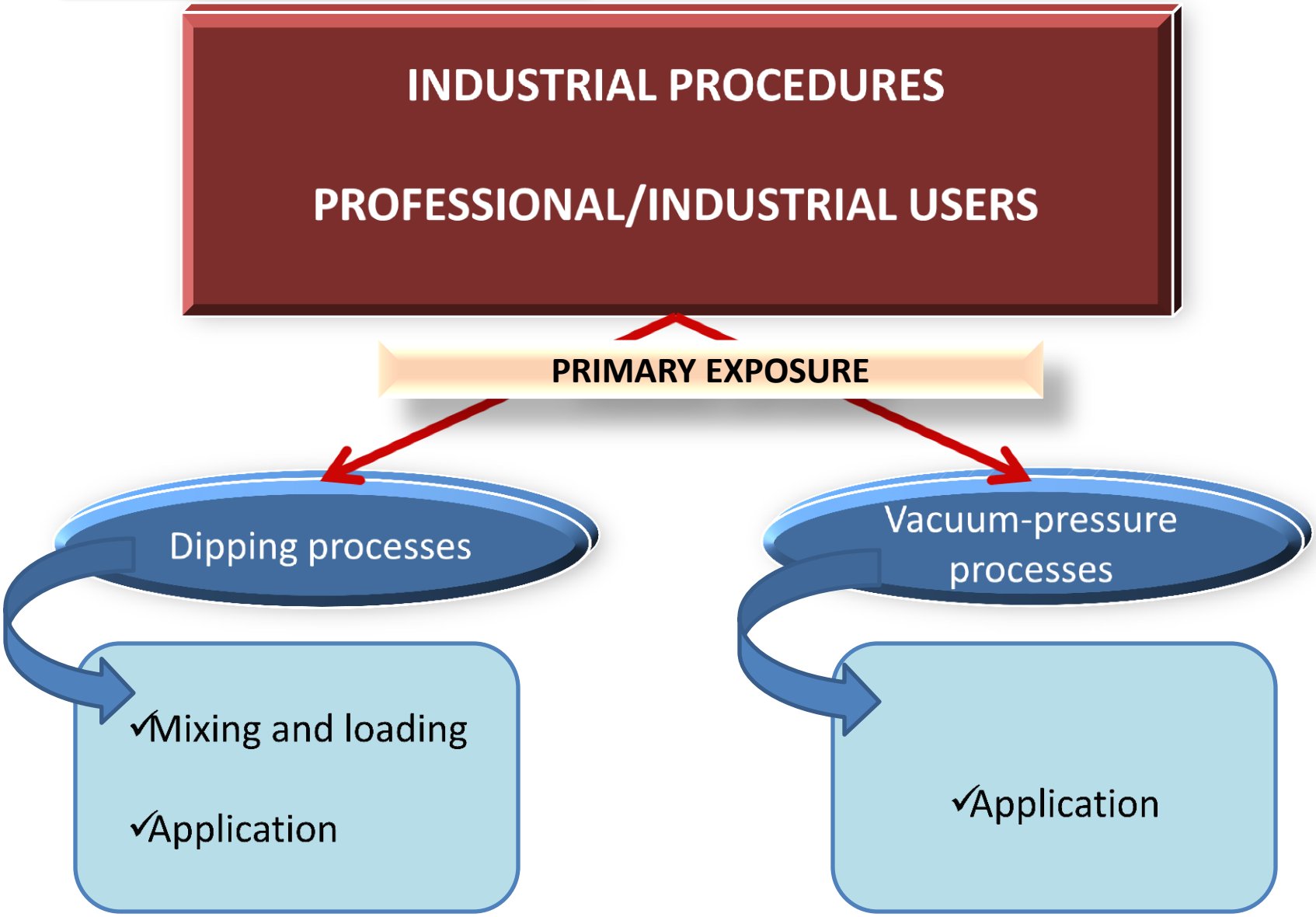
SYSTEMIC EXPOSURE ASSESSMENT
SECONDARY EFFECT DUE TO LIMITED AMOUNT OF A.S. SYSTEMATICALLY AVAILABLE

HUMAN HEALTH EXPOSURE



HUMAN HEALTH EXPOSURE

Primary exposure for systemic effects



Dipping
Tasks duration

Activity	Frequency	Duration	Potential exposure
Transport of wood stack into dipping lift	1x day	10 min	-
Rinsing off, into trough (using dipping lift)	1x day	10 min	-
Pumping wp into trough (using container pump)	2x week	15 min	skin, eyes, lungs
Cleaning pump equipment	2x week	5 min	skin, eyes, lungs
Maintenance of dipping lift (greasing)	1x month	30 min	skin
Maintenance and cleaning of fork-lifter	1x week	30 min	skin
Emptying trough for maintenance	1x year	120 min	skin, eyes, lungs
Trough cleaning and maintenance	1x year	60 min	skin, eyes, lungs
Total daily exposure	20 min/day		
Maintenance	Max: 240 mins		

Vacuum process
Tasks duration

Activity	Frequency	Duration	Potential exposure
Connect tanker transfer lines	3x day	2 min	Dermal: Hands – protective gloves, coverall
Dilute concentrates in plant	3x day		None as dilution done inside plant piping
Load wood onto carrier (bogie) done mechanically	3x day	5 min	Dermal – gloves, coverall
Secure with restraining straps	3x day	5 min	Dermal – gloves, coverall
Push carrier into vessel by mechanical means	3x day	1 min	Potential for dermal pick-up from contaminated controls
Seal door, operate process	3 x day	2 min	Potential for dermal pick-up from contaminated controls
Open door at the end of the cycle	3 x day	1 min	Potential for dermal pick-up from contaminated controls; inhalation of aerosol on opening door
Remove carrier (bogie) from vessel by mechanical means	3 x day	5 min	Potential for dermal pick up from contaminated controls
Release restraining straps	3 x day	2 min	Dermal – gloves, coverall
Convey treated wood to holding area by lift truck	3 x day	5 min	Gloves off to drive lift truck; Potential for dermal pick up from contaminated controls
Maintenance of moving parts (greasing)	1x month	30 min	Skin
Maintenance of conveyor train	1x month	30 min	skin, eyes, lungs
Maintenance and cleaning of fork-lifter	1x week	30 min	skin
Emptying and cleaning of solution reservoir for maintenance	0.5x year	120 min	skin, eyes, lungs
Pressure tube cleaning and maintenance	1x year	60 min	skin, eyes, lungs
Total daily exposure	28 min/cycle 3 cycles day = 84 min/day		
Maintenance	Max: 270 mins		

Automated tasks for all processes with no exposure
Tasks duration

Activity	Frequency	Duration	Potential exposure
Unloading wp-container from truck to stock (by fork-lift)	1x week	15 min	-
Transport from stock to dipping trough/ premix vessel (by fork-lift)	2x week	15 min	-
Filling water into trough/premix vessel (using tap water supply)	2x week	30 min	-
Transport of wood stack into dipping lift	1x day	10 min	-
Dipping of wood by dipping lift (automated)	1x day	540 min	-
Rinsing off, into trough (using dipping lift)	1x day	10 min	-
Pumping treatment solution from premix vessel to solution reservoir (automated)	1x day	5 min	-
Loading the wood stacks into conveyor train (for charging the pressure tube)	2x day	45 min	-
Treatment of wood by automated process control	2x day	240-540 min	-
Transport of treated wood to fixation stock (by fork-lift)	1x day	10 min	-
Removal of treated wood from stock to customer (by fork-lift)	5x day	15 min	-

Wood treatment by dipping

MIXING AND LOADING PHASE

✓**Mixing and loading model 7*** from TNsG Part 2. P 140 - which covers the potential for primary exposure during manual mixing and loading operations by professional operators.

✓Model **RISKOFDERM** Toolkit (*Connecting lines*) has been included in the exposure assessment for automated/pumping process.

DIPPING PHASE

✓**Dipping model 1** from TNsG Part 2, p167 - which includes application and post application exposures.

Wood treatment by vacuum-pressure

VACUUM PRESSURE PHASE

✓**Handling Model 1** from TNsG Part 2, p160 – which estimates primary exposure for professional operators and includes all stages in preservation, from loading the treatment vessel to stacking the treated wood to dry and post application exposure which includes system maintenance and recycling or disposal.

It should be noted that this model presents rates of contamination per cycle. For typical water based treatments, the exposure assessment is based on an average cycle time of 3 hours and there are 3 cycles per day. To derive rate of contamination per minute, the rate per cycle is therefore divided by 180.

Tier 1 - Exposure calculations

The Tier 1 represents the worst-case exposure estimate defined as using the indicative value from a recommended database or from a mathematical exposure model.

In the Tier 1, the estimate of the primary exposure is carried without considering the use of the personal protective equipment (PPE) or a 100% clothing penetration with old gloves.

As concerns the inhalation exposure, an agreed default value for inhalation uptake of 100% has been taken into account.

Mixing and Loading Model 7 - TNsG Part 2 p140

Product data used in calculations:

Active substance	XX
Density	Assumed to be 1 g/mL
Concentration of a.s.	25% product concentrate

Parameters used in model:

Parameter	Value	Source
Body weight of adult	60 kg	ECETOC, 2001
Task duration	10 min	Assumed
Dermal exposure		
Clothing penetration	100%	Default value – TNsG part 2
Dermal absorption of a.s.	9.41% (rounded to 10%)	Calculated value from a vitro dermal absorption study
Inhalation exposure		
Inhalation rate	1.25m3/h (0.021m3/min)	TNsG, Part 3, p30
Inhaled uptake	100%	TNsG, Part 3, p30

Mixing/Loading of 25% XX Concentrate to prepare Dipping Fluid (pump liquid)	
Exposure parameter	**Value(75th%ile from Model where appropriate)**
Body exposure	
Indicative value (mg product/minute)	*0.6* (TNsG part 2, **75th % ile**)
Task duration (min)	*10*
Potential dermal exposure to product (mg)	**6.0**
Clothing penetration (%)	*100*
Actual deposit on skin (mg)	**6.0**
Actual deposit of a.s. on skin (mg)	1.5
Skin penetration (%)	*9.41 (rounded to 10)*
Total dermal exposure to a.s. (mg)	**0.15**
Inhalation exposure	
Indicative value (mg product/ m^3)	*3.9* (TNsG part 2, **50th % ile**)
Task duration (min)	*10*
Volume of air inhaled during task (m^3/min)	*0.021*
Amount of product inhaled (mg)	**0.819**
Amount of a.s .inhaled (mg)	**0.205**
Total systemic exposure (mg/ a.s./day)	**0.35**
Body weight (kg)	*60*
Total systemic dose (mg/kg/day)	**0.0058**

Dipping Model 1 - TNsG Part 2, p167

Product data used in calculations:

Active substance	XX
Density	Assumed to be 1 g/mL
Concentration of a.s.	1.8% in-use dipping solutions

Parameters used in model:

Parameter	Value	Source
Body weight of adult	60 kg	ECETOC, 2001
Task duration	30 min	Default value – User Guidance version 1, p44
Dermal exposure		
Clothing penetration	100%	Default value – User Guidance version 1, p45
Dermal absorption of a.s.	9.41% (rounded to 10%)	Calculated value from a vitro dermal absorption study
Inhalation exposure		
Inhalation rate	1.25m^3/h (0.021m^3/min)	TNsG, Part 3, p30
Inhaled uptake	100%	TNsG, Part 3, p30

Dipping wooden articles (including mixing and loading) 1.8% XX aqueous diluted concentrate	
Exposure parameter	**Value(75th%ile from Model where appropriate)**
Hand-in-gloves exposure	
Indicative value for hand-in-gloves (mg in-use product/min)	*25.7*
Task duration (min)	*30*
Dermal exposure to in-use product (mg)	**771**
Body exposure	
Indicative value (mg in-use product/min)	*178*
Task duration (min)	*30*
Potential dermal exposure to in-use product (mg)	**5340**
Clothing penetration (%)	*100*
Actual deposit of in-use product on skin (mg)	**5340**
Total dermal exposure	
Total deposit of in-use product on skin (mg)	**6111**
Total deposit of a.s. on skin (mg)	**110**
Skin penetration (%)	*9.41*
Total dermal systemic exposure to a.s. (mg)	**10.9**
Inhalation exposure	
Indicative value (mg product/ m^3)	*1*
Task duration (min)	*30*
Volume of air inhaled during task (m^3/min)	*0.021*
Amount of product inhaled (mg)	*0.63*
Amount of a.s .inhaled (mg)	**0.01134**
Total systemic exposure (mg/ a.s./day)	**10.91**
Body weight (kg)	*60*
Total systemic dose (mg/kg/day)	**0.17**

Handling Model 1 - TNsG Part 2, p167

Vacuum pressure treatment

Product data used in calculations:

Active substance	XX
Density	Assumed to be 1 g/mL
Concentration of a.s.	1.8% in-use dipping solutions

Parameters used in model:

Parameter	Value	Source
Body weight of adult		
Cycle duration	3 hours	Model data - User Guidance version 1 p41
Number of cycle per day	3	Model data - User Guidance version 1 p41
Dermal exposure		
Clothing penetration	100%	Default value – User Guidance version 1, p45
Dermal absorption of a.s.	9.41% (rounded to 10%)	Calculated value from a vitro dermal absorption study
Inhalation exposure		
Inhalation rate	1.25m^3/h (0.021m^3/min)	TNsG, Part 3, p30
Inhaled uptake	100%	TNsG, Part 3, p30

Vacuum/pressure treatment 1.8% XX aqueous diluted concentrate	
Exposure parameter	**Value(75th%ile from Model where appropriate)**
Dermal exposure – body	
Indicative value (mg product/cycle)	*8570*
Number of cycle (cycle/day)	*3*
Potential dermal deposit of product (mg)	**25710**
Clothing penetration (%)	*100*
Deposit of in-use product on skin (mg)	**25710**
Dermal exposure – hand (old gloves)	
Indicative value (mg in-use product/cycle)	*1080*
Number of cycle (cycle/day)	*3*
Deposit of in-use product on hands in gloves (mg)	**3240**
Dermal exposure of feet inside shoes	
Indicative value (mg in-use product/cycle)	*501*
Number of cycle (cycle/day)	*3*
Actual deposit of in-use product on skin (mg)	**1503**
Total dermal exposure	
Total deposit of in-use product on skin (mg)	**30453**
Total deposit of a.s. on skin (mg)	**548**
Skin penetration (%)	*10*
Total dermal systemic exposure to a.s. (mg)	**55**
Inhalation exposure	
Indicative value (mg in-use product/m^3)	*1.9*
Duration (min)	*540*
Volume of air inhaled during task (m^3)	**11.3**
Amount of in-use product inhaled (mg)	**21.5**
Amount of a.s inhaled (mg)	**0.34**
Total systemic exposure (mg/ a.s./day)	**55.4**
Body weight (kg)	*60*
Total systemic dose (mg/kg/day)	**0.92**

Tier 2 - Exposure calculations

A Tier 2 assessment has been conducted assuming use of personal protective equipment including protective clothing, gloves and footwear.
The dermal exposure has been assessed assuming clothing penetration of 10% (User Guidance version 1, p42), except for dipping and cleaning out dipping tank, where it is assumed that impermeable coveralls will be worn (penetration = 4%; TNsG - Part 3, p60). Also, to reduce exposure via the hands, operators would be required to wear new protective gloves at the start of each daily dipping session. New gloves reduce hand-in-glove exposure by a factor of 0.6 (TNsG, Part 2, p.192).

The dermal penetration of XX used for this assessment is 9.41% (rounded to 10%), as discussed in Section 4.1 of this document.

The duration of the tasks has been reviewed on the basis of more realistic values. For the dipping process, it has been considered an exposure period of 20 minutes for dermal exposure.
According to the data derived for the vacuum pressur treatment from specific use information, the defaul value of 9-hour inhalation exposure (User Guidance, 3 hours per cycle, 3 cycles per day) deems to be a too long exposure period. Therefore, the inhalation exposure for the vacuum pressure process has been recalculated using the more realistic value of 84 minutes (28 minutes per cycle, 3 cycles per day).
The default value for body weight of an exposed adult is assumed to be 60 kg in order to include women (50th Percentile = 60.3 kg according to ECETOC, 2001).

Mixing and Loading – RISKOFDERM Toolkit (*Connecting lines*)

For automated transfer/pumping the Human Exposure Expert Group (HEEG) has concluded that in case of evaluated available data and models for the assessment of the exposure to operators during the loading of products into vessels or systems in industrial scale the exposure could be considered as negligible, with a very low or accidental exposure during connecting lines.

Alternatively, the RISKOFDERM Connecting lines could be used. (Opinion presented and accepted at the March meeting (2008) in the Technical Meeting in the Biocides Group).
Indicative dermal exposure values for RISKOFDERM Toolkit Connecting lines referred in the HEEG document are 0.066 mg/cm^2/h (0.92 mg/min) for hands. The model is a semi-quantitative model and assumes that small contaminations and no body exposure take place during the task.

Mixing and Loading – RISKOFDERM Toolkit (*Connecting lines*)

Product data used in calculations:

Active substance	XX
Density	Assumed to be 1 g/mL
Concentration of a.s.	25% product concentrate

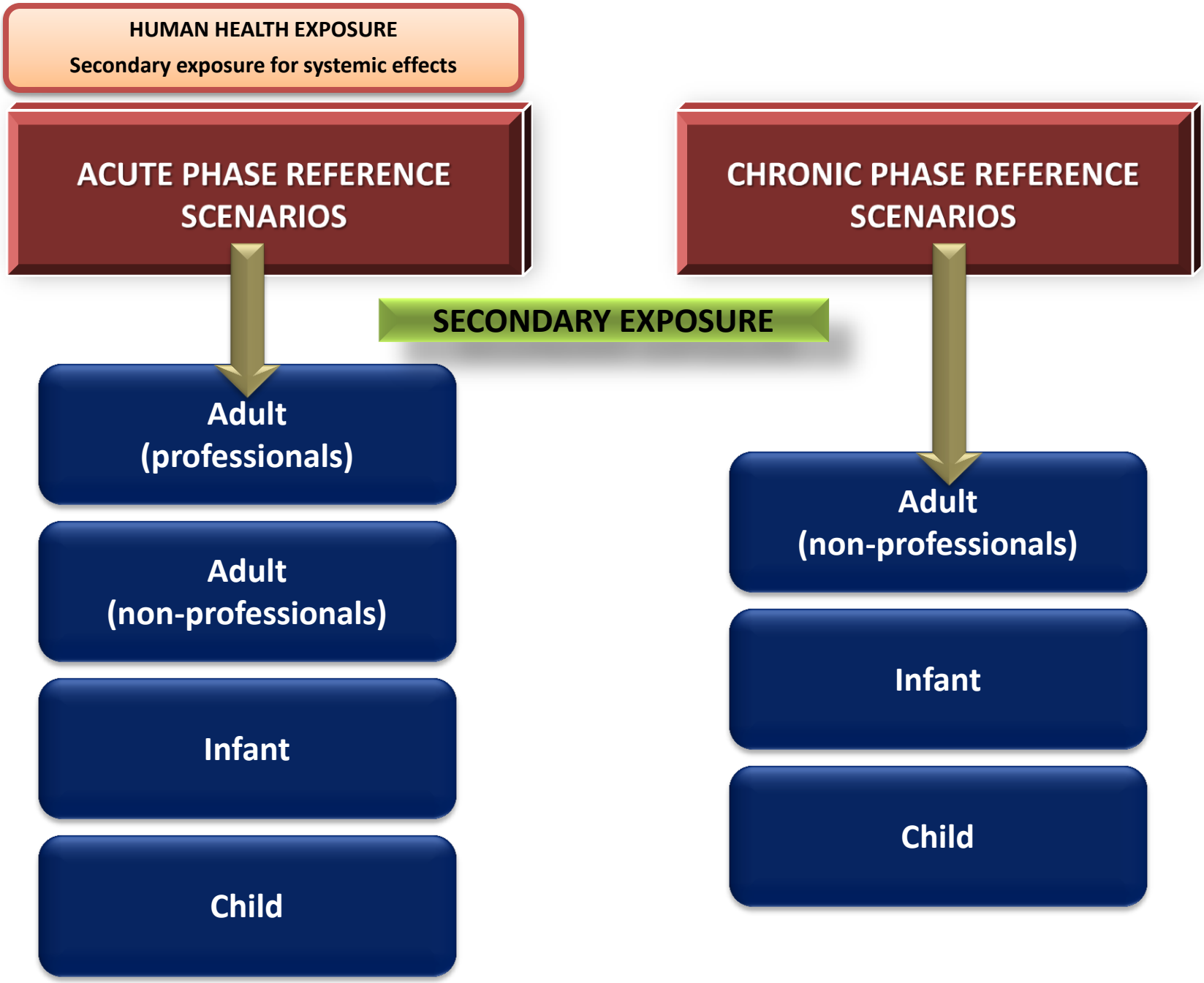
Parameters used in model:

Parameter	Value	Source
Body weight of adult	60 kg	ECETOC, 2001
Task duration	10 min	Assumed
Dermal exposure		
Clothing penetration	0.92 mg/min	RISKOFDERM Toolkit (Connecting lines)
Dermal absorption of a.s.	9.41% (rounded to 10%)	Calculated value from a vitro dermal absorption study

Mixing/Loading of 25% XX Concentrate to prepare Dipping Fluid (pump liquid)	
Exposure parameter	**Value(75th%ile from Model where appropriate)**
Dermal exposure parameter	
Hand exposure - indicative value (mg/min)	*0.92* - default value from RISKOFDERM toolkit (*Connecting lines*)
Task duration (min)	*10*
Hand exposure inside old gloves to product (mg)	**9.2**
Concentration of the a.s. in the product (%)	*25*
Hand exposure to the a.s. (mg)	**2.3**
Operation per day (day^{-1})	*1*
Hand exposure to the a.s. (mg/day)	**2.3**
Dermal penetration (%)	*10* - Calculated value from a vitro dermal absorption study
Dermal uptake (mg/day)	**0.23**
Body weight (kg)	*60*
Dermal systemic uptake (mg/kg bw/day)	**0.004**

Summary of systemic exposure for primary exposure

Exposure scenario	Total Exposure (mg)		Total Systemic dose (mg/kg/d)	
	Tier 1	Tier 2	Tier 1	Tier 2
Dipping Mixing and loading **(25% solution)(Model 7)**	0.35	0.22	0.0058	0.0037
Dipping Mixing and loading (25% solution)(**RISKOFDERM toolkit**)	-	0.23	-	0.004
Dipping Application (1.8% solution)	10.9	0.87	0.17	0.014
Dipping Application (0.3% solution)	1.83	0.14	0.03	0.002
Vacuum/pressure treatment (1.8% solution	55.4	3.2	0.92	0.22
Vacuum/pressure treatment (0.3% solution)	9.26	0.53	0.15	0.04


HUMAN HEALTH EXPOSURE
Secondary exposure for systemic effects
ACUTE PHASE REFERENCE SCENARIOS
CHRONIC PHASE REFERENCE SCENARIOS
SECONDARY EXPOSURE
Adult (professionals)
Adult (non-professionals)
Infant
Child
Adult (non-professionals)
Infant
Child

Acute phase reference scenarios

- Adult (professionals): sanding treated wood from vacuum/pressure impregnated timber - inhalation and dermal route
- Adult (non-professionals): sanding treated wood from vacuum/pressure impregnated timber - inhalation and dermal route
- Infant: chewing wood off-cut – oral route (wood from vacuum/pressure impregnated timber)
- Child: not relevant

Chronic phase reference scenarios

- Adult: inhalation route – not relevant
- Child: playing on playground structure outdoors - dermal route
- Infant: playing on weathered structure and mouthing - dermal and ingestion

The scenarios used are described in the TNsG on **Human Exposure to Biocidal Products,** Part 3, p50-51

Summary of systemic exposure for secondary exposure

Exposure scenario	Total Systemic dose (mg/kg/d)			
	Oral	Dermal	Inhalation	Combined
	Professionals			
Acute				
Adult sanding	--	0.0504	0.0028	0.053
	Non-Professionals			
Acute				
Adult sanding	--	0.0504	0.00047	0.05087
Infant mouthing	0.048	--	--	--
Chronic				
Child playing		0.0048	--	
Infant playing	0.09	0.0072		0.0972

Biocidal product containing THPS

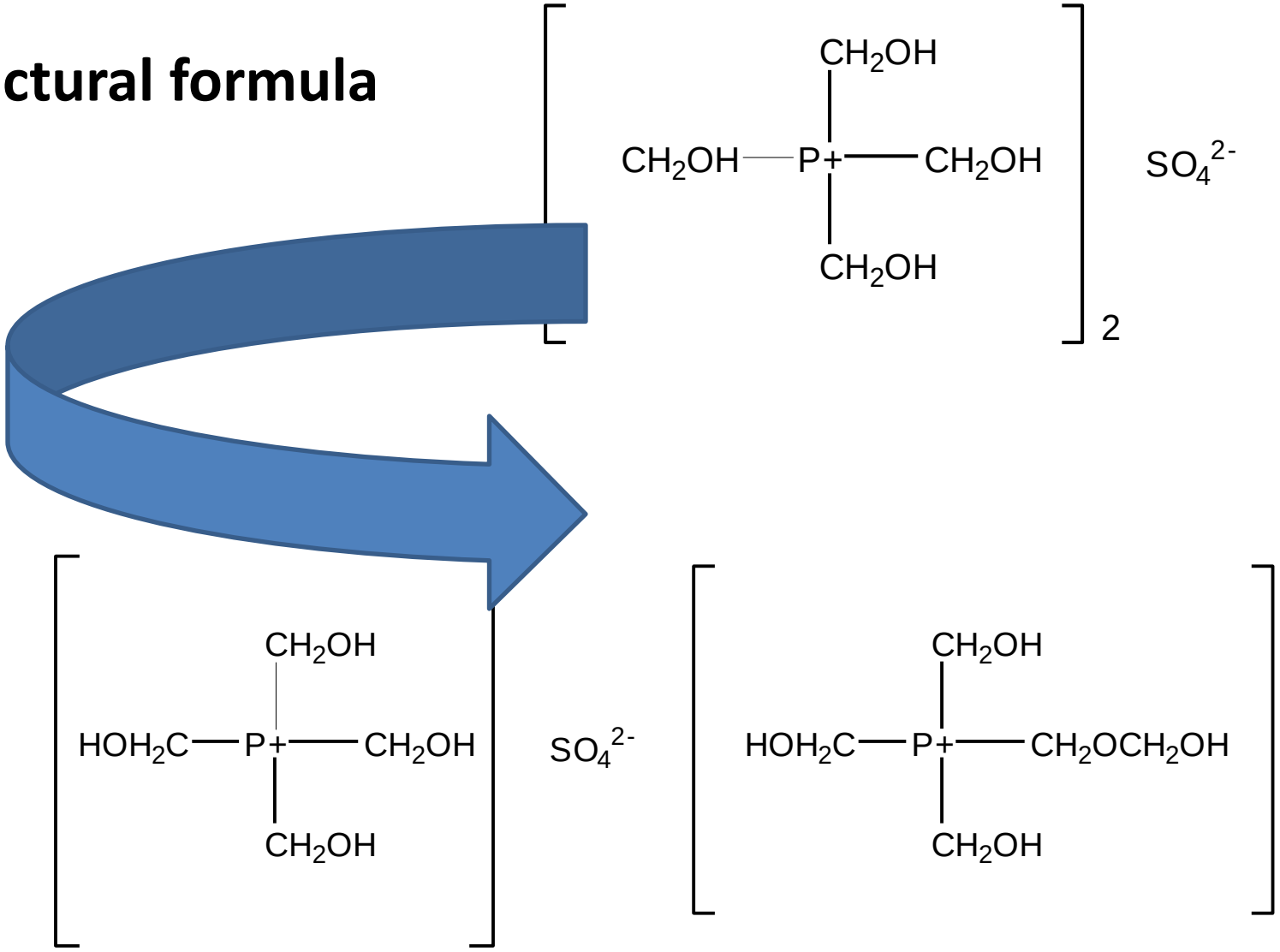
Product types

- PT2 – Private area and public health area disinfectants and other biocidal products
- PT6 - In-can preservative

THE ACTIVE SUBSTANCE

CAS-No.	55566-30-8
EINECS-No.	259-709-0
Other No. (CIPAC, ELINCS)	-
IUPAC Name	Bis[tetrakis(hydroxymethyl)phosphonium]sulfate (salt)
Common name, synonym	Tetrakis(hydroxymethyl)phosphonium sulphate(2:1) Tolcide PS75 THPS THPS 75 DP-435 Octakis(hydroxymethyl)diphosphonium sulphate Tolcide THPS 75%
Molecular formula	$C_4H_{12}O_4P.1/2O_4S$
Molecular weight (g/mol)	406.28

Structural formula



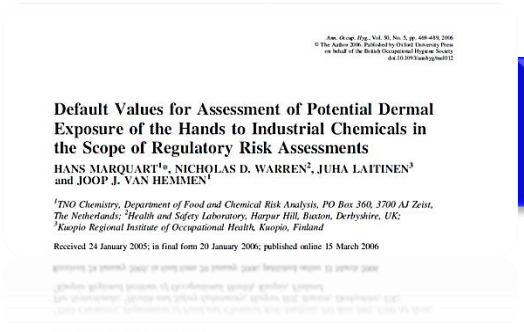
Physical chemical data used

Physical chemical properties	Values
Molecular weight	406.28 g/mol
Melting point	
Boiling point	-
Vapour pressure	2.6×10^{-6} hPa at
Octanol-water partition coefficient (as log)	-9.8
Water solubility	10^{6} mg/l at

Effects & exposure assessment for biocidal product

✓Product type 2 – For use in Private area and public health area disinfectants and other biocidal products
Subsection PT 02.05 Other biocidal products within product type 2 (Treatment of sewage sludge)

✓Product type 6 – In can preservatives
PT6.01 Mineral slurry preservation (Calcium carbonate slurries)
PT6.02 Oil industry drilling fluid preservation (Preservation of drilling muds for off-shore use)



Default Values for Assessment of Potential Dermal Exposure of the Hands to Industrial Chemicals in the Scope of Regulatory Risk Assessments

HANS MARQUART[1]*, NICHOLAS D. WARREN[2], JUHA LAITINEN[3] and JOOP J. VAN HEMMEN[1]

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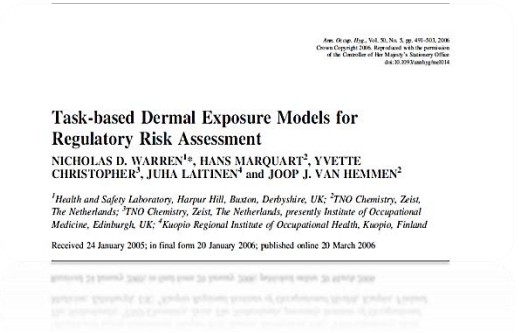
Received 24 January 2005; in final form 20 January 2006; published online 15 March 2006

RISKOFDERM



Task-based Dermal Exposure Models for Regulatory Risk Assessment

NICHOLAS D. WARREN[1]*, HANS MARQUART[2], YVETTE CHRISTOPHER[3], JUHA LAITINEN[4] and JOOP J. VAN HEMMEN[2]

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Received 24 January 2005; in final form 20 January 2006; published online 20 March 2006

EU project RISKOFDERM

New measurements of dermal exposure with detailed contextual information

6 - Dermal Exposure Operation units (DEO units)

- Handling orf contaminated objects
- Manual dispersion of products
- Dispersion of products with a hand held tool
- Spray application of products
- Immersion
- Treatment of solid objects

Dermal Exposure Operation (DEO) units and scenarios

DEO unit	Description	Examples of scenarios within this DEO unit	Some specific examples
1	Handling of contaminated objects	Collecting	Gathering bags of powder in a warehouse
			Gathering drums containers of adhesives in a warehouse
		Transporting of objects	Transporting packages manually or using e.g. a fork-lift truck
		Loading of liquids from a smaller container into a larger vessel or container	Emptying buckets into a mixer
			Emptying drums into a reactor
			Pumping liquids from drums into a reactor
		Filling of containers with liquids from larger vessels or containers	Filling cans with paint (semi-automated)
			Filling drums with a liquid
		Filling of powders into packages	Bagging of powders
			Drumming of powders
		Dumping powders into mixers, reactors, etc.	Cutting open bags and dumping the contents into a mixer
			Dumping powders from a drum into a hopper
		Mixing and diluting	Adding powders to liquids, or liquids together and manually stirring
			Adding several components consecutively with intermediate mixing
		Sampling	Taking a sample from a reactor through a manhole
			Taking a sample from a product by pouring out into a beaker

DEO unit	Description	Examples of scenarios within this DEO unit	Some specific examples
			Taking a sample from a product using a closed sampling loop
		Maintenance, servicing	Taking parts apart, rinsing parts, small scale wiping of parts
2	Manual dispersion of products	Wiping of surfaces with a piece of cloth or a sponge	Manual car washing
			Wiping of laboratory tables
			Manual wiping of floors
			Wiping of wood with wood maintenance products
			Washing of patients in a hospital
3	Dispersion of products with a hand held tool	Brushing	Painting window paints with a brush
		Using a roller	Painting a ceiling with a roller
			Applying polyester with a roller
		Using a comb	Applying inks in silk screen printing
			Applying carpet adhesives
		Using a trowel	Spreading the concrete (like) top layer of a floor
			Spreading plaster
4	Spray application of products	Spraying paints	High pressure low volume spray application
			Powder spraying
			Conventional pressurized spray painting
		Spraying cleaning solutions	High pressure cleaning spraying

Product type 2 – For use in Private area and public health area disinfectants and other biocidal products

IDENTIFICATION OF THE PRODUCT

Trade name	Tolcide PS24	
Manufacturer s development code number(s)	DP1131	
Ingredient of preparation	Function	Content
Tolcide PS75	Bacterial growth limiting agent	31 % (w/w)
Water	Diluent	69 % (w/w)
Physical state of preparation	Liquid	
Nature of preparation	Aqueous	

Exposure assessment

Field of use envisaged

Private area and public health area disinfectants and other biocidal products, sub-section PT 02.05 other biocidal products within product type 2:
Uncoupling agent for reducing biosolids growth in wastewater treatment processes (WWTP)

Main paths of human exposure towards active substance from its use in biocidal product

Exposure path	Industrial use	Professional use	General public	Via the environment
Inhalation	X	N/A	N/A	X
Dermal	√	N/A	N/A	X
Oral	X	N/A	N/A	X

Potential human exposure scenarios – b.p. use as an uncoupling agent to effect a reduction in biosolids growth in wastewater treatment processes

Scenario 1:

APPLICATION

Connection of dosing equipment to biocidal product drum

Task:

Fixing pipework between the drum of biocidal product and the dosing equipment. 23% THPS (main ingredient). Task involves 1 operator and duration of task is ca. 2-mins. Task may be repeated during the week if b.p. delivered in 25-L drum.

Exposure model:

RISKOFDERM Dermal Model (DEO Unit 1, Loading liquids from smaller containers (such as drums) into larger containers (such as mixing vessels)), has been applied. Default value for the task durationhas been used (i.e., 10 minutes).

Potential human exposure scenarios – b.p. use as an uncoupling agent to effect a reduction in biosolids growth in wastewater treatment processes

<u>Scenario 2</u>:

POST APPLICATION - SAMPLING:

A variety of different samples at various locations throughout the treatment process are required to monitor the efficiency of the process and to estimate when treatment has achieved metabolic breakdown of wastes received. B.p dosed to achieve initial concentration of between 0.5 – 1 ppm at injection point. Connection of dosing equipment to biocidal product drum

Task:

Operators are required to cap sampling vessels and forward to Lab. for analysis. Many samples are automatically dosed to sampling vessels others require operator to use specific tools e.g. pumps to affect transfer to sampling vessel.
Typically at least 2 operators are required for between 20-40-mins ca. 3-5-days of each week.

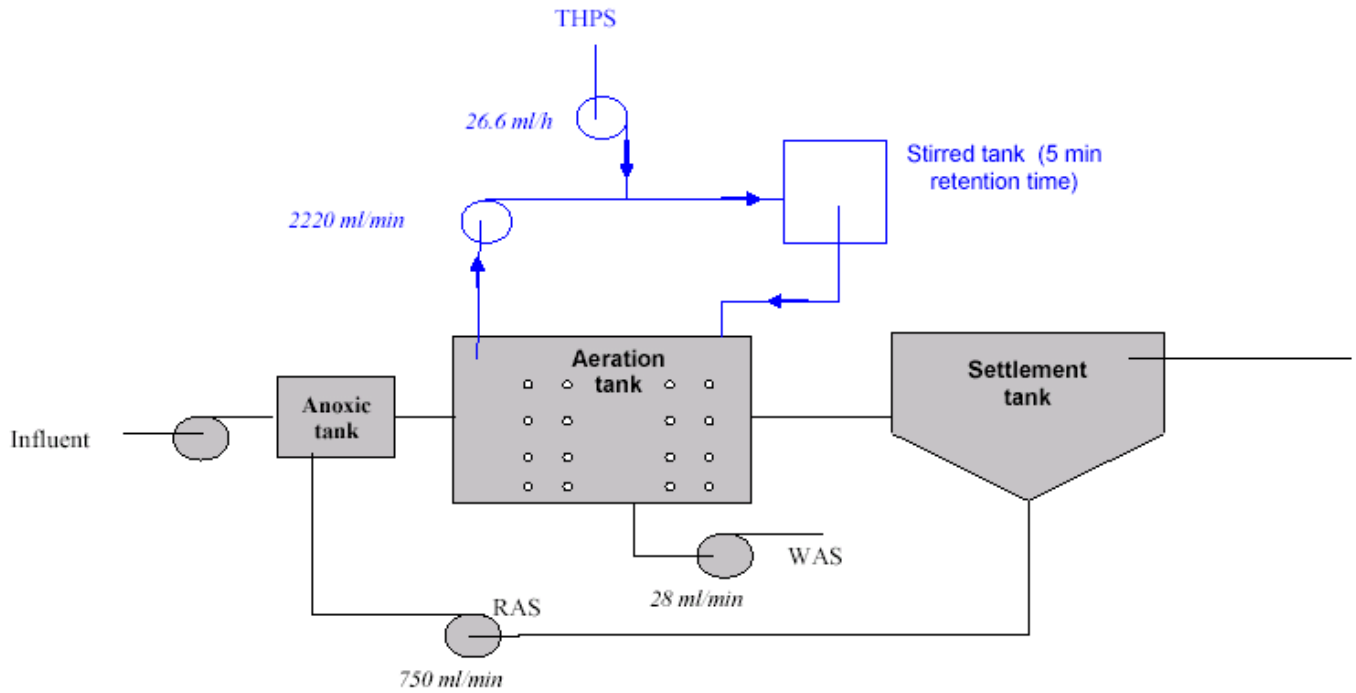
Exposure model:

RISKOFDERM Dermal Model (DEO Unit 1, Collecting of package products), has been applied. Default value for the task durationhas been used (*i.e.*, 10 minutes).

APPLICATION

Once a week a pre-trained operator connects the flexible pipework to the biocidal product drum and the dosing equipment to allow for the injection of THPS main ingredient into the aeration tank following a short retention time

Dosing loop lay-out



Exposure estimation

According to the information submitted in the Dossier, it is clear that the THPS-based product is transferred through an automated system into the application tank. Therefore, it can be foreseen a limited dermal exposure for professional estimated by using the **RISKOFDERM Dermal Model (DEO Unit 1).**

TIER 1

The estimate has been carried out following a tiered approach. In TIER1, the use of Personal Protective Equipments (PPEs) has not been considered and therefore, a clothing penetration rate of 100% has been applied.

Handling (potentially) contaminated objects (DEO unit 1)

Scroll down to see the remainder!

You can move the input messages with the input fields by dragging and dropping

Question	Answer	Additional explanation
What is the task or scenario done with the product or substance?	Loading liquids from smaller containers (such as drums) into larger containers (such as mixing vessels)	
What is the quality of the ventilation related to the task done?	Normal or good ventilation	Good (mechanical) ventilation and/or proper local exhaust ventilation
What is the frequency of (skin) contact with the contaminant?	Rare contact	It happens sometimes, but on average less than once per scenario
What kind of (skin) contact with the contaminant occurs?	Light contact	
What type of product is handled?	Liquid	The product handles is a liquid
Are significant amounts of aerosols or splashes generated in the task?	No	Task does not lead to substantial interaction between product and air, nor to dropping of product on a hard surface *Scroll up or down to see the remainder*
What is the level of automation of the task done by the worker?	Automated or semi-automated task	The task is largely done by a machine and the interaction of the worker with either package, contaminated installation or
What is the use rate of the product (if relevant)?	0.0022	**Give "1"if this is not a relevant parameter, e.g. if no use rate can be established.**

	median	percentile distribution	
Resulting exposure rate hands	.0866	1.39	µL/min or mg/min
Resulting exposure rate body	.033	2.02	µL/min or mg/min

What is the cumulative duration of the scenario during a shift? 10 minutes

	median	percentile distribution	
Exposure loading per shift hands	0.866	13.900	µL or mg
Exposure loading per shift body	0.330	20.200	µL or mg

Output values for TIER1

Resulting exposure rate hands (95%ile) : 1.39 mg/min = Derived from the excel calculator of DEO Unit1
Exposure loading per shift hands : 13.9 mg = Resulting exposure rate hands (95%ile) x Task duration
Actual dermal deposit : 13.9 mg = Exposure loading per shift hands x Clothing penetration (100%)
Dermal dose : 0.67 mg = Actual dermal deposit x Dermal penetration (4.8%)

Systemic dose : 0.012 mg/kg bw/d = Dermal dose / Body weight

Output values for TIER2

Resulting exposure rate hands (95%ile) : 1.39 mg/min = Derived from the excel calculator of DEO Unit1
Exposure loading per shift hands : 13.9 mg = Resulting exposure rate hands (95%ile) x Task duration
Actual dermal deposit : 1.39 mg = Exposure loading per shift hands x Clothing penetration (10%)
Dermal dose : 0.067 mg = Actual dermal deposit x Dermal penetration (4.8%)

Systemic dose : 0.0012 mg/kg bw/d = Dermal dose / Body weight

POST-APPLICATION

Sampling Tasks

The post-application phase covers the scenario of sampling tasks and gives rise to secondary exposure for professionals. The estimate of the dermal exposure has been carried out using the **RISKOFDERM Dermal Model (DEO Unit 1)** for Collecting of package products

Exposure estimation

The exposure was estimated using the RISKOFDERM Dermal Model (DEO Unit 1) for Collecting of package products Only hands are exposed during the post-application sampling task.

TIER 1

The estimate has been carried out following a tiered approach. In TIER1, the use of Personal Protective Equipments (PPEs) has not been considered and therefore, a clothing penetration rate of 100% has been applied. The worst case scenario involves the potential exposure to biocidal product at the injection point of the STP (ca. 0.0001% THPS main ingredient) and assumes both hands may be exposed. Furthermore, the scenario selected takes into consideration that only hands are exposed during the post-application sampling task.

Handling (potentially) contaminated objects (DEO unit 1)

Scroll down to see the remainder!

You can move the input messages with the input fields by dragging and dropping

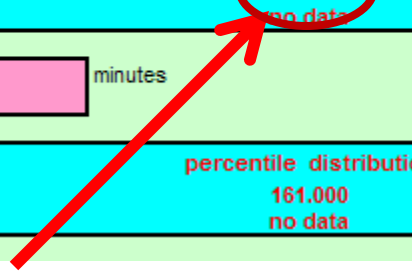
Question	Answer	Additional explanation
What is the task or scenario done with the product or substance?	Collecting of packaged products	
What is the quality of the ventilation related to the task done?	Normal or good ventilation	Good (mechanical) ventilation and/or proper local exhaust ventilation
What is the frequency of (skin) contact with the contaminant?	Rare contact	It happens sometimes, but on average less than once per scenario
What kind of (skin) contact with the contaminant occurs?	Light contact	
What type of product is handled?	Liquid	The product handles is a liquid
Are significant amounts of aerosols or splashes generated in the task?	No	Task does not lead to substantial interaction between product and air, nor to dropping of product on a hard surface *Scroll up or down to see the remainder*
What is the level of automation of the task done by the worker?	Automated or semi-automated task	The task is largely done by a machine and the interaction of the worker with either package, contaminated installation or
What is the use rate of the product (if relevant)?	1	**Give "1"if this is not a relevant parameter, e.g. if no use rate can be established.**

Percentile for the exposure rate distribution to be assessed	95.0%	percentile

	median	percentile distribution	
Resulting exposure rate hands	1.	16.1	µL/min or mg/min
Resulting exposure rate body	no data	no data	µL/min or mg/min

What is the cumulative duration of the scenario during a shift?	10	minutes

	median	percentile distribution	
Exposure loading per shift hands	10.000	161.000	µL or mg
Exposure loading per shift body	no data	no data	µL or mg



Output values for TIER1

Resulting exposure rate hands (95%ile) : 16.1 mg/min = Derived from the excel calculator of DEO Unit1
Exposure loading per shift hands : 161 mg = Resulting exposure rate hands (95%ile) x Task duration
Actual dermal deposit : 161 mg = Exposure loading per shift hands x Clothing penetration (100%)
Dermal dose : 7.73 mg = Actual dermal deposit x Dermal penetration (4.8%)
Dermal dose of active substance : 7.73 x 10^{-6} mg = Dermal dose of product x Concentration of active substance (0.0001%)

Systemic dose : 1.28 x 10^{-7} mg/kg bw/d = Dermal dose / Body weight

Output values for TIER2

Resulting exposure rate hands (95%ile) : 16.1 mg/min = Derived from the excel calculator of DEO Unit1
Exposure loading per shift hands : 161 mg = Resulting exposure rate hands (95%ile) x Task duration
Actual dermal deposit : 16.1 mg = Exposure loading per shift hands x Clothing penetration (10%)
Dermal dose : 0.773 mg = Actual dermal deposit x Dermal penetration (4.8%)
Dermal dose of active substance : 7.73×10^{-7} mg = Dermal dose of product x Concentration of active substance (0.0001%)

Systemic dose : 1.28×10^{-8} mg/kg bw/d = Dermal dose / Body weight

SUMMARY – Professional exposure only

UNCOUPLING AGENT FOR REDUCTION OF BIOSOLIDS GROWTH IN WWTP

Exposure scenario	PPE	Inhalational uptake (mg/m3)	Dermal uptake mg/kg bw/d
APPLICATION:	Y	No	0.0012
POST-APPLICATION:	Y	No	1.28×10^{-8}

AEL: 0.015 mg/kg bw/d

No risk is expected for professional users

Product type 6 – mineral slurry preservation
Preservation of Calcium carbonate slurries

IDENTIFICATION OF THE PRODUCT

Trade name	Tolcide PS24D	
Manufacturer s development code number(s)	DP1132	
Ingredient of preparation	Function	Content
Tolcide PS75	Biocide	31 % (w/w)
Briquest 301-32S	Dispersant	12.2 % (w/w)
Water	Diluent	56.8 % (w/w)
Physical state of preparation	Liquid	
Nature of preparation	Aqueous	

Exposure assessment

Field of use envisaged

In-can preservatives: preservation of aqueous calcium carbonate slurries which are subsequently used in paper manufacturing processes as fillers and for coating applications

Main paths of human exposure towards active substance from its use in biocidal product

Exposure path	Industrial use – ONLY		Professional	General public	Via the environment
	$CaCO_3$ slurry preservation	Paper manufacture & coating			
Inhalation	X	X	N/A	N/A	X
Dermal	√	√	N/A	N/A	X
Oral	X	X	N/A	N/A	X

Potential human exposure scenarios – b.p. use as preservative of $CaCO_3$ slurries

<u>Scenario 1</u>:

APPLICATION

Unloading = Transfer bp (from road tanker/IBC) to dedicated storage tank.

Task:

Fixing pipe work between delivery vessel & storage tank. 23% THPS (main ingredient).

Involves 1 worker; 1/month. Duration 2 x 20 seconds

Exposure model:

For the dermal estimation the RISKOFDERM Dermal Model (DEO Unit 1) has been used. In the excel datasheet the scenario concerning filling of liquids from larger containers (such as mixers or drums) into smaller containers (such as drums or buckets) has been selected

Exposure estimation

According to the information submitted in the Dossier, it is clear that the THPS-based product is transferred through an automated system into the application tank. Therefore, it can be foreseen a limited dermal exposure for professional estimated by using the **RISKOFDERM Dermal Model (DEO Unit 1).**

TIER 1

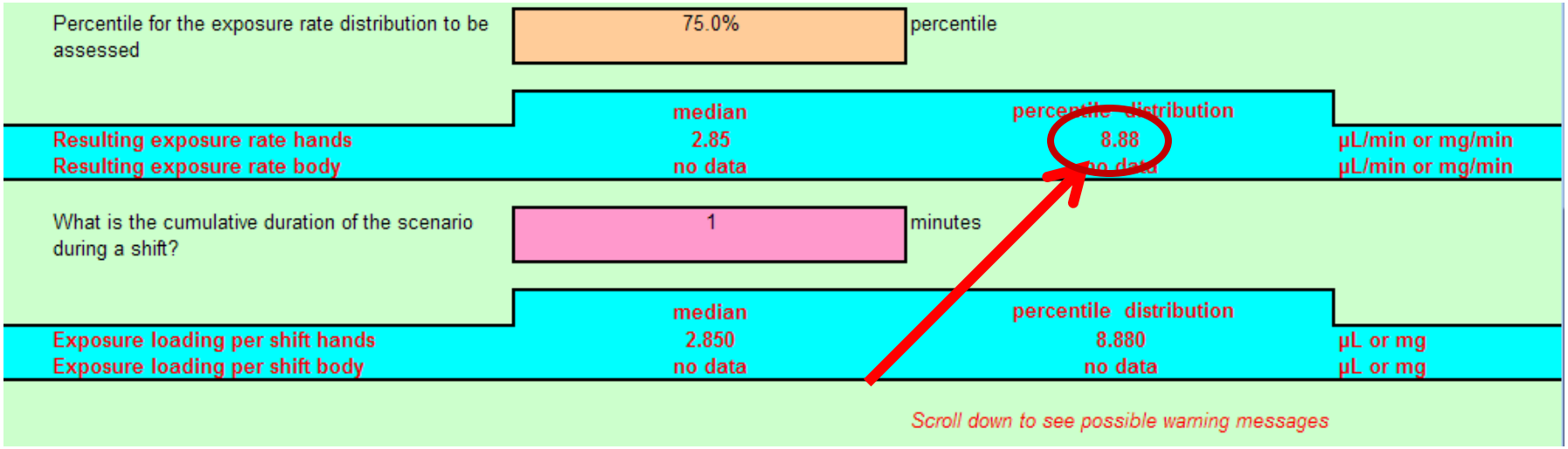
The estimate has been carried out following a tiered approach. In TIER1, the use of Personal Protective Equipments (PPEs) has not been considered and therefore, a clothing penetration rate of 100% has been applied.

Handling (potentially) contaminated objects (DEO unit 1)

Scroll down to see the remainder!

You can move the input messages with the input fields by dragging and dropping

Question	Answer	Additional explanation
What is the task or scenario done with the product or substance?	Filling of liquids from larger containers (such as mixers or drums) into smaller containers (such as drums or buckets)	
What is the quality of the ventilation related to the task done?	Poor ventilation	No good (mechanical) ventilation and no proper local exhaust ventilation
What is the frequency of (skin) contact with the contaminant?	Rare contact	It happens sometimes, but on average less than once per scenario
What kind of (skin) contact with the contaminant occurs?	Light contact	
What type of product is handled?	Liquid	The product handles is a liquid
Are significant amounts of aerosols or splashes generated in the task?	No	Task does not lead to substantial interaction between product and air, nor to dropping of product on a hard surface *Scroll up or down to see the remainder*
What is the level of automation of the task done by the worker?	Manual task	The task is largely done manually with substantial interaction between worker and package, contaminated installation or
What is the use rate of the product (if relevant)?	1	**Give "1"if this is not a relevant parameter, e.g. if no use rate can be established.**


Percentile for the exposure rate distribution to be assessed
75.0%
percentile
median
percentile distribution
Resulting exposure rate hands
2.85
8.88
µL/min or mg/min
Resulting exposure rate body
no data
no data
µL/min or mg/min
What is the cumulative duration of the scenario during a shift?
1
minutes
median
percentile distribution
Exposure loading per shift hands
2.850
8.880
µL or mg
Exposure loading per shift body
no data
no data
µL or mg
Scroll down to see possible warning messages

Output values for TIER1

Resulting exposure rate hands (75%ile) : 8.88 mg/min = Derived from the excel calculator of DEO Unit1
Exposure loading per shift hands : 8.88 mg = Resulting exposure rate hands (75%ile) x Task duration (1min – worst case)
Actual dermal deposit : 8.88 mg = Exposure loading per shift hands x Clothing penetration (100%)
Actual dermal deposit of active substance : 2.04 mg = Exposure loading per shift hands x Active substance concentration (23%) x Clothing penetration (100%)
Dermal dose : 0.098 mg = Actual dermal deposit of active substance x Dermal penetration (4.8%)

Systemic dose : 0.0016 mg/kg bw/d = Dermal dose / Body weight

Output values for TIER2

Resulting exposure rate hands (75%ile) : 8.88 mg/min = Derived from the excel calculator of DEO Unit1
Exposure loading per shift hands : 8.88 mg = Resulting exposure rate hands (75%ile) x Task duration (1min – worst case)
Actual dermal deposit : 0.888 mg = Exposure loading per shift hands x Clothing penetration (10%)
Actual dermal deposit of active substance : 0.204 mg = Exposure loading per shift hands x Active substance concentration (23%)
Dermal dose : 0.0098 mg = Actual dermal deposit of active substance x Dermal penetration (4.8%)

Systemic dose : 0.00016 mg/kg bw/d = Dermal dose / Body weight

AEL: 0.015 mg/kg bw/d