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Exposure Scenario for CSR. An example of consumer exposure to Substances in Articles

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Exposure Scenario for CSR. An example of consumer exposure to Substances in Articles

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Acronyms

AC	Article category
Chesar	Chemical Safety Assessment and Reporting tool
CPR	Construction Products Regulation
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived no effect level
DU	Downstream User
ECHA	European Chemicals Agency
ERC	Environmental release category
ES	Exposure Scenario
IUCLID	International Uniform Chemical Information Database
OC	Operational Conditions
PC	Chemical product category
RCR	Risk characterisation ratio
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation
RMM	Risk management measure
SDS	Safety Data Sheet
SVOC	Semi Volatile Organic Compound
TRA	Targeted Risk Assessment
VOC	Volatile Organic Compound

1. Introduction

1.1 BACKGROUND INFORMATION

The exposure scenario[1] is one of the main innovations of the REACH Regulation. The exposure scenario describes how to use a chemical substance safely. Publishing examples is a good way to show how an exposure scenario looks in practice. Examples help industry and authorities to form a common understanding of the information that an exposure scenario should contain. For this purpose, ECHA, either on its own or by collaborating with industry sectors, has developed a series of examples of exposure scenarios[2] that cover industrial, professional and consumer use and an illustrative example of a chemical safety report (CSR)[3].

Annex I paragraph 0.3 of REACH states that "the chemical safety assessment shall consider the use of the substance on its own (including any major impurities and additives), in a mixture and in an article, as defined by the identified uses. The assessment shall consider all stages of the lifecycle of the substance resulting from the manufacture and identified uses". Therefore, if a substance fulfilling the criteria specified in Article 14(4)[4] becomes part of an article, the subsequent service life or lifecycle stage should be covered by an assessment and the conditions of safe use reported in the exposure scenario.

The case shown in this report involves a purely hypothetical substance used in an article that is installed or used in buildings.

Registrants often do not address or disregard the assessment of exposure to substances in articles in their registration dossiers. This deficiency has been reported in the "Evaluation under REACH - Progress Report 2013"[5]: "*Always think about whether your substance ends up in an article. If so, you need to assess the exposure during the service life and add the necessary exposure scenarios. Failing this, you need to at least explain why you do not think the exposure assessment of the service life is relevant or why the service life is not described. Report the evidence and/or justification in the CSR*".

The illustrative examples in this document give registrants support in addressing the exposure arising from the substances in articles.

1.2 AIM OF THIS DOCUMENT

The main objectives of this document are:

- To highlight the relevance of the article service life in the context of the chemical safety assessment
- To show how the assessment of article service life can be performed and how meaningful exposure scenarios can be generated from it.

1 REACH, Annex I, Section 0.7: "An exposure scenario is the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These sets of conditions contain a description of both the risk management measures and operational conditions which the manufacturer or importer has implemented or recommends to be implemented by downstream users"

2 http://echa.europa.eu/web/guest/support/practical-examples-of-exposure-scenarios

3 http://echa.europa.eu/web/guest/support/practical-examples-of-chemical-safety-reports

4 For substances manufactured or imported in quantities of 10 tonnes or more per year (Article 14(1)) and that are substances fulfilling the criteria for certain hazard classes or categories, or considered as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), the chemical safety assessment (CSA) shall include additional steps: a) an exposure assessment including the generation of exposure scenario and b) a risk characterisation for all identified hazards (Article 14.(4) of REACH)

5 http://echa.europa.eu/documents/10162/13628/evaluation_report_2013_en.pdf

- To illustrate and explain what type of considerations are needed within such an assessment.

The case in this document describes a procedure for assessing consumer exposure to a substance that is present in an article, and how to build an exposure scenario for the CSR once the exposure assessment and risk characterisation are complete. The example focuses on the exposure scenario intended for the CSR and does not include the development of the exposure scenario to be attached to the safety data sheet (SDS)[6].

The example concentrates on the risks arising from the toxicological properties of a substance in an article for consumer use. It does not cover the environmental exposure and the exposure of humans via the environment.

The example also helps to identify possible answers to the following questions:

- How should the conditions of use in an exposure scenario covering article service life be reported, while maintaining the completeness and reproducibility of the exposure assessment?
- To what extent do the currently available exposure estimation tools and models help a registrant to assess exposure to substances in articles?
- How can information on measured releases from article (e.g. generated under other legislation such as the Construction Product Regulation) help REACH registrants in the exposure assessment?

1.3 CONTENT OF THIS DOCUMENT

This document describes a tiered approach for consumer exposure assessment to substances in articles, which in this example is installed or used in buildings. The tiered approach starts with a screening estimation (Tier 1) which is designed to be conservative. If such an assessment demonstrates that exposure for all relevant exposure routes is below the thresholds established from toxicological studies then it can be concluded that there is "no concern" and the risks from the substance in the article are deemed to be controlled. Otherwise, the estimate has to be refined until the risk characterisation indicates that the risks identified are adequately controlled.

The example presented shows the application of the ECETOC TRA Consumer tool as a Tier 1 tool to assess dermal, oral and inhalation exposure and the application of ConsExpo and the RIVM emission tools as Tier II exposure assessment tools for inhalation exposure (see paragraph 3.5 for more details). The example illustrates the level of knowledge and expertise required to make sure that exposure estimation tools are correctly used. More detail on the estimation tools used in this example, and exposure estimation generally, can be found in ECHA's Guidance on information requirements and chemical safety assessment R. 15. – Consumer exposure estimation (v.2, 2010)[7]. Guidance R.15 explains the core concepts, input parameters, strengths and limitations of the different tools. An important aspect of this published example is a practical demonstration of how the inherent limitations within the models can be addressed and reflected in the exposure scenarios for the chemical safety report (CSR).

6 Example of Exposure Scenarios to be annexed to SDS (not including article service life) have been developed by ECHA, see http://echa.europa.eu/web/guest/support/practical-examples-of-exposure-scenarios

7 http://echa.europa.eu/documents/10162/13632/information_requirements_r15_en.pdf, currently under review process

This document contains:

A main part which describes:

- The setting for the example, including the substance properties and the use selected for exemplification (chapter 2).
- The process for the exposure assessment, including a workflow explaining the different steps needed for the assessment, the basic considerations that are needed before the assessment is undertaken, the collection of the conditions of use, and the Tier I and Tier II assessment (chapter 3).
- The reporting of the conditions of use and the outcome of the assessment in the exposure scenario format (chapter 4).
- Useful advice for registrants based on the example described in this document (chapter 5).

Appendix 1, which reports the exposure scenarios for the chemical safety report (REACH Annex 1, Section 9) generated with ECHA's Chemical Safety Assessment and Reporting tool, Chesar[8] (version 2.3).

8 https://chesar.echa.europa.eu/

2. Setting for the example

2.1 SUBSTANCE SELECTION

A hypothetical semi-volatile substance (hereafter called substance A) used in adhesives or binders to produce wooden panels or boards was selected in order to illustrate the gradual release to the air during article use.

2.1.1 Substance data

Table 1: substance data

Property name	IUCLID data
Substance name	Substance A
CAS number	xxx-xx-x
CLP-classification	Eye irritant 2
Physical Form	Liquid
Molecular Weight	120 g/mol
Vapour Pressure	17 Pa at 20 °C
Partition Coefficient (Log Kow)	1.3 at 20 °C
Water solubility	20 g/L at 20 °C
Long term systemic oral DNEL: general population	15 mg/kg bw/day
Long term systemic inhalation DNEL: general population	25 mg/m^3
Long term systemic DNEL dermal: general population	15 mg/kg bw/day

Substance A is an aromatic solvent and has relatively low volatility; however, the volatility of substance A is not insignificant compared to the vapour pressure bands defined, for example, by Tier I consumer tools[9] and some release to air from the article in which it ends up can be expected. The substance shows a relatively low systemic toxicity, which is reflected in the relatively high long-term systemic DNELs for the general population. Long term systemic DNELs have been derived from oral repeated dose toxicity tests via route-to-route extrapolation. The substance is classified as an eye irritant; adverse irritancy effects are controlled by the substance concentration in the mixture (i.e. the adhesive resin, see also paragraph 3.3), and no local effects are expected.

9 Tier I tool ECETOC TRA Consumer (see paragraph 3.4) sets a Vapour Pressure threshold of 10 Pa above which the substance is supposed to be completely released during use.

2.1.2 Technical function of the substance

Substance A is contained in a synthetic resin adhesive used in the production of particleboard wood panels; the resin binds together wood chips and particles in the fabrication of the panels. In the resins system, substance A accelerates the curing reaction, by increasing the cure speed and lowering the viscosity of the binder. It is not expected to react during the application and curing stage – and thus it will eventually evaporate from the article in use.

2.2 USE SELECTION

In the example, the presence of substance A in the resin used in the production of particleboard wood panels (sometimes known as chipboard) is considered in order to show the potential for inhalation exposure to a semi-volatile substance from an article used in a building or construction works.

Substance A ends up in the particleboard wood panel (e.g. used in construction as walls) during the manufacture of the article when the resin binder is applied and mixed together with the wood chips.

The figure below illustrates the particleboard production and its use in construction works.

Figure 1: Particleboard production and use in construction works

The example covers consumer exposure to substance A, which is present in particleboard wood panels used inside buildings, i.e. in buildings as walls; it specifically covers the "passive" exposure by residents after the panels have been installed

The example does not cover the following uses/activities:

- The installation of the panels, performed generally by professional workers (in rare cases also by consumers as a do-it-yourself activity); in such a scenario, the dermal exposure would become more relevant and this should be taken into account when building the exposure scenario and performing the exposure assessment.
- Post-processing of the panels, e.g. when removing paints (including sanding or using abrasive techniques on the surface before repainting). This activities might be performed either by professional workers or by consumers themselves; in such a case, the oral/inhalation exposure from the dust generated during the activity might become relevant.
- Waste stage, when an environmental exposure assessment for the substance in the panel should be taken into account.

The abovementioned activities should in principle be covered by other exposure scenarios or contributing scenarios.

The article category (AC) which describes the use here exemplified is AC11 (wood article) .[10]

2.3 STRENGTHS AND LIMITATIONS

The example illustrates a common case, where a volatile or semi-volatile substance ends up in a building article, which is characterized by large surface area. Releases to the air and subsequent inhalation exposure should be taken into account when performing the exposure assessment. Therefore, the example concentrates on inhalation exposure arising from the gradual releases of the substance into air from large surface areas.

The example does not cover the situation where dermal or oral exposure could become significant or predominant. Oral ingestion of house dust might be relevant, but it is not covered in the example, since the models are still under discussion (see also paragraph 3.2).

Another limitation lies with the toxicity profile of the substance used for this example. The example is probably not suitable for a more hazardous substance, where the available tier II models might also fail in determining safe use. However, in paragraph 3.5.3 a way forward is proposed for those situations where the available models are not capable of demonstrating safe use of a substance in a (building) article.

Moreover, this example does not illustrate the case where, while the substance ends up in an article, the exposure is deemed to be negligible (e.g. because the substance is totally bound into the matrix or is a monomer transformed completely into a polymer). In such case, the key point would be the justification that support the “non relevance” of exposure for consumers.

10 http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf, currently under revision process

3. Exposure assessment: an iterative process

3.1 WORKFLOW EXPLAINING THE ASSESSMENT STEPS

In the following table, the steps to assess the exposure to a substance in an article (in buildings) for consumers are summarised. The second column identifies the kind of actions needed from a registrant to perform an exposure assessment effectively. In the third column, a summary of the information relevant to this example is also reported.

For each step, relevant and more detailed information on the case can be retrieved in other parts of this document: the fourth column provides the reference to a specific paragraph in the document. Finally, in the last column remarks on the relevance of each step are given.

Table 2: Assessment workflow

Step	Registrant's actions to perform the exposure assessment	Information in the example	Reference in this document	Remarks
Step 1	Check possible uses of the registered substance in articles based on information from downstream users supply chain; define type of article(s) covered in the exposure scenario	The registered substance ends up in an adhesive resin used to produce particleboard wood panels used in building (walls)	Paragraph 2.2	This step is always needed when a substance becomes part of an article
Step 2	Describe the expected migration mechanism based on the substance properties, article matrix, article design and conditions of use	Release to air from the particleboard wood panel can be expected (semi volatile substance); the matrix itself and the substance's technical function do not prevent releases to air	Paragraph 3.2	This step is always needed when a substance becomes part of an article
Step 3	Describethe behavioural aspects of the exposed population related to the article: mouthing, skin contact, target population, duration and frequency	Mouthing can be excluded as well as skin contact through crawling; children are not specifically relevant as a target population (as it would be the case for flooring); duration and frequency: continuous	Paragraph 3.2	This step is always needed when a substance becomes part of an article
Step 4	Describe the quantitative characteristics of the article: concentration, amount in the room of use, dimension	Information on the concentration of the substance in the adhesive resin, amount of resin used in wooden panels, dimension of panels can be collected from DUs/literature; room characteristics are assumed from literature	Paragraph 3.3	This step is always needed when a substance becomes part of an article

Step	Registrant's actions to perform the exposure assessment	Information in the example	Reference in this document	Remarks
Step 5	Perform Tier I exposure assessment; check if the Tier I model assumptions are in line with the use covered; get other input parameters if not already available	No other parameter needed for ECETOC TRA Consumers; walls/ flooring assigned as subcategory; adequate risk control for the dermal route is demonstrated while the oral route is considered not relevant. Inhalation route needs a Tier II exposure assessment.	Paragraph 3.4	Exposure estimation can be replaced by robust justification on why exposure is considered negligible
Step 6	Perform Tier II exposure assessment if needed; choose the suitable tool; get other input parameters if not already available	In the example: RIVM emission tool selected for inhalation (suitable for emission to air from solid matrix); other input parameters (diffusion coefficient and mass transfer rate) estimated from literature (support from model documentation); uncertainty analysis with these coefficients to test robustness of the assessment performed; supportive assessment with ConsExpo estimation tool	Paragraph 3.5	Exposure estimation can be replaced by robust justification on why exposure is considered negligible
Step 7	Document outcome of the exposure assessment and the conditions of use in the exposure scenario	See previous steps	Chapter 4	This step is always needed when a substance becomes part of an article

3.2 CONSIDERATIONS FOR STARTING THE ASSESSMENT

A preliminary reflection on some of the exposure elements related to the combination of article and substance characteristics needs to be made. It includes:

1. Release mechanism related to substance properties, article matrix/design and use conditions.

2. Behavioural aspects of the exposed population related to the article type(s) covered by the assessment.

The first element is crucial to define namely the expected release pathways of the substance from the article. The example covers a semi volatile substance, which ends up in particleboard wood panels used in buildings (i.e. walls). The properties of the substance (i.e. a relatively low but not negligible volatility) and its technical function (an accelerator for curing without reaction of the substance itself) support the likelihood of releases to air during the service life. The large surface areas of the wood panels installed onsite could enhance releases to the indoor air to a certain extent. Therefore, the migration into air and subsequent inhalation exposure should be considered by the assessment.

Another potential mechanism of exposure to the substance from the article is through its adsorption onto house dust; the re-deposited dust can then be ingested through hand to mouth contact. This route of potential exposure is not covered in the current example as discussions are still ongoing (e.g. taking place at

OECD level) on how to produce relevant information for the concentration of a specific substance in house dust related to a single article.

The second element relates to the foreseeable behaviour of a consumer in relation to the article type covered by the assessment. It includes the potential route of exposure, target population and duration/ frequency of the exposure. The article type covered by the assessment triggers the following considerations:

- Direct oral exposure can be excluded due to the typical application of the panels (walls).

- Dermal exposure, while still possible, is expected to be not significant for use in construction as walls. A different situation would be expected if the substance was used for wooden flooring (e.g. due to the crawling behaviour of an infant) or for do-it-yourself scenarios where intensive hand contact with the material is to be expected.

- The major route of exposure is inhalation; a particular scenario for child exposure is not needed in this case. This is in line with assumptions made by ECETOC TRA Tier I tool (see paragraph 3.4). Frequency and duration of exposure are related to a residential setting in a house; therefore, continuous exposure (24 hours per day, every day) can be assumed as a reasonable worst case scenario.

3.3 MAIN CONDITIONS OF USE RELATED TO THE ARTICLE

To determine the quantatitive exposure to substance A from wooden wall panels, the main information needs are:

- Mixture (resin adhesive) related information (concentration of the substance in the resin) is usually available at the formulator level.

Formulators reported that the concentration of substance A ranges from 1 % to 2 % in resins used in wooden panel applications. The maximum value (2%) has been taken as the input parameter for assessment purposes in this example.

- Information on the use of the mixture (binder containing substance A) for producing the article (e.g. amount used per kg of particleboard wood panel) is usually available at end-user level (the producer of the article).

In the typical application of wooden panels, the amount of resin containing substance A applied in the manufacture of the panel is up to 4% by weight. The maximum value has been taken for the assessment. This results in a concentration of substance A in the finished article (particleboard panel) of 0.08%.

- Measures that limit the consumers' exposure

Panels are stored unpacked at least one month before distribution and using them as a building construction material. This allows the matrix (particleboard, resin, additives) to properly interact and stabilise and also it allows the most volatile substances evaporate during the storage.

- Dimension of the panels: surfaces from which releases occur, thickness, etc.

The thickness of the wooden panel considered in this example is about 2 cm. The surfaces where the emission of substance A could occur are summarised as follows: 1) Dimensions for one particleboard wooden wall panel of 2.5 m by 3 m, i.e. 7.5 m2; 2) Total surface area (four walls): 30 m2. This results in a total amount of material (wooden panels) of 600 kg, assuming a product density of 1 g/cm3.

- Room characteristics such as ventilation rates and room size which are generally derived from literature (RIVM factsheets).[11]

The exposure scenario will show the potential release into a room of 20 m3 where the walls are made from particleboard panels containing substance A. The standard (low) ventilation rate for this type of residential room is set to 0.6 air exchange per hour.

3.4 TIER I ASSESSMENT

From the assumptions above, it follows that about 480 g of the substance are present in the walls of a default standard room. The challenge for the exposure modelling is to determine the release rate into the indoor air. Depending on the applied model and its degree of sophistication, the estimate can be more or less conservative.

The assessment is performed by a Tier I exposure tool, ECETOC TRA consumer version 3.1[12] . The model provides the equations for the inhalation, dermal and oral routes of exposure. The equations are similar to those given in ECHA's guidance, except for the inhalation route. The equation for inhalation is slightly adapted in ECETOC TRA, reducing the estimated emission by a default factor to account for the limited volatility of substances with a vapour pressure lower than 10 Pa. For the ventilation rate in standard rooms, another default factor was introduced. Furthermore, account is taken for limiting the air concentration to the saturated vapour concentration (upper limit). The air concentration calculated by TRA corresponds to the concentration over the time of the exposure; it is not averaged over the day of the exposure or over the year. This concentration will be compared to the long term DNEL following the provisions of ECHA's R15 Guidance.

The main step is to link the use to be covered by the assessment to an article category (AC) and sub category. The case of particleboard wood panels are well described by AC 11 (wood article), subcategory "Walls and flooring (also applicable to non-wood materials)".

For this subcategory, oral exposure is not considered to be relevant, dermal exposure is limited to the palm of one hand and the target population is adults. This is in line with what has been described in paragraph 3.2 and therefore the assumptions made by the ECETOC TRA model for the assessment can be considered acceptable for the use exemplified here.

The input parameters are those derived in paragraph 3.3 (concentration of the substance in the finished article and amount of article from which releases to air could occur). Other parameters such as exposure time, skin surface, room size and ventilation are provided as default values by the tool and are in line with those expressed in paragraph 3.3. The only relevant substance properties needed by the tool are the vapour pressure and the molecular weight (see Table 1). Table 3 below summarises the input parameters for the assessment.

11 General Factsheet - Limiting conditions and reliability, ventilation, room size, body surface area Updated version for ConsExpo 4, RIVM report 320104002/2006

12 http://www.ecetoc.org/tra

Table 3: Input parameters for ECETOC TRA 3.1 consumers

Input parameter	Value	Source	Route of exposure
Weight fraction	0.0008 (0.08%)	Paragraph 3.3	Dermal/inhalation
Amount of product (article)	600 kg	Paragraph 3.3	Inhalation
Frequency	1 per day	Default TRA	Dermal/inhalation
Exposure time	8 hours*	Default TRA	Inhalation
Room size	20 m3	Default TRA	Inhalation
Ventilation	0,6 air exchange / hour	Default TRA	Inhalation
Skin surface exposed	1 hand palm (428 cm2)	Default TRA	Dermal
Thickness layer	0.001 cm**	Default TRA	Dermal
Dermal transfer factor	1	Default TRA	Dermal

* TRA calculates the air concentration over the duration of exposure. This concentration depends on the amount, the room volume, the ventilation rate and the duration of exposure. A longer exposure duration means a greater number of air exchanges in the room, and therefore a lower concentration of substance A in the air. The TRA assumption on duration of exposure (set by default to 8 hours instead of 24 hours) results therefore in a more conservative estimate of the air concentration in the room.

** As the TRA model is based on an instantaneous release, it includes a default setting on the thickness of the product layer from which the release to the surface and the subsequent loading of skin at the contact area takes place (assuming that the deeper product layers do not take part in this). For liquid mixtures the default thickness is 0.01, for solid material it is 0.001 cm.

Table 4 summarises the outcome of the Tier 1 exposure assessment.

Table 4: Outcome of the ECETOC TRA 3.1 consumers Tier I assessment

Route of exposure	Exposure concentration / dose	DNELs Long term	Risk Characterisation Ratio (RCR)
Inhalation	823.4 mg/m3	25 mg/m3	33
Dermal	0.006 mg/kg/d	15 mg/kg/d	< 0.001
Oral	Not relevant	15 mg/kg/d	0

The risk from dermal and oral exposure is adequately controlled. On the contrary, the risk is inadequately controlled for the inhalation route and a refinement of the exposure assessment is therefore necessary.

3.5 TIER II ASSESSMENT

3.5.1 Main assessment

The most appropriate tool to refine the inhalation exposure estimation is the RIVM emission tool .[13] Specifically developed to estimate the inhalation exposure for the release of chemicals from building materials, the model takes into account the diffusion of a substance in a solid matrix (or material), the mass transfer from the material into air and the removal of the substance from residential air by natural ventilation. The tool simulates a time profile for the air concentration and mean air concentrations in a selected range arising from emission. The model assumes a homogenous matrix from which the emission to air occurs.

For the calculation of the risk characterisation ratio (RCR) one exposure value is compared with the long-term DNEL. As said before, the model simulates a time profile for the indoor air concentration over a certain period (e.g. one year for substances which are gradually released over time). In this example, the exposure concentration during the first day when a consumer can be exposed (i.e. one month after the panel's production due to the storage period, see paragraph 3.3) has been taken forward to the risk characterisation. This is in line with the provisions in the current ECHA Guidance R15 on "Consumer exposure estimation" and R8 on the "Characterisation of dose [concentration]-response for human health". This is also in line with the provision of chamber tests[14] performed under the Construction Products Regulation (see paragraph 3.5.3 for more details) where the measured air concentration in the chamber (which simulates an indoor air concentration) after 28 days is compared to the chronic threshold set by each Member State[15] within the Construction Products Regulation framework.

Some of the input parameters that are needed to run the exposure assessment using the RIVM tools are related to the article (thickness of panels, surface from which exposure could occur, concentration of substance in panels) and the room characteristics (volume and ventilation). These parameters are reported in paragraph 3.3 above.

The RIVM emission tool also requires model specific inputs for the diffusion and partition coefficients of the substance-material combination. If such data are not available, the parameters can be estimated using equations and advice given in the supporting document included in the downloadable package with the RIVM tool: "Emission of chemical substances from solid matrices. A method for consumer exposure assessment" - Report 320104011/2010 J.E. Delmaar, 2010. The analysis below illustrates how this estimation can be performed for the example case.

Crucial parameters to run the RIVM emission model include the diffusion coefficient D of substance A in the article (particleboard panel), the partition coefficient K of substance A between material (wood) and air, and the mass transfer rate hm.

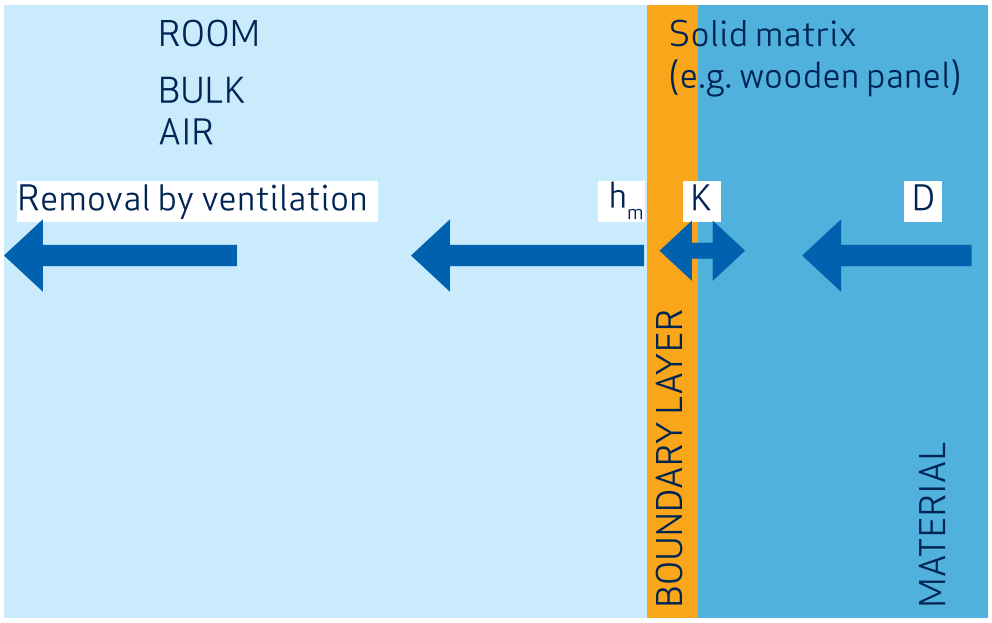
The figure below visualises processes and related coefficients driving releases to air of a substance from a solid matrix.

13 http://www.rivm.nl/en/Documents_and_publications/Scientific/Models/Download_page_for_ConsExpo_software

14 ISO 16000 Series (-3, -6, -9, -10, -11)

15 For example, provisions for chamber tests in Germany are set by "Committee for Health-related Evaluation of Building Products" and reported in the document "Health-related Evaluation Procedure for Volatile Organic Compounds Emissions (VOC and SVOC) from Building Products", see http://www.umweltbundesamt.de/sites/default/files/medien/355/dokumente/agbb_evaluation_scheme_2012_0.pdf

Figure 2: Transport processes and coefficients – RIVM emission model



D, the diffusion coefficient, describes the diffusion of a substance within a material (e.g. wood). The diffusion is assumed to be homogeneous and independent of the concentration of the substance in the material and can thus be described by a constant. This constant is expressed in m^2/s.

K, the partitioning coefficient, represents the tendency of the substance to distribute between the material and air in the vicinity of the separation layer (boundary layer). It is dimensionless. It is the analogue of the partition coefficient used for environment to describe the tendency of a substance to distribute between different phases (water/solid, water/air, etc.).

hm, the mass transfer coefficient, describes the transport velocity of the substance from the material surface to the bulk indoor air; it is in fact expressed as a velocity in m/s.

The mechanism that the model assumes for the substance removal from the room is the ventilation expressed in number of exchange per hour.

In the description of the emission model (Delmaar, 2010), several data and estimation methods for D, K and h_m are discussed. Bodalal et al. (2000) and Cox et al. (2001) (referenced in Delmaar, 2010) suggest an empirical method to estimate the diffusion coefficient:

$$D = \frac{A}{m_w{}^n}$$

In which m_w is the molecular weight in g/mol, and A and n are empirical parameters that are specific for a product/substance class. The diffusion coefficient D is in m^2/s.

For aromatic substances in plywood, which is the best comparable to this particular case (substance family and material), values of $A = 1.4 \times 10^7$ and $n = 8.6$ are suggested by Guo, (2002a;b as cited in Delmaar, 2010). With the molecular weight of 120 g/mol, this method estimates the diffusion coefficient for substance A to be 1.8×10^{-11} m^2/s.

For the material/air partition coefficient of substance A, a method proposed by Guo (2002a;b as cited in Delmaar, 2010) is used. This method is appropriate for VOCs (Volatile Organic Compounds) emitted from building materials:

$\ln K = 8.76 - 0.858 \ln P$

In which case, P, the substance vapour pressure in mmHg, is 0.13 for substance A. This yields an estimate of the material/air partition coefficient of 3.7×10^4.

For the mass transfer rate, typical values in indoor conditions vary between 0.0005 and 0.005 m/s (Delmaar, 2010). As a conservative estimate, the upper bound of this range is taken, i.e. 0.005 m/s.

In the table below, the input parameter to the RIVM emission tool model are summarised.

Table 5: Input parameters for RIVM Emission tool

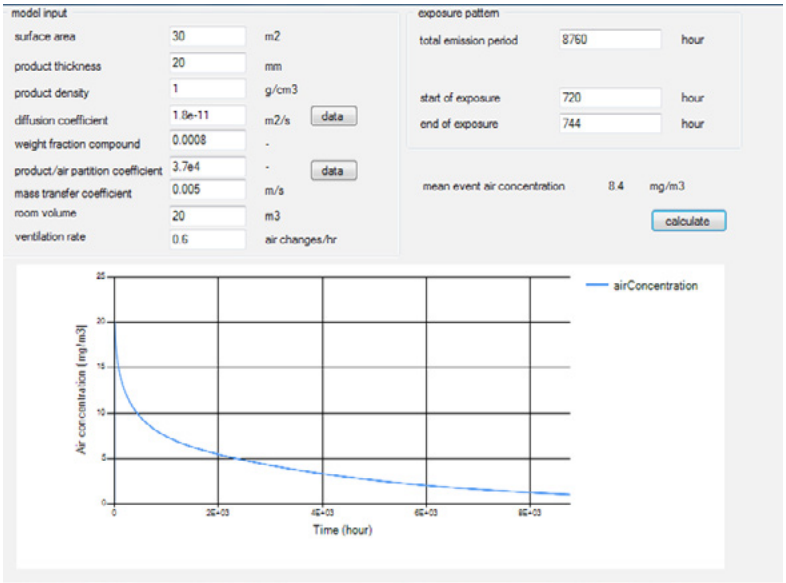
Input parameter	Value	Source
Weight fraction	0.0008 (0.08%)	Paragraph 3.3
Release area	30 m^2	Paragraph 3.3
Thickness of panel	2 cm	Paragraph 3.3
Room size	20 m^3	Paragraph 3.3
Ventilation	0,6 exchange / hour	Paragraph 3.3
Diffusion coefficient	$1,8*10^{-11}$ m^2/s	Estimation (see above)
Material/air partition coefficient	$3.7*10^4$	Estimation (see above)
Mass transfer rate	0.005 m/s	Estimation (see above)
Time when exposure is estimated	31st day after the panel 's production	See above

The air concentration to be taken as the exposure reference for the risk characterisation is 8.4 mg/m^3. It represents the concentration in a room during the first day when consumer exposure could occur, i.e. one month after the panel's production (see paragraph 3.3).

The figure below shows the profile of the indoor air concentration over the year, together with the input parameters and the reference air concentration calculated after one month from the article's (particleboard's) production. The emission profile shows a higher initial air concentration, which is around 20 mg/m^3, with a rapid decline over the year.

The air concentration is below the long-term DNEL for the general population (8.4 mg/m3 against a DNEL of 25 mg/m3). Therefore, the Tier II exposure assessment demonstrates that the risk is adequately controlled in relation to the inhalation route.

Figure 3: Input parameter and air concentration during exposure – RIVM emission tool



To increase the robustness of the assessment, an uncertainty analysis should be carried out in particularly when: a) the risk characterisation ratio is close to 1; in the example the risk characterisation ratio is equal to 0.34 and this is considered to be significant since it has been calculated by means of a Tier II assessment tool, which is much less conservative than the Tier I tool; and b) the range of variability in the exposure estimation parameters is high (as it is in this case, see text below); and c) no worst case assumption has been taken for the estimation of the abovementioned parameters.

The uncertainty analysis focuses on the RIVM model-specific parameters, which show a potential high variability (see table 6). Other inputs to the tool (e.g. concentration, room ventilation, etc.) do not show such high variability and are therefore excluded from the analysis. As discussed in Delmaar (2010), the method to estimate K predicted the correct values in a range within two orders of magnitude around the estimated value selected. Taking this as a confidence interval for K, the upper and lower values of this interval would be 3.7×10^3 and 3.7×10^5 respectively. For the diffusion coefficient, typical values for VOCs in building materials found in a literature survey (Delmaar, 2010) lie in a range of 10^{-13} to 10^{-10} m^2/s.

To assess the uncertainty ranges in the exposure estimate given above, reasonable upper and lower bounds of the estimated parameter values are accounted for by combining the higher boundaries and the lower boundaries into separate exposure estimates. These then provide an estimate of the uncertainty in the assessment (Table 6).

Table 6: Parameter ranges for diffusion coefficient (D), material-air partition coefficient (K) and the mass transfer rate (h_m).

Parameter	Lower bound	Upper bound	Unit
D	10^{-13}	10^{-10}	m^2/s
K	3.7×10^5	3.7×10^3	
h_m	0.0005	0.005	m/s

Using these values, air concentrations for substance A range from 0.79 to 17 mg/m^3 one month after the article's production. The upper range (17 mg/m^3) is still acceptable, since it is lower than the long term DNEL (25 mg/m^3).

3.5.2 Supportive assessment

Another assessment using a limited number of measured data in a room where inhalation exposure could arise or other suitable exposure estimation tools is useful in certain cases to better support the exposure estimation used for for the chemical safety assessment, for example, when some degree of uncertainty in the exposure estimation remains. In the current example, the uncertainty analysis documented above can be considered sufficient to explain the uncertainty related to the exposure estimation; therefore, a supportive assessment in this case would not be necessary; however, a supportive assessment has been developed anyway for illustration purposes.

In this context, ConsExpo 4.1 tool[16] provides a higher tier model with which to estimate indoor air exposure. The evaporation model can be considered to be the most appropriate one within the ConsExpo toolkit, since it determines releases based on product-substance data, considering the diffusion processes and describing higher initial releases, which gradually decrease. However, it should be noted that the ConsExpo 4.1 evaporation model describes the evaporation of substances from liquids (mass transfer rate models) and therefore may not be suitable to properly describe releases from solid materials, as in this example; this is the reason why it was not considered as the main assessment tool in the sections above.

In the table below, the input parameters needed to perform the exposure assessment are reported. Most of them are already discussed above (e.g. paragraph 3.3). The only model specific parameter is the mass transfer rate. Two options are possible to derive the mass transfer rate for the ConsExpo evaporation model, the Langmuir and the Thibodeaux methods. The latter has been selected in this case since it estimates a lower release (as it will be expected from a solid matrix) than the Langmuir method, which would be an unrealistic worst case for the example.

Table 7: Input parameters for ConsExpo 4.1 evaporation model

Input parameter	Value	Source
Weight fraction	0.0008	Paragraph 3.3
Release area	30 m^2	Paragraph 3.3
Amount of product/article	600 kg	Paragraph 3.3
Room size	20 m3	Paragraph 3.3
Ventilation	0,6 exchange / hour	Paragraph 3.3
Application duration	1 year	Paragraph 3.2
Mass transfer rate	0.266 m/min	Estimation (Thibodeaux)
Molecular weight matrix	3000 g/mol	Consexpo default for complex mixtures (glues, paints)

16 http://www.rivm.nl/en/Documents_and_publications/Scientific/Models/Download_page_for_ConsExpo_software

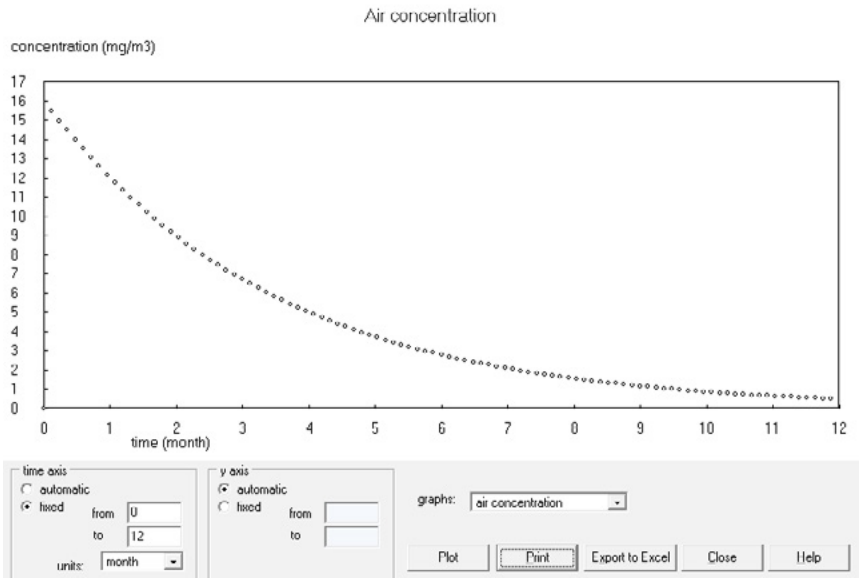
Input parameter	Value	Source
Time when exposure is estimated	31st day after the panel production	See paragraph 3.5.1

The profile of the air concentration over the year determined by the ConsExpo 4.1 evaporation model is reported in the figure below.

The air concentration during the first day of consumer exposure (one month after the panel's production) is about 12 mg/m^3. This value is higher than the one calculated by the RIVM emission tool. However, the value is still lower than the DNEL long-term inhalation for the general population, therefore it can be used to support the main assessment made by the RIVM emission tool.

To increase the robustness of the supportive assessment, a similar uncertainty analysis was performed using the mass transfer rate based on the Langmuir method (3.59 x 10^3 m/min), which resulted in the same outcome. This indicates that for the example the mass transfer rate (a substance specific parameter) is an insensitive parameter.

Figure 4: Exposure profile. ConsExpo 4.1 evaporation model



3.5.3 Other assessment methods

An alternative way of performing the assessment is to make **use of measured data**, which can be used to better support the exposure estimation models or to replace them as the assessment method. This may be required in particular if the tools are not able, due to their conservative nature, to demonstrate the adequate control of risk for the substance.

Measurements[17] can be generated ad hoc by the registrant or might be generated within other legislation frameworks, i.e. product safety legislation. The latter could be very interesting for an assessor under REACH since they may be already available for a representative range of conservative scenarios. In this

17 Measurements can refer directly to exposure concentration resulting from a use of an article or to a parameter (i.e. migration rate from an article) needed for assessing exposure.

context, the Construction Products Regulation (CPR)[18] can be a relevant source of information to support the assessment of articles used as building materials under the REACH Regulation; for example, under this framework, some Member States (e.g. Germany) require the execution of a "chamber test"[19] which simulates the indoor concentration arising from the releases of a selected substance from a construction products .[20]

18 http://ec.europa.eu/enterprise/sectors/construction/legislation/index_en.htm

19 Chamber tests are designed to simulate releases to the indoor air from a construction product (e.g. flooring products, wooden panels) and the resulting air concentration. The latter, can be seen as a reliable estimate of the indoor air concentration of the selected substance, since the test simulates the typical application (e.g. concentration of the substance in the product or article), room size and ventilation. Measurements are taken after three, 28, 60 and 90 days and give a reliable estimate of the indoor air concentrations over time. Data needed for the approval of a construction product (including the outcome of chamber tests) are not publically available. Nevertheless, they can be requested by a REACH registrant to a construction product manufacturer or an article producer in the context of the supply chain communication.

20 Please note that Germany at present does not require the execution of chamber tests for all kinds of construction products, but only for selected ones. More information can be found on https://www.dibt.de/en/Departments/Data/Aktuelles_Ref_II_4_12.pdf; https://www.dibt.de/en/Departments/Section_II4.html#details

4. Exposure scenario

The exposure assessment includes the following elements:

- 1. Title of the exposure scenario presented, including a short description and the use descriptors relevant for that use.
- 2. Conditions of use driving the exposure estimation.
- 3. Exposure estimation and risk characterisation covering all routes/type of effects. It should also be specified what is the main assessment for each route of exposure and, if it is the case, report the outcome of other supportive assessment.

1. Title of the exposure scenario presented

In the present example, the exposure scenario covers the "presence of the substance in wooden wall building material (particleboard)". The use descriptor relevant to be reported is AC 11 ("wood articles").

2. Conditions of use driving exposure estimations

In the exposure scenario, the conditions of use driving the exposure estimation (for human health) are reported.

The main conditions of use are (see paragraph 3.3):

- Concentration of the substance in the final product (particleboard wood panel), with the explanation on how this value has been estimated (concentration of substance A in the resin binder, amount/weight fraction of binder used for panel production)
- Panel characteristics such as the surface area from which the release of substance A will occur, the thickness or weight of the panel.
- Storage time before the panel is installed in the building.
- Room size and ventilation rate to estimate the air concentration.
- Duration and frequency assumed for exposure estimation.

Other important input parameters needed for the estimation of the air concentration (see paragraph 3.5), such as model specific parameters like diffusion coefficient of a substance in the matrix, the partition coefficient K of a substance between material and air, and the mass transfer rate are not regarded as conditions of use, since they depend on the material (wood) or substance properties. Therefore, they are not reported in the exposure scenario format. However, these parameters play a crucial role in the exposure estimation so they should be reported in the exposure part of the CSR to ensure transparency in the assumptions made during the exposure assessment.

3. Exposure estimation

The exposure assessment part contains:

- Exposure estimation and risk characterisation ratio for each relevant route.
- Identification of the tools used for the exposure estimation which are:
    - ECETOC TRA 3.1 for dermal/oral exposure.
    - RIVM emission tool for inhalation exposure. This model has been preferred over ConsExpo 4.1 because it is specifically designed to estimate releases of substances from building materials. ConsExpo outputs are anyway mentioned as supportive assessment, since they also show the safe use of the substance under the assumed conditions of use.
- Further explanations related to Tier II assessment, include:
    - A list of diffusion coefficients for inhalation exposure and how they have been derived, as well as an outcome of the uncertainty analysis.
    - The kind of exposure value that has been used for risk characterisation and the rationale behind it.

It should also be emphasised that:

- The exposure scenario in this report covers the use of substance A in an application, which is a specific article (wooden panels, AC11). It does not cover other possible uses of substance A in different articles. These uses should be covered by their own exposure scenarios. As mentioned in paragraph 2.2 the exposure scenario covers the "passive" consumer exposure to substance A in the wooden panels used for wall construction; do-it-yourself activities by consumers (e.g. the installation of wooden panels or further processing of the panels, for instance to remove paints) are not covered by the exposure scenario exemplified in this document.
- Actors in the supply chain may have an impact in limiting consumer exposure; for example, formulators may produce a mixture for use in construction works with a combination of ingredients which reduce releases of the most dangerous substances in it; or, producers of building articles may apply mixture to produce article in a way that most volatile substances in products are lost during application (e.g. high temperatures application). However, it should be highlighted that the current example covers the article lifecycle stage of substance A only, largely disregarding the upstream lifecycle stages and their potential impact on consumer exposure.

The exposure scenario related to the present example has been generated with ECHA's Chemical Assessment and Reporting Tool, Chesar (version 2.3). All the elements mentioned above are reported in the Chesar format (see appendix 1).

5. Advice for registrants

Advice to registrants following from the development of the example are summarised below:

- Registrants should always consider whether their substance ends up in an article and, if this is the case, cover the use of the article in one or more exposure scenarios with the corresponding exposure estimates.

- The registrant should have a good knowledge of how the substance is used, this relies upon information from downstream users. Important information on possible uses in articles can be collected from formulators, who should know if their mixtures which contain the registered substance are used in the production of an article. Moreover, the improved use maps[21] prepared by downstream sector associations may constitute in the future an important source of information for this purpose.

- Conditions of use needed to assess the exposure to the substance in an article can be collected either through the supply chain communication (formulator of mixtures, article producer) or from literature[22] (e.g. room characteristics). Sector organisations (i.e. article or building product producers) might consider collecting conditions of use related to the articles they produce in a consistent and structured way and making them available to the registrant. This information can be reported in the SCED[23] (Specific Consumer Exposure Determinants) format, that is already available for several consumer products but not (yet) for articles. This will help many registrants in collecting the relevant input parameters for the assessment and limiting the need for ad hoc communication with downstream users to get such information.

- When the material and the article types in which the substance ends up has been defined, the registrant should identify the potential scale and targets of exposure, resulting from migration mechanisms and behavioural aspects of the article use. This preliminary analysis also helps to define the appropriateness of the exposure model and the tools selected for the assessment.

- When building the exposure scenario(s) covering the uses in articles, registrants should take into account the following elements:

    - The appropriate number of exposure scenarios or contributing scenarios depends mainly on the variety type of materials and articles in which the substance ends up, reflecting also the variety in conditions of uses.

    - The selection of the scenario(s) should consider, when appropriate, do-it- yourself activities by consumers and/or specific child scenario.

    - The name describes the scope of the contributing scenario (including, for example, the material and the type of articles covered).

- When selecting a tool for the exposure estimation the registrant should make sure that the assumptions and applicability domain for the selected tool is in line with the article type to be assessed[24]. For example:

    - Tier I tools such as ECETOC TRA consumer 3.1 makes assumptions on the target population

21 More information on use maps can be found in the action area 2 of the CSR/ES Roadmap website: http://echa.europa.eu/csr-es-roadmap

22 Main literature references are included in R15 ECHA guidance on "Consumer exposure assessment" currently under revision

23 http://www.ducc.eu/Activities.aspx

24 Information on the general boundaries of models is available in R15 ECHA guidance on "Consumer exposure assessment" (under revision in 2015). Specific model assumptions are available in the tool documentation.

and route of exposure covered by each article subcategory.

- Some Tier II tools are specifically designed to assess exposure from a solid matrix (article) while other tools are designed to be used for liquid mixtures.

- More advanced Tier II models require model specific input parameters that are often not directly available to a registrant; to overcome this problem the registrant may use the model documentation, which often contains equations to estimate such parameters from substance properties and material type. In this case is always desirable to perform an uncertainty analysis to increase the robustness of the exposure assessment.

- When a Tier II model fails to demonstrate safe use or when there is a need to support the modelled exposure estimation by further evidence, a registrant might use measured migration/release data (e.g. release to air). Such measurements might already be available since they are produced in the context of product/article safety legislation, for example, the Construction Products Regulation.

Appendix 1- Chesar CSR Chapter 9.

9. Exposure assessment (and related risk characterisation)

9.0. Introduction

9.0.1. Overview of uses and Exposure Scenarios

Only the use of substance A in a wooden article (particleboard) has been assessed in this example. Upstream uses such as the manufacture of substance A, the formulation of resin (binder) adhesives and the industrial application of resin binder in the fabrication of particleboard panels are not covered here. Also, other article types beyond wood particleboards are not covered in this example.

Tonnage information:

Assessed tonnage: 10000.0 tonnes/year based on:

- 10000.0 tonnes/year imported

The following table list all the exposure scenarios (ES) assessed in this CSR.

Table 1. Overview of exposure scenarios and contributing scenarios

Identifiers	Market Sector	Titles of exposure scenarios and the related contributing scenarios	Tonnage (tonnes per year)
ES1 - SL-C1		Service life (consumers) - Use in wooden articles with low releases (ERC 11a) - Presence of substance in wooden wall building material (particleboard) (AC 11)	10000.0
Manufacture: M-#, Formulation: F-#, Industrial end use at site: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial site): SL-IW-#, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#.)			

9.0.2. Introduction to the assessment

9.0.2.1. Environment

Scope and type of assessment

Not covered in the example.

9.0.2.2. Man via environment

Scope and type of assessment

Not covered in the example.

9.0.2.3. Workers

Not relevant

9.0.2.4. Consumers

Scope and type of assessment

The scope of exposure assessment and type of risk characterisation required for consumers are described in the following table based on the hazard conclusions.

Table 2. Type of risk characterisation required for consumers

Parameter	Type of effect	Type of risk characterisation	Hazard conclusion (see section 5.11)
Inhalation	Systemic, long-term	Quantitative	DNEL (Derived No Effect Level) = 25 mg/m^3
	Systemic, acute	Not needed	No hazard identified
	Local, long-term	Not needed	No hazard identified
	Local, acute	Not needed	No hazard identified
Dermal	Systemic, long-term	Quantitative	DNEL (Derived No Effect Level) = 15 mg/kg bw/day
	Systemic, acute	Not needed	No hazard identified
	Local, long-term	Not needed	No hazard identified
	Local, acute	Not needed	No hazard identified
Eye	Local	Qualitative	Low hazard (no threshold derived)
Oral	Systemic, long-term	Quantitative	DNEL (Derived No Effect Level) = 15 mg/kg bw/day

9.1. EXPOSURE SCENARIO 1: SERVICE LIFE (CONSUMERS) - USE IN WOODEN ARTICLES

Environment contributing scenario(s):	
Use in wooden article with low releases	ERC 11a
Consumer contributing scenario(s):	
Presence of substance in wooden wall building material (particleboard)	AC 11

Description of the activities and technical processes covered in the exposure scenario:

Substance A is used in synthetic resin (binder) adhesives applied in the fabrication of particleboard panels (wooden articles); it functions as curing agent and viscosity regulator.

Explanation on the approach taken for the ES

The consumer contributing scenario covers the use of particleboard (wooden) used in construction works (walls). It covers the "passive" exposure to substance A by consumers but not do-it yourself activities such the installation or further processing (e.g. removing paints) of the panels. Gradual evaporation of Substance A will occur, due to the combination of substance properties (vapour pressure not negligible), technical function (the substance does not react on use) and matrix characteristics (the matrix itself does not prevent releases of the substance). Dermal and oral exposures are expected to be low / not relevant in this case because skin contact to wooden panels (walls) is only occasional and the exposed body surface is very small; direct oral contact (mouthing behaviour) is no expected .

Conditions of use have been collected either from downstream users (DUs) (formulator of binder containing Substance A and particleboard (wooden) panel producers) or from published literature (e.g. room characteristics).

The exposure estimation has been first performed by a Tier I tool, the ECETOC TRA Consumer v. 3.1. Safe use for oral and dermal exposure can be demonstrated using the Tier I tool, while inhalation exposure needs to be refined.

The Tier II tool selected for the exposure estimation for inhalation is the RIVM emission model, specifically designed to estimate releases from solid matrix (such as wooden panels) and the consequent air concentration in a room where such releases occur. The air concentration carried forward to the risk characterisation is that after one month has elapsed from the panel's production, due to the minimum storage condition of 30 days before the panel's use in building construction application. Adequate control of risk for inhalation route can be demonstrated by the RIVM emission tool.

To better support the Tier II assessment, an uncertainty analysis has been performed on those model specific parameters defining the diffusion of the substance in the matrix and from the matrix to air. These parameters have been estimated using methods suggested in the RIVM emission model documentation for the type of material and substance properties, The outcome of such analysis is documented in the exposure scenario. Moreover, a supporting assessment made via evaporation model in Consexpo 4.1 is also provided.

Both the uncertainty analysis and supportive assessment confirm that the exposure estimation is below the systemic long term DNEL inhalation for the general population.

9.1.1. Environmental contributing scenario 1: Use in wooden article with low releases

Not covered in the example.

9.1.2. Consumer contributing scenario 1: Presence of substance in wooden wall building material (particleboard) (AC 11)

9.1.2.1. Conditions of use

Under the contributing scenario the condition of use driving the exposure estimation for wooden panels used as building material (for wall construction) are reported.

Product (article) characteristics	**Method**
Product/Article subcategory: Walls and flooring (also applicable to non-wood materials)	TRA Consumers 3.1
Concentration of substance in article: = 8E-4 g/g	TRA Consumers 3.1
Oral contact foreseen: No	TRA Consumers 3.1
Concentration of the substance in article: <= 8E-4 g/g *The concentration of the substance A in the resin (binder) adhesive that is used for particleboard (wooden) panels fabrication ranges from 1 to 2%. The maximum value (2%) has been taken as the input parameter for assessment purposes. In the typical application to wooden panels, the typical amount of binder applied in the manufacture of the panel is 4% by weight. Following from the parameters mentioned above, the concentration of the substance A in the finished particleboard (wood) panel is 0.0008 (0.08%), assuming a product density of 1 g/cm3.*	External Tool (RIVM emission tool)
Product thickness: = 2 cm *From particleboard (wood) panel producer*	External Tool (RIVM emission tool)
Product density: = 1 g/cm3	External Tool (RIVM emission tool)
Amount used, frequency and duration of use/exposure	
Exposure time: = 24 hr	External Tool (RIVM emission tool)
Frequency: <= 365 days per year	External Tool (RIVM emission tool)

Other conditions affecting consumers exposure	Method
Body parts potentially exposed: Inside hands / one hand / palm of hands	TRA Consumers 3.1
Dermal transfer factor: = 1	TRA Consumers 3.1
Release area: = 30 m2 *The surface where the emission of substance A could occur are summarised as follow: - Dimensions for one wooden wall panel of 2.5 m by 3 m, i.e. 7.5 m2 - Total surface area (4 walls): 30 m2*	TRA Consumers 3.1
Room where tasks take place: Generic room (Volume: 20 m3; ventilation rate: 0,6 exchange/h)	External Tool (RIVM emission tool)
Minimum storage time before installation: > 30 days *Panels are stored unpacked to let the substances A in the resin binder stabilise and volatilise.*	External Tool (RIVM emission tool)

9.1.2.2. Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 3. Exposure concentrations and risks for consumers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	8.4 mg/m^3 (External Tool (RIVM emission tool)) Additional data not used for RCR: 12 mg/m^3 (External Tool (Consexpo 4.1))	Paragraph 3.3
Dermal, systemic, long-term	0.006 mg/kg bw/day (TRA Consumers 3.1)	RCR < 0.01
Oral, systemic, long-term	0 mg/kg bw/day (TRA Consumers 3.1)	RCR < 0.01
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.34

Remarks on exposure data

External Tool (RIVM emission tool)

- Inhalation, systemic, long-term:

The air concentration taken for the exposure assessment is the one during the first day when a consumer can be exposed, i.e. one month after the panel's production (due to storage period of at least 1 month). The air concentration ranged from 20 mg/m^3 at the beginning of the application and decreases to values close to 0 after 5-6 months. Crucial parameters to run the RIVM emission model include the diffusion coefficient D of Substance A in the product (particleboard), the partition coefficient K of Substance A between material and air, and the mass transfer rate hm. Ideally, such data should be available (or measured) for the substance and the product of consideration. In practice, this will seldom be the case (or feasible). In the description of the emission model (Delmaar, 2010) several data and estimation methods for D, K and hm are discussed. Bodalal et al. (2000) and Cox et al. (2001) (referenced in Delmaar, 2010) suggest an empirical method to estimate the diffusion coefficient: $D=A/(mw)^n$ in which mw is the molecular weight in g/mol, A and n are empirical parameters that are specific for a product/substance class. The diffusion coefficient D is in m^2/s. For aromatics in particleboard, which is best comparable to this particular case, values of $A = 1.4*10^7$ and n = 8.6 are suggested by Guo, 2002 (as cited in Delmaar, 2010). With the molecular weight of 120 g/mol, this method estimates the diffusion coefficient for substance A to be $1.8*10^{-11}$ m^2/s. For the material/air partition coefficient of Substance A a method proposed by Guo (2002) (as cited in Delmaar, 2010) is used. This method is appropriate for VOCs emitted from building materials: ln K=8.76-0.858 lnP in which P is the substances vapour pressure in mmHg, 0.13 for Substance A. This yields an estimate of the material/air partition coefficient of $3.7*10^4$. For the mass transfer rate, typical values in indoor conditions vary between 0.0005 and 0.005 m/s (Delmaar, 2010). As a conservative estimate the upper bound of this range is taken, i.e. 0.005 m/s.

External Tool (Consexpo 4.1)

Remark on exposure estimation

- Inhalation, systemic, long-term:

The exposure value represents the air concentration after 1 month from the particleboard (wood) panel's production, due to the minimum storage before application in wall building construction. The model used, ConsExpo 4.1 evaporation model, describes evaporation of substances from liquids (mass transfer rate models) and therefore may not be suitable for this case. To compensate the expected lower release from articles than from liquids, the Thibodeaux model for mass transfer rate (equal to 0,266 m/min) was selected as this model assumes a slower release than the Langmuir model, which would be unrealistically worst case. In any case, the assumptions made for unknown or uncertain input parameters in the ConsExpo 4.1 evaporation model can be regarded as conservative. The amount used in the assessment (600 kg) corresponds to the weight of 4 panels of 7.5 m^2 each (30 m^2 in total), 2 cm of thickness and density of 1 g/cm^3.

Conditions of use leading to the exposure:

- Concentration of the substance in article: <= 8E-4 g/g
- Release area: = 30 m2
- Amount of product used per application: = 6E5 g/event
- Exposure time: = 24 hr
- Frequency: <= 365 days per year

- Room where tasks take place: Generic room (Volume: 20 m3; ventilation rate: 0,6 exchange/h)
- Duration of application: = 365 days
- Minimum storage time before installation: > 30 days

Conclusion on risk characterisation

Adverse eye irritancy effects are controlled by the substance concentration (< 10 %) in the mixture (binder resin) used in the wooden panel application, and no local effects are expected.

To increase robustness of the assessment, an estimate of the uncertainty should always accompany the exposure evaluation using generalized methods of parameter estimation. As discussed in Delmaar, (2010) the method to estimate K predicted the correct values in a range within 2 orders of magnitude around the estimated value selected. Taking this as a confidence interval for K, the upper and lower values of this interval would be 3.7×10^3 and 3.7×10^5 respectively. For the diffusion coefficient, typical values for VOCs in building materials found in a literature survey (Delmaar, 2010) lie in a range of 10^{-13} to 10^{-10} m^2/s.

To assess the uncertainty ranges in the exposure estimate given above, reasonable upper and lower bounds of the estimated parameter values are accounted for by combining the higher boundaries and the lower boundaries into separate exposure estimates. These then provide an estimate of the uncertainty in the assessment.

Using these values, air concentrations range from 0.79 to 17 mg/m^3 one month after the article production. The upper range (17 mg/m^3) is still acceptable, since it is lower than the long term DNEL (25 mg/m^3).

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