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Abstract

This document will instruct assessors performing chemical safety assessments for plastics additives on how to use the EuPC/EuMBC Use Map

Use Maps for Masterbaching, Compounding, and Converting Processes

By EuPC and EuMBC

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# Introduction

Within the context of the Exchange Network for Exposure Scenarios, an industry-ECHA partnership, the use map package was developed. The use maps package is meant to allow sector organisations to transmit, to registrants of substances that are used by the sector, information on how substances are typically used within the sector.

The plastics industry united in the Plastics Exposure Scenario Team (PEST), an initiative by the whole plastics value chain which started in 2009, developed Generic Exposure Scenarios (GES) for the plastics Industry. It is understood that such GES are precursors to the current Use Map of the use map package.

Other components of a use map package are: a Sector-specific Worker Exposure Description (SWED) and Specific Environmental Release Categories (SpERC); which provide information on human health exposure during production processes and environmental release during different uses, respectively.

The European Masterbatchers and Compounders (EuMBC) and the European Plastics Converters (EuPC) have set out to:

* Provide a General Use Description of processes occurring in the Plastics Masterbatching, Compounding, and Converting Industry.
* Harmonise the GES into a Use Map
* Advise registrants to use the OECD Emissions Scenario Document
* Advise registrants on how to perform their worker exposure assessment

It should be noted that all parameters included in the worker exposure guidance should enable the use of the ECETOC TRA. If an assessor wishes to go beyond this tier 1 tool, one could use the PESTOOL, utilise custom models based on migration modelling[[1]](#footnote-1) and/or mass transfer operations that exists within the plastics industry, and/or other modelling tools. For an example of the value of such custom modelling you can review annex I.

# General Use Description

## Transport and Feeding Steps in Plastisol Production, Plastics Masterbatching, Compounding, and Converting Processes

Within the plastics industry material can be fed into machinery from small or large containers. Frequently this is fed into either an extruder or a mixing unit. Substances in a mixing unit will afterwards be fed into an extruder. For graphical depictions please see Table 1.

Table 1 Graphical depiction of the different possible transport/feeding steps.

| Process Descriptors | Transport | Feeding |
| --- | --- | --- |
| PROC 9 |  |  |
| PROC 9 |  |  |
| PROC 8b |  |  |
| PROC 8b |  |  |

## Plastisol Production

In plastisol production fine PVC powder is mixed with a plasticiser and possibly with other additives. The plastisol is a mixture that when heated in subsequent converting operations becomes a soft PVC material.

After feeding a mixing unit either continuous mixing or batch mixing is performed at perhaps somewhat elevated temperatures, but not sufficiently high temperatures that would allow the PVC powder to melt as this would cause the formation of the soft PVC material.

The process is exclusively relevant for substances/additives that go into PVC and should be removed from the use map if this is not a relevant process for the additive.

| Process | Use Descriptor | Graphical Description |
| --- | --- | --- |
| Continuous mixing | PROC 4 |  |
| Batch mixing | PROC 5 |  |

## Masterbatching and/or Compounding

Formulation occurs either directly in the extruder or indirectly by first performing a mixing step in a mixing unit and then adding the mixture to an extruder. Within the extruder additives and polymer is heated to the polymer melt temperature and the additives are incorporated in the polymer matrix. When a company produce a product that contains a high concentration of additive for later dilution in a converting process it is said to be producing a masterbatch. When a company produces a product that contains an additive concentration meant to be the same as in the final article article it is said to be producing a compound.

Table 2 Graphical description of Masterbatching and/or Compounding

|  |  |  |  |
| --- | --- | --- | --- |
| Process Descriptors | PROC 4 and/or 5 | PROC 14 | PROC 14 |
| Direct mixing in extruder |  |  |  |
| Indirect via mixing unit |  |  |  |

## Converting Processes

In converting processes, masterbatches and compounds are fed into an extruder and one of the processes described in Table 3 occurs.

Table 3 Graphical Description of Converting Processes

| Converter Process | Use Descriptor | Graphical Description |
| --- | --- | --- |
| Injection Moulding | PROC 14 |  |
| Rotamoulding | PROC 14 |  |
| Blow Moulding | PROC 14 |  |
| (Co-)Extrusion | PROC 14 |  |
| Lamination | PROC 14 |  |
| Calendering | PROC 6 |  |
| Roll and/or Spread Coating | PROC 10 | //NO FIGURE AVAILABLE AT THIS TIME |
| Foaming | PROC 12 |  |
| Dip Coating | PROC 13 |  |

## Scrap Recycling

In Masterbatching, Compounding, and Converting operations there will be scraps. These scraps can originate from cut offs, rejected production batches, unsold material from discontinued products, etc. Such scrap can be reintroduced into the production process to produce new products. Sometimes this is done directly, other times an additional gridding step is introduced in order to obtain material that can be fed into the machinery.

| Process | Use Descriptor | Graphical Description |
| --- | --- | --- |
| Grinding | PROC 24 |  |

# General Use Map

Within the context of the Plastics Exposure Scenario Team (PEST) 17 Generic Exposure Scenarios (GES) were defined. These GES separated feeding from production steps and contained unnecessary differentiations (e.g. one GES for open processes with PROC 14 and one for semi-open processes with PROC 14). These PEST GES were condensed by EuPC and EuMBC to produce two uses covering the processes described in the PEST GES. This approach has a number of advantages:

* It allows registrants to accurately assign tonnages to the plastics industry, which is relevant for environmental assessments;
* Combining feeding and processing steps prevent double counting observed in environmental assessments; and
* Such condensation will result in shorter, easier to understand exposure scenarios facilitating compliance of masterbatchers, compounders and converters.

The end result of this work can be observed in Table 4.

Table 4 Use Map

| Life Cycle Stage | Use Name | Contributing Scenario | Use Descriptor |
| --- | --- | --- | --- |
| Formulation | Production of a Plastisol | Production of a Plastisol | ERC 2 |
| Handling of Small Containers Containing Additive | PROC 9 |
| Handling Large Containers Containing Additive | PROC 8b |
| Continuous Mixing Process | PROC 4 |
| Batch Mixing Process | PROC 5 |
| Laboratory/Quality Control Operations | PROC 15 |
| Formulation | Production of Masterbatches and/or Compounds | Production of Masterbatches and/or Compounds | ERC 3 |
| Handling of Small Containers Containing Additive | PROC 9 |
| Handling Large Containers Containing Additive | PROC 8b |
| Continuous Compounding Process | PROC 4 |
| Batch Compounding Process | PROC 5 |
| Extrusion, Pelletisation, and/or Granulation | PROC 14 |
| Scrap Recycling | PROC 24 |
| Laboratory/Quality Control Operations | PROC 15 |
| Industrial Use | Production of Plastic Articles | Production of Plastic Articles | ERC 5 |
| Handling of Small Containers Containing Masterbatches and/or Compounds | PROC 9 |
| Handling Large Containers Containing Masterbatches and/or Compounds | PROC 8b |
| Handling of Small Containers Containing Additive | PROC 9 |
| Handling Large Containers Containing Additive | PROC 8b |
| Use in a Closed and/or Semi-Open Converting Process (e.g. Extrusion, Injection) | PROC 14 |
| Use in an Open Converting Process (e.g. Calendering) | PROC 6 |
| Use in a Spraying Application | PROC 7 |
| Use in Roll and/or Spread Coating | PROC 10 |
| Use in a Foaming Production | PROC 12 |
| Use in Dip Coating | PROC 13 |
| Scrap Recycling | PROC 24 |
| Laboratory/Quality Control Operations | PROC 15 |

The Use Map has been converted to a Chesar input file. This file can be easily imported into ECHA’s Chesar tool by registrants (in the life cycle tree tab right click on Manuf.Imp and select Import Use Map).

# Environment Conditions of Use

The OECD has developed an Emission Scenario Document (ESD) for Plastics Additives. In this ESD the various processes are defined and for each additive type release fractions are specified for the various life cycle stages, which are substantiated by conditions of use. EuPC advises assessors to make use of this OECD ESD in order to complete the Environmental Assessment required in the Chemical Safety Report.

The ESD for plastic additives can be obtained from:

<http://www.oecd.org/chemicalsafety/risk-assessment/emissionscenariodocuments.htm>

# Worker Conditions of Use

EuPC/EuMBC have decided for practical reasons to not produce SWEDs in the standard format[[2]](#footnote-2), it has however developed a EuPC Worker Conditions of Use Tool, which can be found in annex to this guidance. The tool formalises in a structured way the guidance expressed below, which can also be used without the tool.

In order to assist assessors performing chemical safety assessments for plastics additives the following section contains some practical advice on which parameters are normally valid for the Masterbatching, Compounding and Converting processes described in the General Use Map.

It should be noted that some recommendation contained herein are generalisations with conservative assumptions, if a registrant has more specific information on the use of his additive he may choose to deviate from the recommendations contained herein (e.g. if the registrant produces a revolutionary new antioxidant for which far less is needed in the final article to achieve performance this may be incorporated in the assessment).

In addition, it must be noted that, although the parameters contained in this document enable assessors to input relevant/correct parameters for their assessment in normal exposure modelling tools, these tools do not take into account the most relevant risk reducing factor typical to plastics, namely the matrix encapsulation. Standard exposure modelling tools are unable to incorporate the often large sometimes enormous[[3]](#footnote-3) reduction in exposure when substances are incorporated in polymer matrixes.

## Guidance for Assessors

The guidance below will generally follow the input structure that is observed in the Chesar tool. In the Use Map Chesar input file certain parameters have been input already as these are not varying (e.g. general ventilation).

### Product (Article) characteristics

#### Percentage (w/w) of substance in mixture/article

The percentage of a substance entering the market should be known by the registrant. If this is not known 100% should be assumed.

For the production of plastics articles scenario maximum loading levels were obtained per additive type from EuMBC experts, which can be seen in Table 6.

Table 6 Maximum Loading Levels per additive type. Source: Industry Data

| Additive Type | Masterbatch | Compound / Direct use for article production |
| --- | --- | --- |
| Antioxidants | 30% | 0.80% |
| Antistatic Agent | 25% | 1.50% |
| Blowing agent | 70% | 4% |
| Colourants (dyes) | 15% | 6% |
| Colourants (pigments) | 80% | 5% |
| Coupling Agents | 28% | 2% |
| Curing Agents | 15% | 3% |
| Fillers | 80% | 50% |
| Flame Retardants (inorganic) | 75% | 60% |
| Flame Retardants (Organic) | 60% | 23% |
| Heat Stabilisers | 30% | 3% |
| Nucleating Agents | 25% | 0.30% |
| Plasticisers | 75% | 50% |
| Polymeric Impact Modifiers | 15% | 3% |
| Slip Promotors (inorganic) | 25% | 0.50% |
| Slip Promotors (organic) | 25% | 0.50% |
| UV and other weather stabilisers | 50% | 0.50% |
| Viscosity aids | 30% | 0.50% |

If a registrant knows that its additive is mainly used to produce compounds it may use the percentages in the compounds column. If the registrant does not know if mainly masterbatches or compounds are produced containing with the additive he should select the percentage specified under masterbatch.

In any case the final uses of the Production of Plastic Articles scenario should follow the concentrations for compounds as during these steps the article is created an the maximum additive concentration should not be expected to exceed the level in compounds. The same column should be used for additive used directly in the converting of an article as is for example often the case for plasticisers.

| Use Name | Contributing Scenario | Concentration |
| --- | --- | --- |
| Production of a Plastisol | Handling of Small Containers Containing Additive | Registrants Knowledge or 100% |
| Handling Large Containers Containing Additive | Registrants Knowledge or 100% |
| Continuous Mixing Process | Masterbatch / (Compound) |
| Batch Mixing Process | Masterbatch / (Compound) |
| Laboratory/Quality Control Operations | Registrants Knowledge or 100% |
| Production of Masterbatches and/or Compounds | Handling of Small Containers Containing Additive | Registrants Knowledge or 100% |
| Handling Large Containers Containing Additive | Registrants Knowledge or 100% |
| Continuous Compounding Process | Masterbatch / (Compound) |
| Batch Compounding Process | Masterbatch / (Compound) |
| Extrusion, Pelletisation, and/or Granulation. | Masterbatch / (Compound) |
| Scrap Recycling | Masterbatch / (Compound) |
| Laboratory/Quality Control Operations | Registrants Knowledge or 100% |
| Production of Plastic Articles | Handling of Small Containers Containing Masterbatches and/or Compounds | Masterbatch / (Compound) |
| Handling Large Containers Containing Masterbatches and/or Compounds | Masterbatch / (Compound) |
| Handling of Small Containers Containing Additive | Registrants Knowledge or 100% |
| Handling Large Containers Containing Additive | Registrants Knowledge or 100% |
| Use in a Closed and/or Semi-Open Converting Process (e.g. Extrusion, Injection) | Compound |
| Use in an Open Converting Process (e.g. Calendering) | Compound |
| Use in a Spraying Application | Compound |
| Use in Roll and/or Spread Coating | Compound |
| Use in a Foaming Production | Compound |
| Use in Dip Coating | Compound |
| Scrap Recycling | Compound |
| Laboratory/Quality Control Operations | Registrants Knowledge or 100% |

#### Physical form of the used product

The following forms are to be used. Whenever “Registrants Knowledge” is specified it is meant that the registrant inputs the parameter that is relevant to how it places its product on the market.

| Use Name | Contributing Scenario | Form |
| --- | --- | --- |
| Production of a Plastisol | Handling of Small Containers Containing Additive | Registrants Knowledge |
| Handling Large Containers Containing Additive | Registrants Knowledge |
| Continuous Mixing Process | Liquid |
| Batch Mixing Process | Liquid |
| Laboratory/Quality Control Operations | Registrants Knowledge |
| Production of Masterbatches and/or Compounds | Handling of Small Containers Containing Additive | Registrants Knowledge |
| Handling Large Containers Containing Additive | Registrants Knowledge |
| Continuous Compounding Process | Solid Low Dustiness |
| Batch Compounding Process | Solid Low Dustiness |
| Extrusion, Pelletisation, and/or Granulation. | Solid Low Dustiness |
| Scrap Recycling | Solid High Dustiness |
| Laboratory/Quality Control Operations | Registrants Knowledge |
| Production of Plastic Articles | Handling of Small Containers Containing Masterbatches and/or Compounds | Solid Low Dustiness |
| Handling Large Containers Containing Masterbatches and/or Compounds | Solid Low Dustiness |
| Handling of Small Containers Containing Additive | Registrants Knowledge |
| Handling Large Containers Containing Additive | Registrants Knowledge |
| Use in a Closed and/or Semi-Open Converting Process (e.g. Extrusion, Injection) | Solid Low Dustiness |
| Use in an Open Converting Process (e.g. Calendering) | Solid Low Dustiness |
| Use in a Spraying Application | Liquid |
| Use in Roll and/or Spread Coating | Liquid |
| Use in a Foaming Production | Solid Low Dustiness |
| Use in Dip Coating | Solid Low Dustiness |
| Scrap Recycling | Solid High Dustiness |
| Laboratory/Quality Control Operations | Registrants Knowledge |

### Technical and organisational conditions and measures

#### General Ventilation

One may assume that in all Masterbaching, Compounding, and Converting plants general ventilation provides between 3 – 5 air changes per hour. This should always be recommended when a chemical safety report is produced for a plastic additive.

#### Local exhaust ventilation

Local exhaust ventilation should be specified only if general ventilation does not result in a reduction of exposure sufficient to reduce the risk characterisation ratio below 1.

#### Occupational Health and Safety Management System

The Occupational Health and Safety Management System in masterbatching, compounding, and converting plants should be considered to be **always advanced** rather than basic.

### Amount used (or contained in articles), frequency and duration of use/exposure

#### Duration of activity

Only if general ventilation and additional local exhaust ventilation fail to control a risk should the duration of activity be reduced. As a first step duration, should be reduced to <4 hours per shift[[4]](#footnote-4). If this fails to control risk respiratory protective equipment should be specified before any further reduction in activity is recommended.

### Conditions and measures related to personal protection, hygiene and health evaluation

#### Respiratory Protection

Respiratory protection should only be specified if general ventilation, additional local exhaust ventilation, the duration of activity is limited to 4 hours, and the RCR is still above 1.

#### Use of eye protection

Use of eye protection should be specified if the substance has a classification requiring this.

#### Dermal protection

Use of dermal protection should be specified if there is a residual risk for dermal exposure (i.e. if the RCR is >1), or if dermal exposure is significantly contributing to the combined exposure RCR.

For substances classified for local effect, gloves with 90% efficiency (i.e. Wear chemically resistant gloves (tested to EN374) in combination with ‘basic’ employee training.) should be specified if the concentration in the scenario is above the cut off concentration.

### Other conditions affecting workers exposure

#### Place of use

All Masterbaching, compounding, and converting processes take place indoor.

#### Operating temperature

The operating temperature of the various processes

|  |  |  |
| --- | --- | --- |
| Use Name | Contributing Scenario | Temperature |
| Production of a Plastisol | Handling of Small Containers Containing Additive | Ambient |
| Handling Large Containers Containing Additive | Ambient |
| Continuous Mixing Process | Ambient up to 60 °C |
| Batch Mixing Process | Ambient up to 60 °C |
| Laboratory/Quality Control Operations | Ambient |
| Production of Masterbatches and/or Compounds | Handling of Small Containers Containing Additive | Ambient |
| Handling Large Containers Containing Additive | Ambient |
| Continuous Compounding Process | Polymer Dependent |
| Batch Compounding Process | Polymer Dependent |
| Extrusion, Pelletisation, and/or Granulation. | Polymer Dependent |
| Scrap Recycling | Ambient |
| Laboratory/Quality Control Operations | Ambient |
| Production of Plastic Articles | Handling of Small Containers Containing Masterbatches and/or Compounds | Ambient |
| Handling Large Containers Containing Masterbatches and/or Compounds | Ambient |
| Handling of Small Containers Containing Additive | Ambient |
| Handling Large Containers Containing Additive | Ambient |
| Use in a Closed and/or Semi-Open Converting Process (e.g. Extrusion, Injection) | Polymer Dependent |
| Use in an Open Converting Process (e.g. Calendering) | Polymer Dependent |
| Use in a Spraying Application | Polymer Dependent |
| Use in a Foaming Production | Polymer Dependent |
| Use in Roll and/or Spread Coating | Polymer Dependent |
| Use in Dip Coating | Polymer Dependent |
| Scrap Recycling | Ambient |
| Laboratory/Quality Control Operations | Ambient |

During certain process steps elevated temperatures are used which are polymer dependent. **For general purpose additives a reasonable worst case of 300 °C may be assumed**. Registrants of plastics additives should have some knowledge as to the compatibility of their additive with different polymer matrixes, or at least know for which polymer types it advertises the use of the additive (generally in the technical datasheet). This knowledge may be combined with the maximum processing temperatures of those polymers found in literature.

Here below maximum processing temperatures and risk banding for typical polymers may be found (during converting steps here above referred to as “Polymer Dependent”). Here below some typical polymers.

| Band | Polymer | Max output temperature |
| --- | --- | --- |
| I (<200 °C) | Soft PVC | 190 °C |
| Rigid PVC | 200°C |
| II (<300 °C) | HIPS | 240 °C |
| LDPE | 275 °C |
| PS | 280 °C |
| HDPE | 300 °C |
| PP | 300 °C |
| PET | 300 °C |
| III (>300 °C) | PEN | 320 °C |
| PA6.6 | 340 °C |
| High performance polymer s (PPS, PES, PSU, PPSU PEEK) | 280-460°C |

Alternatively, the registrant can use information on the boiling point/decomposition temperature to determine the maximum processing temperature for which the additive can be used[[5]](#footnote-5).

#### Skin surface potentially exposed

At the moment EuMBC/EuPC have not gathered information on the exposed skin surface normally observed in the sector per contributing activity. Therefore, the standard default factors stated in the [ECETOC Technical Report No. 114](http://www.ecetoc.org/wp-content/uploads/2014/08/ECETOC-TR-114-ECETOC-TRA-v3-Background-rationale-for-the-improvements.pdf) may be used.

This ECETOC approach specifies for each PROC a surface area from the following options:

* One hand face only (240 cm²)
* Two hands face only (480 cm²)
* Two hands (960 cm²)
* Two hands and upper wrists (1500 cm²)
* Two hands and forearms (1980 cm²)

Table 7 Exposed Skin Surface per Contributing Activity. Source: [ECETOC TRA version 3: Background and Rationale for the Improvements – Technical Report No. 114](http://www.ecetoc.org/wp-content/uploads/2014/08/ECETOC-TR-114-ECETOC-TRA-v3-Background-rationale-for-the-improvements.pdf)

| Use Name | Contributing Scenario | Exposed skin surface (cm²) |
| --- | --- | --- |
| Production of a Plastisol | Handling of Small Containers Containing Additive | 480 |
| Handling Large Containers Containing Additive | 960 |
| Continuous Mixing Process | 480 |
| Batch Mixing Process | 480 |
| Laboratory/Quality Control Operations | 240 |
| Production of Masterbatches and/or Compounds | Handling of Small Containers Containing Additive | 480 |
| Handling Large Containers Containing Additive | 960 |
| Continuous Compounding Process | 480 |
| Batch Compounding Process | 480 |
| Extrusion, Pelletisation, and/or Granulation. | 480 |
| Scrap Recycling | 1980 |
| Laboratory/Quality Control Operations | 240 |
| Production of Plastic Articles | Handling of Small Containers Containing Masterbatches and/or Compounds | 480 |
| Handling Large Containers Containing Masterbatches and/or Compounds | 960 |
| Handling of Small Containers Containing Additive | 480 |
| Handling Large Containers Containing Additive | 960 |
| Use in a Closed and/or Semi-Open Converting Process (e.g. Extrusion, Injection) | 480 |
| Use in an Open Converting Process (e.g. Calendering) | 960 |
| Use in a Spraying Application | 1500 |
| Use in Roll and/or Spread Coating | 960 |
| Use in a Foaming Production | 240 |
| Use in Dip Coating | 480 |
| Scrap Recycling | 1980 |
| Laboratory/Quality Control Operations | 240 |

### Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply

Several good practices have been defined for various substances. As long as these are not made obligatory the European Plastics Converters and European Masterbatchers and Compounders would encourage registrants to communicate in their exposure scenario references to these best practices.

#### EuPC recommendations of best practice in handling and using

#### ADCA blowing agent

The European Plastics Converters association has issued in January 2015 a best practice guide for the handling of this blowing agent that has been included in the REACH candidate list following a 2 years project investigating into exposure within the plastics value chain and recommending reasonable measures to reduce exposure.

“For best practice advice to minimise exposure to ADCA you are encouraged to implement the EuPC best practices.”

#### NepSi

The crystalline silica industry has for a long time worked on controlling dust exposure due to well-known health issues with silica dust exposure. The gained expertise has been codified in best practice guidance and audio-visual material. The lessons learned can be seen as a best practice for controlling dust exposure in general. Therefore, registrants are encouraged to communicate downstream as a best practice a reference to the NepSi best practices. For example:

“For best practice advice to minimise dust exposure you are encouraged to implement the NepSi best practices. Available at [www.nepsi.eu](http://www.nepsi.eu)”

The Chesar use map file accompanying this guidance this advice this advice in included in the following scenarios:

* Handling of Small Containers Containing Masterbatches and/or Compounds
* Handling Large Containers Containing Masterbatches and/or Compounds
* Scrap Recycling (both Production of Masterbatches and/or Compounds and Production of Plastic Articles use)

If the registrant supplies a solid additive it is recommended to include the advised to include additionally under:

* Handling of Small Containers Containing Additive
* Handling Large Containers Containing Additive
* Laboratory/Quality Control Operations

Once the Chesar use map has been added to Chesar this best practice advice should become available for inclusion in these contributing activities.

##### VECAP

To reduce environmental emissions from plastics additives during use there has for a long time been the Voluntary Emissions Control Action Programme (VECAP) initiative. Certain additive manufacturers actively communicate with their customers in order to have the best practices contained in this initiative adopted by their downstream users. It should be noted that the implementation of these best practices is not required to achieve the release factors described in the OECD ESD as these were based on the standard practices in industry. Rather the implementation of the VECAM best practices would result in lower release factors. Therefore, registrants are encouraged by EuPC/EuMBC to communicate downstream as a best practice a reference to the VECAP initiative. For example:

“For best practice advice to minimise environmental emissions you are encouraged to implement the VECAP best practices. Available at: [www.vecap.info](http://www.vecap.info)”

The Chesar use map file accompanying this guidance this advice is included for all environmental contributing scenarios.

# Annex I: Example of Custom Modelling Approach

Dermal exposure can be modelled using a custom modelling approach (1). The following model, which forms the basis for PESTOOL, considers diffusion out of the polymer matrix followed by a mass transfer resistance through a thin (0.01 cm) water layer and including partitioning at the polymer/water interface. The conceptual model is shown below.

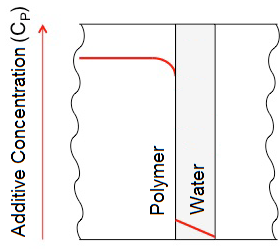


Figure 1 Dermal Exposure Model

The mathematical model is based on the following equation (1):

|  |  |  |
| --- | --- | --- |
|  |  | ( 1 ) |

Where

|  |  |  |
| --- | --- | --- |
|  |  | ( 2 ) |

|  |  |  |
| --- | --- | --- |
|  |  | ( 3 ) |

|  |  |  |
| --- | --- | --- |
|  |  | ( 4 ) |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Total Loss of Additive per unit area of surface at time t | g·cm-2 | Equation 1 |
|  | Additive Concentration in Polymer | g·cm-3 | Stakeholder interviews |
|  | Additive Concentration in Solvent | g·cm-3 | ECETOC TRA input |
|  | Diffusivity in Polymer | cm2·s-1 | Brandsch Model (2) |
|  | Diffusivity in Solvent | cm2·s-1 | Wilke-Chang Model (3) |
|  | Partition Coefficient at Polymer-Solvent Interface | - |  |
|  | Time Diffusion Takes Place | S | ECETOC TRA documentation (4) |
|  | Thickness of Boundary Layer (0.01 cm) | Cm | Assumption |

The model assumes maximum concentration levels of the additive in the polymer matrix as determined by interviews with industry representatives (see Table 6), as this generates the most conservative exposure estimate.

The partition coefficient at the polymer-solvent interface is estimated from the water solubility of the generic substance and the solubility of the substance in the polymer. The solubility in the polymer is assumed to be equal to the maximum concentration reported in the interviews.

A model for the estimation of diffusivity of additives in polymers is used that has been developed specifically for regulatory compliance (2):

|  |  |  |
| --- | --- | --- |
|  |  | ( 5 ) |

|  |  |  |
| --- | --- | --- |
|  |  | ( 6 ) |

|  |  |  |
| --- | --- | --- |
|  | Unit value of | cm2·s-1 |
|  | Conductance of Polymer factor | - |
|  | Conductance parameter |  |
|  | Molecular Weight of Additive | g/mol |
|  | Temperature | K |
|  | Conductance temp. parm. | K |

The authors fitted many data from migration experiments and provided values of representing a 95% confidence that the actual migration will fall below the predicted level. Values for and are shown for different plastics in Table 8. The more conservative values are used for the calculations.

It should be noted that this model becomes invalid at loading levels of more than 5 – 10%, as then the presence of additive influences the diffusivity of the material.

Table 8 Conductance of polymer factors. (5)

|  |  |  |  |
| --- | --- | --- | --- |
| **Polymer** |  |  |  |
| LDPE | 10 | 11.7 | 0 |
| HDPE | 10 | 13.2 | 1577 |
| PP | 9.4 | 12.4 | 1577 |
| PET | 2.2 | 6.35 | 1577 |
| PEN | -0.34 | 3.7 | 1577 |
| PS | -2.8 | -0.7 | 0 |
| HIPS | -2.7 | 0.1 | 0 |
| PA (6,6) | -1.54 | 1.9 | 0 |

The diffusivity in the solvent phase has been modelled using the Wilke-Chang model (3, 6, 7). The authors report an average error of below 1% for 87 solutes in water. In utilizing the model, diffusion volumes had to be estimated from molecular weight. This was done in a conservative way so that errors would overestimate the diffusivity with high confidence.

Exact molar volume for plastic additives are not always available so a correlation was performed whereby a series of molar volumes for additives were calculated with the method of Lebas and correlated with the molecular weights of these additives. The 90% confidence interval resulted in a minimum estimate for brominated flame retardants:

|  |  |  |
| --- | --- | --- |
|  |  | ( 16 ) |

And for all other plastic additives:

|  |  |  |
| --- | --- | --- |
|  |  | ( 17 ) |

Both the model for diffusivity in the polymer and in the water layer assume human body temperature of 310.15 K (= 37 °C).

The following formula was used to model the average worker and determine the total exposure per additive per day:

|  |  |  |
| --- | --- | --- |
|  |  | ( 7 ) |

|  |  |  |
| --- | --- | --- |
|  | Predicted Dermal Exposure according to matrix model | mg/kg bw/day |
|  | Exposed skin dependent on process category (4) | Cm2 |
|  | Mass of worker | Kg |

The bodyweight is taken to be 65 kg and the average time a worker handles material is set to 480 minutes per day. The efficiency of contact is taken to be 100% indicating no gaps in the contact between plastic and skin.

In this specific example a hypothetical additive with a weight of 220 g/mol is modelled.

LDPE is selected as the most conservative polymer as it has the highest diffusivity.

Exposed skin surface is set to 480 cm² which corresponds to PROC 14 estimates.

Results will be calculated for a loading level of 0.8% and 4% and solubility of the additive in water of 0.1 mg/L, 1 mg/L, and 1 mg/L to provide an indicative range of the possible outcome form the modelling approach.

In short:

* Fixed Input
  + Diffusivity parameters: LDPE
  + Skin Contact: 480 cm²
  + Molecular Weight: 220 g/mol
  + Temp: 310.15 K
* Variable Input
  + Loading 0.8% and 4%
  + Water Solubility: 0.1, 1, 10 mg/L

## Results

When reviewing the results one can see that especially for low solubility additives such a modelling approach results in lower exposure estimates.

Table 9 Results of the custom modelling approach. \* taken from [ECETOC TRA version 3: Background and Rationale for the Improvements – Technical Report No. 114](http://www.ecetoc.org/wp-content/uploads/2014/08/ECETOC-TR-114-ECETOC-TRA-v3-Background-rationale-for-the-improvements.pdf) Appendix B PROC 14 and modified with concentration factors of Table 6 page 20.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Exposure (mg/kg/d) with substance with solubility of: | | | TRA Exposure Value\* (mg/kg/d): |
| 0.1 mg/L | 1 mg/L | 1 mg/L |
| 0.8% | 0.01700 | 0.15600 | 0.964 | 0.343 |
| 4% | 0.01700 | 0.16500 | 1.467 | 0.686 |

## References

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6. Wilke CR, Lee CY. Estimation of Diffusion Coefficients for Gases and Vapors. Industrial & Engineering Chemistry. 1955;47(6):1253-7.

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1. Serivice providers that may be able to assist with modelling include: FABES and Fraunhofer. [↑](#footnote-ref-1)
2. The standard format requires one to specify all risk management measures except the concentration and if eye protection needs to be worn. This is not practical as risk management measures are driven by the ingredients that are used. [↑](#footnote-ref-2)
3. E.g. particles >5 nm incorporated in polymer matrixes have been shown not to migrate. A. Störmer , J. Bott, , D. Kemmer, R. Franz (2017) - [Critical review of the migration potential of nanoparticles in food contact plastics](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2844666/) [↑](#footnote-ref-3)
4. Explanatory Note. In many countries, there is a limitation in the length of time a mask may be prescribed to be worn by employees. Furthermore, practical experience shows that wearing a mask for a longer duration of time causes significant unease from the side of the worker increasing the chance of non-compliance. [↑](#footnote-ref-4)
5. e.g. if the additive decomposes and loses functionality at 250 °C then it is unlikely to be used in a process requiring a temperature of 300 °C [↑](#footnote-ref-5)