Guidance on a laboratory leaching test method for materials that are treated with biocides

to fulfil requirements of the European Biocidal Products Regulation

This guidance document describes a laboratory method for determining the leaching of active substances or other compounds from materials that contain biocidal products of main group 2 ‘Preservatives’ according to the BPR [Regulation (EU) No 528/2012], i.e.

Product-type 7 Film preservatives
Product-type 9 Fibre, leather, rubber and polymerised materials preservatives
Product-type 10 Construction material preservatives

that are intended to be used under outdoor conditions out of ground contact and exposed to rain.

This guidance was developed on the basis of

EN 16105:2011 Paints and varnishes - Laboratory method for determination of release of substances from coatings in intermittent contact with water and

OECD Guidance 107 on the Estimation of Emissions from Wood Preservative-Treated Wood to the Environment: for Wood held in Storage after Treatment and for Wooden Commodities that are not covered and are not in Contact with Ground

This procedure is particularly suited to compare leaching behavior of different products or different formulations of a product.

NOTES

The specifications of test conditions, sampling regime and chemical analysis of collected eluates for the materials considered in this guidance document are the same as in EN 16105 and the 2 * 1 h immersion regime described in OECD GD 107.

The equivalent test procedure for coatings according to EN 998-1, EN 1062-1, EN 15824 is defined in EN 16105. The equivalent test method for wood preservatives (product-type 8) is described in OECD GD 107 as 2 * 1 h immersion regime. These documents can be cited for the same test if appropriate. Tests for wood treated with wood preservatives (PT 8) can also be performed according to CEN/TS 15119-1 and CEN/TS 15119-2 depending on the intended use conditions.

This guidance applies to materials that are intended for large-area applications. Small-area application like sealants, or special application techniques require adopted procedures for the preparation of test specimens. Eluates may be collected and analysed as described in this document.

Materials can contain active substances that originate from preservatives for products during storage (product-type 6).
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1 Description of the test method
A wetting and drying method is described in this guidance document. For this purpose, test specimens are immersed into water and allowed to dry in time intervals under laboratory conditions. The water from each immersion cycle is analysed to determine the concentration of leached target substances.

Prior to testing customer and appointed laboratory have to clarify which active substances, relevant transformation products (e.g. metabolites) and other substances of concern according to BPR 528/2012 (guidance in preparation) and additional physical-chemical parameters have to be analysed in the eluates.

2 Terms and definitions
For the purposes of this document, the following terms and definitions apply.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>analyte</td>
<td>determinant, element, ion or substance to be determined by an analytical method; synonym for target substance</td>
</tr>
<tr>
<td>eluate</td>
<td>solution obtained from a leaching test (here: by one immersion)</td>
</tr>
<tr>
<td>emission $E$</td>
<td>liberation of chemical substances from a material, into soil, surface water or groundwater or into the leachant of a test facility</td>
</tr>
<tr>
<td>NOTE</td>
<td>Emission is expressed in units of released mass per surface area, i.e. milligrams per square metre.</td>
</tr>
<tr>
<td>immersion</td>
<td>exposure of test specimen to the leachant</td>
</tr>
<tr>
<td>immersion cycle $i$</td>
<td>sequence consisting of 1 h immersion, 4 h drying and 1 h immersion $i$ is the running number of immersion cycles.</td>
</tr>
<tr>
<td>leachant</td>
<td>liquid that is brought into contact with the test specimen in the leaching procedure</td>
</tr>
<tr>
<td>leaching</td>
<td>release of inorganic and/or organic substances from a solid product by a leachant</td>
</tr>
<tr>
<td>NOTE</td>
<td>The leaching is expressed in units of released mass per surface area, i.e. milligrams per square metre.</td>
</tr>
<tr>
<td>liquid to surface area ratio</td>
<td>ratio between the volume of liquid (L) which in a given step of the test is in contact with the exposed surface area (A) of the test specimen</td>
</tr>
<tr>
<td>L/A</td>
<td>merged eluate</td>
</tr>
<tr>
<td>merged eluate</td>
<td>solution obtained at a specific immersion cycle, consisting of the eluates of the first and the second immersion</td>
</tr>
<tr>
<td>prefabricated treated article</td>
<td>treated article that is produced and marketed in a way that it can be used as test specimen without further substrate</td>
</tr>
<tr>
<td>release/specific release</td>
<td>synonyms for emission and specific emission</td>
</tr>
<tr>
<td>specific emission $E_i$</td>
<td>emission of a target substance from a material during a specific immersion cycle</td>
</tr>
<tr>
<td>NOTE</td>
<td>The unit is mass per surface area, i.e. milligrams per square metre.</td>
</tr>
</tbody>
</table>
substrate  material used as a base to apply treated articles in order to produce a test specimen

target substance  substances (active substances, transformation products and/or substances of concern) to be tested

test material  used synonymously for ‘treated article’ in this document

test specimen  body that is tested for leachability of target substances, may be either a prefabricated treated article or a treated article applied to a substrate

transformation product  substance derived from the original substance, e.g. due to metabolism or abiotic degradation like hydrolysis or photolysis

treated article  according to BPR 528/2012 Art. 3 (11) any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products

NOTE
A coating material is a product, in liquid, paste or powder form, that, when applied to a substrate, forms a film possessing protective, decorative and/or other specific properties [EN ISO 4618:2006]; and a coating is a continuous layer formed from a single or multiple application of a coating material to a substrate.

3 Reagents
3.1 Standard leachant
Deionised water with a pH-value of (6 ± 1) and a water temperature of (22 ± 3) °C shall be used.

NOTES
Use deionised water, unless another test medium is specified and stipulated in the CAR to be more realistic. When there are substances involved having ion exchange properties then the release of the active elements increases with decreasing pH and with increasing water hardness. In the case of ion exchangers it is predictable that deionised water will be ‘best case’.

Treated articles that are usually exposed to different temperatures may additionally be tested at a further relevant temperature.

4 Apparatus
4.1 General
Check the materials and equipment specified in 4.2.1 to 4.2.6 before use for proper operation and absence of interfering elements that might affect the results of the test. The equipment specified in 4.2.2 to 4.2.5 shall also be calibrated.
4.2 Equipment

4.2.1 Immersion container
The container for immersion shall be made of a material inert to the target substances in the eluates (e.g. glass, PTFE coated). If polymer containers are used, validation that the target substances will not adhere to the surface must be done.
The immersion container shall be large enough to allow the test specimens to have the exposed faces completely exposed to water and contain 25 L water per square metre exposed face. The water column below or above the test surface shall be ≥ 10 mm (see Figures in Annex B).

NOTE
For example, a test specimen of 100 cm$^2$ requires 250 ml water.

4.2.2 Analytical balance
Analytical balance, with an accuracy of ± 0.1 g.

4.2.3 Device for measuring
Device for measuring sample dimensions, with an accuracy of ± 1 mm.

4.2.4 Measuring cylinders for volume determination
Measuring cylinders for volume determination, with 1 % accuracy.

4.2.5 pH meter
pH meter, with an accuracy of ± 0.05.

4.2.6 Glass or plastic bottles
Glass or plastic bottles, e.g. glass, HDPE, PMMA, PTFE, PE, PET, PP, PVC.
Use bottles with an appropriate volume, and with screw cap, for eluate collection and preservation of merged eluates. Be aware of adhesion problems when selecting the bottles material.

5 Test specimens

5.1 General
Test specimens are either prepared from prefabricated test materials or by application of a test material (e.g. a coating material) onto a substrate.
The test specimens are representative or typical of commercial treated articles. Alternatively the test specimens may be prepared to be a ‘realistic worst case’ estimation of the emission for a treated article under outdoor exposure out of ground contact.

NOTE
Test specimens of treated articles into which the biocides are usually brought by means of industrial processes (e.g. impregnation of textiles, treatment of fibres and plastics) have to be obtained as
prefabricated treated articles from these procedures, and shall not be prepared by laboratories themselves.

5.2 Sampling of test material
The sample of the test material shall be representative of the product to be tested.

Samples shall be stored and handled in accordance with any written requirements from the supplier.

The sampling and conditioning procedure shall be recorded.

The product shall be analysed for the target substance(s) prior to use if possible.

NOTES
Refer to guidance documents for sampling if available.

It has to be reported whether the original content of target substance(s) was confirmed or not.

5.3 Preparation of test specimens
5.3.1 Number and size of test specimens
The tests shall be performed with at least two replicate test specimens containing target substances and with one control test specimen with the same material, but without target substances, if available. If the material without target substances is not available only the substrate can be used as control test specimen.

The test with the control test specimen may be stopped if no background signal has been determined after the second immersion cycle.

Test specimens shall have a minimum surface area of 100 cm$^2$.

Each test specimen shall be marked to identify it throughout the test.

NOTES
Alternatively the pieces of treated articles can be prepared in a way typical of commercial practice. The actual dimensions shall be stated in the test report.

The number of replicates and/or the size of the test specimens can be increased if the heterogeneity of the test material is expected to be high to improve the validity of the test (see validity criterion under 6.2).

5.3.2 Preparation of test specimens from prefabricated treated articles
Cut test specimens from the prefabricated treated articles with dimensions given under 5.3.1. Lateral faces and reverse sides of porous or water adsorbing materials are end-sealed by a material which prevents water entry. The end-sealer shall remain effective during exposure to the leachant and may not contain target substances.
Calculate the amount of active substance(s) applied to each test specimen and express the result in grams of active substance(s) per square metre of exposed surface area.

5.3.3 Preparation of test specimens from treated articles to be applied to a substrate

5.3.3.1 Substrate

The substrate used to carry the material shall have a homogeneous planar surface, shall be inert and test products shall adhere well to it during the immersion in water. As the substrate can influence the results, it shall be stated in the test report.

Substrates might influence the leaching (e.g. concrete, mineral renders and fibre cement board and wood substrates).

The test material has to be intended for the selected substrate, e.g. paints have to be stable towards alkalinity if fibre cement is selected as substrate.

NOTE
See examples for substrates in Annex B.

5.3.3.2 Preparation of substrate panels for test specimens

Cut panels of the substrate with dimensions given under 5.3.1.

Alternatively, the test material can be applied to larger substrate panels before cutting.

5.3.3.3 Application of test material

Test materials have to be applied on substrates according to the manufacturers instruction.

The substrate shall be clean and dry. The substrate shall be coated with the test material in the specified quantity in accordance with the recommendations of the manufacturer. Determine and record the total mass applied.

Follow the supplier’s instructions for applying surface coating or water-repellent treatment.

Calculate the amount of target substance(s) for each test specimen and express the result in grams of target substance per square metre of exposed surface area if appropriate.

Reject any test specimen with amounts of test material deviating by more than 5 % from the average for that type of test specimen and substitute an appropriate alternative which falls within this range.

NOTES
Apply the maximum amount if a range is given for the application of a coating material.
Lateral faces and reverse sides of porous or water adsorbing substrate are end-sealed by a material which prevents water entry. The end-sealer shall remain effective during exposure to the leachant and may not contain target substances.

5.3.3.4 Conditioning
Condition the test specimens with freely circulating air at (22 ± 3) °C and (60 ± 10) % relative humidity without UV influence for a period based on details provided by the manufacturer. If no details are provided by the manufacturer the conditioning period should be 1-2 weeks.

6 Test procedure
6.1 Immersion method
Perform at least nine immersion cycles in, e.g. on day 1, 3, 5, 8, 10, 12, 15, 17 and 19.
Each immersion cycle i consists of:
- (1 ± 0.03) h immersion,
- (4 ± 0.1) h drying at (22 ± 3) °C and (60 ± 10) % relative humidity and
- (1 ± 0.03) h immersion.

Carry out the immersion at a water temperature of (22 ± 3) °C.

The immersion container shall be washed and dried prior to the first test.

The ratio between volume of leachant and exposed surface area (liquid to surface area ratio L/A) is defined to be 2.5. The required volume of water (e.g. 250 ml per 100 cm²) shall be added. Fresh deionised water shall be used for each immersion.

Determine and record the pH-value of the leachant.

Determine and record the mass of each specimen before each immersion cycle.

The test specimens shall be positioned in the containers (each test specimen in a separate container) in a way that free contact of water to the investigated surface is allowed.

The immersion container shall be covered to avoid evaporation of water during the immersion.

Test specimens shall be removed from the immersion containers for drying.

Merge the eluates of the two immersions of one immersion cycle i for the analysis of the target substances.

Determine and record the pH-values of the merged eluates.

Store the test specimens between the immersion cycles according to 5.3.3.4.
Start the following immersion cycle after a minimum of 42 h.

If the analysis cannot be achieved on the same day, store the merged eluates in a refrigerator (+4 °C) in the dark to reduce microbial activity. Alternatively, the merged eluates may be stored in a freezer at ≤ -10 °C.

NOTES

If eluates are stored, the stability for storage shall be proved for all target substances (e.g. due to information of the manufacturer or appropriate storage tests. EN ISO 5667-3 gives the good practices to preserve water samples.

The mass of the test specimens is recorded to check whether the original weight is reached during the drying period. Further information on water uptake and possible changes of the material is available if masses are recorded before and after each immersion.

The analysis of the merged eluates should be done depending on the stability of the individual substance and depending on the storage conditions which can be applied.

Analysis of additional parameters that provide information on coelution of ions (e.g. conductivity and cation exchange capacity) or further organic substances (dissolved or total organic carbon) is optional.

6.2 Analysis

The target substances in the merged eluates shall be analysed separately for each replicate with an appropriate method. It might be necessary to concentrate the target substances in the merged eluates depending on the concentration and the sensitivity of the analytical method.

The validity of the analytical method for the target substances shall be determined before conducting the test:

a) accuracy;
b) specificity;
c) limit of detection;
d) limit of quantification;
e) precision

It has to be reported if the analysed substances are stable during storage of the eluates until chemical analysis. It has to be included in the test report if there are data on limited stability of analysed substances in water.

The total cumulative emission shall vary for less than 15 % between the two parallel tests. If the cumulative results vary by more than 15 %, the test has to be repeated with additional test specimens. The data for all test specimens have to be reported.
7 Results
7.1 Results in concentrations
Express the analytical results as concentration \( c \) of each target substance analysed in the merged eluate for each immersion cycle in milligram per litre.

7.2 Results in terms of specific emissions
If the analysis of the merged eluates of the control samples shows detectable levels of the target substances, implying a background signal in the water, it shall be subtracted from the analytical results for the test specimens with target substances. The occurrence of a background signal in the control has to be reported and explained in the test report. Convert the analytical results \( c_i \) expressed in milligram per litre to specific emissions \( E_i \) in milligram per square metre for each immersion cycle \( i \) with

\[
E_i = \frac{c_i \times V_i}{A}
\]

where

- \( i \) is the running number of immersion cycles;
- \( E_i \) is the specific emission at the immersion cycle \( i \), in milligram per square metre;
- \( A \) is the surface of the test specimen, in square metre;
- \( c_i \) is the measured concentration of the target substance in the merged eluate at the immersion cycle \( i \), in milligram per litre;
- \( V_i \) is the real volume of the merged eluate after the immersion cycle \( i \), in litre.

Express the result in \( E_i \) as a mean value of the two replicate measurements for each immersion cycle \( i \). Plot the specific emissions \( E_i \) against immersion cycles.

NOTE
Table A.1 shows an example of a recording form for one set of test specimens. Table A.2 summarises the mean specific emissions for all immersion cycles. An example graph is given in Annex B. Further calculations might have to be done.

8 Test report
The test report shall contain at least the following information:

- reference to this guidance document;
- specific and unique name or code of the treated article, the trade or common name of the active substance(s), substances of concern (as defined in the Regulation (EU) No 528/2012);
- all details necessary to identify the test material;
- name of the organisation responsible for the test report and the date of issue;
- name(s) and signature(s) of the persons responsible;
f) date of order, the name and address of the sponsor of the test;
g) results of chemical analysis of the biocides in the test material;
h) conditioning and sampling of the test material;
i) solvent or diluents used (if applied);
j) material of the substrate for application of test materials *;
k) number and dimensions of the test specimens;
l) method and date of application of the test material*;
m) individual and mean amount of test material on the substrate panels in grams or millilitres per square metre as appropriate*;

n) method and drying time after application of the test material and details of post treatment*;
o) method and duration of conditioning or storage of the test specimens;
p) amount of target substances in the test specimens in milligrams per square metre exposed surface area;
q) total surface area of the test specimens exposed to water in square metres;
r) time and date of each immersion and the nominal volume of water used for each immersion in litre;
s) mass of test specimens prior to the immersion cycles
t) analytical methods used to determine target substances in the merged eluates
u) available information on the stability of the analysed substances in water;
v) concentration of the target substance \( c_i \) for each immersion cycle \( i \);
w) specific emission \( E_i \) for each immersion cycle \( i \);
x) plot of specific emissions \( E_i \) versus immersion cycles \( i \);
y) any variation from the method described in this standard and any factors that might have influenced the results;
z) the pH-value of the merged eluates;

aa) particular observations.

* information is not necessary when the test specimen is a prefabricated treated article

It is recommended to add graphs that represent the emission rates (mg/m\(^2\) per immersion day) versus time (or number of immersion days) as well as the cumulative emission (mg/m\(^2\)) versus time (or number of immersion days) for each active ingredient.
### Table A.1 — Form for recording of masses of test specimens and pH-values

<table>
<thead>
<tr>
<th>Day</th>
<th>Immersions</th>
<th>Test specimen mass</th>
<th>pH values of Merged eluates of test specimen</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Date</td>
<td>Time</td>
<td>Cycle Leachant 1 Cycle Leachant 2 Cycle Leachant Control</td>
</tr>
<tr>
<td></td>
<td>Date</td>
<td>Time</td>
<td>No.</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td></td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>19</td>
<td></td>
<td>9</td>
</tr>
</tbody>
</table>
Table A.2 — Analytical results

<table>
<thead>
<tr>
<th>Cycle $i$</th>
<th>Immersion</th>
<th>Concentration $c_i$</th>
<th>Quantity emitted per immersion cycle $E_i$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Control specimen</td>
<td>Test specimen</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>No.</td>
<td>Date</td>
<td>mg/l</td>
<td>mg/l</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
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<td></td>
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<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A separate table should be prepared for each substance that has been analysed.
Annex B (informative)

Figures — Possible orientations of different types of test specimens in the immersion container during the immersion process
Double arrows indicate minimum distance of 1 cm, dark parts of test specimens contain biocidal products, light parts indicate substrates, triangles indicate spacers/supporting points

a) Treated article applied on substrate (heavy)

b) Treated article applied on substrate (light, use spacers to position heavy specimens)

c) Treated article that can emit from all faces, non-porous

d) Treated article that can emit from all faces, porous (surface area unknown)

e) Joint sealer in grooves on a disk

f) Treated article with holes, surface area can be estimated

g) Tubes
Examples for substrates

<table>
<thead>
<tr>
<th>Substrate</th>
<th>Treated article</th>
</tr>
</thead>
<tbody>
<tr>
<td>XPS (extruded polystyrene)</td>
<td>Coating materials, e.g. paints and renders</td>
</tr>
<tr>
<td>EPS (expanded polystyrene)</td>
<td>Coating materials, e.g. paints and renders</td>
</tr>
<tr>
<td>weather-proof glued plywood</td>
<td>paints for wood</td>
</tr>
<tr>
<td>solid wood</td>
<td>paints for wood</td>
</tr>
<tr>
<td>fibre cement</td>
<td>roof paints</td>
</tr>
</tbody>
</table>

Example graph to present emission data from leaching tests

![Graph showing emission data](chart.png)
Range of concentrations of target substances in eluates
(experiences from leaching tests with various materials)

<table>
<thead>
<tr>
<th>Active Substance</th>
<th>Concentrations in eluates</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>mg/l</td>
<td>mg/l</td>
</tr>
<tr>
<td>Carbendazim</td>
<td></td>
<td>0.02</td>
<td>0.25</td>
</tr>
<tr>
<td>DCOIT</td>
<td></td>
<td>0.01</td>
<td>0.1</td>
</tr>
<tr>
<td>Dichlofluanid</td>
<td></td>
<td>0.01</td>
<td>0.15</td>
</tr>
<tr>
<td>Diuron</td>
<td></td>
<td>0.03</td>
<td>2.2</td>
</tr>
<tr>
<td>DMSA</td>
<td></td>
<td>0.04</td>
<td>0.15</td>
</tr>
<tr>
<td>DMST</td>
<td></td>
<td>0.003</td>
<td>0.1</td>
</tr>
<tr>
<td>IPBC</td>
<td></td>
<td>0.05</td>
<td>0.8</td>
</tr>
<tr>
<td>Isoproturon</td>
<td></td>
<td>0.1</td>
<td>2.2</td>
</tr>
<tr>
<td>OIT</td>
<td></td>
<td>0.01</td>
<td>1.5</td>
</tr>
<tr>
<td>Terbutryn</td>
<td></td>
<td>0.002</td>
<td>0.2</td>
</tr>
<tr>
<td>Tolyfluanid</td>
<td></td>
<td>0.001</td>
<td>0.1</td>
</tr>
<tr>
<td>Zinc pyrithione</td>
<td></td>
<td>0.05</td>
<td>0.2</td>
</tr>
</tbody>
</table>
Bibliography


EN 16105:2011 Paints and varnishes - Laboratory method for determination of release of substances from coatings in intermittent contact with water

OECD Guidance 107 (2009) on the Estimation of Emissions from Wood Preservative-Treated Wood to the Environment: for Wood held in Storage after Treatment and for Wooden Commodities that are not covered and are not in Contact with Ground

EN 998-1:2010 Specification for mortar for masonry — Part 1: Rendering and plastering mortar

EN 1062-1:2004 Paints and varnishes — Coating materials and coating systems for exterior masonry and concrete — Part 1: Classification

EN 15824:2009 Specifications for external renders and internal plasters based on organic binders

CEN TS 15119-1:2008: Durability of wood and wood based products – Determination of emissions from preservative treated wood to the environment – Part 1: Wood held in the storage yard after treatment and wooden commodities exposed in Use Class 3 (not covered, not in contact with the ground) – Laboratory method.

CEN TS 15119-2:2012: Durability of wood and wood-based products – Determination of emissions from preservative treated wood to the environment – Part 2: Wooden commodities exposed in Use Class 4 or 5 (in contact with the ground, fresh water or sea water) – Laboratory method.