

Purity declarations for starting substances under the Drinking Water Directive (EU) 2020/2184

Are you ready for the DWD?

What manufacturers need to know and act on now

The Drinking Water Directive (DWD) is changing the rules for manufacturers. New requirements, and new responsibilities mean that you need to act now. In this document, we explain what the DWD means for your organization, what has changed compared to existing regulations, and which actions you need to take now to remain compliant and future ready.

The Drinking Water Directive (EU) 2020/2184 requires product certification for materials and products that come into contact with drinking water and approved market entry in Europe. This certification follows a material based approach that also assesses the starting substances used to manufacture organic materials. As a result, manufacturers of these substances have a clear responsibility to demonstrate the purity of their products and to declare any impurities.

This is done through a statement issued by the substance manufacturer, which is used by the notified conformity assessment body during the certification process. The sections below explain the information that must be included in this statement and when additional evidence may be required.

General purity requirements for all substances

In the conformity assessment procedure, the notified body has to collect information on the purity of/impurities in all starting substances. As these requirements are considered the responsibility of the manufacturer, they come in the form of a statement.

The statement must at least

- Be issued by the substance manufacturer
- Be clearly linked to the substance
- Refer to the amount and identity of impurities in the substance
- Confirm that all impurities have been declared
 - with relative mass percentages above 1 % and
 - with relative mass percentages above 0.1 %, if classified under CLP Regulation No 1272/2008 as Category 1A or 1B.
- Confirm that the substance is suitable for the manufacture of drinking water contact materials.

Specific purity requirements for substances

Besides the general purity requirements, specific purity requirements may apply. These can be linked to a single substance or to groups of substances, like pigments. For these specific purity requirements, more evidence of compliance is needed. A statement of compliance is not accepted. Clear evidence, in the form of test reports, is required. If this evidence is not delivered, all products that contain the substance must be tested fully for migration of all impurities.

As substance manufacturer, you are in the position to test your substances for these requirements and supply customers and the notified body with the required documents.

Purity declarations for starting substances under the Drinking Water Directive (EU) 2020/2184

References


The requirements for substances are given in the Supporting document, chapter 6.1.2.2.1 “Required Information”. The exact text on purity requirements is as follows:

Concerning general purity requirements for starting substances, the manufacturers have a specific responsibility. In view of their knowledge on the composition of substances and mixtures the manufacturer must be aware of possible health risks and must eliminate them if such risks occur.

The manufacturer shall provide the following information concerning impurities for all starting substances to the conformity assessment body:

- All impurities with relative mass percentages above 1 % and
- All substances that are classified under CLP Regulation No 1272/2008 as Category 1A or 1B carcinogenic, mutagenic or toxic to reproduction, with relative mass percentages above 0.1%.

The notified conformity assessment body can omit asking for this information on the identity of the impurities provided the percentage of the impurities is below the respective cut-off value. Additionally, the manufacturer of the starting substance has to confirm that the substance or mixture is suitable for the manufacture of drinking water contact materials.

A close-up photograph of a hand holding a clear glass under a chrome faucet. Water is flowing from the faucet into the glass, creating bubbles. The background is a blurred indoor setting with green plants.

Kiwa, your trusted partner for EU Drinking Water Directive (DWD)