Biocidal Products Regulation
The European Biocidal Products Regulation (Regulation (EU) No. 528/2012) stipulates that biocidal products may only be made available and used on the market if they are certified in accordance with this regulation. Unlike the previous biocidal products legislation, so-called “in-situ” procedures such as electrolysis, chlorine dioxide and ozone now also fall under this certification requirement.

This means that anyone who generates biocidal products “in-situ” is required to have them certified. The result: A huge amount of time and money to gain certification.

What does this mean to you, an operator of “in-situ” systems?
For you, an operator of our system (electrolysis, chlorine dioxide or ozone systems), this means that you operate your systems as prescribed by us. You do not need to worry about product certification. We’ll take care of that!

Ready for you: Anytime, anywhere.
We will arrange for appropriate certification, applicable for you, provided you operate your system as prescribed by us. As soon as certification as a biocidal product is possible, we will inform you of the current status.
Impacts of the European Biocidal Products Regulation on using chlorine dioxide

The EU Regulation No. 528/2012 from 22.05.2012 affects the certification and marketing of biocidal products intended to fight harmful organisms in a chemical or biological manner.

Quote: “The aim of this regulation is to improve the functioning of the single European market by harmonising the specifications for the provision and use of biocidal products while also guaranteeing a high level of protection for humans, animals and the environment. The requirements of this regulation are based on the precautionary principle, which aims to ensure protection of humans, animals and the environment. Particular attention is dedicated to protecting at-risk groups.”

In the first stage of certification, biocidal substances have to be certified as “active substances” and added to what is known as the Union list. This step has already been initiated for chlorine dioxide as part of the previous EU Biocidal Products Directive 98/8 EC.

In the second stage of certification, biocidal products containing such active substances or used as precursors on the market for the in situ production of chlorine dioxide have to be registered and certified in each country of the EU.

The full details of the complete certification process for the in situ generation of chlorine dioxide have not yet been laid down because discussions are still ongoing at the European Commission on consideration of the system technology used to generate chlorine dioxide. However, it is already clear that the sodium chlorite precursor needs certification while hydrochloric acid does not. With this in mind, the official registered name was therefore changed in April 2015 to “Chlorine dioxide generated from sodium chlorite by acidification”.

The process of certifying a substance as a biocidal product can only start once its biocidal active substance has been added to the Union list. We do not currently know when the ongoing approval process for the chlorine dioxide active substance will be complete.

It is important that users of our systems know that they do not need to worry about product certification themselves. We will arrange for appropriate certification, applicable for our customers, provided they operate their system as prescribed by us.

Ready for you:

Important for you: From 1 September 2015, only starting chemicals from sources published in the so-called Article 95 list (http://echa.europa.eu/de/information-on-chemicals/active-substance-suppliers) may be used.

Users of all chlorine dioxide systems must ensure that the sodium chlorite they use comes from a certified source. They should have their chemical suppliers confirm that the sodium chlorite supplied comes from a correct source according to EU Regulation No. 528/2012, Article 95.

ProMinent hereby confirms that BelloZon® chlorite comes from a source included in the Article 95 list.

As soon as certification as a biocidal product is possible, we will inform our customers of the current status.
Impacts of the European Biocidal Products Regulation on using chlorine electrolysis

The EU Regulation No. 528/2012 from 22.05.2012 affects the certification and marketing of biocidal products intended to fight harmful organisms in a chemical or biological manner.

Quote: “The aim of this regulation is to improve the functioning of the single European market by harmonising the specifications for the provision and use of biocidal products while also guaranteeing a high level of protection for humans, animals and the environment. The requirements of this regulation are based on the precautionary principle, which aims to ensure protection of humans, animals and the environment. Particular attention is dedicated to protecting at-risk groups.”

In the first stage of certification, biocidal substances have to be certified as “active substances” and added to what is known as the Union list. This step has already been initiated under the name “Active chlorine generated from sodium chloride by electrolysis”.

In the second stage of certification, biocidal products containing such active substances or used as precursors on the market for the in situ production of chlorine have to be registered and certified in each country of the EU.

The full details of the complete certification process for the in situ generation of chlorine have not yet been laid down because discussions are still ongoing at the European Commission on consideration of the system technology used to generate chlorine.

The process of certifying a substance as a biocidal product can only start once its biocidal active substance has been added to the Union list. We do not currently know when the ongoing approval process for the chlorine active substance will be complete.

Ready for you:

ProMinent has already taken all the necessary measures to be ready for the product certification process.

A letter of access to use the “Active chlorine generated from sodium chloride by electrolysis” active substance dossier already submitted has been obtained by the ProMinent subsidiary Van den Heuvel. It has already been added to the so-called Article 95 list (http://echa.europa.eu/de/information-on-chemicals/active-substance-suppliers).

As soon as certification as a biocidal product is possible, we will inform our customers of the current status.

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Impacts of the European Biocidal Products Regulation on using ozone

The EU Regulation No. 528/2012 from 22.05.2012 affects the certification and marketing of biocidal products intended to fight harmful organisms in a chemical or biological manner.

Quote: “The aim of this regulation is to improve the functioning of the single European market by harmonising the specifications for the provision and use of biocidal products while also guaranteeing a high level of protection for humans, animals and the environment. The requirements of this regulation are based on the precautionary principle, which aims to ensure protection of humans, animals and the environment. Particular attention is dedicated to protecting at-risk groups.”

In the first stage of certification, biocidal substances have to be certified as “active substances” and added to what is known as the Union list. This stage was initiated for ozone on 05.07.2015 when the EurO3Zon organisation set up for this purpose (www.euro3zon.org) submitted a dossier to the relevant authorities. It has already been added to the so-called Article 95 list (http://echa.europa.eu/de/information-on-chemicals/active-substance-suppliers).

ProMinent is a member of EurO3Zon and therefore has full access to the approval for the active substance.

In the second stage of certification, biocidal products containing such active substances have to be registered and certified in each country of the EU. For active substances generated in situ, the chemical precursor substance needed is usually considered as the product requiring certification. In its position paper “CA-May15-Doc.5.1.a - Final”, the European Commission made clear that for ozone this will only be needed if the operating gas oxygen is sold exclusively for the purpose of generating ozone. This procedure does not apply to ozone generation from air or generically available oxygen.

The full details of the complete certification process for the in situ generation of ozone have not yet been laid down because discussions are still ongoing at the European Commission on consideration of the system technology used to generate ozone. The process of certifying a substance as a biocidal product can only start once its biocidal active substance has been added to the Union list. We expect it to take at least a year for the active substance dossier to be approved so do not anticipate ozone being added to the Union list as an active substance before 2017.

Ready for you:

ProMinent is a member of EurO3Zon (www.euro3zon.org) and therefore has full access to the approval for the active substance.

Important for you as a user of our systems: You do not need to worry about product certification.

ProMinent will arrange for appropriate certification, applicable for you, provided you operate your system as prescribed by us.

As soon as certification as a biocidal product is possible for our ozone systems, we will inform our customers of the current status.