EUROPEAN COMMISSION
ENVIRONMENT DIRECTORATE-GENERAL

Directorate B – Protecting the natural environment
B.4 – Biotechnology and Pesticides

ESSENTIAL USE APPLICATION FORM FOR BIOCIDES

1. MEMBER STATES AND EEA STATES

Austria	☐	Belgium	☐	Cyprus	☐	Czech Republic	☐	Denmark	☐
Estonia	☐	Finland	☐	France	☐	Germany	☐	Greece	☐
Hungary	☐	Ireland	☐	Italy	☐	Latvia	☐	Lithuania	☐
Luxemburg	☐	Malta	☐	The Netherlands	☐	Poland	☐	Portugal	☐
Slovenia	☐	Slovakia	☐	Spain	☐	Sweden	☐	United Kingdom	☐
Iceland	X	Norway	☐		☐		☐		☐

2. ACTIVE SUBSTANCE

2.1. Common name	**Copper**
2.2. EC and/or CAS N°	EC No. 231-159-6/ CAS No. 7440-50-8
2.3. Molecular and Structural formula (including details on isomeric composition) – molecular mass	Cu Molecular weight – 63.546 Atomic number – 29
2.4. Method of manufacture (in brief terms)	Precursor of active substance. Copper electrodes are electrolysed to give the active ionic state
2.5.Specification of purity in g/kg or g/l as appropriate	>99.9% w/w
2.6. Identity of impurities and additives – including stabilisers	-
2.7. Origin of substance (in case of a natural substance)	Elemental copper

2.8. Physical chemical properties in accordance with Annex IIA, Point III, to Directive 98/8/EC, as appropriate	
2.9. A summary or toxicological and ecotoxicological information for the substance	A summary on toxicological and ecotoxicologial effects of Copper/copper ions can be found in the VRAR for copper published on ECHAs webpages

3. AVAILABLE INFORMATION ON THE ESSENTIAL USE

3.1. Product type and use(s) for which the derogation is required	Transmission hazards of *Legionella* have been associated with water distribution systems both on shore and offshore (drinking water, bathing water, showering water), public swimming pools (and swimming pools in hospitals) etc. Product type 2 (Private area and public health area disinfectants and other biocidal products) to prevent *Legionella* contamination in hot water including bathing water, showering water, public swimming pools, whirlpool spa water, in public health areas. Product type 5 (Drinking water disinfectants) to prevent *Legionella* contamination in internal cold water distribution systems including use as drinking water. Product type 11 (Preservatives for liquid-cooling and processing systems) to prevent growth of organisms such as microbes, algae and mussels in the main water inlet for offshore oil and gas platforms. The water is used for processing, drinking water and bathing water production, fire fighting and other purposes. To avoid blocking of the water inlet is essential for the safety and the function of the offshore installations. Product type 11 could also include use of copper/silver-ions in cooling tower water treatment as a supplement or alternative to chlorine treatment to combat legionella contamination.
3.2. Method(s) of application	Elemental >99.9% w/w copper electrodes are placed into water and are subjected to an electric current. This current electrolyses the elemental copper, releasing free copper ions (Cu^{2+}) into the water or to produce a concentrate for further dosage into the main water stream.
3.3. Number and timing of applications	The levels of copper ions are regulated by the water flow through a flow sensor. For instance, at no flow no copper ions are produced, at low water flow less current is passed between the copper electrodes and less copper ions are produced and at higher water flow the current that passes between the copper electrodes is higher and more copper ions are produced. Copper ion concentrations are adjusted to accomplish the protection needed in the specific application.
3.4. Classification & Labelling	Not classified.
3.5. Available data on effects on human or animal health and the environment (including exposure and risk assessment and proposals for risk mitigation) from the use	Use is not expected to pose any risk to health and environment since the amount of copper applied with use of the copper systems will result in copper concentrations below the drinking water quality standards. Toxicological and ecotoxicologial effects of Copper/copper ions are well described in the VRAR for copper published on ECHAs webpages

3.6. Information on efficacy	Enhanced antibacterial action when applying copper and silver together, rather than using the two metals alone, are well documented. Use of copper ions together with injection of chlorine ions for PT11 uses, reduce the concentration needed of chlorine and is considered the best practice in this area.

4 - JUSTIFICATION OF THE ESSENTIAL USE

4.1. Significance of the harmful organism

PT2 and 5:

Most serious organism is *the Legionella and the Legionella* has been identified as the causative agents of outbreaks and cases of disease in humans. Some of these cases have been fatal, especially, in immuno-compromised people, such as patients in hospitals.

People can contract legionnaires' disease by inhaling small droplets of water, suspended in the air, containing the bacteria created by a cooling tower, or water outlets.

PT11:
Different marine organism (microbes, algae and mussels) settles in the water inlets and further in the water handling systems of offshore installations. This growth can reduce or block the main water intake and this could be fatal for the health and safety of the staff and the production at the installation (fire fighting, cooling water in sensitive areas, and water supply for drinking water production).
Cooling tower is also an identified source for Legionella outbreaks in Norway.

4.2. Importance of the intended use and estimated scale of use - maximum quantity of active substance per year

Although 'background' copper (existing copper from copper pipework and copper pipes) in water distribution systems is often, between 0.1mg/l and 0.4mg/l at outlets (especially at hot outlets and outlets of water systems treated with oxidising chemicals), it is sometimes necessary to add copper to the copper already in water systems so that enough copper ions is consistently maintained at outlets to control *Legionella* in combination with silver.

The estimated scale of use is, therefore, difficult to predict because the copper and silver levels necessary to maintain *Legionella* control in hot and cold water systems vary from site to site and depend on the intensity of the contamination, the conditions available within the water system that promote *Legionella* growth, and the 'background' copper level already in the water system from existing copper pipework and copper pipes.

It is also difficult to provide a yearly maximum quantity of copper, as Cu^{2+}, that is delivered into the water supply by copper/silver ionisation.

For offshore installations the functioning of the water system is crucial for the supply of freshwater to all necessary activities on the installation offshore. 20-30 platforms in the Norwegian sector in the North Sea are constructed with Cu-chlorinators as antigrowth prevention system in the saltwater inlets. Typically a concentration of 5ug/l free copper ions and 50 ug/l hypochlorite ions are used. The use of Cu-chlorinators is considered BEP for offshore installations.

4.3. If the essential use is not permitted, what would be the consequences for health, safety, protection of cultural heritage or the functioning of society (including cultural and intellectual aspects)?

If use of copper for product types 2 and 5 is not permitted, supply of all copper-silver ionisation systems and associated consumables (replacement electrodes etc.) would need to cease and all existing systems that have been installed will need to be removed and replaced with alternative legionella control modalities. This includes installations in several hospitals, homes for elderly. This would significantly reduce the range of legionella control methods that are available for use in crucial infrastructure and may lead to an increased public health risk and will lead to substantial financial costs to the end users. Further details are given in section 5.2.

Offshore: If copper can no longer be used in existing offshore installation, one alternative would be to increase the dosage of chlorine in the water intake (1000 to 2000ug/l hypochlorite ions). This would in many cases require transport and storage of larger quantities of concentrated chlorine which is not considered favourable from a health and security perspective.

4.4. Need for the biocidal product / active substance in resistance or other pest management programmes (for example integrated pest management)

5 – WHY THE USE OF THIS ACTIVE SUBSTANCE IS ESSENTIAL

5.1. Active substances currently used [elsewhere in the EU/worldwide) to control the problem described in 4.1. and their approval/authorisation status

Chlorine dioxide (CAS Nr 10049-04-4; EC Nr 233-162-8) generated in situ from sodium chlorite (CAS Nr 7758-19-2; EC Nr 231-836-6) as an active substance in the framework of the Biocidal Products Directive has been notified. The following product types have been notified for chlorine dioxide:
PT 2: Private area and public health area disinfectants and other biocidal products
PT 3: Veterinary hygiene biocidal products
PT 4: Food and feed area disinfectants
PT 5: Drinking water disinfectants
PT 11: Preservatives for liquid-cooling and processing systems
PT 12: Slimicides

5.2. Evidence that there are no available technically and economically feasible alternatives or substitutes that could be acceptable from the standpoint of environment and health.

This essential use application for copper in PT 2 and 5 rests on two factors: the need for an adequate range of alternatives to minimise risks from legionella, and the fact that it is not feasible, either on technical or economic grounds, to remove and replace existing Cu/Ag systems.

The essential use application in PT 11 rests on the need to have an adequate range of technical and economic feasible alternatives available to reduce the risk of blocking the main water inlet with the health and safety consequences that could pose to the staff and to the production at the offshore installation.

a) Technical issues – need for an adequate range of alternatives

Current national and international guidance on legionella control sets out detailed principles and guidance on installing water systems for legionella control. It describes a number of options for control modalities and considerations to be taken into account in choosing between them.

These guidance documents clearly demonstrate that selection of a suitable system for control of legionella is complex and depends on a number of parameters including system design, age and complexity and water chemistry. There is no ‘magic bullet’ to enable effective control in every case, and each control method has both benefits and limitations, which are more or less relevant depending on the case. Given the consequences of inadequate control it is vital for the protection of public health that control methods are available that are effective in the widest possible range of circumstances so that risks are minimised. This requires that copper/silver ionisation remains as one of the available options.

Temperature control is the traditional approach to legionella control and is given as a possible option. On this approach hot and cold water are kept at temperatures outside the range at which legionella can multiply. This means that hot water should be stored at 60°C and distributed so that it reaches a temperature of 50°C within one minute at outlets. The water temperature at cold outlets should be below 20°C after running the water for 2 minutes. However, as with all modalities, there can be technical difficulties in maintaining the required hot and cold water temperatures throughout the system, for example, in older buildings with complex water systems. In addition flushing of the whole water pipe system with very hot water for a considerable time has been performed at regular intervals, but the hot water flushing process can pose a scalding risk. Use of hot water flushing would give additional energy consumption.

Other additional control methods can also be used, including the provision of alternative treatments involving other biocide applications. Where biocides are used to treat water systems, they will, however, like the temperature regime, require meticulous control if they are to be equally effective. These include:

Chlorine dioxide - Aside from copper/silver ionisation the major alternative biocide for use in control of legionella is chlorine dioxide. Chlorine dioxide has been shown to be effective in control of legionella in water systems, but its use is subject to constraining factors including the need for levels to be kept sufficient to be effective, but below the national drinking water limits. These issues may be mitigated through good management of the control system, but mean that chlorine dioxide may not be appropriate in every case for example in hospitals with patients groups sensitive to chlorine and vulnerable to allergic reactions from chlorine exposure.

Ozone and UV irradiation – These are also possible alternative control methods for legionella control. However they are severely limited in their utility since they do not provide a residual effect downstream of the point of application and are only intended to be effective close to the point of application and their efficacy in real operating water systems is questioned.

Copper/silver ionisation – This has demonstrated effectiveness in reducing legionella in hot and cold water including importantly, within the biofilm which collects on internal pipework, vessels and outlets within the whole storage and distribution system. However, as with other control methods, there are additional constraining factors that need to be taken into account, including the fact that electrodes can be susceptible to accumulation of scale and effectiveness is sensitive to water pH, meaning that pH control may be required. These are however well understood and may be controlled through an effective, managed service regime.

b) Economic considerations – cost of replacing existing systems.

Temperature control is a relevant possibility for legionella control in healthcare premises. However, there can be a problem with security using temperature control if flushing hot water through all the water pipes and water taps in the building. To avoid scalding when doing this treatment, you have to be very careful to prevent patients and staff using the water during the treatment. Hence, quite a few Norwegian hospitals, care homes and other buildings have moved to using copper/silver systems as their primary/singular modality for Legionella control. In these cases, removing copper/silver systems would at best require thorough redesign of existing systems at health risk and considerable cost and force a return to an inefficacious system.

In the absence of essential use derogation, use of all such systems will need to cease and duty holders will need to replace the decommissioned systems with an alternative to ensure that effective legionella control is maintained. That is not done overnight and therefore a demand for quick phasing out of the copper/silver ionisation systems would leave hospitals and care homes without legionella protection.

A replacement of existing systems in offshore installations (PT11) would require considerable reconstruction and increased operating costs.

6 - PROPOSED PLAN FOR A MORE PERMANENT SOLUTION

6.1. Evidence of a plan to submit a dossier for the evaluation and inclusion of the active substance in one of the annexes to Directive 98/8/EC

Several suppliers of copper and silver ionisation systems have informed the Norwegian CA that their EU-producer will submit a dossier to support copper through the biocide assessment process without delay and that they already have a dossier or are in the process of preparing a dossier.

All actors with copper for such uses on the marked should document that they either prepare and submit a substance dossier by them self, or are legally part of a task force with the same intention. The use pattern of each product on the market should be covered by the example products in the dossier. Deadline should be set at maximum of one year to submit. If dossier is found incomplete and no further work is undertaken to continue, no further derogation should be given. All actors should document that they participate in the work in line with the requirement (EU/528/2012) for all active substance suppliers on the European market.

6.2. Any outline of work carried out to develop an alternative or substitute to the active substance

No alternative required as support for copper will be being made by industry

7- OTHER INFORMATION

E.g.:
- Steps that are being taken to minimise the proposed uses
- Steps to minimise the emissions and human exposure associated with the proposed uses and waste management related to the biocidal product
- Acceptability of the active substance in light of the criteria in Annex VI of Directive 98/8/EC