FREQUENTLY ASK QUESTIONS (FAQ's)

INEOGIENE SDN. BHD. (1317881D)

No. 21, Lorong Valdor Jaya 3, Golden Gateway Perindustrian Valdor, 14200 Sungai Jawi, Pulau Pinang,Malaysia.
Email: contact@ineogiene.com
Website: www.ineogiene.com

1. EFFICACY

Hydrogen peroxide and silver: mechanisms of action

1.1 What is the oligodynamic effect?

The oligodynamic effect was first recognized more than 150 years ago and refers to the fact that some metal ions kill or inhibit the growth of microorganisms. This effect can be observed at extremely low doses. Metals which exhibit the oligodynamic effect include mercury, silver, copper, brass, bronze, tin, iron, lead and bismuth.

Of all metals, the strongest effect is exerted by mercury and silver.

1.2 Why and how silver acts as a biocide

Silver has 3 different mechanisms of action

- Metal ions affect cell membrane permeability. This weakens sensitive micro-organisms and makes them enormously more sensitive to oxidizing biocides.
- Silver binds to sulphur bridges in proteins, disrupting microorganism enzyme activity. (Silver forms a sulphide with thiol groups and reacts with amino and carboxy groups on enzymes, inactivating them.) This limits the cell's ability to generate energy, with the result that they 'starve' to death.
- Silver forms complexes with microorganismal genetic material (DNA and RNA), disrupting reproduction. Reproduction is inhibited or arrested completely.

1.3 What is hydrogen peroxide?

Hydrogen peroxide is a chemical compound consisting of two hydrogen atoms and two oxygen atoms. It was discovered over 200 years ago. It has the chemical formula H2O2. When it decomposes, hydrogen peroxide breaks down into water (H2O) and oxygen (O2).

1.4 How does hydrogen peroxide act as a disinfectant?

Hydrogen peroxide readily decomposes, especially in contact with organic material. This produces highly reactive, short-lived atomic oxygen. This reacts with and attacks the surface of microorganisms, for example.

1.5 Why is it useful to combine hydrogen peroxide with Silver?

Oligodynamic effects take some time to kick in and are not equally effectively against all micro-organisms. Silver therefore primarily exerts a long-lasting, preservative, bacteriostatic effect.
Higher doses of silver do not necessarily work faster or better. One option, therefore, is to enhance the biocidal effect of silver by using it in combination with other substances.

In combination with oxidizing substances such as hydrogen peroxide, the effects are synergistic, producing a highly effective biocidal complex.

2. Health considerations
Questions and answers on the safety and toxicology of hydrogen peroxide and silver

2.1 Is silver a heavy metal?

The term 'heavy metal' is generally used to refer to a group of metals with densities greater than 5.0 g/cm³. Under this definition, silver, which has a density of 10.49 g/cm³, is indeed a heavy metal – as are iron (7.9 g/cm³), nickel (8.9 g/cm³), copper (8.9 g/cm³) and gold (19.32 g/cm³).

Heavy metals which are particularly resistant to corrosion are known as noble metals. These include gold, silver and platinum group metals.

It is their corrosion resistance and lack of reactivity that makes noble metals suitable for use in jewelry and dental implants.

(Fun fact: artificial joints, catheters and plates for broken bones are coated with silver to inhibit bacterial growth.)

2.2 Is silver toxic?

Like almost everything else in this world (salt, alcohol, water, Big Macs, etc.) silver is not completely 'non-toxic'. "The dose makes the poison," as the famous pharmaceutical saying goes.

A number of different maximum doses are therefore defined for silver, depending on the form in which it is used. Conversely, this means that as long as these permitted doses are not exceeded silver is harmless and therefore nontoxic.

…an exciting calculation:

A silver poisoning requires a cumulative dose of at least 1000 mg silver.

One litre of water with an average content of 20 ppm Sanosil contains 0.01 mg of silver. For comparison: one litre of American milk contains between 0.025 and 0.054 mg silver (Murthy and Rhea, 1968).
1000 mg of silver corresponds to 100,000 litres of Sanosil-treated water.

So if you drank 3 litres of water a day, it would take you 33,333 days to drink this amount of silver.

That's 91.3 years. And that's assuming that the silver is 100% water soluble and completely absorbed by the body.

Published research has shown, however, that 90% of silver ingested in food exits the body via the gut (Furchner el al., 1968).

You would therefore have to **drink 3 litres of water disinfected with Sanosil every day for 913 years** before experiencing any toxic effects.

2.3 What are the main reasons for the safety of silver in the Sanosil disinfectant?

- Silver is a noble metal and, like gold and copper, one of the heavy metals.
- Like everything else, at a high enough dose silver can be poisonous. But to poison yourself with the silver contained in Sanosil, is impossible in case of professional application
- To poison yourself with the amount of silver in Sanosil, you would need to drink 3 litres of water containing 20 ppm Sanosil per day for about 910 years.
- For someone weighing 70 kg, the EPA considers an intake of 0.35 mg of silver per day to be safe. That corresponds to 5 litres of water containing 20 ppm Sanosil or 3.5 litres containing 30 ppm Sanosil.
- A litre of water containing 20 ppm Sanosil contains less silver than a litre of American milk. Consequently, no environment agency has ever banned the discharge of coolant water treated with Sanosil into surface water.
- By a surface disinfection with Sanosil, silver remains as a slight residue, and sticks very hard on it. This residue can only be removed by mechanical cleaning. It is impossible that this silver is detached from the surface by itself as dust or vapor and float in the air. Accumulation of the silver strains by repeated spray-and-wipe applications is also not possible.
- Silver residues on a square metre surface cold fogged with Sanosil weigh less than a grain of salt or 1/10 amount of vitamin C in a lemon.

2.4 Is hydrogen peroxide toxic?

Hydrogen peroxide is made up of oxygen and hydrogen atoms. It decomposes into water and oxygen without leaving any residue, and is a powerful oxidising agent. This means it can be harmful at higher concentrations or in greater quantities. At low doses or appropriately diluted, it is immediately neutralised by the catalase and peroxidase enzymes produced by our bodies, which break it down into water and oxygen.
Hydrogen peroxide solutions are used in the healthcare sector for direct disinfection on or in people, e.g. disinfecting the mouth or throat, bladder irrigation, dental cervix treatments, ear irrigation, etc. It is also used as a preservative and disinfectant in a variety of face creams.

At concentrations in excess of 1.5% (30,000 ppm Sanosil) hydrogen peroxide can cause skin irritation. Personal protective equipment is therefore used when applying stronger solutions.

3. Residues
Facts on residues of Sanosil after application

3.1 Water/Drinking water
3.1.1 Safety of silver: limit values and legal anchoring

It's a fact that consuming small quantities of silver is not harmful to humans, but what counts as 'small quantities'?

Although there isn't a definitive rule on this, a comparison of opinions from a range of organisations results in a figure of 0.1 mg in drinking water. The WHO states that: "*Higher levels of silver, up to 0.1 mg/litre (this concentration gives a total dose over 70 years of half the human NOAEL of 10 g), could be tolerated in such cases without risk to health.*"

Different law sources around the world:

Switzerland: TBDV, Verordnung des EDI über Trinkwasser sowie Wasser in öffentlich zugänglichen Bädern und Duschanlagen Version 2017

Silver in drinking water: **0.1 mg/kg**. This is equivalent to about 200 ppm of Sanosil in water.

Germany: Verordnung über die Qualität von Wasser für den menschlichen Gebrauch, TrinkwV 2001 (Ordinance on the quality of water for human consumption)

Substances used for water treatment and disinfection procedures

Silver; silver chloride: **0.1 mg/l**, after finishing treatment 0.8 mg/l

USA: EPA – National Secondary Drinking Water Regulations (NSDWRs)

List of National Secondary Drinking Water Regulations

Silver: 0.1 mg/l

WHO, Guidelines for Drinking Water Quality 2003 (WHO/SDE/WSH/03.04/14)
Where silver salts are used to maintain the bacteriological quality of drinking water, levels of silver **up to 0.1 mg/litre** can be tolerated without risk to health.

3.1.2 Is it possible to give yourself silver poisoning using the regulation dose of Sanosil in drinking water?

Silver poisoning requires a cumulative dose of at least 1000 mg of silver.

One litre of water with an average content of 20 ppm of Sanosil contains 0.01 mg of silver. For comparison: one litre of American milk contains between 0.025 and 0.054 mg (Murthy and Rhea, 1968).

1000 mg of silver corresponds to 100,000 litres of Sanosil treated water.

So if you drank 3 litres of water a day, it would take you 33,333 days to drink this amount of silver.

At 365 days a year, that would take 91.3 years. And that's assuming that the silver is 100% water-soluble and completely absorbed by the body.

However, scientific articles state that 90% of the silver in food exits the body via the gut (Furchner et al., 1968).

You would therefore have to drink 3 litres of water disinfected with Sanosil every day for 913 years before experiencing any toxic effects.

3.2 Surfaces

3.2.1 How much silver is left on the surface after spray-wipe disinfection?

Spray-wipe disinfection of a 1 m² area with 20 ml Sanosil S003 using a damp cloth or mop involves the application of approximately 0.0006 g silver. That's the weight of 2-3 grains of sand.

3.2.2 Is it possible for the silver to be released into the air after application, and be inhaled for example?

The silver binds tightly to the surface and can only be removed by mechanical

cleaning with water and a cleaning agent. This has been verified in practical trials (dry rubbing with laboratory wipes).

3.2.3 Does the silver concentration on a surface increase with repeated spray-wipe disinfection?

Repeated wipe disinfection does not result in the accumulation of silver, because the amount of new silver applied is roughly equivalent to the amount of silver removed through rubbing/adhesion to the cloth.

3.2.4 How long does it take for the hydrogen peroxide to decompose into water and oxygen?

Usually, as long as it takes for the surface to dry.

3.3 Air / Aerosol

3.3.1 What happens to the active substances hydrogen peroxide and silver after Sanosil has been pumped into the air as an aerosol?

Firmly bound to each other, the two substances float through the air as drops until they land on a surface. There the hydrogen peroxide decomposes into water and oxygen, while the silver remains on the surface. It's a bit like the limescale in the water in an ultrasonic humidifier: after a few days of use, this limescale, deposited as a white precipitate, needs to be wiped off the floor around the humidifier.

3.3.2 Is it true that, following aerosol disinfection, the hydrogen peroxide evaporates into the air and that the silver stays in the air in the form of a fine powder and can be inhaled?

No – this is nonsense. Because the silver is tightly bound to the hydrogen peroxide, it is deposited on the surface with the hydrogen peroxide (or with the water formed when it decomposes), and it adheres relatively firmly to this surface. (During practical testing, it was almost impossible to remove any more silver from smooth test surfaces using dry wiping with laboratory wipes.)

3.3.3 Can the silver deposited after Sanosil aerosol disinfection damage electronic equipment?

No. Even after hundreds of disinfection cycles, the amount of silver deposited would be too small to cause this type of damage.

3.3.4 How much silver remains on surfaces after aerosol disinfection?

99.995% of cold fogged Sanosil decomposes into water and oxygen within a useful period of time. An amount of silver residue that equates less than the weight of a grain of sand remains on a 1 m² surface in a room in which Sanosil has been cold fogged at an effective concentration – which approximately corresponds to just a tenth of the amount of vitamin C in a lemon.

4. Aerosol disinfection
Questions and answers about aerosol technology

4.1 Can the aerosol disinfection replace the classic cleaning / spray-wipe disinfection?

No, that will not work. Although aerosol disinfection offers a complete and thus better coverage of all surfaces than wipe disinfection, it has a reduced penetration due to the relatively low quantities of disinfectants.

Aerosol technology is an additional level of safety / measure to mitigate microbiological risks.

4.2 What means AFNOR NFT 72-281 Test?

AFNOR NFT 72-281 designates a French test standard that has become established as the standard method for verifying the effectiveness of airborne surface disinfection systems and is also used by the BPR, the European Biocidal Product Regulation. Around 70% of the aerosol systems offered do not meet AFNOR NFT 72-281 requirements.

Reason: This test standard is extremely strict and difficult to fulfill - germs, which are protected by a film of dried milk fixed on steel platelets, must be killed by an indirect spraying method in a defined time.

Critics complain that while this is a quality feature for systems that meet these conditions, the test conditions do not adequately reflect the reality of a thoroughly pre-cleaned room.

The Sanosil Q-Jet Superior equipped with Sanosil S015 has passed the AFNOR NFT72-281 test. (This also applies to the identical Q-Jet Advanced).

4.3 Why is even a system with passed AFNOR-NF T 72-281 test not a full replacement for a classic spray-wipe disinfection?

In order to comply with the AFNOR-NFT 72-281, a relatively large amount of disinfectant with high hydrogen peroxide must be introduced into the room.

Although this ensures proper disinfection, even if the surfaces are not perfectly cleaned, but the decomposition of the peroxide and thus the earliest possible reuse of the room will take longer.

In the end, it is always a balance of the various pros and cons, how cleaning, wipe disinfection and aerosol disinfection are combined to a method that best suits the customer's needs.

4.4 Is a dosage of 1-4 ml / m3 with a 3-5% H2O2 product even effective?

It is sometimes claimed to be able to achieve useful disinfection results even with 1-4 ml of hydrogen peroxide-containing (active substance concentration 3-5%) disinfecting agent per m3 of air ...

This is not completely a lie, but you have to see such statements in the right proportions.

If a space of 5m x 4m x 2.5m = 50m3 or 85m2 surface (floor, walls, ceiling) is loaded with 1ml / m3, the concentration of active substance reaches 0.59 ml / m2.

Ideally, such dosage is barely sufficient on a perfectly pre-cleaned area with weak test bacteria such as e.g. E-Coli to achieve a measurable result with Log 1-2.

Claims that it would be possible to reach log 4 (99.99% germ reduction) with such low dosages are certainly dubious!

According to our experience, for simple standard disinfection with different aerosol devices, at least 8 ml / m2 of disinfectant (with at least 5% hydrogen peroxide concentration) is required.

For more demanding tasks, such as an AFNOR NFT 72-281 test, volume and concentration must be increased accordingly.

4.5 How quickly can a room be reused after an aerosol disinfection?

This depends on the amount of disinfectant used, which in turn is related to the requirements of the user (decontamination at low bacterial load up to demanding tasks under hard AFNOR NFT-72-281 conditions).

We recommend a minimum waiting time of at least 120 minutes under standard conditions.

4.6 How much silver remains on surfaces after aerosol disinfection?

99.995% of cold fogged Sanosil decomposes into water and oxygen within a useful period of time. An amount of silver residue that equates less than the weight of a grain of sand remains on a 1 m² surface in a room in which Sanosil has been cold fogged at an effective concentration – which approximately corresponds to just a tenth of the amount of vitamin C in a lemon.

4.7 Could it be, following aerosol disinfection, the hydrogen peroxide decomposes and that the silver stays in the air in the form of a fine powder?

No – this is nonsense. Because the silver is tightly bound to the hydrogen peroxide, it is deposited on the surface with the hydrogen peroxide (or with the water formed when it decomposes), and it adheres relatively firmly to this surface. (During practical testing, it was almost impossible to remove any more silver from smooth test surfaces using dry wiping with laboratory wipes.)

4.8 Can the silver deposited after Sanosil aerosol disinfection damage electronic equipment?

No. Even after hundreds of disinfection cycles, the amount of silver deposited would be too small to cause this type of damage.

5. EU Biocide Regulation and BPR

Biocide Product Registration

Legislation on access for hydrogen peroxide and silver in the course of the EU Biocidal Law

5.1 What's the ECHA?

The european agency for chemical registration owns and mainteances a data base with authorized substances in the European Union. Biocides are a separated part uf this list.

5.2 What is regulated in the EU biocide regulation?

Biocidal products may only be marketed in the EU (and other countries such as Switzerland) if they are authorized under the EU Biocidal Products Regulation. This also applies to preservatives which are added to other products for preservation. The aim of this regulation is that only tested and "safe" biocidal products can be marketed more easily within the EU and associated countries.

5.3 Can every manufacturer register biocidal products according to BPR?

No, only companies and manufacturers who have access to the ECHA-listed biocidal active substances (LoA = Letter of Access) may do so.

Sanosil AG holds a LoA for hydrogen peroxide (CAS 7722-84-1) and silver (CAS 7440-22-4).

5.4 Can every manufacturer sell biocidal products?

No, only companies and manufacturers who register their disinfection products in the EU in compliance with BPR are allowed to do so.

5.5 Are the Sanosil raw materials and products biocide - compliant?

The patented Sanosil products contain the active ingredients hydrogen peroxide (CAS 7722-84-1) and silver (CAS 7440-22-4). Both products are listed at ECHA. Thus, the sale and use in the EU (and other states that follow their directives) is legal. This certificate is also known as a letter of access. Following the final EU assessment of the raw materials, the individual Sanosil products are registered in the respective product groups according to BPR.

5.6 What does this mean for Sanosil customers / partners?

The market access of Sanosil products to the EU is and will be ensured in the long term and will be further consolidated.

6. Copycat Products
Copycats, further hydrogenperoxide & silver biocides

6.1 Are there any Sanosil copycat/replica products on the market?

Yes, there are. Word of the exceptionally successful combination of hydrogen peroxide and silver has of course spread and has spurred the occasional imitator into action. Fortunately, deliberate counterfeits (i.e. products which are fraudulently sold under the Sanosil name) are rare.

6.2 Are there any differences between the original Sanosil product and these copies?

There are a few Sanosil copies which, as long as they are fresh, have a very similar concentration of active ingredients to the original. However, we have been told by a number of sources that the shelf life and stability of these products over a period of several months presents problems in many cases.

In addition, many of our imitators do not have legal access to silver, to enable them to properly declare it in accordance with ECHA (European Chemicals Agency) regulations. As a result, these companies often either avoid mentioning the silver content or deny its biocidal effect, with silver instead being listed as a 'hydrogen peroxide stabiliser'.

6.3 "Silver-stabilised hydrogen peroxide"

Some manufacturers of copycat products claim that silver is not a biocide and is merely included as a stabiliser for hydrogen peroxide. Why is that?
To legally market and sell a biocide, all biocidal active substances must be registered in accordance with the EU Biocides Directive and the ECHA list. Sanosil has of course completed this protracted and costly process. However, to save money, certain imitators have omitted this step, and are therefore not legally permitted to describe the silver in their products as a biocide. For this reason, they slyly omit to mention the silver content, or cleverly maintain that the silver is just there as a 'stabiliser'. Because as long as you don't mention the biocidal effect, it doesn't come under the Biocides Directive…

Why is it so easy to debunk this claim?

In the European Union, biocidal products are subject to the Biocidal Products Regulation (Regulation (EU) 528/2012). Article 3(1) of this regulation defines a biocidal product as:

"*Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,*"

And

"*Any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.*"

According to this definition, silver and silver salts are quite clearly biocides. The literature contains countless documents testifying to its oligodynamic effects, and that it therefore meets the criteria set out in the EU Biocidal Products Regulation. Silver and silver salts are also listed as biocides in the ECHA list, Directive 98/8/EC (Biocidal Products Directive) and Regulation (EU) 528/2012.

Faced with this weight of evidence, anyone who tries to claim that silver is just

a stabiliser is either oblivious or is simply unscrupulous.

7. Patents and Distribution Rights
Sanosil product patents

Patents

7.1 Is Sanosil patented?

The original Sanosil composition and manufacturing process was patented in all relevant markets and industrial nations in order to protect our intellectual property. In 2011, we achieved market readiness for a modified, improved manufacturing process, which was also immediately registered for patent protection.

7.2 So how is it possible that there are other hydrogen peroxide and silver biocides on the market despite Sanosil's patents?

Because a patent eventually expires, legal generic versions of the product can be brought to market, assuming the manufacturer possesses the necessary expertise. However, these are based exclusively on the obsolete manufacturing process from 1983, for which the patent has expired.

In addition, without expending an enormous amount of effort, it is not possible to stop certain unscrupulous competitors from marketing their products as "stabilised hydrogen peroxide" whilst avoiding any mention of, or concealing the silver content of their products. We are of the opinion that this is a clear case of deception and we reject all such practices.

8. Sanosil Product History
About the invention of the Sanosil disinfectants

8.1 Who invented Sanosil and its combination of hydrogen peroxide and silver, and how?

In 1980, an innovative young chemist, who would go on to be the CEO of Sanosil, noticed that there were very few water disinfection methods and products on the market and that all of the available products had serious drawbacks. They were either very short-lived (chlorine, bromine, or ozone) or very harmful to the environment (chromium, isothiazolinone, or QACs).

It would fantastic if someone could create a fast-acting, environmentally friendly disinfectant with long-lasting effects. Although combining hydrogen peroxide and silver is not a new idea, no-one had ever managed to combine

the two without them sooner or later breaking each other down.

With the aid of countless attempts and the generous support of a former mentor and chemistry professor at the University of Zurich, he finally managed for the first time to produce a solution which was and remained stable. Sanosil Super 25 was born. After a lengthy odyssey of approval processes by the required approval authorities, patent offices and expert laboratories, he established the Sanosil AG company in 1982.

***Mr. Janos H. Gömöri**, CEO and Founder of Sanosil Ltd.*

8.2 Was Sanosil the first company to sell a hydrogen peroxide/silver formulation?

Yes, Sanosil AG was the first company to sell biocides with this combination of active ingredients.

9. Product Safety
About the National Pharmaceutical Regulatory Agency (NPRA)

9.1 What is National Pharmaceutical Regulatory Agency (NPRA)?

The National Pharmaceutical Regulatory Agency (NPRA), formerly known as the National Pharmaceutical Control Bureau (NPCB), was set up in October 1978 under the quality control activity of Pharmacy and Supply Programme.

Beginning 1985, NPRA was given the task of ensuring the **quality**, **efficacy** and **safety** of pharmaceuticals through the registration and licensing scheme. This is achieved through evaluation of scientific data and laboratory tests on all products before they are marketed. A system to monitor products in the

market was set-up. Information on drugs for medical professionals and consumers was made available through a drug information service.

In 1996, NPRA was given an international recognition by the World Health Organisation (WHO) as a "WHO Collaborating Centre for Regulatory Control of Pharmaceuticals". This recognition is an acknowledgement from WHO for NPRA's contribution in the field of regulatory affairs.

9.2 What is the purpose of National Pharmaceutical Regulatory Agency (NPRA)?

The infrastructure and facilities were designed to meet the requirements for testing and quality control activities.

9.3 Is Sanosil S010 a KKM's approved product?

Yes, Sanosil S010 is KKM approved product as Surface Disinfectants. The product registration of Sanosil S010 product is approved with product registration number SD20220400010 with valid date from 1st April 2022 until 31st March 2024 for the use area of deodorant sprays in the food industry, domestic and public institutions.