



NANOPOWDERS USED IN THE MEDICAL INDUSTRY

1. Case metadata

▪ ***Country/ies of origin:***

Romania

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▪ ***Sector:***

8610 Hospital activities

▪ ***Keywords:***

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24361C Good practice

24401C Case studies

40251B Nanoscale materials

40271B Nanotechnology

40256C Nanoparticles

19641D Risk assessment

18161E Chemical safety

01201D Small and medium-sized companies

2. Organisations involved

SC VELFINA SA, Campulung, Arges

Clinical Hospital Timisoara

Children's Emergency Hospital Cluj-Napoca

Buzau Country Hospital

3. Description of the case

3.1. ***Introduction***

There are multiple ways to achieve bacterial or fungal decontamination, but all methods have a high risk concerning human health.

Many researches have revealed that the most important characteristic of zinc oxide is the strong antibacterial and fungicidal activity, the result of photocatalytic effect due to UV radiation. Due to this, zinc oxide can be used successfully in different fields, especially in medical wards with a high risk factor for infection with pathogenic microorganisms.

But numerous studies demonstrate that the inhalation of zinc oxide fine particles can have catastrophic consequences for human health. The inhalation of these particles leads to their lodging in the lungs, which causes cardiovascular disease, or other diseases.

Because of this, researchers have tried to find new ways to use the antiseptic properties of zinc oxide without affecting the health of those who are using this substance.

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Specialists from Velfina SA have implemented the result of the research that was conducted by researchers at IMNR Bucharest in collaboration with other specialised institutes in Romania.

These researchers have developed a technology for the impregnation of bioactive, antimicrobial and UV protection textiles. Zinc oxide particles were embedded in polymer matrices, which represent a good example of functional nanostructures with potential in UV protection for textiles applications and antibacterial finishes on textile materials for medical use.

Together they conducted research on titanium dioxide, which has been used in the gas phase synthesis process, from which were obtained micro-and nanospheres of titanium dioxide doped with silver, gold, platinum or iron. The results reveal the ability of the process to synthesise nano-crystalline powders with controlled grainometric size dispersion.

Using these nanoparticles with antibacterial and antimicrobial properties, such as those that contain silver, embedded in an oily base to be applied, ideally, on a substrate of polyester mesh, can bring a real benefit for patients and users in case of existence risk of wound infection.

The steps to be taken to achieve such a product consist, by large, in establishing the characteristics of an impregnation base, establishing the characteristics of the bandage support, to define their packaging, clinical trials for toxicity and tolerance in the binding in conformity with ISO 10993, in terms of cytotoxicity, irritability and sensitivity.

Romanian researchers have conducted studies to determine the mechanisms and process parameters that influence the characteristics of interface / surface and material properties in order to achieve textile impregnation with zinc oxide or titanium dioxide nanopowders doped with silver.

These nano-structured powders with applications in developing antiseptic impregnated materials have been developed and tested at Velfina SA.

The precautions for the protection of employees who will produce these products on a large scale were assessed at Velfina SA.

Before applying these products in Romanian hospitals such as the emergency hospital in Timisoara, Cluj Napoca children's hospital and the emergency hospital of Craiova, Velfina Sa representatives organised training sessions in hospital for medical staff on the correct use of these products.

3.2. Aims

Zinc oxide nanostructured powder with 1.5% Ag is a new product, being the result of experimental research of the National Institute for Research and Development of Nonferrous and Rare Metals - IMNR, Nanostructured Materials Laboratory, for the Project INNOVATION 202/2008 'Impregnated bandages with triglycerides and ZnO nanoparticles with Ag for treatment of wounds at risk of super infection.'

Impregnated dressing manufacturing process in SC Velfina SA, is made in the Clean Room cleanliness class D (ISO Class 8), in accordance with SR EN ISO 14644-1: 2002-Cleanrooms and associated controlled environments - Part 1: Classification of air cleaning and SR EN ISO 14644-2:2002 - Cleanrooms and associated controlled environments - Part 2: Specifications for testing and monitoring to demonstrate compliance with ISO 14644-1.

The aim of the Velfina is to get products more efficient (respecting the above mentioned standards) and more cleaner with minimal risks for workers exposed to nanopowder.

3.3. What was done, and how?

Velfina SA decided to undertake a number of technical and organisational measures to prevent the exposure to zinc oxide and titanium dioxide nanoparticles that are used for antimicrobial impregnation of textiles used for medical use.

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They use mixers in the closed system, which do not allow nanoparticles to be dispersed into the air. (See Figure 1). This closed mixer contains the hydrogels based on zinc oxide or titanium dioxide doped with silver.

Figure 1: Mixer for obtaining hydrogels based on zinc oxide and titanium dioxide doped with silver



The impregnated dressing manufacturing process in SC Velfina SA, is made in the Clean Room cleanliness class D (ISO Class 8), in accordance with SR EN ISO 14644-1: 2002-Cleanrooms and associated controlled environments - Part 1: Classification of air cleaning and SR EN ISO 14644-2:2002 - Cleanrooms and associated controlled environments - Part 2: Specifications for testing and monitoring to demonstrate compliance with ISO 14644-1.

The workspace is separated from the other workplaces, where the environmental conditions (temperature, pressure, humidity) are controlled.

To protect workers during the process in which nanoparticles are used, the organisation took a series of measures that were based on information contained in the safety data sheet issued by the manufacturer.

Storing the product is made in the original container, pack brown bottle, labelled, sealed, and protected in bubble wrap or expanded polyethylene, in cardboard boxes, in a closed space, under the strict supervision of trained and designated staff for this purpose.

Product handling is done by trained personnel who is equipped with appropriate work equipment consists of trousers, shirt, capelin, work shoes and personal protective equipment (PPE) consisting of goggles, protective mask and latex gloves. The appropriate hygienic measures (changing rooms, showers, rest room, sanitary materials) are provided. Also the technologic process of obtaining impregnating substance comprises of an initial phase in which the mixture between the nanostructured powder of zinc oxide with silver and triglycerides is obtained, then it is mixed with the other components to minimise the limits of occupational exposure for the risk of dust formation in higher concentrations. The blending is done in a mixer that is hermetically sealed.

Organisational measures:

Provided first aid measures that were aimed as interventions in cases of inhalation, skin contact, eye contact, and ingestion.

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Measures to be taken in case of accidental loss are isolation and product collection with a vacuum cleaner or by wet cleaning. The resulting waste product is disposed of in a controlled manner, in airtight containers, in compliance with environmental protection measures.

The personnel involved in the manufacturing process is properly and regularly trained in accordance with the applicable legislation and specific internal procedures specific of the Integrated Quality and Environment Management, OHSAS implemented in SC Velfina SA, which includes system procedures and work instruction, health and safety instructions, first aid measures, fire fighting measures, measures of environmental protection.

3.4. What was achieved?

- Product handling is done by trained personnel, who is equipped with appropriate work equipment consisting of trousers, shirt, capelin, work shoes and protective equipment consisting of goggles, protective mask and latex gloves. Also, are provided appropriate hygienic measures (changing rooms, showers, rest room, sanitary materials).
- Technologic process of obtaining impregnating substance comprises an initial phase in which is obtained the mixture between the nanostructured powder of ZnO with Ag and triglycerides, then it is mixed with the other components to minimise the limits of occupational exposure to the risk of dust formation in higher concentrations. The blending is done in a mixer that is hermetically sealed.
- Personnel involved in the manufacturing process is properly and regularly trained in accordance with applicable legislation and specific internal procedures specific of the Integrated Quality and Environment Management, OHSAS implemented in SC Velfina SA, which includes system procedures and work instruction, health and safety instructions, first aid measures, fire fighting measures, measures of environmental protection.

3.5. Success factors

Specialists from Velfina SA have implemented the result of the research that was conducted by researchers at IMNR Bucharest in collaboration with other specialised institutes in Romania.

These researchers have developed a technology for the impregnation of bioactive, antimicrobial and UV protection textiles. ZnO particles were embedded in polymer matrices, which represent a good example of functional nanostructures with potential in UV protection for textiles applications and antibacterial finishes on textile materials for medical use.

Together they have made research and TiO₂, which has been used in the gas phase synthesis process, after which we obtained micro-and nanospheres of TiO₂ doped with Ag, Au, Pt or Fe. The results reveal the ability of the process to synthesise nano-crystalline powders with controlled grainometric size dispersion.

Using these nanoparticles with antibacterial and antimicrobial properties, such as those that contain silver, embedded in an oily base to be applied, ideally, on a substrate of polyester mesh, can bring a real benefit for patients and users in case of existence risk of wound infection.

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The workers from Velfina get competitive products that are very good for hospital activities, without inhaling nanopowders during the production process.

3.6. Further information

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3.7. *Transferability*

Investigations performed on the synthesis and characterisation of nanostructures based on zinc oxide and titanium impregnated in textile materials showed the efficiency and reproducibility of methods of synthesis of nanostructures developed based on textile impregnated with the ZnO nanoparticles doped with Ag. These underpin the application in wound bandages to reduce risk in case of hyper-infection, serious burns and injuries.

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4. References, resources:

- www.velfina.com
- <http://www.imnr.ro/sinaps/anunt.html>