



# Copper Inside

## MUNNBIND

TYPE IIR

CE-sertifisering EN14683:2019 +AC:2019

### TÜV TEST

#### Summary of Test Results

NO	TEST ITEM	TEST STANDARD	JUDGEMENT
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
2	Differential Pressure Test	EN 14683:2019+AC:2019(E) Annex C	Pass
3	Synthetic Blood Penetration Test	ISO 22609:2004	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	Pass

### TRYGT I BRUK

#### 1. "A Novel Anti-Influenza Copper Oxide Containing Respiratory Face mask"

a. Mengden kobber som frigjøres fra munnbindet til omgivelsene er langt under grensen som er satt av USA's Occupational Safety and Health Administration (OSHA), ( $>10^5$  ganger lavere)

b. Mengden kobber som inhaleres fra masken er langt under grensen som er satt (the lowest observed-adverse-effect levels (LOAELs), ( $>10^6$  ganger lavere)

#### 2. "Safety of Using Copper Oxide in Medical Devices and Consumer Products"

a. Produkter med kobberoksid har blitt testet i 9 kliniske studier og i mange ikke-kliniske studier og funnet å være ikke-irriterende, ikke-sensibiliserende og trygge å bruke, uten at det er registrert en eneste negativ effekt hverken i kontakt med intakt eller skadet hud

b. Bruk av kobberoksid i konsumentprodukter og medisinsk utstyr som kommer i kontakt med hud er trygt og sikkert



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## Safety of Copper Oxide Impregnated Fabrics

The safety of impregnated external nonwoven fabric layers were tested according to the biocompatibility tests described in the table below. All tests were conducted in independent laboratories using Good Laboratory Practices (GLP) All tests passed successfully, demonstrating the high safety of the masks.

TEST	STANDARD	RESULT	LABORATORY
Cytotoxicity	ISO 10993-5	No Cytotoxicity	Namsa, USA
Skin Irritation	ISO 10993-10	No irritation	Namsa, USA
Intracutaneous reactivity	ISO 10993-10	No reactivity	Namsa, USA
Systemic Toxicity	ISO 10993-11	No toxicity	Namsa, USA
Maximization sensitization	ISO 10993-10	No skin sensitization	Namsa, USA
Pyrogenicity	ISO 10993-11	No pyrogenicity	Namsa, USA
Particle Leaching	FDA cleared protocol	No leaching at all of copper microparticles	Scientific Solutions, Israel
Elution of copper during breathing	FDA cleared protocol	>10 <sup>5</sup> fold below toxic threshold	Scientific solutions, Israel
Elution to simulated saliva	FDA cleared protocol	>4 times lower than minimal risk level (MRL) for oral exposure to copper	Scientific Solutions, Israel

MedCu copper-oxide impregnated nonwoven fabrics have been used safely for years in adult diapers, antimicrobial wound dressings and medical face masks, which have been cleared by the FDA and other regulatory bodies

**Jørn Klein**  
**Professor i mikrobiologi**

*«Kobber har potente egenskaper som kan slå hjel levende organismer og derfor kan kobber inaktivere bronkittvirus, poliovirus, hiv og influensavirus. Når produkter impregneres med kobberoksid, skapes en antiviral overflate som har selvsteriliserende egenskaper. Kobberoksid som inkorporeres i masker, dreper viruspartikler som lett forblir i vanlige munnbind. Dette er av stor betydning ettersom virus forblir smittsomme i vanlige munnbind»*



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Current Chemical Biology

## Safety of Using Copper Oxide in Medical Devices and Consumer Products

Gadi Borkow

### Abstract:

Copper has two key properties that make it an active ingredient in the medical devices currently being developed. First, copper is an essential trace element needed by humans, which plays a key role in many physiological processes in different tissues. For example, copper has been shown to be involved in angiogenesis and in wound healing. Second, copper has very potent antibacterial, antifungal, antiviral, and acaricidal properties.

Recently, a novel technology has been developed that introduces copper oxide particles into polymeric materials, where they serve as a slow release source of copper ions. For example, by using this technology, copper oxide containing wound dressings that enhance wound healing; copper oxide containing antiviral respiratory masks that reduce the risk of infection; socks that protect from athlete's foot, and acaricidal bedding products that kill dust mites, have been developed.

While copper oxide is used as the source of copper in mineral and vitamin supplements and is considered safe, its use in medical devices, as well as in industrial and consumer products, is novel. The current manuscript reviews the safety aspects of the use of copper oxide in products that come in contact with open and closed skin.

Copper oxide products have been tested in 9 clinical trials and in several non-clinical studies and have been found to be non-irritating, non-sensitizing, and safe to use, with not even one adverse reaction recorded, both when in contact with intact and broken skin. This is in accordance with the extremely low risk of adverse reactions attributed to dermal exposure to copper.

### In conclusion

Copper is an essential trace element for humans. Its use in medical devices is considered safe to humans, as demonstrated by the widespread (millions of women) and prolonged (more than 10 years by a single individual) use by women of copper intrauterine devices [41,48,49].

The use of copper oxide in consumer and medical products that come in contact with skin is safe. The lack of adverse reactions due to exposure of skin to copper oxide impregnated products, as described above, is in accordance with the extremely low risk of adverse reactions due to dermal contact with copper [58,59], including in wounds [8], and with copper being an integral component of many of the over-the-counter treatments for wound healing [60,61].



# Copper Inside

## A Novel Anti-Influenza Copper Oxide Containing Respiratory Face Mask

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### Discussion

#### ***Could the addition of copper oxide into the masks result in an unsafe product for use?***

Several tests carried out in independent laboratories using good laboratory practices, which are not detailed in this report, have clearly shown that such is not the case. The amount of copper that eluted to the air from the test mask during 5 hours under simulated breathing conditions was  $0.467 \pm 47$  pg, a level that is far below ( $>10^5$  folds) the respiratory copper permissible exposure limit (PEL) set by the USA Occupational Safety and Health Administration (“OSHA”).

The lowest observed-adverse-effect levels (“LOAELs”) for chronic copper inhalation exposure was determined to be  $0.64$  mg/m<sup>3</sup> [37]. Again, the copper levels eluted during the simulated breathing test from the copper containing masks ( $0.09$  pg/m<sup>3</sup>) are a tiny fraction ( $>10^6$  folds) of this copper LOAEL.

Even when simulating a worst case scenario, in which the masks would be soaked in saliva, and all the saliva would be ingested, the amount of copper eluted from the mask into the saliva was  $\sim 7.24$  µg/hr (average of three replicates minus the background), which is significantly lower than  $20.8$  µg/hr, the minimal risk level (MRL) for oral exposure for a person weighing 50 kg.

Importantly, the outer layers of the masks, which contain  $\sim 2.2\%$  copper oxide particles, did not cause any skin sensitization or skin irritation as determined in animal studies (data not shown). Also similar fabrics containing 6 times higher amounts of copper oxide did not cause any skin irritation [28]. These findings are in accordance with the very low risk of adverse skin reactions associated with copper [38] and with the lack of any adverse toxic irritations on the facial skin with ointments containing up to 20% copper [39]. In addition, the copper oxide containing masks passed flammability tests in accordance with US FDA (21 CFR Part 58) regulations, as determined in an independent FDA approved lab (Nelson Labs) using GLP.

In summary, we demonstrate that copper oxide impregnated masks safely reduce the risk of influenza virus environmental contamination without altering the filtration capacities of the masks. Due to the potent antiviral and antibacterial properties of copper oxide, we believe that these masks also confer protection from additional pathogens, and, as such, are an important additional armament in the combat against the spread of and infection by dangerous pathogens. It is suggested that copper oxide should be also included in other personal protective equipment to further confer protection to the wearer and to the environment.

<https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0011295&type=printable>