DROMEDARY INDUSTRIES

ECA MED

The easiest, safest and most efficient way to protect yourself and other people.

WHO ARE WE?

Dromedary Industries as a commercial group with the producer ECAmed (as a division of ECA N.V.), provides various sectors internationally with the most sustainable, safe and comfortable face masks. We are therefore convinced that high-quality and sustainable masks from European production (in Belgium and the Netherlands) are essential to strategically contain the urgent spread of the coronavirus. Together, we supply and produce premium (medical) face masks with the highest possible protection and comfort as the first alternative for the lower quality (Asian) masks.

ECA N.V., as the producer of the face masks, is founded in 1948 and is mainly active in the automotive industry. In different locations in Europe and in the world, they are producing interior parts for different brands. To give an indication and reference are the customers of ECA the following: Ford, PSA, Toyota, BMW, Porsche, Mercedes, Aston Martin, Bentley, Jaguar, Land Rover,....etc. In the automotive world, the ECA Group is known as very flexible and reliable with an outstanding quality. This is in fact also the mission statement of our company and we also apply these core values for the face mask production.

Dromedary Industries works with ECAmed under an exclusive collaborative partnership for the distribution of face masks. The masks are now supplied in large quantities internationally to different customers like governments and care institutions. At the beginning of the corona crisis, the initiative was taken to set up a production of medical masks in Belgium, initially under the NBN-EN 14683:2019 Type 2 and Type 2R standard. The quantity that ECAmed manufactures and Dromedary Industries supplies is unique in Europe and we have built up a strategic and first position within the European market, as we are completely independent from Asian material manufacturers and machines. ECA uses only high-quality materials through European material manufacturers that produce exclusively and directly for ECA, so there is always a large quantity of materials available for the production.

The masks are certified by SGS, which is the authority for inspection and the validation of quality. This has ensured that ECA with Dromedary Industries provide the ultimate safety standards of (medical) masks due to the premium material quality and exclusive developed mask composition.
These medical masks even meet the FFP2 standard according to various independent notified test bodies for the fact that we supply type 2R masks with filtering capacity qualified as FFP2/N95.
The masks could as a result be named as surgical FFP2 Masks and can be qualified as Comfort FFP2 masks too because the premium materials fit lighter and tighter compared to a standard FFP2 mask to guarantee maximal comfort and protection. When the face masks are worn, they cover and seal the face on a larger surface as these masks are larger than the standard type 2R masks. The filtering capacity of this FFP2 qualified masks is also exceptional due to the unique meltblown composition.

Besides supplying surgical masks with FFP2 qualified filtering capacity with our exclusive production partner ECA N.V., we are now the first in the world who is able to manufacture virucidal masks directly as an even more protective version of the standard medical masks. In short, these are face masks that automatically eliminate the coronavirus when it comes into contact with the mask. These virucidal face masks are easy to distinguish as they are always white with purple ear elastics.

INTRODUCTION VIRUCIDAL FACE MASKS – The optimal protection for others and yourself

The definition of "virucidal" is the ability to destroy or inactivate viruses. In short, this means that a virucidal mask kills the virus when it comes into contact with the mask. This is the ultimate safety solution and protection standard that everybody needs. With this application, the risk of contamination is fundamentally reduced and even eliminated. No concessions are made to the safety of the mask and the wearing comfort is also maximized due to the unique composition of the mask material.

Originally, the face masks were promoted to avoid infecting other people around you. The protection that this face mask gives to yourself is also incomparable with the protection from a standard FFP2 mask, because the contamination could also occur through contact with the mask itself. Virucidal masks provide the highest possible protection because a virucidal mask protects not only the other people around you, but it also guards the users of the mask in the best possible way.

However, the wearers of masks still come too often (unconsciously) into contact with the mask with possibly contaminated hands or gloves. In addition, there are other factors that increase the risk of transmission of infection through the mask itself for the fact that a mask is a hotspot for viruses and bacteria. If the potentially contaminated aerosols are spreading, it means that the contaminated virus droplets could also settle on the outside of mask of other people round you. This can happen in case that the lower quality Asian masks don't cover the face well enough, so the aerosols could escape in the air via the sides of the mask.

The virucidal functionality deactivates viruses which have landed on the mask by reducing the risk of contamination due to accidental manipulation or cross contamination. In addition to this potential contamination rate, other studies showed that human error was a substantial cause of contamination. For example, nearly 40% of healthcare staff made errors in touching the front of their masks before removing them. In a pandemic situation, less trained and experienced staff that must wear masks for a long time (even outside the acute care setting) are also exposed to COVID-19 infected patients, which unknowingly increases the risk of infection. It is a consequence a concern for face masks wearers to not self-contaminate while manipulating their facemask during the period they wear it and/or when they remove it by touching the front of their PPE.

A study by the SHEA (The Society for Healthcare Epidemiology of America) found that 21% of healthcare workers tested positive for skin contamination for respiratory viruses after working in acute care. Incidentally, 21% of coats and 12% of face masks also tested positive for virus contamination. Masks are as a result highly positive for virus contamination. This because people still come unknowingly into contact with surfaces that may be infected and afterwards, they come in contact with his mouth mask that can cause a direct infection. Human error is therefore a substantial cause of contamination and the major issue for spreading the virus for people who wear a mask in is that they touch their masks too often with their hands or gloves.

The substructure of this virucidal mask is based on the premium EN 14683 type 2R masks (+ the children's masks) which are developed by ECA N.V. exclusively. As stated, these masks are already exceptional as filtering capacity qualified as FFP2.

INNOVATION OF VIRUCIDAL TREATMENT

The medical masks of ECAmed are composed of 4 layers:

External layer (outside): Non-woven spunbond. The Virucidal functionality is applied on the outside of the external layer of the face masks.

Middle layer: A double filtering layer that consist of two thin layers of melt blown to optimize the breathability and bacterial filtration efficiency. This is also the reason why our masks have FFP2 quality specifications.

Internal layer: Non-woven spunbond that is anti-allergic for skin friendly contact.

The virucidal functionality represents an extra level in the manufacturing process of face masks. It comprises of treating the spunbond (external layer) that is provided in rolls from the material suppliers. This establishes in the first stage of the face masks manufacturing process, as the roll is simply inserted into the face masks machine. This new step comes with additional safety measures regarding the entire manufacturing process of face masks. ECA N.V. is the only one in the world who can make a virucidal mask like this.

For the virucidal application do we make use of plasma technology for the virucidal treatment of the outer layer. The plasma activates the surface of the to be functionalized material (which is the spunbond, as the outer layer of the mask) and at the same time activates the molecules into the plasma to create a covalent bounding to the surface. This extra coating brings the virucidal functionality to the surface of the spunbond rolls. The chemical substance that has proved the ultimate virucidal activity is citric acid, also known as CAS 77-92-9. The following grounds confirm and declare this choice:

- It is an authorized food additive by the FDA and it has always shown an excellent efficacy.
- Advice provided by the Biocidal Products Committee of the European Chemicals Agency ECHA/BPC/088/2016 dated 16/02/2016 concluding that: "The use of citric acid in antiviral face wipes does not pose an unacceptable risk to human health or the environment."
- Citric acid is an authorized food additive in Europe and is known in the European Union's food additives database as E330.
- Ingestion: No acceptable daily intake has been set by any of the well-known organizations FDA, EFSA and OMS. The natural daily intake from natural sources of citric acid is up to 500mg/kg body weight/day.
- Skin contact: The Scientific Committee on Consumer Safety in its report SCCS/1274/09 considered that "the use of citric acid in cosmetic products, at a concentration up to 0.2%, as a preservative does not pose a risk to consumer health.

The treatment of the spunbond rolls (outer layer of the mask) is done before the process of manufacturing the mask in the current production process. This establishes by treating the spunbond rolls "virucidally" first and the application can be visualized as a "cartridge" that is implemented in the manufacturing process. The provision of citric acid will happen by using cartridges that are equipped with an Radio Frequency Identification (RFID) instrument. The RFID instrument will be scanned by the machine and the information will be validated. Inside the RFID message, The precursor type, purity, and expiration date will be validated in the RFID message. In case that the information in the RFID message is not valid, the machine to make this virucidal layer will not start.

PLASMA COATING TECHNOLOGY

Plasma is typically used in industry as a tool to optimize the intended adhesion of for example inks and glues. In this case, the plasma is generated by the addition of electrical energy to a gas, typically air or nitrogen. This energy is brought to the gas by having the gas going through a powerful electric arc. The plasma is then blown

on a surface in order to increase the surface energies of the surface.

This technology is based on a plasma which is created using magnetic fields and electric fields, eliminating the electric arc used in technologies mentioned above allowing the generation of a super-low energy plasma. This enables the introduction of highly sensitive organic precursors in the plasma in order to graft these precursors onto surfaces. The plasma activates the surface of the to be functionalized material and at the same time activates the precursor molecules introduced in the plasma to enable a covalent bonding of the precursor to the surface. To apply this plasma technology, ECA N.V. uses a full plasma installation within the Belgian factory.

PERFORMANCE RESULTS

The validated performance of the virucidal functionality for medical face masks ensures that 99.9% of the present viruses are inactivated. This performance is achieved after only a few minutes of contact of the viruses with the outer layer of the mouth mask.

The current shelf life time and expiry date of the mask is the same as the regular face masks and the packaging in sealed plastic wraps and storage conditions are also the same. The certified performance of the medical facemasks (as tested per EN 14683 for filtration) and breathability is not influenced by the very thin layer of citric acid on the outer layer, which is not the filtration layer in this mask design. The polypropylene of spunbonded nonwovens used on the outer layer of medical facemasks is highly resistant to citric acid. Accelerated ageing tests have been performed to demonstrate that the coating process and presence of citric acid do not interfere with the performance of the facemask over time. Tests have also confirmed the performance and virucidal efficacy at temperatures up to 55°C, as this is well above the recommended storage conditions. Further testing is on-going to determine efficacy after exposure to high moisture and for longer periods.

INTENDED USE

The normal intended use of a face mask remains unchanged despite the addition of the virucidal functionality:

- The device remains a single use device
- It stays a non-sterile device
- The maximum usage duration remains the same as normal masks.
- The repeated use of masks (if changed every 4h or in case of degradation) is not changed.
- The mask does not replace the other protections measures:
  - Washing hands regularly
  - Physical distancing
  - Reduction of contacts with other persons: It can be said that neither the purpose, nor the usage principles of the ordinary Class I, Type I and Type II is changed when treated by the virucidal functionality.

VIRUCIDAL FUNCTIONALITY – RISK ASSESMENT

Based on the information from different studies and literature, there can be concluded about citric acid that:

- There is no proof that Citric acid could be reprotoxic
- There is no proof that Citric acid could be embryotoxic,
- There is no proof that Citric acid could be neurotoxic
- There is no proof that Citric acid could be genotoxic in vivo or in vitro,
- There is no proof that Citric acid could be carcinogenic
- There is no proof that Citric acid could be teratogenic

All this information from various countries and official representative organizations confirms the choice of citric acid as a safe, widely used product without known medicinal effect on humans.

The last element considered in the design regarding the chemical precursor is the purity of the citric acid to be used. In this case, the purity taken into account has been the one specified in the Opinion provided by the Biocidal Products Committee of the European Chemicals Agency ECHA/BPC/088/2016 from 16/02/2016 – reference 1 which is greater than 99.5% w/w. This level of purity has been identified to limit the non-intentionally added substances (NIAS) when manufacturing the mask.

Risk elements to be considered by design: the following risks have been analyzed based on the intended use and potential reasonably foreseeable misuse:

- Ingestion: No Acceptable Daily Intake (ADI) has been specified by any of the well-known organizations FDA, EFSA and OMS. The natural daily intake by natural sources of citric acid goes up to 500mg/kg body weight/day. Nevertheless, any time an assessment had to be done by European regulatory organizations regarding the intake of citric acid, the generally used value is 100mg/kg bw/day.
- Contact with Skin: The scientific committee on consumer safety assessed in its report SCCS/1274/09 that "the use of citric acid in cosmetic products, at a concentration up to 0.2%, as a preservative does not pose a risk to the health of the consumer."
- Breathing: Even if citric acid is a known irritant for eyes and skin and is often used as a simulant for cough threshold testing, the amounts considered are way above the amounts implemented on the masks. Further investigating this subject, on the ECHA website (https://echa.europa.eu/fr/registration-dossier/-/registereddossier/15451/7/5/1), the following statement is made: "In accordance with REACH Annex XI Section 2, the sensitization study does not need to be conducted because citric acid and its salts have been used for many years as a permitted additive for human food, medicines and cosmetics. During this time, there has been no documented evidence that citric acid could be a sensitizer. Therefore, there is no scientific basis for recommending animal studies to investigate this endpoint."
- Citric acid degradation product: The degradation of citric acid within the expected use of the product should not be of safety concern as these have been considered in similar usage conditions by FDA and EFSA in order to allow Citric Acid as food additive. A further literature study confirmed this statement, citric acid is stable below 70 degrees Celsius, it can be degraded upon heating into pyrocitric acids such as aconitic acid, itaconic acid and citric acid. Al the mentioned pyrocitric acids are safe and recognized food additive or used in dermatological usage.

The wide presence of citric acid in nature, in food, as a food additive, etc... and the fact that all instances (FDA, EFSA, WHO, etc...) have not emitted any safety concern on citric acid has lead ECA N.V. to choose citric acid as the precursor of choice for its Virucidal functionality. Given the risks mentioned and the worst-case scenario defined, we now can evaluate the risk related to the usage of virucidal functionalized medical face masks:

- Ingestion: with the threshold value mentioned for risk assessment of 100mg/kg bw/day, the total amount of citric acid which can be ingested by a 50 kg human being per day without raising any safety concern is 5000mg. This means that if the total content deposited on the mask would be ingested for each mask worn by this human being during the day, this human being could wear 5000/33 = 151 masks per day. Therefore, the Virucidal functionality cannot be considered as a relevant risk with regard to citric acid ingestion.

- Contact with skin: Based on the worst-case scenario quantity and comparing with the various quantities mentioned in the literature, there are no evidence that a so low amount of Citric acid can cause any skin irritation.
- Degradation products: The degradation products of an amount of citric acid as mentioned in the worst-case scenario can be considered as negligible as per their nature and the potential amount which might be created.
- Breathing: Based on the worst-case scenario quantity and comparing with the various quantities mentioned in the literature, there are no evidence that a so low amount of Citric acid could cause coughing or other breathing induced issues. If accidentally some of the coating is extracted and ends in the respiratory tract, mucosa irritation tests have shown that the coating on the facemask is not irritating even in direct contact.

Given the mentioned thresholds related to citric acid, it can be easily said that the quantity of citric acid deposited using the technology of ECA N.V. cannot be considered as a safety concern. It represents a negligible amount in the view of the daily exposure humans (including infants) are facing. The impregnated virucidal functionality by using plasma technology does not change the disposal procedure currently applied to the medical face masks. The fact that citric acid is a substance present in natural foodstuffs and in food in general, demonstrates that the Virucidal functionality does not represent any harm for the environment.

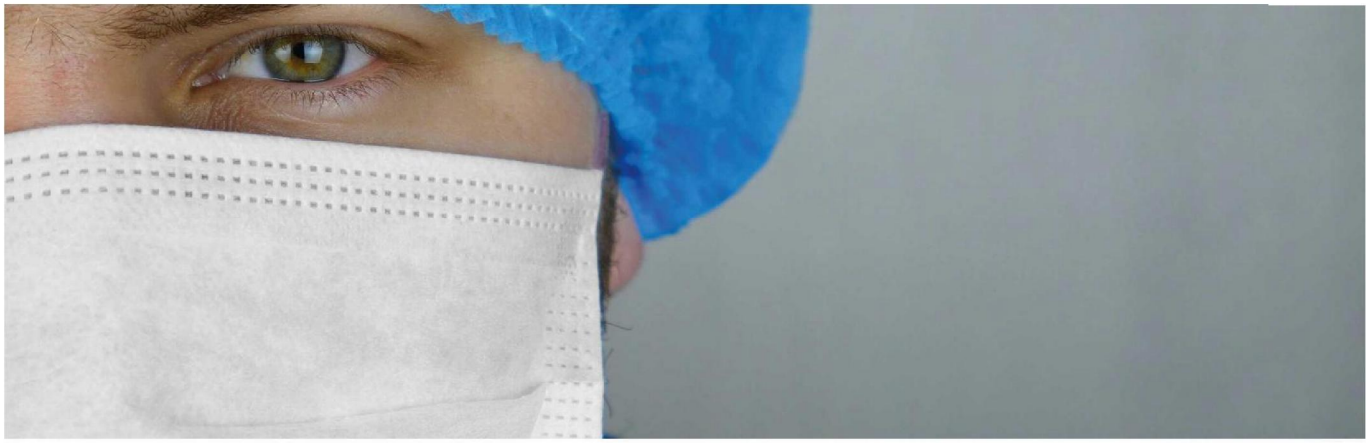
VIRUCIDAL FUNCTIONALITY – PERFORMANCE ASSESMENT

After a study review of model viruses used in such cases having a good representability of human corona virus pathogens, the Escherichia Virus MS2 virus was identified as the model of choice as a surrogate of the Sars-Cov-2 virus.

Escherichia virus MS2 is an icosahedral, positive-sense single-stranded RNA virus that infects the bacterium Escherichia coli and other members of the Enterobacteriaceae. MS2 is a member of a family of closely related bacterial viruses that includes bacteriophage f2, bacteriophage Q, R17, and GA. Bacteriophages are easy to work within the context of disinfectant testing and can provide valuable information about product efficacy. MS2 is a bacteriophage that infects "male" Escherichia coli. Male E. coli are bacterial cells capable of passing a portion of their genetic material (typically in plasmid form) to other bacterial cells through a structure called a pilus. This process of horizontal gene transfer is a vehicle of genetic change within bacterial populations and is particularly well known for spreading antibiotic resistance to previously antibiotic-susceptible bacterial populations.

Morphologically, MS2 is a non-enveloped, icosahedral virus. MS2's lack of lipid envelope means that it is generally resistant to chemical disinfectants and is also able to withstand environmental stressors like temperature changes, desiccation, and osmotic pressure. Viral disinfectant efficacy testing has a reputation for slow study turnaround times and high costs, largely because of the time and work it takes to propagate viruses and maintain host cell lines. MS2 is an exception to this rule because it requires a bacterial host (which replicates rapidly) instead of mammalian host cells (which replicate slowly). MS2 virions are 23-28 nm in diameter, putting them in the category of small non-enveloped viruses like canine parvovirus and human poliovirus. MS2 is more sensitive than its counterparts to various methods of disinfection, including UVC light exposure and quaternary ammonium compounds.

In short, MS2 is generally more resistant to inactivation than enveloped viruses but is more sensitive to inactivation than other small non-enveloped viruses. MS2's documented moderate sensitivity makes it easy to use data gathered from MS2 testing to gauge the efficacy of a product before starting larger, more complex mammalian virus studies. The use of MS2 bacteriophage specifically as a viral representative is also recognized by EPA. On the basis of its morphological characteristics, the EPA considers MS2 to be an adequate viral representative for water filtration and purification testing.



Besides protecting others, you can also guard yourself with these premium quality and optimal protective masks.

Dromedary Industries is together with ECAmed unique for this virucidal face masks treatment, as no other group can provide these masks on a large scale to prevent the urgent spread of the virus as efficient as possible.

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