

LUCA V-Defense Nasal Spray

Prevention of respiratory viral infections

LUCA AICell, Inc.
Bio-Platform Company
based on the Artificial Intelligence of Ultimate Nanotechnology



| The global trend to lift outdoor mask mandate

While most OECD member countries have lifted the obligation to wear indoor and outdoor masks and declared daily recovery, in the case of Korea, as of January 2023, the outdoor and indoor mask mandatory has been lifted.

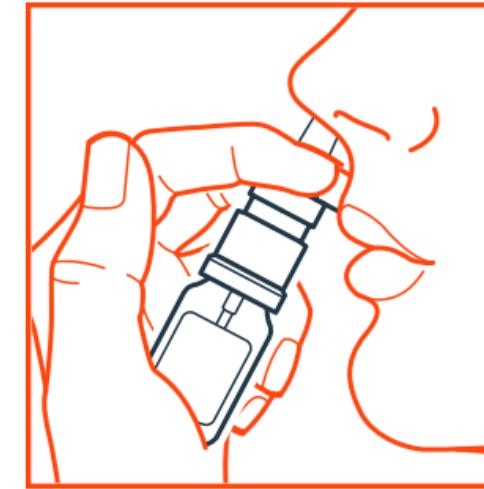
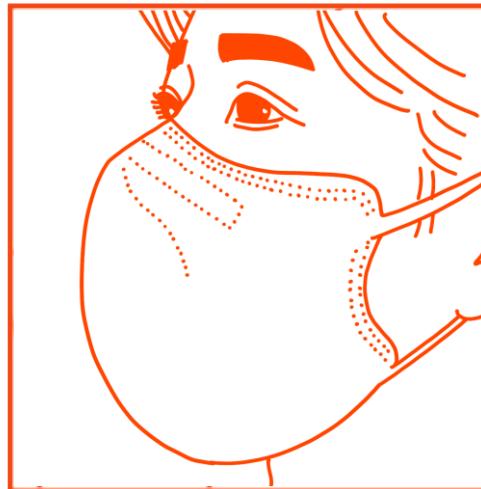
【 The status of mandatory indoor/outdoor masks in OECD countries 】

Country	January 2023							
	United States	United Kingdom	Germany	France	Singapore	New Zealand	Japan	South Korea
Outdoor	X	X	X	X	X	X	X	X
Indoor	X	X	X	X	X	X	X	X
Mask mandatory facility			Medical facility, Long-distance train		Medical facility and sanatorium, Public transportation	Medical facility and sanatorium		Medical facility, Public transportation

Safety devices to replace masks are required

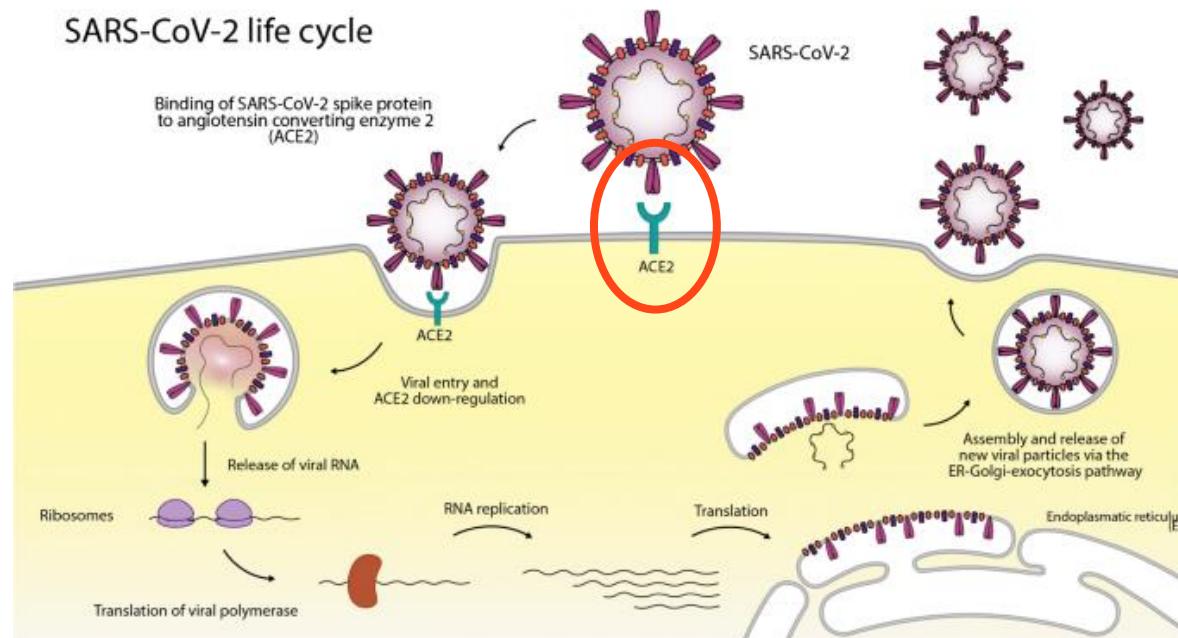
The risk of respiratory viral infection remains as the COVID-19 mutant virus continues to emerge, and seasonal flu is also prevalent periodically.

The LUCA V-Defense Nasal Spray is
a minimal safety device that can prevent respiratory viral infections
such as COVID-19 and influenza, replacing the mask used for a long time.



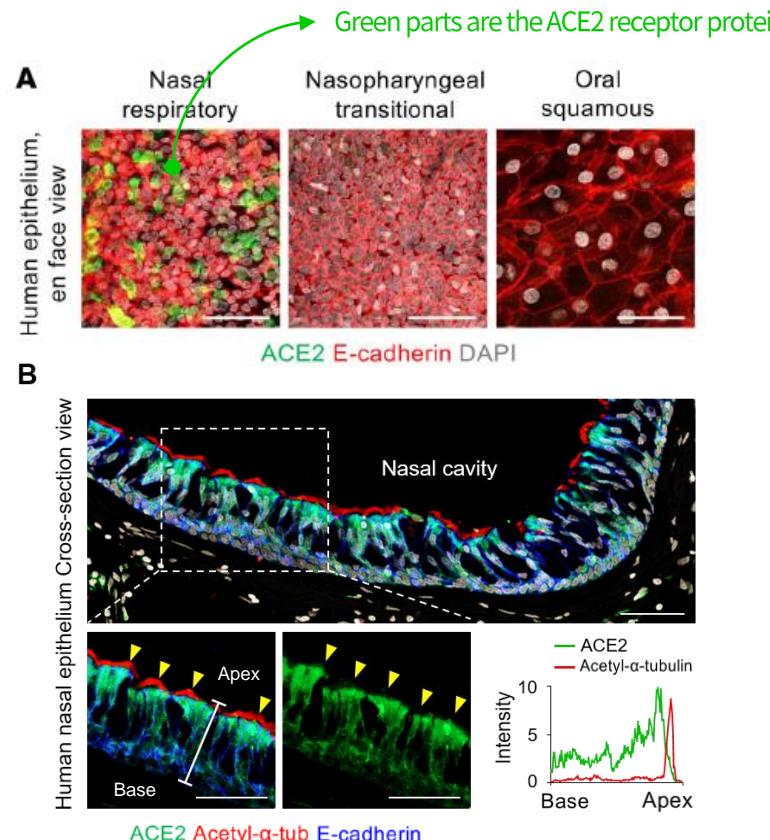
COVID-19 Virus Infection Route(1/3)

COVID-19 virus penetrates cells through **ACE2 receptors** and causes infection.



COVID-19 Virus Infection Route(2/3)

Large amounts of **ACE2 receptors** exist only in the nasal respiratory epithelium, and the nasal respiratory epithelium is the first route for the COVID-19 virus to penetrate the human body.



The human upper respiratory tract is composed of nasal respiratory epithelium, nasopharynx transitional epithelium, and oral squamous epithelium. **It has been found that large amounts of ACE2, the receptor for the COVID-19 virus exist only on the surface of the nasal respiratory epithelium.**

ACE2 receptors are concentrated at the top end of the nasal respiratory epithelium in contact with air.

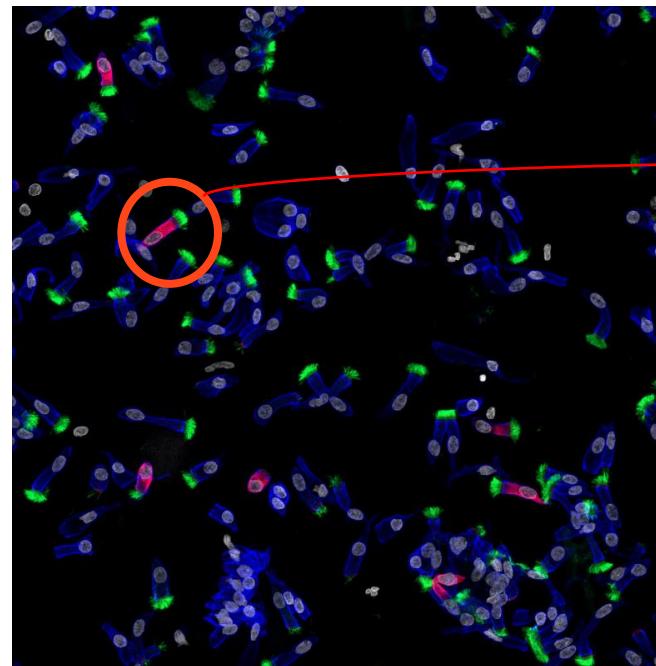
The nasal respiratory epithelium is the first path where the COVID-19 virus penetrates the human body. Blocking this penetration path is very important in preventing infection.

* Source : Nasal Ciliated Cells are Primary Targets for SARS-CoV-2 Replication in Early Stage of COVID-19, Journal of Clinical Investigation (2021)

COVID-19 Virus Infection Route(3/3)

As a result of visual analysis through immunofluorescence staining, it was confirmed that the COVID-19 virus first replicated/proliferated through **nasal ciliated cells**.

[Reference] Tracking the first infection route of the COVID-19 virus through cell smear immunofluorescence staining



Among nasal cells, only ciliated cells (Green) have been found to replicate/proliferate the COVID-19 virus (Red)

- Blue: Nasal epithelial cells
- Green: Nasal ciliated cells
- Red: COVID-19 virus

* Source : Nasal Ciliated Cells are Primary Targets for SARS-CoV-2 Replication in Early Stage of COVID-19, Journal of Clinical Investigation (2021)

Product Specification

It physically coats the nasal mucosa to prevent respiratory viral infections such as COVID-19, the flu, and the common cold.

Intended purpose

- To protect the nasal mucous membrane from infection by the respiratory viruses via formation of a physical membrane when spraying this product to the nose.

Principles of operation

- This product contains an unscented, colourless, a transparent viscous lipid and lambda carrageenan provided in nasal spray devices which consist of high-density polyethylene containers, caps, nozzles, and safety clips. When sprayed to the nose, this product forms a **physical film in the nasal mucosa to prevent respiratory tract infections by viruses.**

The main ingredients

- Lambda Carrageenan, SPAN20, Sodium Hydroxide, Eucalyptol, L-menthol, D-Sorbitol Solution 70%, Benzoic Acid, Benzyl Alcohol, Purified Water

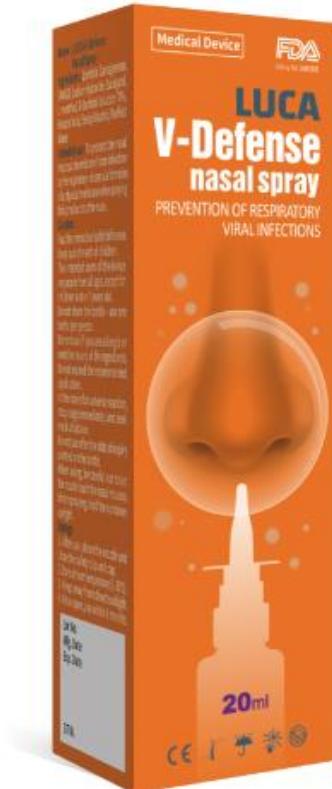
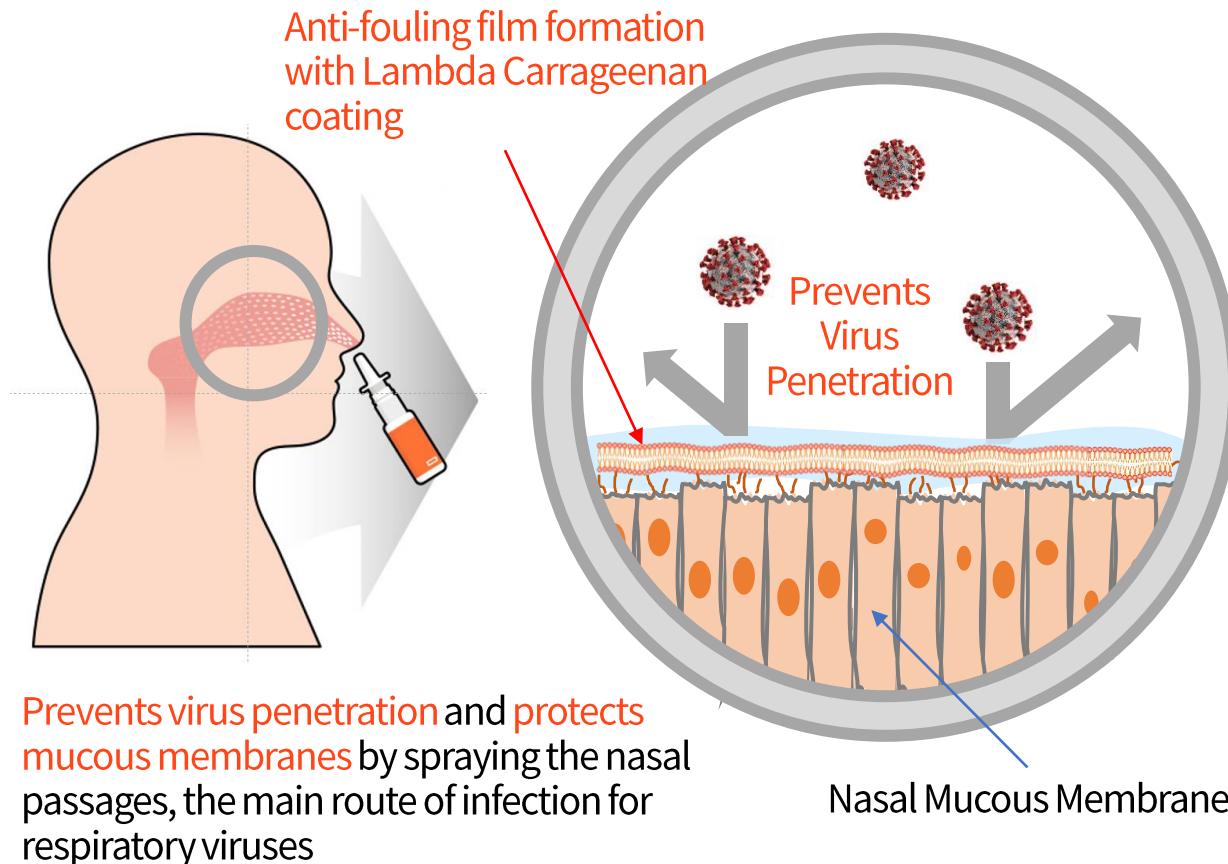
Capacity of Product

- 20ml (About 200 times and 1 month usage)



Prevention of respiratory viral infections

It physically coats the nasal mucosa to prevent respiratory viral infections such as COVID-19, the flu, and the common cold.



Use Case

It is recommended for use in various environments requiring the protection of the nasal mucosa.



Before and after
visiting concert halls
and playgrounds



Days with a lot of
fine dust and pollen



Before visiting a place
where you can
communicate with
many people, such as
school or company



When riding the subway,
bus or plane
(Can be brought on board)



When concerned about
respiratory viruses
(COVID-19, flu, etc.)



How to Use

Usage instructions and steps for using a pump bottle

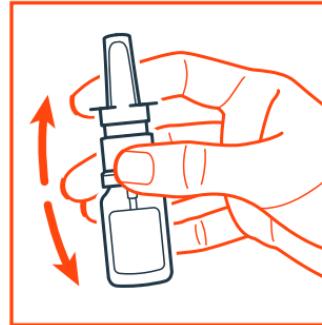
Spray the product three times a day through each nostril to prevent respiratory virus infections of nasal epithelium. If there are any signs or symptoms of virus infection, spray the product several times a day and/or each time through each nostril.

01



Clean inside of your nose

02



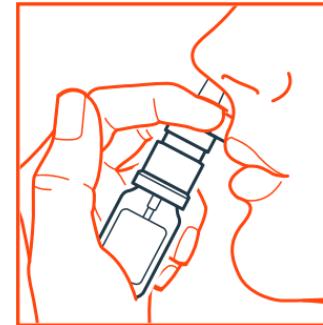
Shake the product gently and open the safety clip and cap.

03



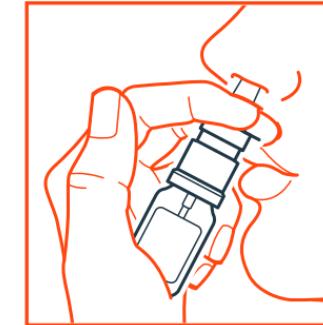
For first-time application, pump 2-3 times in the air.

04



Hold the container upright and insert the nozzle into the nose.

05



Hold your breath for a moment, spray 1 time into each nostril and inhale lightly.

06



After use, clean the nozzle and close the safety clip and cap.

Antiviral performance study result

99.7%

Mahidol University, a Thai professional testing and certification agency, confirmed 99.7% sterilization performance within **a minute** as a result of an antiviral study using viruses causing COVID-19.

According to detection method namely virus inhibition assay and 50% tissue culture infectious dose assay (TCID50), we found that **"LUCA V-Defense Nasal Spray"** with concentrated solution can reduce the amount of Severe Acute Respiratory Syndrome **Coronavirus 2 (SARS-CoV-2)** at 99.70% with the minimal contact time of 1 minute.



MAHIDOL UNIVERSITY
No. TM78.115/0303
14 February 2022

ML (THAILAND) CO., LTD
283/48, Unit No. 1005-2, 10th floor, Home place,
Soi Sukhumvit 55 (Thonglor 15), Klongtoey Nua,
Watthana Bangkok 10110 Thailand

According to detection method namely virus inhibition assay and 50% tissue culture infectious dose assay (TCID50), we found that "LUCA V-Defense Nasal Spray" with concentrated solution can reduce the amount of Severe Acute Respiratory Syndrome **Coronavirus 2 (SARS-CoV-2)** at 99.70% with the minimal contact time of 1 minute.

Sincerely yours,
P. Leungnugroh
Pomswan Leungnugroh (Ph.D)
Associate Professor,
Head, Department of Microbiology and Immunology,
Head, Tropical Medicine Diagnostic Reference Laboratory

MAHIDOL UNIVERSITY
TEST REPORT
Company Name: ML (THAILAND) CO., LTD
Address: 283/48, Unit No. 1005-2, 10th floor, Home place, Soi Sukhumvit 55 (Thonglor 15), Klongtoey Nua, Watthana Bangkok 10110 Thailand

TEST PRODUCT INFORMATION

Received Date	17 December 2021	Testing Date	02 February 2022
Reported Date	14 February 2022	Sample No.	BI-395-02
Product Name	LUCA V-Defense Nasal Spray		
Product Characteristics	Saline spray		
Packaging	Spray bottle		
Active Ingredient	1. Sodium bicarbonate 2. L-Lactide 3. Sodium hydroxide 4. Eucalyptol 5. L-menthol		
Supplier	LUCA AICELL INC.		
Distributor	ML (THAILAND) CO., LTD		
Reg. No.	-	Lot No.	-
Mfg. Date	-	Exp. Date	-
Size of Sample	20 ml	No. of Samples	1 bottle

TEST SYSTEM

Test Method	Virus Inhibition Assay and 50% Tissue Culture Infectious Dose Assay (TCID50)
Reference Standard	ASTM E2055-20: Standard Practice to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces
Test Organism	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Human isolated) Titer = 5x10 ⁵ TCID50/ml

RESULTS

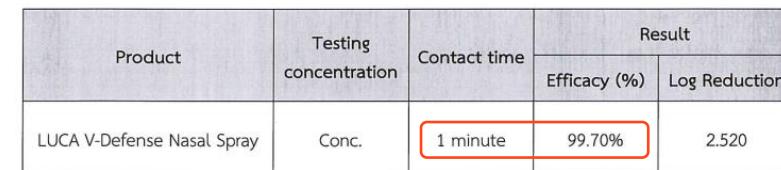
The purpose of this study was to determine the virucidal efficacy of "LUCA V-Defense Nasal Spray" against Severe Acute Respiratory Syndrome **Coronavirus 2 (SARS-CoV-2) Human isolated**. At the concentrated solution with a contact time of 1 minute, the tested product has the efficacy as shown in the table.

Product	Testing concentration	Contact time	Result
			Efficacy (%) Log Reduction
LUCA V-Defense Nasal Spray	Conc.	1 minute	99.70% 2.520

A. J. H. (Assistant Professor Assoc. Dr. Jintinithipap)
Sincerely,
14 February 2022

P. Leungnugroh (Associate Professor Dr. Pomswan Leungnugroh)
Technician Microbiology
14 February 2022

Test report only applies to the product mentioned in the test report.
Test report may not be duplicated in whole or in part without prior written permission.
Test report does not authorize to use as advertising materials.



Product	Testing concentration	Contact time	Result	
			Efficacy (%)	Log Reduction
LUCA V-Defense Nasal Spray	Conc.	1 minute	99.70%	2.520

Papers related to efficacy (1/4)

As a result of testing the **carrageenan** coating ability, it was confirmed that the **multi-layer** composition was perfectly coated on the surface and protected by forming a **nano-sized physical film**.

K-carrageenan/chitosan nanolayered coating for controlled release of a model bioactive compound

Innovative Food Science and Emerging Technologies 16 (2012) 227–232

ELSEVIER

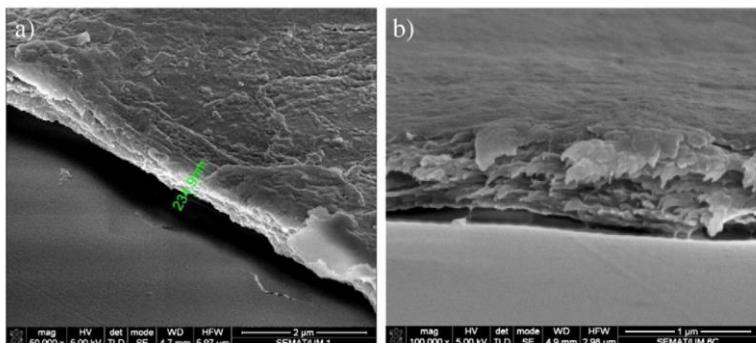
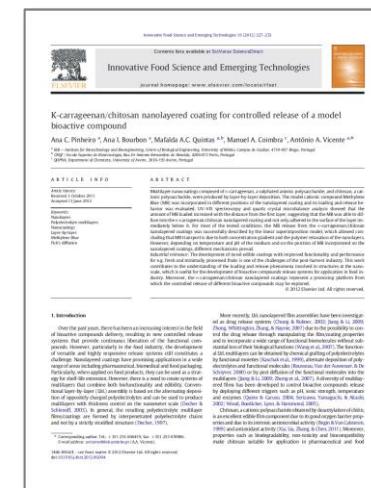


Fig. 4. SEM images of the k-carrageenan/chitosan coating with MB in the 6th layer. Thickness of the layers (a). Detail of the structure of the layers (b).

- Carrageenan and chitosan nanolayers were demonstrated using equipment capable of measuring nanoscale, such as SEM images.
- The SEM image of the coating with MB in the 6th layer was shown as an example.
- The total thickness of the carrageenan/chitosan layers was 234.9 nm (Fig.4 a).



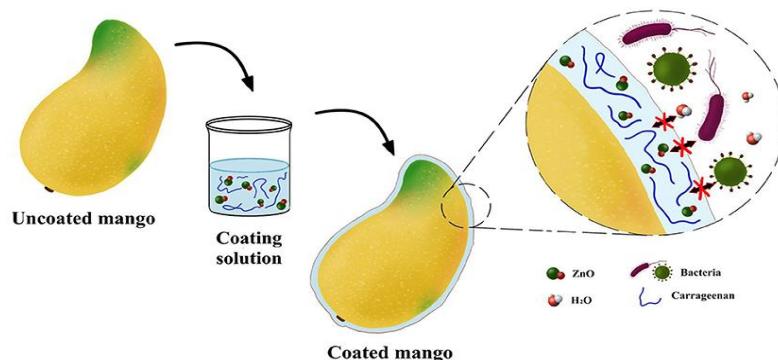
- Related paper
<https://repositorium.sdum.uminho.pt/bitstream/1822/23356/1/1-s2.0-S1466856412000902-main.pdf>

Papers related to efficacy (2/4)

As a result of the carrageenan film formation experiment, **excellent coating ability** and **film retention ability** were confirmed.

Recent advances in carrageenan-based films for food packaging applications

Frontiers in Nutrition, 10.3389/09 Sep. 2022



- The film-forming function of carrageenan and its principle were explained, and its application was demonstrated.
- As one of the methods, carrageenan was coated on fruit (mango), and the coated fruit was fresher for 14 days than the uncoated fruit.
- Because the addition of zinc oxide nanoparticles allowed the composite coating to significantly increase the tensile strength by 43%, reduce the water vapor transmission by 9%, and inhibit the growth of *E. coli*, compared with that of pure carrageenan coatings.



- Related paper
<https://pubmed.ncbi.nlm.nih.gov/36159449/>

Papers related to efficacy (3/4)

It has been confirmed that carrageenan is a safe ingredient that is **not absorbed into the human body** because it has a large molecular weight and **cannot be absorbed into the nasal mucosa or skin**.

Non-Clinical Safety Evaluation of Intranasal Iota-Carrageenan

PLOS ONE | DOI:10.1371/journal.pone.0122911, April 13, 2015

Table 1. Comparison of P_{app} Values for Indicated Test Compounds across Bovine Nasal Mucosa.

	pH 7.5 P_{app} [$\times 10^{-6}$ cm/s]	pH 5.5 P_{app} [$\times 10^{-6}$ cm/s]
Sodium Fluorescein	11.17 ± 1.02	5.20 ± 2.12
FD10	0.51 ± 0.51	0.30 ± 0.09
FD40	0.18 ± 0.13	0.31 ± 0.24
FD70	0.07 ± 0.06	0.17 ± 0.10
MANT	17.62 ± 1.19	11.41 ± 4.59
MANT-iota-carrageenan	< 0.01	< 0.01

Data are means ± SD of 3 (MANT) or 5 (all other compounds) experiments.

P_{app} = apparent permeability coefficient.

doi:10.1371/journal.pone.0122911.t001

- It was confirmed that carrageenan was not absorbed into Bovine Nasal Mucosa by mixing MANT dye with carrageenan.
- MANT dye is a substance absorbed by Bovine Nasal Mucosa, but it was measured that it was not absorbed by Bovine Nasal Mucosa when mixed with carrageenan.
- A pH of 7.5 indicates normal bovine nasal mucosa and a pH of 5.5 indicates inflamed bovine nasal mucosa.

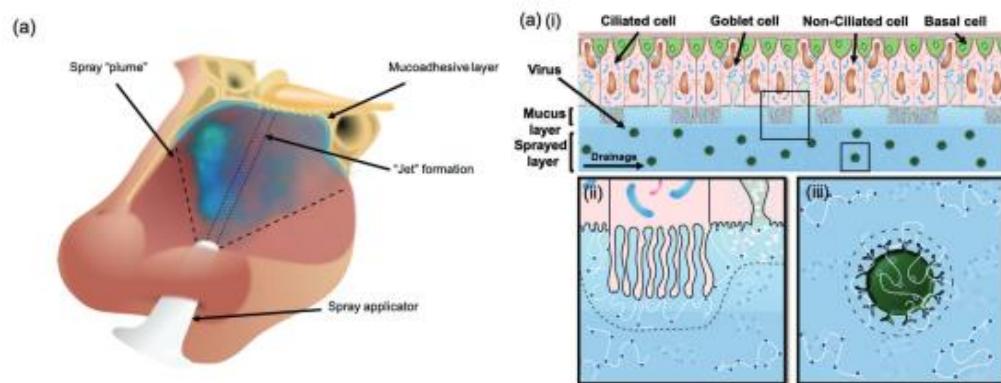
- Related paper
<https://journals.plos.org/plos-one/article?id=10.1371/journal.pone.0122911>

Papers related to efficacy (4/4)

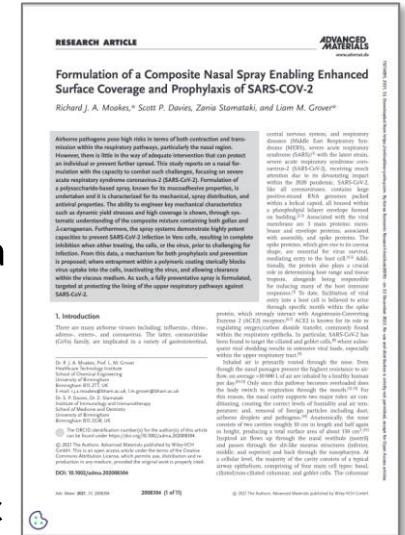
Nasal sprays have been shown to be a very effective way to block the transmission of the virus to humans.

Formulation of a Composite Nasal Spray Enabling Enhanced Surface Coverage and Prophylaxis of SARS-CoV-2

July 2021 *Advanced Materials* 33(26):2008304



- On application, nasal sprays directly contact the nasal mucosa lining the epithelium.
- Demonstration of potential removal of the virus via trapping within the sprayed layer and elimination through natural nasal clearance mechanisms (sneezing/nose-blowing/swallowing).
- Demonstration of potential blocking of virus uptake into the cells as the polymer creates a steric barrier across the cell interface.
- And demonstration of potential inhibition of virus uptake by creating a steric barrier around the interface of the virus.



- Related paper
https://www.researchgate.net/publication/352025483_Formulation_of_a_Composite_Nasal_Spray_Enabling_Enhanced_Surface_Coverage_and_Prophylaxis_of_SARS-COV-2

Menthol Scent

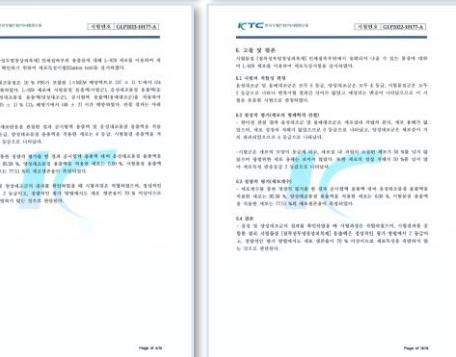
LUCA V-Defense Nasal Spray contains **everyone's favorite menthol scent**, you can use it comfortably.



Pre-Clinical Report

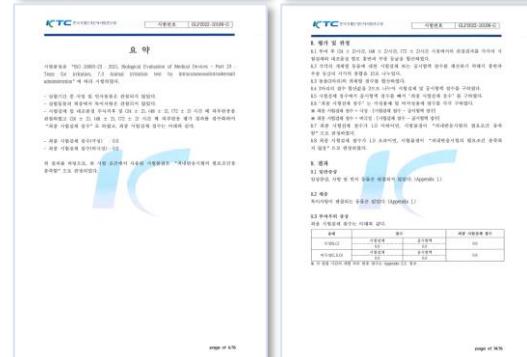
The safety test results have been confirmed to be safe as if it is harmless to the human body by the authentication institution.

[Cytotoxicity Test]



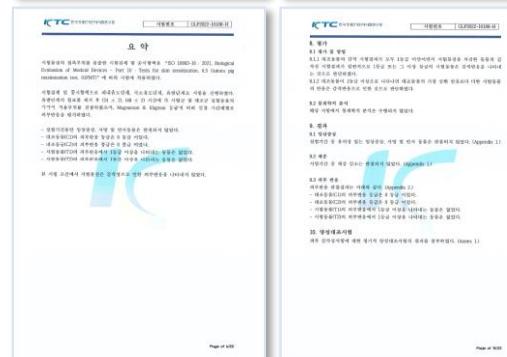
It does not cause cytotoxicity reactions

[Intracutaneous Reactivity Test]



There are no adverse reactions as a result of the intracutaneous reactivity test

[Skin Sensitization Test]



It does not cause skin sensitization reactions

Test Report

The stability test results, such as container extractable, shelf-life, and loss on drying test, **all passed without problems**.

[Container Extractable Test]



[Shelf-Life Test]



[Loss on Drying Test]



There is no adverse reaction in the results of the elution test of containers, such as property, pH, and heavy metals

All test items, including microbial testing within 2 years of validity and 6 months of opening, have been passed

Loss on drying test passed

Certifications

Obtained permission for manufacturing nasal spray medical device and domestic/export product permission from the Ministry of Food and Drug Safety of Korea (MFDS).

Document Number : D5QN-86UT-TWNT-BNN

Document Number : PX09-S0BF-BW01-F048

Certifications

LUCA AICell has obtained the Medical Device Certificate of GMP and ISO13485:2016.



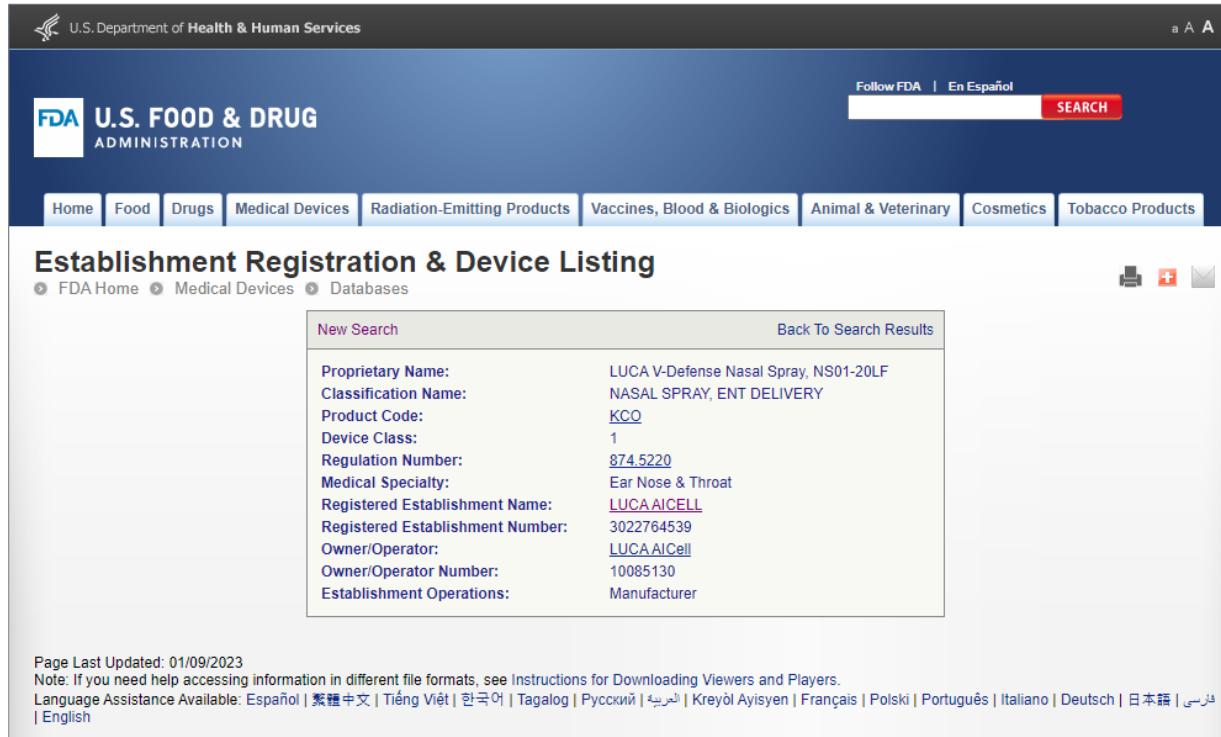
Certifications

This is to certify that LUCA AICell has obtained US FDA Registration & Listing Clearance on the device below.



Certifications

This is to certify that LUCA AICell has obtained US FDA Registration & Listing Clearance on the device below.



The screenshot shows the FDA's "Establishment Registration & Device Listing" page. The page header includes the U.S. Department of Health & Human Services logo, a search bar, and links for "Follow FDA" and "En Español". The main navigation menu includes Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The current page is "Establishment Registration & Device Listing". Breadcrumbs indicate the user is on the "Medical Devices" section. The main content area displays a table of device registration details:

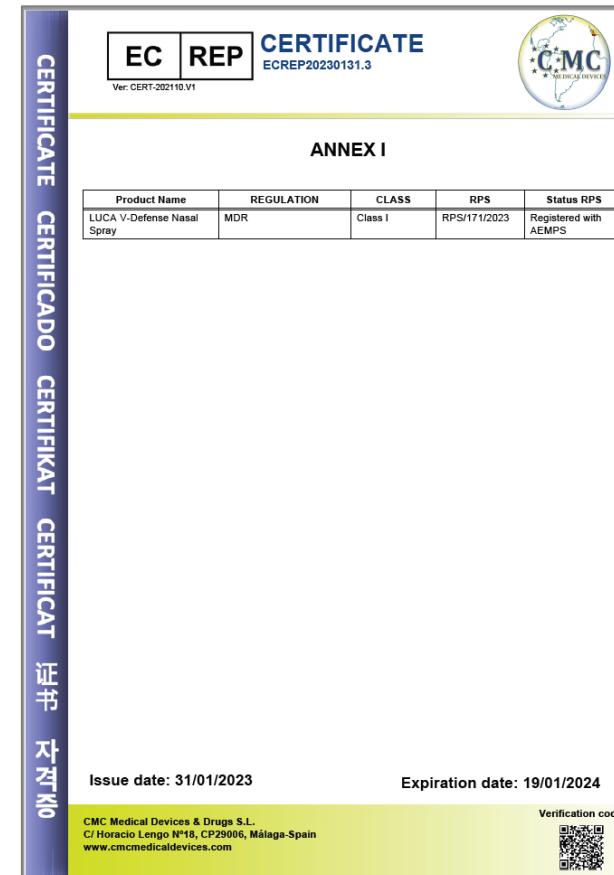
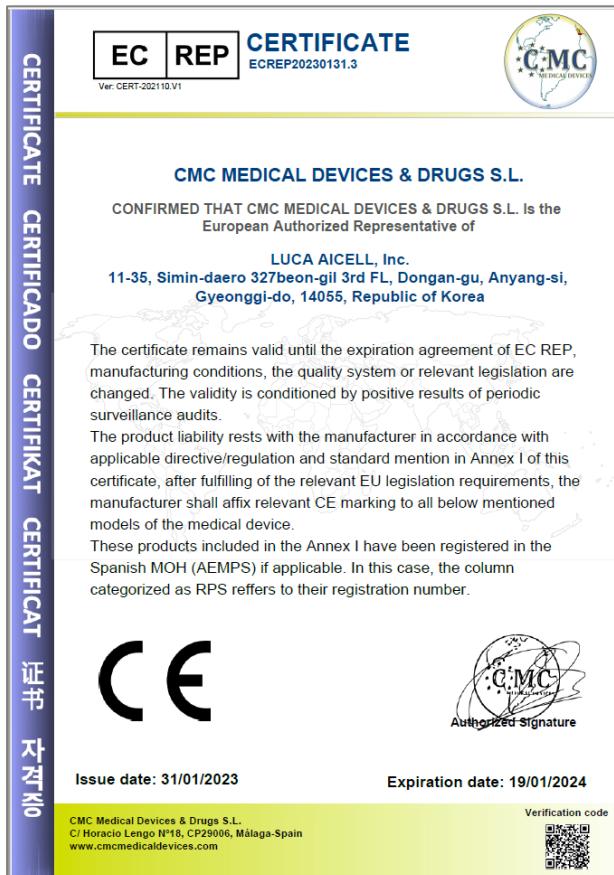
New Search		Back To Search Results
Proprietary Name:	LUCA V-Defense Nasal Spray, NS01-20LF	
Classification Name:	NASAL SPRAY, ENT DELIVERY	
Product Code:	KCO	
Device Class:	1	
Regulation Number:	874.5220	
Medical Specialty:	Ear Nose & Throat	
Registered Establishment Name:	LUCA AICELL	
Registered Establishment Number:	3022764539	
Owner/Operator:	LUCA AICell	
Owner/Operator Number:	10085130	
Establishment Operations:	Manufacturer	

At the bottom of the page, there is a note about page last update, instructions for file formats, and language assistance available in multiple languages.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?id=818572&lpcd=KCO>

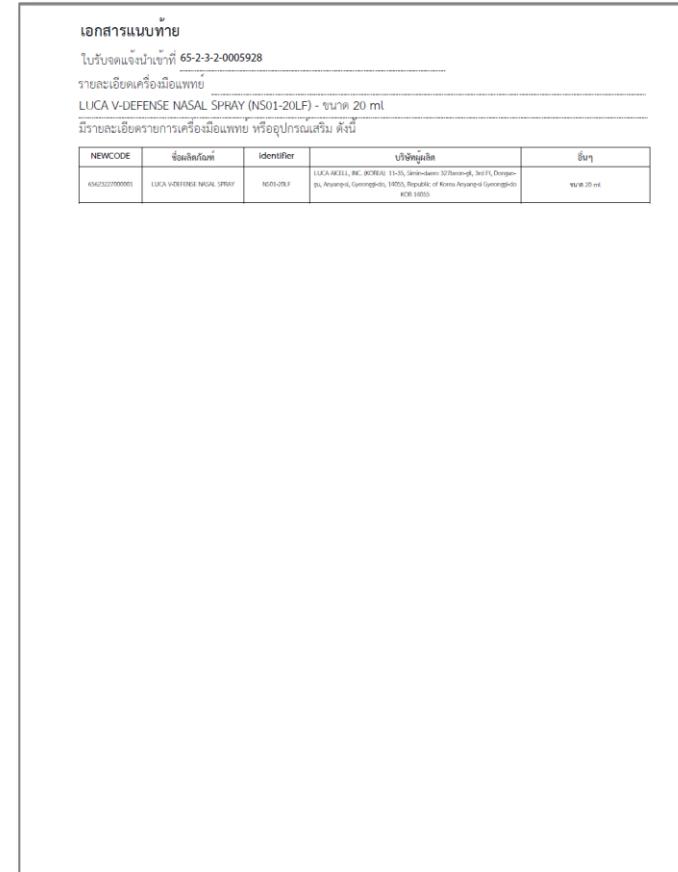
Certifications

LUCA AICell has obtained European CE MDR certification.



Certifications

LUCA AICell has obtained import and marketing authorization from the Thai FDA.



Package Information

Box Package Information

Model#	Product Name	Product Box Info		RRP Box Info			Carton Box Info			
		Size(mm)	Weight(g)	Q'ty(EA)	Size(mm)	Weight(Kg)	Q'ty(EA)	Q'ty(RRP)	Size(mm)	Weight(Kg)
NS01-20LF	LUCA V-Defense Nasal Spray	35x35x115	40	10	185x75x119.5	0.435	180	18	575x480x140	8.50

Shipping Information

Container Size & Type	CT/Pallet	Pallet size(cm)	Pallet/Container	Q'ty on the Pallet (EA)	Additional Q'ty in CT (EA)	Total Q'ty (EA)	Total Weight (Kg)
20FT Reefer Container	52	110x110x211	8	74,880	15,120	90,000	4,298
40'HQ Reefer Container	60	110x110x242	20	216,000	12,240	228,240	10,898
20FT Container	52	110x110x211	10	93,600	-	93,600	4,480
40'HQ Container	60	110x110x242	20	216,000	24,480	240,480	11,476

LUCA V-Defense Nasal Spray



주식회사 루카에이아이셀 (LUCA AICell Inc.)

✉ sales@lucaaicell.com

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📞 031-8091-1000

📠 031-8091-0010