RAW MATERIAL INFORMATION

NATURA-TEC MARINE CELLSHIELD AP

Product identification

Manufacturer : Natura-Tec

Country of origin : France

Custom Tariff : 29159070

Manufacturing process and chemical composition

Manufacturing process:

Natura-Tec Marine CellShield AP is obtained by the careful combination of the Caprylic Capric Triglyceride with the Pavlova Lutheri Extract following a maceration process in a closed container at cold temperature under specific agitation during a controlled time. The final product is then packed under nitrogen
The microalgae inoculum of Pavlova Lutheri is cultivated in closed photobioreactor, in our plant on the Riviera,
The bioreactors is provided with appropriate sunlight and CO2

The inoculum multiplies in a specific culture medium and the microalgae biomass is obtained following a certain time of cultivation .
The biomass is then harvested , dried and controlled .
The biomass is then extracted to obtain the Pavlova Lutheri Extract.

Chemical composition:

INCI/USA	INCI/EEC	CAS No.	EINECS / ELINCS No.	Function	%
Caprylic/Capric Triglyceride	Caprylic/Capric Triglyceride	73398-61-5	277-452-2	Active	QSP
Pavlova Lutheri Extract	Pavlova Lutheri Extract	2101635-97-4	--		< 5%

Our **Natura-Tec Marine CellShield AP** does not contain additives

Impurities:

Impurities	Nature	Specification, ppm
Residual solvents		None
Monomers		None
Heavy metals	Pb	<LOQ (LOQ = 0.05ppm)
	As	<LOQ
	Cd	<LOQ
	Hg	<LOQ
	Cr	<LOQ
	Ni	<LOQ
	Others	Σ < 3 ppm
Pesticides		None

Decontamination by radioactivity

We hereby certify that the product **Natura-tec CellShield AP** has not been treated with ionising radiation.

Reach compliance / CLP classification

Reach (CE regulation n°1907/2006)

INCI/USA	CAS No.	EINECS / ELINCS No.	Pre-registration	Registration number
Caprylic/Capric Triglyceride	73398-61-5	277-452-2	Yes	01-2119492306-35-0012
Pavlova Lutheri Extract	2101635-97-4	--	Exempted	

CLP classification

Natura-tec Marine CellShield AP is not classified under regulation CE 1272/2008

Ingredient of vegetable origin

General description of the vegetable ingredients		
INCI name of the ingredient of vegetable origin	Caprylic/Capric Triglyceride	Pavlova Lutheri Extract
Name of the vegetable (genus – species - family)	Genus :Cocos Species : C. nucifera Family : Arecaceae	Family : Pavlovaceae Genus : Pavlova Species : Pavlova Lutheri
Part used	Fruit	Microalgae inoculum
Geographical origin	Dominican Republic	Northern sea
Is the plant cultivated or natural?	Cultivated	Cultivated
Is it a regulated vegetal species (CITES, IUCN red list…)?	No	No

Storage conditions

Packaging : Plastic canisters of 1Kg, 10Kg and 25Kg net.
Storage : Store in a cool dry place, below 10°C, away from light in original unopened packaging.
Shelf life : 12 months in original unopened packaging

Toxicological data

From information available, **Natura-Tec CellShield AP** is non-toxic under normal conditions of use.

Cytotoxicity test – MTT test
MTT - In vitro evaluation of the cytotoxicity of a cosmetic product with an assay on Normal Human Epidermal Keratinocyte (NHEK) cell cultures (UNI/EN ISO 10993-5: 2009 (E)
The MTT assay (colorimetric test) evaluates in vitro the viability of cells exposed to different concentrations of the investigated cosmetic product in comparison with untreated cells.

Results : Natura-Tec Marine CellShield AP is non cytotoxic from 0,1%, to 2,0% of use.

Regulatory information - Certificates

Cosmetic directive compliance
In conformance to the EC Directive n° 1223/2009 in respect to the use in cosmetic products, **Natura-Tec Marine CellShield AP** is exempted of prohibited substances (Annex II) and restricted substances (Annex III). **Natura-Tec Marine CellShield AP** is exempted of Phtalates, nonylphenol, alkylphenols, phenol, nitrosamines, glycol ethers.

GMO certificate
We hereby certify that **Natura-Tec Marine CellShield AP** does not contain ingredients from genetically modified organisms in accordance with EC Regulations 1829/2003 and 1830/2003.

Non animal testing
We hereby confirm that **Natura-Tec Marine CellShield AP** of our manufacture, has not been tested on animals.

Absence CMR
It is certified that the product **Natura-Tec Marine CellShield AP** does not contain carcinogenic, mutagenic or reprotoxic (CMR) substances of categories 1, 2, 3 or 1A, 1B or 2 listed in regulation 1272/2008 and amendments: commission regulation (CE) n° 790/2009 and n°286/2011.

Absence of allergens certificate
It is hereby certified that the product **Natura-Tec Marine CellShield AP** of our manufacture, does not contain any of the 26 allergens listed in the Cosmetic Directive CEE / 76 / 768 and amendments

Absence SVHC
It is certified that the product **Natura-Tec Marine CellShield AP** of our manufacture does not contain substances identified as SVHC featuring in the "REACH candidate list" published**.**
The "REACH candidate list" is present on ECHA web site at the following link.
Link: http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

BSE statement
We, the undersigned, certify that during the manufacturing process of our **Natura-Tec Marine CellShield AP**:
- No material derived from animal has been used during the manufacture, processing or packing / re-packing.
- There is no risk of cross contamination from products derived from animal during the manufacture, processing or packing / re-packing

Gluten free
We certify that the product **Natura-Tec Marine CellShield AP** that we manufacture is Gluten free.

Microbiological specification
Natura-Tec Marine CellShield AP respects the below specifications :
- Total aerobic mesophilic bacteria < 100 cfu/g/ml
- Yeasts and molds < 100 cfu/g/ml
- Absence of pathogen micro-organisms :
  - Absence of Pseudomonas aeruginosa
  - Absence of Escherichia coli
  - Absence of Staphyloccocus aureus
  - Absence of Candida albicans

Nanomaterial free
We hereby certify that our **Natura-Tec Marine CellShield AP** does not contain nanomaterials.

Preservative free
We hereby certify that our **Natura-Tec Marine CellShield AP** does not contain preservatives

Global restriction

Europe	No restriction
USA	No restriction
Canada	No restriction
Japan	No restriction
China	Registered under : Caprylic/Capric Triglyceride (and) Algae Extract - Species : “Pavlova Lutheri”
Australia	No restriction
Korea	No restriction

Efficacy tests

PROPERTIES

Natura-Tec Marine CellShield AP is an amazingly effective anti-pollution active ingredient with rapid and significant protective effect against outdoor and indoor pollution.
Natura-Tec Marine CellShield AP strongly decreases oxidation and inflammation responses in the skin, improves the skin protective barrier and boosts skin hydration contributing to an improvement of skin health conditions and cell viability.

Natura-Tec Marine CellShield AP is the result of extensive research by our joint group Biotechnology center and is produced using our patented closed circuit low carbon footprint photobioreactor technology which ensures consistent quality and purity combined with environmental compliance and minimal carbon footprint (B.E.S.T. - Beautiful Earth Sustainable Technology).

To counteract external aggression to the skin, our Biotechnology center developed a new microalgae active, **Natura-Tec Marine CellShield AP**, based on the Pavlova Lutheri species. This particular species was selected due to its high content in omega 3, long chain EPA and DHA fatty acids, shown by scientists to help the body to fight against the oxidative stress of PM (particulate matter) and offer global skin protection.

EVALUATION OF PROTECTIVE EFFECTS AGAINST POLLUTION.

VIABILITY OF KERATINOCYTES INTOXICATED BY URBAN AND INDOOR DUST– IN-VITRO TEST

Aim of study

Evaluation of the protective effects of our **Natura-Tec Marine CellShield AP** from 0,1% to 2% of use against pollution on normal human epidermal keratinocytes (NHEK) during 48 and 72 hours.
More specifically, the effects of the compounds were evaluated on the viability of NHEK intoxicated with urban (Urban dust 1649b) or indoor (Indoor dust 2584) pollutant, following a standard MTT reduction protocol.

Pollutant standards :

1- **URBAN DUST** : Standard Reference Material® 1649b of the National Institute of Standards and Technology (NIST)

Standard Reference Material® 1649b
This Standard Reference Material (SRM) is intended for use in evaluating analytical methods for the determination of selected **polycyclic aromatic hydrocarbons (PAHs), nitro-substituted PAHs (nitro-PAHs), polychlorinated biphenyl (PCB) congeners, chlorinated pesticides, and inorganic constituents** in atmospheric particulate material and similar matrices
Particulate Matter = PM = Complex mixture of small particles, 10 µmeters of diameter or smaller

2- INDOOR DUST : Standard reference Material® 2584 of the National Institute of Standards and Technology (NIST)

Standard Reference Material® 2584
Trace Elements in Indoor Dust
(Nominal Mass Fraction of 1 % Lead)
This Standard Reference Material (SRM) is intended for use in the evaluation of methods and for the calibration of apparatus used to determine lead and other trace elements in dust. SRM 2584 is composed of dust collected from vacuum cleaner bags used in the cleaning of interior dwelling spaces. An SRM unit 2584 consists of 8 g of particulate matter, more than 99% of which passes through a 100 µm sieve (No. 145).

Certified Mass Fractions INDOOR DUST

Element Mass Fraction	(mg/kg)
Arsenic (As)	17.4 ± 4.2
Cadmium (Cd)	10.0 ± 1.1
Chromium (Cr)	135.0 ± 9.1
Lead (Pb)	9761 ± 67
Mercury (Hg)	5.20 ± 0.24

Preliminary cytotoxicity assay

Cell type : NHEK in culture medium
Incubation time : 72 hours
Evaluation parameters : MTT reduction assay and morphological observations with a microscope

Results : **Natura-Tec Marine CellShield AP** is non cytotoxic from 0,1%, to 2,0% of use.

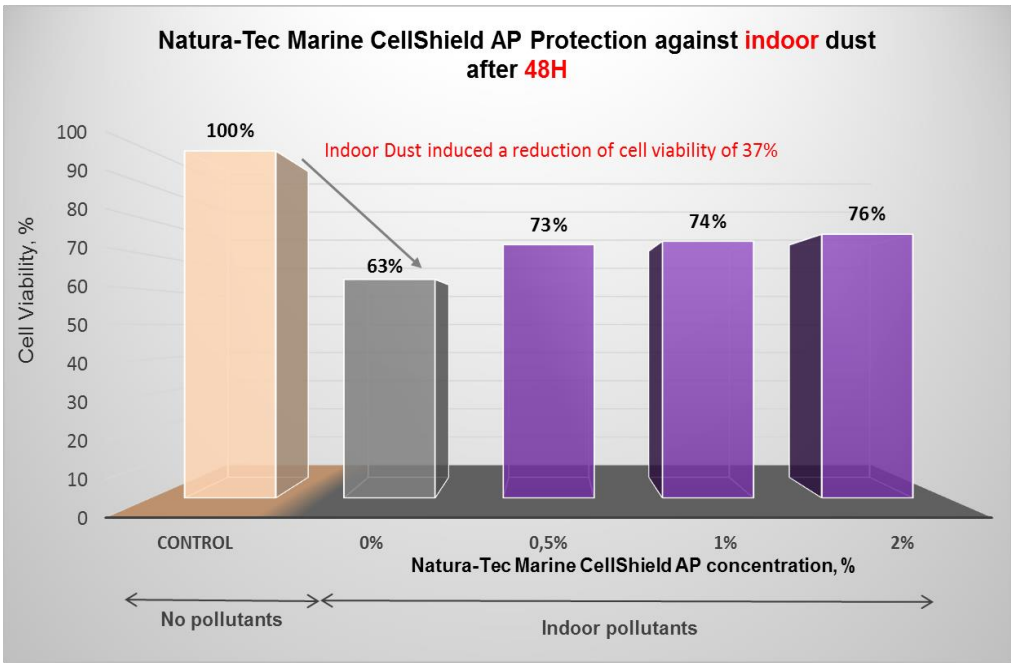
Pollutant effects on cell viability

Under the experimental conditions of this study, the intoxication of the NHEK with urban dust or with Indoor dust induced a strong decrease of cell viability associated with a decrease of cell growth that was clearly observed already after 48 hours of incubation.

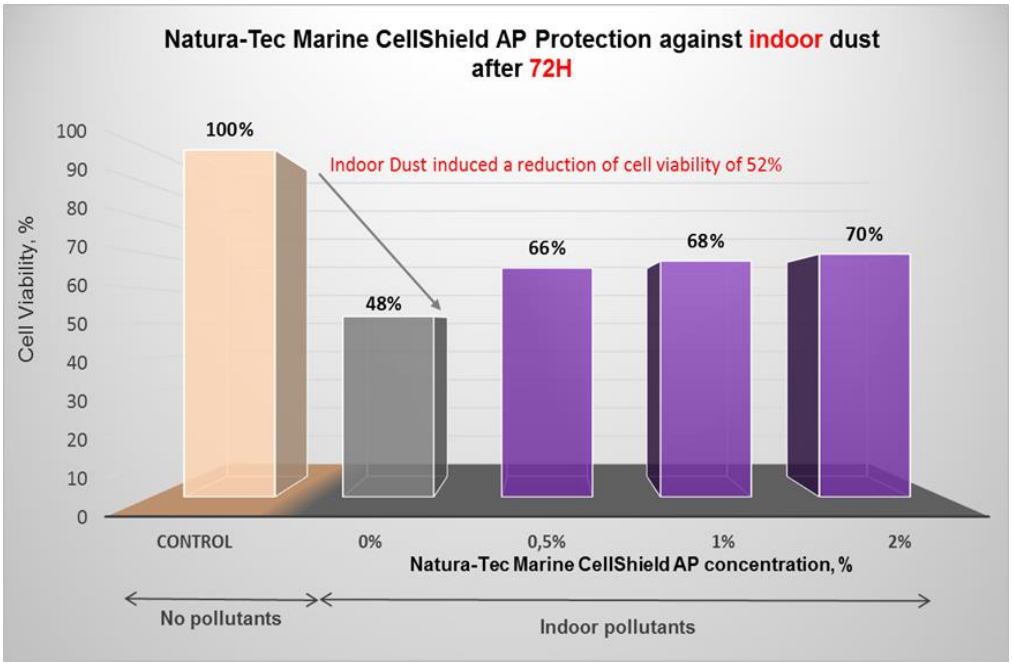
Results after 72 hours add relevance to the test, subjecting keratinocytes to extreme conditions.
The significance of the results obtained at 72 hours confirms the objectivity of this in-vitro test.

Anti-Pollution Test – against indoor dust

After 48 hours incubation



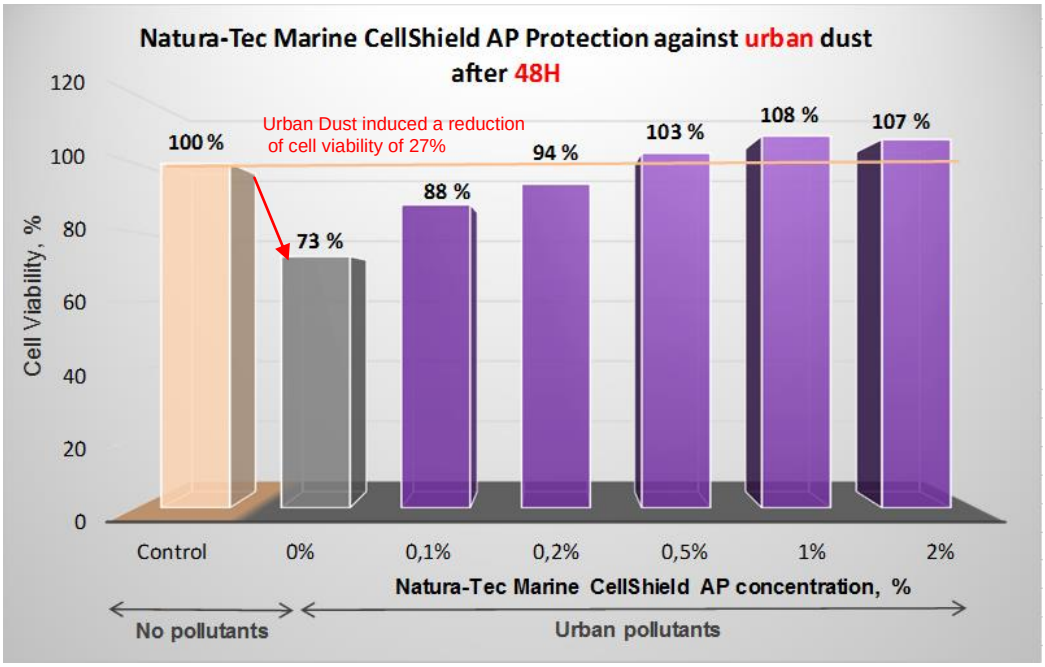
After 72 hours incubation



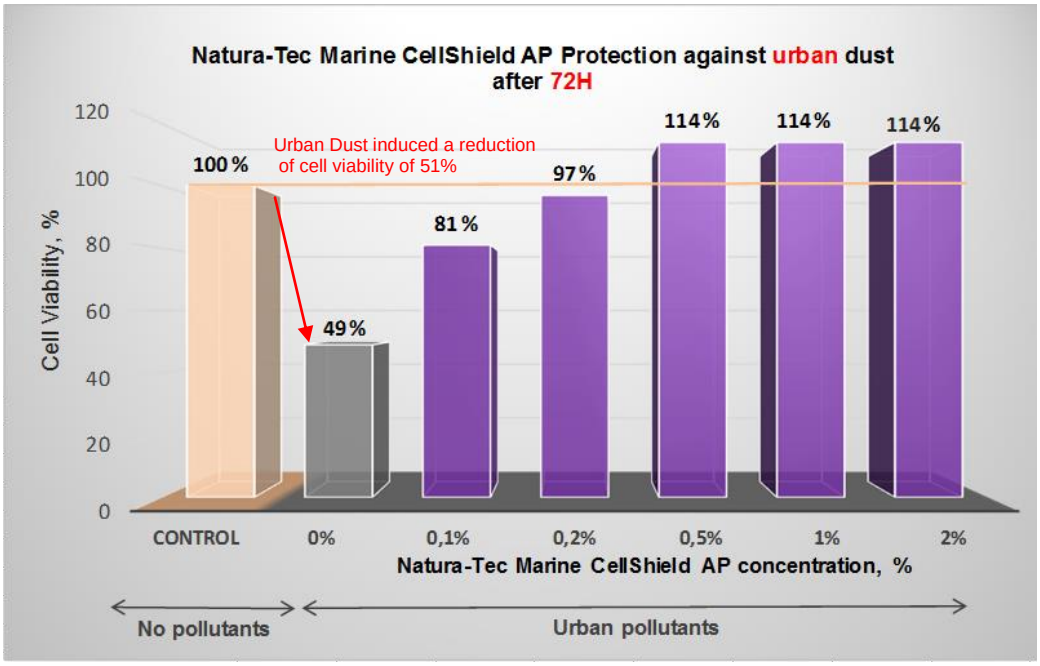
After 48hours and 72 hours incubation, we see that the Indoor dust has a negative impact on the cell viability : pollutants decrease cell viability respectively of 37% and 52%.
When we use our active**, Natura-Tec Marine Cell Shield AP**, we see an immediate protective effect when tested at 0,5%, 1%, and 2% already after 48 hours of incubation.

Anti-Pollution Test – against Urban dust

48 hours incubation



After 72 hours incubation



After 48 hours and 72 hours incubation, we see that Urban dust has a negative impact on cell viability : pollutants decrease cell viability respectively of 27% and 51%.
When we use our active**, Natura-Tec Marine Cell Shield AP** , we see an immediate protective effect already with 0,2% after both 48 and 72 hours of incubation.
And then from 0,5% of use, we achieve a maximum cell protection level and observe cell viability greater than in the non-intoxicated condition.

Conclusion :

After 48 and 72 hours incubation,
Indoor Dust induced reduction of cell viability of 37% and 52% respectively
Urban Dust induced reduction of cell viability of 27% and 51% respectively

These results demonstrate that Indoor pollutants are more aggressive than urban dust.

Against Indoor dust, with 2% of use of **Natura-Tec Marine CellShield AP** we observe an increase of the cell viability of 13% after 48h and 22% after 72h.
This result means a significant protection against indoor pollutants.

Against urban dust, we observe a significant increase of cell viability already with 0,2% of use and from 0,5% of use we can observe a total inhibition of pollution damage.
This active is an excellent shield against urban dust.
Our results indicate that viability and cell stimulation are improved by using our active **Natura-Tec Marine CellShield AP.**

Overall protection from environmental aggression and detoxification effect are essential.
Natura-Tec Marine CellShield AP offers a global protection concept and efficacy to help the formulators develop cosmetics that can help combat the adverse effects of environmental stress and skin exposure to the elements.

Advise for use: 0,2 – 2,0%
In all kinds of formulations for a “Blue” protection claim.

Regulatory Affairs Manager : Pascale Goyat

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