

Home > Dispositivi Medici di Classe I,IIa/b,III > Dispositivo Medico (DM)

Dispositivo Medico (DM)

Criteri di Ricerca

Ricerca su tutti i DM Ricerca i DM in To-do List

Progressivo di sistema attribuito al Dispositivo:

Fabbricante:

Codice attribuito dal fabbricante (identificativo catalogo):
 da:
 a:

Nome commerciale e modello:

Classificazione CND: [Cerca](#)

Stato del DM:

Ruolo dell'utente rispetto al DM:

Immissione in commercio:

Iscritti al Repertorio:

Progressivo di sistema attribuito al Dispositivo	Fabbricante	Codice attribuito dal fabbricante (identificativo catalogo)	Nome commerciale e modello	Classificazione CND	Stato del Dispositivo	Data Fine Commercio	Seleziona <input type="checkbox"/>
12345678 *	GAAP TECHNOLOGY OÜ	NCNMR2-VAR.1.2020	CARBON NANOCLUSTERS ANTI PARTICULATED RESPIRATOR NCN MR2	R030199 - MASCHERE RESPIRATORIE - ALTRE	V		<input checked="" type="checkbox"/>

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Stato del Dispositivo: L=IN LAVORAZIONE C=CONSOLIDATO V=VALIDATO P=PUBBLICATO U=CANCELLATO D'UFFICIO

Se il progressivo di sistema del DM è seguito dal simbolo (*) vuol dire che sono presenti in banca dati collegamenti con altre notifiche.

Qualora siano presenti piu' pagine riferibili al risultato della ricerca, l'attivazione del check 'Seleziona tutti' selezionerà solo i record della pagina corrente e non quelli presenti nelle pagine successive. Per selezionare i record delle restanti pagine utilizzare i link 'precedente' / 'successiva' ed attivare, per ciascuna pagina, il relativo check ('seleziona tutti')

Seleziona: Cliccare su uno dei quadratini in corrispondenza del componente o dei componenti presenti nella lista a seconda delle operazioni

Operazioni attivabili:

- Inserisci:** Consente di inserire un nuovo DM.
- Copia:** Consente di effettuare la copia del DM selezionato, al fine di semplificare l'inserimento di un altro DM, riutilizzando le informazioni già inserite.
- Modifica:** Consente di modificare il DM selezionato per modificarne i dati precedentemente inseriti. E' possibile modificare DM che si trovano solo nello stato "in Lavorazione" o

* Per richiesta del N° di certificato contattare: info@gaaptech.com



DICHIARAZIONE DI CONFORMITÀ

AI SENSI DELLA DIRETTIVA EUROPEA 93/42/CEE COSÌ COME MODIFICATA DA DIRETTIVA EUROPEA 2017/745/CE

MASCHERINA FACCIALE
VARIANTE: COD.: NCN MR2
RESPIRATORE CON FETTUCCE ELASTICHE

La scrivente Gaap Technology OÜ, con sede a Tallinn (Estonia) in Harju Maakond Kesklinna-Linnaosa – Sakala tn 7-2, fabbricante del Dispositivo Medico sopra descritto, dichiara sotto la propria responsabilità che,

Il Dispositivo Medico di classe I denominato NCN MR2 (allegato 1) soddisfa tutte le disposizioni applicabili nella Direttiva 93/42/CEE è stato progettato e fabbricato in accordo ai requisiti previsti dall'allegato VII della Direttiva.

A tale scopo la scrivente garantisce sotto la propria responsabilità che:

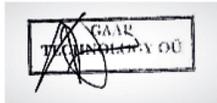
- Il Dispositivo in oggetto soddisfa i requisiti essenziali richiesti dall'Allegato I della Direttiva 93/42 CEE
- Il Dispositivo in oggetto è da considerarsi appartenente alla Classe I;
- Il Dispositivo in oggetto non è uno strumento di misura;
- Il Dispositivo in oggetto non è destinato ad indagini cliniche;
- Il Dispositivo in oggetto viene commercializzato in confezione non sterile;
- Il procedimento di produzione del Dispositivo Medico in oggetto è prodotto secondo il sistema di qualità GAAP TECHNOLOGY OÜ.

Si dichiara inoltre che la presente dichiarazione è parte integrante del Fascicolo Tecnico del Dispositivo in oggetto e che la medesima è a disposizione delle Autorità Sanitarie.

Tallinn, 24 Febbraio 2020

In fede

Gaap Technology OÜ



Il legale rappresentante

GAAP TECHNOLOGY OÜ
Harju Maakond Kesklinna-linnaosa – Sakala tn 7-2
10141 Tallinn (Estonia)
Company Registration Number 14845824



Allegato A Elenco prodotti

Articolo	Descrizione	Colore
NCN MR2	Mascherina Protezione vie respiratorie	Nero

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NITE CARBON NANOCCLUSERS HYDRO LINE

NCN HYDRO LINE

MATERIAL SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name: NITE CARBON NANOCCLUSERS HYDRO LINE

Product Number: 161293

Supplier: Nite Technology OÜ

Harju Maakond, Tallin

Kesklinna-Linnaosa – Sakala tn 1, 15041

Company Registration Number 14628050

Revised On: 31/03/2019

Product Uses: Food-Cosmetic – Dermocosmetics – Food Supplements - Biological

SECTION 2: COMPOSITION/ INFORMATION INGREDIENTS

INGREDIENT	CAS NUMBER	WEIGHT %
Carbon Nano Clusters material from <i>Vitis Vinifera Grape Seed</i>	Proprietary	100

SECTION 3: HAZARDS IDENTIFICATION

Classification according to Regulation (EC) No 1272/2008

Eye irritation (Category 2), H319 Specific target organ toxicity

For the full text of the H-Statements mentioned in this Section, see Section 16.

Labelling according Regulation (EC) No 1272/2008

Pictogram



Supplemental Hazard Statements: none

SECTION 4: FIRST AID MEASURES

Description of first aid measures

General advice Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin, contact wash off with soap and plenty of water. Consult a physician.

NITE CARBON NANOCCLUSERS HYDRO LINE MSDS REV 01/2018



In case of eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling and/or in section 11

Indication of any immediate medical attention and special treatment needed: No data available

SECTION 5: FIRE-FIGHTING MEASURES

Suitable extinguishing media Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide

Special hazards arising from the substance or mixture: No data available

Advice for firefighters Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation.

Evacuate personnel to safe areas. Avoid breathing dust. For personal protection, see section 8.

Environmental precautions: Do not let product enter drains.

Methods and materials for containment and cleaning up Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Reference to other sections: For disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling Avoid contact with eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

Normal measures for preventive fire protection; for precautions see section 2.2.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Eye/face protection: Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

Wash and dry hands

Body Protection Impervious clothing, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Black- Grey powder

Dimension. (Medium size): 120-150 nm

Odor: No data available

NITE CARBON NANOCCLUSERS HYDRO LINE MSDS REV 01/2018



Odour Threshold No data available
pH No data available
Melting point/freezing point Melting point/range: > 280 °C - lit.
Initial boiling point and boiling range No data available
Flashpoint > 94 °C
Evaporation rate No data available
Flammability (solid, gas) No data available
Upper/lower flammability or explosive limits No data available
Vapour pressure No data available
Vapour density No data available
Relative density 1,600 g/cm³ at 20 °C
Auto-ignition temperature No data available
Decomposition temperature No data available
Viscosity No data available
Explosive properties No data available
Oxidizing properties No data available

SECTION 10: STABILITY AND REACTIVITY

Reactivity No data available
Chemical stability Stable under recommended storage conditions.
Possibility of hazardous reactions No data available
Conditions to avoid No data available
Incompatible materials Strong oxidizing agents
Hazardous decomposition products Hazardous decomposition products formed under fire conditions Carbon oxides
Other decomposition products - No data available In the event of fire: see section 5

SECTION 11: TOXICOLOGICAL INFORMATION

Acute toxicity No data available
Skin corrosion/irritation No data available
Serious eye damage/eye irritation No data available
Respiratory or skin sensitization No data available
Germ cell mutagenicity No data available
Carcinogenicity IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity No data available
Specific target organ toxicity - single exposure Inhalation - May cause respiratory irritation.
Specific target organ toxicity - repeated exposure No data available
Aspiration hazard No data available



Additional Information RTECS: Not available

SECTION 12: ECOLOGICAL INFORMATION

Toxicity No data available
Persistence and degradability No data available
Bioaccumulative potential No data available
Mobility in soil No data available
Results of PBT and vPvB assessment: PBT/vPvB assessment not available as chemical safety assessment not required/not conducted
Other adverse effects No data available

SECTION 13: DISPOSAL CONSIDERATIONS

Product Offer surplus and non-recyclable solutions to a licensed disposal company.
Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Contaminated packaging Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

SECTION 15: REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006. 15.2
Chemical safety assessment for this product a chemical safety assessment was not carried out

FURTHER INFORMATION

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