



Milano, 27 marzo 2020

Rely+On™ Virkon™ in soluzione 1% sviluppa 1050 ppm di cloro disponibile, pari allo 0,105%.

Il Ministero della Salute nella circolare 5443 del 22-02-2020 indica come disinfettanti per superfici adeguati a trattamenti di disinfezione anti Covid19 tutti "i comuni disinfettanti per uso ospedaliero quali Ipoclorito di sodio (0,1%)".

Rely+On™ Virkon™ sviluppa oltre 0,1% di cloro e risponde pertanto ai requisiti indicati dal Ministero.

Inoltre, Rely+On™ Virkon™ è ufficialmente testato come efficace per abbattere Coronavirus, come da lettera Lanxess e test di laboratorio indipendente ATS Lab negli USA ed è ampiamente utilizzato come disinfettante in ambito ospedaliero in quanto Presidio Medico Chirurgico con efficacia Virucida (allegata approvazione del Ministero della Sanità del 23 settembre 2009).

In fede.

Carlo Radolovich
ARCO Srl





Ministero del Lavoro, della Salute e delle Politiche Sociali

DIPARTIMENTO DELL'INNOVAZIONE
DIREZIONE GENERALE DEI FARMACI E DISPOSITIVI MEDICI
DELL'EX MINISTERO DELLA SALUTE

IL DIRETTORE

Dell'Ufficio VII – Prodotti di interesse sanitario diversi dai dispositivi medici

D.G.F.D.M.3240.

VISTO l'articolo 189 del T.U. delle Leggi Sanitarie approvato con R.D. 27/7/1934, n.1265 e successive modifiche ed integrazioni;

VISTO il D.P.R. 6 ottobre 1998, n.392, recante disposizioni in materia di produzione ed immissione in commercio di presidi medico chirurgici;

VISTA la legge 3 agosto 2001, n. 317 che ha istituito il Ministero della Salute identificandone le attribuzioni;

VISTO il decreto legislativo 30 marzo 2001, n. 165 recante norme generali sull'ordinamento del lavoro alle dipendenze delle amministrazioni pubbliche.

VISTO il D.M. 17 maggio 2001 con il quale sono stati individuati gli uffici centrali e periferici di livello dirigenziale di questo Dicastero;

VISTA la legge 15 luglio 2002, n.145 riportante disposizioni per il riordino della dirigenza statale;

ATTESO che la titolarità dell'Ufficio VII è attribuita, con decorrenza 1°ottobre 2004, alla dr.ssa Marcella Marletta;

VISTO il D.P.R. 28 marzo 2003, n.129, recante il regolamento di organizzazione del Ministero della Salute;

VISTO il D.M. 12 settembre 2003 , recante l'individuazione degli uffici dirigenziali di livello non generale del Ministero della Salute, come modificato dal D.M. 23 giugno 2004;

VISTO il D.L. 16 maggio 2008, n. 85 concernente disposizioni urgenti per l'adeguamento delle strutture di governo;

VISTO il DM. datato 18 marzo 1991 e successive modifiche con cui questa amministrazione ha autorizzato l'immissione in commercio del presidio medico chirurgico, registrazione n. 16765 attualmente denominato **VIRKON** con validità fino a 3 anni - prodotto presso l'officina Antec Intl. Ltd Chilton Industrial Estate Windham Road, Sudbury, Suffolk CO102XD (England) e commercializzato nelle confezioni da kg g 5-10-50-500 e kg. 5

ATTESO che la titolarità del presidio medico chirurgico predetto è attualmente attribuita alla Società **ANTEC Intl. Ltd** – A DuPont Company – sita in Windham Road, Chilton Industrial Estate – Sudbury – Suffolk – Co102XD – Regno Unito rappresentata in Italia dalla società **BIOSEC ITALIA Srl** con sede legale in Vedelago (Treviso) Via G. Marconi, 110 3 codice fiscale 03635790268;

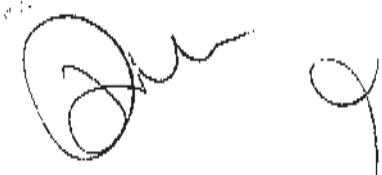


Rely+On™ Virkon®
PRESIDIO MEDICO CHIRURGICO

TESTATO E SPERIMENTATO
EFFICACE CONTRO

- BATTERI (EN 1276, EN 13697):
*Pseudomonas aeruginosa, Escherichia coli,
Staphylococcus aureus, Enterococcus hirae*
- FUNGHI (EN 1650, EN 13697):
Candida albicans e Aspergillus niger
- VIRUS (EN 14476)
Adenovirus type 5 e Poliovirus type 1

TESTATO E SPERIMENTATO
EFFICACE CONTRO

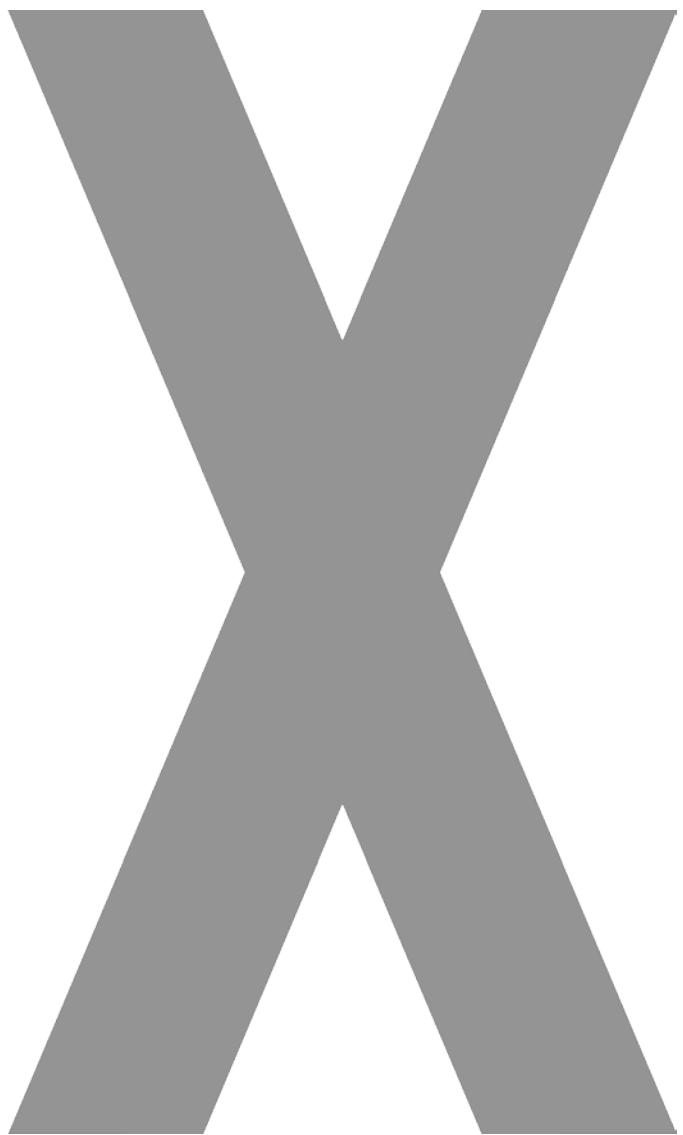
A handwritten signature in black ink, appearing to read "Ditta S.p.A." followed by a date.

Rely+On™ Virkon™ Safety of 1% Solutions

20.01.2020

Antec International Limited
A Company of the Lanxess Group
Windham Road
Chilton Industrial Estate
Sudbury
Suffolk
CO8 5BX
United Kingdom

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Executive summary

Rely+On™ Virkon™ is intended to be used at concentrations of 1% or less in most situations, at which dilution rate the product is considered to be of low hazard and safe for the intended uses as any hazards associated with the powder are diluted by a factor of at least 100X.

1% concentration (or lower) solutions of Rely+On™ Virkon™ are therefore not classified as hazardous according to the Globally Harmonized System for hazard classification (GHS).

This document is intended to support your risk assessment and as a general guide on safe use of Rely+On™ Virkon™ working solutions (1% concentration or lower). As exposure potential varies greatly between users, use areas and application methods, individual risk assessments will need to be conducted that are specific to your conditions of use and in accordance with the relevant national or regional legislation. Always follow the instructions of your risk assessment when using the product.

This document is not intended as a safety data sheet as per the meaning within European 1907/2006 (REACH) or equivalent legislation.

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1. Identification of the product and manufacturer

Product name: Rely+On™ Virkon™ (1% dilution in water)
Manufacturer: Antec International Limited – a company of the Lanxess-Group
Windham Road
Chilton Industrial Estate
Sudbury, Suffolk, CO10 2XD
United Kingdom
Tel: +44 (0) 1787 377 305
Em. Tel: +49 214 30 993000

2. Hazard Classification

All information refers to diluted solutions of Rely+On™ Virkon™ at a concentration of 1% or lower in water, unless specified otherwise, and is made in accordance with the Globally Harmonised System of classification, labelling and packaging of substances and mixtures.

Hazard pictograms:	None (not classified as dangerous)
Signal word:	None
Hazard statements:	None
Precautionary statements:	None

3. Basis for Hazard Classification

According to the Globally Harmonised System of classification, labelling and packaging of substances and mixtures (GHS), 1% solutions of Rely+On™ Virkon™ are not classified as dangerous. The justification for this is summarised below.

Calculation methods referred to below are those described in the abovementioned GHS text.

3.1. Toxicological profile

Endpoint	Result	Justification
Skin irritation	Not irritating	Calculation method
Eye irritation	Not irritating	Calculation method and independent test data following OECD Test Guideline 405 (eye irritation)
Skin sensitisation	Not sensitising	Calculation method and independent test data following OECD Test Guideline 406 (skin sensitisation)
Acute oral toxicity	Not harmful	Independent test data according to OECD 401 for Rely+On™ Virkon™ powder demonstrating that the product has a low toxicity and therefore not harmful. Dilution to 1% will reduce the toxicity proportionally, to the extent that it is considered to be of very low toxicity
Acute dermal toxicity	Not harmful	Independent test data for Rely+On™ Virkon™ powder demonstrating that the product has a low toxicity and therefore not harmful. Dilution to 1% will reduce the toxicity proportionally, to the extent that it is considered to be of very low toxicity
Acute inhalation toxicity	Not harmful	Calculation method

6. Storage

Store unused solutions out of direct sunlight in loosely sealed containers. Prevent from contamination which could lead to a reduction in activity of the solution.

Prevent from contact with strong alkalis.

Do not leave in application equipment after use. Rinse thoroughly.

7. Personal Protection

Below is a guide on typical personal protective equipment (PPE) for common tasks involving solutions of Rely+On™ Virkon™ at a concentration of 1% or less. Selection of appropriate PPE will depend on many factors, many of which are specific to your operation and area of use. As a result, the required PPE must be defined by your own risk assessment.

7.1. Wiping and spraying, small areas

PPE:



Use of skin coverings is recommended, such as a laboratory coat. In case of poor ventilation and nuisance mists, a dust mask may also be required.



e.g. FFP2
dust mask



Task: Application of Rely+On™ Virkon™ 1% solutions by wiping or spraying to surfaces and equipment through small, manual hand-held equipment (e.g. trigger spray).

7.2. Manual spraying, large areas

PPE:



In cases of poor ventilation and nuisance mists:



e.g. FFP2
dust mask



Task: Application of Rely+On™ Virkon™ 1% solutions by low-pressure spraying to surfaces and equipment in LARGE facilities using pressure washers and other powered hand-held equipment.

8. Stability and Reactivity

The product is considered to be stable at normal temperature ranges within which it is used.

Avoid contact with alkalis, acids, halides and metal salts.

9. Disposal Considerations

Rely+On™ Virkon™ solutions may generally be disposed of via drains leading to a foul sewer but not via drains leading to surface waters.

Disposal to foul sewer is typically subject to discharge consent with the appropriate local authority and normally requires prior approval and control of the volumes discharged.

Always seek guidance from your local authority prior to discharge.

Note: Rely+On™ Virkon™ is generally considered to be of low risk to municipal sewage treatment facilities and data can be provided in support of any discharge consent procedures.

Data can be supplied upon request to support any discharge consent applications.

3.2. Specific health effects

Endpoint	Result	Justification
Carcinogenicity	Negative	Formulation does not include any substances classified as carcinogenic within the meaning of GHS
Mutagenicity	Negative	Formulation does not include any substances classified as mutagenic within the meaning of GHS
Toxicity for reproduction	Negative	Formulation does not include any substances classified as teratogenic within the meaning of GHS

3.3. Physical and chemical effects

Endpoint	Result	Justification
Flammability	Negative	Formulation does not include any substances classified as flammable within the meaning of EC/1272 /2008
Oxidising	Negative	Testing on Rely+On™ Virkon™ POWDER according to method A17 of CD 92/69/EEC demonstrating that the product is not oxidising.

3.4. Ecological effects

Endpoint	Result	Justification
Aquatic toxicity	Not harmful	Testing on Rely+On™ Virkon™ POWDER demonstrates an aquatic toxicity within the range 1 – 100 mg/L. Taking the lowest concentration (daphnia) of 1 – 10 mg/L and account for the dilution of 100X for the 1% solution, this equates to a toxicity within the range of 100 – 1000 mg/L and is therefore not considered harmful
Degradability	Not persistent	Calculation method

4. First Aid Advice

4.1. Human Exposure

Whilst the solutions will not cause skin/mucous membrane irritation and eye damage/irritation within the meaning of GHS, contact with eyes may cause discomfort and skin contact may lead to mild skin irritation in some cases and with sufficient contact. Therefore, where contact with skin or eyes is expected, skin coverings and eye protection are recommended.

When facing spray mists and aerosols of the diluted product, respiratory protection may also be required, depending on the extent of potential exposure.

4.2. First aid advice

Route of exposure	Potential symptoms	Response
Inhalation	Mild irritation, coughing	If irritation or discomfort occurs following inhalation, remove from exposure. Use PPE and/or ventilation
Ingestion	Upset stomach, nausea	Ingestion of the solution is unexpected as a route of exposure. In case of ingestion, give small quantities of water to drink. Stop if the person feels sick. Seek medical attention
Skin contact	Mild irritation, reddening	In case of irritation flush skin with plenty of water
Eye contact	Irritation, watering, reddening, discomfort	Flush with water. If irritation persists, seek medical attention

5. Fire-fighting measures

As an aqueous solution without any physical or chemical properties of concern to firefighting (e.g. flammability, oxidisation), contact of 1% Rely+On™ Virkon™ solutions will suppress any fire that it comes in contact with.
