

REPORT
NO. ORYREP 2717

(Issued: 19 May 2026)

**COMPLIANCE TESTING OF
HYDROMED GLOSS PER FDA 21
CFR 175.300 - FDA PARTS 170-199
(INDIRECT CONTACT)**

Client: Dekro Paints (Pty) Ltd



Report Details

Report No	ORYREP 2717
Report Title	Compliance testing of Hydromed Gloss per FDA 21 CFR 175.300 - FDA Parts 170-199 (indirect contact)
Project Code	PC244626
Date	19 May 2026
Client	Dekro Paints (Pty) Ltd
Client Address	24 Fabriek Street, Kuils River, 7579.
Product Name/s	Hydromed Gloss
Report by	Sunette van Allemann
Reviewed by	Dr. Darelle Janse van Rensburg
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Authorisation



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1. REQUEST AND REPORT OBJECTIVE

To evaluate the suitability of a water-based coating for use in environments involving indirect food contact, in accordance with FDA 21 CFR 175.300 and FDA Parts 170–199 requirements. The assessment included compositional analysis and extractive limits (migration) testing to determine whether potentially harmful substances may be released under foreseeable conditions of use.

Testing was conducted to verify the generic coating type, determine the presence of heavy metals, volatile organic compounds (VOCs), and residual solvents, and evaluate the potential migration of substances into food simulants, including distilled water, 3% acetic acid, and 10% ethanol. Distilled water was used to represent aqueous exposure and general moisture conditions, while 3% acetic acid represented mildly acidic conditions that may be encountered in food-processing environments. In addition, 10% ethanol was included as a standard food simulant to assess the migration potential of organic compounds.

The coating is not expected to be exposed to heat, steam, or significant mechanical stress during normal service conditions. As the product is primarily used as a decorative coating in dry food-handling environments, the evaluation was conducted to confirm its suitability and safety for indirect food-contact applications.

2. REFERENCES

The following standards and references apply:

- FDA 21 CFR 175.300 – *Resinous and Polymeric Coatings, United States Food and Drug Administration (FDA), Code of Federal Regulations.*
- FDA 21 CFR Parts 170–199 – *Food Additives Regulations, United States Food and Drug Administration (FDA), Code of Federal Regulations.*
- ISO 11890-1:2024 – *Paints and varnishes — Determination of volatile organic compounds (VOC) and/or semi volatile organic compounds (SVOC) content. Part 1: Gravimetric method for VOC determination.*
- ASTM D4017-02 – *Standard test method for water in paints and paint materials by Karl Fischer method.*
- ISO 3251 – *Paints, varnishes, and plastics – Determination of non-volatile matter content.*
- ISO 2811-1:2016 – *Paints and varnishes — Determination of density — Part 1: Pycnometer method.*

3 SAMPLE SUBMISSION AND DESCRIPTION

- 3.1 During March 2026, a sample was submitted by SGS South Africa (Pty) Ltd for testing.
- 3.2 The sample reference code, quantity, and description are given in Table 1.

Table 1 Sample code, quantity, and client reference.

Orytech Sample Ref. Code/s	Quantity	Client Reference
S5937A0326	1-litre	Hydromed Gloss 10.03.2026

3.2 Sample Preparation

Moulds were prepared (where applicable) for the various tests of the coating system. Following application, the prepared samples were left to dry for a period of 7 days at a controlled temperature of $23 \pm 2^{\circ}\text{C}$ and a relative humidity of $50 \pm 5\%$ before undergoing testing.

4. TEST METHODS AND RESULTS

4.1 ATR-FTIR Analysis

The coating was analysed by means of Attenuated Total Reflectance - Fourier Transform Infrared (ATR-FTIR) Spectroscopy, which is a technique used to obtain an infrared spectrum of absorption or “fingerprint” of a solid, liquid or gas. The results are presented in Table 2 and Figure 1.

The ATR-FTIR spectrum is divided into four regions, namely, the single bond region at $2500 - 4000\text{ cm}^{-1}$ (N-H, O-H and C-H), the triple bond region at $2000 - 2500\text{ cm}^{-1}$ ($\text{C}\equiv\text{N}$ and $\text{C}\equiv\text{C}$), the double bond region at $1500 - 2000\text{ cm}^{-1}$ ($\text{C}=\text{N}$, $\text{C}=\text{O}$ and $\text{C}=\text{C}$) and the ‘fingerprint’ region at $600 - 1500\text{ cm}^{-1}$.

Table 2 ATR-FTIR results.

Orytech Sample Ref. Code/s	Client Reference	Best Match (%)	Generic Type (Best match in Orytech database)
S5937A0326	Hydromed Gloss	97.20	Acrylic water-based enamel

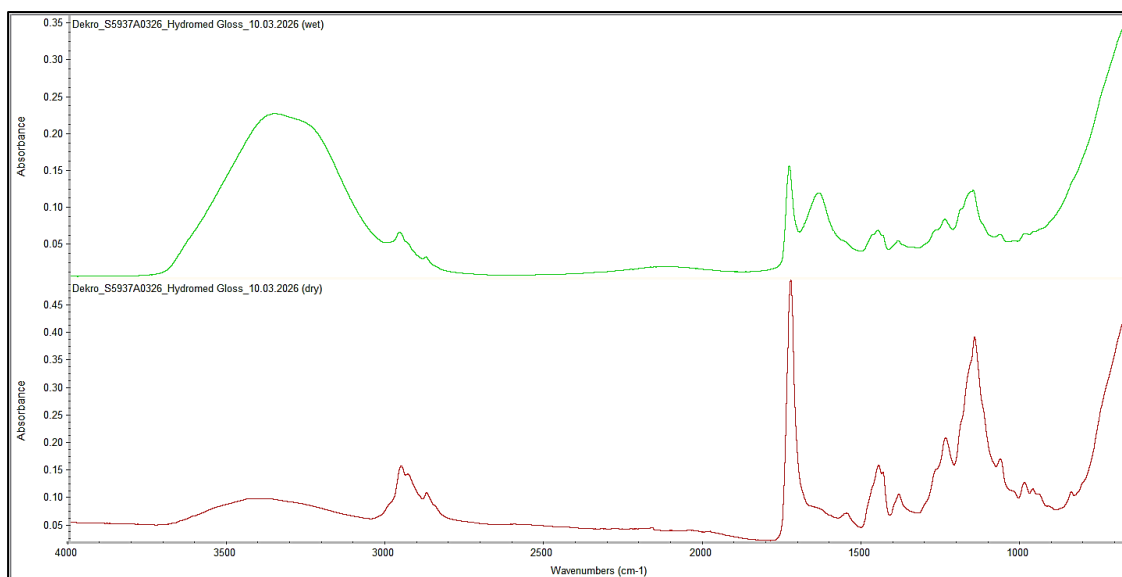


Figure 1 ATR-FTIR fingerprint of Hydromed Gloss (*wet and dry*).

Key Findings of Hydromed Gloss:

The ATR-FTIR spectra obtained for the wet and dry coating samples indicate a predominantly water-based acrylic formulation containing inorganic pigment and mineral filler components. The spectra of the wet and dry samples show similar characteristic absorption bands, confirming that the primary polymeric structure remains consistent after drying, while the intensity of water-associated bands decreases in the dry film.

A broad absorption band in the region of approximately 3200–3600 cm^{-1} in the wet sample is attributed to O–H stretching vibrations associated with water and hydroxyl-containing components. The reduced intensity of this band in the dry sample confirms evaporation of water during the drying process, supporting the classification of the coating as a waterborne formulation. Absorption bands between approximately 2850–2950 cm^{-1} correspond to aliphatic C–H stretching vibrations associated with organic polymeric binder materials typically present in acrylic or styrene-acrylic coating systems. A prominent absorption band near 1720 cm^{-1} is characteristic of carbonyl (C=O) stretching vibrations associated with ester functional groups commonly found in acrylic resin emulsions.

Strong absorption features observed within the 1000–1250 cm^{-1} region are attributed to C–O and C–O–C stretching vibrations, further supporting the presence of ester-containing polymer binders and ether functionalities within the coating matrix. Additional bands within the fingerprint region (approximately 600–1500 cm^{-1}) are consistent with inorganic pigments and mineral fillers, including titanium dioxide and silicate-based extenders.

4.2 XRF Analysis

XRF (X-ray fluorescence) is a non-destructive analytical technique used to determine the elemental composition of materials. The element range of the Mining Plus analyser mode used ranges from Mg (Magnesium) to U (Uranium) on the periodic table of elements. However, only elements found above the detection limits were reported (Table 3).

Table 3 Elemental composition of Sample S5937A0326.

Elemental Composition	Concentration (%)	Error (σ)	Concentration by Weight (mg/kg or ppm)
Si (Silicon)	0.790	± 0.419	7900
Cl (Chlorine)	1.740	± 0.025	174000
S (Sulphur)	0.518	± 0.025	5180
Ti (Titanium)	24.055	± 0.253	240500
V (Vanadium)	0.166	± 0.074	1660
Fe (Iron)	0.018	± 0.028	180
Zr (Zirconium)	0.110	± 0.001	1100
Pb (Lead)	ND	± 0.001	< 5
Zn (Zinc)	0.0472	± 0.001	472
Nb (Niobium)	0.004	± 0.001	40

ND – Not Detected (Below detection limit).

Elements not listed in the table are also below the detection limit (Mining Plus analyser mode).

XRF analysis cannot detect elements 1 – 12 on the periodic table due to their low atomic numbers and limited ability to emit characteristic X-rays. Light Elements (LE) in the context of X-ray fluorescence refer to elements 1–12 of the periodic table.

According to Table 3, the lead (Pb) content in S5937A0326 was < 5 ppm. Based on this result, the coating complies with the South African regulatory limit of 90 ppm, as specified in Government Gazette No. 50665 (2024), and the 90-ppm limit set by international standards such as the Consumer Protection Act and the Restriction of Hazardous Substances (RoHS) Directive.

XRF further indicated that the coating is predominantly composed of inorganic pigment and mineral components typically associated with decorative and protective coatings. Titanium (Ti) was present at the highest concentration, likely due to the presence of titanium dioxide (TiO₂), a commonly used white pigment and opacity enhancer. Chlorine (Cl) and sulphur (S) were also detected at moderate concentrations, suggesting the presence of chlorinated compounds, sulphates, or additive materials within the coating formulation. Minor concentrations of silicon (Si), zirconium (Zr), vanadium (V), iron (Fe), zinc (Zn), and niobium (Nb) were additionally identified, which are likely associated with fillers, pigments, extenders, or trace raw material impurities. Overall, the elemental composition is consistent with a conventional decorative coating system intended for indirect food-contact environments.

4.3 Volatile Organic Compound (VOC) Content

The volatile organic compound (VOC) content, non-volatile matter, and water content of each coating were determined according to the procedures outlined in ISO 11890-1. The results are presented in Table 4.

Equations used:

$$\text{Density } (P_s) = \frac{m_2 - m_1}{v}$$

$$\text{VOC} = (100 - \text{NV} - W_w - W_{ex}) \times P_s \times 10$$

Where;

P_s is the density of the product, in grams per milliliter, at 20°C.

M_1 is the mass, in grams, of the pycnometer and wet coating.

M_2 is the mass, in grams, of the pycnometer.

VOC is the VOC content, in grams per liter, of the product "ready to use".

NV is the non-volatile matter content, as percentage by mass.

Table 4 VOC test results.

Orytech Sample Ref. Code/s	Density (20°C) g/ml	Residue Non-volatiles (%)	Water Content (%)	VOC Content (%)	VOC Content (g/L)
S5937A0326	1.22	54.6	45.2	0.2	2.4

The VOC results confirm that Sample S5937A0326 is a water-based coating formulation with a very low volatile organic compound (VOC) content. The residue non-volatiles content was determined to be 54.6%, indicating that more than half of the coating composition remains as solid material after drying or curing. This portion typically consists of binders, pigments, fillers, and other non-volatile additives responsible for the coating's protective and decorative properties.

The measured VOC content was very low at 0.2% by mass, equivalent to 2.4 g/L. This value is below typical regulatory VOC limits for decorative and industrial coatings and indicates minimal emission of volatile organic compounds during application and drying. The low VOC concentration suggests reduced environmental impact, lower odour emissions, and decreased occupational exposure risks compared to conventional solvent-based coatings.

4.4 Determination of Residual Volatile Organic Compounds (VOCs) by GC-MS Analysis

Volatile organic compounds (VOCs) were extracted from the wet coating and analysed by gas chromatography–mass spectrometry (GC-MS) to determine the residual organic vapour content (Table 5).

Table 5 Residual volatile organic compounds

Determinant ↓	Result mg/m ³
Acetone	0,195
Pentane	0,052
n-Hexane	< 0,005
Methylethylketone	0,016
Ethyl Acetate	< 0,004
Chloroform	< 0,005
1,1,1-Trichloroethane	< 0,003
1,2-Dichloroethane	< 0,005
Isopropyl Acetate	< 0,005
Benzene	< 0,004
Cyclohexane	< 0,006
Carbon Tetrachloride	< 0,010
Isooctane	< 0,004
Heptane	< 0,006
Trichloroethylene	< 0,005
1,4-Dioxane	< 0,005
Propyl acetate	< 0,005
Methyl Isobutyl Ketone	< 0,005
Toluene	0,040
Isobutyl Acetate	< 0,006
Tetrachloroethylene	< 0,007
1,2-Dibromoethane	< 0,010
Butyl Acetate	0,367
Chlorobenzene	< 0,005
Ethylbenzene	0,012
m+p-Xylene	0,021
Styrene	< 0,006
o-Xylene	0,011
Nonane	< 0,009
Cumene	< 0,004
Propylbenzene	< 0,006
1,3,5-Trimethylbenzene	< 0,007
1,2,4-Trimethylbenzene	< 0,004
Decane	< 0,008
1,2-Dichlorobenzene	< 0,007
Naphthalene	< 0,008
Benzyl Alcohol	< 0,005

Results in units specified

Approximate quantitation limit signified by “<” followed by the limit value

In-house media used for blank correction

The GC-MS analysis of residual volatile organic compounds (VOCs) in Sample S5937A0326 identified only trace concentrations of organic solvents and volatile compounds, indicating that the coating contains a very low level of residual organic vapours. Most analytes were reported below the analytical detection limits, demonstrating that the formulation contains minimal quantities of volatile solvent components.

Among the compounds positively detected, butyl acetate (0.367 mg/m³) and acetone (0.195 mg/m³) were present at the highest concentrations, followed by pentane (0.052 mg/m³), toluene (0.040 mg/m³), m+p-xylene (0.021 mg/m³), methyl ethyl ketone (0.016 mg/m³), ethylbenzene (0.012 mg/m³), and o-xylene (0.011 mg/m³). These compounds are commonly associated with residual solvents, coalescing agents, or trace raw material impurities used in coating manufacture.

The absence or near absence of chlorinated solvents, aromatic hydrocarbons, and other regulated VOC species suggests that the coating formulation is controlled and predominantly water-based. Compounds such as benzene, chlorobenzene, trichloroethylene, carbon tetrachloride, and 1,2-dichloroethane were below detection limits, which is favourable from both environmental and occupational health perspectives.

Overall, the GC-MS results correlate with the total VOC content of 2.4 g/L, confirming that S5937A0326 is a low-VOC coating system with minimal solvent emissions. The low residual VOC concentrations indicate reduced potential for odour generation, airborne solvent exposure, and environmental impact during application and curing.

4.5 Extractive Limits /Migration Testing

Extractive limits testing was conducted to evaluate the potential migration of soluble or extractable substances from the coating film under controlled exposure conditions, based on the principles of FDA 21 CFR 175.300 for resinous and polymeric coatings intended for food-contact applications.

Coating films were prepared and cut into test specimens. Each specimen was placed in a clean test vessel and exposed to the selected food simulant. The simulants used included distilled water, 3% acetic acid, and 10% ethanol, selected to represent aqueous, mildly acidic, and alcohol-containing food-contact conditions, respectively.

The test vessels were sealed or covered to minimise evaporation and incubated at 40°C for 24 hours. Following the exposure period, the coating specimens were removed from the simulants. The extract solutions were then evaporated to dryness, and the residue mass was determined gravimetrically. The mass of each vessel/residue was recorded before and after evaporation to determine the total extractive residue.

Control samples containing only the respective food simulants, without exposure to the coating specimens, were prepared and treated under the same conditions. These controls were used to determine background residue contributions from the simulants and test vessels. The final extractive values were corrected against the corresponding control results where applicable.

The extractive residue was calculated as the difference in mass before and after evaporation and expressed relative to the exposed coating area and/or the volume of simulant used (Table 6). The results were compared with the applicable extractive limits specified in FDA 21 CFR 175.300 to assess the suitability of the coating for the intended indirect food-contact application.

Table 6 Extractive limits/migration test results of Sample S5937A0326.

Simulant	Control Residue (g)	Coating Residue (g)	Extractives (mg/in ²)	FDA Limit Direct Contact (mg/in ²)	FDA Limit Indirect Contact (mg/in ²)
Distilled Water	0.0023	0.0038	9.68	≤ 0.5	-
3% Acetic Acid	0.0025	0.0045	12.90	≤ 0.5	-
10% Ethanol	0.0015	0.0015	0.00	≤ 0.5	-

Although FDA 21 CFR 175.300 specifies extractive limits primarily for direct food-contact resinous and polymeric coatings, the extractive testing conducted in this study was intended for screening and safety evaluation purposes relevant to the product's intended indirect food-contact application. The coating exhibited measurable extractive residues under aqueous and mildly acidic conditions, while negligible extractive migration was observed for the 10% ethanol simulant. Given that the product is intended for use as a decorative and protective coating in indirect food-contact environments, such as walls and ceilings in food-processing and food-handling facilities, the results should be interpreted as an indication of relative extractive behaviour rather than direct regulatory non-compliance against direct food-contact extractive limits.

5. CONCLUSIONS

Based on the analytical results obtained during this investigation, Sample S5937A0326 (Hydromed Gloss) was identified as a low-VOC, water-based acrylic coating formulation containing conventional inorganic pigments and mineral filler components typically associated with decorative and protective coatings intended for indirect food-contact environments.

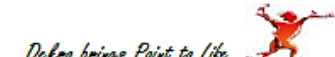
ATR-FTIR analysis confirmed the coating to be chemically consistent with an acrylic water-based enamel system, while XRF analysis indicated compliance with applicable lead (Pb) regulatory requirements, with lead concentrations below the detection limit (< 5 ppm) and well below the maximum allowable limit of 90 ppm specified in South African and international regulations.

VOC analysis further demonstrated that the coating contains a very low volatile organic compound content of 2.4 g/L, with GC-MS analysis confirming only trace concentrations of residual solvent compounds. These findings indicate minimal solvent emissions, reduced environmental impact, and low potential for occupational exposure during normal application and service conditions.

Extractive limits (migration) testing demonstrated measurable extractive residues in the distilled water and 3% acetic acid simulants, while negligible extractive migration was observed in the 10% ethanol simulant. However, it should be noted that FDA 21 CFR 175.300 extractive limits are primarily intended for direct food-contact resinous and polymeric coatings. In this study, the extractive testing was conducted as a screening and safety evaluation exercise relevant to the product's intended indirect food-contact application, rather than as a direct compliance assessment against food-contact coating limits.

Considering the intended use of the product as a decorative and protective coating for indirect food-contact environments such as walls and ceilings in food-processing and food-handling facilities, the overall results indicate that the coating is potentially suitable for its intended application under normal service conditions, provided that all performance requirements and parameters specified in the product datasheet, including washability, cleanability, and correct application procedures, are adequately met.

ANNEXURE A

		
HYDROMED GLOSS		
Page 1 of 3		
CODE: 306001	REVISION: 02	DATE: 09 December 2025
GENERAL DESCRIPTION		
Water based Acrylic coating which protects and prevents against microbial growth.		
USES AND PROPERTIES		
Hydromed Gloss is a tough, flexible, water based Acrylic coating which provides the ultimate safeguard against the growth of micro-organisms such as bacteria, mould (fungus) and yeasts. Sterility is achieved by the incorporation of a permanently effective, non-leaching, protective system which is free from heavy metal complexes, phenols and other toxic elements. Hydromed Gloss cures to form a pleasing, semi-gloss, decorative skin that responds to thermal and structural movement without flaking and cracking associated with conventional paint. It also resists damage from blistering and loss of adhesion on damp substrates, because of its vapour permeable structure which permits the escape of substrate moisture. Special flow characteristics facilitate a high build, impact resistant finish, whilst minimising the number of coats required. Hydromed Gloss is ideal for use on ceilings and both internal and external walls. It can also be applied to vessels, tanks and associated equipment, and where positive pressure is essential such as fruit storage, hospitals, wine cellars and food manufacturing plants. It produces a hard-wearing coating that will tolerate harsh cleaning agents and other chemicals and allows building owners to comply with even the most stringent hygiene related legislation.		
TECHNICAL DATA		
Binder Type	:	Water based Acrylic coating
Drying Time	Surface Dry	<1 hour (at 23°C and 50% humidity)
	Hard Dry	<4 hours (at 23°C and 50% humidity)
Drying Process	:	Water evaporation followed by coalescence
Overcoating	:	4 hours
Viscosity	:	120 - 130KU
Specific Gravity	:	1,20 ±0,05kg/litre
Mass Non-Volatile Content	:	50% ±3%
Volume Solids	:	38% ±3%
Gloss	:	Gloss
Coverage	:	8m²/litre
Dry Film Thickness	:	48 microns at 8m²/litre
Colour Range	:	White and Pastel
Clean Equipment With	:	Water
Pack Sizes	:	5 litre, 20 litre
Technical data is based on Hydromed Gloss White , code 306001.		
Coverage/spreading rate of Hydromed Gloss depends largely on the condition and porosity of the substrate being painted and manner in which the product is applied.		
e-mail: info@dekro.co.za Toll Free: 0800 222 423 http://www.dekro.co.za		
  		



HYDROMED GLOSS

Page 2 of 3

APPLICATION

Correct surface preparation is essential for good product performance and all surfaces should be prepared as per the standard Dekro Preparation Specifications. Copies of these are available on request from Dekro Paints or can be downloaded from our website – www.dekro.co.za.

Do not apply when ambient temperatures are $<4^{\circ}\text{C}$ or $>40^{\circ}\text{C}$.

After correct surface preparation, prime with Dekro Hydrolock Primer and overcoat within 24 hours. Stir thoroughly and apply a minimum of 2 coats of **Hydromed Gloss** by brush, roller or spray at the specified spread rate. Allow to dry between coats as per technical data.

SAFETY INSTRUCTIONS

Always keep out of reach of children and animals.

Wear a suitable dust mask and goggles when preparing surfaces.

Ensure good ventilation during application and drying.

If accidental contact with skin, wash immediately with soap and water or a recognised skin cleaner.

If accidental contact with eyes, rinse immediately with plenty of water and seek medical advice.

Harmful if swallowed. Seek medical attention and do not induce vomiting.

GENERAL

Different surfaces and environmental conditions require specific painting systems to produce the best possible results.

It is therefore recommended that you contact a Dekro Sales representative for advice on all your painting requirements whenever possible.

PREVENTING PROBLEMS AND GENERAL INFORMATION

IMPORTANT: Walls (cement plaster, concrete or masonry) must be dry before painting and should not exceed a moisture content of 10% as measured with a Protimeter Surveymaster Moisture Meter or equal.

The ambient temperature must be between 4°C and 40°C and humidity between 10% and 85%.

Excessive application thickness and/or rapid drying could lead to mud cracking.

Avoid applying under adverse weather conditions as this could result in poor product performance.

Work from corner to corner, or from a natural cut off point to another.

Do not attempt touch ups, but redo complete panels.

Always keep a wet edge and avoid downing tools during the application process to prevent lap marks and variances in colour or texture.

To ensure consistent appearance ensure that the batch numbers on all containers used are the same.

Where batch numbers on containers differ, intermix containers before use.

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HYDROMED GLOSS

Page 3 of 3

CLEANING, STORAGE AND DISPOSAL

Remove as much paint as possible from application equipment and wash immediately after use with water. Close containers tightly after use and store in a cool well-ventilated area. Do not empty contents or wash water into drains or water courses. When disposing please follow local authorities' regulations and recycle the container after use. Avoid storing in direct sunlight and heat.

Technical Data Sheet



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The technical data furnished is given to the best of our knowledge based on controlled laboratory tests under ideal application conditions. No guarantee of any performance characteristic is therefore given or implied and we do not hold ourselves responsible for any consequential damage of whatsoever nature that may arise from use of our products. In the event of a proven product fault our liability will be limited to the replacement of the product only. It is the user's responsibility to confirm the currency of product data sheets.

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