The *in-vitro* physical performance characteristics of ConvaMax™ Superabsorber

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Introduction

In hard to heal (or chronic) wounds, or when managing edema, exudate management is a crucial function of a chosen wound dressing[1]. Dressings for moderate to highly exuding wounds, commonly known as 'superabsorbents' are available to help manage this exudate where dressings with lower absorbency levels may not be sufficient[1].

Superabsorbent dressings absorb and retain high levels of exudate to help a wound to heal. These dressings also have the ability to continue to absorb exudate when under moderate levels of compression such as compression bandaging or clothing, ensuring their compatibility with a range of wound management methods. To ensure the dressing remains comfortable for the patient to wear, it is important that these dressings do not become too bulky and retain softness and comfortability during use.

As the composition of wound exudate includes a range of harmful constituents such as bacteria, enzymes and proteinases, minimising the impact of this corrosive exudate to the wound and surrounding skin is critical to encouraging wound healing[2, 3]. Therefore, the effective management of fluids and exudate, and the criticality of removing these harmful constituents from the wound surface is key to encouraging a wound to heal and prevent further skin breakdown[3].

To further support a protocol of care, superabsorbent dressings may also be used with a primary wound dressing, e.g. antimicrobials, where infection is suspected to be present.

A range of superabsorber dressings, all with the primary design to absorb and control wound exudate, were assessed, alongside ConvaTec's new offering, ConvaMax™ Superabsorber dressing, to compare their *in-vitro* performance.

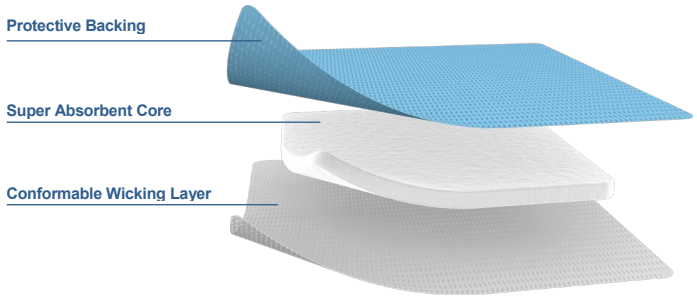
ConvaMax™ Superabsorber, a new dressing for moderate to highly exuding wounds, available in non-adhesive and silicone adhesive formats

ConvaMax™ Superabsorber is a dressing designed to manage moderate to high levels of fluid and exudate. The superabsorbent central pad absorbs exudate and forms a gel, locking it away in the core, preventing release back to the wound. The protective blue backing minimizes the risk of leakage and strikethrough of exudate into bandaging, clothing or bedding. The conformable wicking layer provides an interface with the wound and wicks fluid into the core.

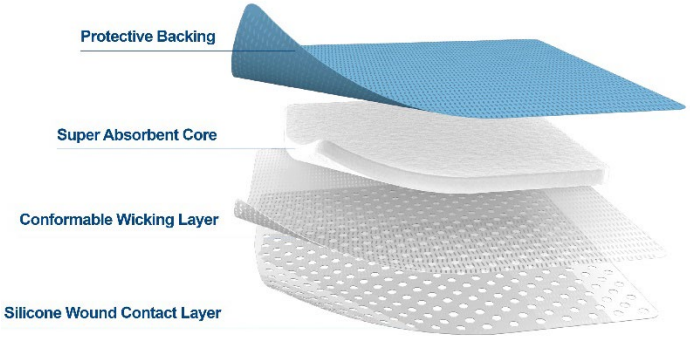
ConvaMax™ is available in a non-adhesive version suitable for all types of moderate to highly exuding wounds.

ConvaMax™ is also available in a version with adhesive silicone across the wound contact surface. The silicone provides additional protection to fragile skin by aiding gentle, skin friendly removal to minimize tissue damage. The adhesive version may also be used in anatomical areas where additional adhesive fixation could cause discomfort, but clothing could support the dressing (e.g. dressing a pilonidal sinus) to minimize dressing movement.

ConvaMax™ is available in a range of sizes providing complete flexibility to support your care protocol. The correct size of dressing should be chosen based firstly on exudate levels, taking into account wound size.



Dressing Size		Pack Size	Product Code
ConvaMax™ Superabsorber Non-Adhesive			
7.5cm x 7.5cm	3.0in x 3.0in	10	422566
10cm x 10cm	3.9in x 3.9in	10	422567
10cm x 20cm	3.9in x 7.9in	10	422568
12.5cm x 12.5cm	4.9in x 4.9in	10	422569
15cm x 15cm	5.9in x 5.9in	10	422570
15cm x 20cm	5.9in x 7.9in	10	422571
20cm x 20cm	7.9in x 7.9in	10	422572
20cm x 30cm	7.9in x 11.8in	10	422573
20cm x 40cm	7.9in x 15.7in	10	422574



Dressing Size		Pack Size	Product Code
ConvaMax™ Superabsorber Adhesive			
7.5cm x 7.5cm	3.0in x 3.0in	10	422575
10cm x 10cm	3.9in x 3.9in	10	422576
10cm x 20cm	3.9in x 7.9in	10	422577
15cm x 15cm	5.9in x 5.9in	10	422579
15cm x 20cm	5.9in x 7.9in	10	422580
20cm x 20cm	7.9in x 7.9in	10	422581

ConvaMax™ Superabsorber is designed to effectively manage fluid in moderate to highly exuding wounds

ConvaMax™ rapidly absorbs and retains fluid during use, locking it in the core of the dressing away from the wound. The hydrated dressing maintains structural integrity due to the welded edges and maintains softness and conformability even when hydrated[4].

Free swell absorbency

Method

Laboratory testing was completed to assess the total fluid absorption capacity of a dressing, unrestrained. This *in-vitro* test method was carried out based upon Appendix C of the current draft of BS EN 13726-1[5]. This revision considers the superabsorbent nature of multilayer products.

The test sample is weighed [W1] and placed into an absorption container. Warmed hydrating fluid (37°C (±2°C) sodium/calcium chloride BP [Solution A]) is added to the container until the sample is covered and the fluid is deemed to be in excess. Samples are then incubated for 30 minutes (±1 min) at 37°C (±2°C).

The sample is removed from the solution and positioned diagonally onto a perforated plate at an angle of approximately 10° to drain for approximately 30 seconds. The sample is weighed again [W2].

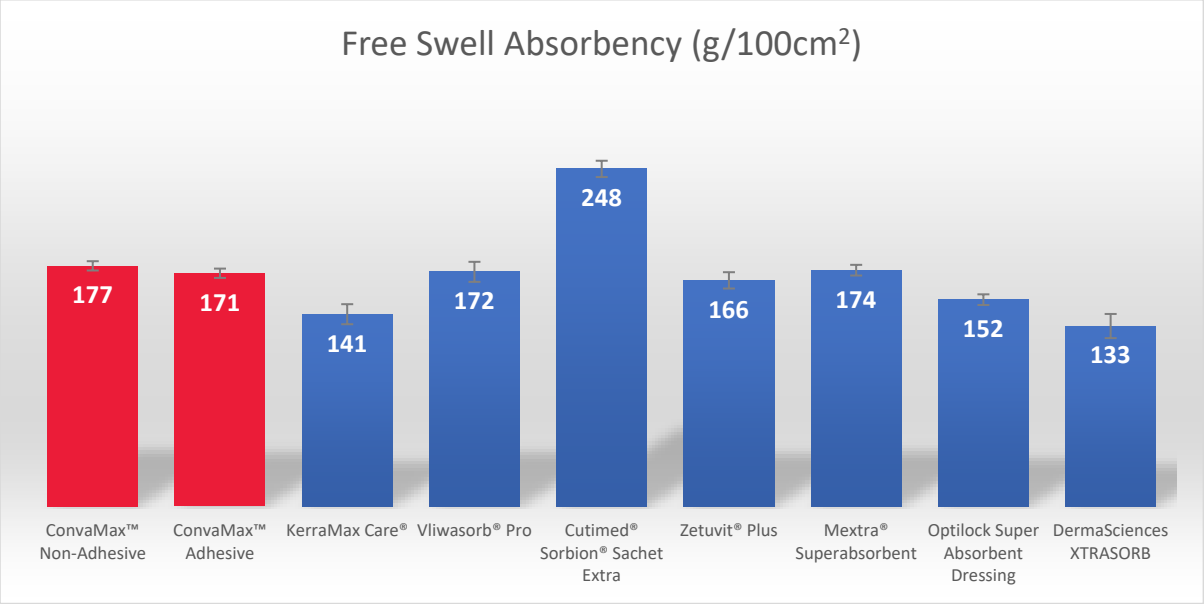
Absorbency Calculation:

$$Fluid\ uptake\ per\ unit\ area = \left(\frac{W2-W1}{area}\right) x\ 100\ \text{g/100cm}^2$$

Results

During this assessment, it was demonstrated that ConvaMax™ has an average absorbency of 174g/100cm^2. ConvaMax™ has equivalent or superior fluid absorbency per unit area, when compared to all other dressings tested, with the exception of Cutimed® Sorbion® Sachet Extra.

Figure 1 Free Swell Absorbency of Superabsorbent dressings *(n=6)* [4]



Absorbency under 40mmHg compression

Method

Testing was also completed to assess the total fluid absorption capacity of a dressing, to assess the ability of the dressing to absorb fluid, when restrained by bandaging, clothing etc or the patient's own weight.

This *in-vitro* test method was carried out based upon Appendix D of the current draft of BS EN 13726-1. This revision considers the superabsorbent nature of multilayer products.

The area [A1] of the dressing pad is calculated with image processing software. This area is used to calculate the weight required to exert 40mmHg of compression over the dressing pad.

The test sample is then weighed [W1] and placed onto a stainless-steel perforated plate. The calculated weight to exert 40mmHg of compression is placed onto the sample pad area.

Hydrating fluid (20°C (±2°C) sodium/calcium chloride BP [Solution A]) is added to the container until the stainless-steel perforated plate is covered and leave in place for 24 hours at 20°C (±2°C).

The sample is removed from the solution and positioned diagonally onto a perforated plate at an angle of approximately 10° to drain for approximately 30 seconds.

The sample is weighed again [W2].

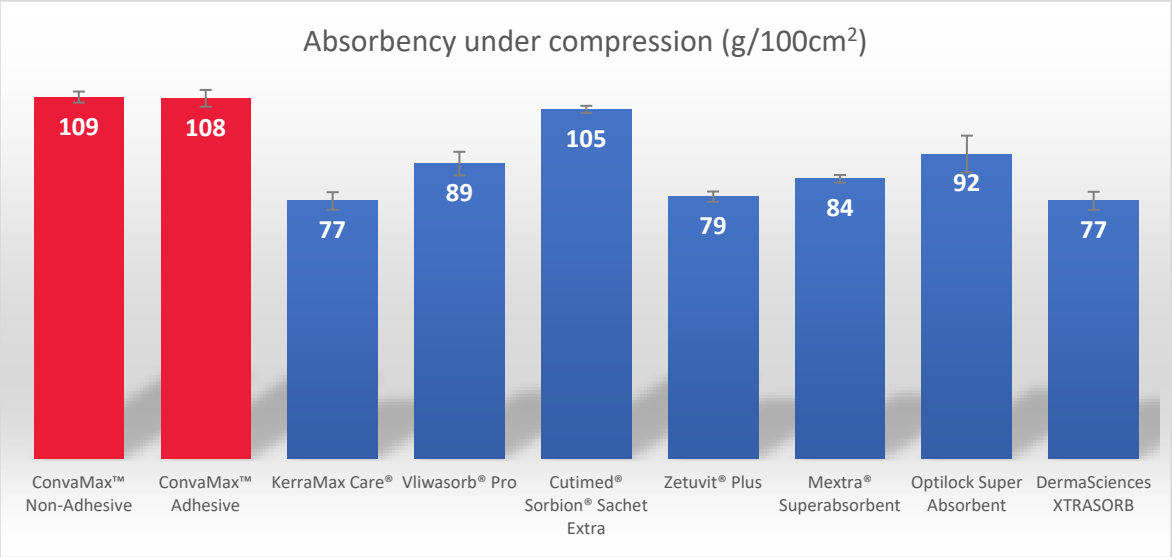
Absorbency Calculation:

$$Fluid\ absorbed\ per\ unit\ area = \left(\frac{W2-W1}{A1}\right) x\ 100\ \text{ g/100cm}^2$$

Results

During testing, is was demonstrated that ConvaMax™ can absorb and retain fluid while under standard 40mmHg of compression, a commonly used therapy, particularly on lower limb wounds or weeping edema. ConvaMax™ absorbed the most fluid compared to all competitors in this assessment.

Figure 2 Absorbency of Superabsorbent dressings under 40mmHg compression *(n=3)* [4]



ConvaMax™ Superabsorber is suitable for use with Hydrofiber® Technology as a filler dressing

ConvaMax™ Superabsorber can be used as either a primary dressing, secured in place by bandaging or other fixation methods, or as a secondary dressing, with a wound filler. A recommended filler to use under a ConvaMax™ dressing is a Hydrofiber® based dressing such as AQUACEL® EXTRA™ or AQUACEL® Ag Advantage where there is risk of infection.

ConvaMax™ Superabsorber with a Hydrofiber® wound filler

An *in-vitro* test was completed to demonstrate that ConvaMax™ continues to absorb fluid when used in combination with a Hydrofiber® based wound filler. This is a non-standard test method, developed in the laboratory to demonstrate the movement of fluid through a dressing sample. A purpose-built test rig is used to demonstrate how fluid can move through a primary, Hydrofiber™ based dressing, into a secondary superabsorbent dressing[6].

Method

Two 8 x 8cm pieces of AQUACEL® EXTRA™ are cut to fill the recess in the flow rig, weighed together (W_{1a}) and placed in the sample platform. The test superabsorbent dressing is weighed (W_{1s}) and placed over the AQUACEL® EXTRA™ and taped at the edges. The rig is lightly wrapped in bandaging to secure the dressings in place. Horse serum (Biowest, Cat# 50900-500) is placed into one 150ml syringe and attached to a syringe pump; horse serum is delivered to the dressings through a port at the base of the rig, at a rate of 4.3ml/hour for 24 hours.

After 24 hours, the dressings are visually inspected for signs of leakage into the bandaging. The bandaging is removed, the superabsorbent removed and reweighed (W_{2s}), and the AQUACEL® EXTRA™ dressings removed, allowed to drain for 30 seconds, and reweighed (W_{2a}).

<u>Calculations:</u>

Fluid uptake per unit area for AQUACEL® EXTRA™= $(W_{2a}-W_{1a})/128$ g/cm^2

Fluid uptake per unit area for superabsorbent dressing= $(W_{2s}-W_{1s})/A_{1s}$ g/cm^2

Note: A_{1s} for this is taken from the calculations previously completed for absorbency.

Results

The testing demonstrates that fluid passes through the Hydrofiber® filler layer and into the secondary superabsorbent dressing. This test also demonstrates the ConvaMax™ locks away fluid without leakage into bandaging compared to a non-backed superabsorbent competitor when assessed in the same test.

Use of a Hydrofiber™ based wound contact layer such as AQUACEL® EXTRA™ combines the superior fluid absorption properties of ConvaMax™, together with the wound management properties of Hydrofiber™.

Figure 3 ConvaMax™ and KerraMax Care® dressings in the test, pre-hydration

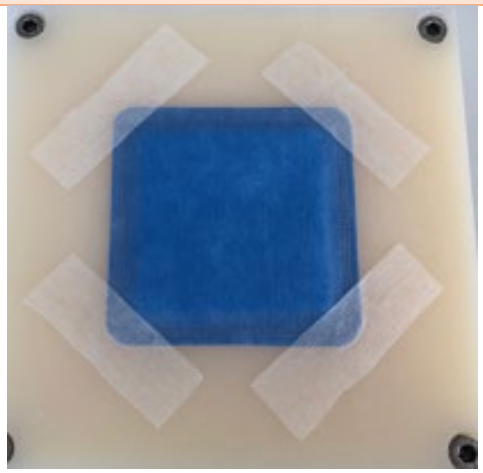
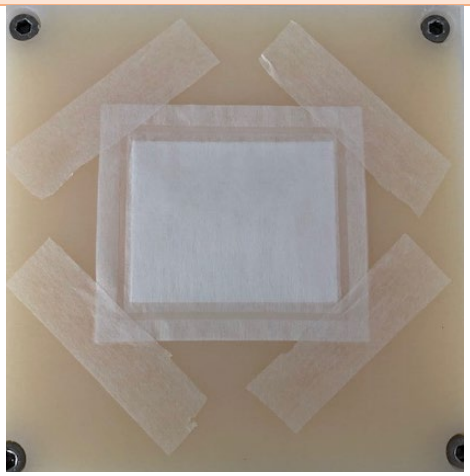
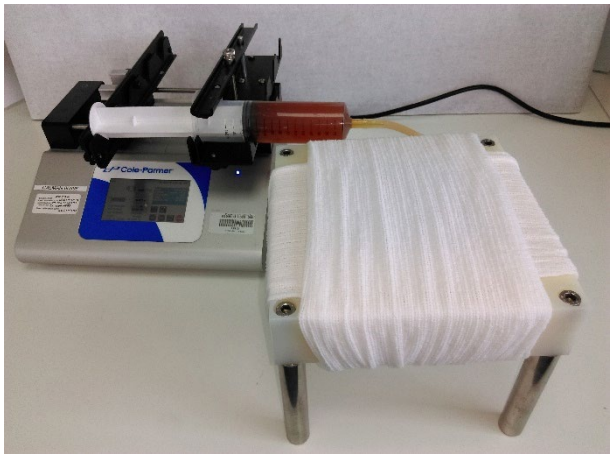
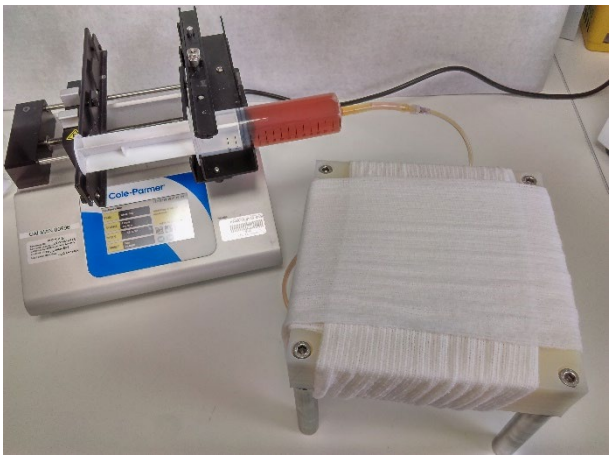
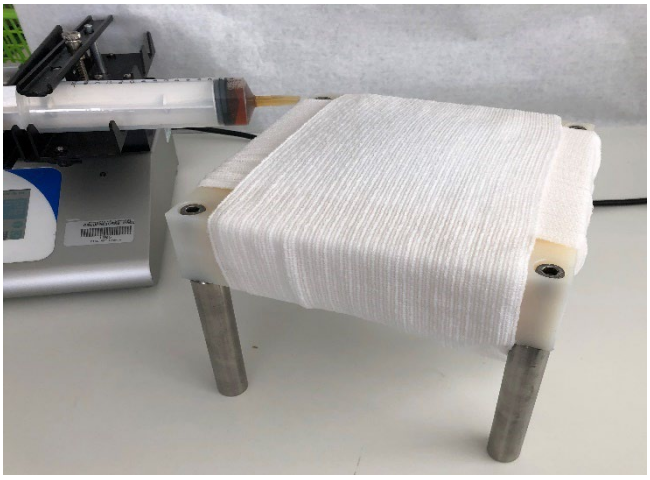
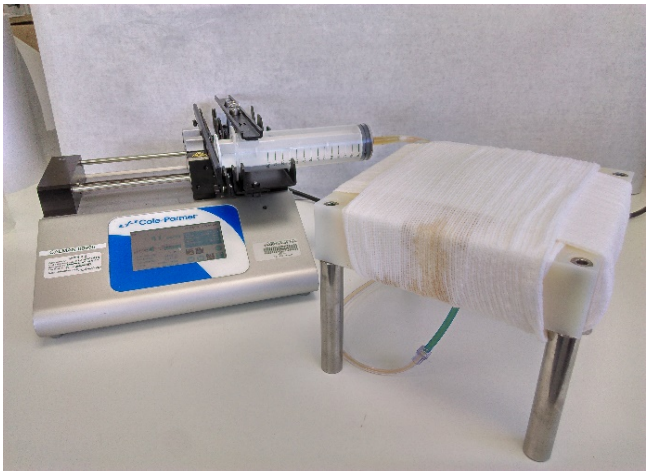
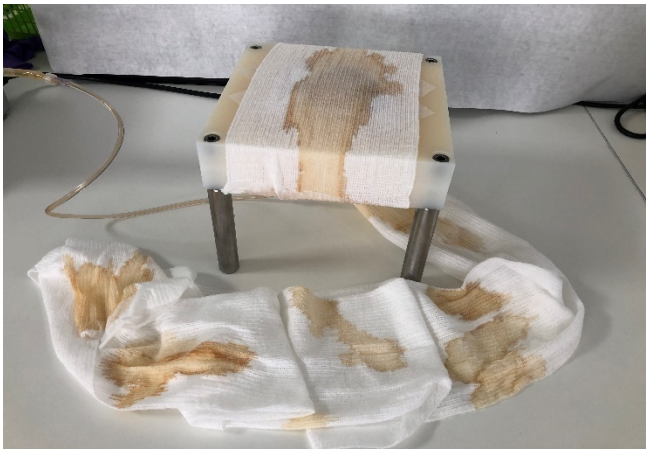
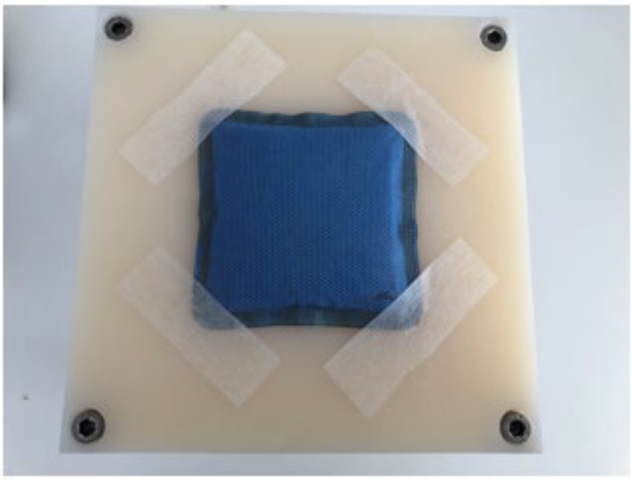
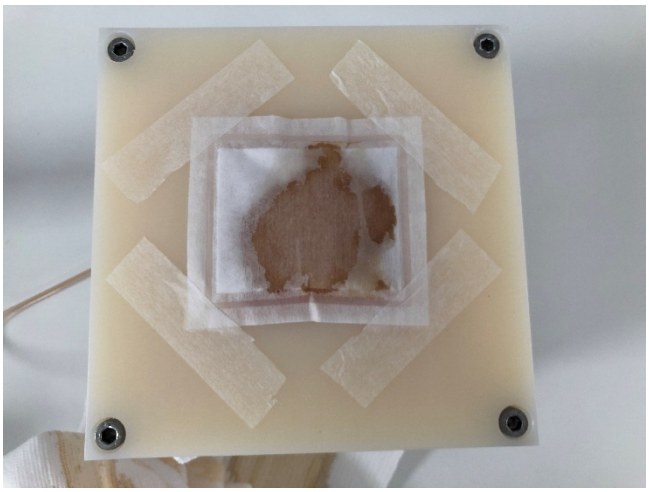
ConvaMax™ Non-Adhesive A 'backed' superabsorbent dressing	**KerraMax Care®** A 'non-backed' superabsorbent dressing
Pre-Hydration	
 AQUACEL® EXTRA™ (primary dressing) and ConvaMax™ superabsorber (secondary dressing) attached to rig with tape.	 AQUACEL® EXTRA™ (primary dressing) and KerraMax Care® (secondary dressing) attached to rig with tape.
 Dressings wrapped with light bandaging and attached to syringe pump. Fluid flows in from base of recess at a rate of 4.3ml/hour for 24 hours.	 Dressings wrapped with light bandaging and attached to syringe pump. Fluid flows in from base of recess at a rate of 4.3ml/hour for 24 hours.

Figure 4 ConvaMax™ and KerraMax Care® in the *in-vitro* test, after 24-hours

ConvaMax™ Non-Adhesive Superabsorbent dressing	KerraMax Care®
After 24-hours of fluid application	
 After 24 hours, no leakage can be seen in bandaging	 After 24 hours, simulated exudate has leaked into bandaging
 No leakage can be seen in any of the bandaging layers	 Leakage can be seen in all bandaging layers
 Fully saturated ConvaMax™ attached to rig after 24 hours. ConvaMax™ has absorbed in an evenly distributed manner across the dressing.	 KerraMax Care® attached to rig after 24 hours. Dressing has only absorbed in the center but not the edges.

ConvaMax™ Superabsorber with an antimicrobial Hydrofiber® wound filler

Where the wound is infected, or at risk of infection, an antimicrobial dressing may be chosen as the wound filler of choice. An *in-vitro* laboratory method was developed by ConvaTec to confirm the continued ability of AQUACEL® Ag Advantage to reduce wound bioburden when used as a primary dressing, in conjunction with ConvaMax™ as a secondary dressing[6].

Method

A culture of community associated methicillin resistant *Staphylococcus aureus* (CA-MRSA) was prepared on a gauze substrate and placed on agar plates to simulate a colonized wound bed (n=3 per timepoint). AQUACEL® Ag Advantage was applied to the plate and hydrated with simulated wound fluid. ConvaMax™ was hydrated with simulated wound fluid and applied on top of the AQUACEL® Ag Advantage dressing. Dressings were secured in place with a bandage. Rehydration with an addition 3.5ml of simulated wound fluid was completed at 96hours due to the high absorbency of the ConvaMax™ superabsorbent dressings, to ensure the model did not dry out.

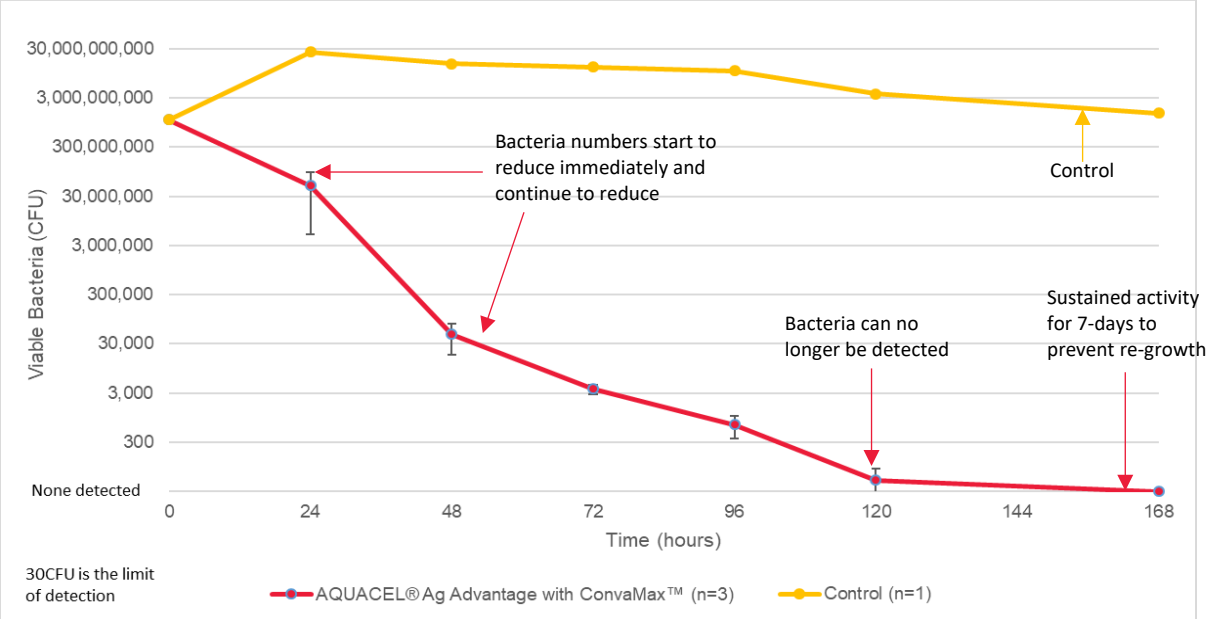
A colonized gauze without a dressing was included as a negative control to monitor bacteria viability over the course of the challenge period (n=1 for each time point).

Samples were incubated at 35°C (±3), samples were tested at 24, 48, 72, 96-hours and 7-days. After removal of the dressings, testing consisted of homogenizing the gauze substrate in Dey-Engley Neutralizing Broth (DENB) (to neutralize residual antimicrobial activity), to release bacteria from the gauze substrate such that total viable counts (TVCs) could be performed on the resultant solutions.

Results

In the below graph, it can be seen that AQUACEL® Ag Advantage with ConvaMax™ steadily reduces bacteria in the model over time, no bacteria can be detected by 120-hours (day 5), and this is sustained to 168-hours (day 7). The results of the testing demonstrated that when ConvaMax™ is used with an antimicrobial wound filler, antimicrobial activity is maintained under ConvaMax™, therefore combining the benefits of both dressings.

Figure 5 Antimicrobial activity of AQUACEL™ Ag Advantage with ConvaMax™ as a secondary cover dressing

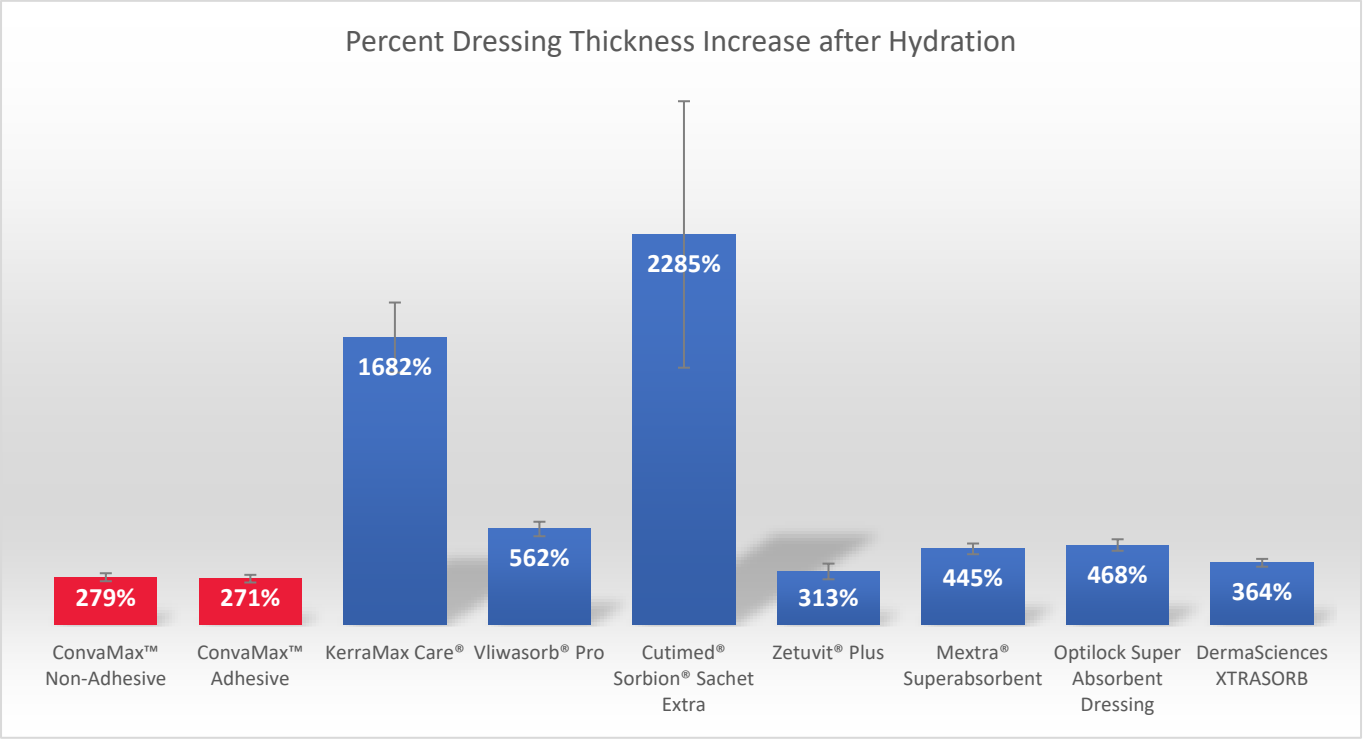


ConvaMax™ Superabsorber has a soft and conformable design

On absorbing exudate or fluid, the core within all superabsorbent dressings turns from a powder to a gel[1], which locks away and retains fluid in the core. As these dressings can absorb high amounts of fluid, they can therefore swell significantly in size and thickness as they form a gel[7], and this results in some dressings becoming bulky during use. Therefore, ensuring that a dressing can balance high absorption with minimal swelling is a desirable characteristic of a superabsorbent dressing.

During *in-vitro* testing (for absorbency, method detailed above), it was observed that when ConvaMax™ absorbs fluid, it absorbs it evenly across the dressing and without excessive dressing swelling, compared to competitors. ConvaMax™ has the smallest percentage increase in thickness after full hydration compared to all competitors[4], making it ideal for use under compression[7].

Figure 6 Increase in thickness on hydration of superabsorbent dressings *(n=3)*



Soft and Conformable

As a further evaluation, a subjective assessment was completed by 18 internal assessors (a mixture of clinically trained, and office-based staff to assess trained and untrained users).

Users were provided with ConvaMax™ adhesive and non-adhesive dressings, in the dry and hydrated states, to evaluate the dressings for softness and conformability. Users were asked, with the support of anatomical models, to determine if they felt the dressings would be soft and conformable for use and wear.

100% of users evaluated that ConvaMax™ dressings are soft, and conformable, when both dry and hydrated[6].

ConvaMax™ Superabsorber is designed to retain bacteria within the absorbent core

Bacteria are present in all wounds, whether the wound has become infected or not[8]. The ability of a wound dressing to retain (sequester) bacteria within the dressing core and therefore remove them from the wound surface is a beneficial property[9].

Method

This *in-vitro* laboratory method was developed by ConvaTec to assess the ability of dressings to retain (or sequester) bacteria within the dressing core[6].

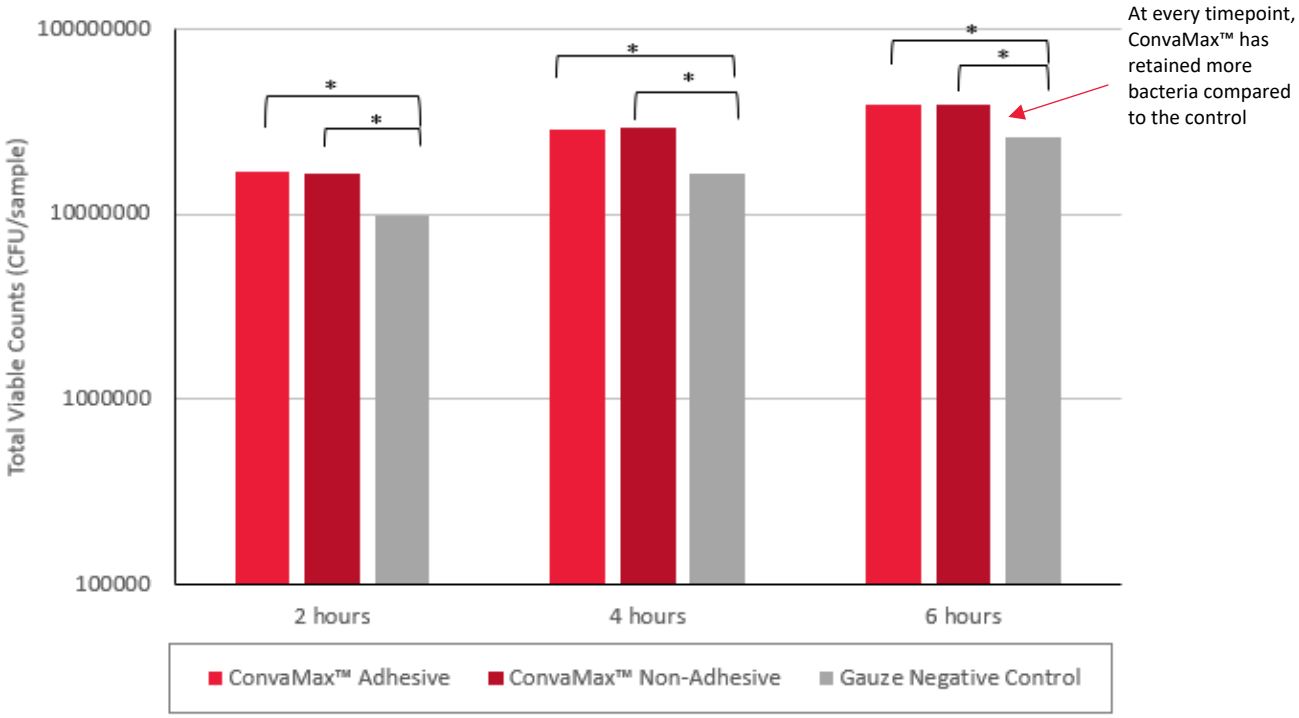
Superabsorbent dressings (plus a gauze negative control) are inoculated with 10ml of 1 x 10^6 CFU/ml challenge suspension of two antibiotic resistant bacteria; community acquired methicillin resistant *Staphylococcus aureus* (CA-MRSA) and antibiotic resistant *Pseudomonas aeruginosa*. Dressings are tested at 2, 4 and 6 hours. For the 4-hour assessment, dressings are reinoculated at the 2-hour point with a further 10ml of 1 x 10^6 CFU/ml challenge suspension. For the 6-hour assessment, dressings are reinoculated at the 2-hour and 4-hours point with a further 10ml of 1 x 10^6 CFU/ml challenge suspension.

At each time point, samples are transferred to stomacher bags containing 150ml Max Recovery Diluent media and stomached for 2 minutes at 260rpm. Total viable counts are performed on the resultant suspension. A higher count means the dressing sequestered more bacteria within the dressing.

Results

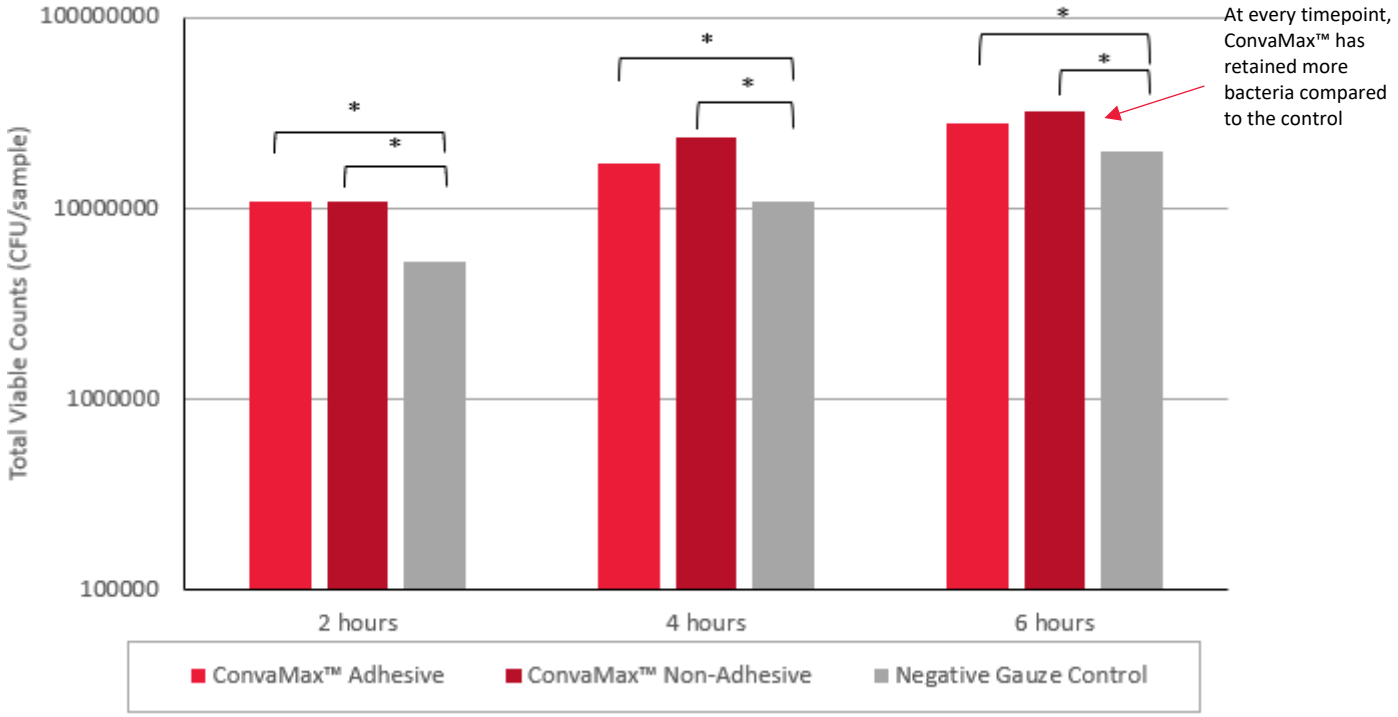
As can be seen from the data below, at all timepoints, for both types of common microorganisms, ConvaMax™ has retained/sequestered more bacteria within the core than standard gauze. This ability to lock bacteria within the core of the dressing is a key benefit to aiding wound healing.

Figure 7 Sequestration of MRSA within ConvaMax™



*Statistical significance denoted by * (* p<0.001)*

Figure 8 Sequestration of *Pseudomonas aeruginosa* within ConvaMax™



*Statistical significance denoted by * (* p<0.001)*

ConvaMax™ Superabsorber is designed to reduce excess MMPs

Matrix metalloproteinases (known as MMPs) are present in all healing wounds, both acute and hard to heal (chronic). When regulated, they play a significant role in wound epithelialization. However, in chronic wounds, their presence can become unregulated and levels can increase. This excess protease activity can impair the healing process, leading to a hard to heal wound[10].

There are a range of MMPs with various roles in wound healing. Two of these are shown to be significantly elevated in chronic wound exudate, MMP-2 and MMP-9,[11,12] which are involved in angiogenesis (formation of new blood vessels)[10].

Method

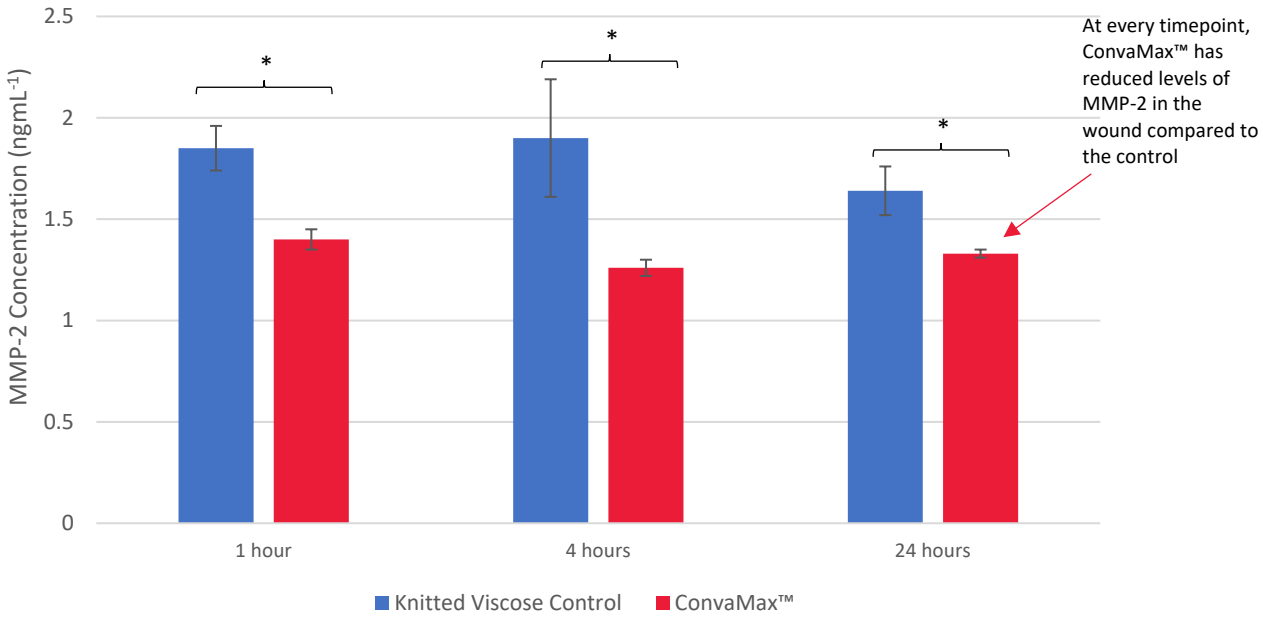
In-vitro laboratory testing was completed externally to assess the protease modulation properties of ConvaMax™ of both MMP-2 and MMP-9[6].

Dressing samples are placed into 24-well plates, and solutions of MMP-2 or MMP-9 proteinase are added to each sample. Knitted viscose is used as a negative control, as well as a plate with the proteinase only as a no dressing control. The plates are incubated at 37°C and 50rpm for 1, 4 or 24 hours. After the allotted time, sterile phosphate buffer saline is added to each sample, and samples collected. MMP concentration is then determined via enzyme-linked immunosorbent assay (ELISA).

Results

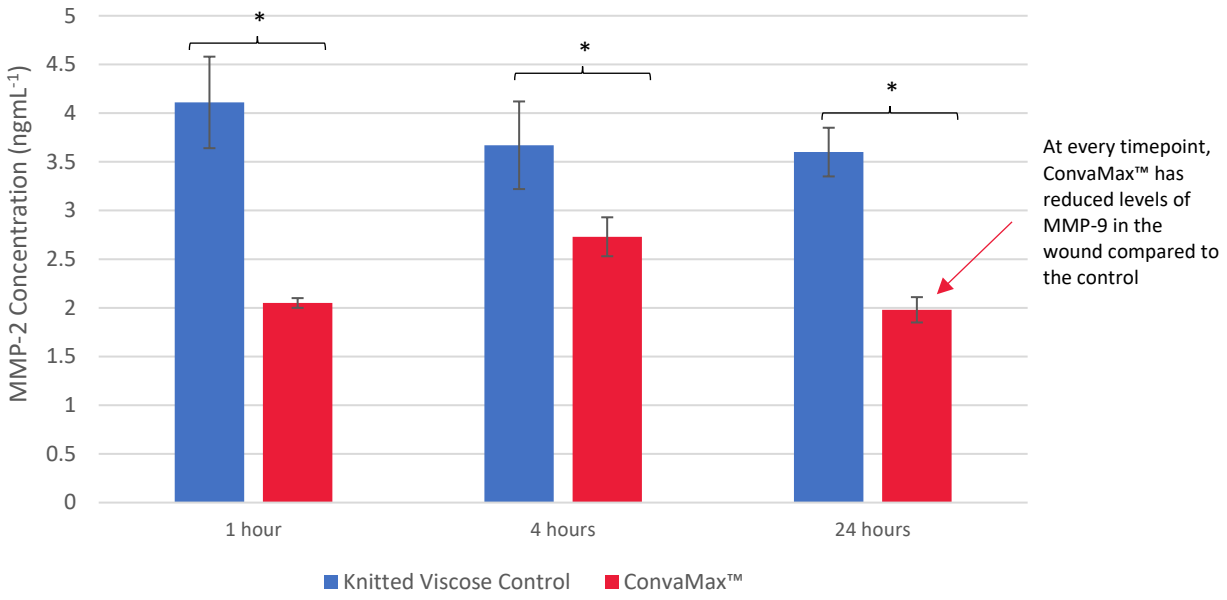
It can be seen from the data below that ConvaMax™ has been demonstrated *in-vitro* to absorb MMP-2 and MMP-9, thereby potentially reducing excess levels of these proteinases in the wound environment to encourage wound healing.

Figure 9 ConvaMax™ Superabsorber MMP-2 Absorption over time



*Statistical significance denoted by * (* p<0.05)*

Figure 10 ConvaMax™ Superabsorber MMP-9 Absorption over time



*Statistical significance denoted by * (* p<0.05)*

Conclusions

A range of *in-vitro* assessments have demonstrated that ConvaMax™ Superabsorber dressing has the ability to effectively manage exudate produced from moderate to highly exuding wounds. It absorbs fluid into the superabsorbent core, turning to a gel therefore retaining the fluid to minimize risk or maceration. ConvaMax™ can also effectively manage this exudate if used under compression or under clothing. ConvaMax™ manages to balance this high absorption while retaining softness and conformability to ensure patient comfort during use.

ConvaMax™ is suitable for use in combination with Hydrofiber® products, where a Hydrofiber® wound contact layer may be desired. If used in conjunction with an antimicrobial wound contact layer, efficacy is maintained, allowing the antimicrobial action to kill at the wound surface and ConvaMax™ to continue to absorb excess exudate.

The ConvaMax™ superabsorbent core allows for retention of any bacteria absorbed, ensuring they are removed from the wound surface. The superabsorbent core also assists in reducing excess MMPs potentially present in the wound. Removing these harmful components of exudate can help a wound to heal.

ConvaMax™ Superabsorber Dressing

Exudate Managed, Skin Protected

Note: *All in-vitro testing was carried out using a validated in-vitro test method. Results obtained by different test methods should not be directly compared, as different test methods may lead to different test results.*

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