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## **Terra Universal Application Note – Takiron IVYONE versus Traditional PVC Cladding Systems**

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### **Executive Summary**

When designing a new cleanroom or simply renovating an existing cleanroom space, the stakeholders should have a complete understanding of the requirements for the wall/ceiling cladding system. Besides internal technical requirements there are FDA, USDA, Insurance and cGMP standards to consider. It is imperative that the cladding system possess these key attributes to ensure compliance:

- Impermeable so that contaminants cannot pass through the cladding in either direction
- Little to no pores where contaminants grow
- Excellent chemical resistance so that cleaning agents/disinfectants used to sanitize surfaces on a frequent basis do not damage, discolor or compromise the performance of the cladding.
- High impact resistance to minimize scratches, dents and cracks caused by human contact and errant equipment damage.
- In the accidental event of a fire the panel must be able to suppress the spread of fire and minimize damage due to smoke generation.
- Has a long life with minimal maintenance resulting in a low “Total Cost of Ownership.”

What makes the choice of cladding systems challenging is the many types of these systems that claim to meet most of these requirements when in fact they fall far short on many of them, thus, jeopardizing the cleanroom’s ability to remain sanitary and functional. When you consider what is at risk in a Pharmaceutical cleanroom, users and management should be sure not to purchase inferior wall systems simply to save upfront money. Over time, the Total Cost of Ownership of these inferior systems will far exceed the Takiron Total Cost of Ownership.

This Application Note reviews the Takiron IVYONE system and outlines the features and benefits when used in a Pharmaceutical cleanroom as compared to traditional PVC cladding systems.

### **Background**

Takiron is a pioneer in developing the superior workability, chemical resistance, and economy of hard Polyvinyl Chloride (PVC). Takiron began production of hard PVC based industrial PVC plates in 1954, and since then has accumulated production experience of more than half a century. During that time, Takiron has devoted a lot of time, money and resources researching and developing improved products with higher quality, better heat/flame resistance, superior chemical resistance and higher impact capabilities. Takiron, having ample experience and achievements, provides an assortment of many highquality and high-functional products.

Takiron’s IVY-ONE is a cPVC (chlorinated polyvinyl chloride) sheet material that combines flame retardant technology and chemical resistance technology for synthetic resin materials. This product is the world’s first material for cladding walls/ceilings of pharmaceutical or food processing plants that is capable of withstanding cleaning and sterilization with chemical solutions at frequent intervals. The high heat resistance and flame-retardant capability has allowed the Takiron IVY-ONE to be one of the few cladding systems certified to the FM4882 standard.

IVYONE is manufactured in Japan and stocked in the Philadelphia area by the North America exclusive Distributor – Terra Universal.

## IVYONE Design

Takiron's IVYONE is a specially formulated cPVC that is manufactured in a unique way resulting in a cladding system providing superior performance that surpasses most competitive standard PVC products.



### 1. IVYONE Chemical Composition

PVC or Polyvinyl chloride is a thermoplastic polymer and is considered to be third most widely used kind of plastic. It is an extremely versatile and useful substance that is generally found in either rigid or flexible forms. The Rigid form is used in construction and for profile application such as on doors and windows. PVC can be turned into a softer and flexible form by adding plasticizers to it. PVC, in this form, is used in plumbing, electric cable insulation, as imitation leather and the likes.

IVYONE panels are made using a specially formulated plastic composition that uses a cPVC or chlorinated polyvinyl chloride. cPVC is a modified form of PVC where the chlorine content is increased, resulting in many new properties which will be discussed shortly.

### 2. IVYONE Manufacturing Process

Many cleanroom panels are manufactured using an extruded plastic process. This process cannot guarantee that the panel surface is uniformly clear of pores. Takiron uses a manufacturing process that uses a mold of the panel. Laminated layers are placed in the mold and heat and high pressure are applied to form each sheet. The resulting panel has the highest density and blemishfree surface with virtually no pores.

### 3. IVYONE Benefits

The IVYONE unique chemical composition and manufacturing process results in numerous product features and benefits that make it ideal for Pharmaceutical cleanroom applications. This section will examine each of these benefits in terms of how it meets the most stringent cleanroom specification.

#### **3a. Wetting Factor**

An important attribute of a cladding system is the wetting factor of the panel. Wetting is the ability of a liquid to maintain contact with a solid surface, resulting from intermolecular interactions when the two are brought together.

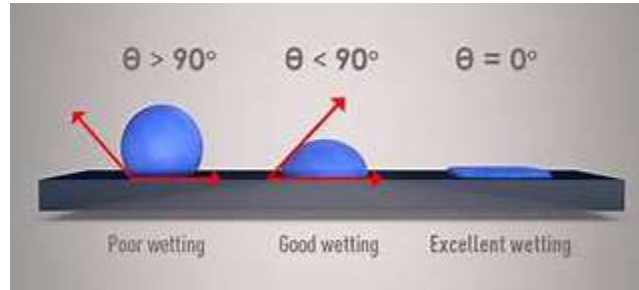
The contact angle ( $\theta$ ), is the angle at which the liquid meets the solid interface. The contact angle is determined by the balance between adhesive and cohesive forces. As the tendency of a drop to spread out over a flat, solid surface increases, the contact angle decreases. Thus, the contact angle provides an inverse measure of wettability.

A contact angle less than  $90^\circ$  (low contact angle) usually indicates that wetting of the surface is very favorable, and the fluid will spread over a large area of the surface. A wettable surface may also be termed "hydrophilic". A liquid droplet would spread over a hydrophilic surface, enter any pores and totally wet the surface. Most extruded PVC is considered hydrophilic and not favorable for cleanroom environments where the panels are frequently exposed to liquids.



Contact angles greater than 90° (high contact angle) generally means that wetting of the surface is unfavorable, so the fluid will minimize contact with the surface and form a compact liquid droplet rather than spread out on the surface.

A surface that resists getting wet is called “hydrophobic”. A liquid droplet would try not to touch as much area of a hydrophobic surface as possible. The droplet would take the shape of a sphere. The hydrophobic material would have minimal pores into which the liquid could penetrate. IVYONE is highly hydrophobic and resists liquids from spreading across its surface.



**3b. Chemical Inertness**

IVYONE is inherently inert to acids, bases, salts and aliphatic hydrocarbons, all of which tend to eat away at materials. It’s this inherent chemical resistance that provides it with long life even under conditions of frequent cleanings as is typically in a Pharmaceutical cleanroom environment.

The common use of SporKlenz and other industrial cleaners or disinfectants can cause discoloration and longterm degradation in typical PVC panels whereas it has virtually no effect on the Takiron cPVC panels.

**3c. Ultra Hygienic features**

The extra chlorine in cPVC prevents the growth of any bacteria or mold on the panel and thus is considered antibacterial. It is impermeable and nonabsorbent which prevents the migration of contaminants from the substrate side into the cleanroom and vice versa. cPVC resists corrosion for longer periods of time than typical PVC panels.

**3d. High Impact Resistance**

The chemical composition and manufacturing process result in the IVYONE panel being a very dense and strong panel. It can withstand the impact of most carts, equipment and human interaction found in these environments. It also has excellent abrasion resistance. It is inevitable that cleanroom panels will be exposed to inadvertent contact. If the panel system is not strong enough it could chip, flake or crack which then jeopardizes the ability of the cladding system to maintain sanitary conditions. Independent hardness testing has shown the superior impact quality of IVYONE versus typical PVC panels:

**Rockwell Hardness Scale**

	IVYONE	PVC	Test Method
M scales	73	72	JIS K 7202
R scale	120	90	

Due to Takiron IVYONE’s unmatched durability, it is very commonly installed as a wainscoting application providing superior wall protection.

**3e. High Heat Resistance**

A key property of cPVC is its higher heat resistance. Takiron’s IVYONE panels can work in environmental conditions or withstand cleaning fluids up to a maximum temperature of 140°F (60°C). In the event of exposure to higher heat typical PVC panels will distort whereas IVYONE maintains its structural integrity.

Many cleaning procedures in the industry commonly require these extremely high temperatures to ensure no bacterial growth is possible – Takiron is a product that stands up to these temperatures.

### **3f. FM4882 Approval - Fire Resistance**

IVYONE is one of the few cleanroom cladding systems that is FM4882 approved. FM4882 is a new standard of interior wall and ceiling materials for clean room, pharmaceutical manufacturing and storage areas, food preparation and storage areas developed by FM Global. Utilizing FM approved materials qualifies Users for FM insurance savings.

FM 4882 standard was developed to minimize the possible safety hazards and risks in the event of an unexpected fire. The standard addresses the need for the cladding system to suppress the spread of fire and minimize possible damage due to smoke generation. The FM4882 standard consists of FM4880 standard + ASTM E84 standard + 16ft High parallel panel test.



### **FM4880 Standard Evaluation items:**

- Room Fire Test - Qualifies Panels for Use Up to 10 ft in Height
- 25 ft Corner Test (Optional) - Qualifies Panels for Use Up to 30 ft in Height
- 50 ft Corner Test (Optional) - Qualifies Panels for Use to Unlimited Heights

### **ASTM E84 Standard Evaluation items:**

- ASTM E84 Standard is for surface burning characteristics of Building materials.
- FSI (Flame Spread Index)
- SDI (Smoke Developed Index)
- Criteria for conformance to the standard
- Class U/B SDI:2675, FSI≤450
- Class V/C SDI:76200, FSI≤450

### **16ft High Parallel Panel Test Evaluation items:**

- FM Approvals 4.9m(16ft) High Parallel Panel Test
- Average Smoke emission rate (Gsmoke)
- Takiron IVYONE is an FM4882 standard approved product for applications involving heights of up to 30 ft.



Takiron "IVY-ONE" (IVY573)



Non FM Plastics Sheet (Polypropylene)

There are some cladding systems on the market that claim to have an FM approval. In many cases the FM standard they are certified to is FM4880 which is not as stringent as the FM4882 standard. With the FM4882 approval IVYONE's design has greater fire resistance than these other panels. The IVYONE panel does not tend to catch fire as easily as these other panels and it often extinguishes itself if it is not directly sitting in an open flame.

### **3g. Installation Method**

IVYONE installation uses a process which helps ensure that the area in which the panels are installed is a completely sealed room. Using doublefaced adhesive tape, specially formulated adhesive glue and heat welded seams, a hermetically sealed envelope is created. This guarantees that contaminants are contained in the cleanroom and that no contaminants can leech into the room from the exterior. Other panel systems use a filler seam or even caulk that cannot guarantee the same type of seal. Those systems using caulking also pose a maintenance challenge as the caulk will deteriorate over time and create voids in the cladding. Without knowing when the caulk will deteriorate Users must replace caulking at regular intervals to ensure the seal is maintained.

## **4. IVYONE Total Cost of Ownership (TOC)**

Owners must be cognizant of the Total Cost of Ownership of a cleanroom panel system. First and foremost, the panel system must meet all the Owner's technical requirements. Then, cost comes into play, but it is not just the acquisition cost that should be considered. Annual maintenance cost must be considered. IVYONE is designed to be virtually maintenance free for its life whereas other panel systems may require regular maintenance. IVYONE should not require any repairs to fix cracks, ripples or defective seams. Cleanrooms that require frequent cleanings represent a harsh environment for a cladding system. Some panel systems will discolor, come loose and just plain degrade over time. It is not uncommon for Owners to have to replace some of these cladding systems after only 5 years of use.

Shortsighted purchasing decisions often have long term financial impact on the organization. IVYONE's chemical composition, manufacturing process and installation method allows it to stand up in these conditions for years.

## **Executive Summary**

The design of Pharmaceutical Clean Rooms must be carefully considered to address the normal operating conditions. The technical requirements along with FDA, USDA, Insurance and cGMP standards can be daunting and require a cladding system that is specially designed, manufactured and installed to meet these requirements. Biopharmaceuticals cannot afford unplanned downtime in critical production areas. Every effort must be made to minimize shutdowns due to failures of cladding systems. IVYONE is one of the few cladding systems designed specifically for Pharmaceutical cleanroom and is backed by FM certification. With a low Total Cost of Ownership IVYONE provides owners with piece of mind.