INNOVATING TO A BETTER BALANCE

A Technical Review of the PURELL® Healthcare Surface Disinfecting Wipes

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INTRODUCTION

Healthcare-associated infections (HAI) are a common complication of hospital care and on any given day, approximately one in 31 hospital patients has at least one HAI.[1] These infections lead to significant morbidity, mortality, and excess cost.[2] While there are varying factors associated with HAI, contaminated surfaces and equipment can contribute to the problem due to frequent contamination with pathogens resulting in cross-transmission of microorganisms, predominantly via hands.[3,4]

> Although hand hygiene is an important disruptor of this transfer, improved cleaning and disinfection of medical equipment and environmental surfaces is fundamental to reducing their potential contribution to HAI.[5]

While experts agree that proper surface disinfection is essential, not all disinfectants are created equal, and selecting the best product can be challenging for healthcare facilities. Rutala and Weber outline four criteria for selecting a healthcare surface disinfectant.[6] They recommend that the product be easy to use, provide fast-acting broad-spectrum activity against relevant pathogens, and be safe for use and non-damaging for surfaces.

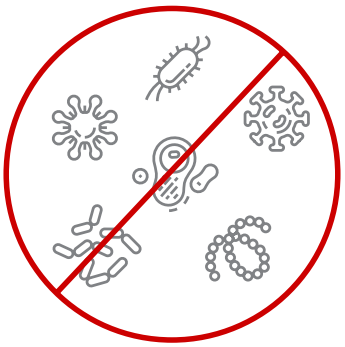
PURELL® Healthcare Surface Disinfecting Wipes are convenient, ready-to-use wipes designed to kill the most relevant pathogens while providing the safety profile and material compatibility that is essential in healthcare. Successfully formulating a disinfecting wipe involves balancing many factors while minimizing trade-offs. The PURELL® wipe is designed to leverage the strengths of ethyl alcohol through formulation innovation to meet the above-mentioned criteria for a surface disinfectant.

EFFICACY

PURELL® Surface Disinfecting Wipes contain 20% ethyl alcohol, which has a long, trusted history of use as an antimicrobial and is commonly used in healthcare.[7] Ethyl alcohol works through two separate mechanisms. First, alcohol damages cell membranes, and then once alcohol has access to the contents inside the cell, it inactivates or denatures proteins present inside the cell. Protein function is essential for survival, and the activity of denaturing the proteins kills the microorganism.[8,9] Ethyl alcohol's robust mechanism of action and prompt dissipation result in a low propensity for microbes developing resistance against it.[10]

The U.S. Environmental Protection Agency (EPA) requires, at minimum, efficacy against Staphylococcus aureus and Pseudomonas aeruginosa to be considered a healthcare disinfectant.[11] Beyond this minimum requirement, disinfectants used in healthcare should demonstrate efficacy against a wide variety of relevant healthcare pathogens. PURELL® Healthcare Surface Disinfecting Wipes achieve broad-spectrum efficacy and deliver rapid kill times of 1-minute or less for 30 of the 36 organisms tested with an overall 2-minute contact time for the wipe as per the label. Rapid kill-times are important for supporting busy clinical workflows.

HAI are caused by a variety of organisms including bacteria, fungi, and viruses. However, pathogens responsible for the majority of HAI, that also have the highest risk of mortality and resultant increased healthcare costs, are caused by a group of bacteria commonly referred to as ESKAPE pathogens.[12] They are named for their ability to "escape" the biocidal action of antimicrobial drugs. The ESKAPE mnemonic stands for Enterococcus faecium/faecalis, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa and Enterobacter species. To support infection prevention efforts, surface disinfectants must have fast-acting efficacy against these pathogens. PURELL® Healthcare Surface Disinfecting Wipes rapidly kill ESKAPE pathogens (Table 1). In addition, the PURELL® wipes have efficacy against other relevant healthcare organisms including seven of the most common drug-resistant bacteria and viruses significant to the healthcare environment, including bloodborne pathogens, SARS-CoV-2 (the virus responsible for the COVID-19 pandemic), influenza A, respiratory syncytial virus, and norovirus (Table 1).



PURELL® Healthcare Surface Disinfecting Wipes Rapidly Kill ESKAPE Pathogens

Table 1: PURELL® Surface Disinfecting Wipes Efficacy and Kill-Times for Relevant Healthcare Pathogens

HEALTHCARE PATHOGENS	PURELL® SURFACE DISINFECTING WIPES KILL-TIME (IN SECONDS)
ESKAPE Pathogens*	
Vancomycin-resistant Enterococcus faecalis (VRE)	60s
Staphylococcus aureus	110s
Klebsiella pneumoniae (multi-drug resistant)	60s
Acinetobacter baumannii (multi-drug resistant)	60s
Pseudomonas aeruginosa	60s
Enterobacter aerogenes	75s
Other Multi-Drug Resistant Bacteria*	
Escherichia coli (Carbapenem-resistant and O157:H7)	60s
Methicillin-resistant Staphylococcus aureus (MRSA)	90s
Vancomycin-intermediate Staphylococcus aureus (VISA)	80s
Streptococcus pneumoniae (penicillin-resistant)	60s
Viral Pathogens+	
SARS-CoV-2	30s
Human hepatitis B virus	20s
Human hepatitis C virus	20s
Human immunodeficiency virus (HIV)	15s
Respiratory Syncytial Virus (RSV)	15s
Rotavirus	30s
Influenza A (H1N1)	15s
Influenza B (B/Hong Kong)	15s
Murine Norovirus	120s

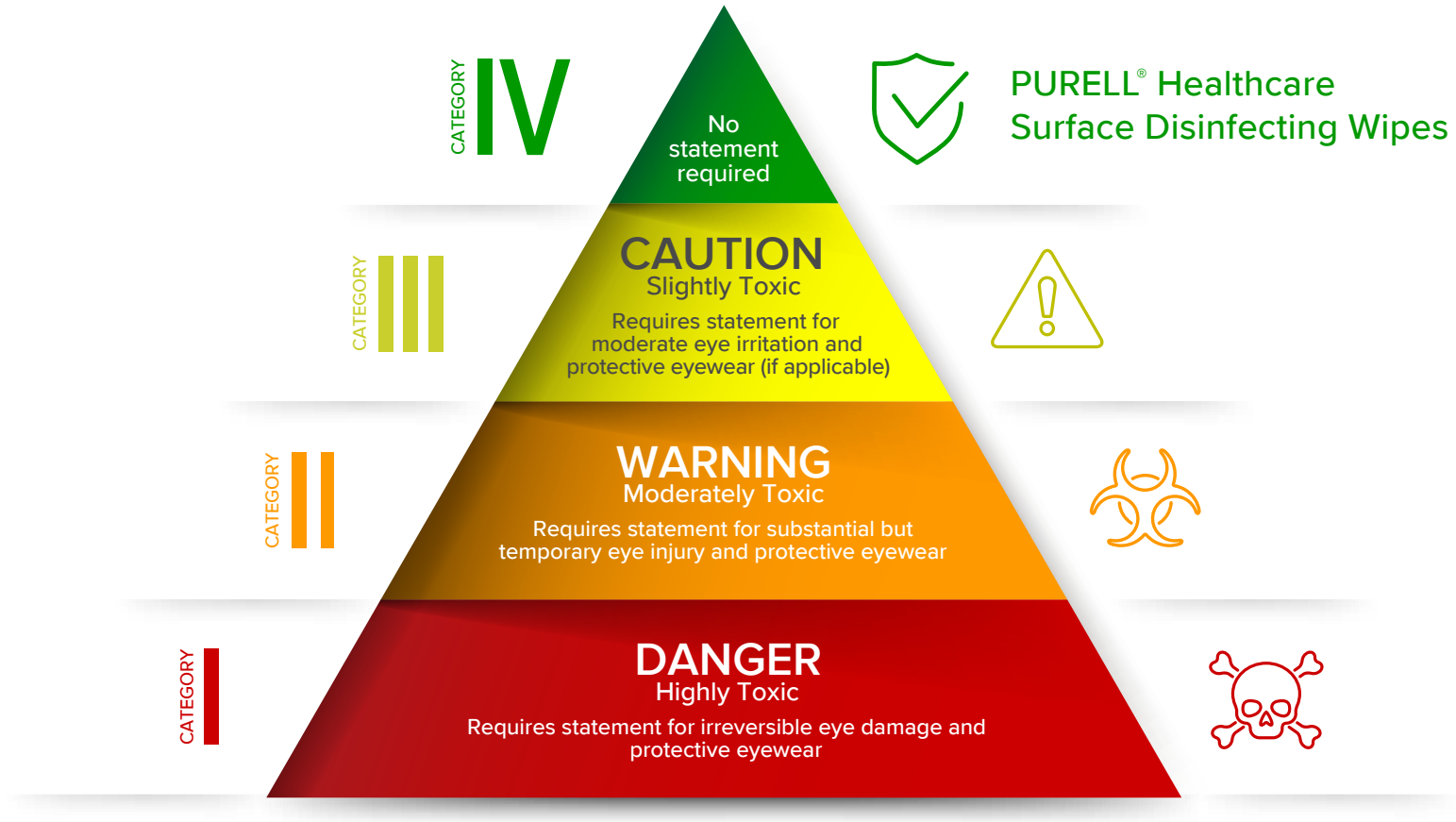
*Tested according to ASTM E2362-15. +Tested according to ASTM E1053-11. All testing conducted in accordance with OCSPP 810.2200 Product Performance Test Guidelines. Accuratus Lab Services, Eagan, MN 55121; Microbac Laboratories, Sterling, VA 20164. Above chart is not all-inclusive; see product technical bulletin for a complete list of pathogens.

EPA TOXICITY PROFILE

Healthcare disinfectants can require precautionary labeling based on their performance in acute toxicity (i.e., safety) testing. The EPA uses a categorization system that communicates toxicity ratings and safety profiles. These range from Category I (danger) to Category IV (no precautionary statements required).[13] Precautionary statements refer to either the level of personal protective equipment (PPE) required or the reaction the product may elicit during use. Examples of the required statements based on eye irritation potential for the different categories are shown in Figure 1.

The ideal surface disinfectant should be in the safest toxicity category to use and non-toxic. PURELL® Healthcare Surface Disinfecting Wipes were tested in accordance with the EPA guidelines and achieved the lowest toxicity rating (Category IV) for a surface disinfectant/ sanitizer product. Therefore, they do not require the use of PPE or precautionary statements regarding use on their label. However, it is important to note that gloves should be worn when cleaning and disinfecting surfaces contaminated with blood or other potentially infectious materials per the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard.[14]

Figure 1: U.S. Environmental Protection Agency (EPA) Toxicity Categories



FOOD-CONTACT SURFACES

PURELL® Healthcare Surface Disinfecting Wipes are approved as a no-rinse food-contact surface sanitizer. Meeting this requirement means that the EPA has evaluated the formulation of the product and has indicated that it is safe for use on food-contact surfaces without a post-application water rinse. This makes the PURELL® wipe ideal for use on surfaces near the patient that may come in contact with food, such as over-bed tables, utensils, dishware, and trays. PURELL® wipes are also FDA Food Code compliant, eliminating worry about the product being used in regulated food handling settings such as cafeterias or concerns regarding unintentional violations during inspector audits.

It's important to note that it is rare for hospital-grade surface disinfectants to also meet the EPA requirements for use as no-rinse food-contact surface sanitizers. It is even more rare for a hospital-grade surface disinfectant meeting the EPA requirements for a no-rinse food-contact surface sanitizer to have such an extensive range of efficacy, including ESKAPE pathogens, drug-resistant bacteria, viruses, and bloodborne pathogens as previously discussed.

CONTACT TIME

Contact time, as defined by the EPA, is the amount of time the disinfectant product must be "wet" and "in contact" with the surface to effectively kill all of the organism(s) that were tested and submitted for EPA approval.[15,16] The "wet" or "contact" time begins as soon as the product is placed on the surface. As the product begins to dry, wetness may be difficult to see. Looking horizontally at the surface, a "sheen" may be noted indicating it is still wet. The surface should remain visibly wet, including the sheen, or detectably wet if touched with a tissue during the entire contact time as noted on the disinfectant's EPA Master Label. The surface should remain undisturbed for the given contact time.

HEALTHCARE TERMS

There are several terms used within healthcare that are often incorrectly used interchangeably. It is helpful to clarify them to avoid confusion:

CONTACT TIME (wet time, kill time, or dwell time)
The amount of time the disinfectant product must be "wet" and "in contact" with the surface to effectively kill all of the organism(s) that were tested.

DRY TIME
Time from application until the surface is fully dry. This time should be at least as long as the contact time to ensure efficacy.

UNDISTURBED CONTACT TIME
Time the surface remains untouched after product application. This term implies the surface does not need to remain wet for the contact time but just untouched. This term is sometimes used by industry or in the field, but it is an oversimplification and does not match regulations and guidance. Per the EPA and CDC, the surface must remain wet, and not just undisturbed, for the time specified on the label.

KEY TAKEAWAY

The EPA is clear that the disinfectant product must be wet or in contact with the surface to effectively kill all of the organisms that were tested and submitted for EPA approval. The concept of wet time is made confusing by companies that have contact times or kill-times longer than the surface remains wet. In these cases, they should be instructing the user to use additional wipes to keep the surface wet for the entire kill-time required.

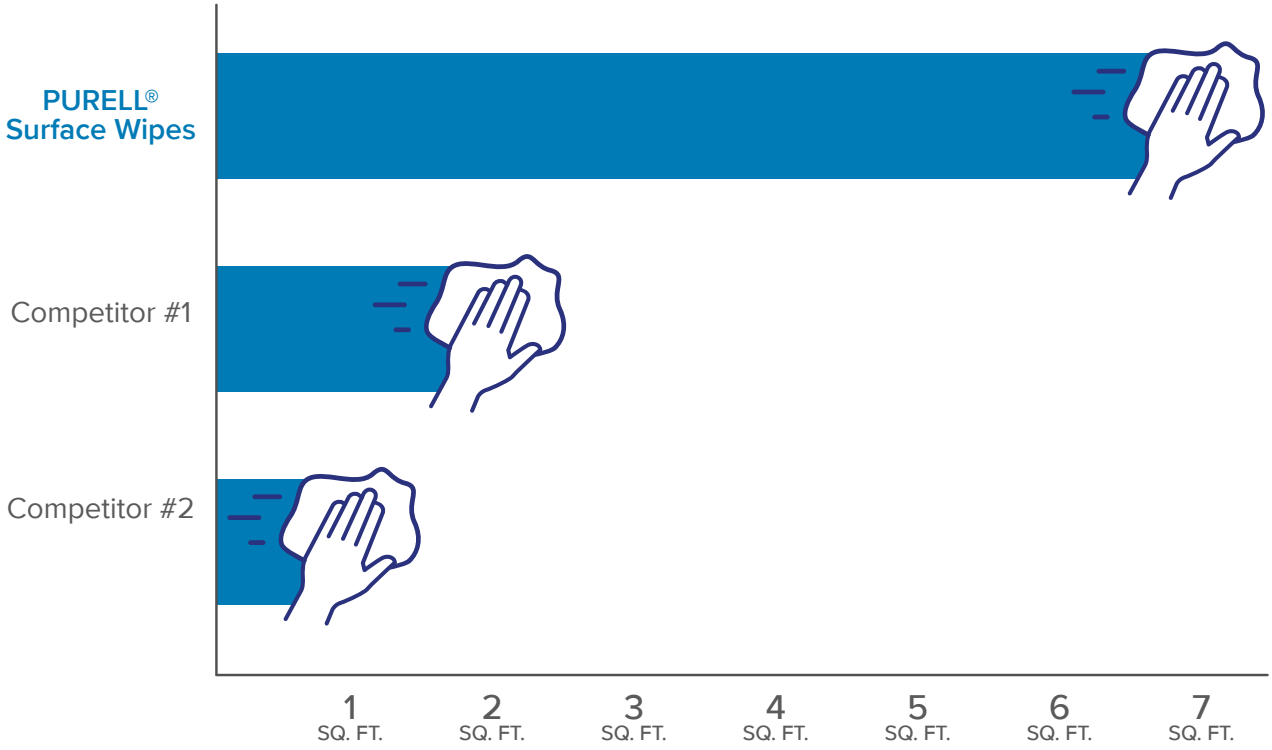
COVERAGE AREA

A critical component of contact time is how much surface area one wipe is able to effectively keep "wet" for the required duration. The concept of wet time is made confusing by companies that have contact times or kill-times longer than they are able to keep the surface wet. According to the EPA, if the surface in question dries more quickly than the required time for efficacy, another wipe should be used – and so on until the desired surface area has been covered for the entire kill-time required. Given that a primary objective of surface wipes is on-demand efficient and effective cleaning, it is reasonable for healthcare facilities to select a product that offers the optimal ratio of surface area coverage to labeled kill-time with one wipe.

When used as directed, PURELL® Healthcare Surface Disinfecting Wipes keep surfaces wet for the indicated disinfection contact time of 2 minutes with a single, one-wipe application. Each wipe, on average, covers and maintains wetness of up to 7 square feet of surface area, which is three to five times the coverage offered by two of the leading healthcare surface disinfecting wipes (Figure 2). PURELL® Surface Disinfecting Wipes are based on a novel, patent-pending formulation that enables them to be highly effective at only 20% ethanol, and they have an advantage in keeping surfaces wet for the required contact time compared to higher alcohol products. Humidity, temperature, and air flow have the potential to impact the assessment of wet times; a controlled test of multiple surface wipe products conducted in the same environment, under the same conditions at the same time allows for the relative comparison of product performance with certainty. Given that wetness for the duration of the contact time is critical for efficacy, this provides reassurance in use and ensures only one pass with one wipe is needed.

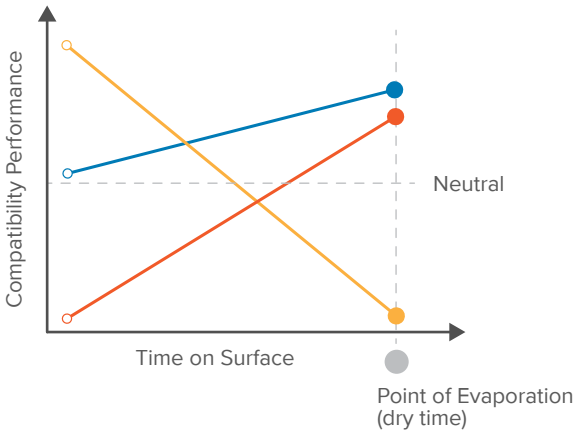
FIGURE 2: SURFACE WIPE DISINFECTING COVERAGE

Contact time: 2 minutes



Coverage for 1 Surface Wipe
(Average in Square Feet)

Figure 3: Compatibility Performance Trends of Surface Disinfection Products over Time



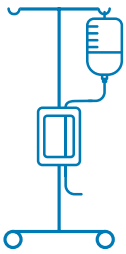
PURELL® Surface Wipes
Starts good and gets better over time

Alcohol/Quat Wipes
Evaporates faster over time

Benzyl Alcohol Containing Wipes
Longer time on surface = negative outcome

KEY TAKEAWAY

PURELL Surface Wipes' low ethanol formula allows for good initial compatibility performance that improves as the formula sits on the surface. Competing formulas will either start off worse or worsen as they sit, potentially requiring a secondary cleaning step to preserve surfaces.



MATERIAL COMPATIBILITY

Surface material compatibility is a critical component of the overall performance of disinfectant wipes used in healthcare settings. Costs associated with damaged equipment are a major concern and topographical changes to a surface due to the use of an incompatible formulation may permit the harboring of microorganisms and contribute to cross-transmission of pathogens.[17] Further, damaged surfaces may negatively influence patient perceptions of the aesthetics and cleanliness of the hospital and environment. With increased dependence on electronic equipment in healthcare, concerns around compatibility with this class of devices are accelerating.

Two material categories, metals and plastics, make up the vast majority of hard non-porous surfaces used in healthcare. Metal compatibility is predominantly decided by either oxidation potential or electrolytic corrosion. As an example, the chemical composition of quaternary ammonium compound (quat) based formulas is more like salt water than fresh water. Therefore, by their nature, quat-based formulas increase the electroyte load in the solution and thus increase electrolytic corrosion of metals, just as salt water corrodes faster than fresh water. Plastics are susceptible to a number of interactions such as plasticization (changing the molecular structure), additive leeching, strength degradation, and environmental stress cracking, much of which is driven by plastic's miscibility with organic solvents.

Miscibility is the ability of substances to combine and mix, creating a homogeneous by-product. For example, oil is not miscible with water and therefore will not mix. In contrast, ethyl alcohol is miscible with water, and the resulting mixture of ethanol and water will have a new set of miscibility and solubility properties that is a combination of the two starting substances. Organic solvents, such as ethyl alcohol, isopropyl alcohol or benzyl alcohol, when used alone show high miscibility with many plastics,[18] allowing them to "blend" with the material, leading to changes in additive (e.g., pigments, UV inhibitors) levels, changes in macro-molecular structure of the material, and potential contribution to the dissolution. However, the miscibility properties of a substance such as ethyl alcohol can be altered by mixing them with another substance.

Formulators counteract the negative effects of organic solvents by decreasing the concentration of these ingredients in aqueous solutions, driving the miscibility closer to water. PURELL® Healthcare Surface Disinfecting wipes utilize a 20% ethyl alcohol concentration mixed in an aqueous solution, creating a new set of miscibility and solubility properties and thereby eliminating most

of the compatibility risk associated with the use of ethyl alcohol on plastics. In addition, one of the most important interactions in real-world applications, which is distinguished by adding drying cycles to testing, is the difference between volatile organic solvents and non-volatile organic solvents. After a product is used on a surface, different ingredients will evaporate at different rates. Ethyl alcohol and isopropyl alcohol evaporate faster than water, effectively decreasing their concentration (and increasing compatibility performance) over time. Benzyl alcohol, which is not part of the PURELL® Surface Disinfecting Wipes formula, evaporates slower than water, effectively increasing the concentration (and decreasing compatibility performance) over time (Figure 2).
There are multiple test methods for surface compatibility.[19,20] These existing methods offer general guidance and factors to consider, allowing for flexibility in the development of specific methods. One of the most important factors expressed is the need for testing conditions to be reflective of in-use conditions, which is especially true for healthcare disinfectants as the use condition differs significantly from simple immersion.

> GOJO utilizes a series of immersion and dry cycles to test the surface compatibility of formulas to reflect in-use conditions and fully capture the effects evaporation has, both on the surfaces being tested and the formula composition.

Many materials in healthcare are chosen specifically for their resistance to chemical degradation. Plastics, which are a cost-effective and lightweight alternative to stainless steel, are often used in the construction of device casings and are prime candidates for disinfection. PURELL® disinfecting wipes have been tested and shown to be compatible with materials very commonly used in the healthcare industry which are known for chemical resistance.[21]

In contrast, some materials are used in healthcare despite known sensitivity to chemical degradation because they have other properties that make them highly valuable despite the sensitivity to chemicals (Table 2). Most disinfecting products may have one or more "sensitive" materials which prevent their usage in certain areas. PURELL surface disinfecting wipes, however, have shown to be compatible with all of the sensitive materials common in healthcare settings as shown in Table 2.

Table 2: PURELL® Surface Disinfecting Wipes Materials Compatibility

			Compatible with:			
Surface Type	Material	Potentially Found In:	PURELL® Surface Wipes	Alcohol/ Quat Formulas	Hydrogen Peroxide Formulas	Bleach Formulas
Plastics	Polyurethane	Foam, surface coating, furniture, protective covers, tubing, mattresses and mattress covers	✓	X	X	X
	Acrylics (PMMA)	Phone displays, incubators, plexiglass, protective shields, sneeze guards	✓	X	X	X
	ABS	Keyboards, mice, phones, pumps, molded plastic components, electronic assemblies	✓	✓	X	X
Metals	Aluminum	Walkers, carts, seating, shelving/storage	✓	X	X	X

While these are some of the most common materials used in healthcare, it is by no means an exhaustive list of materials compatible with the PURELL® Healthcare Surface Disinfecting Wipes. In addition to more than 30 base materials, the PURELL wipes have been tested on and shown to be compatible with various electronic devices, including Apple, Samsung, and Microsoft touchscreen products. Wipes are being used more frequently than ever to reduce cross-transmission of pathogens, and it is essential that disinfecting wipes used in healthcare environments have good compatibility with the widest range of surface types and devices.

CONCLUSION

Wipes exist to make cleaning and disinfecting healthcare surfaces and devices easier and more efficient for healthcare workers. Choosing a product with healthcare-relevant efficacy, speed of contact time, materials/device compatibility, and safety profile are all critical components for consideration. PURELL® Healthcare Surface Disinfecting Wipes provide the antimicrobial performance expected of a healthcare wipe including an overall contact time of 2 minutes with efficacy against organisms that are the most problematic in healthcare environments. PURELL® wipes meet the EPA's lowest toxicity rating available (Category IV) and do not have precautionary statements, do not require PPE, contain no harsh odors or toxic chemicals, and are food-contact, no-rinse approved, allowing them to be used in areas where patients eat. This unique blend of efficacy, safety, and compatibility make it a differentiated option that can help support a healthcare facility's infection prevention and patient safety programs.

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