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An evaluation of the effectiveness of polymeric flooring compared with "peel-off" mats to reduce wheel- and foot-borne contamination within cleanroom areas

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It has been established that, in order to maintain the highest levels of cleanliness within a cleanroom environment, it is essential to prevent the ingress of particles and micro-organisms into the critical area from the surrounding environment. Principles of good manufacturing practice (GMP) and quality assurance demand that particle and microbiological contamination levels within any critical area should be minimised to prevent contamination entering the product. Two major sources of viable and non-viable particle contamination entering critical environments are from operators' feet and trolley wheels. This paper compares two different types of floor covering used to reduce foot- and wheel-borne contamination, namely the "peel-off "/ acrylic mat and "polymeric" floor covering. The results of this comparison demonstrate that "polymeric" flooring is a more effective means of controlling foot- and wheel-borne contamination, thereby effectively reducing the number of micro-organisms entering the critical environment.

Introduction

The entry into critical environments should be protected within the manufacturing facility, so as to minimise the presence of both viable and non-viable contamination during manufacture performed under cleanroom conditions. It is recognised that foot- and wheel-borne contamination are two major sources of both viable and non-viable contamination[1-2]. Therefore, some form of control or preferable elimination of these particles into cleanroom areas is of paramount importance, as particulate contamination affects product yield, productivity, product quality and cost. Studies of current practice suggest that this type of contamination can reduce product yield by as much as 20%[3].

Research was undertaken within the Ware facility at GlaxoSmithKline to evaluate the effectiveness of "Dycem polymeric" flooring and "peel-off" mats to reduce contamination from operators' footwear and trolley wheels. Since people are a major source of particulate contamination through body regenerative processes, operator behaviour and work habits, particulate contamination can be readily transferred into critical cleanroom environments from operators' footwear or from inanimate objects, such as wheels, materials or equipment.

Therefore, in order to minimise particulate contamination, some form of floor contamination control system is required, since it is less expensive and easier to control foot- and wheel-borne contamination prior to the critical environment.

The study described in this paper was performed within the Pharmaceutical Microbiology Unit (PMU) at GlaxoSmithKline's Research and Development facility in Ware, Hertfordshire. Dycem polymeric floor covering was placed for a trial period within the corridor area at the entrance to the cleanroom facility. The cleanroom facility is used primarily for water testing within the Pharmaceutical Microbiology Unit, Building 5, at the Ware facility, where it is a requirement that particle and microbiological contamination levels should be minimised.

Test methodology

The two types of floor covering, "polymeric" flooring and the peel-off mat, were evaluated using the swabbing technique. Swabs were moistened with sterile 0.9% peptone water and samples taken from trolley wheels (two wheels from each trolley were each sampled approximately one half of a wheel circumference). This was performed before contact with polymeric flooring or the peel-off mat. In addition, the soles of operators' footwear, wearing overshoes at the entry to the corridor area (5F068) of the PMU clean suite (5F069) were also swabbed (as described previously).

Swabs were plated out onto Tryptone Soya Agar (TSA) plates for bacteria and Sabouraud's Dextrose Agar (SDA)

plates selective for yeasts and moulds, and incubated at 30-35ºC for 3 to 5 days and at 20–25ºC for 5 to 7 days, respectively.

The above procedure was repeated, where swabs were taken from trolley wheels (two wheels from each trolley) after being pushed across the polymeric floor covering or the peel-off mat, where the remaining half of the trolley wheel was swabbed. In addition, swabs were taken from operators' footwear after walking across either type of floor covering and making at least four imprints onto the flooring. The surface swabs were plated out using the procedure described previously.

The experimental investigation was performed under test conditions comparable with those used in practice. The length of polymeric flooring allowed a minimum of at least four imprints or footfalls (that is, two imprints for each foot) and also four rotations of trolley wheels onto the flooring. Surface swabs were taken from operators' footwear using overlapping strokes to obtain maximum recovery.

Table 1: Results for mean viable counts and percentage reduction values for wheel- and foot-borne contamination for "peel-off mats".

Contamination surface	Mean viable counts (cfu/40cm²)				Mean percentage reduction	
	Before "peel-off" mat		After "peel-off" mat			
	TSA	SDA	TSA	SDA	TSA	SDA
Wheel-borne	539	151	403	110	25.2%	27.15%
Foot-borne	698	226	618	192	11.5%	15.0%

Table 2: Results for mean viable counts and percentage reduction values for wheel- and foot-borne contamination for "polymeric" flooring.

Contamination surface	Mean viable counts (cfu/40cm²)				Mean percentage reduction	
	Before "polymeric" flooring		After "polymeric" flooring			
	TSA	SDA	TSA	SDA	TSA	SDA
Wheel-borne	347	53	2	0	99.4%	100%
Foot-borne	472	122	1	0.2	99.8%	99.8%

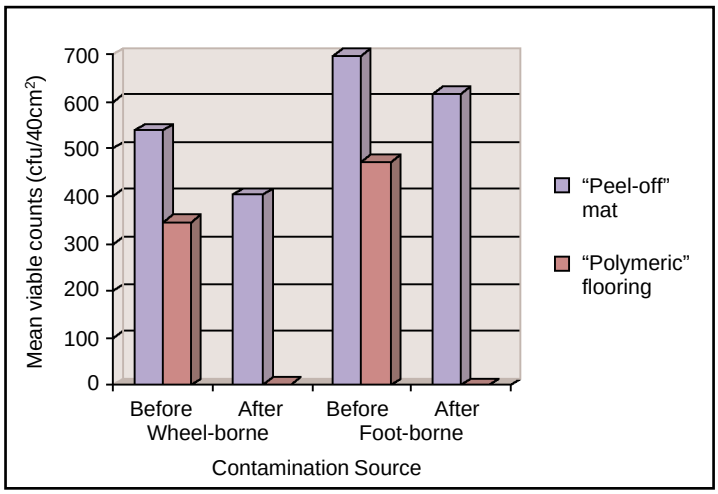

Figure 1. Graphical representation of mean viable counts for wheel- and foot-borne contamination, using Tryptone Soya Agar.

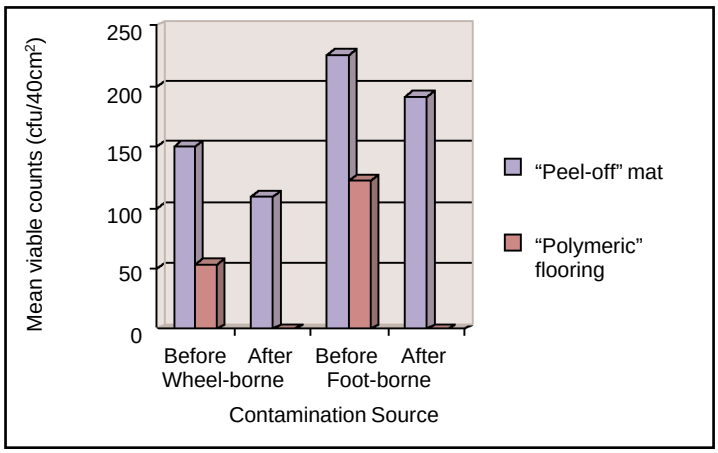

Figure 2. Graphical representation of mean viable counts for wheel- and foot-borne contamination, using Sabouraud's Dextrose Agar

Acceptance criterion

The acceptance criterion for this investigation is to demonstrate a reduction in the microbial count for foot- and wheel-borne contamination after contact with polymeric flooring, in comparison with peel-off mats.

Results

The results of this investigation are shown in **Tables 1** and **2**.

To evaluate wheel-borne contamination, ten samples were taken and plated onto TSA plates, and ten samples onto SDA plates both before and after the peel-off mat and "polymeric flooring". A similar procedure was applied when assessing foot-borne contamination. On each occasion, the results were averaged and mean percentage reduction values were calculated.

The mean percentage reduction values for polymeric flooring were 99.4% for TSA plates and 100% for SDA plates for wheel-borne contamination and 99.8% for both TSA and SDA plates for foot-borne contamination.

In contrast, the mean percentage reduction values after contact with peel-off mats were much lower for both types of contamination sources, notably, 25.2% for TSA plates and 27.15% for SDA plates for wheel-borne contamination, and 11.5% for TSA plates and 15% for SDA plates for foot-borne contamination.

In summary, mean percentage reduction values for polymeric flooring were much greater than for peel-off mats for both wheel- and foot-borne contamination.

Graphical representations of mean viable counts for wheel- and foot-borne contamination using TSA and SDA are shown in **Figures 1** and **2**, respectively.

Discussion and conclusions

This initial investigation has demonstrated that polymeric flooring is highly effective in controlling microbiological contamination of both bacteria and yeasts/moulds from operators' footwear and trolley wheels. Indeed, polymeric flooring is much more effective in controlling both viable and non-viable particles than peel-off mats. The acceptance criterion was achieved, whereby there is a much greater reduction in the microbial count for both wheel- and foot-borne contamination after contact with the polymeric flooring compared with that achieved for peel-off mats.

Further investigative work is required to assess the minimum number of foot-prints required to achieve effective reduction of microbiological contamination from operators' footwear after contact with polymeric flooring. Similarly, further study is required to establish the minimum contact required for trolley wheels after contact with polymeric flooring to effectively reduce microbiological contamination of both viable and non-viable particles.

Recommendation

It is recommended for industries which manufacture products under critical cleanroom conditions to evaluate polymeric flooring.

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