



WHITEPAPER STUDY

**75% REDUCTION IN AIRBORNE
CONTAMINANTS BY SWITCHING TO
DYCEM POLYMERIC FLOOR COVERINGS**

75% REDUCTION IN AIRBORNE CONTAMINANTS BY SWITCHING TO DYCEM POLYMERIC FLOOR COVERINGS

This paper describes a study undertaken by a major medical device company in the US which examined processes for significant airborne reduction count in cleanroom environments. This study identified the amount of particulate reduction, highlights costs, time savings and the sustainability of reusable contamination control floor coverings.

KEY WORDS: CONTAMINATION CONTROL, FLOOR LEVEL, POLYMERIC FLOORING, PEEL-OFF MATS, TACKY MATS, SUSTAINABILITY, PARTICLE COUNTS, AIRBORNE, CLEANROOMS

INTRODUCTION

A major medical device manufacturer revealed a significant reduction in airborne particulate counts by evaluating their floor-level contamination control methods. The facility, based in the USA, was using several hundred cases of peel-off tacky mats per year (Figure 1) to address contamination within their controlled hybrid manufacturing areas.

BACKGROUND

The device manufacturer conducted an analysis of consumables utilized in a key gowning room within the facility. These consumables encompassed items such as ESD (electrostatic discharge) shoes, garments, and single-use disposables, including hair covers, face masks, gloves, and peel-off tacky mats. The purpose of the blue tacky mats was to capture dirt from operatives' "street shoes" upon entering the gowning room to mitigate potential contamination [2]. The analysis revealed an annual expenditure of \$24,000 on blue tacky mats in that specific building. Furthermore, it brought to light the disposal of approximately one ton (2028 lbs.) of used plastic peel-off mat sheets on a yearly basis.

CLEANROOM MATS DEFINED

Adhesive or "tacky" mats are comprised of numerous layers (typically 30-60 per mat) of plastic polyethylene sheets coated with an acrylic adhesive. The mat exhibits a "tacky" or sticky quality, capturing dirt and debris from shoe soles upon contact.

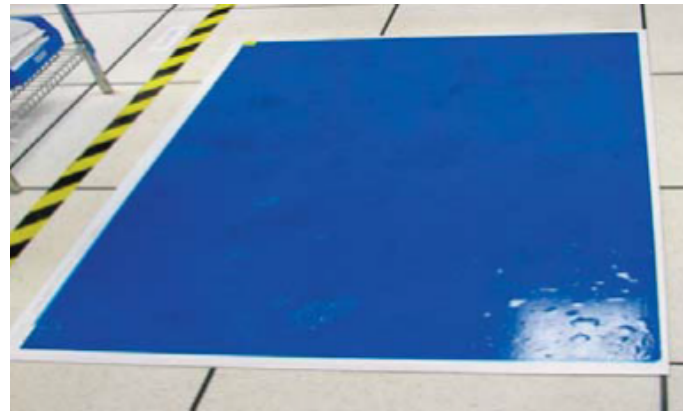


Figure 1: One peel-off tacky mat being used in a gowning area

upon contact. These mats are intended to be disposable. Depending on the facility's protocol, the top layer is peeled off once it becomes saturated or after a specified duration (e.g., per shift) and is then disposed of. It's worth noting that the removal of the top layer can introduce a degree of contamination redistribution into the environment. Particles may become dislodged from the adhesive surface during the peeling process and re-enter the air [5].

On the other hand, polymeric flooring features an optically smooth surface crafted from a non-toxic, plasticized material. This surface possesses a high natural tack and surface energy, effectively capturing both viable and non-viable particulate contamination upon contact.

75% REDUCTION IN AIRBORNE CONTAMINANTS BY SWITCHING TO DYCEM POLYMERIC FLOOR COVERINGS

Electrostatic forces bind particles to the surface until they are removed through cleaning and disinfection, typically as part of the facility's wet cleaning schedule. Importantly, the polymeric surface remains effective between cleanings, presenting a reusable, long-term solution [5].

AN OPPORTUNITY FOR IMPROVEMENT WAS IDENTIFIED

A polymeric floor covering, Dycem, was identified as an alternative to the blue tacky mats currently being used in the gowning room. The Dycem flooring material was selected due to its longevity, efficacy, possible cost savings, and reduction in daily waste. The average lifespan of Dycem flooring is 3+ years on average with a one-time upfront cost. During that period, the comparative spend on tacky mats was estimated to be at least \$72,000.

PROJECT EVALUATION

A project plan was developed and presented to manufacturing management. Financial feasibility was analyzed for several areas of Dycem flooring implementation. The cost of the Dycem trial areas was equivalent to 20 months' worth of tacky mat spend and the Dycem material would cover an area 10 times as large. A financial benefit was forecasted based on the average expected lifespan of Dycem. Management approved the plan and airborne particle counters were installed in the gowning room to measure the performance of the Dycem material.

THE EXPECTED BENEFITS OF DYCEM

- Less particles in the gowning room.
- Improved yields.
- Reduced product rejects.
- Reduced ongoing expense (no peel-off mats will need to be purchased, stored, and peeled).
- A more sustainable solution and reduction in waste (plastic peel-off mat sheets will not need to be disposed of in the trash) [4].
- Reduced cleaning costs due to no adhesive carry-over into the critical production areas.



Figure 2: Changing area covered with Dycem CleanZone polymeric floor covering

TESTING

Particle data measurements were gathered during a 12-week period using the initial peel-off tacky mats. Subsequently, Dycem material was installed during a production downtime period (see Figure 2), and particle data measurements were conducted over an additional 12 weeks. The results of a week's worth of tests for both solutions are presented in the following graphs—Figure 3.A and Figure 3.B.

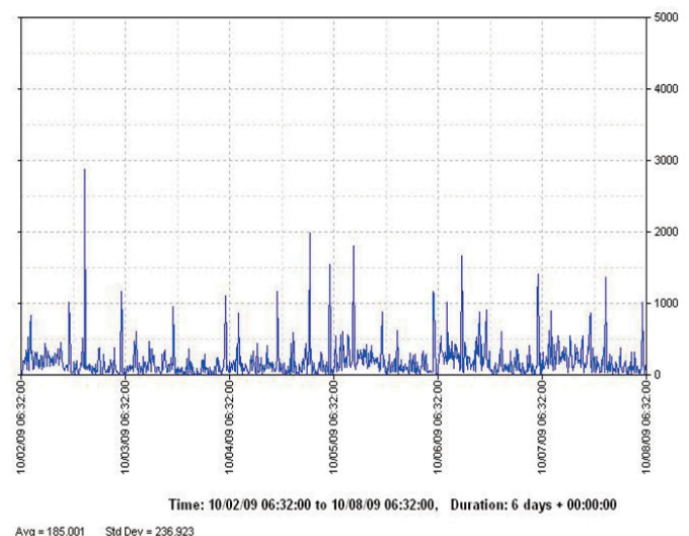


Figure 3.A: One Week of Particle Data with Tacky Mats

The graph above shows airborne particle counts in the gowning room when the tacky mats were in place. The spikes in the graph reflect when the tacky mats are being peeled. Note the average airborne count during this week was 185, 0.5 micron and larger particles per cubic foot of air.

75% REDUCTION IN AIRBORNE CONTAMINANTS BY SWITCHING TO DYCEM POLYMERIC FLOOR COVERINGS

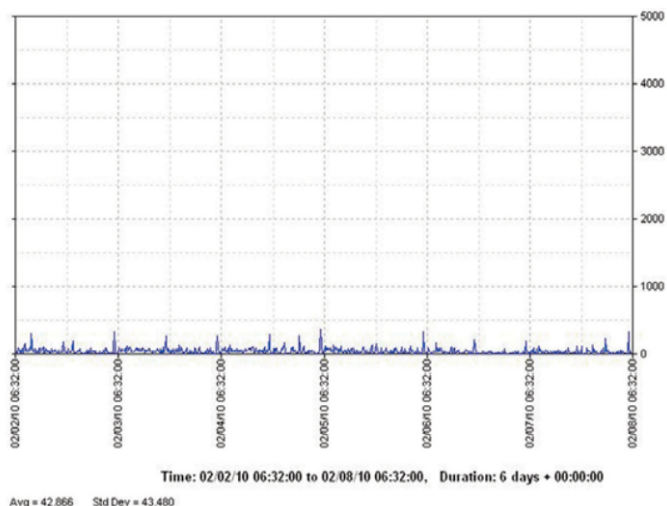


Figure 3.B: One Week of Particle Data with Dycem

The graph above shows airborne particle counts in the gowning room after the Polymeric Floor Covering was in place. Note the average airborne count during this week was 43, 0.5 micron and larger particles per cubic foot of air.

RESULTS

- Airborne particles in the gowning room were reduced by 75% as a result of using Dycem polymeric floor coverings.
- Particle shedding levels were reduced as tacky mats were not being used and no peeling of contaminated layers took place. (Figure 4)

SUMMARY

- The test results showed that the gowning area is cleaner with a significant particle reduction.
- Cost savings were evident due to the 3+ year lifespan of the Dycem polymeric floor coverings, an expected \$80,000 will be saved over purchasing peel-off tacky mats.
- Time-Saving – Custodians reported a time saving of 2 hours per day due to not having to peel and dispose of tacky mats.
- A greener solution – less plastic going into the trash – more than 5 tons of plastic over a five-year period will be saved from going into a landfill [4].

RECOMMENDATIONS

Considering the notable reduction in particles both at floor level and in the air, coupled with evident cost savings and positive environmental impact, it is strongly advised that facilities operating in the Life Sciences sector or other cleanroom environments assess the viability of Dycem polymeric floor coverings as a superior alternative to peel-off tacky mats for contamination control [6].



Figure 4: Blue tacky mats no longer needed

REFERENCES

1. Sandle, Tim. (2012). "Examination of air and surface particulate levels from cleanroom mats and polymeric flooring." *European Journal of Parenteral and Pharmaceutical Sciences*, 17, 110-119.
2. Sandle, T. "Environmental monitoring." In: *Microbiology and Sterility Assurance in Pharmaceuticals and Medical Devices*. Saghee MR, Sandle T, Tidswell EC, Eds. New Delhi: Business Horizons, 2001, pp.293-326.
3. Clibbon, C. "An evaluation of the effectiveness of polymeric flooring compared with 'peel off' mats to reduce wheel- and foot-borne contamination within cleanroom areas." *Eur J Parent Sci*, 2002; 7(2):13-15.
4. Prout, G. "A comparison of polymeric flooring and disposable mats in pharmaceutical cleanrooms." *Pharmaceutical Technology*, 2010. Online article: <http://www.pharmtech.com/pharmtech/article/articleDetail.jsp?id=691057> (Accessed December 30, 2011).
5. Sandle, T. "The use of polymeric flooring to reduce contamination in a cleanroom changing area." *EJPPS*, 2006; 11(3):75-80.
6. International Standards Organisation. ISO 14644-1:1999 – Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness. Geneva, Switzerland: ISO, 1999.