

The nature and environmental impact of control of floor level contamination

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Abstract

The nature of particulate contamination in the operation of cleanrooms is reviewed; particulate of greatest significance and most numerous is less than 10 microns and emanates primarily from movement of personnel. Significant contamination at floor level results from carryover of foot- and wheel-borne particulate and is normally controlled by the use of peel-off adhesive mats or, increasingly, by polymeric contamination-control flooring. Previously reported research on control of contamination is briefly reviewed to illustrate the distribution of particle sizes at floor level and the efficiency with which they are collected by peel-off mats and by proprietary contamination-control flooring. Polymeric flooring is shown to demonstrate significantly superior performance on particulate collection to peel-off mats for both viable and non-viable particulate and over a full range of particle sizes, especially on particulates less than 10 microns. Research undertaken over the past ten years has reported on studies related to footwear types commonly in use in cleanrooms and their influence on control of particulate contamination. Footwear with smooth soles releases particles most efficiently to the control surfaces of both peel-off mats and polymeric flooring; other soling types with ridged or patterned soles behave less predictably. Polymeric flooring demonstrates superior performance to peel-off mats for all soling types; the efficiency of peel-off mats is influenced adversely by some soling types in use, which can render peel-off mats almost totally ineffective. Comparative costs and ecological implications are reviewed by reference to an industrial case study. It is demonstrated that in a large installation requiring ten controlled entries, cost savings of as much as \$300,000 can be achieved over a two-year

period by the use of polymeric flooring in place of peel-off mats which have a high manufacturing and disposal cost. The installed area of the polymeric flooring, being 35 times greater than that of the ten mats combined, represents a substantially larger barrier against contamination. As polymeric flooring is disinfected with antimicrobial disinfectants, disposal poses no health hazard to humans or the environment compared with peel-off mats.

Key words: Cleanrooms, mats, polymeric flooring, particles, footwear, environmental impact.

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Table 1: Relative sizes of particles visible to the human eye

Particle	Size (microns)
Human hair	100
Particles in normal light	50
Particles on reflective surface	10
Particles in intense light	5
Particles in optical microscope	0.5–0.8

Table 2: Shapes of particles from different sources

Shape	Source
Spherical	Smoke and pollen
Irregular – cubical	Minerals
Flakes	Epidermal tissue
Fibres	Lint from clothing

Table 3: Size ranges of different particles

Particle	Size (microns)
Human hairs	150–50
Dust from floors	100–1
Bacteria	50–0.5
Tobacco smoke	1–0.1

The nature of particulate contamination

As broad bench marks, particle sizes that are within the limits of human experience are shown in Table 1. Particles of 10 microns or less with which cleanroom operators are particularly concerned are thus mainly invisible to the naked eye, are of differing shapes and derive from a wide range of sources (Table 2). Comparative size ranges that are of practical significance are shown in Table 3.

People are a major source of contamination through body regenerative processes (skin flakes, oils, hair), behaviour (rate of movement, sneezing, coughing) and attitude (work habits, communication). Personnel activity rapidly accelerates the rate of generation of particles (Figure 1, Table 4).

Table 4: Particles generated during personnel activity

Activity	Particles per minute (0.3 micron and larger)
Motionless – standing or seated	100,000
Walking – about 2mph	5,000,000
Walking – about 3.5mph	7,000,000
Walking – about 5mph	10,000,000

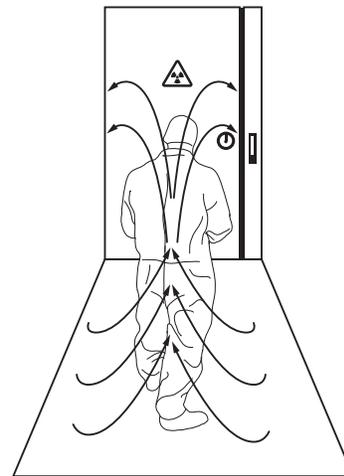


Figure 1. Vortices created by movement of personnel

Control of particulate contamination from personnel movement is thus a critical factor in manufacturing operations undertaken under cleanroom conditions affecting:

- Product yield
- Productivity
- Cost
- Quality
- Reliability.

Studies of current practice in the semi-conductor industry suggest that particulate contamination can reduce product yield by as much as 20%. To remain competitive, continued research must be directed towards the progressive reduction and control of particulate contamination from all potential sources. In other sectors of the industry, such as pharmaceuticals and medical device manufacture, the additional control of viable or biologically active particulate is of critical importance in preventing active contamination entering the cleanroom or causing cross-contamination between working areas. There are no published data relating to product yield loss from either viable or non-viable particulate contamination.

The reduction of particulate contamination from people is thus of paramount importance for the operation of cleanrooms and is normally achieved in a progressive manner, from the point at which personnel enter the building through to the critical areas of the gowning room and subsequent entrance to the controlled production area itself. At the point of entry to the gowning room where gowns, gloves, hoods and overshoes are donned, any gross contamination of footwear will normally have been removed.

Nonetheless, large numbers of both viable and non-viable particulate can be carried on the feet of operators or on cart wheels. Research has demonstrated that more than 20,000 2-micron particles per cm² can be measured on the feet of operators under controlled experimental conditions. The more systematic removal of foot-borne small particulate at this stage, most of which cannot be seen by the naked eye, is essential. At the point of entry from the gowning area to the cleanroom itself, controlled procedures to reduce carry-over of foot-borne particulate should be impossible to avoid within normal movement of personnel and wheeled traffic. A typical

arrangement to achieve this would be the use of a step-over bench.

In normal industrial practice, control of foot-borne contamination is attempted by the use of adhesive peel-off disposable mats or, increasingly and more effectively, the use of polymeric contamination-control flooring.

Flooring products for control of foot- and wheel-borne contamination must not only be inherently effective but must also be used in a disciplined management regime directed to contamination control as a whole. Such a regime must be:

- Simple: Requiring minimum overt action by personnel
Allow continuous flow of traffic
Maintainable within existing cleaning schedules
- Effective: Unavoidable and large enough to accommodate personnel and carts
Capable of removing and holding the finest (and most numerous) particles
Able to handle large personnel movements at shift changes.

These requirements are uniquely fulfilled by the use of polymeric flooring when used as full-floor coverage in the gowning area, prior to air-showers and air-locks and at the entrance to the cleanroom area. In many cleanroom situations the flooring may also be used

between areas as an additional aid to the control of small particulate or cross-contamination from viable particulate.

Installation of up to 100 square metres of polymeric flooring may be specified for gowning areas and provide the only fully effective means of control. By comparison with the use of adhesive peel-off mats, a greater efficiency of particulate removal is achieved over a much larger control area, with a consequent increase in product yield. Major cost savings can be achieved over the service life of polymeric flooring compared to peel-off mats.

In an increasingly resource-conscious world, the polymeric products are economical and relatively environmentally friendly. Polymeric flooring products avoid the waste of resources associated with the manufacture and disposal of adhesive peel-off mats. On completion of their service life, the polymeric flooring products may be readily recycled into less critical uses.

Control of foot- and wheel-borne contamination

A detailed review of polymeric flooring and its role in the control of foot- and wheel-borne contamination was presented at CleanRooms East in Boston in 1996 and was subsequently published in *CleanRooms*.¹

The mechanism of particulate control by polymeric flooring was shown to be attributable to the short-range electromagnetic forces acting over the

Polymeric contamination control flooring

Alan Fisher, Contamination Control Specialist at Dycem Limited, manufacturers of polymeric contamination control flooring, has very kindly provided this explanation:

Our polymeric contamination control flooring is manufactured from a proprietary blend of specially formulated polymeric compounds. The properties of the cocktail of materials used and the sophisticated manufacturing process together create a material that has a very optically smooth, soft and supple surface with a natural tack and a high level of short-range electromagnetic forces, known as van der Waals forces.

These properties enable the surface to attract, collect and retain particles ranging in size from over 100 microns down to a few nanometers. To enhance the performance of the material special additives are mixed in to give static-dissipative and anti-microbial properties.

To remain effective the product needs periodic cleaning to maximise its effectiveness. Cleaning procedures and cleaning equipment vary considerably across the range of markets where polymeric contamination control flooring is used. Most cleaning agents can be used and cleaning processes range from a simple mop, bucket, detergent and rinsing system (two buckets) through to ride-on cleaners with motorised brushes.

optically flat, flexible surface of the product and their ability to retain particulate over a wide range of particle sizes.

Earlier laboratory research² had suggested that the efficiency of particulate removal by polymeric flooring was greater than that which could be achieved by adhesive peel-off mats, particularly for the smaller and most numerous particle sizes, and the results of a research programme undertaken under practical operating conditions in a cleanroom were described.

This investigation was undertaken in a Class 10,000 cleanroom suite in the Centre for Drug Formulation Studies at the University of Bath, UK.³ In summary, this investigation demonstrated that, in comparison with peel-off mats:

- Polymeric flooring shows a significantly higher removal of particulate over all particle sizes, and especially with small particulate (Table 5).
- Polymeric flooring is very effective in the control of viable, biologically active, particulate under circumstances where adhesive peel-off mats can be almost totally ineffective (Table 6).

During the course of these investigations a number of “rogue” results were obtained, particularly with peel-off mats, where the number of particle counts after treading on the control surface was greater than the count before. This somewhat surprising result has been attributed to a proportion of operators picking up additional contamination from areas of mat where operators had previously trodden and has been investigated in two further programmes at different locations.⁴⁻⁶

A subsequent study showed that after a year of arduous use, the performance of the polymeric flooring

Table 5: Foot-borne particulate collection as a function of particle size. Comparison of polymeric flooring with peel-off mats, Bath University, 1996

Particle size (microns)	Particles removed (%)	
	Polymeric flooring	Peel-off mats
2	57.3	10.9
10	67.8	31.8
20	69.3	36.8
50	85.3	61.7
100	>80	>70

was superior to that of new peel-off mats for all particle sizes and particularly so for the smaller sizes.

The total count of small particles after passing over the peel-off mats was found to be higher than the control. This apparently surprising result can be attributed to particulate from the feet of operators at the early stages of the trial being transferred back to the feet of later operators. The different results between the polymeric flooring and peel-off mats can be considered to be similar to the relative performance of the flooring between cleaning operations and to the peel-off mat between mat changes (Table 7).

Taking the mean of the total for each operator, it is clear that the polymeric systems remove literally thousands of particles at the 10- and 2-micron level, at which the peel-off mats are totally ineffective.

A further series of tests was undertaken in the demonstration cleanroom suite in Strasbourg, France, comprising Class 10,000, Class 1,000

and Class 100 areas. In these tests, undertaken in April 1997, similar analytical procedures were employed to those used earlier at Bath University to measure retained particulate from the shoes of 20 operators each making four footfalls over the polymeric flooring or over a peel-off mat prior to entering the cleanroom suite. Particulate counts were measured at particle sizes of 2, 5, 10, 25, 50, 100 and 125 microns.

Above 25 microns the performance of both polymeric flooring and peel-off mats is largely similar, with both systems recording percentage reductions of particulate in the range 80–95%.

For particulate of 10 microns and below the results are radically different and are broadly in line with those of previous work (Table 8).

In examining these figures, which clearly demonstrate the superiority of polymeric flooring over peel-off mats within this range of particulate size, it should also be borne in mind that the mean figures quoted are based only on the number of observations in which

Table 6: Foot- and wheel-borne viable particulate control, Bath University, 1996

Viable counts Before	Viable counts after		Reduction (%)	
	Polymeric flooring	Peel-off mats	Polymeric flooring	Peel-off mats
Foot-borne >1000	567	967	43	3
Wheel-borne >1000	17	764	98	23

Table 7: Total reduction in particle count, Bath University, 1997

Particle size (microns)	Polymeric (>1 year)	Polymeric (new)	Peel-off mats
2	4,708	8,504	-3,967
10	5,051	5,948	-1,208
25	543	639	552

Table 8: Reduction in particle count for different particle sizes, Strasbourg, 1997

Control medium	Reduction in particle count (%)		
	2 microns	5 microns	10 microns
Polymeric flooring	71.1	64.9	68.4
Peel-off mat	15.2	43.1	38.1

Table 9: Increase in particle count for different particle sizes, Strasbourg, 1997

Control medium	Increase in particle count (%)		
	2 microns	5 microns	10 microns
Polymeric flooring	Nil	Nil	10
Peel-off mat	15	45	35

an actual reduction of particulate was observed, discounting the cases where an increase took place. For the peel-off mats, particularly, a significant number of observations at each particle size displayed an increase in particulate counted after walking over the control medium; the number of observations of this type as a percentage of the total is illustrated in Table 9.

In the total of 60 observations within this particulate range, almost one third of the observations on peel-off mats showed an increase in particulate count to offset an almost identical average percentage reduction in particulate on the remaining 40 observations.

The clear inference is that, as a means of control of particulate less than 10 microns in cleanrooms, the use of adhesive peel-off mats provides little significant benefit. The performance of polymeric flooring within the range of 2–10 microns of particulate has been shown to be consistently effective. The control of biologically viable particulate was also evaluated and the flooring found to be very effective.

Small variations of results on the polymeric flooring between observers and locations can almost certainly be attributed to other variables in the trials. These are discussed in the following section.

Operational variables in contamination control

The overall efficiency of contamination control in a practical operating situation is clearly dependent on a number of variables other than the inherent properties of the control surface, reviewed in the previous sections. These include:

- *The effective area of the control surface:* In recommended practice a full-floor coverage of between 20 and 30

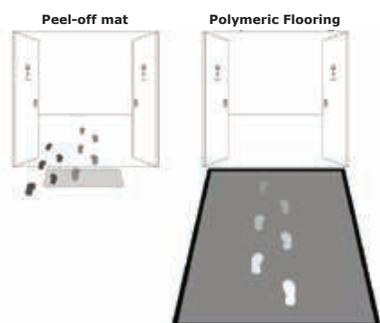


Figure 2. The overall efficiency of contamination control is dependent on the effective area of the control surface.

square metres will replace a peel-off mat of some 1 square meter such that the control area of the flooring is approximately 25 times greater than that of the peel-off mat (Figure 2).

- *Cleaning or mat replacement procedures:* Regular cleaning of the flooring is essential in order to remove contamination and to renew the control surface; this can normally be accommodated at no extra cost within existing cleaning schedules. Replacement of peel-off mats, however, is frequently undertaken on an irregular basis “when the mat appears dirty” but, as noted earlier, most of the important small particulate is invisible to the naked eye.
- *Other variables:* Research undertaken to date, together with theoretical considerations of particulate control developed during this period, had suggested that the type of soling used on footwear could be a significant factor and had suggested that footwear with smooth soling would offer advantages, especially in the removal of small particulate. This has been evaluated as follows:

Using the well-established procedures developed for use in the cleanroom suite at Bath University, particle counts before and after polymeric flooring and peel-off mats were undertaken in which the

participants wore varying types of footwear in common use within industrial cleanrooms, as follows:

- Commercial cleanroom shoe with smooth sole.
- White overshoe with light textured pattern.
- Blue overshoe with heavy textured pattern.
- Grey shoe with checked patterned sole.
- Shoe with heavy ridged sole.

Using polymeric flooring as the control surface, the highest level of particulate reduction was obtained from the smooth-soled shoe, but a generally high level of particulate control was achieved with all soling types (Table 10).

Using peel-off mats as the control surface, the highest level of particulate reduction was also obtained from the smooth-soled shoe, but at a lower level of particulate control than that which was achieved with polymeric flooring. Other soling types showed extreme variability but a uniformly adverse effect on particulate removal; for the heavy ridged sole, control of particulate by peel-off mats was almost entirely ineffective (Table 11).

The performance of the two systems based on the average particulate reduction for all soling types is compared in Table 12.

Overall, this series of tests clearly supports the view that the type of soling employed on shoes worn by cleanroom

Table 10: Particle reduction using polymeric flooring with various shoe soles, Bath University, 1998

Sole type	Particle reduction (%)		
	2 microns	5 microns	10 microns
Smooth	92.6	93.5	86.1
White overshoe	85.0	87.8	86.6
Blue overshoe	76.8	79.6	76.1
Grey pattern	74.3	82.2	87.2
Ridged sole	83.7	86.4	87.6
Mean	82.5	85.9	84.7

Table 11: Particle reduction using peel-off mats with various shoe soles, Bath University, 1998

Sole type	Particle reduction (%)		
	2 microns	5 microns	10 microns
Smooth	77.1	78.9	57.4
White overshoe	78.4	64.2	32.8
Blue overshoe	37.7	45.1	39.2
Grey pattern	25.4	19.0	11.6
Ridged sole	0.0	5.0	0.0

Table 12: Polymeric flooring vs peel-off mats – average all soling types, Bath University, 1998

Control surface	Particle reduction (%)		
	2 microns	5 microns	10 microns
Peel-off mats	43.7	42.4	28.2
Polymeric flooring	82.5	85.9	84.7

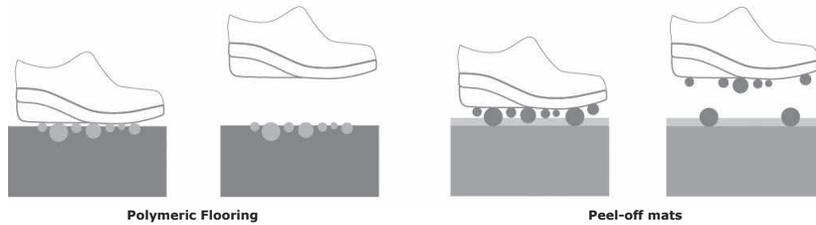


Figure 3. Polymeric flooring is largely effective with all soling types although most effective when smooth-soled shoes are used.

Table 13: Cost/ecobalance study comparing polymeric flooring and peel-off mats. Basis for comparison: US plant with installation of polymeric flooring replacing peel-off mats at 10 locations over two years

Item	Polymeric flooring	Peel-off mats
1. Contamination-control area	2,800ft ²	80ft ²
2. Cost		
Material cost	\$50,000	\$250,000 (approx. 600,000 mats)
Maintenance cost	\$15,000 (clean)	\$125,000 (replace/dispose)
Total cost	\$65,000	\$400,000
3. Materials		
Product	700kg	18,500kg
Packaging	35kg	500kg
Total materials	735kg	19,000kg
4. Energy used in manufacture		
4.1 Per kilo		
Materials	75MJ	88MJ
Conversion	75MJ	100MJ
Total energy per kilo	150MJ	188MJ
4.2 Total energy/2 years	105,000MJ	3,500,000MJ
5. Greenhouse gas emissions (kg CO ₂)		
Manufacture	3,500kg	70,000kg
Disposal (incineration)	1,120kg	55,000kg
Total	4,620kg	125,000kg

Calculation of energy and greenhouse gas emission derives from ecoprofiles 3, 6 and 10 published by the Association of Plastics Manufacturers Europe, Brussels, 1997.

operators can have a significant effect on the efficiency of contamination control achieved at floor level, dependent on the type of control system used (Figure 3).

- Polymeric flooring is largely effective with all soling types, although most effective when smooth-soled shoes are employed.
- Peel-off mats are significantly less effective with all soling types and

performance is highly variable, being most effective with smooth soling and almost entirely ineffective with heavily patterned or ridged soles.

Costs and environmental considerations

The preceding sections review the operational performance of polymeric contamination-control flooring and

peel-off mats in the control of foot-borne particulate contamination. In an operating industrial situation consideration will also be given to operating costs.

Additionally, and not least in an age that is increasingly resource conscious, the environmental impact of the products in use will also be reviewed by responsible cleanroom operators. In the form of the flooring products described, their use avoids the waste of resources associated with the manufacture and disposal of adhesive peel-off mats, since on completion of their service life, the polymeric flooring products may be readily recycled into less critical uses.

While the balance of cost and environmental impact will clearly vary significantly between different industrial applications, broad conclusions can be drawn from the case study of a large US installation in which polymeric flooring at full-floor coverage replaced peel-off mats at 10 control points (Table 13). It is recognised that these data are from a single source, albeit a reputable one. Further research is necessary to confirm the validity of the information.

In summary it is demonstrated that in this large installation:

- Cost savings of as much as \$300,000 can be achieved over a two-year period by the use of polymeric flooring over the full floor area in place of the ten peel-off mats;
- The installed area of the flooring is 35 times greater than that of the ten mats combined, representing a substantially larger barrier of contamination;
- Over the period, the use of the recyclable flooring saves approximately 18 tonnes of raw material;
- Over the period some 3-4 million MJ of energy used in the manufacture of the peel-off mats is saved.
- Assuming that the peel-off mats are subsequently disposed of by incineration, the emission of greenhouse gases (CO₂) in manufacture and disposal is reduced by over 120 tonnes.

A further consideration, with an environmental impact, is the disposal of the discarded peel-off mats if they are not incinerated. Most of these contain acrylic adhesives and polyethylene film. The cost of removal of the acrylic adhesives is substantial, and should

be effected before disposal in landfill of the remainder of the used “peel-off” materials. Contamination peel-off mats from hospitals are required to be “de-contaminated” before being sent to landfill. Currently there is a requirement for a four log₁₀ reduction in microbial contamination before clinical waste can be consigned to landfill. This can lead to the risk of serious infection from waste thus disposed. Polymeric flooring, on the other hand, can be disinfected using antimicrobial disinfectants and therefore poses no health hazard to humans or the environment.

Conclusions

A series of tests and studies has demonstrated that polymeric contamination-control flooring is more effective than peel-off mats at preventing foot- and wheel-borne viable and non-viable particulate contamination from tracking into cleanrooms. In addition very substantial cost savings can be made by replacing peel-off mats with polymeric contamination-control flooring, even taking into account that the polymeric flooring covers a much larger area of the floor which in itself is an advantage. The manufacture and disposal by incineration of peel-off mats consume a large amount of energy giving a

high emission of greenhouse gases. If disposal of peel-off mats is to landfill, then expensive processing is required to remove certain chemicals as well as any microbial contamination.

Acknowledgements

I wish to express my grateful thanks to the late Dr Geoffrey Barrett who researched most of the environmental and ecological data presented in this paper. His knowledge about, and enthusiasm for, the field of contamination control was unsurpassed and his presence is greatly missed.

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Gerry Prout has worked in the pharmaceutical industry for almost 45 years. He has been involved in Manufacturing, QA, QC, R&D, GMP Training and Quality Auditing. He is a founder and Honorary Life Member of the PHSS (formerly The Parenteral Society), a Fellow of the Royal Society of Medicine and a Registered Biomedical Scientist. Gerry has written a considerable number of papers on contamination control and recently was a student at the Royal Agricultural College, studying for an MBA in Wine Business Management. He has been a consultant to over 100 companies on a worldwide basis and now advises several vineyards on viticulture and vinification.

1. Barrett GFC. Polymeric flooring demonstrates particle retention properties. *CleanRooms*, November 1996.
2. Whyte W, Shields T. Cleanroom mats: an investigation of particle removal. *Journal of the Institute of Environmental Sciences* 1996; **39**(4): 19–27.
3. Prout G. A comparative study of two floor-cover materials in control of foot- and wheel-borne contamination. *Eur J Parenter Sci* 1997; **2**(4): 109–111.
4. 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 Parenter Sci* 2002; **7**(1): 13–15.
5. Sandle T. A final floor show for bugs. *Cleanroom Technology*, April 2006.
6. Russell T. How clean is your floor? *Cleanroom Technology*, November 2007.

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