Control of Foot and Wheel-Borne Contamination in Clean Environments =
The Application of Polymeric Flooring Technology
A Presentation to S2C2 Annual Technical Meeting
Birmingham NEC, Wednesday 2nd June 1999
Geoffrey F.C. Barrett, Ph.D., Consultant

ABSTRACT:

Research undertaken over the last three years on the nature and control of contamination at floor level and its transfer through the feet of operators and the wheels of trolleys is reviewed, together with the development of a new contamination control flooring for use in areas of heavy wheeled traffic.

The particulate of greatest significance and most numerous at floor level is less than 10 micron, invisible to the naked eye, and emanates primarily from movement of personnel. In controlled experiments the number of 2micron particles on a shoe sole can be as high as 20,000 and significant contamination in clean areas can result from carryover of foot- and wheel-borne particulate. This is normally controlled by the use of peel-off adhesive mats or by polymeric contamination control flooring, of which two types are considered.

Research undertaken in 1996 and 1997 is reviewed to illustrate the distribution of particle size 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 particulate less than 10 micron.

Further research, undertaken in 1997 and 1998, is reported on studies related to footwear types commonly in use in cleanrooms and their influence on control of particulate. Footwear with smooth soles releases particulate 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 and the efficiency of peel-off mats is influenced adversely by some soling types in use which can render peel-off mats almost totally ineffective.

The polymeric flooring reviewed in this research retains particulate between cleaning operations through a combination of the strong short-range electromagnetic forces associated with very smooth surfaces and the flexible nature of the surface allowing intimate contact with particles over a range of sizes. It is primarily intended for use in gowning areas and entries to classified cleanrooms used primarily by personnel and light wheeled traffic. A new type of polymeric contamination control flooring has now been introduced, however, with a harder wearing surface, intended for use in heavier wheeled traffic areas such as entries to clean packaging areas. Previously unreported research undertaken at the end of 1998 is reported and demonstrates similar performance to the earlier product

The polymer compositions employed in the manufacture of contamination control flooring are of a versatile nature and can be employed in other applications - these are briefly reviewed.

1) THE NATURE OF FOOT AND WHEEL-BORNE PARTICULATE CONTAMINATION

Particles of 10 micron or less with which cleanroom operators are particularly concerned are mainly invisible to the naked eye, are of differing shapes and derive from a wide range of sources.

People are a major source of contamination through body regenerative processes, behaviour and work attitudes and personal activity rapidly accelerates the rate of generation of particles as illustrated by the following data:

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

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

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 control of viable or biologically active particulate is of similar critical importance in preventing active contamination entering the cleanroom or causing cross-contamination between working areas

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 a variety of techniques are employed. 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 and research has demonstrated that over 20,000 particles per $25cm^2$ of 2 micron particles 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 and at the point of entry from the gowning area to the cleanroom itself controlled procedures to eliminate or reduce carry over of foot-borne particulate should be unavoidable within normal movement of personnel and wheeled traffic.

In normal industrial practice, control of foot-borne contamination is attempted by the use of adhesive peel-off disposable mats or by the use of polymeric contamination control flooring. Two main generic types of this product are now available:

- Type 1, established worldwide for a number of years, intended for use in gowning areas and entries to classified cleanrooms used predominantly by personnel and light wheeled traffic
- Type 2, newly introduced at the end of 1998 of a harder wearing nature intended for areas subject to heavier wheeled traffic such as packaging areas

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 management 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 readily fulfilled by the use of the polymeric flooring reviewed when used as full floor coverage in the gowning area, prior to air-showers and air-locks and at the entrance to the clean-room area itself. In many cleanroom situations also the flooring may also be employed between areas as an additional aid to the control of small particulate or cross-contamination from viable particulate.

Dependent on the type of installation and number of operators, installations of up to 100 square metres are now being regularly specified for gowning areas and provide a 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; additionally, major cost savings can be achieved over the service life of the flooring.

Additionally, and not least in an age which is increasingly resource conscious, the products are economical and eco-friendly. 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. On completion of their service life, the polymeric flooring products may be readily recycled into less critical uses.

2. THE 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 Magazine (ref.1).

The mechanism of particulate control by polymeric flooring was shown to be attributable to the short-range electromagnetic forces acting over the optically flat, flexible surface of the product and their ability to retain particulate over a wide range of particle sizes.

Earlier laboratory research (ref.2) 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.

A research programme was undertaken in 1996 under practical operating conditions in a Class 10,000 cleanroom suite in the Centre for Drug Formulation Studies at the University of Bath, England. This has also been reported, with full details of the experimental procedures employed, in the European Journal for Parenteral Sciences (ref.3).

In summary, this investigation demonstrated that:

- Polymeric flooring shows a significantly higher removal of particulate over all particle sizes than adhesive peel-off mats - especially with small particulate, as illustrated in Table 1 below:

Table 1
Bath University 1996
Foot-Borne Particulate Collection
As a Function of Particle Size.
Comparison of Polymeric Flooring (Type 1) with Peel-off Mats
% Particles Removed

Particle Size (micron)	Polymeric flooring (1)	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

- 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, as illustrated in Table 2 below.

Table 2
Bath University 1996
Foot and Wheel-Borne Viable Particulate Control

Viable Counts	Viable Counts After		% Reduction	
Before	Polymeric Flooring (1)	Peel-off mats	Polymeric Flooring (1)	Peel-off mats
Foot-borne >1000	567	967	43%	3%
Wheel-borne >1000	17	764	98%	23%

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 that 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:

The first set of research data was obtained at Bath University, using the same test protocols as for the research undertaken in 1996. The primary objectives of the research were two-fold:

- Since polymeric flooring compositions are intended for continuous use as a contamination control medium for a service life of two to three years, it was considered necessary to assess the efficiency of particulate collection on flooring which had been under particularly arduous use for over a year.
- As a further objective, additional studies on the efficiency of collection of small particles were felt to be of value, particularly in respect of 'carry-over' of particulate .

After a year of arduous use, the performance of the polymeric flooring was shown to be superior to that of new peel-off mats for all particle sizes and particularly so for the smaller sizes.

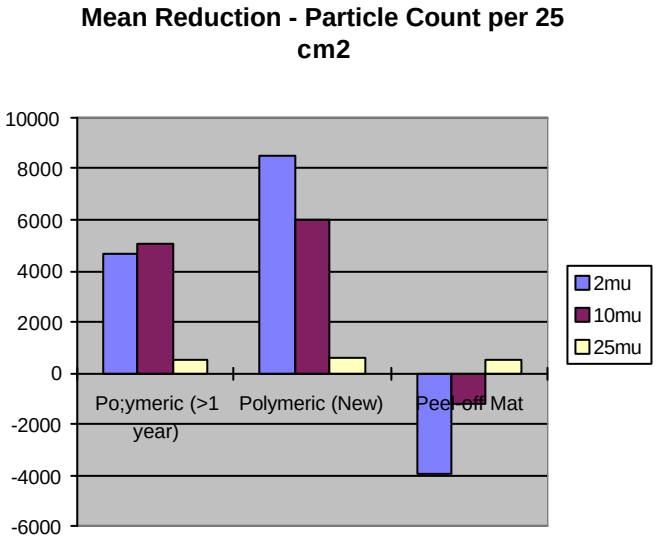
The use of average figures in previous tables and charts, however, tends to disguise the imp act of the very large number of particles involved at the 2 micron level. When the total number of particulate collected after the completion of the test by all the operators is compared, it can be concluded that very significant reductions in total count of 2 micron particulates can be achieved by the polymeric flooring compositions both when new and after a year of continuous service.

By contrast, the total count of small particles after passing over the peel-off mats is actually 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.
Actual results supporting this finding are shown in the table and chart following:

Table 3
Bath University 1997
Total Reduction in Particle Count

Particle Size	Polymeric (1) (>1 year)	Polymeric (1) (New)	Peel-off Mat
2mu	4708	8504	-3967
10mu	5051	5948	-1208
25mu	543	639	552

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 with a higher number of total particles counted after the peel-off mat than before due, as suggested, to transfer of particulate from the mat to the feet of participants in the trial. This is also clear from the chart below:



A further series of tests were undertaken in the demonstration cleanroom suite operated by Clestra in Strasbourg, France, comprising Class 10,000, Class 1,000 and Class 100 areas. In these tests, undertaken in April 1997, using this facility, similar analytical procedures were employed to those used earlier at Bath University.

Above 25 micron 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 to 95%.

For particulate of 10 micron and below the results are radically different and are broadly in line with those of previous work as shown in Table 4 below:

Table 4
Clestra, Strasbourg 1997
Reduction in Particle Count (%)

Control Medium	Particle Size		
	2mu	5mu	10mu
Polymeric flooring (1)	**71.1**	**64,9**	**68.4**
Peel-off mat	**15.2**	**43.1**	**38.1**

In examining these figures it should also be borne in mind that the mean figures quoted are based only on the number of observations in which 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 5 following.

Table 5
Clestra, Strasbourg 1997
Observations showing increase in Particle Count (%)

Control Medium	Particle Size		
	2mu	5mu	10mu
Polymeric flooring (1)	**nil**	**nil**	**10**
Peel-off mat	**15**	**45**	**35**

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 % reduction in particulate on the remaining 40 observations.

It can be inferred that, as a means of control of particulate less that 10 micron in cleanrooms, the use of adhesive peel-off mats provides little significant benefit. In view of the widespread use of peel-off mats for this purpose users will, no doubt, seek to verify this conclusion for themselves.

Notwithstanding this, the performance of polymeric flooring within this range of particulate has been shown to be consistently effective; as in previous trials the control of biologically viable particulate was also evaluated and the flooring found to be totally effective - the detailed results, however, have been omitted from this paper.

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.

3) OPERATIONAL VARIABLES IN CONTAMINATION CONTROL AT FLOOR LEVEL

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 200 and 300 square feet will replace a peel-off mat of some 8 square feet, such that the control area of the flooring is over 25 times greater than that of the peel-off mat.
- **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 accomodated 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 important variables include Shoe Soling and Traffic Volume:**

Shoe Soling:

The research described, 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:

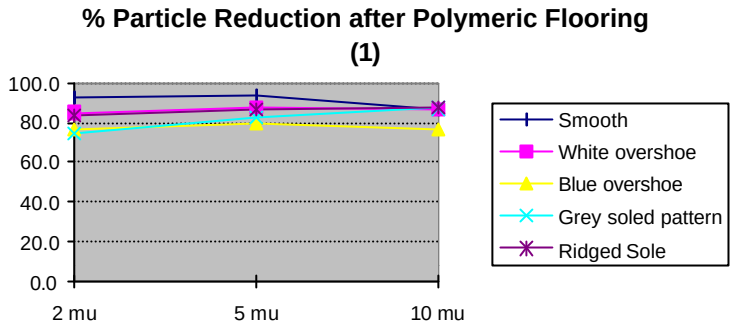
Using the well established procedures developed for use in the cleanroom suite at Bath University, particle counts before and after polymeric flooring and peel-off mats were undertaken in which the participants wore varying types of footwear in common use within industrial cleanrooms as follows:

- 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. Results are shown in the following table and chart.

Table 6 Bath University 1998
Polymeric flooring (1) with varied shoe soles

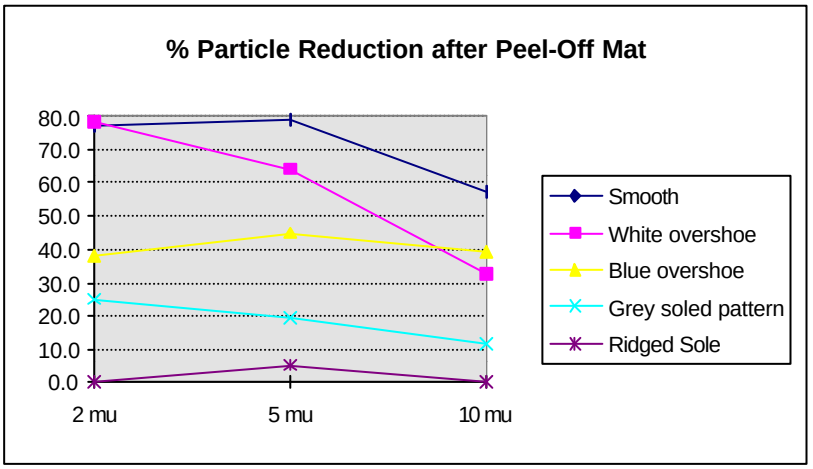
Sole type	**% Particle Reduction**		
	2 mu	**5 mu**	**10 mu**
Smooth	92.6	93.5	86.1
White overshoe	85.0	87.8	86.6
Blue overshoe	76.8	79.6	76.1
Grey pattern	74.3	82.2	87.2
Ridged Sole	83.7	86.4	87.6
Mean	82.5	85.9	84.7



Using peel-off mats as the control surface, the highest level of particulate reduction was also obtained from the smooth soled shoe. A lower level of particulate control was achieved, however, than that with polymeric flooring. Other soling types showed extreme variability but a uniformly adverse affect on particulate removal; for the heavy ridged sole, control of particulate by peel-off mats was almost entirely ineffective. Results are illustrated in the following Table 7 and associated chart.

Table 7 Bath University 1998
Peel-off Mats with varied shoe soles

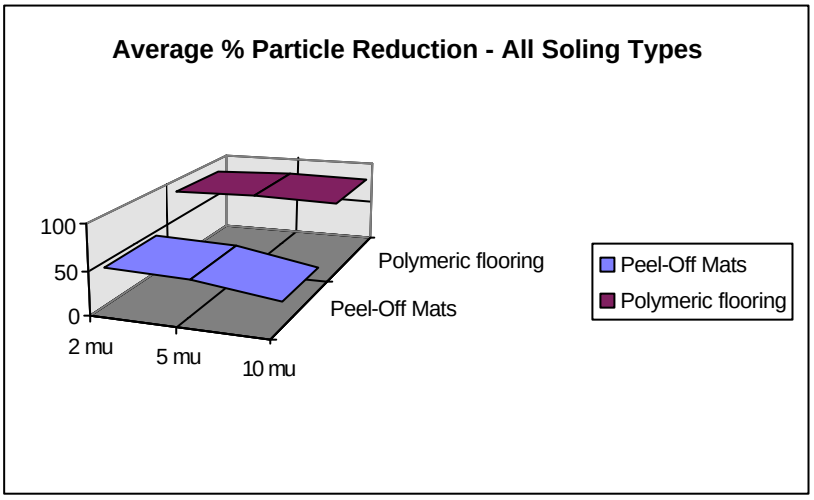
Sole type	**% Particle Reduction**		
	2 mu	**5 mu**	**10 mu**
Smooth	77.1	78.9	57.4
White overshoe	78.4	64.2	32.8
Blue overshoe	37.7	45.1	39.2
Grey pattern	25.4	19.0	11.6
Ridged Sole	0.0	5.0	0.0



A comparison of performance of the two systems based on the average particulate reduction for all soling types is given in the table and chart below, which are largely self explanatory.

Table 8 Bath University 1998
Polymeric flooring (1) vs Peel Off Mats - Average all Soling Types

Control Surface	% Particle Reduction		
	2 mu	5mu	10 mu
Peel-Off Mats	43.7	42.4	28.2
Polymeric flooring	82.5	85.9	84.7



Overall, this series of tests clearly supports the view that the type of soling employed on shoes worn by cleanroom operators can have a significant effect on the efficiency of contamination control achieved at floor level, dependent on the type of control system used.

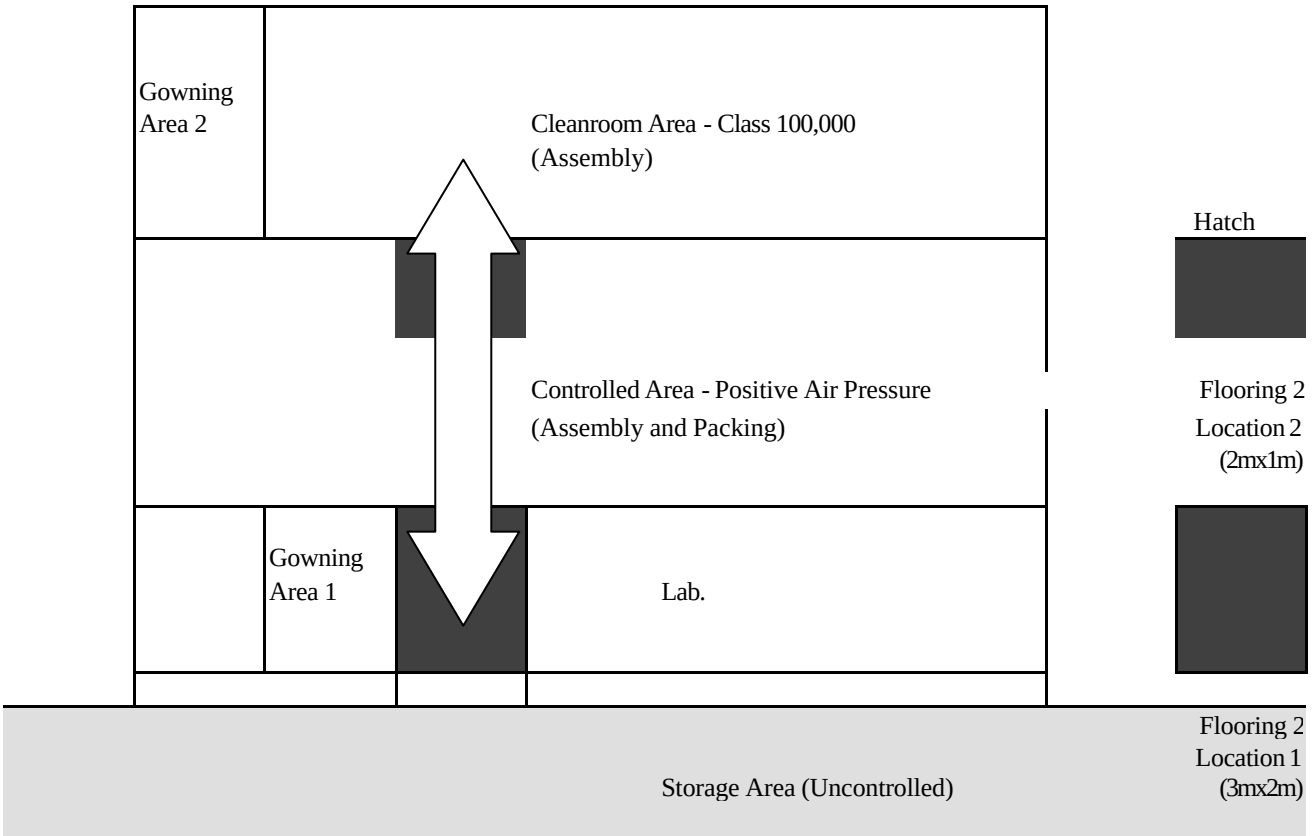
- Polymeric flooring is largely effective with all soling types although most effective when smooth soled shoes are employed.
- Peel-off mats are significantly less effective with all soling types and performance is highly variable - most effective with smooth soling and almost entirely ineffective with heavily patterned or ridged soles.

Traffic Volume

The research described in the preceding paragraphs was undertaken using the polymeric flooring designated as Type 1, intended for use in areas associated with classified cleanrooms subject primarily to personnel and light wheeled traffic. In many manufacturing facilities, however, clean areas used for packaging and assembly operations are subject to a higher volume of heavier wheeled traffic including fork-lift trucks. In response to the need for control at floor level in such areas, a harder wearing product, designated here as polymeric flooring Type 2, was developed in 1998.

A research programme on this product was undertaken during November, 1998 in the premises of a UK medical device manufacturer, the relevant areas of which are as shown in the schematic plan following.

Schematic Layout of Test



Components for assembly and packaging, together with packaging materials are drawn from the uncontrolled storage area and loaded on trolleys which pass initially into an area of controlled positive air pressure, where some assembly and all packaging operations are carried out. The majority of assembly operations are carried out in the Class 100,000 cleanroom area, where goods are accessed by means of the trolleys passing through a hatch, as shown in the diagram.

In previous practice, peel-off adhesive mats were placed in the gowning areas at the entrances to the controlled areas but no control was exercised on contamination arising from the movement of trolleys. For the purpose of the trials, polymeric flooring type 2 was installed at the entrance to the controlled area and at the entrance to the hatch leading into the cleanroom as shown in the diagram.

Test Methods.

Swabs were taken from each of the four nylon wheels on loaded and unloaded trolleys, at each of the following locations:

- At the point of entry from the storage area, before passing over location 1.
- In the controlled area after passing over location 1.
- In the cleanroom area after passing through the hatch and over location 2.

Measurement of non-viable particle counts over a range of particle sizes was then undertaken using a liquid particle counter and viable particulates measured from agar cultures. Full details of the test procedures employed are available on request.

Detailed Results – Trolley Wheels – non-viable Particulate

These are presented below in Table 9 and demonstrate a relatively even level of particulate reduction of 45 to 55 % across the range of particle sizes for each of two passes across the polymeric flooring type 2.:

Pass 1: from uncontrolled area to controlled area
Pass 2: from controlled area to cleanroom

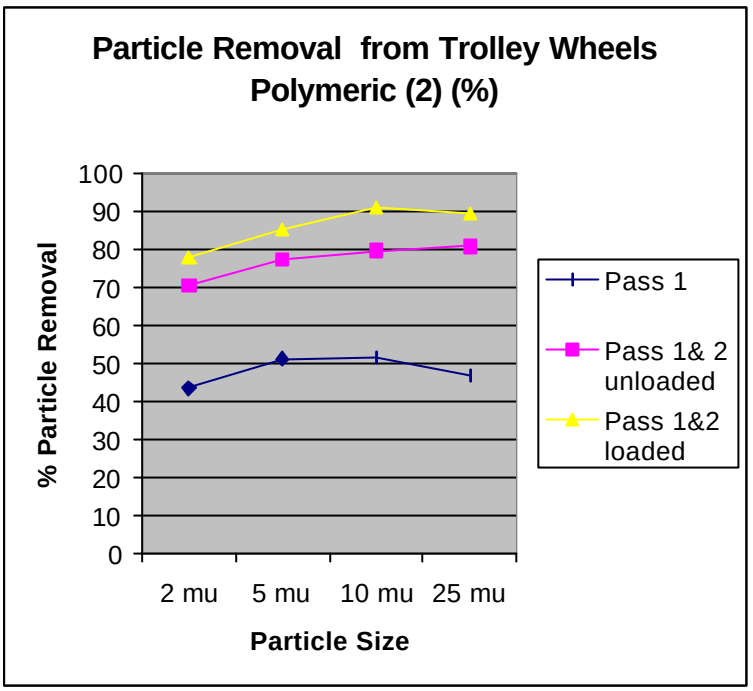
Table 9

% Particle Removal from Trolley Wheels

Particle Size	**2 mu**	**5 mu**	**10mu**	**25mu**
Pass 1	43.6	51.4	51.7	46.8
Pass 1& 2 unloaded	70.5	77.4	79.8	81.0
Pass 1&2 loaded	**78.2**	**85.6**	**91.1**	**89.6**

Cumulatively for the two passes a reduction of particulate between 70 and 80% is achieved on 2 mu particles and 80 to 90% on 25 mu particles dependent on the loading of the trolley. (A similar result would have been achieved in one pass if the length of flooring for the first pass had been extended from 3 metres to 5 metres).

Data is also presented in absolute terms of particle removal in Table 10 following. Particularly noteworthy is the large number of 2 mu particles removed.

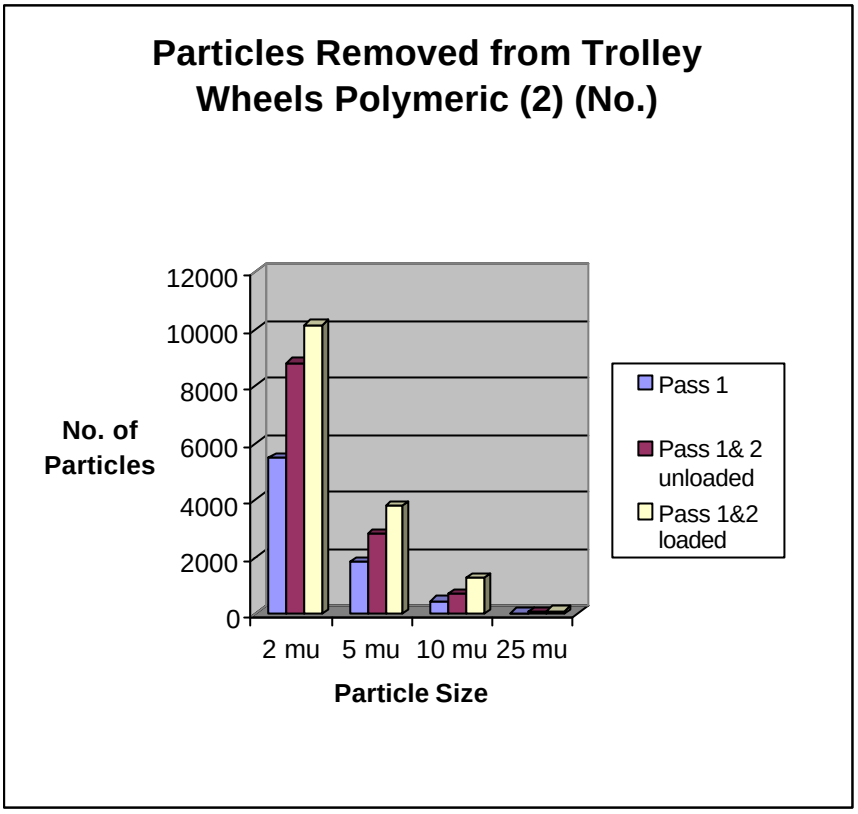


Particle counts are based on number per 10 cm2 of area of wheel (about half the complete wheel area). For this area, a removal of 8 to 10,000 particles per wheel on the double pass described is obtained. This approximates to 30 to 40,000 particles per trolley, per 10 cm2 of wheel area. Allowing for the actual wheel area, therefore, the number of particles removed will be approximately twice this figure at 60 to 80,000.

Table 10

Particles Removed from Trolley Wheels

Particle Size	**2 mu**	**5 mu**	**10mu**	**25mu**
Pass 1	5462	1866	468	41
Pass 1& 2 unloaded	8832	2810	723	72
Pass 1&2 loaded	**10162**	**3776**	**1279**	**115**



Detailed Results – Trolley Wheels – Viable Particulate

Results for control of viable particulate show a similar progressive pattern of particulate removal, although a higher percentage reduction of between 65 and 85% of viable particulate is removed on the second pass and the results are significantly better with the loaded trolley.

The results are tabulated in Table 11 below.

Table 11

% Viable Particulate Removed

	Pass 1	**Pass 2**	**Pass 1+2**
Unloaded	**47.7**	**68.0**	**83.3**
Loaded	**51.6**	**83.6**	**92.0**

In combination, the results confirm that in wheeled traffic areas where control of both viable and non-viable particulate is critical, the installation of polymeric flooring type 2 to provide control areas of 3 to 5 metres in length can reduce wheel-borne contamination by 80 to 90%. This coupled with the durable and easy care nature of the product presents the pharmaceutical and medical device manufacturing industries with a new weapon in the ongoing battle to reduce the risk of contamination.

5) FORWARD OUTLOOK:

Further research is planned on the properties and performance of the polymeric contamination control flooring reviewed and will be regularly presented in future.

The polymer compositions used in the manufacture of the flooring, however, offer a versatile technology which can be used in the manufacture of other products such as rollers, mouldings and coated film or sheet A number of these applications are in use in cleanrooms or being evaluated for similar contamination control purposes. Further information can be supplied, together with full details of installation and cleaning procedures for polymeric flooring which have not been covered in the course of this paper

References:

1) Barrett, G.F.C.: "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, July/August 1996.
3) Prout, G.; "A comparative study of two floor cover materials in control of foot- and wheel-borne contamination"; European Journal of Parenteral Sciences, Vol. 2 1997.