Comparison of the removal of macroparticles and MCPs in cleanrooms by surface deposition and mechanical ventilation

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Abstract

The removal of macroparticles (particles ≥5µm) and microbe-carrying particles (MCPs) from cleanroom air occurs by surface deposition or ventilation. In an operational ISO Class 8 cleanroom, small particles ≥0.3µm and ≥0.5µm are mostly removed by air (>99%). The size where half the particles are removed by deposition and half by mechanical ventilation is about ≥10µm, and 90% of particles are removed by deposition when the particle size is ≥40µm. Results were calculated for other ISO cleanroom classifications, and for particles ≥5µm the percentage deposited onto surfaces varied from about 11% to 37%. The percentage of MCPs removed by surface deposition in Grade B, C and D cleanrooms that are graded according to the EU Guidelines to Good Manufacturing Practice (2005), varied from 8% to 26%.

Introduction

Cleanrooms are used to manufacture products that are sensitive to particle and MCP contamination. To minimise contamination, cleanrooms are ventilated with a copious supply of particle-free air that dilutes and removes airborne contaminants and, therefore, minimises deposition of contamination onto vulnerable surfaces. However, it is not possible for all airborne contaminants to be removed by ventilation, and surface deposition occurs.

The mechanisms that cause deposition of airborne particles onto cleanroom surfaces have been investigated and reported[1]. A variety of mechanisms are involved, but for macroparticles (particles ≥5µm), the most important mechanism is gravitational deposition, with over 80% of particles ≥10µm being shown to deposit by that mechanism.[1] Use of this information and a survey of the scientific literature shows that gravitational settling is the main mechanism down to about 5µm, and an important one down to about 0.5µm.

The source of airborne MCPs in cleanrooms is almost exclusively from personnel, and microbes in the air are normally carried on skin and clothing detritus, with an average equivalent aerodynamic diameter of 12 µm.[2, 3] Because of their size, gravitational deposition is the main mechanism of surface deposition from air of MCPs.

In a sealed room with no ventilation, the removal of particles and MCPs from air must be entirely by surface deposition, and in a room built like a high-speed wind tunnel, most airborne contamination will be removed by air. In intermediate ventilation situations found in cleanrooms, some particles and MCPs will be removed by deposition and some by ventilation. However, information on the comparative importance of these two mechanisms is lacking, and is investigated and discussed in this article for particles greater than 5µm, as well as MCPs, with some addition information about particles less than 5µm.

Equivalent diameter of airborne particles

Naturally-occurring particles found in cleanroom air exist in a variety of sizes, shapes, and specific gravities, and these properties affect their deposition velocity through the air. When airborne particles are counted by an airborne particle counter, the actual size, shape and density of particles are not measured, but the amount of light scattered. This scattered light is used to determine the equivalent diameter of a polystyrene latex sphere that scatters the same amount of light as the particle being measured.

In other situations, airborne particles are measured in terms of the equivalent aerodynamic particle diameter, which is the diameter of a sphere with a specific gravity of 1000kg/m^3 that has the same aerodynamic properties i.e. gravitation settling and impaction, as the particle being considered. If the particle concentration and deposition rate of a given size of particle is measured in a cleanroom, the deposition velocity can be obtained. This method has been previously described[4] and used to obtain the deposition velocities of a range of cumulative sizes of particles considered in this article. Knowing the deposition velocity, the equivalent aerodynamic diameter can be calculated by the Stokes settling equation (Equation 1). The equivalent aerodynamic diameter can also be measured by instruments such as a cascade sampler, or time-of-flight sampler, these instruments being described by Hinds.[5]

The main source of particles and MCPs in a typical cleanroom is personnel, who disperse these from their skin and garments. The specific gravity of skin particles has been reported by Leider and Buncke[6] as 1100kg/m^3, and polyester, which is normally used in the construction of cleanroom garments, has a specific gravity of 1380kg/m^3; it is therefore reasonable to assume an average specific gravity of 1200kg/m^3 for airborne particles in cleanrooms.

Calculation of deposition velocity of discrete sizes of airborne particles by the Stokes settling equation

The deposition velocity of an equivalent aerodynamic diameter of a discrete size of particle that settles through air under the influence of gravity can be calculated. A comprehensive treatment of this subject is given in Hinds' book[5], where the calculations are based on the Stokes equation, which is as follows.

Equation 1

$$v_D = \frac{\rho_p.g.d^2.C_C}{18\eta}$$

Where:
v_D = the deposition velocity (m/s),
ρ_p = specific gravity of particle (kg/m^3),
g = acceleration due to gravity (9.81 m/s^2),
d = equivalent aerodynamic particle diameter (m),
C_C = Cunningham slip factor,
η = viscosity of air (1.18 x 10^{-5} kg/m.s).

Included in Equation 1 is the Cunningham slip factor, which should be used with particles that have a diameter less than about 1.5 µm, as the deposition velocity is affected by 'slip' at the surface of the particle. The Cunningham slip factor is calculated as follows:

$$C_C = 1 + \frac{2.52\lambda}{d}$$

where, λ = mean free path of 0.066 µm at 20°C and 1 atmosphere, and the units of d are given in micrometres.

When particles are larger than about 75µm, Equation 1 will overestimate the deposition velocity, and Equation 2 should be used.

Equation 2

$$v_D = \left(\frac{\eta}{\rho_a d_p}\right) \exp(-3.070 + 0.9935.J - 0.0178.J^2)$$

Where:
ρ_a = the density of air at 20ºC (1.2 kg/m^3),
J is calculated as follows:

$$J = \ln\left(\frac{4.\rho_p.\rho_a.d^3.g}{3\eta^2}\right)$$

The deposition velocities of a range of discrete sizes of particles can be calculated by the equations given above, and are given in the second column of Table 1.

Deposition velocity of cumulative sizes of particles

Concentrations of particles in air and surfaces are normally measured in cleanrooms cumulatively, to include all particles larger than the stated size. The deposition velocities of a range of cumulative sizes of particles have been determined by both experiment and theory in an ISO Class 8 cleanroom[4] and the results are given in Table 1.

Calculation of the removal of particles by deposition using the equivalent virtual air change rate method

A method that can be used to measure the removal of airborne particles by surface deposition uses the 'equivalent virtual air change rate'.[7] This gives the air change rate that produces the same reduction of airborne particle concentration as obtained by surface deposition. Using this approach, the removal of particles by surface deposition can be directly compared to the removal by mechanical ventilation.

It has been shown[7] that the equivalent virtual air change rate can be calculated by the following Equation 3.

Equation 3

$$N_E = \frac{v_D}{H}$$

Where:
N_E = the equivalent virtual air change rate,
H = the height of the room.

If the equivalent virtual air change rate is calculated by Equation 3, and the overall air change rate in the cleanroom is known, then the removal of particles by surface deposition can be calculated by Equation 4 as a percentage of the total number of particles removed by both deposition and ventilation.

Equation 4

$$\text{Surface deposition of total airborne contamination (\%)} = \frac{N_E}{N_E + N_V}.100$$

Where:
N_V = overall air change rate in a cleanroom.

Calculation of the removal of particles by deposition using time of decay

An alternative approach to calculating the percentage of particles removed by surface deposition is to calculate the time it takes for a given proportion of airborne particles to decay by surface deposition. This time can then be compared to the time it takes for the same proportion of particles to decay by mechanical ventilation.

Time of decay of airborne particles by surface deposition

In a cleanroom, the rate of change of the concentration of macroparticles over a short time interval by means of surface deposition is given by the following differential equation:

$$\frac{dC}{C} = \frac{v_D.dt}{H}$$

Where:
C = particle concentration,
v_D = deposition velocity of particles,
t= time,
H = height of room.

Table 1: Deposition velocities of particles

Equivalent aerodynamic particle diameter (µm)	Deposition velocity (cm/s) of particles with discrete diameters	Deposition velocity (cm/s) of particles with cumulative diameters
0.3	0.0005	0.003
0.5	0.0012	0.006
5	0.09	0.29
10	0.36	0.91
25	2.3	4.2
40	5.8	9.1
50	9.0	13
100	29	41

This equation can be integrated to give the following equations:

$$\frac{C}{C_0} = \exp\left(\frac{-v_D.t}{H}\right) \quad \text{or}$$

$$\frac{C_0}{C} = \exp\left(\frac{v_D.t}{H}\right)$$

Where:
C_0 = concentration at time zero,
C = concentration after time t.

By taking natural logs and rearranging the equation

$$t = \frac{H.\ln(\frac{C_0}{C})}{v_D}$$

Changing from natural to base 10 logs

$$t = \frac{2.3.H.\log_{10}(\frac{C_0}{C})}{v_D}$$

When 90% of the particles have deposited, C_0/C is equal to 10, and Equation 5 is obtained, and from this equation the resulting time of deposition (t_D) can be calculated.

Equation 5

$$t_D = \frac{2.3.H}{V_D}$$

Removal of airborne particles by mechanical ventilation

The removal of particles in a non-UDAF cleanroom by mechanical ventilation conforms to an exponential decay, and the decrease in concentration over time is calculated by the following equation.[7]

$$C = C_0.e^{-N_V.t}$$

Where:
C = concentration at time t,
C_0 = concentration at time zero,
N_V = number of air changes in cleanroom, owing to mechanical ventilation,
t = time.

Rearranging the equation, and taking natural log of both sides,

$$\ln\left(\frac{C}{C_0}\right) = -N_V.t \quad \text{or}$$

$$\ln\left(\frac{C_0}{C}\right) = N_V.t$$

Rearranging,

$$t = \frac{\ln(\frac{C_0}{C})}{N_V}$$

Changing from natural logs to base 10 logs,

$$t = \frac{2.3.\log_{10}(\frac{C_0}{C})}{N_V}$$

When 90% of the particles have been removed by ventilation, C_0/C is equal to 10, and Equation 6 is obtained, and from this equation the resulting time of removal by ventilation (t_V) can be calculated.

Equation 6

$$t_V = \frac{2.3}{N_V}$$

If the removal of 90% of particles by deposition is calculated by Equation 5, and the removal of 90% of particles by ventilation is calculated by Equation 6, the removal by surface deposition can be calculated by Equation 7 as a percentage of the total number of particles removed from the cleanroom air.

Equation 7

Percentage of particles removed by surface deposition

$$= \frac{t_D}{(t_V + t_D)}.100$$

Calculation of the removal of airborne particles by deposition using the equivalent virtual air change method

To calculate the equivalent virtual air change rate for different cumulative diameters of particles, the deposition velocity of particles settling through air is required. Table 1 gives the deposition velocities (cm/s) of a range of cumulative particles sizes that were previously obtained by experiments carried out in an ISO Class 8 operational cleanroom.[4] The cleanroom had a height of 2.7m, and an air change rate of about 13 per hour (0.0036/s). Using this information, the equivalent virtual air change rates for a range of cumulative sizes of particles are calculated, and the removal of airborne particles by deposition as a percentage of the total of particles removed are ascertained. The results are given in Table 2.

It can be seen in Table 2 that less than 1% of small particles of ≥0.3µm and ≥0.5µm are removed by surface deposition. However, approximately 50% of the particles ≥10µm are removed by surface deposition, and 90% are removed when the size is ≥40µm.

Table 2: Percentage of particles deposited in a cleanroom

Cumulative particle size (µm)	Deposition velocity (m/s) of cumulative particle size	Equivalent virtual air change rate/hour owing to surface deposition	Percentage of particles deposited in cleanroom with 13 air changes/hour
0.3	0.000028	0.04	0.3
0.5	0.000064	0.09	0.65
5	0.0029	4	23
10	0.0091	12	48
25	0.042	56	81
40	0.091	121	90
50	0.13	173	93
100	0.41	547	98

Table 3: Percentage of different sizes of particles deposited in a cleanroom

Cumulative particle size (µm)	Number of seconds to decay to 90% of airborne concentration owing t o surface deposition	Number of seconds to decay to 90% of airborne concentration owing to mechanical ventilation	Percentage of particles deposited in cleanroom
0.3	222075	638	0.29
0.5	97158	638	0.65
5	2144	638	23
10	683	638	48
25	148	638	81
40	68	638	90
50	48	638	93
100	15	638	98

Calculation of the removal of airborne particles by deposition using the decay method

To calculate the percentage of airborne particles deposited by the time of decay method, deposition velocities (m/s) are required. These are given in Table 1 for an ISO Class 8 cleanroom in operation, which has a height of 2.7m and 13 air changes per hour (0.0036/s). The number of seconds for the airborne particles to decay to 90% of their concentration by surface deposition was calculated by means of Equation 5, and the number of seconds to decay to 90% of their airborne concentration by mechanical ventilation was calculated by Equation 6; both sets of results are given in Table 3. The percentage of deposited particles of the total removed by both surface deposition and ventilation was then calculated by means of Equation 7, and the results given in Table 3. It can be seen that these percentages are identical to those reported in the previous section, where the results were calculated by the equivalent air change method.

Surface deposition of particles ≥5µm with respect to airborne cleanliness

The results calculated in the previous two sections are based on deposition velocities that were obtained from experiments carried out in an ISO Class 8 cleanroom.[4] In cleaner cleanrooms with a greater air change rate, a higher percentage of particles may be removed by ventilation. However, it is also known that higher air supply rates are associated with higher deposition velocities of particles,[4, 8] which may partly balance their greater removal by ventilation. This possibility was investigated.

The rate that particles deposit onto cleanroom surfaces is determined by the particle deposition rate (PDR), which is the rate of deposition of particles onto a standard surface area e.g. 1 m^2, in a standard time e.g. 1 hour. The PDR is measured by exposing a witness plate, or collection surface of an instrument, and the number of particles of a specified size that deposit onto the collection surface in a given time is obtained, and then the PDR. In cleanrooms, it is the cumulative number of particles of different sizes that are usually measured.

It has been reported by Hamburg[8] that the PDR of particles ≥5µm onto cleanroom surfaces varies, with a higher deposition rate in cleaner rooms. Cleanrooms that ranged in airborne cleanliness from ISO Class 5 to ISO Class 9 were studied, and the following relationship (modified to SI units) reported. A similar relationship has also been reported by Parasuraman et al.[9] The relationship reported by Hamburg, when converted to metric units, is as follows.

$$PDR \geq 5\mu m = 0.0226.C_{\geq 5\mu m}{}^{0.773}$$

Where:
$PDR_{\geq 5\mu m}$ = deposition rate of particles ≥5µm/m^2/s,
$C_{\geq 5\mu m}$ = airborne concentration per m^3 of particles ≥5µm

However, it is known[4] that

Equation 8

$$PDR = C_D.v_D$$

Where:
C_D = airborne concentration per m^3 of particles of cumulative size of D µm, and
v_D = deposition velocity (m/s) of particle diameter, D.

Therefore,

Equation 9

$$v_{\geq 5\mu m} = \frac{0.0226.C_{\geq 5\mu m}{}^{0.773}}{C_{\geq 5\mu m}} = 0.0226.C_{\geq 5\mu m}{}^{-0.227}$$

ISO 14644-1[10] cleanrooms of Class 5, and cleaner, have low concentrations of particles ≥5µm and, therefore, these particles are not used to specify class limits. Also, the low particle concentrations in ISO Class 5 and cleaner cleanrooms are unlikely to be achieved by non-unidirectional airflow systems, but by means of the more effective unidirectional airflow system. However, the calculation of the percentage deposition in this article uses air change rates and, therefore, calculations of the percentage of surface deposition can only be carried out in ISO classes 6 to 9.

The deposition velocities of particles ≥5µm in ISO Classes 6 to 9 in the operational state are calculated by Equation 9 and given in Table 4. Also given in Table 4 is the PDR limit for this range of cleanrooms, as calculated by Equation 8. Using a ceiling height of 2.7m, the equivalent virtual air change rate owing to deposition is calculated by use of Equation 3, and the results given in Table 4.

Table 4: Percentage of particles ≥5µm removed by deposition in a range of ISO cleanroom classes

ISO Class	6	7	8	9
Class limit (no./m^3) for particles ≥5µm	293	2930	29300	293000
Deposition velocity (m/s)	0.00623	0.00369	0.00219	0.00130
PDR limit of particles ≥5µm per m^2 per hour	6566	38931	230834	1368673
Equivalent virtual air change rate/hour owing to surface deposition	8.3	4.9	2.9	1.7
Typical air changes/ hour	30 to 70	20 to 40	5 to 15	5
Particles removed by surface deposition (%)	22 to 11	20 to 11	37 to 16	26

To calculate the proportion of airborne particles removed by surface deposition as a percentage of the total removed by both deposition and ventilation, it is necessary to know the air change rates needed to achieve the ISO class of cleanroom being studied. Unfortunately, it is not possible to use an exact air change rate. There are two main reasons for this. Firstly, the air cleanliness of a cleanroom is determined by the air supply rate and not by the air change rate,[7] and for the same ISO class limit of particle concentration, the smaller the cleanroom, the greater the air change rate required. Secondly, the airborne cleanliness of a cleanroom is directly related to contamination dispersed into the air by personnel and other sources of contamination. This will vary between cleanrooms and, therefore, so will the air change rate required for a given ISO Class of cleanroom. Taking these reasons into consideration, a range of air change rates for each ISO class are given in Table 4 that the authors considered to be typical of those found in cleanrooms. Using these air change rates, the percentage of particles ≥5µm removed by surface deposition can be calculated by use of Equation 7, and the results are given in Table 4.

Percentage of MCPs removed by deposition

Shown in Table 5 is the airborne concentration of MCPs given in the EU Guidelines to Good Manufacturing Practice (EU GGMP): 2008[11] for Grade B, C and D cleanrooms. Grade A clean zones are not included in the table as these normally use unidirectional airflow and, therefore, cannot be analysed by the method used in this article. Also shown in Table 5 are the ISO 14644-1 classes that correspond to the EU GGMP grades in the operational state.

Micro-organisms are not usually found in cleanroom air as unicellular organisms, as they are dispersed by personnel on skin and clothing detritus, and known as microbe-carrying particles (MCPs), with an average equivalent aerodynamic diameter of about 12 µm.[2, 3]

It has been reported[12] that the deposition velocities of airborne MCPs increase with airborne cleanliness in a similar manner to particles, as discussed in the previous section. The deposition velocity of MCPs can be calculated by the following equation given in the referenced article.[12]

Equation 10

$$v_{D:MCPs} = 0.0161.C^{0.6571}$$

Where:
$v_{D:MCPs}$ = deposition velocity of MCPs (m/s),
C = concentration of airborne MCPs /m^3.

Shown in Table 5 are the average deposition velocities calculated by Equation 10 using the concentrations of MCPs expected in Grade B, C and D cleanrooms. Also shown in Table 5 are the equivalent virtual air change rates caused by surface deposition as calculated by Equation 3, when the ceiling height is 2.7 m. To obtain the surface deposition as a percentage of the total amount removed by both deposition and ventilation, the air change rate is required for the three grades of cleanrooms, and a range of air changes that are typical of pharmaceutical cleanrooms are given in Table 5. It can be seen that the air change rate is higher than given in Table 4 for similar ISO classes, this being partly owing to the greater need for a higher air supply to achieve the required concentration of MCPs.[13] Finally, in the last column of Table 5 is the percentage of airborne MCPs removed by surface deposition as a percentage of the total removal by both deposition and ventilation. It can be seen that in a typical EU GGMP Grade B cleanroom, surface deposition of MCPs will remove about 9% to 24% of the airborne MCPs. In a Grade C cleanroom it will be 8% to 18%, and in a Grade D it will be 10% to 26%.

Discussion and conclusions

Particles and microbe-carrying particles (MCPs) in cleanroom air are removed by means of mechanical ventilation or by surface deposition, and this article provides information about the relative importance of these two removal mechanisms. The importance of surface deposition is expressed as the percentage of particles deposited of the total number of particles removed by both deposition and ventilation.

The percentages of a cumulative range of particles sizes removed by surface deposition were calculated from the deposition velocity of a cumulative range of particle sizes obtained in an operational ISO Class 8 cleanroom.[4] The calculation of percentage deposition was carried out using two different approaches. The first approach was to calculate the particles deposited onto surfaces in terms of equivalent virtual air change, which is the air change rate that produces the same reduction in airborne particles as obtained by surface deposition. The equivalent virtual air change rate was then compared with the actual air change rate owing to mechanical ventilation. The second approach was to calculate the time for

Table 5: Percentage of surface deposition in different grades of airborne microbial cleanliness

EU GGMP cleanroom grade	ISO Class (operational)	Upper limit of airborne MCP concentration/ m^3	Deposition velocity of MCPs (m/s)	Equivalent virtual air changes per hour	Typical range of air changes per hour	Surface deposition (%)
Grade B	7	10	0.0073	9.7	30-100	24% to 9%
Grade C	8	100	0.0033	4.4	20-50	18% to 8%
Grade D	Not defined	200	0.0026	3.5	10-30	26% to 10%

airborne particles to decay by both deposition and ventilation to 90% of their concentration. The number of particles deposited was then calculated as a percentage of the total number of particles removed by both deposition and ventilation.

The results of the two types of calculations are given in Tables 2 and 3, where it can be seen that they give identical results and, therefore, give confidence in the correctness of the overall analytical approach. For cumulative particles sizes of ≥0.3μm, ≥0.5μm, ≥5μm, ≥10μm, ≥25μm, ≥40μm, ≥50μm, and ≥100μm, the percentage removed by surface deposition was 0.3%, 0.65%, 23%, 48%, 81%, 90%, 93% and 98%, respectively. It can, therefore, be seen that (a) smaller particles of ≥0.3μm and ≥0.5μm are mostly removed by ventilation (b) the size where 50% of the particles are removed by deposition is close to ≥10μm and (c) about 90% of the particles are deposited at a size of ≥40μm.

In sealed and unventilated rooms, all particles will be removed from the air by surface deposition, but in a room designed like a high-speed wind tunnel, most particles would be removed by ventilation. Cleanrooms will take some intermediate position, where some particles are removed by deposition and some by ventilation.

The results reported in the previous paragraphs were calculated from information previously reported from experiments carried out in an operational ISO Class 8 cleanroom.[4] However, it would be expected in cleaner rooms with higher air supply rates that the removal of particles by ventilation would be higher, and the removal by surface deposition, lower. However, it is also known that as the airborne cleanliness improves and the air supply increases, the deposition velocity of particles increases, and more surface deposition occurs.[4, 8] The effect of these two mechanisms may balance each other and a change in the percentage deposited may not be as much as speculated. This possibility was investigated.

Using information available on the relationship of particle deposition rate and air cleanliness for particles ≥5μm,[4, 8] the percentages of surface deposition were calculated for cleanrooms that ranged from ISO Class 6 to ISO Class 9, and the results given in Table 4. However, to calculate the deposition percentage over a range of ISO classes, it is necessary to make assumptions as to what air change rates are associated with what cleanliness classes. Because of the reasons given, the air change rates needed to obtain a required ISO class will vary. Therefore, a range of air changes that are typical of each ISO class was used, and the calculated percentage deposited also given as a range. These results show that the deposition percentage of particles ≥5μm varied from about 11% to 37% across cleanroom classes of 6 to 9, with a tendency for a higher deposition percentage to be associated with poorer cleanliness classes. However, this tendency was not clear, but until further experimental results are available, the results of percentage deposition that apply to an ISO Class 8 can be applied to ISO Classes 6, 7 and 9.

An investigation was also carried out to ascertain the percentage deposition of MCPs in cleanrooms. Microbes are not normally found in cleanroom air in unicellular form, as they are dispersed by personnel on skin and clothing detritus, and have an average equivalent aerodynamic size of about 12μm.[2, 3] Similar to particles, the deposition velocity of MCPs is known to increase with the cleanliness of the cleanroom[12] and, using the calculated deposition velocities, the deposition percentages of MCPs in EU GGMP (2008) Grades B to D cleanrooms were calculated. These percentages were based on a range of typical air change rates found in these grades of cleanrooms, and the percentage varied from about 9% to 26%. Similar to the results with particles ≥5μm, the percentage of deposition does not appear to be significantly affected by the grade of cleanroom.

It is commonly assumed that the air supply to a cleanroom will remove most of the airborne contamination from cleanrooms. However, it has been shown in this article that a substantial percentage of macroparticles and MCPs are not removed by air but deposited onto surfaces. The percentage deposited varies according to particle size and the amount of mechanical ventilation required to achieve a specific standard of air cleanliness. The importance of surface deposition shows that when the control of airborne contamination of surfaces is being considered, more thought should be given to monitoring of the PDR,[14] and consideration of activities such as walking and touching of surfaces that will cause deposited macroparticles and MCPs to re-enter the cleanroom air, and subsequently deposit onto vulnerable surfaces. Effective control of such contamination cannot be achieved solely by mechanical ventilation and attention must be given to efficient and frequent cleaning of surfaces.

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