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Material Compatibility Study of IMAGO & Getter Disinfectants

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Abstract: ***The study was aimed to evaluate different materials mostly present in Pharma manufacturing industries, cleanrooms, Healthcare, Institution etc. for resistance to disinfectant chemicals, simulating performance in potential end use environments. Disinfectant chemicals can include commonly used chemical compound or in combination of two or more compounds that the test material may be expected to come in contact with. Different disinfectants are not compatible with all types of surfaces [2]. The disinfectants must not damage the material to which they are applied to and can cause corrosion or discoloration [6]. Control is important for product safety and cost factor to the end users. The test includes provisions for reporting changes in weight, dimensions, appearance and strength properties. Provisions are made for various exposure times and strain conditions.The simple test procedure wasdeveloped compared to as described in Chemical Compatibility - ASTM D543 Standard[3].***

Keywords: Pharma industries, cleanrooms, Disinfectant chemicals, Material compatibility, Chemical compatibility.

1. Introduction

Disinfectants are of great importance for controlling the microbial population in cleanrooms. However, the selection of the most appropriate disinfectants to use is not straightforward.Cleanrooms play an important role in hospitals, from special environments for the preparation of medicines in pharma companies to providing clean air zones for operations [8]. Cleanrooms are designed with special air filters (high efficiency particulate air) to provide 'clean air', have positive pressure differentials to prevent the ingress of less clean air, and have strict entry and clothing requirements for personnel. Nevertheless cleanroom surfaces can become contaminated with microorganisms, transported in from consumables and equipment or shed from personnel. Surfaces pose a risk if they harbour high numbers of bacteria and fungi as such microorganisms can be readily transferred [1]. Thus, an important part of contamination control within a cleanroom requires the use of cleaning and disinfection agents. The use of hand disinfectants is also part of the process of good contamination control. Disinfectants used on cleanroom surfaces, manufacturing facilities, and for hand sanitization need to be of a high quality and be effective at killing microorganisms. The range and choice of disinfectants can make the selection process difficult. There are several factors to be considered for selection of disinfectants, one of them is the Material compatibility of disinfectant chemicals to be used for disinfection [5].

2. Materials and Methods

Disinfectant:
Disinfectant range of Products(Imago & Getter, Mumbai)

Apparatus:
Material Specimens typically used are of Stainless steel 316, Epoxy, Glass, PVC, Plastic, Terrazzo tiles, PU (Polyurethane), GI powder coated, Rubber and Fibreglass. Specimens size used for testing were disks-plate of 3 inch x 3 inch in duplicate. Analytical balance (Contech) and Glasswares.

Test Method:
All test material specimens were prepared before testing by washing with hot water and dish liquid, followed by cleaningwith acetone. Then they are rinsed with distilled water. The specimens were kept for drying at room temperature. All the specimens were weighed and measured prior to contact with the Disinfectant chemicals[8].

The Disinfectant products (from Imago & Getter) were diluted in Deionised water as recommended by the manufacturer or supplier. Depending upon the type of contact anticipated for the test material specimens, the exposure to the disinfectant chemicals was done by immersion; one of the material specimens was dipped in the disinfectant solution & then sealed in a container and left at room temperature. The other specimen i.e. control was kept as it is at room temperature. This technique was applied so that both the material specimens can be easily observed and distinguished. After resting time the specimens are taken out, rinsed with distilled water and air dried. After drying, both the material specimens are removed and evaluated for desired properties such as change in weight, visual appearance or tensile properties vs controls [3].The most typical physical strength properties evaluated are tensile strength and elongation. This procedure was repeated every day for 15 sequent working days.

3. Results and Discussion

The parameters such as visual appearance and weight were observed and checked for any changes as well as tactile versus control, every day from Day 1 to Day 15. The results of Day 1 and Day 15 for visual observation and change in weight are tabulated as in Table 1 and Table 2 respectively.

Table 1: Material compatibility result chart against disinfectant products (Day 1 – Visual observation)

Sl. No.	Imago Getter Disinfectant products	Chemical composition	Dilution	Material Specimens									
				SS 316	Epoxy	Glass	PVC	Plastic	PU	Rubber	GI powder coated	Ceramic tiles	Fibreglass
Control													
-				A	A	A	A	A	A	A	A	A	A
Test													
1	ID 401	Blend of Quaternary Ammonium compounds (DDAC & ADBAC - 16.5% Min.)	0.4%	A	A	A	A	A	A	A	A	A	A
			0.8%	A	A	A	A	A	A	A	A	A	A
2	Surfacept Strong	Quaternary Ammonium compound (ADBAC - 5% Min.)	1.0%	A	A	A	A	A	A	A	A	A	A
3	Surfacept	Quaternary Ammonium compound (ADBAC - 3% Min.)	2.5%	A	A	A	A	A	A	A	A	A	A
4	Ultrabasil 3Q	Blend of Quaternary Ammonium compounds (ADEBAC & ADBAC - 4.5% Min.)	1.5%	A	A	A	A	A	A	A	A	A	A
5	Imagard Biquat	Blend of Quaternary Ammonium compound (DDAC) & Biguanide (PHMB) - 14% min.	1.0%	A	A	A	A	A	A	A	A	A	A
			1.5%	A	A	A	A	A	A	A	A	A	A
6	Ultrabasil Plus	Combination of 1,6 Dihydroxy, 2-5 Dioxahexane, Glutaraldehyde, BKC - 24 %	1.5%	A	A	A	A	A	A	A	A	A	A
			2.0%	A	A	A	A	A	A	A	A	A	A
7	Envishield	Combination of Hydrogen peroxide & Silver nitrate solution - 11% min.	10.0%	A	A	A	A	A	A	A	A	A	A
			20.0%	A	A	A	A	A	A	A	A	A	A
8	Imagard HDL	Combination of Hydrogen peroxide, Peracetic acid and Acetic acid - 25% min.	0.5%	A	A	A	A	A	A	A	A	A	A
			2.5%	A	A	A	A	A	A	A	A	A	A
9	Imagard HD	Peracetic acid	1.0%	A	A	A	A	A	A	A	A	A	A
10	Aseptol	Chlorhexidine Gluconate & Cetrimide solution - 22.5% min	1.0%	A	A	A	A	A	A	A	A	A	A

Table 2: Material compatibility result chart against disinfectant products (Day 1 – change in weight)

Sl. No.	Imago Getter Disinfectant products	Chemical composition	Dilution	Material Specimens									
				SS 316	Epoxy	Glass	PVC	Plastic	PU	Rubber	GI powder coated	Ceramic tiles	Fibreglass
Control													
-				NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
Test													
1	ID 401	Blend of Quaternary Ammonium compounds (DDAC & ADBAC - 16.5% Min.)	0.40%	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
			0.80%	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
2	Surfacept Strong	Quaternary Ammonium compound (ADBAC - 5% Min.)	1.00%	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
3	Surfacept	Quaternary Ammonium compound (ADBAC - 3% Min.)	2.50%	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
4	Ultrabasil 3Q	Blend of Quaternary Ammonium compounds (ADEBAC & ADBAC - 4.5% Min.)	1.50%	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
5	Imagard Biquat	Blend of Quaternary Ammonium compound (DDAC) & Biguanide (PHMB) - 14% min.	1.00%	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
			1.50%	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
6	Ultrabasil Plus	Combination of 1,6 Dihydroxy, 2-5 Dioxahexane,Glutaraldehyde,BKC - 24 %	1.50%	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
			2.00%	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
7	Envishield	Combination of Hydrogen peroxide & Silver nitrate solution - 11% min.	10.00%	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
			20.00%	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
8	Imagard HDL	Combination of Hydrogen peroxide, Peracetic acid and Acetic acid - 25% min.	0.50%	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
			2.50%	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
9	Imagard HD	Peracetic acid	1.00%	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
10	Aseptol	Chlorhexidine Gluconate & Cetrimide solution - 22.5% min	1.00%	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC

Also the results of Day 15 for visual observation and change in weight are tabulated as in Table 3 and Table 4 respectively.

Table 3: Material compatibility result chart against disinfectant products (Day 15 – Visual observation)

Sl. No.	Imago Getter Disinfectant products	Chemical composition	Dilution	Material Specimens									
				SS 316	Epoxy	Glass	PVC	Plastic	PU	Rubber	GI powder coated	Ceramic tiles	Fibreglass
Control													
-				A	A	A	A	A	A	A	A	A	A
Test													
1	ID 401	Blend of Quaternary Ammonium compounds (DDAC & ADBAC - 16.5% Min.)	0.4%	A	A	A	A	A	A	A	A	A	A
			0.8%	A	A	B	A	A	A	A	A	A	A
2	Surfacept Strong	Quaternary Ammonium compound (ADBAC - 5% Min.)	1.0%	A	A	B	A	A	A	A	A	A	A
3	Surfacept	Quaternary Ammonium compound (ADBAC - 3% Min.)	2.5%	A	A	A	A	A	A	A	A	A	A
4	Ultrabasil 3Q	Blend of Quaternary Ammonium compounds (ADEBAC & ADBAC - 4.5% Min.)	1.5%	A	A	B	A	A	A	A	A	A	A
5	Imagard Biquat	Blend of Quaternary Ammonium compound (DDAC) & Biguanide (PHMB) - 14% min.	1.0%	A	A	A	A	A	A	A	A	A	A
			1.5%	A	A	B	A	A	A	A	A	A	A
6	Ultrabasil Plus	Combination of 1,6 Dihydroxy, 2-5 Dioxahexane, Glutaraldehyde, BKC - 24 %	1.5%	A	A	A	A	A	A	A	A	A	A
			2.0%	A	A	A	A	A	B	A	A	A	A
7	Envishield	Combination of Hydrogen peroxide & Silver nitrate solution - 11% min.	10.0%	A	B	A	A	A	A	A	A	A	A
			20.0%	B	B	A	A	A	B	B	A	A	A
8	Imagard HDL	Combination of Hydrogen peroxide, Peracetic acid and Acetic acid - 25% min.	0.5%	A	A	A	A	A	A	A	A	A	A
			2.5%	B	B	A	A	A	B	B	A	A	A
9	Imagard HD	Peracetic acid	1.0%	A	A	A	A	A	B	A	A	A	A
10	Aseptol	Chlorhexidine Gluconate & Cetrimide solution - 22.5% min	1.0%	A	A	A	A	A	A	A	A	A	A

Evaluation

Visual changes of the materials specimens are documented as Ratings –

A	No effect – Excellent (Non-critical)
B	Minor effect – Good (Semi-critical): slight corrosion, or discoloration.
C	Moderate effect – Fair (Semi-critical): not recommended for continuous use. Softening or loss of strength, and swelling may occur.
D	Severe effect – (Critical): Not recommended for any use.

Table 4: Material compatibility result chart against disinfectant products (Day 15 – Change in weight)

Sl. No.	Imago Getter Disinfectant products	Chemical composition	Dilution	Material Specimens									
				SS 316	Epoxy	Glass	PVC	Plastic	PU	Rubber	GI powder coated	Ceramic tiles	Fibreglass
Control													
-				A	A	A	A	A	A	A	A	A	A
Test													
1	ID 401	Blend of Quaternary Ammonium compounds (DDAC & ADBAC - 16.5% Min.)	0.4%	A	A	A	A	A	A	A	A	A	A
			0.8%	A	A	B	A	A	A	A	A	A	A
2	Surfacept	Quaternary Ammonium compound	1.0%	A	A	B	A	A	A	A	A	A	A

	Strong	(ADBAC - 5% Min.)											
3	Surfacept	Quaternary Ammonium compound (ADBAC - 3% Min.)	2.5%	A	A	A	A	A	A	A	A	A	A
4	Ultrabasil 3Q	Blend of Quaternary Ammonium compounds (ADEBAC & ADBAC - 4.5% Min.)	1.5%	A	A	B	A	A	A	A	A	A	A
5	Imagard Biquat	Blend of Quaternary Ammonium compound (DDAC) & Biguanide (PHMB) - 14% min.	1.0%	A	A	A	A	A	A	A	A	A	A
			1.5%	A	A	B	A	A	A	A	A	A	A
6	Ultrabasil Plus	Combination of 1,6 Dihydroxy, 2-5 Dioxahexane, Glutaraldehyde, BKC - 24 %	1.5%	A	A	A	A	A	A	A	A	A	A
			2.0%	A	A	A	A	A	B	A	A	A	A
7	Envishield	Combination of Hydrogen peroxide & Silver nitrate solution - 11% min.	10.0%	A	B	A	A	A	A	A	A	A	A
			20.0%	B	B	A	A	A	B	B	A	A	A
8	Imagard HDL	Combination of Hydrogen peroxide, Peracetic acid and Acetic acid - 25% min.	0.5%	A	A	A	A	A	A	A	A	A	A
			2.5%	B	B	A	A	A	B	B	A	A	A
9	Imagard HD	Peracetic acid	1.0%	A	A	A	A	A	B	A	A	A	A
10	Aseptol	Chlorhexidine Gluconate & Cetrimide solution - 22.5% min	1.0%	A	A	A	A	A	A	A	A	A	A

Acceptable change of weight for material specimens during the test

Starting weight	Change of weight
≥ 1 g	< 0.5%
< 1 g	< 1%
< 0.5 g	< 2.5%
< 0.2 g	< 5%

Critical / Semi-critical / Non-critical. The evaluation non-critical occurs when the change of weight is in an acceptable range.

NC – No change

The results obtained in this material compatibility study of the disinfectants from Imago & Getter showed Excellent and Good results after 15 days. Report data includes visual evidence of decomposition, swelling, clouding, crazing, cracking, and/or change in physical properties such as tensile strength and elongation also change in weight was observed.Imagard ID-401, Surfacept, Imagard Biquat, Ultrabasil Plus, Imagard HDL, Imagard HD and Aseptol at low concentration shows excellent ratings against all material specimens. Hence they can be declared as Non-critical for use.Good rating was observed at high concentration for Surfacept Strong, Ultrabasil 3Q and Envishield against Glass & PU specimen, Imagard HD against PU specimen.Whereasat high concentration, Good ratingwas shown by Imagard ID-401 and Imagard Biquat against Glass specimen, Envishield and Imagard HDL against SS 316, Epoxy, PU and Rubber. Therefore these can be declared as Semi-critical for use.

No change in weight was observed in all material specimens from Day 1 to Day 15 for all disinfectants.

4. Conclusion

Disinfectants are of great importance for controlling the microbial population in cleanrooms. However, the selection of the most appropriate disinfectants to use is not straightforward [7]. This study has examined the material compatibility as key criteria for the selection of disinfectants. Whilst selection is important, disinfectants must be applied and used appropriately. Given that the objective of the disinfectant is to kill microorganisms and to reduce the surface bioburden then the real test of whether a disinfectant is efficacious, is with the numbers of microorganisms present. . Any disinfectant will only be effective if it is used at the correct concentration and by mopping the disinfectant onto the compatible surface. This study and result table provides a quick guidance and reference for end usersfor the selection of suitable Imago & Getter disinfectants as per their material of construction of the surfaces to be disinfected at particular concentration. The viable microbiological environmental monitoring can be done by using surface techniques like contact plates and swabs. Further evidence as to how effective a disinfectant is can be shown with the types of microorganisms recovered (the 'microflora'). Finally, the selection of disinfectants should not be thought of as a one-off decision; it must remain part of the on-going quality reviews undertaken by clean room manager.

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