Solvent-Free Polyurethane based Pressure Sensitive Adhesive for Transdermal Drug Delivery Patch System

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This research is carried out to focus on the development of solvent free polyurethane based pressure sensitive adhesive for medical patch products by using simulation methods. It presents an interesting class of product that offers great potential to produce a new generation of palm oil bio-based pressure sensitive adhesive with excellent properties that follow medical requirements. The objective of this study is to optimize the formulation of palm oil-based solvent free polyurethane pressure sensitive adhesive. It focuses on making a highly tolerable, comfortable product, characterized for good skin, and optimal release. This study also focuses on the effect of different percentages and types of anti-flaming agent and various types of tackifiers on fire resistance and mechanical properties of polyurethane based pressure sensitive adhesive. Development in solvent-free polyurethane based pressure sensitive adhesive describe the variety of solvent free polyurethane composition, residue monomers content, quality of tack, peel adhesion level repeating during time, biocompatibility of solvent free polyurethane adhesive layers, permeability to air, water vapor, and their practical for medical application. The flammability resistance of pressure sensitive adhesive, flammability test being was simulated and anlalysed according to the ASTM D 635 standard test method for rate and / or extent and time of burning of plastics in a horizontal position. For mechanical properties, the simulation of testing was performed according to ASTM D 3330 method b for 180 degree peel adhesion to the backing of single coated tapes of pressure sensitive tape, and ASTM D 2979–95 for pressure sensitive adhesive tack test. This research was performed using Comsol Multiphysics software simulation. This research is very important, and the testing method used in this research may enhance the strength and toughness of pressure sensitive adhesive. It may be useful to engineers in the medical industry to increase the strength of the pressure sensitive adhesive in the critical area of joining.

Key Words : *Pressure Sensitive Adhesive, Polyurethane based adhesive, simulation study*

1. INTRODUCTION

Pressure sensitive adhesive (PSA) is typically used for a variety of self-adhesive materials such as adhesive one-sided, double-sided, adhesive labels, and protective foils such as medical pads.

According to Singh et al., (2011), adhesive meant for attaching two surfaces together mainly for ensuring surfaces remain attached with each other. For this, adhesives are applied on the surfaces to be attached with each other. An adhesive is a liquid or semi-liquid mixture that adheres or bonds two or more objects together. Adhesives can be natural or synthetic, and the sorts of materials that can be bonded are numerous, but they are particularly useful for bonding thin materials.

Polyurethane adhesive contains carbamate groups -NHCOO- or isocyanate groups in strand adhesive of -NCO. Polyurethane adhesive has some characteristics which is higher reactivity, to containing active hydrogen or substrate adhesive strength with higher of water imbibition, can be used in room temperature curing, can also be heating and curing, structure of crosslinking easy to form, high glue-line hardness, convenience easy to operate, low temperature resistant, excellent performance, good flexibility, fatigue performance is good, vibration, and impact resistance. Incorvia. (2015).

In comparison to other groups of petroleum-based polyurethane, pressure sensitive adhesives based on certain types of palm oil-based solvent-free polyurethane provide intriguing advantages. As a solvent-free system, a solvent-free polyurethane pressure-sensitive adhesive can be used. Excellent ageing properties, resilience to high temperatures and plasticizers, remarkable optical clarity due to polyester compatibility, and non-yellowing are just a few of the benefits. It possesses the best adhesion, cohesiveness, and water resistance

The capability of medical solvent-free polyurethane based on pressure sensitive adhesive to adhere well to varying skin types, both dry and moist, is one of the most demanding performance requirements. It should not irritate the skin and can be removed without leaving adhesive residue or causing skin harm. Medical pressure sensitive adhesive adheres strongly to the skin but can be easily removed with little or no stress to the skin due to adhesion capabilities and without adhesive due to cohesion properties. Pressure sensitive adhesive adhere too aggressively might cause skin irritation and pain. Low tack or peel adhesion strength values render a patch aesthetically undesirable when applied on the skin for a long time, as adhesive oozes leave adhesive residue on the outside edge of the backing layer. Patches might leave noticeable remains when they are removed. Tack and peel adhesion strength are hence extremely important pressure sensitive adhesive characteristics.

Basic trending criteria in the development of pressure sensitive products are the type of raw materials, accessible technologies, and application. The use of highly tolerant compounds with low allergenic potential is the most important aspect when it comes to raw materials, and the options are further limited by other factors. Pressure sensitive adhesive for patches must be biologically inert, non-irritating, and non-sensitizing at the skin's surface, and it must provide good adhesive properties to the end product. Singh et al., (2011).

(1) Problem Statement

Solvent-free polyurethane-based pressure sensitive adhesive is now widely utilized in a variety of industries due to its excellent drying and adhesive qualities, particularly endurance. However, solvent polyurethane based pressure sensitive adhesive can be unexpectedly tricky particularly for the research.

When solvent polyurethane based pressure sensitive adhesive is performed improperly, this can result in a few different defects because it uses petroleum-based derived components which are polyether polyol or polyester. Because of this situation, the new research of solvent-free polyurethane based pressure sensitive adhesive using bio-based oil should be looked out for. We already know that existing solvent systems in industries are also flammable and can cause health problems.

Solvent systems are also flammable that can contribute to fires and explosions. It is important to know the flashpoint to describe when enough points are discharged, a spark of flame can ignite. Flammability may be identified when flammable solvents have a flash point temperature of less than 100° F, while combustible solvents have a higher flash point temperature. By the way, the solvent system is also flammable in a structural material or part of the product being made and used either for resource or external adhesive loads being applied.

Secondly, solvents can harm health and have two different effects on skin. First, certain solvents can be absorbed via the skin, where they might damage organs or other systems. Solvents can bring harmful compounds with them in some cases. The second way is to irritate the skin, resulting in dermatitis. Many solvents attack the natural oil that protects the skin, causing it to dry out or break out. Solvents can also aggravate or cause skin allergies, causing painful irritation. As the skin is exposed to more solvent, it becomes more sensitive, which worsens the irritation.

Therefore, this research will focus on formulating the invention of solvent-free polyurethane based on pressure sensitive adhesive using bio-based oil like palm based oil that we believe to overcome the problem.

(2) Objective

- To optimize the formulation of palm oil based solvent free polyurethane pressure sensitive adhesive by using Taguchi method.
- To study the effect of different percentages and types of anti-flaming agent on fire resistance properties of polyurethane based pressure sensitive adhesive by simulation using Comsol Multiphysics.
- To assess the effect of various types of tackifier on mechanical properties of polyurethane based pressure sensitive adhesive by simulation using Comsol Multiphysics.

(3) Significant of Project

The significance of this study is, it gives back the benefits to the society and industries considering that a new biodegradable solvent free polyurethane based pressure sensitive adhesive for medical patch products is an important role in manufacturing new technologies of pressure sensitive adhesive.

Pressure sensitive adhesive is unique in that it does not solidify into a solid material and instead remains viscous. As a result, it is always tacky and can wet surfaces when it comes into contact with it. According to Ebnesajjad, S. (2011)., By putting the adhesive sheet into contact with the substrate and exerting pressure, bonds are formed. It works well for temporary adhesion.

The viscoelastic nature of pressure sensitive adhesive response to mechanical and climatic stress in terms of durability is different from most structural adhesives. There are many sectors that use the pressure sensitive adhesive such as packaging, automotive, building, medical and health, etc. Bahadori, A. (2015).

2. METHODOLOGY

(1) Stages of research

To fulfil the objectives and goals of the research, three steps of scientific research must be completed in order to assure the systematic collection of data as well as intelligence and to improve the precision of the findings. This research began with the design of an experiment utilizing the Taguchi method to determine the best formulation, followed by a simulation study on adhesive bonding preparation and characterization, and ultimately the validation process.

(2) Characterization of solvent free polyurethane adhesive bonding

This simulation scenario is focusing on different percentages and types of anti-flaming agent, and also to assess the effect of various types of tackifiers on mechanical properties of polyurethane based pressure sensitive adhesive.
The simulation mimicking real life experiment and there are three important testing model that need to be constructed which is:

Flammability test

According to ASTM D 635: Standard test method for rate of burning and / or extent and time of burning of plastics in a horizontal position, this fire test response test technique describes a small-scale laboratory screening approach for comparing the relative linear rate of burning, or extent, and time of burning, or both, of plastics in the form of bars, molded, or cut from sheets, plates, or panels, and tested horizontally.

This standard is used to measure and describe the response of materials, products, or assemblies to heat and flame in controlled settings, but it lacks the information needed to assess fire hazards or risk in materials, products, or assemblies under actual fire circumstances. Load, U. F., & Meth, V. F. T. (2003).

Factors including density, pigments, any anisotropy in the material, and the thickness of the specimen affect the rate of burning and other burning events. Whether comparing the same or different materials, test data should only be compared for specimens of identical thickness. With increasing thickness, the rate of burning and other burning phenomena will change. Load, U. F., & Meth, V. F. T. (2003).

Tack test

According to ASTM D 2979-95, pressure sensitive tack of adhesives using an inverted probe machine, the probe tack test is designed to be used with adhesives on flexible or stiff backings. The tests are used for quality assurance and research. Polyken Tack Tester was used to create the standard procedure. A variety of probes can be used. The standard probe is a stainless steel probe with a radius of 5 mm. This results in a contact area of about 20 mm2. To reduce the chance of air trapping between the probe and the adhesive, the probe can be somewhat domed. Contact pressure (100 g cm-2), dwell time (1 s), and test speed are the normal test settings (1 cm s-1). ASTM, (2001).

Peel test

According to ASTM D 3330 method b – 180 degree peel test adhesion to backing of single-coated tapes is quite similar to method a, which measures the adherence of two layers of single coated tapes to each other, but method b measures the adherence of two layers of single coated tapes to each other. For information, application of method a is usually used for measuring the adhesion of fastening tapes while method b is usually used for measuring the adhesion of masking and packaging tapes. The result of this test is used to determine the adhesion uniformity of a pressure sensitive adhesive tape. A strip of tape is put to a stiff substrate in this test, and then another strip is applied to the backing of the first strip. After that, it is put to the test for peel adhesion. ASTM, (2003).

(3) Parameters

As we all know, parameters were the most important thing in the process of making a new solvent free polyurethane based pressure sensitive adhesive. Three formulation parameters level rates have been selected based on the anti-flaming agent type, anti-flaming agent content, and type of tackifier. Usually, there are each certain function for each type of the parameter. Table below show the specific parameter use in this research:

Table 1 Selected values of process parameter

Code	Factors	Levels		
		1	**2**	**3**
AFA	Anti flaming agent types	Phosphorous flame retardant	Nitrogen flame retardant	Halogen flame retardant
AFC	Anti flaming contents	0.5%	1.0%	1.5%
T	Type of tackifiers	Hydrocarbon resins	Rosin resins	Terpene resin

Table 2 Orthogonal array design

Simulation no.	Control factors		
	AFA	**AFC**	**T**
1	1	1	1
2	1	2	2
3	1	3	3
4	2	1	2
5	2	2	3
6	2	3	1
7	3	1	3
8	3	2	1
9	3	3	2

3. RESULTS AND DISCUSSION

The result from simulation studies consists of three different testing which are flammability, peel, and probe tack tests. The data will show in the stripes of color from red which means highest to dark blue which means the lowest. The result stripes also show the maximum and minimum value area of testing and being discussed in the results data by simulation. The simulation tests run smoothly without any problem.

(1) Flammability test

Simulation of flammability testing is conducted following ASTM D 635 standard test method for rate and / or extent and time of burning plastics in a horizontal position.

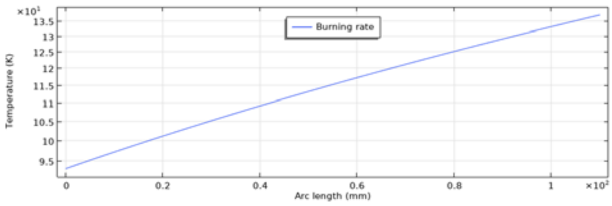

Fig. 1 Flammability test simulation 1

Fig.1 shows a plot of simulation models that have been carried out from the flammability testing. It is shown that the distribution of heat transfer of the burning range in the simulation model spreads the heat energy outward. This is because the surface of the model first contacts the heat source in the start area. This first area of the model has high energy particles that move aggressively then collide with other particles which are lower energy while spreading the heat energy to the other particles.

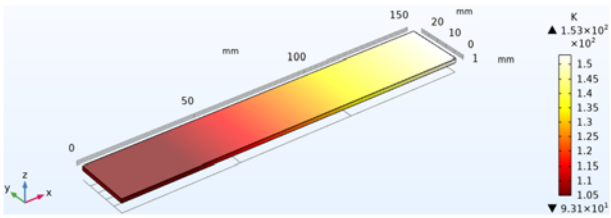

Fig. 2 Flammability test simulation model 1

The stripe color was the red spot which had the highest heat input, and the yellow spot at the end of the simulation model with the lowest heat temperature. This proves that from the simulation of the flammability test, the burning range of heat energy has been transferred from high energy to lower energy in the end of the model area spread outward from it based on the stripe color. The stripe color shows the formation of heat transfer of the burning range where the formation and the size of the flame test start from red spot to yellow spot.

(2) Probe tack test

Simulation of probe tack testing is conducted following ASTM D 2979-95 standard test method for pressure sensitive adhesive using an inverted probe machine for tack test. The graph shows simulation models that were conducted as a result of the probing tack testing. According to the results, the greatest recorded force necessary to detach the adhesive surface from the cylindrical probe represents the tack of adhesion.

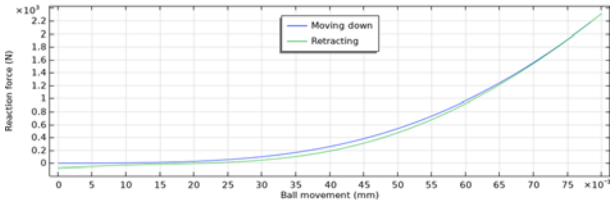

Fig. 3 Probe tack test simulation 1

This is due to the fact that the test examines the brief time of adhesion with low pressure on a flat and cylindrical probe to the adhesive surface. The greatest recorded force necessary to separate the adhesive surface and the cylindrical probe represents the tack of adhesion and decohesion strength.

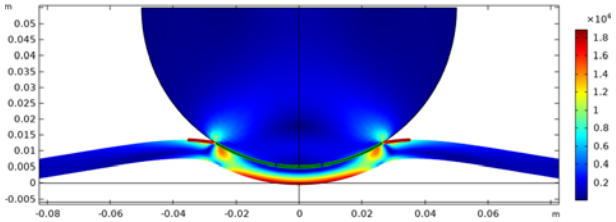

Fig. 4 Probe tack test simulation model 1

The pressure sensitive adhesive tape was simulated in fixed condition, which eliminates tape backing effects. The speed with which the cylindrical probe approaches the adhesive surface, which was controlled by the simulation force, and the speed with which the cylindrical probe is removed from the adhesive surface, which is controlled by the test, measures the short time with low pressure of adhesion on a flat and the cylindrical probe to the adhesive surface. Red stripe color spot which has been loaded with high impact pressure, and the blue spot at the lower with lowest impact pressure. This has proven that, from the simulation of the probe tack test, the greatest recorded force necessary to separate the adhesive surface and the cylindrical probe depending on the stripe color represents the tack of adhesion strength. It should be noted that when different materials are utilized to simulate probe tack tests, the simulation results may different.

(3) Peel test

Simulation of peel testing was conducted following ASTM D 3330 Method B for 180-degree peel adhesion to the backing of single coated tapes of pressure sensitive tape.

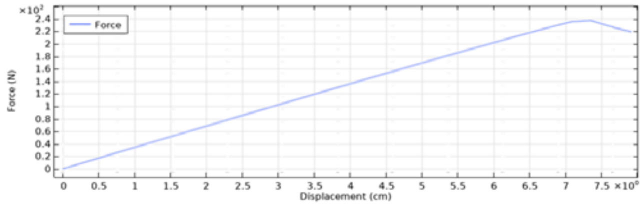

Fig. 5 Peel test simulation 1

The graph shows graphs of simulation models that have been carried out from the 180 degree peel testing. The result shows that the peel of maximum recorded force required to separate the adhesive surface from the specified stainless steel plate surface represents adhesion. This is because the test measures the adhesion peel strength of the adhesive's surface, which can be classified as low, medium, or high.

High or low peel force is not really a good indicator of a pressure sensitive adhesive's effectiveness. Most stick-to-skin applications would not require a particularly strong pressure sensitive adhesive, and a blood glucose meters display would not require an easy peel pressure sensitive adhesive.

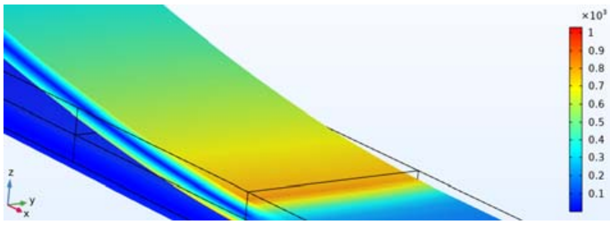

Fig. 6 Peel test simulation model 1

The pressure sensitive adhesive tape is simulated in 180 degrees peel angle condition. This test is to measure the release liner's adherence to the adhesive and the pressure sensitive tape's adhesion uniformity. The liner is pulled from the sticky surface and the adhesive tape is simulated with the linear side up. The peel adhesion of pressure sensitive adhesive with a 180-degree peel is also measured in this test. The stripe color is the red spot which has been loaded with high force pressure, and the blue spot at the lowest force pressure. This proves that from the simulation of the peel test, the adhesion strength of maximum force necessary to separate the adhesive release liner of pressure sensitive adhesive tape based on the stripe color. From this peel simulation, it can improve the comprehension of the element that influences the feel force, which has previously been linked to skin trauma generated by peeling pressure sensitive adhesive tape.

Table 3 Orthogonal array design

Simulation no.	Control factors AFA	AFC	T	Flammability rate (V)	Peel strength (N)	Tack strength (N)
1	1	1	1	1.85	2.39	2.2
2	1	2	2	1.88	2.25	2.05
3	1	3	3	1.96	2.45	2.15
4	2	1	2	1.81	2.45	1.7
5	2	2	3	1.91	2.05	1.93
6	2	3	1	1.86	2.4	1.7
7	3	1	3	2.0	2.05	2.09
8	3	2	1	1.66	2.18	1.68
9	3	3	2	2.08	2.3	1.95

(4) Optimization by Taguchi and ANOVA

The Taguchi analysis has proven to be an effective means of increasing productivity in research and development. As a result, higher-quality products can be created rapidly and at a low cost. This technique also be used to limit the number of test subjects and arrange the study schedule.

1-Taguchi analysis: Flammability rate (V), Peel strength (N), Tack strength (N) versus Anti-flaming agent types, Anti-flaming contents, Types of tackifiers.

Response table for signal noise ratios: Larger is better

Table 4 Signal to noise ratio

Level	AFA	AFC	T
1	6.460	6.116	5.759
2	5.728	5.717	6.093
3	5.913	6.269	6.251
Delta	0.732	0.552	0.492
Rank	1	2	3

Response table for means

Table 5 Means value

Level	AFA	AFC	T
1	2.131	2.060	1.991
2	1.979	1.954	2.052
3	1.999	2.094	2.066
Delta	0.152	0.140	0.074
Rank	1	2	3

Table 5 shows the means that get from the Taguchi method in Minitab 18. The rank is the influence for the factor because the number 1 rank is most important because of anti-flaming agent types give a specific level of ignition resistance followed by rank number 2 which is anti-flaming agent contents that provide particular level of flame spread. For rank number 3 which is type of tackifier, the best tackifier compounds help balance pressure sensitive adhesive and adhesive properties.

For selected process parameters as per Taguchi method L9 orthogonal array design system, nine sets of simulation have been performed in Table 3 with the purpose of optimizing process parameters. It is considered to be the result parameter and therefore, the signal to noise ratio has been calculated for all nine experiments and the S/N ratios major effect was plotted as shown in Fig. 7.

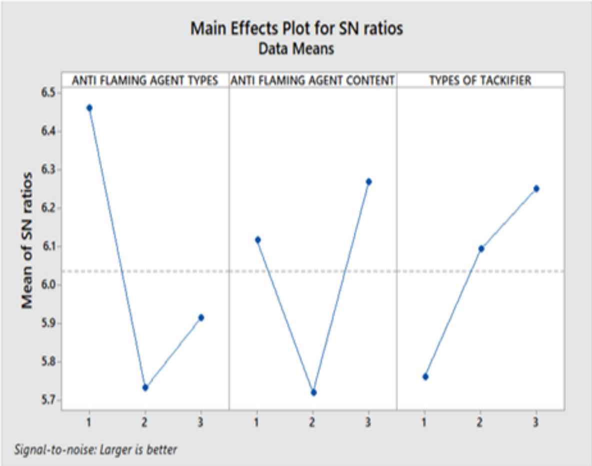

Fig. 7 Plot for SN ratio

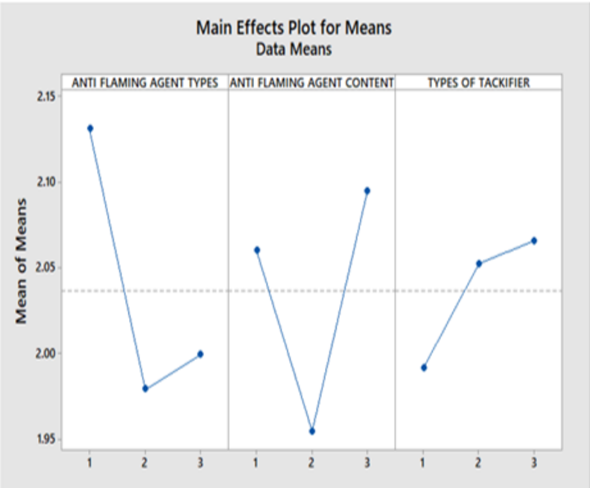

Fig. 8 Plot for means data

The signal noise ratio response graph is given in Fig. 8 and the best set of optimum parameters can be determined by the level with highest signal noise ratio by each factor which is A1B1C1.

Table 6 Optimal Value of Parameter

Parameter	Optimal Value
AFA	Phosphorus flame retardant
AFC	0.5 %
T	Hydrocarbon resin

(5) Anova analysis

Variance of Analysis (ANOVA) was a collection of statistical models and their related estimation techniques such as the variation between and between groups used to evaluate group mean differences in a sample. The anova was based on the law of total variance, where the observed variance was divided into components attributable to different sources of variation in a particular variable. Anova provides a statistical test in its simplest form to determine whether two or more population means are equal, thus generalizing the t-test beyond two means.

5.1 Regression analysis: Flammability rate (V) versus Anti-flaming agent types, Anti-flaming agent contents, Types of tackifiers

Analysis of variance

Table 7 Flammability rate (V) analysis of variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Regression	3	0.051683	0.017228	1.35	0.358
AFA	1	0.000417	0.000417	0.03	0.864
AFC	1	0.009600	0.009600	0.75	0.425
T	1	0.041667	0.041667	3.27	0.130
Error	5	0.063717	0.012743		
Total	8	0.115400			

Model summary

Table 8 Flammability rate (V) model summary

S	R-sq	R-sq (adj)	R-sq (pred)
0.112886	44.79 %	11.66 %	0.00 %

Coefficients

Table 9 Flammability rate (V) coefficients

Term	Coef	SE Coef	T-Value	P-Value	VIF
Constant	1.627	0.164	9.92	0.000	
AFA	0.0083	0.0461	0.18	0.864	1.00
AFC	0.0400	0.0461	0.87	0.425	1.00
T	0.0833	0.0461	1.81	0.130	1.00

Regression equation

Flammability rate (v) = 1.627 + 0.0083AFA + 0.0400AFC + 0.0833T

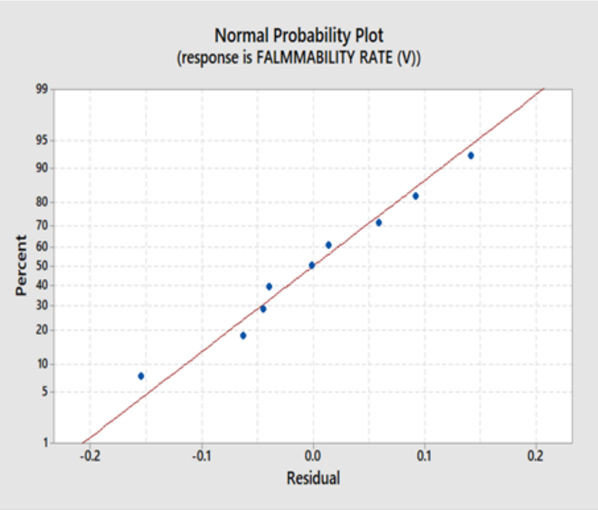

Fig. 9 Flammability rate (V) plot graph

5.2 Regression analysis: Peel strength (N) versus Anti-flaming agent types, anti-flaming agent contents, types of tackifiers

Analysis of variance

Table 10 Peel strength (N) analysis of variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Regression	3	0.09293	0.03098	1.43	0.339
AFA	1	0.05227	0.05227	2.41	0.181
AFC	1	0.01127	0.01127	0.52	0.503
T	1	0.02940	0.02940	1.36	0.297
Error	5	0.10847	0.02169		
Total	8	0.20140			

Model summary

Table 11 Peel strength (N) model summary

S	R-sq	R-sq (adj)	R-sq (pred)
0.147287	46.14 %	13.83 %	0.00 %

Coefficients

Table 12 Flammability rate (V) coefficients

Term	Coef	SE Coef	T-Value	P-Value	VIF
Constant	2.520	0.214	11.78	0.000	
Anti-flaming agent types	-0.0933	0.0601	-1.55	0.181	1.00
Anti-flaming agent contents	0.0433	0.0601	0.72	0.503	1.00
Types of tackifier	-0.0700	0.0601	-1.16	0.297	1.00

Regression equation

Peel strength (N) = 2.520 -0.0933AFA + 0.0433 AFC – 0.0700T.

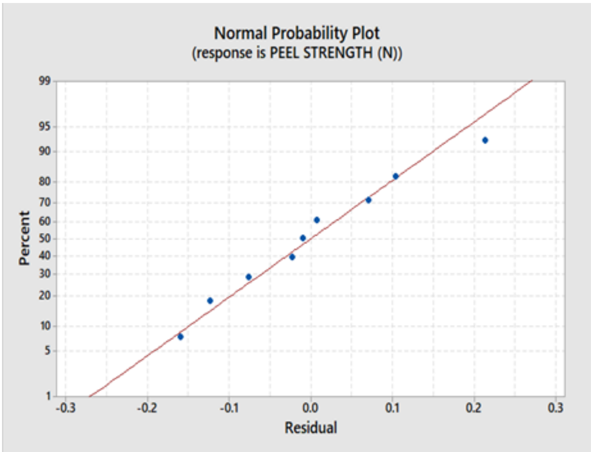

Fig.10 Peel strength (N) plot graph

5.3 Regression analysis: Tack strength (N) versus Anti-flaming agent types, anti-flaming agent contents, types of tackifier

Analysis of variance

Table 13 Tack strength (N) analysis of variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Regression	3	0.141100	0.047033	1.25	0.385
AFA	1	0.077067	0.077067	2.05	0.212
AFC	1	0.006017	0.006017	0.16	0.706
T	1	0.058017	0.058017	1.54	0.269
Error	5	0.188189	0.037638		
Total	8	0.329289			

Model summary

Table 14 Tack strength (N) model summary

S	R-sq	R-sq (adj)	R-sq (pred)
0.194005	42.85 %	8.56 %	0.00 %

Coefficients

Table 15 Flammability rate (V) coefficients

Term	Coef	SE Coef	T-Value	P-Value	VIF
Constant	2.032	0.282	7.21	0.001	
AFA	-0.1133	0.0792	-1.43	0.212	1.00
AFC	-0.0317	0.0792	-0.40	0.706	1.00
T	0.0983	0.0792	1.24	0.269	1.00

Regression equation

Tack strength (N) = 2.032 – 0.1133AFA – 0.0317 AFC + 0.0983T.

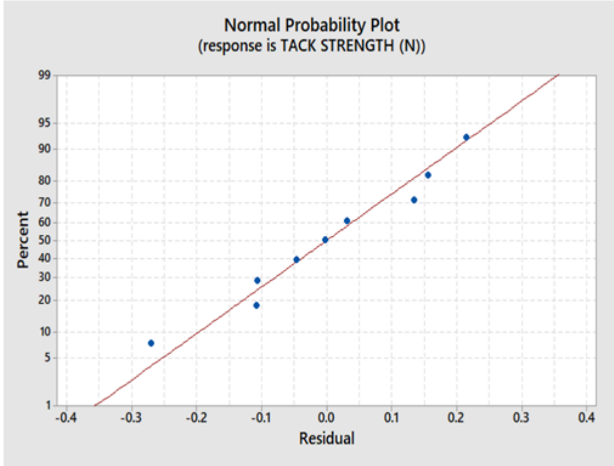

Fig. 11 Tack strength (N) plot graph

The analysis of variance (Anova) was used to determine the significance of the parameter. The larger the F-value, the greater the effect on simulation performance, and the smaller the P value, the greater the significance of the parameter.

Analysis of variance (Anova) has been conducted to analyze the larger the value of F-value, the larger effect on the simulation performance and the smaller the P value, the more significant to the parameter. It is safe to conclude that, the benefits of flammability rate, peel strength, and tack strength are correctly given a specific level of ignite or flame spread resistance and best tackifier compounds will help balance pressure sensitive adhesive and cohesive properties.

4. CONCLUSION

In this study, the best categories of anti-flaming agent and mechanical properties of solvent free polyurethane based pressure sensitive adhesive have been discovered. The results show that, to achieve the optimal result for flammability, tack, and peel test, each parameter has its own role. It can be concluded that the optimum combination of parameter factors for the solvent free polyurethane based pressure sensitive adhesive is simulation number 1 which is AFA1-AFC1-T1. The anti-flaming agent type is phosphorus flame retardant, the anti-flaming agent content is 0.5 %, and lastly the type of tackifier is hydrocarbon resin.It is also concluded that the types of anti-flaming agent give a specific level of ignite or flame spread resistance. The anti-flaming agent content provides a particular level of flame spread and the type of tackifier compound helps balance pressure sensitive adhesive and cohesive properties.

ACKNOWLEDGMENT

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