



DISCLOSURE OF INGREDIENTS USED IN DRUGS, COSMETICS AND MEDICAL PRODUCTS WITH SPECIAL REFERENCE TO SANITARY NAPKINS

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Abstract

Nearly 40% of the Indian women are utilizing sanitary napkins as they find it comfortable. There are many research works that have done many clinical experiments explaining the toxic ingredients present in a sanitary napkin. The test standard for the testing the quality of sanitary napkins is set by the BIS, which are not updated since 1980. Nowadays, many people demand the ingredients of the sanitary napkins as that would help women to utilize other safer options instead of sanitary napkins. Sanitary napkins are classified under medical products but from this research we come to a conclusion that most women are not aware of such classification. This paper examines the preference given for medical devices under the recent bill passed by the union government, Drugs, Cosmetics and Medical Devices Bill, 2022.

Introduction

Health and sanitation play a crucial role in every individual's life. There are circumstances in which we are forced to take drugs and medicines to save our lives. In that threatful moment, our entire hope lies on the Almighty and doctor and not the harmful side effects or hazards that we are about to face due to the ingredients added to the medicine. And practically, it's even not needed as, saving one's life will be the primary aim of the entire humanity. But what in case of products that we utilize in our everyday life? Many of us even don't care of certain products being classified as medical products as it becomes a usual routine to consume those products. One such product is sanitary napkins. In India, the introduction of sanitary napkin was itself a great epic and today many uses it. But now raises a question, what are these sanitary napkins made of? Why are the ingredients not mentioned as how its mentioned in any other consumer product? Why these products are inserted in the list of medical products? Let's get into a rough analysis of the non-disclosure of the ingredients of any medical product or cosmetics or drugs.

Objective

1. To examine whether women have noticed that the ingredients of sanitary napkin are not mentioned in the label.
2. To study the need of the disclosure of ingredients of a sanitary napkin



3. To figure out the convenience of women in using sanitary napkins.
4. To define sanitary napkins classified under medical devices under relevant acts and bill.
5. To recommend the factors that are to be considered when drugs, cosmetics and medical devices are exempted from disclosing the components of the products.

Significance

1. The research gives an analysis of the wider scope of medical devices proposed under the Drugs, Cosmetics and Medical Devices Bill, 2022.
2. This paper gives the factors based on which the components of the sanitary napkins are to be disclosed.
3. The research states to what extent women are conscious about the disadvantages of using sanitary napkins.

Hypothesis

Almost most of the women, though are aware of the toxic substances especially plastic being used in the sanitary napkins, use them as they are comfortable for them to use. Most of them are not aware that sanitary napkins are classified under medical products as per Indian law as they use them like a grocery item.

Literature Review

1. An article published in Times of India states that a woman on an average in her life time uses, 11,000 to 17,000 sanitary napkins. When this is the case, it is obviously the right of a woman to select the nature-friendly and body-friendly choice. Though sanitary napkins are better option compared to cloths, the research findings providing the presence of toxic substances such as dioxins are still risky.¹
2. An article in the Hindu paper, have explained about the union government's step for the drafting of New Drugs, Cosmetics and Medical Devices Bill, 2022. The article states that it is a good step for the formulation of the separate rules for drugs, cosmetics and medical devices.²
3. In the research article, "A Research Study about the Expectations from Sanitary Napkins, Current Problems and Design of a Functional Sanitary Napkin" it was determined that women

¹ TNN, A sanitary pad DOESN'T disclose ingredients: Know what goes inside it!, 2018

² Perappadan, 2021



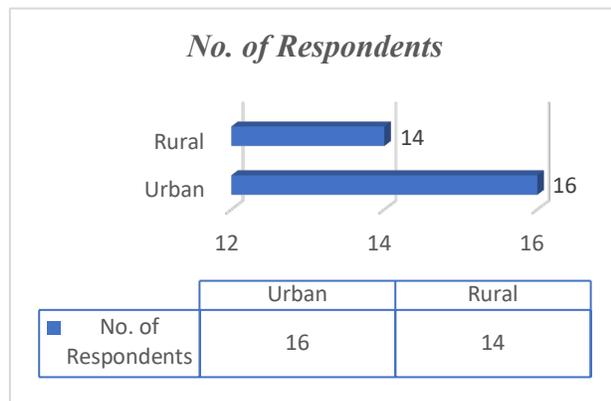
focused on odourless and soft surface sanitary napkins in addition to the absorption properties and this makes them to be more comfortable with the usage of sanitary napkins.³

Methodology

This is a doctrinal and non-doctrinal research done among 30 women, who are 18 to 25years old, through an online questionnaire.

Sample space:

Figure 1: Composition of sample space



All the respondents were of the age group of 18 to 25 years and all were women. Out of it, 53.34 percent are from urban area and 46.66 percent of them are from rural area.

Source: Survey

Limitations of the study

1. The study has been done with a limited respondents who are in the age group of 18 to 25 years.
2. The sample space is limited to Tamil Nadu.

Sanitary Napkins as an Essential Product

Following the list of basic necessities, health and sanitation, without any doubt, secures a place for it. It is an undeniable truth that menstrual health has to be maintained with utmost care, which means the supporting medical products, such as sanitary pad, tampons, menstrual cups, etc., also becomes very much important. The way Indian people perceive menstruation is changing day by day. The science behind menstruation and the sanitary products are fast spreading throughout the country. We need to appreciate that nearly 40% of the women use pads. But still, we cannot deny the fact that even today, in many parts of India, especially in village areas, undeveloped and remote areas, people follow various restrictions and rules during their menses. On the other hand, the government has made all possible steps to lend hand for women to meet their personal needs. The

³ Kara, 2021



scheme, Menstrual Hygiene Scheme introduced by the Ministry of Health and Welfare for the promotion of menstrual hygiene among adolescent girls in the age group of 10-19 year in rural areas, is one of such government's step.⁴

The judiciary have also contributed a lot so that no women is denied of their rights unnecessarily and in an unreasonable manner. The best example could be Sabari mala case⁵, in which the rule 3(b) of the Kerala Hindu Places of Public Worship (Authorization of Entry) Rules, 1965 was challenged by a group of women advocates. The rule prohibits the entry of women who are in their menstruating age. This rule was overruled by the bench headed by Chief Justice Deepak Misra on a 4:1 majority as it was violative of Article 14, 15 and 17. This case, creates a landmark by overruling a centuries-old rule for the empowerment of women and this also states to what extent the Indian society is giving importance to very citizen's right and how much our society has normalized the concept of menstruation. As a next step to it, a petition filed by two law students, Nikita Gore and Vaishnavi Gholave, alleging that the central and state government have not taken adequate measures for the menstrual hygiene of women especially girls in the adolescence age, for which the bench headed by Chief Justice Datta has directed the Maharashtra District Legal Authority to supervise and conduct surprise checks in such schools.⁶

During the pandemic period of covid 19, the union government also stated that they have provided provisions for Reproductive, Maternal, Newborn, Child, Adolescent, Health Plus Nutrition (RMNCAH+N)⁷. Even though India's Prime Minister has insisted on the importance of sanitary pads in the 74th Independence Day Speech on August 15, 2020, still these measures from the government side are not sufficient.⁸ Now, it is important to discuss how far the sanitary napkins are safe to use. There can be no method without disadvantages. Sanitary napkins are found to contain synthetic plastic materials, pesticide and bleach, dioxin, fragrance chemicals, dyes which might result in hormone disruption, cancer, birth defects, dryness, and infertility. In that case, the ingredients of the sanitary napkins are to be disclosed to the public so that the public will be able to get a complete knowledge about the components of the sanitary napkins. Now, let's get into a crisp analysis of the reason behind this non-disclosure of ingredients.

Disclosure of Ingredients

In this diversified secular country, we find people with various beliefs and practices. So the raw materials used or the ingredients used to prepare a medicine may not be convenient for certain people to take them but when it comes to be a threat for life, even under Article 21 of Indian Constitution, no person is provided with the right to take risk of their life by way of not taking up the tablet or syrup or any product which is classified as medicine or drug under the statutes enacted

⁴ National Health Commission

⁵ Indian Young Lawyer's Association v. State of Kerala & Ors, 2006

⁶ Shaikh, 2022

⁷ PTI, 2020

⁸ Chauhan, 2021



for the regulation of the medicine industry which includes, The Drugs and Cosmetics Act, 1940 and the Medical Device Rule, 2014.

Still this a heating debate that in yet other cases, as already mentioned, in case of a sanitary napkin or menstrual cups or tampons, the ingredients of the drugs or medicines administered is to be expressly disclosed to the public. Default of which, it is the infringement of Fundamental Rights guaranteed under Part III of Indian Constitution under Article 19(1)(a) and Article 21. Article 19(1)(a) guarantees the right to speech and expression and it includes one's right to get know the ingredients of the product that are use.

Under Article 21, after the evolution of the concept, 'due process' in Maneka Gandhi case⁹, with no doubt, it is the legal right in rem for a person to live with freedom and liberty and, to lead a peaceful life such that no statute deprives their right without any just, fair and reasonable ground. It is being fast spread in many blogs and newspapers, about the usage of bleaching technique in sanitary napkins. Though many clinical research and NGOs state the presence of much more hazardous chemicals such as SAP¹⁰, being used in sanitary napkins, it is still expected by the manufacturing companies to mention the ingredients as it could be a reliable source of information.

Now, comes the question, if it is not that healthy for women, how could Bureau of Indian Standards allow the usage of such product? And how about the testing? It is still a left-over area by the Indian government that the Indian Standard Specification for Sanitary napkins (IS 5405) dates back to 1980 without any further updates¹¹. The test for sanitary napkin's quality includes, test of materials being used in napkins, size, finishing, absorbents, disposability, and pH value. This quality testing standard needs to be updated for the betterment of the increased production of feminine-friendly sanitary napkins.

Sanitary napkins are classified under medical products and hence there is no obligation upon the manufacturer to provide the ingredients. When the question of disclosure of ingredients gains public interest, how long could it be kept as a secret? When maximum people start to use a particular commodity in a regular basis it also becomes as an obligation upon the government to impose rules and regulations for the disclosure of its components. In failure of which, women are forced to shift to an alternative, though it seems to be uncomfortable for them as there is difference of opinion. It is also to be noted that if 40%¹² of women use sanitary napkins, its not all the 40% of them are facing side effects due to sanitary napkins. But it's the concept of greatest good for the greatest number of people has to be upraised and for the greatest good, the product components are to be revealed so that people's right to choose is not violated.

Drugs, Medical Devices and Cosmetics Bill, 2022

⁹ Maneka Gandhi v. Union of India, 1978

¹⁰ AU - Shibly, 2021

¹¹ TNN, A sanitary pad DOESN'T disclose ingredients: Know what goes inside it!, 2018

¹² Ibid.



Recently the central government has proposed the New Drugs, Medical Devices and Cosmetics Bill, 2022 by the committee of eight members headed by Drug Controller General of India, VG Somani.¹³ The bill concentrates on the regulation of medical devices, clinical trials and online pharmacy. The Bill proposes the constitution of Drugs Technical Advisory Board (DTAB), Medical Devices Technical Advisory Board (MDTAB) and a Drugs, Medical Devices and Cosmetics Consultative Committee (DMDCCC) to advise the central and state government in technical aspects relating to drugs, medical devices and cosmetics. The drafted bill provides new a definition for the term, “medical devices” under section 3(zd) of the proposed bill, which includes an instrument, implant, apparatus, application, material or other article manufactured for the specific use for human beings or animals for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder or injury or disability, or, for supporting or sustaining life. The earlier definition, mentioned under section 3(zb) of Medical Devices Rules, 2017, was specific with the devices by way of notification in the official gazette. Thus, sanitary napkins are classified into the class of medical products but the exemption of their duty to mention the components in the label is not fair. It is unreasonable. It cannot be said that they are used for the similar purpose and in the similar manner as how other medicines are utilized. Hence, considering two unequal products as equal is an infringement of Article 14, the right to equality.

The usage of quality medical devices that is, the devices which don't meet prescribed standards, such as misbranded, adulterated or spurious are strictly prohibited by the bill. The bill doesn't give the instructions for the labelling of the medical devices for which we have to go to the Medical Devices Rule, 2017 which doesn't make it as an obligation for the manufacturers from mentioning the components of the medical device under chapter VI. As already discussed, mentioning of all the components of any life-saving medical device is not practically possible as it would cause a hesitation among people if it contravenes their beliefs. In other sense, it is really difficult to mention the components of the medical devices as basically there would be a wide range of process and ingredients whose origin may be even impossible to explain, as argued by the learnt senior council on behalf of the appellant, in the case *Indian Soaps & Toiletries Makers vs Ozair Husain & Ors*¹⁴.

The proposed bill has stated a wide range of power vested on the central government under section 158, according to which the central government may after the consultation of Medical Devices Technical Advisory Board, may provide rules for any of the provisions provided under section 158(2). Under clause (b) sub-section (2) of section 158 of the proposed bill, it is stated that the central government may make any rules with regard to the manner of labelling of the medical device. Though such a power is vested on the central, the bill itself doesn't provide any detailed labelling regulations.

There is a need to express the components of any particular medical device or be it drug or

¹³ Singh, 2022

¹⁴ *Indian Soaps & Toiletries Makers ... vs Ozair Husain & Ors*, 2013



cosmetics, when it is widely used by people, the central government should take the necessary steps for listing out such widely used medical device or drug or cosmetics in order to disclose their components to the public. To be more specific, all basic commodities that people purchase without the prescription of a doctor or physician, without violating any law in force, should have all the ingredients utilised in it and in case of sanitary napkins, the ingredients used for the fragrance, the white colour and soft texture of the pads are to be mentioned as, sanitary napkin is a basic essential commodity. Nowadays, People have wider option of alternatives such as sanitary pads made out of natural raw materials like cotton, menstrual cups, reusable napkins which are eco-friendly, though they too have their own disadvantages. (Ref. table 1)

Table 1: Current Alternative Sanitary Products and its Longevity

<i>Product</i>	<i>Material</i>	<i>Usage</i>
<i>Sanitary napkins and tampons</i>	<i>Contains Super Absorbent Polymers (SAP) and plastics</i>	<i>One time</i>
<i>Cloth-based sanitary napkins</i>	<i>Cloth and Hemp (plant material)</i>	<i>Reusable – 1 to 2 years</i>
<i>Menstrual Cups</i>	<i>Medical grade silicone</i>	<i>Reusable – 5 to 10 years</i>
<i>Compostable/ Biodegradable sanitary napkins</i>	<i>Natural ingredients like cotton, wood pulp, banana fibre, sugarcane. Organic cotton with bioplastic layer in some cases.</i>	<i>One time</i>

Source: WaterAid and MHAI (Menstrual Hygiene Alliance of India)

There need to be certain utility ratio to be fixed as a standard measure on attaining of which the ingredients of the medical products or drugs or cosmetics should be disclosed to the public. This utility ratio has to be based on the number of people who uses it, their alternatives for the commodity, the manner of purchasing it, whether with or without medical practitioner’s consult, the frequent usage of the commodity, the emergency in the purpose of administration of the commodity and the purpose for which maximum people uses it.

Findings

From the table 3, it is clear that 90 percent of the respondents use sanitary napkins rather than other sanitary products. Only 10 percent of the respondents are using biodegradable sanitary pads.

Table 2: Sanitary products that the respondents prefer

<i>Native/Sanitary product used</i>	<i>Sanitary Pad</i>	<i>Biodegradable Sanitary Pad</i>	<i>Total</i>
<i>Rural</i>	<i>13</i>	<i>1</i>	<i>14</i>



	(43.33%)	(3.33%)	(46.66%)
Urban	14 (46.67)	2 (6.67%)	16 (53.34%)
Total	27 (90%)	3 (10%)	30 (100.00%)

Source: Survey

From table 3, only 53.33% of the respondents are aware that the ingredients are not mentioned in the sanitary napkins and 46.67% of them are not aware that the ingredients are not mentioned. It is a sad part that nearly 50% of the users of napkin are not noticing the ingredients. 20 percent of the respondents though they are aware that ingredients are not mentioned and the sanitary napkins are made of toxic substances, they do not believe them. They are in need of certified information, probably from the manufactures to believe them.

Table 3: Whether the respondents are aware that the ingredients are not mentioned in sanitary napkins?

<i>Native/Whether they are aware or not</i>	<i>Yes</i>	<i>No</i>	<i>Total</i>
Rural	8 (26.66%)	6 (20.00%)	14 (46.66%)
Urban	8 (26.67%)	8 (26.67%)	16 (53.34%)
Total	16 (53.33%)	14 (46.67%)	30 (100.00%)

Source: Survey

26.67 percent of the respondents though are aware of the presence of toxic substance being used in sanitary napkins, and not aware of the non-disclosure of components, they demand a certified information to believe the news that they are aware of. Only 23.33 percent of the respondents believe that sanitary napkins are made up of toxic substances even without any certified ingredients label from the manufacturers and in spite of believing the same, they use the same napkins for their comfort.

Table 4: Respondent’s awareness about the hazards of using of sanitary napkins



	<i>Aware that sanitary napkins are made of some toxic substances</i>	<i>Not aware that sanitary napkins are made of some toxic substances</i>	<i>Total</i>
<i>Aware that Ingredients are not mentioned</i>	12 (40.00%)	4 (13.33%)	16 (53.33%)
<i>Not aware that Ingredients are not mentioned</i>	11 (36.67%)	3 (10.00%)	14 (46.67%)
<i>Total</i>	23 (76.67%)	7 (23.33%)	30 (100.00%)

Source: Survey

Table 5: Whether the believe that bleaching agents are used for bringing out the white colour of sanitary napkins?

<i>Awareness of Presence of toxicity</i>	<i>Yes</i>			<i>No</i>			<i>Total</i>
	<i>No</i>	<i>Yes</i>	<i>Certified information is needed</i>	<i>No</i>	<i>Yes</i>	<i>Certified information is needed</i>	
<i>Awareness of Ingredients are not mentioned/ Respondent's Belief</i>							
<i>Yes</i>	2 (6.67%)	6 (20.00%)	4 (13.33%)	1 (3.33%)	1 (3.33%)	2 (6.67%)	16 (53.33%)
<i>No</i>	3 (10.00%)	0 (0.00%)	8 (16.67%)	1 (3.33%)	0 (0.00%)	2 (6.67%)	14 (46.67%)
<i>Total</i>	5 (16.67%)	6s (20.00%)	12 (20.00%)	2 (6.66%)	1 (3.33%)	4 (13.34%)	30 (100.00%)

Source: Survey

The remaining, 76.67 percent of the people, though aware or not of the facts, they need certified information to believe it. (Ref table 4 and 5). From table 7, 60 percent of the respondents are not aware that sanitary napkins are medical products and only 40 percent of the respondents are aware



that sanitary napkins are medical products. In rural area, the percentage of respondents who are not aware is less than the percentage who are aware of it. In urban area, it is the vice versa.

Table 6: Whether the respondents know that sanitary napkins are medical products?

<i>Native/Whether they are aware or not</i>	<i>Yes</i>	<i>No</i>	<i>Total</i>
<i>Rural</i>	3 (10.00%)	11 (36.67%)	14 (46.67%)
<i>Urban</i>	9 (30.00%)	7 (23.33%)	16 (53.33%)
<i>Total</i>	12 (40.00%)	18 (60.00%)	30 (100.00%)

Source: Survey

Table 7: Whether it is necessary to mention the components of a sanitary napkin in order to be aware of the hazardous products used in it?

<i>Native/Whether the ingredients are to be mentioned or not</i>	<i>Yes</i>	<i>No</i>	<i>Total</i>
<i>Rural</i>	13 (43.34%)	1 (3.33%)	14 (46.67%)
<i>Urban</i>	14 (46.67%)	2 (6.66%)	16 (53.33%)
<i>Total</i>	27 (90.00%)	3 (10.00%)	30 (100.00%)

Source: Survey

Table 8: Respondent's alternative for sanitary napkins, if they are receiving an authorized information that, sanitary napkins contain skin-allergic and other disease-causing components.

<i>Native/ Alternatives</i>	<i>Cloths</i>	<i>Menstrual Cups</i>	<i>Organic and biodegradable napkins</i>	<i>Reusable sanitary napkins</i>	<i>Tampons</i>	<i>Total</i>



Rural	2 (6.67%)	2 (6.67%)	7 (23.33%)	1 (3.33%)	2 (6.67%)	14 (46.67%)
Urban	1 (3.33%)	4 (13.33%)	8 (26.67%)	1 (3.33%)	2 (6.67%)	16 (53.33%)
Total	3 (10.00%)	6 (20.00%)	15 (50.00%)	2 (6.66%)	4 (13.34%)	30 (100.00%)

Source: Survey

It can be concluded from table 9 that 50 percent of the respondents, would utilize biodegradable sanitary napkins if they are receiving any authorised information about the ingredients of the sanitary napkins and it is clear that maximum everyone would shift to an alternative. But to the sad part, 10 percent of respondents preferred cloths as their alternative which is still a dangerous option. (Ref table 8). From table 10, 83.33 percent of the people are not aware that testing standards are not updated since 1980.

Table 9: Whether the respondents are aware that the testing standards of napkins in Indian market are not since 1980

Native/Whether they are aware or not	Yes	No	Total
Rural	2 (6.67%)	12 (40.00%)	14 (46.67%)
Urban	3 (10.00%)	13 (43.33%)	16 (53.33%)
Total	5 (16.67%)	25 (83.33%)	30 (100.00%)

Source: Survey

From this graph below, we come to the conclusion that 56.7 percent of the respondents suggest that, as they have a wider option of sanitary products, they need to know the ingredients of a sanitary napkin so that they could choose other options, if they such sanitary napkins contain hazardous, toxic substances. 40 percent of the respondents suggest that it is their right to information to know about the details of the components of the product that they use. 23.3 percent of the respondents suggest that since wider range of people use them, the government is in an



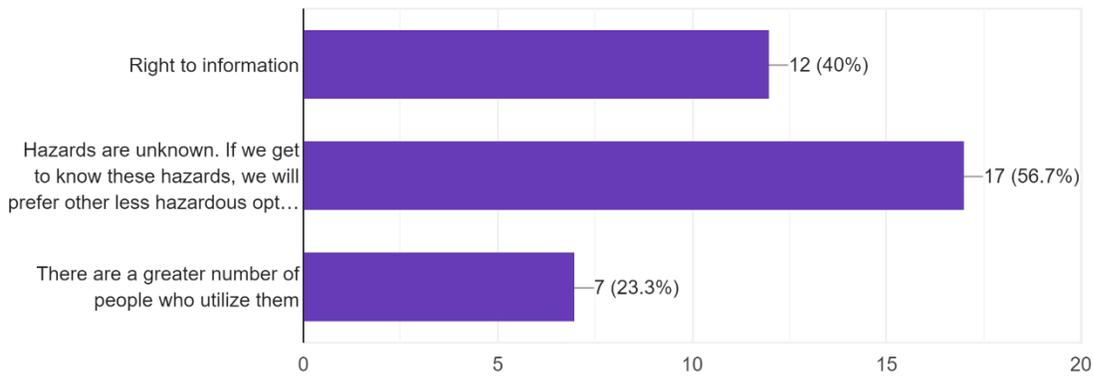
obligation to reveal its components.

Major Findings

- Majority of women utilize sanitary pads as they feel comfortable. 73.34 percent of the women do not believe completely on various researches that conveys the fact that sanitary napkins are made of toxic substances. But they demand the certified information from the government especially the manufacturers. Most of them being aware of such information, they still use sanitary napkin for their comfort.

What are all the reasons you think are now demanding for the disclosure of ingredients in napkins?

30 responses



- But when the question was asked as whether they would shift for any alternatives, if the manufacturers are obligated to mention the ingredients and they mention any toxic substance, except those who are using already bio-degradable napkins, the rest of them preferred some sort of alternatives. Majority of them suggest such alternatives to be as a reason for the obligation vested on government to disclose it’s ingredients.
- Thus, when an authorized person exactly mentions the components, people do not waive their right to choose the best for their life and most of them also demands the same. hat
- 60 percent of the respondents who utilize napkins are not aware that they are medical products and this shows that napkins are not treated like that of any other medicine by maximum respondents.

Recommendation

There need to be new standards set up for the disclosure of the ingredients in a drug or medicine



or cosmetics. Simply as because they come under the category of such commodities, they should not be exempted from the purview of disclosing their ingredients or components. The number of people who use it is to be considered.

The quality testing standards of BIS is to be periodically updated which would in turn help in the further development of feminine-friendly sanitary napkins as most of the people consider it to be comfortable.

Conclusion

Human beings are provided a personality which is accompanied by the character of choice, which is a unique feature that other living organisms are not provided with. Hence, such a character should not be deprived by unreasonable classification. People right to easy access of information cannot be neglected and hence, the products which are widely used by the people, whether it is a medical product or cosmetics or consumer product or a drug, it's an obligation upon the manufacturers to display their components.

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