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REGULATORY, USES AND SAFETY ASPECTS OF MICROBEADS SUSTAINED RELEASED SYSTEM IN COSMETICS

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Abstract :
Microbeads, commonly found in cosmetics and personal care items, have attracted considerable interest due to their functional advantages, especially in sustained-release delivery systems. These tiny polymeric particles, which can encapsulate active ingredients, improve product effectiveness by allowing for a controlled and prolonged release while reducing negative side effects. Their growing application in exfoliants, cleansers, creams, and related products has fueled expansion in the global market; nevertheless, the environmental and health risks tied to synthetic microbeads have raised concerns as well. This review brings together existing knowledge about the different types, uses, regulatory frameworks and safety assessment. Regulations from India, the United States, the European Union, United kingdom, China, Thailand and South Korea are analyzed to emphasize the developing compliance requirements and the difficulties that manufacturers encounter.

Keyword : Microbeads, Sustained-release delivery systems, Cosmetics and personal care products, Regulatory frameworks, Safety assessment .

INTRODUCTION

Cosmetics are preparations that have been used by humans for a long time, primarily for regenerative purposes, and are appreciated by both genders. They can be defined as preparations that are typically used externally and can be formulated from a single or combination of substances obtained from either natural or artificial sources.[1] According to Section 3(a) of the Drugs and Cosmetics Act, 1940 “Cosmetic can be explained as a product anticipated for coating, gushed, dispersed or sprayed on, or instigate into, or else dermally used on the humans or any part of the things just mentioned for cleansing, embellishing, enhancing attractiveness, or changing the looks, and includes any product intended for a component of cosmetic”.[2] The use of microbeads is becoming more popular due to improvements in microsphere quality and functionality, an accordingly, they have increasingly been used in food science and separations and as exfoliants in cosmetics and personal care products.[3] Multiple unit dosage forms such as microspheres or micro beads have gained in popularity as oral drug delivery systems because of more uniform distribution of the drug in the gastrointestinal tract, more uniform drug absorption, reduced local irritation and elimination of unwanted intestinal retention of polymeric material, when compared to non-disintegrating single unit dosage form. Microbeads are small, solid and free flowing particulate carriers containing dispersed drug particles either in solution or crystalline form that allow a sustained release or multiple release profiles of treatment with various active agents without major side effects.[4] Microbeads are commonly found in products like facial scrubs, body washes, toothpastes, and creams.[5]

Personal care companies (including Unilever, Target, Johnson & Johnson, Procter & Gamble, and L’Oreal) were somé of the largest producers of microsphere-containing products. In 2014, the global market for microspheres had attained $2.3 billion and was expected to reach $3.5 billion by 2020, registering a compound annual growth rate (CAGR) of 7.8% from 2015 to 2020. The medical technology market segment for microspheres alone was expected to grow from $504 million in 2015 to $810 million in 2020, at a CAGR of 10.0% from 2015 to 2020. However, as synthetic polymers have found widespread application in the global market, they have become more ubiquitous in the environment, leading to increasing concern about their environmental impacts.[6]

TYPES OF MICROBEADS

There are two types of microbeads; microcapsules and micrometrics. Microcapsules are those in which entrapped substance is distinctly surrounded by distinct capsule wall, and micro matrices are those in which entrapped substance is dispersed throughout the matrix. Microbeads are sometimes referred to as microparticles. Microspheres can be manufactured from various natural and synthetic materials. Microbeads play an important role in improving conventional drugs' bioavailability and minimizing side effects.[7-10]

USES OF MICROBEADS

Microbeads have been seen in personal care products such as deodorants, toothpaste, shaving creams etc. Apart from personal care products they are also found in consumer products such as printing toner, cleaning products. They are also part in industrial products such as plastic blasting, textile printing and medical applications. Some of these products are used on a daily basis in our houses that could lead to around 95,000 microbeads particles released to water, as per study. A Canadian Cosmetic, Toiletry, and Fragrance Association (CCTFA) survey says that annual volume of microbeads within Canada ranged from 30 Kg to 68,000 kg per year.[11]

1.In order to provide exfoliation, microbeads are added to toothpaste, face scrubs, soaps, and other cosmetics and personal hygiene items. To make over-the-counter medications simpler to swallow, they could be added.

2.Microbeads are utilised in fluid visualisation, process troubleshooting, microscopy techniques, fluid flow analysis in biological and health science research. [12]

3.Creams and lotions have a smooth texture and are easily spread because of the ballbearing effect caused by sphericity and uniform particle size. Roundness and smoothness can act as lubricants. Cosmetic goods look more appealing when they contain coloured microsphere.[13]

MICROPLASTIC :

Plastic debris is a contaminant of emerging concern that is often discussed in society, science, the media and policy. It is visible to the naked eye and easily linked to our daily lives, which explains part of the public concern. One size fraction of plastic debris is called microplastics.[14-16] The vast majority of microplastics come from the breakdown of larger plastic waste. The diversity of sources is reflected in the heterogeneity of microplastic properties (shape, size, density and polymer type),[17- 19] transport characteristics, and in vivo and in vitro biological effects and therefore also in its risks. [20]

The presence of contaminants in microplastic adds to this diversity.[21] Together with a high probability of being ingested and absorbed by a large range of species, this diversity in multiple dimensions has contributed to the concern that microplastics may constitute a risk to humans and the environment.[14,22-28] Microplastics have been detected in air, soil, fresh water, drinking water, the oceans, aquatic and terrestrial biota, food products, and human placenta and stools.[29]

REGULATIONS OF COSMETIC MICROBEADS:

The Bureau of Indian Standards (BIS) has categorised microbeads as “unsafe” in the year 2017 and proposed a ban on its usage in cosmetics products, however, initially slated to come into effect in the year 2020, the ban has not been implemented so far.[30] Indicating a lackadaisical approach towards this problem which needs prompt corrective action in the form of regulatory framework. Policy and regulations from a few jurisdictions are briefly discussed below before moving on to suggestions for a microplastics framework for India.

The increase in plastic pollution needs a collaborative effort from “regulators, scientists and the general public about how to deal with this problem that affects ecosystems and human health”. [31] Due to inadequate awareness among the masses about the dangers of microplastics, enough actions are not being taken to regulate it at all. Before the situation gets any worse, prudent regulatory actions must be taken, the results of which can be observed quickly. The problem of microplastics in India is dire, with an estimated release of “around 391,879 tones of microplastics in the environment by the end of year 2024”, which is only set to increase. The Central Pollution Control Board (CPCB) has also “acknowledged the presence of microplastics in India’s water bodies and organisms, primarily entering through sewage, wastewater, and surface runoff, due to inadequate filtration in treatment systems and contributions from plastic infrastructure”.[32] In terms of composition, the majority of microplastic pollution in India is attributed to the “textiles market, which is dominated by polyester synthetic fibres and the personal care products, 45% of which contains microbeads”.

USA: The Microbead-Free Waters Act of 2015 was passed by the US Congress to handle the issue of “microbeads present in the water supply, prohibiting its manufacturing, packaging, and distribution in rinse-off cosmetics and personal care products along with non-prescription drugs containing plastic microbeads”.[33] The law aims to reduce microplastic pollution by eventually phasing-out the use of these microbeads in certain products.

UK: The UK government first pledged to ban plastic microbeads in September 2016, following a US ban in 2015. The Environmental Protection (Microbeads) (England) Regulations of 2017 was enacted by the Parliament in 2018, banning manufacture and sale of plastic microbeads used in cosmetics and personal care products. The aim of the law was to protect the environment and the food supply from further pollution by microbeads and to build consumer confidence in products without these harmful particles.[34]

EU: The EU issued a Commission Regulation (EU) 2023/2055 in the year 2023 to “regulate synthetic polymer microparticles also known as microplastics, as substances on their own and in mixtures”. This framework falls under the “Registration, Evaluation, Authorization and Restriction of Chemicals or REACH regulation, which protects human health and the environment from the risks that can be posed by chemicals”.[35]

CHINA: The Ministry of Ecology and Environment had implemented a phased ban on production and sale of chemicals containing plastic microbeads from the year 2020 onwards in a bid to prevent plastic pollution. Production of daily chemicals containing plastic microbeads, such as rinse-off cosmetics including facial cleansers, shampoos, bath lotions, soaps, and toothpastes, was prohibited nationwide by December 31, 2020.Sales of these products were banned by December 31, 2022, providing a buffer for inventory depletion and supply chain adjustments. [36]

THAILAND: The import, manufacture, and sale of rinse-off cosmetics containing plastic microbeads has been banned by the Ministry of Public Health since the year 2020 to reduce plastic waste and protect the marine environment .The policy, published in the Royal Gazette on December 24, 2019, aligns with Thailand's push against plastic pollution, including oxo degradable plastics, promoting environmental safeguards for ecosystems and public health.[37]

SOUTH KOREA: The Government has banned production and sale of microbeads contained in rinse-off cosmetics in the year 2017. Additionally, a Special Act on Microplastic Reduction and Control has been proposed with the objective to ban manufacture, import, and sale of products with excessive primary microplastics, including spanning cosmetics, health foods, consumer chemicals, quasi-drugs.[38]

INDIA: The regulatory framework in India must be inclusive and all-encompassing in nature containing a suitable definition of microplastics, so that maximum restrictions can be placed on a variety of pollutants i.e. microbeads, microfibres , microspheres, etc. The provisions must contain labelling requirements on products, standard of acceptable levels of microplastics in water, air, soil and food items, along with additional requirements on industries to reduce microplastics. Greenwashing of products to be strictly restricted and ban on intentional microplastic additives in wash-off cosmetic products. Compliance mechanism for industry, to ensure all the requirements are strictly followed, must also be incorporated so that the regulation does not remain a mere toothless document.

Global Regulations on Plastic Microbeads:[33-38]

Country	Law/Regulation	Key Clauses / Provisions	Year Enforced
USA	Microbead-Free Waters Act of 2015	• Ban on manufacturing microbead cosmetics (2017) • Ban on sale (2018) • Defines microbeads <5mm in rinse-off cosmetics	2015
UK (England)	Environmental Protection (Microbeads) Regulations 2017	• Ban on manufacture (Jan 2018) • Ban on sale (June 2018) • Applies to rinse-off cosmetics	2018
EU	Commission Regulation (EU) 2023/2055	• Ban on placing products with added microplastics on market • Applies to cosmetics, detergents, paints, fertilizers • Definition: synthetic polymer particles<5mm	2023
China	Microbead Ban (Ministry of Ecology & Environment)	• Phased ban on production (2020) • Ban on sale (2021) • Targets rinse-off cosmetics	2021-2022
Thailand	Ministry of Public Health Ban	• Ban on import, manufacture, and sale • Applies to rinse-off cosmetics	2020
South Korea	MFDS Microbead Ban	• Ban on production and sale • Applies to rinse-off cosmetics	2017
India	Bureau of India Standards (BIS)	• Ban on its usage in cosmetics products	Not been implemented so far

Table no 1:- Global Regulations on Plastic Microbeads

WAY FORWARD

While research efforts are ongoing to tackle the issue of microplastics and "scientists are exploring plastic-eating microorganisms, along with plastic alternatives, individuals can advocate for reduced plastic manufacturing and more recycling."[39] Better choices can be made by shifting to eco- friendly alternatives such as bioplastics, which are biobased and biodegradable plastics, eventually reducing the use of fossil-based plastic in a bid to achieve sustainability. Meanwhile, policy and regulatory efforts are an aspect that can be strengthened by further putting restrictions in place and bring about a shift in governance. Management of microplastics through a multidimensional approach including technological innovation, improved waste management practices, shift towards sustainable materials and consumption along with stricter regulation seems to be the best foot forward in tacking the menace of microplastic pollution.

SAFETY :

Uses of microplastics in cosmetics have emerged as a major environmental concern. At the same time the popularity and worldwide prominent sale of these cosmetic products containing microplastics make it difficult to eliminate those products from use. Hence a safer substitute is required to replace these environmentally hazardous constituents. World plastics production has experienced almost constant growth for more than half a century, rising from approximately 1.9 tons in 1950 to approximately 330 million tons in 2013[40]. A recent study had revealed that 5.25 trillion plastic particles weighing some 269,000 tons are floating on the surface of the sea [41]. The option to remove the accumulated plastic load from the ocean is time consuming, costly as well as non viable on some aspects. Moreover, this operation will simultaneously remove the normally abundant microscopic yet significant planktons and other flora and fauna from the food chain which may disrupt the entire marine ecosystem [42]. Thus, the only option is to minimize and if possible cease the entrance of more plastic in the lakes, rivers, seas and ocean. Ocean Conservancy, Plastic Pollution Coalition, 5 Gyres, etc organizations are working with the scientists, politicians and industries to aware the public about the problems related with the use and discharge of microplastic beads [43]. As part of the overarching contribution in providing sustainable solutions, representatives of plastics organizations from around the globe have announced a 'Declaration for Solutions on Marine Litter' at the 5th International Marine Debris Conference in Honolulu. The declaration describes steps that the industries will take and suggest approaches and platforms for global cooperation and future partnerships. As of 2015, 60 world plastic organizations from 34 countries signed the pledge. Different multinational companies like Avon, Beiersdorf, Colgate-Palmolive, Henkel, L' Oréal, Oral B, Procter and Gamble, Unilever, etc had announced that they would phase out the use of microplastics in their cosmetics products. Many other personal care product companies are voluntarily phasing out the use of microplastics in their products. Chinese plastic industry associations are the conglomerate of major plastic producers of the world. They have recently joined the global effort to prevent used plastics from entering the environment. New legislations are thus required to chalk-out strategies in manufacturing sustainable and biodegradable plastics, handling plastic products more responsibly after utilizing them during their life cycle through proper recycling, safe disposal and extended responsibility from the producers' end. A possible alternative to traditional microbeads for cosmetics and personal health care products was suggested to be the biodegradable polyhydroxyalkanoate (PHA) microbeads. [44] Being soluble PHAs minimize the potential threats of microplastic beads in the environment. PHAs can biodegrade in either aerobic or anaerobic environments. The authors have also demonstrated the faster biodegradation rate of PHAs in comparison with other traditional synthetic polymers. Havens et al. [45] have applied for a patent on the method for reducing marine pollution using PHA microbeads. They have claimed that the described method by incorporating PHA microbeads into personal care formulations such as exfoliants, cosmetics and toothpaste would reduce aquatic pollution significantly

CONCLUSION

Sustained-release microbeads constitute a significant improvement in cosmetic formulations because they increase product efficacy, improve user experience, and allow for controlled release of active ingredients. Their widespread usage in industrial, cosmetic, and scientific applications demonstrates their usefulness, but growing worries about human exposure and environmental contamination have led to tighter international restrictions and more scientific focus. Although their methods differ, the comparison of regulatory regimes shows that various areas prioritise safety, transparency and compliance. The need for biodegradable microbeads and more robust, welldefined regulatory frameworks is growing as the cosmetics sector shifts to safer and more ecologically friendly formulations. Sustained-release microbeads will continue to be safe, efficient, and ecologically friendly ingredients in cosmetic products if technological developments are in line with legal standards.

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