# DISCUSSION PAPER

# REMOVING COSMETIC PRODUCTS AND INGREDIENTS FROM INDUSTRIAL CHEMICALS REGULATION

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**Introduction**

Medicines Regulatory Solutions Pty Ltd has been engaged by Accord Australasia Ltd to provide advice on structural change to the regulation of cosmetics[1] under the industrial chemicals regulatory scheme.

This paper is designed to promote discussion on the manner in which cosmetics are dealt with under the current industrial chemicals regulatory scheme by examining the scheme, outlining major issues arising from these arrangements and detailing some possible approaches for future change.

Comment on the paper's evaluation of the system of controls will assist in promoting the case for changes to the current arrangements.

**Limitations**

The scope of this paper deals with the current regulatory framework relating to cosmetic products and their ingredients and is not intended to include consideration of current Australian control requirements for therapeutic sunscreen products. This paper does not constitute legal advice.

**The Current System of Cosmetic Regulation**

Current Australian controls for cosmetics primarily reside at the federal level and involve a suite of controls that are the responsibility of three regulators, the Therapeutic Goods Administration (TGA), the Australian Competition and Consumer Commission (ACCC) and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

State and Territory involvement in the regulation of cosmetics is limited to matters that are the responsibility of State and Territory Departments of Fair Trading. However, a further important consideration are the public health access control issues in instances where products that are indicated for cosmetic purposes contain a substance included in the schedules of the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP). The responsibility for including substances in the SUSMP rests with the Advisory Committee on Chemical Scheduling (ACCS) as the body that provides appropriate public health risk assessment recommendations to the relevant Commonwealth delegate.

In broad terms the roles of the three federal regulatory agencies can be categorised as follows –

<u>TGA</u>

The TGA does not regulate cosmetics per se unless they want to make specific therapeutic claims. The *Therapeutic Goods (Excluded Goods) Order No. 1* – 2011 is the legislative instrument used by the TGA to exclude products meeting certain cosmetic requirements from its regulatory scheme.

<u>ACCC</u>

The ACCC is considered to be the primary regulator for cosmetics and is responsible for the consumer safety and ingredient labelling aspects of cosmetic products. These control aspects are given effect through a mandatory standard under the provisions of the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulation* 1991 and are further enhanced through the ACCC's product safety

[1] For the purposes of this paper, cosmetics and personal care items are considered to be the same.

requirements and system of adverse events reporting which are mandatory under Australian Consumer Law.

NICNAS

NICNAS is the agency responsible for the *Cosmetics Standard* 2007, a document developed under the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989. In terms of its objective, this standard sets out permissible claims for various types of cosmetics, as well as referencing the Australian and New Zealand Standard dealing with the evaluation and classification of sunscreen products. Cosmetic ingredients are also subject to the requirements of NICNAS's notification and assessment requirements as specified for industrial chemicals.

**The Issue for Industry**

On face value, it appears that each agency involved in the regulation of cosmetics has its own distinct roles and responsibilities. However, a closer examination of the current regulatory framework provides a clear indication that the scheme does not reflect a best practice control model.

Industry's view is that the current cosmetics regulatory scheme is inefficient and prohibitive in terms of its ability to facilitate the introduction of new and innovative ingredients and products. This is primarily based on the fact that cosmetic products and ingredients are subject to the requirements of the industrial chemicals regulatory framework, a scheme for which the objectives do not align with the low risk regulatory burden posed by these products and their ingredients.

While general agreement exists that cosmetics should be regulated, significant ongoing concerns have been raised by industry as to the appropriateness of the increased level of regulatory intervention that exists under the current framework of controls.

**The System of Controls – Rationale**

Cosmetics are a significant item of commerce in the Australian marketplace. In terms of industry statistics and market size, the Cosmetic and Toiletry Retailing Market Research Report (July 2015) states that the cosmetics and toiletries retail industry generates revenue of $4bn annually and employs approximately 18000 people. Annual Market growth of 2.1% has occurred since 2011 which has been largely attributed to technological advances within the industry, as well as consumers' willingness to purchase an increasing range of complex formulated products and premium green products.

Globally, Australian cosmetic account for 1.3% percent of the world market.

Cosmetic control objectives are designed to mitigate risk, primarily through ensuring cosmetic products are formulated with ingredients that do not cause harm, are labelled in a manner that clearly informs the user of the product's contents and ensures that, in applicable circumstances, claims for cosmetics are regulated appropriately.

From a strategic perspective, industry considers the purpose of the current regulatory framework dealing with cosmetic products and ingredients is to ensure their safety, quality and efficacy. In circumstances where environmental concerns around cosmetic products are raised, these can be adequately managed by the Department of the Environment as they will be subject to the requirements of the Department's risk management framework.

**Safety**

The ACCC, as the primary regulator, possesses a sufficient suite of controls to adequately address matters that deal with the safety aspects of cosmetic products. These controls include requirements for cosmetic ingredient labelling under the *Trade Practices (Consumer Product Information Standards)(Cosmetics) Regulations 1991*, a mandatory adverse event reporting regime for cosmetic suppliers and various post-market compliance activities which can include regulatory audits, cosmetic product surveys and national surveillance programs. In terms of its approach to regulation, it is important to note that the ACCC has adopted the European Union (EU) approach to product liability and safety.

In addition, safety-related matters identified by the ACCC which are outside their legislative reach, such as matters relating to some specific public health issues, are effectively dealt with by referral to appropriate bodies. This can include committees with the appropriate risk assessment knowledge such as the Advisory Committee on Chemical Scheduling (ACCS), for relevant considerations and subsequent controls under the SUSMP.

**Quality**

Ensuring cosmetics incorporate a level of quality that prevents harm to the user is an integral part of the control framework. The quality aspects of cosmetics must be such that products are free from defects and contain ingredients that meet specified standards. Products that are of a sub-standard quality impact on consumer trust and undermine overall confidence in the market.

The Department of Agriculture and Water Resources also places requirements on the importation of cosmetic products and their ingredients. These biosecurity measures stipulate requirements for finished cosmetic products with an animal component of less than 20% and raw ingredients, partially manufactured products and finished products with an animal component of greater than 20%.

**Efficacy**

Matters concerning the efficacy of cosmetic products and their ingredients are dealt with by the ACCC under the false and misleading conduct provisions of the Australian Consumer Law. In addition, should it be required, relevant standards can be introduced by the ACCC under its legislative framework to address new or unique compliance issues.

From a strategic viewpoint, it is reasonable to assert that the main objectives of the cosmetic regulatory framework, that is, ensuring the safety, quality and efficacy of cosmetic products, can be satisfactorily achieved through the legislative controls and post-market compliance and surveillance activities undertaken by the ACCC.

**Cosmetic Products and Ingredients**

Finished product that is either manufactured locally or imported is seen as the norm in terms of the Australian market sector for cosmetics. As previously stated, the safety, quality and efficacy requirements for these products are adequately controlled by the ACCC and through public health controls under the SUSMP.

If the level of regulatory oversight provided by the ACCC is seen as appropriate, then the question to be considered relates to the necessity for additional controls as provided by NICNAS through the *Cosmetics Standard 2007* and its capture of cosmetic ingredients under the industrial chemicals legislative framework.

Notwithstanding any regulatory imperative to retain the Standard in terms of its ability to add value to the legislative scheme, a major issue remains with the current regulatory arrangements. Specifically, this relates to any continued requirement for NICNAS to focus its efforts on the regulation of products, as opposed to chemical ingredients. This requirement appears entirely inconsistent with NICNAS's role as a notification and assessment agency.

Further, an argument can be mounted that, based on the risk profile of cosmetics as a class of product, there is very little justification for any form of pre-market intervention by any agency. Comparisons with other existing pre-market regulatory schemes such as those undertaken by the TGA and Australian Pesticides and Veterinary Medicine Authority (APVMA) are valid. These involve the assessment of classes of product with a significantly higher risk profile and highlight an inconsistency which supports the argument that cosmetic products and their ingredients are subject to more than minimum effective regulation.

An examination of the controls around cosmetic ingredients also highlights that the level of said controls are not commensurate with any potential risk. Removal of cosmetic ingredients from the industrial chemical legislative scheme would not undermine the overall level of regulatory oversight as these substances would be subject to the requirements of the ACCC's legislative scheme. The likelihood of a novel and unique cosmetic ingredient requiring inclusion on the Australian Inventory of Chemical Substances (AICS) is extremely low given that Australia accounts for approximately 1.3% of the world cosmetic market. If this were to occur, then referral of any such substance to the ACCS to establish any public health and access control requirements would be an appropriate risk management process.

To further assess the appropriateness of the current regulatory arrangements, a critical evaluation of the current regulatory scheme against recognised principles and performance metrics has been undertaken to gain some insight as to whether the current level of regulatory "touch" is appropriate.

The table below contains a set of best practice principles for regulators developed by the New Zealand Treasury and obtained from sources such as the World Bank, the Organisation for Economic Co-operation and Development (OECD) and the Asia Pacific Economic Co-operation (APEC).

| Principle | Comment |
|---|---|
| **Proportionality** | The burden of rules and their enforcement should be proportional to the benefits that are expected to result. This would include that a regime is effective in meeting its objectives and that any change has benefits that outweighs the costs of disruption. One indicator that this principle is being met might be the presence of a cost-benefit regulatory framework and evidence of risk-based decision-making by regulators. |
| **Certainty** | The regulatory system should be predictable to provide certainty to regulated entities, and be consistent with other policies. There can be a tension between certainty and flexibility. A principles or performance- based regime that provides for safe harbours such as deemed-to-comply standards tries to resolve this tension, but ensuring both attributes are optimally reflected is a challenge. |

| Principle | Comment |
|---|---|
| **Flexibility** | A regulatory regime is flexible if the underlying regulatory approach is principles or performance-based, and policies and procedures are in place to ensure that it is administered flexibly, and non-regulatory measures, including self-regulation, are used wherever possible. |
| **Durability** | The regulatory system has the capacity to evolve to respond to new information and changing circumstances. Flexibility and durability are closely related; a regime that is flexible is more likely to be durable, so long as effective feedback systems are in place to assess how the regime is working in practice and to adjust systems and processes accordingly. |
| **Transparency and accountability** | Rules development and enforcement should be transparent. In essence, regulators must be able to justify decisions and be subject to public scrutiny. This principle also includes non-discrimination, provision for appeals and sound legal basis for decisions. |
| **Capable** | The regulator has the people and systems necessary to operate an efficient and effective regulatory regime. A key indicator is that capability assessments occur at regular intervals, and subject to independent input or review. |

Source: New Zealand Treasury (2012).

These principles will have a varying degree of relevance to the regulatory scheme as a whole, as well as the individual agencies that are responsible for the scheme. However, an inability to clearly recognise the objectives of these principles in the day-to-day operations of the scheme's regulators indicates a lack of transparency and robustness associated with the current framework.

**How Appropriate are the Current Arrangements?**

An assessment of each principle against the current industrial chemical controls dealing with cosmetic products and their ingredients would seem to support ongoing concerns as identified by industry.

Proportionality

The presumption around proportionality as a principle in best practice regulation can be defined as follows. Is the burden imposed on the cosmetics industry by the requirements of the industrial chemical control framework proportionate with any benefit (perceived or real) in establishing and maintaining said controls? Indications would suggest that the enactment of the *Cosmetics Standard* in 2007 and the capture of cosmetic ingredients in the industrial chemicals scheme unnecessarily complicates the regulatory framework by expanding the number of agencies involved in the regulation of cosmetic products and their ingredients. Further, it appears the basis for increasing the regulatory burden on industry was a result of NICNAS's interpretation of cosmetic regulation under its Low Regulatory Concern Chemicals (LRCC) reform

program. This interpretation and the enactment of the *Cosmetics Standard 2007*, is inconsistent with the objectives of the LRCC reforms which advocated for a lighter regulatory "touch" in this area.

This was specifically identified in the Productivity Commission (PC) Research Report into Chemical and Plastics Regulation when it commented on the recognition of NICNAS's efficiency and effectiveness principles –

"The Commission accepts that some worthwhile improvements have been made in the design and administration of the scheme, which have had the effect of more appropriately balancing the costs of assessment with the benefits of reducing the risks posed by industrial chemicals. But in some cases, such as the administration of chemicals of low regulatory concern, elements of undue risk aversion are creeping back into the system."(p59).

Certainty

The enactment of the *Cosmetics Standard 2007* and the capture of cosmetic ingredients under industrial chemical framework increases the unpredictability of the regulatory scheme dealing with cosmetic products and their ingredients. The addition of a third agency into the cosmetic product regulatory arena effectively fragments the suite of controls through the development of policy in isolation, thereby increasing the compliance burden on industry. An additional consideration around the introduction of a new legislative instrument and the inclusion of an additional regulatory framework for cosmetics is the inconsistency these arrangements created in relation to other internationally recognised regulatory frameworks that deal with cosmetics. Barriers to trade with major trading partners such as the European Union, the United States, Canada, Japan, the ASEAN economies and New Zealand created by this inconsistency significantly affects the ability of the Australian cosmetic industry to effectively compete in the world market.

A direct example of the effect the current regulatory arrangements have had on industry is highlighted by the following.

A regulatory consultant advises: "Every time a cosmetic is considered for Australia, I have to assist to see if we face issues. If materials are used above 1% and/or a low volume exemption is not feasible, the product is then not considered for sale in Australia. And therefore, the Australian consumer loses."

"NICNAS and AICS have been quite a challenge for cosmetic ingredients for our business. Many times, the use levels are so low, that our ingredient suppliers have no intention to list with NICNAS. It costs more time and capital than the little business they would gain. Therefore, I am left with obtaining data and assessing whether I can use a low volume or <1% cosmetic exemption. Once that is complete, I then have to monitor EACH AND EVERY PRODUCT SKU that will be imported into Australia from Sept 1 to August 31. Then assemble the calculations and file the appropriate NICNAS exemption form with our annual NICNAS license renewal. This exercise is not value added. These cosmetic ingredients are available for use in the EU without restriction. This is not improving consumer safety. This is a cost and unnecessary burden to enter the market."

Flexibility and Durability

The introduction of the *Cosmetics Standard 2007* has decreased the flexibility of the regulatory scheme and its ability to clearly enunciate its policy objectives with respect to controls over cosmetic products and their ingredients. The piece-meal nature of the system and its associated rigid approach to regulated

entities stifles innovation and the ability for industry to introduce new products. The following is an example of the current regulatory burden and its effect on industry.

One multinational company advises that: "We spend quite some time and effort meeting their (NICNAS) requirements. We have spent over the last 24 months - $140,000 on consultants fees (mostly related to NICNAS), $44,600 on NICNAS registration fees, and $46,800 on chemical assessments. It is hard to put a cost or quantity on corporate time "Regulatory Affairs and R&D" in Australia, and the US/EU in meeting our requirements under the current legislative arrangements. However we do whatever is required. Due to the changing nature of cosmetics, currently we have 16 ingredients that we have had assessed over the last 7 years (at $15,000 + expenses say $20,000 each) due to them going over the 100kgs per annum limit at some time. Of these, 6 and possibly 8, are now used much less and are under this assessment quantity level, therefore making the assessment effectively a waste of time and money. The net result is we spend a great deal of time and effort assessing ingredients that are, in the end, found to be perfectly acceptable (as we would expect) and this therefore proves that the process we follow on cosmetic ingredients in Australia, does not add any value and if anything only confirms that the safety and regulatory regime followed by the cosmetics companies (protecting their own customers), and conforming to international standards, is quite sufficient."

A major consideration concerning the rigidity of the system is the difficulty involved in moving to a more proportionate model through processes such as the adoption of recognised standards and deemed-to-comply provisions. The use of internationally-recognised standards would increase the user-friendliness of the scheme and provide consistency with the Government's policy of Accepting Trusted International Standards. The use of internationally-recognised Standards will be discussed in more detail later in this paper.

Transparency and Accountability

The basis for the decision taken by NICNAS to amend the cosmetics regulatory scheme in 2007 remains unclear. The question that requires consideration in terms of this regulatory principle and the capture of cosmetics in the industrial chemicals framework hinges around the justification for these arrangements.

Closer examination of the content of the *Cosmetics Standard* shows that its intent is to ensure that:

- Face, nail and skin care products imported/manufactured and marketed in Australia which have a primary cosmetic purpose and which also contain a sunscreen component (secondary sunscreen products) comply with the relevant Australian and New Zealand standards for sunscreens; and
- Anti-bacterial and anti-acne skin care products, oral hygiene products and anti-dandruff hair care products imported/manufactured and marketed in Australia can only be presented in certain ways (permitted and non-permitted claims).

The question dealing with the justification for the arrangements can be examined in two parts -the first being the need for such a standard at all and, if such a need is established, the appropriateness of including the Standard as part of the industrial chemicals legislative framework.

Capable

A key indicator around the robustness of any regulatory system relates to the capabilities of the entities that are responsible for the system. This essentially translates to the efficiency and effectiveness of the regulators. Additional considerations relate to the role of the regulator in relation to the objectives of the scheme and whether the activities undertaken by the regulator are actually part of its defined core business activities.

It is clear that the role of NICNAS is that of a notification and assessment agency. This is confirmed through examination of the objectives of the *Industrial Chemicals (Notification and Assessment) Act 1989* and a review of the website dealing with the role, governance and structure of NICNAS. While the objectives of the Act make mention of standard setting and enforcement in relation to cosmetics, this role would seem inconsistent with the primary functions of NICNAS where downstream referral to regulators and/or risk managers in the areas of public health and environmental protection are the norm.

The inconsistency identified in terms of regulating cosmetic products and ingredients, together with the defined core business activities of NICNAS raise the question as to whether this is an agency that can undertake this function efficiently, effectively and transparently.

This assertion is highly relevant given the previous discussions relating to the suite of controls, as well as the compliance and surveillance activities that the ACCC utilises in its role as the primary regulator for cosmetic products in Australia.

**Previous Reviews**

In 2008, the PC released a Research Report into Chemicals and Plastic Regulation reviewing in detail the regulatory arrangements concerning cosmetics. As a result of this review the PC made the following comments -

"The Commission is concerned with the overlap and confusion that results from having more than one regulator involved in cosmetics regulations and, as noted, it is recommending NICNAS be reconstituted to focus solely on scientific assessment of the hazards and risks of industrial chemicals." (p 118).

"The Commission considers the most effective and efficient option is to transfer the standard to the ACCC to administer. It contains the relevant compliance monitoring and enforcement powers and mechanisms. As well, it already regulates similar issues through its consumer information standards and other regulations on product claims." (p 118).
With the following recommendation being made –

Recommendation 5.5 - The Australian Government should transfer responsibility for the administration and enforcement of the *Cosmetics Standard 2007* (Cwlth) from NICNAS to the ACCC.

Despite a detailed assessment of the regulatory arrangements being included in the final report of this major review into chemical regulation, together with a clear recommendation for change, no definitive action has been taken to progress this issue and address the inadequacies of the system of controls.

**Trade and Trusted International Standards**

Agreements such as the Trans-Pacific Partnership (TPP) specifically identify cosmetics as an item of commerce that are currently subject to inconsistent regulatory treatment and, as such, have been included within the provisions of the TPP that deal with Technical Barriers to Trade (TBT). Annex 8B of the TBT details the requirements to facilitate aligning the cosmetic controls of signatories while maintaining a high

standard of product quality and safety. Any changes to the current Australian system of controls should reflect legislative control models that ensure trade barriers are minimised and promote innovation and ease of access to local and overseas markets. The current Australian regulatory system causes cosmetics to be treated uniquely compared to the controls imposed by Australia's major trading partners. This is detrimental to the industry and does not reflect the risk profile of cosmetic products and their ingredients.

Adopting trusted international standards and improving regulation forms part of the Government's policy framework relating to regulatory reform. The recent release of the Government's National Innovation and Science Agenda confirms this policy position. The use of trusted standards to support a more flexible Australian system of controls for cosmetic products and their ingredients would provide a mechanism to ensure an appropriate level of legislative oversight while facilitating closer alignment with the regulatory systems of Australia's major trading partners.

Relevant examples in relation to existing international assessments of cosmetic ingredients would be the use of data from recognised international scientific authorities such as the US Cosmetic Ingredient Review (CIR) and the European Union (EU) Scientific Committee on Consumer Safety (SCCS). In addition, acceptance of verified international Standards such as those developed by the International Fragrance Association (IFRA) would improve alignment with established overseas regulatory systems.

Further, regulations based on the EU Cosmetic Regulation have been adopted by the Association of South-East Asian Nations (ASEAN), New Zealand and South Africa. Processes such at this highlight the difference in the approach to cosmetic controls taken by Australia compared to major trading partners.

From a trans-Tasman trade perspective, the PC found in its recent Research Report on Mutual Recognition Schemes that there was a case to remove the permanent exemption dealing with hazardous substances, industrial chemicals and dangerous goods so as to further reduce barriers to trade between Australia and New Zealand. This includes cosmetics.

The following specific comments by the PC concerning the current permanent exemption are relevant –

"The Commission has not received any evidence to suggest that the outcomes achieved by Australia and New Zealand's regulatory regimes for hazardous substances, industrial chemicals and dangerous goods substantially differ, or that mutual recognition of these goods would pose a real threat to public health and safety or the environment in either country." (p99).

"Significant costs could result from ignoring trans-Tasman regulatory cooperation in current ongoing reforms (chapter 7). A program of regulatory cooperation should commence immediately with the objective of removing the permanent exemption by end 2018 (by which point reforms to NZ's work health and safety regime and Australia's NICNAS will have been completed)."(p99).

**Summary**

The information provided in this paper on the current Australian legislative scheme dealing with cosmetic products and their ingredients indicates that there is no valid argument for treating them uniquely and that, the current level of controls imposed on this low-risk class of products translates to over-regulation.

There is clear evidence that the number of agencies involved in maintaining regulatory control over cosmetic products and their ingredients needs to be rationalised. Examination of the respective roles of each regulatory agency shows that the ACCC is considered the primary cosmetic regulator and the role of the TGA is focussed on supporting controls in relation to therapeutic goods. However, an examination of

the role of NICNAS highlights the fact that regulating cosmetic products and their ingredients under the industrial chemicals legislative scheme is inappropriate.

The use of contemporary regulatory practices, such as the adoption of trusted international standards and deemed-to-comply provisions, are methodologies that can be incorporated into the legislative scheme to assist it in meeting current Government policy objectives concerning minimum effective regulation. A reduction in regulatory burden, together with streamlining the current control framework will reduce the fragmented approach of the current scheme, together with its lack of flexibility and transparency. These remedial processes will facilitate industry innovation and greatly reduce the current barriers to trade.

**Issues for Consideration**

This paper has identified a number of issues concerning the legislative framework dealing with cosmetic products and their ingredients. Its purpose has been to critically evaluate the current Australian cosmetic control system with the view of providing a basis for further stakeholder discussion on realistic and achievable reform measures.

To facilitate these discussions, issues which form the basis for reforming the current system of controls have been listed below.

**The *Cosmetics Standard 2007***

Preferred Approaches

- Transfer the legislative responsibility for the *Cosmetics Standard 2007* to the ACCC.

  This is consistent with recommendation 5.5 from the PC Research Report into Plastics and Chemical Regulation.

- as an alternative, Repeal the *Cosmetics Standard 2007.*

  This is the preferred option in terms of simplifying the current legislative scheme and ensuring that all requirements for cosmetic products and their ingredients reside with one primary regulator. By default, the current *Cosmetics Standard 2007* requirements are covered under the TGA's Excluded Goods Order and repealing the Standard will also preclude the requirement to continue to mirror amendments in two legislative documents. This will increase consistency within the schemes.

**Cosmetic Ingredient Requirements**

- Remove cosmetic ingredients from the scope of the industrial chemicals regulatory framework.

  This would result in the legislative requirements that are currently captured by the industrial chemicals scheme defaulting to the ACCC in collaboration with any public health control requirements under the SUSMP. This maintains the mature co-operative arrangements between the Commonwealth and the States and Territories in terms of safety and public health considerations concerning cosmetic products and their ingredients.

**Trusted International Standards**

- Incorporate the EU Cosmetic Directive controls into the Australian legislative framework.

  In New Zealand, the Cosmetic Products Group Standard which adopts the cosmetic annexes to the EU Cosmetic Regulation is used to approve and manage cosmetics containing hazardous substances. Australian incorporation mechanisms could involve adopting these into the existing ACCC framework or inclusion in the requirements of the SUSMP.

- In addition, consideration could be given to adopting the fragrance ingredient requirements of the IFRA Code into Australia's legislative framework dealing with cosmetic products and their ingredients as above.

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