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Mr James Lawson
27 Coolangatta Street
Coomba Park NSW 2428

9 September 2022

Dear Mr Lawson

Re: Algola Seaweed Cream Our Reference: C259 259-2013

We have reviewed your draft label text shown at Attachment 1 for compliance with the requirements for 'cosmetics' in Australia. To meet the requirements for cosmetics a product must:

- Meet the definition of cosmetic in the Industrial Chemicals Act 2019;
- Not be scheduled in schedules 2, 3, 4 or 8 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP);
- Include only ingredients that are listed on the AICIS Inventory database or are exempt from listing on the database;
- Not include any prohibited chemicals and meet any conditions for use of restricted chemicals;
- Meet any applicable conditions of a cosmetics standard that applies to the product (if any);
- Meet the labelling requirements of the Trade Practices (Consumer Product Information Standards)(Cosmetics)Regulations 1991; and
- Be marketed as a cosmetic.

To be a cosmetic, the product must meet the definition of cosmetic in Australia under section 9 of the Industrial Chemicals Act 2019, namely:

cosmetic means:

(a) a substance or preparation intended for placement in contact with any external part of the human body, including:

- (i) the mucous membranes of the oral cavity; and*
- (ii) the teeth;*

with a view to:

- (iii) altering the odours of the body; or*
- (iv) changing its appearance; or*
- (v) cleansing it; or*
- (vi) maintaining it in good condition; or*
- (vii) perfuming it; or*
- (viii) protecting it; or*

- (b) a substance or preparation prescribed by rules made for the purposes of this paragraph; but does not include:*
- (c) a therapeutic good within the meaning of the Therapeutic Goods Act 1989; or*
- (d) a substance or preparation prescribed by rules made for the purposes of this paragraph.*

The ingredients and CAS numbers have been provided by the manufacturer as shown in Attachment 2. We have assessed whether the ingredients and CAS numbers shown are included in the AICIS Inventory and the SUSMP and our findings are shown in Attachment 2.

The ingredient quantities have not been provided, so we are unable to verify the manufacturer's statement that they are listed in the correct order on the product label (Attachment 1).

The manufacturer has stated that the iodine content of the product and the quantities of bergamot oil and lime oil included in it are below the schedule cut off levels, so the product is unscheduled and no additional label warnings are required.

In our view, the product will meet the requirements for a cosmetic provided that:

- the product is labelled with the text as shown in Attachment 1, and
- the formulation only includes ingredients with the CAS numbers shown in Attachment 2, in quantities that mean that the product is unscheduled and
- the product meets the requirements listed above.

This product can be marketed without specific approval from the Therapeutic Goods Administration or AICIS as long as it continues to comply with the above requirements.

In providing this advice we note that there are subjective elements to decisions on whether a claim is 'cosmetic' or not. However, if challenged, we believe you can probably support the position that these products are appropriately regulated as 'cosmetics'.

Yours sincerely,



Julie Emery
Director

Attachment 1 – Label text

Draft 3 provided 31 August 2022

Algola

SEAWEED CREAM

with Aloe Vera

“As nature intended”

Algola’s Seaweed Cream Softens, hydrates, soothes and helps to moisturise rough, dry, damaged, irritated, cracked, chafed, sunburnt and wind burnt skin, and new and old tattoos. It can be used to improve the appearance of wrinkles, ageing, stretch marks, cellulite and pimples. It may also be used to moisturise the dry skin associated with conditions such as eczema, dermatitis, sunspots, psoriasis and rosacea. For best results use 2 - 3 times per day. **Storage** Store and transport in a cool dry place out of direct sunlight. **Caution** Avoid direct contact with eyes. If irritation occurs, discontinue use and seek medical advice. **Ingredients** (Aloe Vera) Leaf Juice, Ascophyllum Nodosum (Kelp/Seaweed) Extract, (Coconut) Oil, (Olive Leaf) Extract (and) Ethanol, Glycerin, Cetearyl Oliviate (and) Sorbitan Oliviate, (Jojoba) Seed Oil, (Avocado) Oil, (Shea) Nut Butter, (Rosehip) Oil, Xanthan Gum, (Bergamot) Oil, (Lime) Oil, (Cedarwood) Oil and Citric Acid.

100ml

BARCODE (Black and White)

Australian Made Logo (Black and White)

Algola

P.O. Box 9, Pacific Palms

NSW 2428, AUSTRALIA

www.algola.com.au

Algola is a registered trademark in Australia

Attachment 2 – Formulation assessment

Ingredients:	CAS No	AICIS Inventory	SUSMP
Aloe barbadensis (Aloe Vera) Leaf Juice*	85507-69-3	Included - no obligations	Unscheduled
Ascophyllum nodosum (Kelp) Extract*	84775-78-0	Included - no obligations	Unscheduled Iodine content of the cream stated by manufacturer to be less than 2.5%
Cocos nucifera (Coconut) Oil*	8001-31-8	Included - no obligations	Unscheduled
Olea europaea (Olive) Leaf Extract*	8001-25-0	Included - no obligations	Unscheduled
Ethanol*	64-17-5	Included - no obligations	Unscheduled
Glycerin*	56-81-5	Included - no obligations	Unscheduled
Cetearyl Olivatate	92797-33-6	Included - no obligations	Unscheduled
Sorbitan Olivatate	97358-61-7	Included - no obligations	Unscheduled
Simmondsia chinensis (Jojoba) Seed Oil*	61789-91-1	Included - no obligations	Unscheduled
Persea gratissima (Avocado) Oil*	8024-32-6	Included - no obligations	Unscheduled
Vitellaria paradoxa (Shea) Nut Butter*	91080-23-8	Included - no obligations	Unscheduled
Rosa canina (Rosehip) Oil*	84696-47-9	Included - no obligations	Unscheduled
Xanthan Gum	11138-66-2	Included - no obligations	Unscheduled
Citrus aurantium bergamia (Bergamot) Oil	8007-75-8	Included - no obligations	Unscheduled. Manufacturer has stated that the product contains less than 0.4% bergamot oil.
Citrus aurantifolia (Lime) Oil	8008-26-2	Included - no obligations	Unscheduled. Manufacturer has stated that the product contains less than 0.5% lime oil.
Cedrus atlantica (Cedarwood) Oil	8000-27-9	Included - no obligations	Unscheduled
Citric Acid	77-92-9	Included - no obligations	Unscheduled