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# Bio-Oil® Skincare Oil Product Information Sheet

Version 10  
Revision date: 01/07/2020



## Product

Bio-Oil® Skincare Oil (formulation reference GL/SCO/001.2).  
It is also marketed under the brand names Bi-Oil® and Bioil®.

## Volume

25ml / 0.85 fl.oz.  
60ml / 2 fl.oz.  
125ml / 4.2 fl.oz.  
200ml / 6.8 fl.oz.

**Description**

A cosmetic composition consisting of a blend of natural and synthetic oils and esters, with vitamins, essential oils, antioxidants, parfum and colourant.

**Purpose**

Bio-Oil® is a specialist skincare oil formulated to help improve the appearance of scars, stretch marks, uneven skin tone, ageing skin and dehydrated skin.

**Formulation**

Formulation (INCI and Hybrid listings, including CAS and EINECS numbers) are provided separately.

**Fragrance allergens declared in the Ingredient listing**

Alpha-Isomethyl Ionone  
Amyl Cinnamal  
Benzyl Salicylate  
Citronellol  
Coumarin  
Eugenol  
Farnesol  
Geraniol  
Hydroxycitronellal  
Limonene  
Linalool

**Ingredient Functions**

Ingredient functions are provided separately.

**Safety Assessment**

The product has been classified as safe for the intended use (including for use by pregnant women). A full Cosmetic Product Safety Report is provided separately.

**Toxicology Assessment**

Refer to the Cosmetic Product Safety Report.

**Product Specifications**

Refer to the Certificate of Analysis.

**Certificate of Analysis**

Certificate of Analysis is provided separately.

**Safety Data Sheet**

Safety Data Sheet is provided separately.

**Shelf-life and Stability**

Expiry: 60 months

PAO: 36 months

Storage: Store out of direct sunlight.

3-month accelerated stability tests, freeze and thaw tests and light stability tests are provided separately.

## **Microbiological Specifications**

Bio-Oil® Skincare Oil is tested according to a predetermined testing plan, in accordance with the International Organisation for Standardisation (ISO). As a manufacturer, we follow the Good Manufacturing Practices as described in ISO 17516 (Cosmetics – Microbiology – Microbiological Limits) and ISO 29621 (Cosmetics – Microbiology – Guidelines for the risk assessment and identification of microbiologically low-risk products) respectively.

## **Labelling Requirements**

Apply twice daily for a minimum of three months. During pregnancy apply from the first trimester until after birth. Individual results will vary. Suitable for sensitive skin and non-comedogenic. For external use only. Do not use on broken skin. In the unlikely event of skin irritation, discontinue use. Avoid contact with eyes. If product gets into the eyes, rinse thoroughly with water. Keep out of reach of children. Store out of direct sunlight.

## **Claim Substantiation**

Substantiations for the following claims are provided separately:

- Helps improve the appearance of scars (proDERM 2010, MEDUNSA 2005, Ayton-Moon 2002).
- Helps improve the appearance of facial acne scars (Peking University 2012).
- Helps improve the appearance of stretch marks (proDERM 2010, MEDUNSA 2005).
- Helps improve the appearance of uneven skin tone, pigmentation marks and blemishes (Stephens 2011, MEDUNSA 2005).
- Helps smooth and tone ageing and wrinkled skin on the face and body (Stephens 2011).
- Effective for dehydrated skin / helps supplement the skin's natural oils (MEDUNSA 2011, AVR Consulting 2012).
- Non-comedogenic (Complife 2019).
- Suitable for sensitive skin (Complife 2019).
- Rapidly absorbed (proDERM 2011).
- Soothing after-sun treatment (AVR Consulting 2012).
- Occlusivity (Prof Dr J Wiechers 2008, AVR Consulting 2019).

## **Certifications**

Halal/Halaal and Kosher certification is provided separately.

## **Brand Owner**

Union Swiss (Pty) Ltd.

## **Manufacturer**

Union Swiss (Pty) Ltd.

Conforming to the requirements of ISO 22716:2007 (Guidelines on Good Manufacturing Practice (GMP) for Cosmetic Products). Certificate is provided separately.

## **Manufacturing Process**

Bio-Oil® Skincare Oil raw materials and packaging materials are quarantined on receipt, sampled and tested before being released for use in production. A total of 14 ingredients are combined in a cold-mix process to manufacture a 50 ton batch of Bio-Oil® Skincare Oil. Ten active ingredients are mixed for one hour in a 1200 litre stainless steel vessel fitted with a bottom entry homogeniser. The carrier oil and the remaining large mass active ingredients are pumped directly into a 50 ton stainless steel vessel. The premix is then also transferred into the main vessel and the batch is agitated using a side entry stirrer until a homogenous mix is achieved. The entire process takes place at ambient conditions. The mixed oil flows directly into an automated production line where bottles are filled, plugged, capped and placed into cartons. Cartons are placed in shippers, which are then transferred to the finished goods warehouse. The manufacturing and packaging operations are conducted in accordance with a defined process and relevant documentation is available at every stage.

## Country of Origin

South Africa.

## Raw Materials

Raw material ingredient specifications and other technical documentation are provided separately.

## Animal Testing

Bio-Oil® Skincare Oil and its constituent raw materials are manufactured in compliance with EU regulations pertaining to animal testing for cosmetic purposes, that is, in accordance with Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast).

## REACH

REACH documentation (including registration and pre-registration numbers for applicable ingredients) is provided separately.

## Packaging

The packaging is suitable for cosmetic use without migration of harmful substances or presence of impurities. Technical documentation is provided separately.

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### Revision History

Version	Date	Reason for change
1	16/08/2013	New
2	01/10/2015	Updates to Certifications and Raw Materials sections
3	30/06/2017	Updates to Volume section and product range image
4	23/10/2017	Updates to Formulation, Labelling Requirements, Manufacturing Process and Raw Materials sections; new section included for Microbiological Specifications
5	12/02/2018	Updates to Microbiological Specifications, Manufacturer, Raw Materials and Animal Testing sections
6	09/11/2018	Updated layout
7	29/01/2019	Updates made to Description, Safety Assessment, Microbiological Specifications, Labelling Requirements, Manufacturing Process and Raw Materials
8	25/02/2019	Updates made to Formula Reference, Microbiological Specifications and Claim Substantiation sections
9	27/03/2019	Update made to Certifications
10	01/07/2020	Updates to Volume section and product range image, and to Labelling Requirements