Company Technical Specifications

TN 22

Birch bark extract oleogel (jojoba oil)

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Version	Date	Developed by	Approved by

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DEFINITION

The technical specifications (**TS**) apply to the cosmetic ingredient "**Birch bark extract oleogel (jojoba oil)**", manufactured by the JSC "Latvijas Finieris" division "Betulin Lab". The producer guarantees the compliance of the product with the requirements of these technical specifications throughout its shelf life, if all transport, storage and use instructions have been followed.

Birch bark extract oleogel (jojoba oil) is a raw material of birch (*Betula Pendula Roth; Betula pubescens Ehrh*.) bark origin intended for use as a cosmetic ingredient, the major mass part of which consists of jojoba oil with a mixture of betulin, betulinic acid and lupeol. It can concurrently serve as a preservative, antioxidant, and additional emulsifier, as well as promote skin regenerating mechanisms. **Birch bark extract oleogel (jojoba oil)** can be used as a raw material for all skin type-appropriate cosmetic water-in-oil skincare products for daily use, such as creams, lotions, or balms.

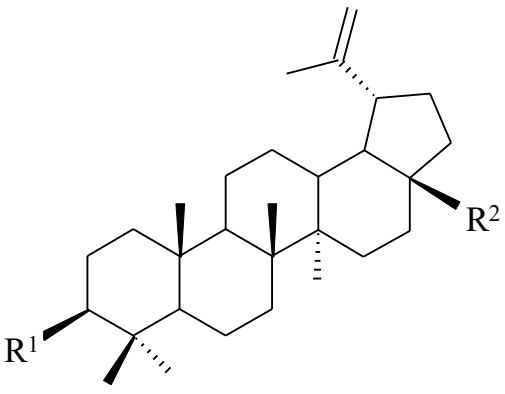
1. Information about the product

1.1. Purpose of Birch bark extract oleogel (jojoba oil)

Type of component: oleogel;
Purpose: raw material for the production of cosmetic products.

1.2. Composition of Birch bark extract oleogel (jojoba oil)

Birch bark extract oleogel (jojoba oil) is an oleogel with a golden color, consisting of jojoba oil and birch bark extract (INCI: BETULA ALBA BARK EXTRACT). This extract contains various components: pentacyclic triterpenes, phenolic compounds, etc.. The major mass part, excluding jojoba oil, consists of three lupane-type pentacyclic triterpenes: betulin, betulinic acid and lupeol, the chemical structures of which can be seen in Figure 1.



Pentacyclic triterpenes

R^1	**R^2**	
OH	CH_2OH	betulin;
OH	COOH	betulinic acid;
OH	CH_3	lupeol.

Figure 1. Chemical structures of pentacyclic triterpenes.

1.2.1. Characterization of pentacyclic triterpenes

Betulin

IUPAC name:	Lup-20(29)-ene-3β,28-diol
CAS number:	473-98-3
Molecular mass:	442,7

Betulinic acid

IUPAC name:	(3β)-3-Hydroxy-lup-20(29)-ene-28-oic acid
CAS number:	472-15-1
Molecular mass:	456,7

Lupeol

IUPAC name:	(3β, 13ξ)-Lup-20(29)-ene-3-ol
CAS number:	545-47-1
Molecular mass:	426,7

1.2.2. Characterization of jojoba (Simmondsia chinensis) oil

INCI:	SIMMONDSIA CHINENSIS SEED OIL
CAS number:	61789-91-1

Typical content

Fatty acid	Fatty acid chain length and number of double bonds
Palmitic acid	C16:0
Oleic acid	C18:1
Eicosanoic acid	C20:1
Erucic acid	C22:1
Nervonic acid	C24:1

2. Technical requirements

2.1. Compliance of Birch bark extract oleogel (jojoba oil) with requirements

Birch bark extract oleogel (jojoba oil) must comply with required levels of properties outlined further and its production process takes place in accordance with the technological instructions developed and approved by JSC "Latvian Finieris", observing all requirements set out in accordance with **Birch bark extract oleogel (jojoba oil)** as a cosmetic ingredient:

- Cabinet of Ministers regulation no. 354 „Procedure for ensuring the essential requirements of cosmetics";
- Regulation (EC) No. 1223/2009 of the European Parliament on cosmetic products;
- Regulation (EC) No. 1907/2006 of the European Parliament concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

References to current versions of regulations and compliance practices can be found in the Compliance evaluation for "Betulin Lab".

2.2. Characterization of Birch bark extract oleogel (jojoba oil)

Name: Birch bark extract oleogel (jojoba oil).

Based on organoleptic and content indicators, **Birch bark extract oleogel (jojoba oil)** must meet the requirements specified in Table 1.

Table 1

No.	Property	Requirements	Methods
1.	Appearance	Transparent to opaque, homogenous soft to moderately firm gel	Visually
2.	Color	Golden yellow	Visually
3.	Scent	Characteristic	Organoleptically

Based on microbiological indicators, **Birch bark extract oleogel (jojoba oil)** must meet the requirements specified in Table 2.

Table 2

No.	Property	Requirements	Methods
1.	Mesophilic aerobic microorganism count, CFU/1 g	Not more than 10^2	LVS EN ISO 21149 LVS EN ISO 4833-1 +A1
2.	*Candida albicans*, CFU/1 g	Must be below LOD of method*	LVS EN ISO 18416 LVS ISO 21527-2
3.	*Staphylococcus aureus*, CFU/1 g	Must be below LOD of method*	LVS EN ISO 22718 LVS EN ISO 6888-1
4.	*Pseudomonas aeruginosa*, CFU/1 g	Must be below LOD of method*	LVS EN ISO 22717 ISO/TS 11059
5.	*Escherichia coli*	Must be below LOD of method*	LVS EN ISO 21150 LVS EN ISO 16649-3
6.	Yeasts and molds, CFU/1 g	Not more than 10^2	

* LOD – limit of detection.

Based on toxin and heavy metal content, **Birch bark extract oleogel (jojoba oil)** must meet the requirements specified in Table 3.

Table 3

No.	Property	Requirements	Methods
1.	Quicksilver (Hg), mg/kg	Not more than 0,1	LVS 346 BIOR-T-012-148
2.	Arsenic (As), mg/kg	Not more than 0,5	LVS ISO 11466 LVS EN ISO 15586 BIOR-T-012-148
3.	Lead (Pb), mg/kg	Not more than 1,0	LVS ISO 11047 BIOR-T-012-148

4.	Cadmium (Cd), mg/kg	Not more than 0,2	LVS ISO 11047 BIOR-T-012-148
5.	PAH (polycyclic aromatic hydrocarbons), µg/kg	Not more than 10,0	
	Benzo[a]pyrene, µg/kg	Not more than 0,5	
	PAO4 (sum of benzo[a]anthracene, benzo[b]fluoranthene, benzo[a]pyrene and chrysene), µg/kg	Not more than 5,0	
6.	Pesticides	Must be below LOD of method*	

* LOD – limit of detection.

3. Safety requirements

Birch bark extract oleogel (jojoba oil) is a raw material for the production of cosmetic products and as such complies with the requirements outlined in the Cabinet of Ministers Regulation no. 354 and Regulation (EC) No. 1223/2009 of the European Parliament on cosmetic products. It does not have eye- or skin-irritating, or phototoxic properties.

4. Requirements for batch release and distribution

Completed batches of **Birch bark extract oleogel (jojoba oil)** are added to the production register. A batch is understood as an amount of product of one type and name, that is homogeneous, complies with the requirements stated in Tables 1-3, and which has one of each of the following:

- Batch serial number;
- Mass of batch;
- Date of completion of production.

5. Testing methods

Samples of **Birch bark extract oleogel (jojoba oil)** are taken from each completed batch for further testing according to the properties listed in Table 4. Sample collection is in accordance with JSC “Latvijas Finieris” sample collection and preparation documentation. Samples of **Birch bark extract oleogel (jojoba oil)** must be stored in their original packaging.

Testing methods and frequency for samples of **Birch bark extract oleogel (jojoba oil)** must comply with those listed in Table 4.

Table 4

No.	Property	Method	Frequency
1.	Appearance	Visually	Every batch
2.	Color	Visually	Every batch
3.	Scent	Organoleptically	Every batch
4.	Density at 20°C, g/cm³	PB-381 ed. II	On request
5.	Refraction coefficient at 20°C	Brookfield method DVIII ultra	On request
6.	Rheology	Determined using standard methods selected by the testing laboratory	On request
7.	Peroxide value, meq active oxygen/kg	AOAC 965.33	On request
8.	Iodine value, g iodine/100g	LVS EN ISO 3961	On request
9.	Mesophilic aerobic microorganism count, CFU/1 g	LVS EN ISO 21149 LVS EN ISO 4833-1 +A1	For each representative batch
10.	*Candida albicans*, CFU/1 g	LVS EN ISO 18416 LVS ISO 21527-2	
11.	*Staphylococcus aureus*, CFU/1 g	LVS EN ISO 22718 LVS EN ISO 6888-1	
12.	*Pseudomonas aeruginosa*, CFU/1 g	LVS EN ISO 22717 ISO/TS 11059	
13.	*Escherichia coli*	LVS EN ISO 21150 LVS EN ISO 16649-3	
14.	Yeasts and molds, CFU/1 g	LVS EN ISO 16212	
15.	Quicksilver (Hg), mg/kg	LVS 346 BIOR-T-012-148	
16.	Arsenic (As), mg/kg	LVS ISO 11466 LVS EN ISO 15586 BIOR-T-012-148	
17.	Lead (Pb), mg/kg	LVS ISO 11047 BIOR-T-012-148	
18.	Cadmium (Cd), mg/kg	LVS ISO 11047 BIOR-T-012-148	
19.	PAH (polycyclic aromatic hydrocarbons), µg/kg Benzo[a]pyrene, µg/kg PAO4 (sum of benzo[a]anthracene, benzo[b]fluoranthene,	Determined using standard methods selected by the testing laboratory	

	benzo[a]pyrene and chrysene), µg/kg		
20.	Pesticides		

6. Packaging and labeling

6.1. Packaging of Birch bark extract oleogel (jojoba oil)

Birch bark extract oleogel (jojoba oil) is packaged in polypropylene (PP) containers with lids, produced according to the requirements of the manufacturer. The contents of each packaging unit match the mass stated on the packaging.

6.2. Labeling of Birch bark extract oleogel (jojoba oil)

Labeling of **Birch bark extract oleogel (jojoba oil)** must comply with:

- Regulation (EC) No. 1907/2006 of the European Parliament concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
- Regulation (EC) No. 1223/2009 of the European Parliament on cosmetic products;
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures;
- Cabinet of Ministers regulation no. 354 „Procedure for ensuring the essential requirements of cosmetics".

Labeling must be easy to read and permanent.

The labeling of **Birch bark extract oleogel (jojoba oil)** must contain the following information:

- Raw material for cosmetic products – **Birch** (*Betula Pendula Roth; Betula pubescens Ehrh*.) **bark extract oleogel (jojoba (*Simmondsia chinensis*) oil)**;
- Producer: "Betulin Lab"; Finiera 2, Riga, LV-1016, Latvia, info@betulin-lab.com;
- The country of origin for **Birch bark extract oleogel (jojoba oil)** is: EU member state – Latvia;
- Contents – listed using the International Nomenclature of Cosmetic Ingredients (INCI);
- Batch serial number;
- Netto mass;
- Date of completion of production;
- Shelf life after date of completion of production: **18 months**;
- Storage conditions: store in original packaging in a dry and cool environment; keep away from direct sunlight; store between 5-25°C.
- Application: **Birch bark extract oleogel (jojoba oil)** is an ingredient for cosmetic products;
- **Birch bark extract oleogel (jojoba oil)** batch serial numbers: **JO2000-X-Y**, etc. The batch serial number begins with the letters "JO", which denote the oil used – jojoba oil; "2000" indicates the year the batch was completed; "X" indicates the week production of the batch was started and "Y" denotes the batch number within the given year.

7. Transport and storage

Birch bark extract oleogel (jojoba oil) must be stored in original packaging in a dry and cool environment; kept away from direct sunlight; and stored between 5-25°C**.**

Birch bark extract oleogel (jojoba oil) is transported in appropriately sized polypropylene (PP) containers with lids.

The shelf life of **Birch bark extract oleogel (jojoba oil)** from the date of completion of production has been determined as 18 months.

8. Production criteria

The purpose of a quality management system (EN ISO 9001:2015 “Quality management systems – Requirements”) is to ensure that manufacturing processes are documented and repeatable, the product meets client and legal requirements, and potential risks have been evaluated and prevented. This international standard is an expansion of EN ISO 9000:2015 “Quality management systems – Fundamentals and vocabulary”, which explains the basic principles necessary for quality management.

Quality criteria have been implemented in the production processes of “Betulin Lab”, according to the requirements of EN ISO 9001:2015. Some examples include:

- Process traceability;
- Internal audits;
- Management review protocols;
- SOP (standard operation procedures) system.

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The original with signatures can be found in the Quality Management, System and Product Certification department.

Document history:

No.	Version	Date	Description of changes
1.	Version 1	08.05.2026.	Creation of document.
		14.05.2026.	Document came into effect.