

CONFIRMED BY



Dr.biomed. Rimantas Peciuira

1. Description of the Product

Product Name

Basalis Cream 500 G

Responsible Person

Lithuanian University of Health Sciences, Sukileliu pr. 13, LT-50162 Kaunas, Lithuania

Category

Body care products

Formulation Name

Skin Care Cream, Lotion, Gel

Ingredients

Pos. N.	Name (<i>according to International Nomenclature of Cosmetic Ingredients</i>)
1.	Water (Aqua purificata, 01/2009:0008 EUROPEAN PHARMACOPOEIA 7.0)
2.	Liquid paraffinum (Paraffinum perliquidum, 01/2008:0240 EUROPEAN PHARMACOPOEIA 7.0)
3.	White softt paraffin (Vaseline album, 07/2009:1799 EUROPEAN PHARMACOPOEIA 7.0)
4.	Stearic Acid (Acidum stearicum, 07/2010:1474 EUROPEAN PHARMACOPOEIA 7.0)
5.	Glyceryl Stearate (Glycerol monostearate 40-55, 01/2008:0495 EUROPEAN PHARMACOPOEIA 7.0)
6.	Triethanolamine (Trolaminum, 07/2010:1577, EUROPEAN PHARMACOPOEIA 7.0)
7.	Acrylates/C10-30 Alkyl Acrylate Crosspolymer (Carbomera, 04/2009:1299 EUROPEAN PHARMACOPOEIA 7.0)

2. Cosmetic Product Safety Report

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SAFETY DATA REPORT

SECTION 1: Identification

- **Finished Product Name/Code:** Basalis Cream
- **Recommended Use:** Hand & Body Cream
- **Manufacturer's Name:**
Lithuanian University of Health Sciences
Sukileliu pr. 13, LT-50162 Kaunas, Lithuania
+37037722733
- **In case of medical emergencies, please contact your local poison control center.**

SECTION 2: Hazards Identification

Hazard Classification & Statement:

This is a personal care or cosmetic product that is non-hazardous and safe for consumers and other users under intended and reasonably foreseeable use. This product does not contain ingredients considered hazardous as defined by Regulation No 1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetics products.

POTENTIAL HEALTH EFFECTS:

- **Eye:**
Contact may cause mild, transient irritation. Some redness and/or stinging may occur.
- **Skin:**
Not expected to be sensitizing, photo allergenic, or phototoxic when used as intended. If irritation occurs following intended use or prolonged contact it is expected to be mild and transient.
- **Inhalation:**
Not expected to be irritating to the respiratory system. Non-volatile therefore limited inhalation exposure anticipated.
- **Ingestion:**
Product used as intended is not expected to cause gastrointestinal irritation. Accidental ingestion of undiluted product may cause mild gastrointestinal irritation with nausea, vomiting, and diarrhea.
- **Chronic Health Effects:**
This is a personal care or cosmetic product that is safe for consumers and other users under intended and reasonably foreseeable use.
- **Signs/Symptoms:**

This is a personal care or cosmetic product that is safe for consumers and other users under intended and reasonably foreseeable use.

● **Target Organs:** No data available.

● **Aggravation of Pre-Existing:** None generally recognized.

SECTION 3: Composition/Information on Ingredients

Complete Ingredient List:

Water (Aqua), Paraffinum Liquidum, Petrolatum, Stearic acid, Glyceryl Stearate, Acrylates/C 10-30 Alkyl Acrylate Crosspolymer, Triethanolamine.

This product does not contain ingredients considered hazardous as defined by Regulation No 1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetics products.

SECTION 4: First Aid Measures

● **Eye:**

Thorough rinsing for 15-20 minutes of the affected eye with water is recommended. If discomfort or irritation persists, contact a physician.

● **Skin Problems.**

Discontinue use of product. Apply cold compresses to affected areas to relieve any discomfort. If discomfort persists, contact a physician.

● **Inhalation:**

If respiratory irritation occurs, remove individual to fresh air.

● **Ingestion:**

Accidental ingestion of product may necessitate medical attention. Contact local poison control center or physician immediately

● **Information for Doctor:**

No information available.

SECTION 5: Fire Fighting Measures

● **Extinguishing Media:**

Suitable extinguishing agents: Use chemical foam, dry chemical, carbon dioxide, or water

Unsuitable media: No applicable information has been found

● **Specific Hazards arising from the substance or mixture:** Thermal degradation may produce oxides of carbon and/or nitrogen. Hydrocarbons and/or derivatives.

● **Fire Fighting Instructions:**

Contact emergency personnel. Use self-contained breathing apparatus and full protective gear, if large quantities of product are involved. Hazardous decomposition products may be released.

SECTION 6: Accidental Release Measures & Disposal Procedures

● Procedure for Spill/Leak Clean-up:
For Household Settings: Remove excess product and wash the area using dilute detergent. Keep out of reach of children.
For Non-Household Settings: Use safety glasses or goggles if splash hazards exist; use gloves and other protective clothing to prevent skin contact. Product is water dispersible. Avoid strong acids, alkalis and oxidizing agents.

Reference to other sections:
 See Section 7 for information on safe handling.
 See Section 8 for information on personal protection equipment.
 See Section 13 for information on disposal

SECTION 7: Handling & Storage

● Precautions for Safe Handling:
For Household Settings: Keep away from children. Store in cool area.
For Non-Household Settings: No unusual handling or storage requirements. Storage in large quantities (as in warehouses) should be in a well-ventilated, cool area. Avoid extremes of temperature.

● **Specific End Use(s):** No further relevant information available.

SECTION 8: Exposure Controls & Personal Protection

● Exposure Controls:
For Household Settings: This is a personal care or cosmetic product that is safe for consumers and other users under normal and reasonably foreseen use. Keep away from children and foodstuffs. Avoid contact with eyes.
For Non-Household Settings: Use the following protective equipment for large quantities of the material. Always follow good hygienic work practices. Avoid prolonged contact with skin & clothing. No further information on exposure controls available.
Protective Gloves: Any type of protective glove material.
Eye Protection: Safety Glasses or goggles

SECTION 9: Physical & Chemical Properties

● Color, Odor, & Appearance: Thick, white lime scented emulsion.	● Melting Point: Not determined
● Physical State: Non-flowing .	● Boiling Point/Range: 195- 212 ° F (90 – 100 ° C)
● pH: 8,0-9,5	● Solubility in Water: Dispersible
● Flashpoint: Not determined	
● Ignition Temperature: Not determined	
● Decomposition Temperature: Not determined	
● Auto Igniting: Product is not self igniting	
● Danger of Explosion: Product is not explosive.	
● Vapor Pressure: Not determined	● Density at 25°C (77°F): 0.80-1.0
● Vapor Density: Not determined	

SECTION 10: Stability & Reactivity

- Reactivity:

Chemical Stability: Thermal decomposition to be avoided. No decomposition if used according to directions.

Possibility of hazardous reactions: No dangerous reactions known

Conditions to Avoid: No further relevant information available.

Incompatible materials: Strong acids, alkaline materials, strong oxidizers

Hazardous decomposition products: Carbon monoxide and carbon dioxide. Thermal degradation may produce oxides of carbon and/or nitrogen. Hydrocarbons and/or derivatives

SECTION 11: Toxicological Information

- Information on toxicological effects:

This is a personal care or cosmetic product that is safe for consumers and other users under intended and reasonably foreseeable use.

Acute Toxicity: Finished product is not expected to have acute toxicity health effects when used as intended.

Chronic Toxicity: Finished product is not expected to have chronic toxicity health effects.

This product does not contain ingredients considered hazardous as defined by Regulation No 1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetics products.

SECTION 12: Ecological Information (Non-mandatory)

- Ecological Effects:

Aquatic toxicity: No relevant information available

Persistence and degradability: No relevant information available

Bioaccumulative potential: No relevant information available

Mobility in soil: No relevant information available

Other adverse effects: No relevant information available

General notes: Do not allow large quantities of undiluted product to reach ground water, water course or sewage system.

SECTION 13: Disposal Considerations (Non-mandatory)

- **Disposal Methods:** Where possible, recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of in compliance with local, state, and federal regulations.

- **Disposal Considerations:** When disposed as waste, this product is considered nonhazardous waste.

Reference to other sections:

See Section 8 for information on personal protection equipment

SECTION 14: Transport Information (Non-mandatory)

- **Ground Transportation (DOT):** Non-Hazardous

- **Vessel Transportation (IMDG):** Non-Hazardous

- **Air Transportation (IATA):** Non-Hazardous

- **Marine Pollutant:** No relevant information available

SECTION 15: Regulatory Information (Non-mandatory)

This is a personal care or cosmetic product that is non-hazardous and safe for consumers and other users under intended and reasonably foreseeable use. This product does not contain ingredients considered hazardous as defined by Regulation No 1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetics products.

SECTION 16: Other Information

SDS Creation Date: 06/15/2015

DISCLAIMER:

The information in this SDS was obtained from current and reliable sources. However, the data is provided without any warranty, expressed or implied, regarding its correctness or accuracy. Since the conditions for use, handling, storage and disposal of the product are beyond the control of Lithuanian University of Health Sciences, Inc., it is the user's responsibility both to determine safe conditions for the use of this product and to assume liability for loss, injury, damage, or expense arising out of improper use of this product.

3. Method of manufacture and a statement of GMP compliance

Cosmetic product is manufactured by mixing, heating, homogenizing, packing and labeling by skilled personnel in rooms and equipment according to cosmetic GMP requirements. Manufacture is in accordance with the relevant harmonised standards, the references of which have been published in the Official Journal of the European Union, and compliance with GMP confirmed National Public Health Centre by the Ministry of Health of Lithuanian Republic (*see document below*).

Translated from Lithuanian

NATIONAL PUBLIC HEALTH CENTRE BY THE MINISTRY OF HEALTH

PERMIT – HYGIENIC PASSPORT

08/04/2016 No. LHP.2-3(17.7.1.2,11)

Kaunas

1. General information about holder of permit – hygienic passport:

- 1.1. Full name of legal person: Lithuanian University of Health Sciences
- 1.2. Code of legal person: 302536989
- 1.3. Address of legal person: 9 A. Mickeviciaus str., Kaunas

2. Information about economic commercial activity, with regard to which the permit – hygienic passport has been issued:

- 2.1. Name of economic commercial activity: production of cosmetic products
- 2.2. Address of implementation of economic commercial activity: 13 Sukileliu ave., Kaunas

Director of Kaunas Department

signature

Gintautas Kligys

Seal: National Public Health Centre by the Ministry of Health

2

Information about status of permit – hygienic passport:

1. Name of the part of economic commercial activity
2. Date and number of decision
3. Status (legal status) of the permit-hygienic passport: suspension of the permit-hygienic passport, cancellation of suspension of the permit-hygienic passport or cancellation of the permit-hygienic passport

(name of office)

(signatures)

(name, surname)

L. S.

Information about status of permit – hygienic passport:

1. Name of the part of economic commercial activity
2. Date and number of decision
3. Status (legal status) of the permit-hygienic passport: suspension of the permit-hygienic passport, cancellation of suspension of the permit-hygienic passport or cancellation of the permit-hygienic passport

(name of office)

(signatures)
L. S.

(name, surname)

Information about status of permit – hygienic passport:

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(name of office)

(signatures)
L. S.

(name, surname)

Translated from Lithuanian

NATIONAL PUBLIC HEALTH CENTRE BY THE MINISTRY OF HEALTH

**Specification of the Certificate on Evaluation of Implementation Conditions of Economic
Commercial Activity No. 39-0605(6) issued on 27/11/2014**

08/04/2016 No. LHP.2-4(17.7.1.2,11)

Kaunas

I specify the Certificate on Evaluation of Implementation Conditions of Economic Commercial Activity No. 39-0605(6) issued on 27/11/2014 by replacing the line 2 “4 Eiveniu str., Kaunas” with the following text: “13 Sukileliu ave., Kaunas”. This line will look like this:

2. Location of economic commercial activity

Implementation address of economic commercial activity (city, region, village, street, building, premises No.): 13 Sukileliu ave., Kaunas

Director of Kaunas Department

signature

Gintautas Kligys

Seal: National Public Health Centre by the Ministry of Health

2

Valid only together with the Certificate on Evaluation of Implementation Conditions of Economic Commercial Activity No. 39-0605(6) of 27/11/2014.

*Translated from Lithuanian***KAUNAS PUBLIC HEALTH CENTRE**

Budgetary institution, 24 K. Petrausko str., 44156 Kaunas, phone: (8 37) 331688, fax: (8 37) 331680, e-mail:
info@kaunovsc.sam.lt, the data are collected and stored in the Register of legal Persons, code 191349265

***CERTIFICATE ON EVALUATION OF IMPLEMENTATION CONDITIONS OF ECONOMIC
COMMERCIAL ACTIVITY***

27th of November 2014 No. 39-0605(6)

Kaunas

1. Data about the applicant

Name of legal person/subsidiary and entity's code/ name, surname and personal number of natural person: Lithuanian University of Health Sciences, 302536989

Number of application to receive permit-hygienic passport: 899

2. Location of economic commercial activity

Implementation address of economic commercial activity (*city, region, village, street, building, premises No., phone, fax, e-mail*): 4 Eiveniu str., Kaunas

Buildings and premises, where the economic commercial activity is planned or implemented, their purpose (*number, date of cadastral measurement file of buildings or premises, indexes of building or premises*): Building – centre of the up-to-date pharmaceutical and health technologies of “Santaka” valley, purpose of science, 7C6b, indexes of premises from 1-30 to 1-32, 1-38, 1-42, 1-43, from 1-45 to 1-60. The cadastral data were recorded on the 09th of September 2013.

Basis to use buildings and premises, where the economic commercial activity is planned or implemented (*title, date and No. of the document*): according to the data of the certificate No. 44/253256 of 16/10/2014 of the Centre of Registers, the premises are the property of the Republic of Lithuania. The premises are managed by the right of trust.

3. Description of conditions of economic commercial activity

Territory, buildings, premises, etc., where the economic commercial activity is planned or implemented: the evaluation of implementation conditions of the activity is carried out. The permit-hygienic passport has been issued for the same economic activity at 51 Sukileliu ave., Kaunas. The production of cosmetic products is carried out in the industrial premises of the pharmacy of the Lithuanian University of Health Sciences of the centre of the up-to-date pharmaceutical and health technologies of “Santaka” valley. All the premises necessary for production of cosmetic products have been prepared: cloakrooms for outerwear, staff's cloakrooms with showers, WC, premises for receipt of raw materials, production, storage, administrative, quality control and auxiliary premises. Total area of premises is 381,76 sq. m. The movement of flows of staff, raw materials and production satisfies the requirements. We do not see any cross pollution.

Engineering equipment

	Description, mode (type)	Factors, which may affect the public health	Remarks
1. Water supply	Urban systems	-	-

2. Wastewater disposal	Urban systems	-	-
3. Heating	Central urban systems	-	-
4. Ventilation	Mechanical exhauster – inflow recuperation	-	-
5. Illumination	Mixed	-	-
6. Other (indicate)		-	-

Buildings, premises, their setting

	Description, mode (type)	Factors, which may affect the public health	Remarks
1. Internal finish	Surfaces are smooth, lightly smooth, moisture-resistant	-	-
2. Used equipment, its maintenance	Reactors of aqueous and oil phase, mixing boiler, vacuum station, pre-packing robot, electronic scales, distiller	-	-
3. Waste management	Performed	-	-
4. Other (indicate)		-	-

Implementation of other requirements of legal acts on safety of public health

	Evaluation of compliance with requirements of legal acts on safety of public health	Remarks
1. Health examination of employees	The employees have checked their health preventively	-
2. Obligatory training of employees about first aid and/or obligatory training of hygienic skills	The employees are trained following the procedure set in the institution	-
3. Installation of self-control systems	Descriptions of procedures have been prepared according to LST EN ISO 22716:2008 Cosmetics - Guidelines on Good Manufacturing Practices	-
4. Domestic premises	Staff's cloakrooms, WC, showers and rest rooms have been prepared	-
5. Other requirements (indicate)	The inventory of cleaning of premises has been put in set. The compliance with requirements of hand hygiene is ensured	-

4. Evaluation of factors related to the conditions of economic commercial activity, which may affect public health

Factors, which may affect the public health	Relevance of factor (yes/ no)	Requirement of legal act (enter legal act)	Evaluation of the factor (results of laboratory tests/measurements, if the factor is not relevant, present motivation)

1. Physical factors	-	-	-
2. Chemical factors	-	-	-
3. Biological factors	-	-	-
4. Other factors	-	-	-

5. Conclusion

The implementation conditions of production of cosmetic products satisfy the requirements of legal acts on safety of public health.

Deputy Director
Director at interim

signature

Ona Gedgaudiene

Seal: Republic of Lithuania
Kaunas Public Health Centre

4. Proof of effect for the product

Product according to composition belongs to emollients group. Emollients are moisturising treatments applied directly to the skin to reduce water loss and cover it with a protective film (<http://www.nhs.uk/conditions/Emollients/Pages/Introduction.aspx>).

5. Data on animal testing

No animal testings were performed of the cosmetic product or its ingredients.

6. Last update of P.I.F

21/06/2021

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