



STANDARDIZED INFORMATION ON DIETARY INGREDIENTS (SIDI) COLEUS FORSKOHLII EXTRACT (FORSKOLIN 10%)

Section 1. PRODUCT INFORMATION	
PRODUCT NAME & CODE:	Coleus forskohlii extract 10% & N21014
COMMON OR USUAL NAME OF PRODUCT:	Coleus forskohlii extract
SCOPE OF DOCUMENT:	This document provides information specific to Coleus forskohlii extract
GENERAL PRODUCT INFORMATION:	Coleus forskohlii extract is derived from the Roots of Coleus forskohlii and standardized for Forskolin . This is used in weight management formulations

Section 2. MANUFACTURING INFORMATION	
NAME AND ADDRESS OF MANUFACTURING SITE:	Biogenero Labs Pvt. Ltd., Shed No. 1A, S.Y No.179/5, B.G. Road, Hullahalli, C.K. Palya, Bangalore-560 083
AGRICULTURAL PROCESS	Cultivated
MODE OF MANUFACTURING:	Extraction and standardization
MANUFACTURING PROCESS:	Process flow chart enclosed. Refer Page No. 3
GMP COMPLIANCE:	Ayush GMP
STERILIZATION OR FUMIGATION METHOD(S):	None
KNOWN OR POTENTIAL SOURCES OF IMPURITIES AND/OR CONTAMINANTS:	The possible impurities are heavy metals and residual solvents. Coleus forskohlii extract complies with USP for above mentioned impurities.

Section 3. PHYSICAL/CHEMICAL INFORMATION				
INGREDIENT(S)				
COMMON OR USUAL NAME:	SYNONYM:	ORIGIN:	CAS NUMBER:	PERCENT:
Coleus forskohlii extract	Coleus forskohlii	India	66428-89-5	60 to 70%
Water			-	1 to 2%
Dextrin	-	India	9050-36-6	30 to 40%
CURRENT PRODUCT SPECIFICATION SHEET ATTACHED:	Yes. Refer page No.4			
BIOASSAY METHOD:	Refer page No. 6 and 7			

Section 4. LABELING INFORMATION	
REQUIRED FINISHED PRODUCT LABEL STATEMENTS:	Labeling as per DSHEA.
RECOMMENDED RESTRICTIONS OF USE:	Consult a physician if you are using any prescription medication, or if pregnant or nursing
NUTRITIONAL/SUPPLEMENT FACTS LABELING:	Nutritional Labeling education act of 1990
OTHER:	None

Section 5. REGULATORY INFORMATION	
PATENT COVERAGE:	None
COMPENDIAL GRADE:	None

REGULATORY STATUS AND SUPPORTING DOCUMENTS:	USA: Coleus forskohlii extract freely sold in USA under Dietary Supplement Health Education Act. EU: Approved as Cosmetic and health supplements Canada: Natural Health Product Australia: Coleus forskohlii extract is classified as Active and eligible for use in medicines Listed on the Australian Register of Therapeutic Goods for supply in Australia.
PRODUCT MASTER FILE(S):	Available
BSE/TSE INFORMATION:	BSE/TSE questionnaire attached. Refer page Nos. 8 and 9
VEGAN OR VEGETARIAN STATUS:	Suitable for Vegan and Vegetarian
ALLERGENS/ HYPERSENSITIVITES:	Allergen statement is enclosed. Refer Page Nos. 10 and 11
PRESERVATIVES (or PROCESSING AIDS):	None
KOSHER/HALAL/ORGANIC STATUS*:	Yes
GM STATUS (for each dietary ingredient):	Non-GMO statement attached. Refer Page No. 12
TARIFF CODE FOR IMPORT/EXPORT:	1301.90.9090

* Include certifying agency/authority

Section 6. MISCELLANEOUS PRODUCT INFORMATION	
BATCH/LOT NUMBERING SYSTEM:	Manufacturing facility/Year/Finished product/Sequential number
BATCH DEFINITION:	N15001, N: Nachurel ; 15: For the year 2015; 001: Sequential number
EXPIRATION DATING:	Three years
RECOMMENDED STORAGE CONDITIONS:	Store at Room temperature
OTHER OPTIONAL INFORMATION:	None
PACKAGE SIZE(S):	1kg and 25kg
RECYCLED PACKAGING MATERIALS:	None
SUGGESTED PRODUCT CLAIMS, SUPPORTING DOCUMENTATION INCLUDED:	Weight management support.* *These statement have not been evaluated by USFDA
MSDS ATTACHED:	Yes. Refer Page No. 13
OTHER PRODUCT SAFETY INFORMATION:	Refer MSDS

Section 7. REVISIONS			
REVISION DATE:	None	REVISION LEVEL:	New

Section 8. CONTACT INFORMATION			
OTHER PRODUCT SAFETY INFORMATION:		Refer MSDS	
COMPANY NAME:		Nachurél Ingredients LLC	
CONTACT NAME:	Velmurugan S	TITLE:	VP-Technical Affairs
CONTACT PHONE:	732 204 8990	EMAIL:	vp@nachurel.com

MANUFACTURING PROCESS FLOW CHART COLEUS FORSKOHLII EXTRACT (FORSKOLIN 10%)

Coelus forskohlii Root Powder



Extraction with Toluene

Toluene extract



Concentration

Concentrate



Wash with hexane

Coleus forskohlii purified extract



Formulate with Dextrin
Mill, Sieve and Pack

Coleus forskohlii extract (Forskolin 10%)

Nachurél Ingredients LLC

FINISHED PRODUCT SPECIFICATION

Product: COLEUS FORSKOHLII EXTRACT (FORSKOLIN 10%)			Code No.: N21014	
Issue No.	Supersedes	Effective date	Review date	Page Number
1.0	None	June 10, 2015	June 09, 2018	Page 4 of 17

Botanical/Scientific name	<i>Coleus forskohlii</i>		
CAS No.	66428-89-5		
Plant part used	Roots		
Preparation type	Extraction		
Final extract ratio	25 to 35:1		
Standardization	Forskolin		
Excipients used	Dextrin		
Excipients details	Name	% used	CAS No.
	Dextrin	30 to 40%	9050-36-6

Parameter	Specification	Protocol
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Physical

Description	Brown to dark brown powder*	Organoleptic
Identification	To comply by HPLC	HPLC
Solubility	Partially soluble in alcohol	USP
Loss on drying	Not more than 6.0% w/w (dried at 105°C)	USP <731>
Loose bulk density	Between 0.20g/ml and 0.40g/ml	USP <616>
Tapped bulk density	Between 0.30g/ml and 0.70g/ml	USP <616>
Sieve test (passes through)		
-60 mesh	Not less than 100% w/w	USP <786>

Chemical

Content of Forskolin by HPLC	Not less than 10.0% w/w and not more than 12.0% w/w on dried basis	HPLC
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Others

Lead	Not more than 3.0ppm	ICP-OES
Arsenic	Not more than 1.0ppm	ICP-OES
Cadmium	Not more than 1.0ppm	ICP-OES
Mercury	Not more than 0.1ppm	ICP-OES

FINISHED PRODUCT SPECIFICATION

Product: COLEUS FORSKOHLII EXTRACT (FORSKOLIN 10%)			Code No.: B21014	
Issue No.	Supersedes	Effective date	Review date	Page Number
1.0	None	June 10, 2014	June 09, 2017	Page 5 of 17

Microbiological profile

Total aerobic microbial count	Not more than 3000 cfu/g	USP<2021>
Total yeast and mould count	Not more than 100 cfu/g	USP<2021>
<i>Escherichia coli</i>	Negative/10 g	USP<2022>
<i>Salmonella</i>	Negative/10 g	USP<2022>
<i>Staphylococcus aureus</i>	Negative/10 g	USP<2022>
<i>Pseudomonas aeruginosa</i>	Negative/10 g	USP<62>
<i>Enterobacteriaceae</i>	Negative/10 g	USP<2021>

Additional information

Sanitizing treatment	Non-irradiated and not treated with ETO
Certification status (Kosher / Halal)	Kosher and Halal Certified
Genetic Modification Status	GMO free
BSE / TSE status	BSE / TSE free
Country of origin	India
Cultivated or wild crafted	Cultivated
Manufactured by	Biogeno Labs Pvt. Ltd Bangalore. 560 076. India
Shelf life	3 years
Storage Condition	Store at room temperature

*Since it is a herbal origin, there may be minor color variation because of the geographical and seasonal variations of the raw material.

NAP – Not applicable
NAV – Not available

DETERMINATION OF FORSKOLIN CONTENT IN COLEUS FORSKOHLII EXTRACT BY HPLC

Mobile phase A

Use filtered and degassed acetonitrile.

Mobile phase B

Use filtered and degassed water.

Standard solution

Sonicate a quantity of Forskolin working standard in acetonitrile to obtain a solution having a known concentration of about 1.0 mg/mL.

Sample solution

Transfer an amount of Powdered Forskohlii Extract equivalent to about 25 mg of Forskolin to a 25-mL volumetric flask, and add 15 mL of acetonitrile. Sonicate and heat in a water bath for about 10 min, cool, dilute with acetonitrile to volume, and mix. Before injection, filter through a membrane filter having a 0.45- μ m or finer pore size, discarding the first 5 mL of the filtrate.

Mobile phase

See the gradient table below.

Time(min)	Mobile phase A(%)	Mobile phase B (%)
0	45	55
25	45	55
28	95	5
35	95	5
36	45	55
45	45	55

Reagents required

HPLC water
Acetonitrile (HPLC Grade)
Methanol (HPLC Grade)

Chromatographic Conditions

Equipment : Shimadzu liquid chromatograph equipped with UV/Vis Detector.
Column : C18, 250 X 4.6mm, 5 μ
Column temperature : 30°C
Wavelength : 220nm
Injection volume : 20 μ l
Flow rate : 1.8mL/min
Run time : 45min

Relative standard deviation

Not more than 2% determined from the forskolin peak in repeated injections, *Standard solution*

Samples

Standard solution and Sample solution

Calculate the percentage of forskolin in the portion of Powdered Forskohlii Extract taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of Forskolin from the *Sample solution*
 r_S = peak response of Forskolin from *Standard solution A*
 C_S = concentration of USP Forskolin RS in *Standard solution A* (mg/mL)
 C_U = concentration of Powdered Forskohlii Extract in the *Sample solution* (mg/mL)

On dried basis

Calculate the Assay on dried basis as follows.

$$\text{Assay} \times 100/100\text{-LOD}$$

BSE AND TSE QUESTIONNAIRE COLEUS FORSKOHLII EXTRACT (FORSKOLIN 10%)

Version No. 1

Date: June 10, 2014

1. Is the product partly or fully of animal origin? (i.e., tissue, tissue extract or fluid such as milk, serum, blood, etc.)

Yes (Please specify)_____

No

2. Are any materials of animal origin used as starting material or in the manufacturing process of the product?

Yes (Please specify)_____

No

3. Is the product derived from Microbiological or cell culture fermentations?

Yes (Please specify)_____

No

If Yes, are any components used in the media culture derived from animal origin?

Yes (Please specify)_____

No

4. Is the product purified using chromatography media (e.g., specific ligand columns) or buffers that contain components of animal origin?

Yes (Please specify)_____

No

5. Is any of the equipment used for processing or storage of the product in contact at any time with other materials of animal origin?

Yes (Please specify)_____

No

6. Is the product, for any other reason, at any time, in contact with materials of animal origin?

Yes (Please specify)_____

No

This is to certify that our Coleus forskohlii extract (Forskolin 10%) is free from BSE (Bovine Spongiform Encephelopathy) and TSE (Transpongiform Encephelopathy). This product does not contain or not manufactured by using any animal derived products.



Velmurugan Shanmugham
Vice President-Technical Affairs

ALLERGENS AND INGREDIENTS LABELLING QUESTIONNAIRE COLEUS FORSKOHLII EXTRACT (FORSKOLIN 10%)

Version No. 1

Date: June 10, 2014

According to major food allergen specified in the US Federal law of Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and EU Directive 2003/89/CE amending Directive 2000/13/CE.			
Allergen and/or Component	Present	Absent	If present, please specify ingredient(s)
Peanut or its derivatives, e.g., pieces, protein, oil, butter, flour, and such.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Tree Nuts (almonds, Brazil nuts, cashews, hazelnuts (filberts), macadamia nuts, pecans, pine nuts, pistachios and walnuts or their derivatives, e.g., nut butters and oils, etc.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Sesame or its derivatives, e.g., paste and oil etc.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Milk or its derivatives, e.g., milk caseinate, whey, yogurt powder, etc.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Egg or its derivatives, e.g., frozen yolk, egg white powder, egg protein isolates, etc.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Fish or its derivatives, e.g., fish protein and extract, etc.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Shellfish (including crab, crayfish, lobster, prawn, and shrimp)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

Mollusks (including snails, clams, mussels, oysters, cockle and scallops) or their derivatives, e.g., extracts, etc.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Soy or its derivatives, e.g., lecithin, oil, tofu and protein isolates, etc.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Wheat or its derivatives, e.g., flour, starch and bran, etc.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Barley, Rye, Oats, Spelt, Kamut, Triticale or its derivatives, e.g., flour, starches, etc.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Sulfites e.g., sulfur dioxide and sodium meta-bisulfites, etc.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Celery or its derivatives	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Corn or its derivatives	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Dextrin used as excipient
Seeds (Poppy, Sunflower, etc) or its derivatives	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Gluten	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Trans Fatty Acids	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Sulphur dioxide and sulphate at concentrations of more than 10 mg/kg or 10 mg/l expressed as SO ₂	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Lupin (<i>Lupinus Albus</i>) and products thereof	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

June 10, 2015



**NON-GMO STATEMENT
TO WHOM IT MAY CONCERN**

We declare that the product or raw materials used in the manufacture of our **COLEUS FORSKOHLII EXTRACT (FORSKOLIN 10%)** does not contain or is not derived/ produced from Genetically Modified Organism.

GM labeling is not required according to EU regulation EC No. 1829/2003 and traceability is assured according to EU regulation EC No. 1830/2003.

A handwritten signature in blue ink that reads "Velmurugan".

Velmurugan Shanmugham
Vice President-Technical Affairs

Nachurel Ingredients LLC

SAFETY DATA SHEET COLEUS FORSKOHLII EXTRACT (FORSKOLIN 10%)

Version No. 1.0

Issue date: June 10, 2015

1. IDENTITY

Supplier's Name and Address	Nachurél Ingredients LLC #2404, Birchwood Court, North Brunswick, New Jersey-08902, USA
Telephone No. for Information	732 204 8990
Emergency Telephone No.	732 204 8990
Name	Coleus forskohlii extract (Forskolin 10%)
Synonyms	Coleus forskohlii extract
INCI Name	Coleus forskohlii extract root extract
Applications	Dietary supplements

2. IDENTIFICATION OF THE HAZARDS

Emergency Overview

OSHA Hazards

None

Target Organs

None

GHS Label elements, including precautionary statements

Pictogram

None

Signal word

Warning

Hazard statement(s)

H303

May be harmful if swallowed

H315

Causes skin irritation

H319

Causes serious eye irritation

H335

May cause respiratory irritation

Precautionary statement(s)

P261

Avoid breathing dust/fume/gas/mist/vapors/spray

P264

Wash skin thoroughly after handling

P271

Use only outdoors or in a well-ventilated area

P280

Wear protective gloves/eye protection/face protection

P302 + P352 IF ON SKIN:

Wash with plenty of soap and water.

P304 + P340 IF INHALED:

Remove victim to fresh air and keep at rest in a position comfortable for breathing

P305 + P351 + P338 IF IN EYES:

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do.

Continue rinsing

P312

Call a POISON CENTER or doctor/physician if you feel unwell

P321

Specific treatment (see supplemental first aid instructions on this label)

P332 + P313

If skin irritation occurs: Get medical advice/attention

P337 + P313

If eye irritation persists: Get medical advice/attention

P362

Take off contaminated clothing and wash before reuse

P403 + P233

Store in a well-ventilated place. Keep container tightly closed

P405

Store locked up

P501

Dispose of contents/container to an approved waste

Health hazard: 2, Flammability: 0, Physical hazards: 0

HMIS Classification
NFPA Rating
Potential Health Effects
Inhalation

Health hazard: 2, Fire: 0, Reactivity Hazard: 0

May be harmful if inhaled. Causes respiratory tract irritation

Skin

May be harmful if absorbed through skin. Causes skin irritation

Eyes

Causes eye irritation

Ingestion

May be harmful if swallowed

3. INGREDIENTS/IDENTITY INFORMATION

COMPONENT	CAS No	EINECS No.	Mol. formula	Mol. Wt
Coleus forskohlii extract (Forskolin 10%)	66428-89-5	-	-	-

4. PRECAUTIONS FOR SAFE HANDLING AND USE

FIRST AID MEASURES

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area

If inhaled

If breathed in, move person into fresh air. If not breathing give artificial respiration Consult a physician
 Wash off with soap and plenty of water. Consult a physician

In case of skin contact

Wash off with soap and plenty of water. Consult a physician

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician

5. FIRE AND EXPLOSION HAZARD DATA

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or CO₂

Special protective equipment for fire-fighters

Wear self contained breathing apparatus for firefighting if necessary

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation

Environmental precautions

Do not let product enter drains

Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection

Conditions for safe storage

Keep container tightly closed in a dry and well-ventilated place

Recommended storage temperature

Room temperature, Keep in a dry place

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Components	CAS-No.	Value	Control parameters	Update	Basis
Coleus forskohlii extract (Forskolin 10%)	66428-89-5	TWA	15.0mg/m3*	1993-06-30	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants

*Particulates not otherwise regulated, Total Dust)

Personal protective equipment

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95 (US) or type P1 (EN 143) respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN EU).

Hand protection

Handle with gloves

Eye protection

Safety glasses with side-shields conforming to EN166

Skin and body protection

Choose body protection according to the amount and concentration of the dangerous substance at the work place

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Powder
Color	Pale brown to brown
Odor	Characteristic
Boiling point (°C)	NA
Melting point (°C)	NA
Flash point (°C)	NA
Flammable limits (°C)	NA
Self-flaming (°C)	NA
Explosion limits (°C)	NA
Combustion properties	NA
Vapor pressure (mm Hg)	NA
Refractive index (20°C)	NA
Density, g/cm ³ (20°C)	NA
Solubility in water	Slightly soluble
Solubility other	NA
Sharing coefficient	NA

10. STABILITY AND REACTIVITY DATA

Chemical stability	Stable under recommended storage conditions.
Conditions to avoid	No data available
Materials to avoid	No data available
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions - Carbon oxides
Hazardous polymerization:	

11. HEALTH HAZARDOUS

Primary Route(s) of Entry	Inhalation. Ingestion
Acute toxicity	No data available Inhalation: No data available

Skin corrosion/irritation	No data available
Respiratory or skin sensitization	No data available
Germ cell mutagenicity	No data available
Carcinogenicity	No components of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC
IARC	
ACGIH	No components of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH
NTP	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP
OSHA	No components of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA
Reproductive toxicity	No data available
Specific target organ toxicity - single exposure (GHS)	May cause respiratory irritation
Specific target organ toxicity - repeated exposure (GHS)	No data available
Aspiration hazard	No data available
Potential health effects	May be harmful if inhaled. Causes respiratory tract irritation
Inhalation	
Ingestion	May be harmful if swallowed
Skin	May be harmful if absorbed through skin. Causes skin irritation
Eyes	Causes eye irritation
Signs and Symptoms of Exposure	To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated
Additional Information	RTECS: MI5230000

12. ECOLOGICAL INFORMATIONS

Toxicity	No data available
Persistence and degradability	No data available
Bioaccumulative potential	No data available
Mobility in soil	No data available
PBT and vPvB assessment	No data available
Other adverse effects	No data available

13. DISPOSAL CONSIDERATIONS

Product	Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material.
Contaminated packaging	Dispose of as unused product

14. TRANSPORT INFORMATION

DOT (US)	Not dangerous goods
IMDG	Not dangerous goods
IATA	Not dangerous goods

15. REGULATORY INFORMATION

OSHA Hazards	None
DSL Status	All components of this product are on the Canadian DSL list
SARA 302 Components	SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302
SARA 313 Components	SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
SARA 311/312 Hazards	Acute Health Hazard, Chronic Health Hazard

16. OTHER INFORMATION

The information contained herein is applicable solely Coleus forskohlii extract (Forskolin 10%) and does not relate any other use of the substance described. Its use is intended by persons having technical skill and at their own discretion and risk. The information has been developed by Nachurél Ingredients LLC Laboratory staff from resources considered reliable but has not been independently verified by Nachurél Ingredients LLC. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OR MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

NA: Not available