

Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Registrant Details

1. Registration Number	UK API 28255
2. Name or corporate name of registrant	RUTLAND BIODYNAMICS LIMITED
3. Permanent or legal address of registrant	RUTLAND BIODYNAMICS LIMITED, TOWN PARK FARM, OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	RUTLAND BIODYNAMICS LIMITED, TOWN PARK FARM, OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED KINGDOM
5. National legal basis of registration	Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)
6. Name of responsible officer of the competent authority of the member state validating the registration	Confidential
7. Date	18/05/2026

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

RUTLAND BIODYNAMICS LIMITED, TOWN PARK FARM, OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

LIQUIFIED PHENOL
2000008503

E	General Finishing Steps
	E.1 Physical Processing Steps Mix Phenol and water. Adjust to final specification
	E.2 Primary Packaging

	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

TOLU BALSAM SOLUTION

4000010509

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

RHEUM PALMATUM

2000012870

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

BOSWELLIA SERRATA EXTRACT

1000019859

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
	B.5 Modification of Extracted Substance
E	General Finishing Steps
	E.1 Physical Processing Steps Solvation
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

CIMICIFUGA RACEMOSA

2000011320

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

HYSSOPUS OFFICINALIS HERB

3000018457

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification

	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

COCILLANA LIQUID EXTRACT

4000009545

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

PAEONIA LACTIFLORA UNPEELED ROOT

4000014426

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

DRIMIA INDICA
1000007667

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

COMMIPHORA MYRRHA RESIN
4000014423

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

VERBENA OFFICINALIS HERB
4000014428

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification

	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

ARCTIUM LAPPA ROOT

4000014422

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

TOLU BALSAM TINCTURE

4000010511

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

BAPTISIA TINCTORIA

1000006597

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

MARRUBIUM VULGARE HERB

4000014430

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

SCUTELLARIA LATERIFLORA

2000012996

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification

	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

OPIUM TINCTURE

2000008161

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
	B.5 Modification of Extracted Substance
E	General Finishing Steps
	E.1 Physical Processing Steps Solvation
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

CAMPHORATED OPIUM TINCTURE

1000006847

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
	B.5 Modification of Extracted Substance
E	General Finishing Steps
	E.1 Physical Processing Steps Solvation
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

CHLOROFORM AND MORPHINE TINCTURE

3000004780

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
	B.5 Modification of Extracted Substance
E	General Finishing Steps
	E.1 Physical Processing Steps Solvation
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

THYMUS SERPYLLUM HERB

4000014431

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

MELISSA OFFICINALIS QUANTIFIED DRY EXTRACT

4000011423

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification

	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

COAL TAR SOLUTION

2000011380

B	Extraction of Active Substance from Natural Sources
	B.4 Mineral Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Solvation
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

CARAPICHEA IPECACUANHA ROOT

2000017650

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

LOBELIA INFLATA

100007633

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

FUMARIA OFFICINALIS HERB

4000014424

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

HYPERICUM PERFORATUM

2000011927

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification

	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

VITEX AGNUS-CASTUS FRUIT

4000014432

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

POLYGALA SENEGA ROOT

4000014427

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

VALERIANA OFFICINALIS ROOT
2000016573

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

EPHEDRINE
1000002754

E	General Finishing Steps
	E.1 Physical Processing Steps Mix Phenol and water. Adjust to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

FUCUS VESICULOSUS
2000011728

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging

F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

COCILLANA EXTRACT

4000009543

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

TOLU FLAVOUR

1000004861

E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

GUAREA RUSBYI

2000011388

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction

E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

ANISE OIL

4000010114

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

TOLU-FLAVOUR SOLUTION

2000004001

E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

BELLADONNA TINCTURE

2000008372

E	General Finishing Steps
	E.1 Physical Processing Steps Mix Phenol and water. Adjust to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

PREPARED COAL TAR

2000007910

B	Extraction of Active Substance from Natural Sources
	B.4 Mineral Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Solvation
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

GLYCYRRHIZA GLABRA ROOT

4000013679

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

	F.2 Microbiological testing (excluding sterility testing)
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Active substance

AVENA SATIVA

1000009783

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

ECHINACEA

1000006672

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

MATRICARIA CHAMOMILLA FLOWERS

4000014429

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction

E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

INULA HELENIUM ROOT

4000014425

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

PASSIFLORA INCARNATA

2000012458

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing

	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

TOLU BALSAM SYRUP

1000009310

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Adjustment to final specification
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

COAL TAR SOLUTION STRONG

4000014216

B	Extraction of Active Substance from Natural Sources
	B.4 Mineral Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Solvation
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

2. IMPORTATION AND DISTRIBUTION OPERATIONS

- B Distribution
- LIQUIFIED PHENOL (2000008503)
 - TOLU BALSAM SOLUTION (4000010509)
 - RHEUM PALMATUM (2000012870)
 - BOSWELLIA SERRATA EXTRACT (1000019859)
 - CIMICIFUGA RACEMOSA (2000011320)

HYSSOPUS OFFICINALIS HERB (3000018457)
COCILLANA LIQUID EXTRACT (4000009545)
PAEONIA LACTIFLORA UNPEELED ROOT (4000014426)
DRIMIA INDICA (1000007667)
COMMIPHORA MYRRHA RESIN (4000014423)
VERBENA OFFICINALIS HERB (4000014428)
ARCTIUM LAPPA ROOT (4000014422)
TOLU BALSAM TINCTURE (4000010511)
BAPTISIA TINCTORIA (1000006597)
MARRUBIUM VULGARE HERB (4000014430)
SCUTELLARIA LATERIFLORA (2000012996)
OPIUM TINCTURE (2000008161)
CAMPHORATED OPIUM TINCTURE (1000006847)
CHLOROFORM AND MORPHINE TINCTURE (3000004780)
THYMUS SERPYLLUM HERB (4000014431)
MELISSA OFFICINALIS QUANTIFIED DRY EXTRACT (4000011423)
COAL TAR SOLUTION (2000011380)
CARAPICHEA IPECACUANHA ROOT (2000017650)
LOBELIA INFLATA (1000007633)
FUMARIA OFFICINALIS HERB (4000014424)
HYPERICUM PERFORATUM (2000011927)
VITEX AGNUS-CASTUS FRUIT (4000014432)
POLYGALA SENEGA ROOT (4000014427)
VALERIANA OFFICINALIS ROOT (2000016573)
EPHEDRINE (1000002754)
FUCUS VESICULOSUS (2000011728)
COCILLANA EXTRACT (4000009543)
TOLU FLAVOUR (1000004861)
GUAREA RUSBYI (2000011388)
ANISE OIL (4000010114)
TOLU-FLAVOUR SOLUTION (2000004001)
BELLADONNA TINCTURE (2000008372)
PREPARED COAL TAR (2000007910)
GLYCYRRHIZA GLABRA ROOT (4000013679)
AVENA SATIVA (1000009783)
ECHINACEA (1000006672)
MATRICARIA CHAMOMILLA FLOWERS (4000014429)
INULA HELENIUM ROOT (4000014425)
PASSIFLORA INCARNATA (2000012458)
TOLU BALSAM SYRUP (1000009310)
COAL TAR SOLUTION STRONG (4000014216)