

# 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 298
2. Name or corporate name of registrant	WELEDA UK LIMITED
3. Permanent or legal address of registrant	WELEDA UK LIMITED, HEANOR ROAD, ILKESTON, DE7 8DR, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	WELEDA (UK) LIMITED, HEANOR ROAD, ILKESTON, DE7 8DR, 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	14/05/2024

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

**WELEDA (UK) LIMITED**, HEANOR ROAD, ILKESTON, DE7 8DR, UNITED KINGDOM

#### 1. MANUFACTURING OPERATIONS

##### Active substance

CHAMOMILLA RADIX 10% MOTHER TINCTURE  
2000019280

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps

	E.1 Physical Processing Steps Press, filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

THUJA OCCIDENTALIS 33% MOTHER TINCTURE  
4000015554

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Press, filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

ARGENTUM NITRICUM 10% MOTHER TINCTURE  
2000019277

B	Extraction of Active Substance from Natural Sources
	B.4 Mineral Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Press, filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

ARNICA PLANTA TOTA 50% MOTHER TINCTURE  
2000019278

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps

	E.1 Physical Processing Steps Press, filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

MATRICARIA CHAMOMILLA 33% MOTHER TINCTURE  
2000019281

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Press, filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

VALERIANA OFFICINALIS 10% MOTHER TINCTURE  
2000019904

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Pressing, Filtering
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

ACONITUM NAPELLUS 50% MOTHER TINCTURE  
4000015549

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps

	E.1 Physical Processing Steps Press, filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

ANGELICA ARCHANGELICA ROOT PH EUR  
2000019285

E	General Finishing Steps
	E.1 Physical Processing Steps Drying, grinding
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

RUTA GRAVEOLENS 33% MOTHER TINCTURE  
4000015553

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Press, filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

HYPERICUM 33% PLANTA TOTA MOTHER TINCTURE  
2000019283

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Press, filtration

	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

WEED, GRASS, CEREALS AND TREE MIXED POLLEN WELEDA  
1000020699

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
	B.6 Purification of Extracted Substance - PLANT
E	General Finishing Steps
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

HYPERICUM PERFORATUM 33% MOTHER TINCTURE  
2000019282

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Press, filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

ALLIUM CEPA 50% MOTHER TINCTURE  
2000019276

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Press, filtration

	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

BELLADONNA 50% MOTHER TINCTURE

2000019286

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Press, filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

PASSIFLORA INCARNATA 33% MOTHER TINCTURE

4000016078

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Pressing, Filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

NATRUM MURIATICUM 10% MOTHER TINCTURE

2000019284

B	Extraction of Active Substance from Natural Sources
	B.4 Mineral Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Filtration

	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

KALIUM PHOSPHORICUM 1% MOTHER TINCTURE

2000019287

B	Extraction of Active Substance from Natural Sources
	B.4 Mineral Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Press, filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

RHUS TOXICODENDRON 50% MOTHER TINCTURE

4000015552

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Press, filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

CALENDULA OFFICINALIS 50% MOTHER TINCTURE

4000015551

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Press, filtration

	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

AVENA SATIVA 50% MOTHER TINCTURE

2000019903

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Pressing, Filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

HUMULUS LUPULUS 10% MOTHER TINCTURE

4000016077

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Pressing, Filtration
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

**Active substance**

ARNICA MONTANA 33% MOTHER TINCTURE

4000015550

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
E	General Finishing Steps
	E.1 Physical Processing Steps Press, filtration

	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing