

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
25/09/2023

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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