

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 19108
2. Name or corporate name of registrant	DSM NUTRITIONAL PRODUCTS (UK) LIMITED
3. Permanent or legal address of registrant	DSM NUTRITIONAL PRODUCTS (UK) LIMITED, DELVES ROAD, HEANOR GATE INDUSTRIAL ESTATE, HEANOR, DE75 7SG, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	DSM NUTRITIONAL PRODUCTS (UK) LIMITED, DRAKEMYRE, DALRY, KA24 5JJ, 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	23/04/2024

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

DSM NUTRITIONAL PRODUCTS (UK) LIMITED, DRAKEMYRE, DALRY, KA24 5JJ, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

CALCIUM PANTOTHENATE
4000010962

A	Manufacture of Active Substance by Chemical Synthesis
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Filtration, extraction
E	General Finishing Steps

	E.1 Physical Processing Steps Drying
	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

PANTHENOL

1000009614

A	Manufacture of Active Substance by Chemical Synthesis
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Filtration
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

ASCORBIC ACID

1000009903

A	Manufacture of Active Substance by Chemical Synthesis
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, milling and sieving
	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

SODIUM ASCORBATE

2000007558

A	Manufacture of Active Substance by Chemical Synthesis
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying,milling and sieving
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)