

LEPIVITS Belgium
4 Avenue Franklin – Unité 16
1300 Wavre
BELGIQUE



Fiche technique – Harpago +

Code EAN : 5430002936338 (60 gélules)
*NUT : 3760/1

DOSSIER TECHNIQUE - SPECIFICATION SHEET Devil's claw extract 10% harpagosides

INFORMATIONS SUR LA PLANTE

PLANT INFORMATION

RAW MATERIAL INFORMATION

Botanical name	<i>Harpagophytum procumbens</i>
Family	Pedaliaceae
Common name	Devil's Claw
Plant part used	Root
Risk of adulteration or confusion	No
Type of culture (cultivated/wild)	Agricultural
Geographical origin of the plant	
- Continent	Asia
- Country	China
- Region	
Is the plant concerned by the regulation 388/97/CE	No
Method of harvest (manual/mechanical)	Manual
Period of harvest (month(s) of harvest)	September to November
Stage of harvest (development stage of the plant)	Mature
Has the plant been dried after harvest	Yes
If so, what is the drying method	Natural
Has the plant been treated before harvest	No
If so, specify	
Has the plant been treated after harvest	Yes
If so, specify	Cleaning
Compliance with Good Agricultural and Collection Practices (GACP)	Yes, GACP form no available

RAW MATERIAL IDENTIFICATION

Reference monograph of raw material	Chinese pharmacopoeia (CP)
Identification of raw material	TLC
Active compound	Harpagosides
Constituents responsible of adverse effects	Iridoids

(Substance to be monitored : according to French regulation)*

**Limited substances are tested in control plan. Unlimited substances are tested on customer's request.*

INFORMATIONS SUR L'EXTRAIT

EXTRACT INFORMATION

EXTRACT CHARACTERIZATION

Extraction information

Process of herbal preparation	<input checked="" type="checkbox"/> Extraction	<input type="checkbox"/> Supercritical CO2
	<input type="checkbox"/> Ultrason	<input type="checkbox"/> Microwave-assisted extraction
Extract solvent (%)	100% water	
Native extract ratio (NER) :	20-22/1 expressed on <input checked="" type="checkbox"/> dry or <input type="checkbox"/> fresh plant	
Final extract ratio (DER) :	20/1 expressed on <input checked="" type="checkbox"/> dry or <input type="checkbox"/> fresh plant	
Continent of manufacture	China	

Extract composition

Ingredient(s)	Content (%)	Function
Native extract	90-100%	Ingredient
Maltodextrin	0-10%	Carrier

Analytical data

Appearance*	Yellow brown powder
Identification - Monograph	Positive by TLC
Loss on drying	NMT 8.0%
Ash	NMT 10.0%
Bulk density	0.40-0.65 g/mL
Tapped density	0.50-0.60 g/mL
Particle size	80 mesh
Assay – Test method	NLT 10% Harpagosides by UV method

Storage conditions / Shelf life

Type of packaging	P.E
Packaging	Suitable for food industry
Storage conditions	Store at temperature below 25°C, in a well closed bag away from moisture and direct sun light
Shelf life	2 years if stored in accordance with recommendations
Batch size	Batch size depends of our suppliers and of customer order (kg to tons)
Stability data	No

**For products from plant origin, minor color variation can be observed due to geographical and seasonal variation of the raw material*

IMPURITIES*

Contaminants and residues		Analysis		Not tested	Content- limit	Reference and/or method
		Each batch	Control plan			
Heavy metals	Lead (Pb)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<3ppm	Atomic absorption
	Cadmium (Cd)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<1ppm	Atomic absorption
	Mercury (Hg)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<0.1ppm	Atomic absorption
	Arsenic (As)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<2ppm	Atomic absorption
Microbiological control	Total plate count	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<50 000 cfu/g	USP
	Yeast & moulds	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<500 cfu/g	USP
	Bile tolerant gram – bacteria (enterobacteria)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
	E. coli	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Negative	USP
	Salmonella	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Negative	USP
	Staphylococcus aureus	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
	Others ...	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	
Contaminants control	Residual solvent ...	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	
	Pesticides	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Meets EP requirements	GC
	Aflatoxin B1	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	
	Sum of B1, B2, G1, G2	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	
	Ochratoxin A	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	
	Dioxins and PCBs	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	
	Benz(o)apyrene	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<10ppb	GC
	Sum of PAH (benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<50ppb	GC
	Melamine and its structural analogues	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	-
	Iodine (algae)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	-
	Microcystin (algae)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	-
	Other contaminants :					
	Pyrrolizidine alkaloids	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>On customer's request</i>	-
	3-MCPD (3-monochloro-propanol-1,2-diol)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	-	-

*Information given by our supplier on the date of updating of data sheet

ATTESTATIONS - STATEMENTS

GMOs FREE STATEMENT

According to the manufacturer's declaration and to the European Regulations:

- Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed

- Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning tractability and labelling on GMOs and tractability of food and feed products produced from GMOs and amending Directive 2001/18/EC

GMOs FREE

Yes **No**

If no, name and quantity (%):

NON-IRRADIATION STATEMENT

According to the manufacturer's declaration and to the European Directive 1999/2/EC and 1999/3/EC of the European Parliament and of the Council:

NON-IRRADIATION

Yes **No**

BSE/TSE FREE STATEMENT

According to the manufacturer's declaration:

BSE/TSE FREE

Yes **No**

NANOMATERIALS FREE STATEMENT

According to the manufacturer's declaration and to the EU Regulation No 1169/2011 of the European Parliament and of the Council of 25 October 2011:

NANOMATERIALS FREE

Yes **No**

If no, name and quantity (%):

ALLERGENS AND CROSS CONTAMINATION STATEMENT

According to the manufacturer's declaration and to the EU Regulation No 1169/2011 of the European Parliament and of the Council of 25 October 2011, this product is:

ALLERGENS FREE	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<i>(if no see below)</i>		
	Present in the product (Yes/No)	Quantity (ppm) In case of presence	Presence of allergen on the production site or on the same production line (On Natural site and supplier site)		
Cereals containing gluten, namely: wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof (1)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Crustaceans and products thereof	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Eggs and products thereof	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Fish and products thereof (2)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Peanuts and products thereof	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Not applicable
Soybeans and products thereof (3)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Milk and products thereof (including lactose) (4)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Nuts, namely: almonds (<i>Amygdalus communis</i> L.), hazelnuts (<i>Corylus avellana</i>), walnuts (<i>Juglans regia</i>), cashews (<i>Anacardium occidentale</i>), pecan nuts (<i>Carya illinoensis</i> (Wangenh.) K. Koch), Brazil nuts (<i>Bertholletia excelsa</i>), pistachio nuts (<i>Pistacia vera</i>), macadamia or Queensland nuts (<i>Macadamia ternifolia</i>), and products thereof (5)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Celery and products thereof	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Mustard and products thereof	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Not applicable
Sesame seeds and products thereof	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO ₂ (6)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Lupin and products thereof	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Not applicable
Molluscs and products thereof	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable

The risk of cross contamination on Natural site and supplier site is avoided by cleaning procedures.

EUROPEAN FOOD REGULATIONS

According to the manufacturer's declaration, this product is

EUROPEAN REGULATIONS	COMPLIANT		
Contaminants (Regulation 1881/2006/EC)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Heavy metals (Regulation 629/2008/EC)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Pesticides (Regulation 396/2005/EC)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Extraction solvents (Directive 2009/32/EC)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Not applicable
PAH and benzoapyrene (Regulation 2015/1933/EC)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
Food additive (Regulation 231/2012/CE and 1333/2008/EC)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Not applicable

FOOD GRADE

According to the manufacturer's declaration, this product is:

STATEMENTS

Suitable for humans	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not specified
Gluten free (<20mg/kg - Regulation 828/2014)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Not analyzed
Suitable for vegetarians	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not specified
Suitable for vegans	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not specified
Halal* (until XX/XX/XXXX)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Not specified
Kosher* (until XX/XX/XXXX)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Not specified

**Product certified by the supplier. Natural is not halal and kosher certified*

NON-ANIMAL TESTING STATEMENT

According to the manufacturer's declaration and to the European regulations Directive 2003/15/CE and 2003/80/CE:

NON-ANIMAL TESTING

Yes No Not specify

INFORMATIONS COMPLEMENTAIRES

OTHER INFORMATION

REGULATORY STATUS

The plant used for this product is approved in:

- French decree - Arrêté plante du 24 juin 2014
- Belgian decree - Arrêté royal du 29/08/97 tel que modifié Février 2017
- Italian decree - Décret du 10 août 2018
- Other : *Croatia and Denmark*

Europe : Risk of requalification as a medicinal product (According to EMA monograph) <i>(National restriction possible)</i>	No
Plant present in list B of the French Pharmacopoeia	No
If plant present listed in the list B of the French Pharmacopoeia : according to the Public Health Code, food supplements containing plant or parts of plants appearing on list B of the French Pharmacopoeia can't be sold by other people than pharmacists.	

Country	Source	Plant part	Substance to be monitored	Additional information
Belgium	Positive list, Royal decree 29/08/97 as amended February 2017	Secondary tuber	Iridoids (≤ 40 mg)	
France	Positive list, Law of 24 June 2014 Doctrine List of plants article 15 April 2016, Doctrine teledeclaration June 2017 Doctrine List of plants article 15 April 2016, Doctrine teledeclaration June 2017	Underground parts, subterranean organs Underground parts, subterranean organs Tuber	Iridoids	Additional doctrine for plant parts specified in Law of 24 June 2014. Can be notified according to article 15 with electronic declaration, even if not specified in Law of 24 June 2014.
Italy	Positive list, Decree 10 August 2018, Annex 1 updated on 9 January 2019 and 26 July 2019	Root, Tuber		The Italian authorities do not accept botanicals claims on hold at European level, because Italy already had national provisions: physiological effects listed in the last column of the list of plants authorized in Italy (« LG MINISTERIALI DI RIFERIMENTO PER GLI EFFETTI FISILOGICI »).

Information given as an indication according to our current knowledge only for Belgian, German, French and Italian regulations. This product is intended to be used in food supplements. It is up to the final user to determine its terms of use, according to the applicable regulation

ALERTE RASFF*

RASFF alert known on the product on the date of updating the data sheet:

No

Yes, see below:

**Indicative information*

FICHE DE SÉCURITÉ

Material Safety Data Sheet

Material Safety Data Sheet contains information about employee health protection and safety. MSDS apply to dangerous substances and blends containing dangerous substances. MSDS aim at keeping the user's attention on the dangers and the caution related to the product and its conservation.

The above-mentioned substance or preparation does not meet the criteria for classification as dangerous (European regulation n° 1272/2008 and its modifications) and therefore is not subject to the obligation to provide a Material Safety Data Sheet (European regulation n°1907/2006 and its modifications).

This statement is based on our current knowledge at the date indicated on this document. Attention of the users is required on potential risks caused by a usage of the product that would differ from what it was conceived for. Specifically, this item is intended for an industrial application, must not be consumed as is, and must be handled with the usual precaution.

NOVEL FOOD*

This product is :

Used before 15 May 1997 (according to Novel food catalogue**):

As food or food ingredient, so is not subject to the Novel Food Regulation

Only as or in food supplements, so is not subject but other food use has to be authorized pursuant to the Novel Food Regulation (*possible national restrictions*).

Not used before 15 May 1997 and:

Authorized and Listed in the Union List of Novel Foods in accordance with Regulation (EU) 2017/2470

Request in progress, further information is required.

Not authorized. Therefore, before it may be placed on the market in the EU as a food or food ingredient a safety assessment under the Novel Food Regulation is required.

No information available - Not in the positive list or in Catalogue of Novel Food at the date of writing.

** Indicative information*

*** The Novel Food Catalogue lists products of animal and plant origin and other substances subject to the Novel Food Regulation, based on information provided by the EU Member States. It is a non-exhaustive list and serves as orientation on whether a product will need an authorization under the Novel Food Regulation (national restrictions are possible)"*

Rice Starch

Remy B KA

- Description**
- Remy B KA is a food starch manufactured from polished broken rice.
 - Remy B KA is a coarse neutral rice starch powder with stringent microbiological criteria.

Specifications

Physical and Chemical Parameters

Parameter	Limit	Unit	Method ²	Frequency
Moisture ¹	max. 14	g/100 g	ISO 712	Each batch
Protein (N* 6.25) ¹	max. 1.0	g/100 g d.m.	ISO 1871	Each batch
Ash ¹	max. 1.0	g/100 g d.m.	ISO 3593	Each batch
pH (10 g to 100 mL) ¹	5.5 – 7.5		Potentiometric	Each batch
Oxidising substances as hydrogen peroxide	max. 0.002	g/100 g	Ph. Eur. 2.5.30	Each batch
Arsenic, inorganic	max. 0.1	mg/kg	ICP-MS	Monitoring
Lead	max. 0.1	mg/kg	ICP-MS	Monitoring
Cadmium	max. 0.1	mg/kg	ICP-MS	Monitoring

¹ on Certificate of Analysis

² or validated equivalent

Microbiological Parameters

Parameter	Limit	Unit	Method ²	Frequency
Total mesophilic bacteria ¹ (aerobes)	max. 1 000	cfu/g	ISO 4833	Each batch
Yeasts and moulds ¹	max. 100	cfu/g	ISO 21527	Each batch
Enterobacteriaceae ¹	max. 10	cfu/g	ISO 21528	Each batch
Salmonella	negative	/25 g	ISO 6579	Each batch

¹ on Certificate of Analysis

² or acknowledged and validated equivalent

Additional Information

Information relevant for Nutrition Declaration

Nutritional information provided in the table shall enable food manufacturers to calculate the contribution of Remy B KA in their food products in compliance with applicable EU/US food legislation. More detailed information is available upon request.

Nutrient	Typical Value ¹	Unit per 100 g
Energy value/calories	1530/360	kJ/kcal
Fat ²	0.7	g
saturates	0.3	g
Carbohydrates	88	g
sugars	Negligible ³	g
starch	88	g
Fibre	Negligible ³	g
Protein	0.5	g
Salt (sodium)	0.25 (0.10)	g
Vitamins, Minerals ⁴	Negligible ³	g

¹ Proposed values are typical values.

² for US: trans fats and cholesterol negligible

³ Negligible means "0" for macronutrients according to applicable rounding rules in EU and US.

⁴ Rice starch is not a typical source of vitamins/minerals.

Other information

Appearance*	White powder
Taste*	Neutral
Odour*	Neutral
Labelling (EU)	(Rice) starch
Labelling other countries	Information available upon request
Customs code	1108 1910 00
Packaging	25 kg multiply paper bags
Recommended storage conditions	Original (unopened) packaging in a dry place protected against odours and pests
Minimum durability	4 years from date of production under recommended storage conditions
Compliance and Certification	Kosher (certificate available upon request) Halal (certificate available upon request) Suitable for vegetarians & vegans Suitable for gluten-free products: gluten ≤ 10 mg/kg Rice is not listed as allergen in Annex II of Regulation (EU) No 1169/2011 nor as a major allergen in Section 201(qq) [21 U.S.C. 321] of the Food, Drug and Cosmetic Act. Product is not derived from genetically modified organisms (GMO). Product is produced in Belgium in compliance with applicable European Food Law (e.g. Regulation (EC) No 178/2002, Regulation (EC) No 852/2004), Belgian Law and Codex Alimentarius standards.

Natural Pullulan Capsules

General parameters

Description	Empty, two-piece, cylindrical hard natural capsules, typical in taste and odour.		
Manufacturer	Shanxi Guangsheng Medicinal Capsule Co., Ltd.		
Manufacturer certifications	BRC, NSF-GMP, ISO9001, ISO14001, OHSAS18001, Halal, and Kosher		
Legal status	EU legislation for food supplements	Country of origin	China
Composition	Pullulan (FCC & E-1204) and purified water (Ph. Eur.)		
Colour range	Clear transparent and opaque, with colours according to agreement		
Imprint	Text and colour according to agreement	Ink type	Edible
Excipients	Gellan gum, xanthan gum, carrageenan, and potassium chloride. <small>[†] The excipients are suitably controlled by the rules laid down by Commission Regulation 1333/2008/EC on food additives; however they are not required to be included in the list of ingredients as they serve no technological function in the finished capsules (Commission Regulation 1169/2011/EU, Article 20 (b)[i]).</small>		

Galenic properties (AQL-defect rate: Critical: 0.01 %, Major: 0.10 %, Minor: 0.40 %, on fully automatic testing machines)

Size	000	00	0	1
Weight, mg	186 ±9	140 ±8	108 ±7	78 ±6
Volume, cc	1.35	0.93	0.68	0.50

Dose (mg/capsule) as function of bulk density

- 0.6 g/cc	810	558	408	300
- 0.8 g/cc	1080	744	544	400
- 1.0 g/cc	1350	930	680	500
- 1.2 g/cc	1620	1116	816	600

Length, mm

- Cap	13.1 ±0.4	11.8 ±0.4	10.9 ±0.4	9.8 ±0.4
- Body	22.0 ±0.4	20.2 ±0.4	18.6 ±0.4	16.5 ±0.4
- Overall closed (filled)	25.7 ±0.5	23.4 ±0.5	21.7 ±0.5	19.3 ±0.5

External diameter, mm

- Cap	9.85 ±0.05	8.55 ±0.05	7.66 ±0.05	6.95 ±0.05
- Body	9.49 ±0.05	8.20 ±0.05	7.35 ±0.05	6.65 ±0.04

Single wall thickness, mm

- Cap	0.115 ±0.02	0.105 ±0.02	0.100 ±0.02	0.100 ±0.02
- Body	0.110 ±0.02	0.105 ±0.02	0.100 ±0.02	0.095 ±0.02

For elongated or other sizes: please request our full dimensions table.

Analytical parameters

Galenic properties

Disintegration time ≤ 30 min. (EP, 37°C, guided disc)

Chemical

Arsenic (As)	NMT 1.0 mg/kg	
Lead (Pb)	NMT 1.0 mg/kg	
Cadmium (Cd)	NMT 1.0 mg/kg	
Mercury (Hg)	NMT 0.1 mg/kg	
Sulphated ash, clear trans.	NMT 2.0% w/w	
Sulphated ash, opaque	NMT 5.0% w/w	
Loss on drying	10.0 to 15.0 % w/w	105°C, 4 hours or constant weight

Microbiology

Total viable count	≤ 1000 cfu/g	
Yeasts and moulds	≤ 100 cfu/g	
Enterobacteria	≤ 100 cfu/g	
E. coli	Negative in 1 g	Ph. Eur. 2.4.12./13 or equivalent
Salmonella	Negative in 10 g	
Staphylococcus aureus	Negative in 1 g	
Pseudomonas aeruginosa	Negative in 1 g	

Packaging

Size	000	00	0	1
Capsules/box	50 000	70 000	100 000	125 000
Packaging material	Double polyethylene food grade bag in sturdy cardboard-box			
Box dimensions	585 x 385 x 730 mm (length x width x height)			

Storage and handling

Storage	Store between 10°C and 25°C and relative humidity (RH) between 35% and 65%, in tightly closed packing, protected from direct light.
Pre-filling	Recommended storage between 20°C and 24°C and RH between 45% and 65% at least 12 hours before opening.
Handling and filling	Temperature between 20°C and 24°C and RH between 45% and 65% during usage. Use only stainless steel scoops and spatulas. Do not leave capsules in a filling machine hopper for prolonged period, when not in use. Keep mouth of the bag closed when not in use.
Shelf life	5 years from date of manufacturing, when stored and handled as described.