A.Erre & Co.
Specialità per l'industria cosmetico-farmaceutica

TECHNICAL DATA SHEET

DESCRIPTION

HYDRORUTIN is an experimental multicomposite of
Rutin/ Maltodextrin / sucrester / arginine in a w/w ratio 25 / 65 / 5 / 10
HYDRORUTIN is a multicomposite powder resulting by the application of technology at solid state (no solvents) to a mixture of Rutin and selected excipients. The technology does not introduce any chemical modification to the single components, only physic-chemical properties are improved.
It may be used in the formulation of nutricosmetics.
Recommended dosages for HYDRORUTIN are those necessary to achieve the desired effect according to formulation – keeping into account that the content of Rutin is 20%.

INFO ON COMPONENTS

Ingredient	*Rutin NF11*	*Maltodextrin*	*Sugar Esters*	*L-Arginine*
w/w %	20	65	5	10
Description / Chemical Name	- Origin: purified from Sophora Japonica L. flowers - Geographical origin: Asia	Maltodextrin	Mixture of sucrose mono-, di- and tri-esters (palmitate: 60-65%, stearate: 12-15%, di- and tri-esters: <20%)	2-Amino-5-Guanidinovaleric Acid
Molecular Formula	$C_{27}H_{30}O_{16}$. $3H_2O$	$(C_6H_{10}O_5)_n$ .H_2O	$C_{28}H_{52}O_{12}$ $C_{30}H_{56}O_{12}$	$C_6H_{14}N_4O_2$
CAS Nr.	153-18-4	9050-36-6	26446-38-8 25168-73-4	74-79-3
EC Nr.	205-814-1	232-940-4	247-706-7 246-705-9	200-811-1
INCI Name	Rutin	Maltodextrin	Sucrose palmitate	Arginine
Mol. Weight	664.56	Polymer, depends on "n"	/	174.20
Other Info	Rutin content : 95%	/	/	/

Parameter	Provisional Specification	Method/ Reference
PHYSICO-CHEMICAL		
Appearance	Yellow powder	Organoleptic
Odour	Faint Characteristic	Organoleptic
Identity	Conform to UV spectrum of starting Rutin	UV (Internal SOP)
Assay	≥ 18.0 mg Rutin /100 mg anhydrous	UV (Internal SOP)
Water content	≤ 15.0 %	KF (Internal SOP)
Poured density	n.d.	Pharm. Eu. Curr.Ed.
Tapped density	n.d.	Pharm. Eu. Curr.Ed.
MICROBIOLOGICAL		
Total viable aerobic count	$<10^2$ cfu/g or ml	Pharm. Eu. Curr.Ed.
Yeasts and moulds	$<10^2$ cfu/g or ml	
Enterobacteria, gram negative	$<10^2$ pnb/g or ml	
Salmonella	free in 10 g or ml	
Escherichia coli	free in 1 g or ml	
Staphylococcus aureus	free in 1 g or ml	

A.Erre & Co. S.r.l.
Capitale sociale
€ 51.000 int. Vers.

Sede legale e Amministrativa:
Via Tanaro, 15 – 20017 Rho (Milano) Italy
Tel. +39.029304946 r.a. – fax +39.02.93508238
e-mail: info@aerreita.com
www.aerreita.it

Partita IVA e cod. fiscale: 11596890159
Iscr.Reg. Ditte Milano: 1482383
Iscr. R.E.A. Milano: 857379

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Following parameters are checked on single ingredients of HYDRORUTIN as per internal Self-Control Plan		
Parameter	**Reference**	**Ingredient**
PESTICIDES	DM 27/8/2004 396/2005/CE 178/2006/CE 149/2008/CE	Rutin Maltodextrin Sugar Esters L-arginine
HEAVY METALS	Reg CE 629/08	Rutin Maltodextrin
	Reg. 231/2012	Sugar Esters
	Pharm. Eu. Curr.Ed.	L-arginine
RESIDUAL SOLVENTS	Dir CE 2009/32	Rutin L-arginine
	Reg. 231/2012	Sugar Esters
AFLATOXINS	Reg. 1881/2006/CE	Rutin Maltodextrin
POLYCYCLIC AROMATIC HYDROCARBONS (IPA)	Reg.(UE) 2015/1933	Rutin L-arginine

Declarations (based on raw material suppliers declarations and HYDRORUTIN manufacturing process)		
Parameters	**Reference**	**Declaration**
BSE/TSE	Guidelines EMEA 410/01 rev.2 Reg.999/2001/CE	Free
GMO	Reg. 1829/2003/CE Reg. 1830/2003/CE	Free
IRRADIATION	Dir.1999/2/CE Dir.1999/3/CE D.Lgs. 94, 30/01/01	Not irradiated
ALLERGENES	Reg.1169/2011/CE	See attached declaration
MELAMINE	Reg. 594/2012/CE	Complies

FOOD GRADE	Hydrorutin is manufactured according to HACCP requirements (aut. 126 Jul. 12th 04, implemented Mar. 03rd 11 Reg n. IT0610102851

SHELF LIFE	Shelf life for HYDRORUTIN is 6 months in its originally sealed container. At the end of its shelf life the product can be retested.
STORAGE	Avoid humidity and direct light exposure Store in a cool, dry place

MSDS	A safety data sheet is available

Disclaimer: Data submitted in this publication are based on our current knowledge and experience. They do not constitute a guarantee in the legal sense of the term and, in view of the manifolds factors that may affect processing and application, do not relieve processors from the responsibility of carrying their own tests and experiments. Any relevant patent rights and existing legislation and regulations must be observed.

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