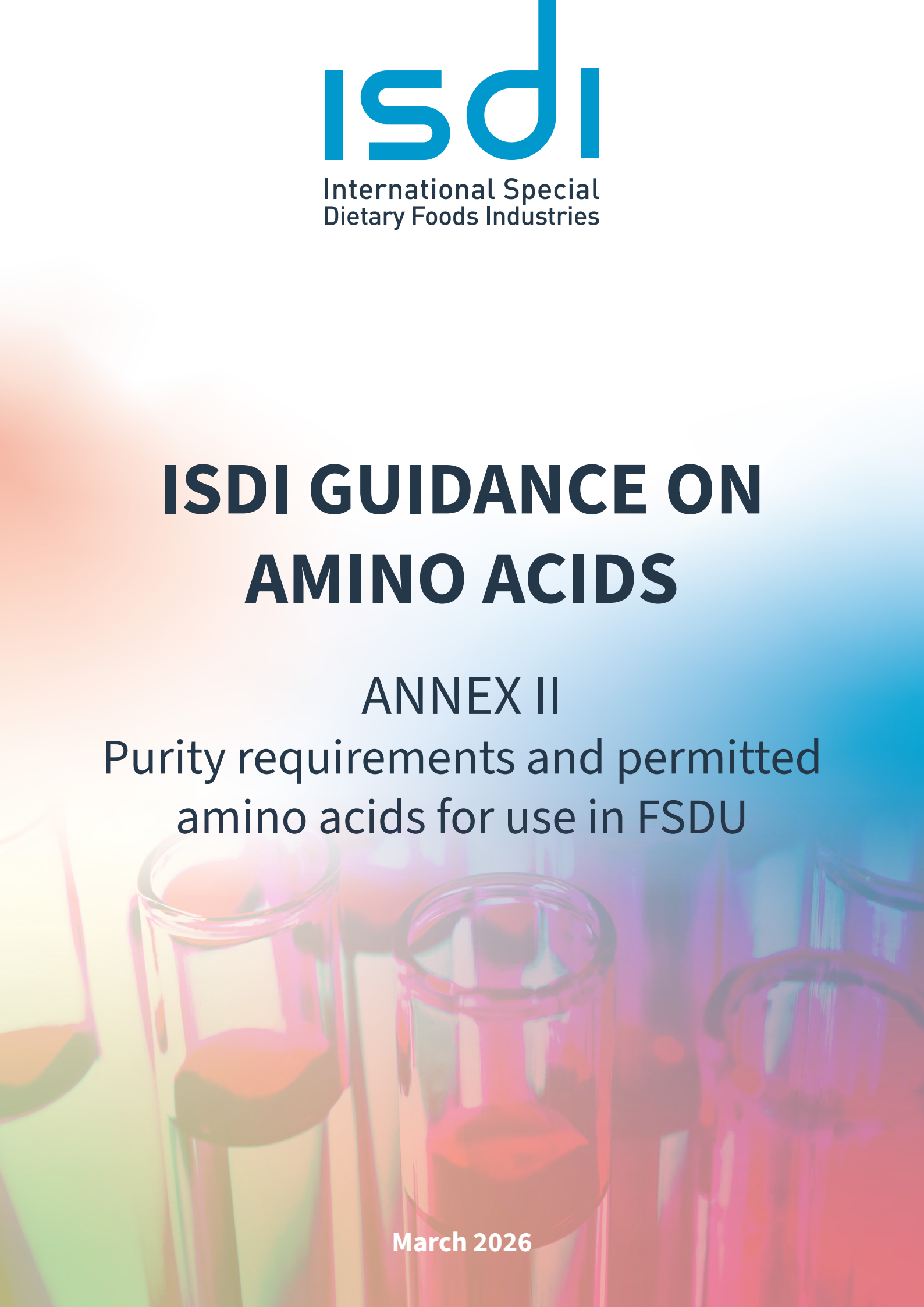
International Special
Dietary Foods Industries

ISDI GUIDANCE ON AMINO ACIDS

ANNEX II
Purity requirements and permitted amino acids for use in FSDU



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SUMMARY OF PURITY REQUIREMENTS AND PERMITTED AMINO ACIDS FOR USE IN FSDU ACCORDING TO NATIONAL REGULATIONS[1]

This document is intended to serve as an additional reference resource, complementing the **ISDI Guidance on Amino Acids**. Its purpose is to provide an overview of how different jurisdictions regulate the use of amino acids in Foods for Special Dietary Uses (FSDU), highlighting permitted substances, their recognized forms, and applicable purity standards.

Abbreviations for food standards	Abbreviations for national and international bodies
BF = Baby Foods	BP = British Pharmacopoeia
CBF = Canned baby food	CAC = Codex Alimentarius Commission
DRWC = Diet replacement for weight control	DAB = Deutsches Arzneibuch
FUF = Follow-up formula; For China, this refers to FUF for ages 6-12 months, only	DAC = Deutscher Arzneimittel-Codex
IF = Infant Formula	FCC = Food Chemicals Codex
PCBF = Processed cereal-based foods for infants and young children	Jap Food Stan = Japanese Food Standard
FSDU = Food for special dietary uses - Uses for supplying particular dietary needs (diseases, allergic hypersensitivity to food, underweight, and overweight). Uses for supplying particular dietary needs which exist by reason of age (infant - not more than 12 months old, child-more than 12 months)	JECFA = Joint FAO/WHO Expert Committee on Food Additives
FSMP = Food for special medical purposes other than infant formula	MI = Merck Index
FSMPi = Formulas for special medical purposes intended for infants	MP = Martindale Pharmacopoeia
FSMPiy = Food for special medical purposes for infants and young children[2]	EP = Pharmacopoeia Europaea
SF = Sports food	Ph Int = International Pharmacopoeia
VLED = Very low energy diet	USP = The United States Pharmacopoeia

[1] **Disclaimer**: While every effort has been made to ensure that the information presented is accurate and up to date, regulatory frameworks evolve and may change over time. This document is reviewed and updated periodically; however, it may not fully reflect the most recent developments in all jurisdictions. Users are therefore advised to consult the latest national regulatory sources when making compliance decisions.

The table on the following page summarises:

- The amino acids that may be used in FSDU products,
- The monographs (national or international) that define their purity requirements, and
- Whether these amino acids are permitted in key regulatory markets (EU, United States, China, Australia and New Zealand), including—where applicable—the specific FSDU categories in which their use is authorized.

[2] The abbreviation of FSMPiy refers to “FSMP for Infants and Young Children” as cited in Codex Guideline CXG 10-1979 (“Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children”). Whereas the abbreviation FSMPi refers to “Formulas for Special Medical Purposes Intended for Infants,” as cited in CXS 72-1981 (Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infant). ISDI notes that, from standards perspective, Codex distinguishes between two categories:

1. Formulas for Special Medical Purposes Intended for Infants (below 12 months), and
2. Food for Special Medical Purposes (above 12 months).

This differentiation is based on distinct risk assessment approaches applied to products intended for infants. For the population aged 12 to 36 months, the advisory list suggests that CXG 10-1979 should be considered, noting that this is not exhaustive and other optional ingredients are possible.

Nutrient source	Purity requirements by		Use in food standards applicable to FSDU & FSMP				
	CAC	International and/or national bodies	EU[1]	US[2]	China[3]	Australia & New Zealand	Codex[4]
1.1 L-Arginine		FCC, USP, Ph Eur, BP, DAB	IF, FUF, PCBF, BF, FSMP, DRWC	FSDU, IF, FSMP	FSMP, FSMPi	SF, VLED, FSMP	IF, FUF, PCBF, CBF - only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use) FSMPi, FSMPiy - allowed
1.2 L-Arginine hydrochloride		FCC, USP, Ph Eur, BP, DAB	IF, FUF, PCBF, BF	FSDU, IF, FSMP	FSMP, FSMPi	VLED, FSMP	
1.3 L-Cystine		FCC, USP, Ph Eur	IF, FUF, PCBF, BF FSMP, DRWC – any form of cystine allowed	FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF	VLED, FSMP	
1.4 L-Cystine dihydrochloride		MI	IF, FUF, PCBF, BF	FSDU, IF, FSMP		VLED, FSMP	
1.5 L-Cysteine		DAB	IF, FUF, PCBF, BF, FSMP, DRWC	FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF	IF, FUF, FSMPi, SF, VLED, FSMP	
1.6 L-Cysteine hydrochloride		FCC, Ph Eur	IF, FUF, PCBF, BF	FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF (monohydrate form) IF, FUF (anhydrous form)	VLED, FSMP	
1.7 L- Histidine		FCC, USP, Ph Eur, DAB	IF, FUF, PCBF, BF, FSMP, DRWC	FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF	IF, FUF, FSMPi, SF, VLED, FSMP	
1.8 L- Histidine hydrochloride		FCC, Ph Eur, DAB	IF, FUF, PCBF, BF	FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF (monohydrate form)	VLED, FSMP	
1.9 L-Isoleucine		FCC, USP, Ph Eur, DAB	IF, FUF, PCBF, BF, FSMP, DRWC	FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF, SF	IF, FUF, FSMPi, SF, VLED, FSMP	
1.10 L-Isoleucine hydrochloride		FCC, USP	IF, FUF, PCBF, BF	FSDU, IF, FSMP		VLED, FSMP	
1.11 L-Leucine		FCC, USP, Ph Eur, DAB	IF, FUF, PCBF, BF, FSMP, DRWC	FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF, SF	IF, FUF, FSMPi, SF, VLED, FSMP	
1.12 L-Leucine hydrochloride		MI, FCC, USP	IF, FUF, PCBF, BF	FSDU, IF, FSMP	FSMP	VLED, FSMP	

[1] For amino acids used in infant formula, follow-on formula, processed cereal-based food and baby food only the hydrochloride specifically mentioned may be used. For amino acids used in food for special medical purposes and in total diet replacement for weight control, as far as applicable, also the sodium, potassium, calcium and magnesium salts as well as their hydrochlorides may be used.

[2] The food additive amino acids may be safely used as nutrients if they consist of one or more of the following individual amino acids in the free, hydrated, or anhydrous form, or as the hydrochloride, sodium, or potassium salts.

[3] Conditions to meet: a) Non-edible animal and plant raw materials shall not be used as the source of monomer amino acid, b) Wherever applicable, amino acids can be used in free, aqueous or aqueous states, as well as hydrochloric acid compounds, sodium salts and potassium salts of amino acids. (for food for special medical purposes only).

[4] As far as applicable, also the free, hydrated and anhydrous forms of amino acids, and the hydrochloride, sodium, and potassium salts of amino acids may be used for FSMP.

Nutrient source	Purity requirements by		Use in food standards applicable to FSDU & FSMP				
	CAC	International and/or national bodies	EU[1]	US[2]	China[3]	Australia & New Zealand	Codex[4]
1.13 L-Lysine		USP	IF, FUF, PCBF, BF, FSMP, DRWC	FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF	IF, FUF, FSMPi, SF, VLED, FSMP	IF, FUF, PCBF, CBF - only for improving the nutritional quality of the protein (when the protein is nutritionally inadequate for its intended use) FSMPi, FSMPiy - allowed
1.14 L-Lysine hydrochloride		FCC, USP, Ph Eur, DAB	IF, FUF, PCBF, BF	FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF	VLED, FSMP	
1.15 L-Methionine		Ph Int, FCC, USP, Ph Eur, DAB	IF, FUF, PCBF, BF, FSMP, DRWC	FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF	IF, FUF, FSMPi, SF, VLED, FSMP	
1.16 L-Phenylalanine		FCC, USP, Ph Eur	IF, FUF, PCBF, BF, FSMP, DRWC	FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF	IF, FUF, FSMPi, SF, VLED, FSMP	
1.17 L-Threonine		FCC, USP, Ph Eur, DAB	IF, FUF, PCBF, BF, FSMP, DRWC	FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF	IF, FUF, FSMPi, SF, VLED, FSMP	
1.18 L-Tryptophan		FCC, USP, Ph Eur, DAB	IF, FUF, PCBF, BF, FSMP, DRWC	FSDU, IF, FSMP	FSMP. FSMPi, IF, FUF	IF, FUF, FSMPi, SF, VLED, FSMP	
1.19 L-Tyrosine		FCC, USP, Ph Eur, DAB	IF, FUF, PCBF, BF, FSMP, DRWC	FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF	IF, FUF, FSMPi, SF, VLED, FSMP	
1.20 L-Valine		FCC, USP, Ph Eur, DAB	IF, FUF, PCBF, BF, FSMP, DRWC	FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF, SF	IF, FUF, FSMPi, SF, VLED, FSMP	
1.21 L-Alanine		FCC, USP, Ph Eur, DAB	FSMP, DRWC	FSDU, IF, FSMP	FSMP, FSMPi	SF, VLED, FSMP	FSMPi, FSMPiy
1.22 L-Arginine-L-aspartic acid		Ph Eur	FSMP		FSMP	VLED, FSMP	
1.23 L-Aspartic acid		FCC, USP, Ph Eur	FSMP	FSDU, IF, FSMP	FSMP, FSMPi	SF, VLED, FSMP	
1.24 L-Citrulline		USP, DAC	FSMP		FSMP	VLED, FSMP	
1.25 L- Glutamic acid		JECFA (1987), FCC, USP, Ph Eur	FSMP, DRWC	FSDU, IF, FSMP	FSMP, FSMPi	SF, VLED, FSMP	
1.26 L-Glutamine		FCC, USP, DAB	FSMP, DRWC	FSDU, IF, FSMP	FSMP, FSMPi, SF	SF, VLED, FSMP	
1.27 Glycine		FCC, USP, Ph Eur	FSMP	FSDU, IF, FSMP	FSMP, FSMPi	SF, VLED, FSMP	
1.28 L-Ornithine		MI, FCC	FSMP, DRWC			SF, VLED, FSMP	

Nutrient source	Purity requirements by		Use in food standards applicable to FSDU & FSMP				
	CAC	International and/or national bodies	EU[1]	US[2]	China[3]	Australia & New Zealand	Codex[4]
1.29 L-Ornithine monohydrochloride		DAB			FSMP	VLED, FSMP	FSMPi, FSMPiy
1.30 L-Proline		FCC, USP, Ph Eur, DAB	FSMP	FSDU, IF, FSMP	FSMP. FSMPi	SF, VLED, FSMP	
1.31 L-Serine		USP, Ph Eur, DAB	FSMP	FSDU, IF, FSMP	FSMP, FSMPi	SF, VLED, FSMP	
1.32 N-Acetyl-L-cysteine		USP, Ph Eur, DAB	FSMP		FSMP		
1.33 N-Acetyl-L-methionine		FCC	FSMP (in products intended for persons over 1 year of age)		FSMP, FSMPi, IF, FUF	VLED, FSMP	FSMPi, FSMPiy – not for infants
1.34 L-Lysine acetate		FCC, USP, MP; Ph Eur	FSMP, DRWC		FSMP. FSMPi, IF, FUF	VLED, FSMP	FSMPi, FSMPiy
1.35 L-Lysine L-Aspartic acid		Jap Food Stan	FSMP		FSMP	VLED, FSMP	
1.36 L-Lysine L-glutamatic acid dihydrate		Jap Food Stan			FSMP		
1.37 Magnesium L-aspartate		Ph Eur			FSMP, FSMPi	VLED, FSMP	
1.38 Calcium L-glutamate	1991	JECFA, FCC, Jap Food Stan			FSMP (tetrahydrate form)	VLED, FSMP	
1.39 Potassium L- glutamate		JECFA, FCC, Jap Food Stan		FSDU, IF, FSMP	FSMP (monohydrate), FSMPi	VLED, FSMP	
1.40 Asparagine				FSDU, IF, FSMP		VLED, FSMP	
1.41 DL-Methionine				FSDU – not for infant foods			
1.42 Taurine						SF	
1.43 Arginine acetate						VLED, FSMP	
1.44 L-lysine-L-glutamate			FSMP			VLED, FSMP	
1.45. L-Carnitine		FCC, USP, Ph Eur		FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF, SF only endurance product	IF, FSMPi, FUF, FSMP, VLED	FSMPi, FSMPiv
1.46. L-Carnitine tartrate		FCC, Ph Eur		FSDU, IF, FSMP	FSMP, FSMPi, IF, FUF, SF only endurance product	IF, FSMPi, FUF, FSMP, VLED	
1.47. L-Carnitine hydrochloride		FCC, Ph Eur			FSMP, FSMPi, IF, FUF, SF only endurance product	IF, FSMPi, FUF, FSMP, VLED	

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