



Technical Alert

New Ingredient Names Available in ELF for Metal Amino Acid Chelates

The Therapeutic Goods Administration has made additions to the List of Australian Approved Names for Metal Amino Acid Chelates included in the Electronic Listing Facility (ELF). This now makes 19 new specific names for metal amino acids chelates available for use.

The new names (marked with an * below) have been added to allow sponsors to identify ingredients more accurately. The ingredient names in the ELF include the approved name and molecular formula for each ingredient. The associated ingredient rules are consistent with chelate names in Part 3 Schedule 4 of the *Therapeutic Goods Regulations 1990*. That is, the relevant mineral is a mandatory component and the purpose for use for all amino acid chelates is restricted to mineral supplementation.

It is important to clarify that the addition of new specific names for metal amino acid chelates to the Australian Register of Therapeutic Goods (ARTG) is not an approval of new ingredients for use in listed medicines. The new ingredient names are based on metal amino acid components that are themselves already eligible and available for use in listed medicines. Therefore, the generation of compositional guidelines and listing notices for gazettal of new ingredients is not required.

Background -The issue of naming and characterisation ambiguities associated with metal amino acid chelates was originally discussed at the Interim Joint Expert Advisory Committee on Complementary Medicines as part of the Permitted Ingredients List Project, where a list of ingredients for review was identified as part of this project.

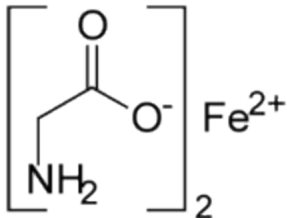
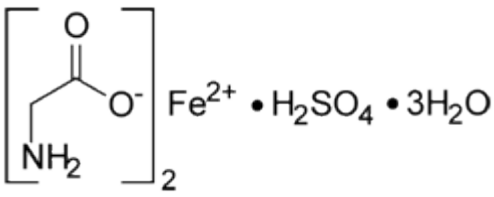
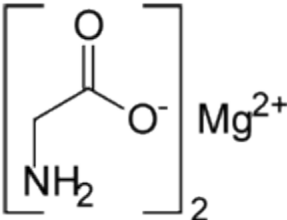
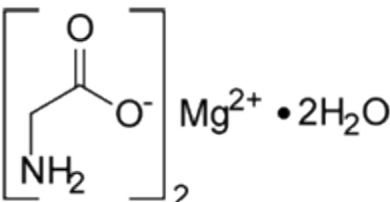
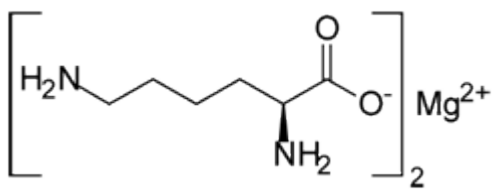
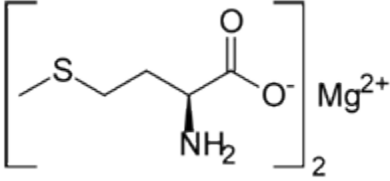
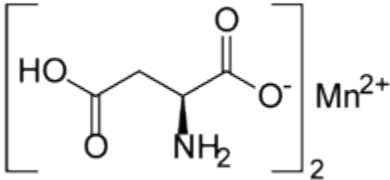
The Office of Complementary Medicines and Industry Consultative Group (OICG) have since undertaken extensive work regarding the chelate ingredient names, identifying the ingredients most relevant to the Australian market.

The CHC is now able to provide the updated list of specific ingredient names that are available for use in ELF (see attachment below).

List of Australian Approved Names for metal amino acid chelates included in ELF

Approved Name	Molecular formula	Chemical structure	CAS Registry Number	Acceptable limits of metal content (%)
Calcium aspartate	$C_4H_5NO_4Ca$		21059-46-1	22.2-24.6
Calcium diaspertate	$(C_4H_6NO_4)_2Ca$		39162-75-9	12.5-13.8
Calcium aspartate hydrochloride dihydrate	$CM_4H_5NO_4Ca \cdot HCl \cdot 2H_2O$		92533-40-9	15.6-17.3
Calcium glycinate	$(C_2H_4NO_2)_2Ca$		35947-07-0	20.2-22.4
*Calcium glycinate dihydrate	$(C_2H_4NO_2)_2Ca \cdot 2H_2O$		92533-40-9	15.6-17.3
Calcium lysinate	$(C_6H_{13}N_2O_2)_2Ca$		6150-68-1	11.5-12.7
Calcium methioninate	$(C_5H_{10}NO_2S)_2Ca$		819-17-0	11.3-12.5

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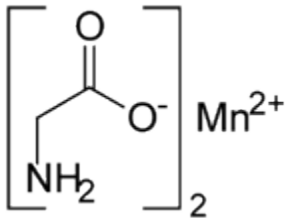
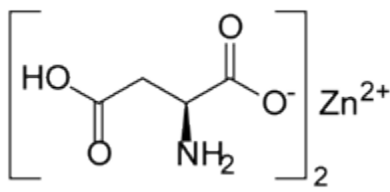
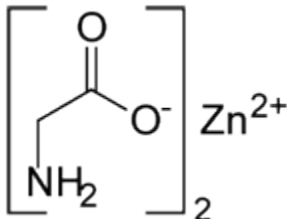
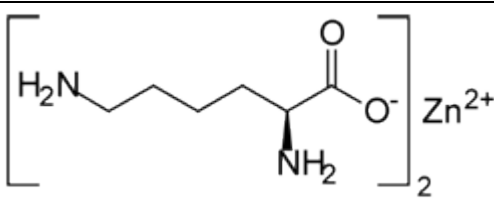
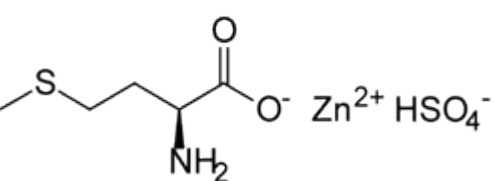
Approved Name	Molecular formula	Chemical structure	CAS Registry Number	Acceptable limits of metal content (%)
Iron (II) glycinate Synonym = Ferrous bisglycinate	$(C_2H_4NO_2)_2Fe$		20150-34-9	26.0-28.8
*Iron (II) bisglycine sulfate trihydrate	$(C_2H_5NO_2)_2 \cdot FeSO_4 \cdot 3H_2O$		Nil	14.9-16.5
Magnesium glycinate	$(C_2H_4NO_2)_2Mg$		14783-68-7	13.4-14.8
*Magnesium glycinate dihydrate	$(C_2H_4NO_2)_2Mg \cdot 2H_2O$		Nil	12.7-15.6
Magnesium lysinate	$(C_6H_{13}N_2O_2)_2Mg$		151753-50-3	7.3-8.1
Magnesium methioninate	$(C_5H_{10}NO_2S)_2Mg$		106207-65-2	7.2-8.0
Manganese (II) diaspertate	$(C_4H_6NO_4)_2Mn$		Nil	16.4-18.1

Complementary Healthcare Council of Australia

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Approved Name	Molecular formula	Chemical structure	CAS Registry Number	Acceptable limits of metal content (%)
Manganese (II) glycinate	$(\text{C}_2\text{H}_4\text{NO}_2)_2\text{Mn}$		14281-77-7	25.7-28.4
Zinc diaspartate	$(\text{C}_4\text{H}_6\text{NO}_4)_2\text{Zn}$		36393-20-1	18.9-20.8
Zinc glycinate	$(\text{C}_2\text{H}_4\text{NO}_2)_2\text{Zn}$		14281-83-5	29.1-32.2
Zinc lysinate	$(\text{C}_6\text{H}_{13}\text{N}_2\text{O}_2)_2\text{Zn}$		23333-98-4	17.5-19.3
Zinc methionine sulfate	$\text{C}_5\text{H}_{11}\text{NO}_2\text{S} \cdot \text{ZnSO}_4$		56329-42-1	20.0-22.1