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| **Raw Material Questionnaire**  **Allergens and Substances of Concern Information** |

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| Introduction |
| This questionnaire is developed for raw material suppliers to provide information to manufacturers and sponsors. The questionnaire collects information on allergens and substances of concern, that may be present within raw materials for which there are Australian regulatory requirements. Use of the questionnaire helps ensure compliance with these requirements.  Complementary Medicines Australia (CMA) and the Australian Self Medication Industry (ASMI) and have jointly developed this questionnaire in consultation with member companies. |
| |  | | --- | | 1. **Company and Contact Details** | |
| |  |  | | --- | --- | | 1.1 Company Name: |  | |
| |  |  | | --- | --- | | This document was completed by: |  | |
|  |
| |  |  | | --- | --- | | Signature |  | |
| |  |  | | --- | --- | | Name: |  | |
| |  |  | | --- | --- | | Title: |  | |
| |  |  | | --- | --- | | Date: |  | |

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| |  |  | | --- | --- | | |  | | --- | | **2 Product Information** | | |
| |  |  | | --- | --- | | 2.1 Code: |  | |
| |  |  | | --- | --- | | Product Name: |  | |

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| |  |  | | --- | --- | | |  | | --- | | **3 Declarable Substance Information** | | | | | | |
| Ingredient[1](#Note1) | | Present and/or used to produce product[2](#Note2) | **Quantity present by analytical verification** | Source and description[3](#Note3) |
| **Major allergens** | Celery derived ingredients[4](#Note4) |  |  |  |
| Cereal grain derived ingredients[5](#Note5) |  |  |  |
| **Crustacean derived ingredients**[**6**](#Note6) |  |  |  |
| **Dairy derived ingredients**[**7**](#Note7) |  |  |  |
| **Egg derived ingredients**[**8**](#Note8) |  |  |  |
| **Fish derived ingredients**[**9**](#Note9) |  |  |  |
| **Gluten**[**10**](#Note10) |  |  |  |
| Lupin derived ingredients[11](#Note11) |  |  |  |
| Mollusc derived ingredients[12](#Note12) |  |  |  |
| Mustard derived ingredients[13](#Note13) |  |  |  |
| **Peanut derived ingredients**[**14**](#Note14) |  |  |  |
| **Pollen**[**15**](#Note15) |  |  |  |
| **Propolis** |  |  |  |
| **Royal jelly** |  |  |  |
| **Sesame derived ingredients**[**16**](#Note16) |  |  |  |
| **Soy derived ingredients**[**17**](#Note17) |  |  |  |
| **Sulfites**[**18**](#Note18) |  |  |  |
| **Tree nut derived ingredients**[**19**](#Note19) |  |  |  |

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| **Substances of concern** | **Antibiotics**[**20**](#Note20) | |  |  |  |
| **Aspartame** | |  |  |  |
| **Benzoates**[**21**](#Note21) | |  |  |  |
| **Ethanol**[**22**](#Note22) | |  |  |  |
| **Hydroxybenzoic acid esters**[**23**](#Note23) | |  |  |  |
| **Phenylalanine**[**24**](#Note24) | |  |  |  |
| **Potassium**[**25**](#Note25) | |  |  |  |
| **Saccharin**[**26**](#Note26) | |  |  |  |
| **Sodium**[**27**](#Note27) | |  |  |  |
| **Sorbates**[**28**](#Note28) | |  |  |  |
| **Sucralose** | |  |  |  |
| **Sugars All**[**29**](#Note29) | |  |  |  |
| **Galactose**[30](#Note30) | |  |  |  |
| **Lactose** | |  |  |  |
| **Sugar alcohols**[**31**](#Note31) | |  |  |  |
| **Tartrazine** | |  |  |  |
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| **Risk Analysis Key:** | | | | | | |
| Yes - PV | | | Present at stated quantity – analytically verified. | | | |
| Yes - PN | | | Present at stated quantity – not analytically verified. | | | |
| Yes - AN | | | Added during production of material – absence not analytically verified. | | | |
| Yes - LN | | | Likely to be present (as a component or likely contaminant) – absence not analytically verified. | | | |
| No - UN | | | Unlikely to be present – absence not analytically verified. | | | |
| No - UV | | | Unlikely to be present – absence analytically verified at limit of detection/quantification (LOD/LOQ) stated on specification. Sponsors determining whether to declare a substance on a label should not rely on the detection limits of impurity tests for substances where TGO 92 has not defined a cut-off quantity or safe level. | | | |
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| **Notes:** | | | | | | |
| 1 | | Provides a description of the allergens and ingredients of concern, classified into two categories - major allergens and ingredients of concern.  TGO 92 Schedule 1 substances are indicated in bold.  The list of allergens and ingredients of concern is derived from the *Therapeutic Goods Order No.92 Standard for Labels of Non-Prescription Medicines*, Food Standards Australia New Zealand (FSANZ) Food Standards Code Standard 1.2.3 Information Requirements - Warning Statements, Advisory Statements and Declarations, European Union Commission Directive 2007/68/EC and US Federal Register Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II). | | | | |
| 2 | | Provides codified information on the specified ingredient and whether it is present and/or used to produce product. | | | | |
| 3 | | Provides additional information on the specified ingredient. | | | | |
| 4 | | Includes celeriac, celery seed oil, celery leaf, celery seed and all ingredients derived from celeriac (*Apium graveolens* var. *rapaceum*) and celery (Apium graveolens). | | | | |
| 5 | | Includes barley (*Hordeum vulgare*), einkorn (*Triticum boeoticum*, *Triticum monococcum*), emmer (*Triticum dicoccum*), kamut (*Triticum turanicum*), oats (*Avena sativa*), rye (*Secale cereale*), spelt (*Triticum* *spelta*), triticale (*Triticale hexaploide*), wheat (*Triticum durum*), their hybridised strains and all ingredients derived from cereal grains. | | | | |
| 6 | | Includes chitin, chitosan, crab, crayfish, krill, lobster, prawns, shrimp, and all ingredients derived from fresh water and marine crustaceans. | | | | |
| 7 | | Includes bovine colostrum, bovine lactoferrin, casein, caseinates, hydrolysed milk protein, lactose, lactic acid, milk, whey and all ingredients derived from dairy. | | | | |
| 8 | | Includes egg lecithin, egg albumin, egg yolk, egg white and all ingredients derived from eggs. | | | | |
| 9 | | Includes cod liver oil, fish gelatin, fish oil, isinglass, omega-3 marine triglycerides, omega-3 acid ethyl esters and all ingredients derived from fresh water fish, marine fish including sharks and diadromous fish. | | | | |
| 10 | | Gluten when present at ≥ 20 mg/kg. | | | | |
| 11 | | Includes Australian sweet lupin (*Lupinus angustifolius*), Andean lupin (*Lupinus mutabilis*), white lupin (*Lupinis albus*), plants in the genus *Lupinus* and all ingredients derived from lupins. | | | | |
| 12 | | Includes green lipped mussel oil, green lipped mussel powder, octopi, oysters, squid, squid oil, concentrated omega-3 marine triglycerides - squid and all ingredients derived from molluscs. | | | | |
| 13 | | Includes mustard seed, mustard seed oil and all ingredients derived from mustard (*Brassica juncea*), (*Brassica nigra*) and (*Sinapis alba*). | | | | |
| 14 | | Includes arachis oil, peanut flour and all ingredients derived from peanuts (*Arachis hypogaea*). | | | | |
| 15 | | Pollen includes plant materials such as flowering plant tops that are likely to include pollen, unless it is likely that the pollen has been removed through extraction processes. | | | | |
| 16 | | Includes sesame oil, sesame seed and all ingredients derived from sesame (Sesamum indicum). | | | | |
| 17 | | Includes lecithin, soy bran, soy fibre, soy isoflavones, soy oil, soy protein, soy sterols, tocopherols and all ingredients derived from soy (*Glycine max*). TGO 92 allows sponsors to exclude: soya oil that is fully refined; d-alpha tocopherol, d-alpha tocopheryl acetate, d-alpha tocopheryl acid succinate, mixed (high-alpha type) tocopherols concentrate, or mixed (low-alpha type) tocopherols concentrate when derived from soybean sources; vegetable oils derived phytosterols and phytosterol esters from soybean sources; plant stanol ester produced from vegetable oil sterols from soybean sources. | | | | |
| 18 | | Includes bisulfites, metabisulfites, potassium metabisulfite sodium metabisulfite, sodium sulfite, sulfites and sulfur dioxide when present at any level, including when present as a residue, for example in gelatin. | | | | |
| 19 | | Includes almond (*Prunus dulcis*), black walnut (*Juglans nigra*), brazil (*Bertholettia excelsa*), cashew (*Anacardium occidentale*), chestnut (*Castanea sativa*), hazelnut (*Corylus avellana*), macadamia (*Macadamia ternifolia*), pecan (*Carya illinoinensis*), pistachio (*Pistacia vera*), walnut (*Juglans regia*) and all ingredients derived from tree nuts. | | | | |
| 20 | | Includes all ingredients containing antibiotics when present at ≥ 10 mg/kg. | | | | |
| 21 | | Includes benzoic acid and sodium benzoate. | | | | |
| 22 | | Ethanol when present at ≥ 3% w/w. | | | | |
| 23 | | Includes ethyl hydroxybenzoate, methyl hydroxybenzoate, propyl hydroxybenzoate, sodium ethyl hydroxybenzoate, sodium methyl hydroxybenzoate and sodium propyl hydroxybenzoate. | | | | |
| 24 | | Includes aspartame, soy (*Glycine max*) and other legumes in the family Fabaceae, spirulina (*Arthrospira platensis*, *Arthrospira maxima*) and all ingredients containing phenylalanine. | | | | |
| 25 | | Includes potassium ascorbate, potassium chloride, potassium bicarbonate, potassium salts and all ingredients containing potassium. | | | | |
| 26 | | Includes saccharin calcium and saccharin sodium. | | | | |
| 27 | | Includes sodium ascorbate, sodium chloride, sodium bicarbonate, sodium salts and all ingredients containing sodium. | | | | |
| 28 | | Includes potassium sorbate, sorbates and sorbic acid. | | | | |
| 29 | | Includes fructose, galactose, glucose, honey, invert sugar, lactose, maltose, sucrose and all ingredients defined as monosaccharides and disaccharides. | | | | |
| 30 | | Galactose presence must be separately identified on labels as well as included in general sugars. | | | | |
| 31 | | Includes erythritol, glycerol, isomalt, lactitol, maltitol, mannitol, polydextrose, sorbitol, xylitol and all ingredients defined as sugar alcohols. | | | | |
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| **References:** | | | | | | |
| Therapeutic Goods Order No.92 Standard for Labels of Non-Prescription Medicines <https://www.legislation.gov.au/Details/F2016L01287>  Food Standards Australia New Zealand (FSANZ) Food Standards Code Standard 1.2.3 Information Requirements - Warning Statements, Advisory Statements and Declarations <https://www.legislation.gov.au/Details/F2017C00418>  European Union Commission Directive 76/768/EEC <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1473829615036&uri=CELEX:31976L0768>  European Union Commission Directive 2007/68/EC <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1473829686361&uri=CELEX:32007L0068>  US Federal Register Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II) <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm> | | | | | | |

**Document Revision**

This questionnaire should be updated when any information changes or every three years.

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| **Document Revision History** | | |
| **Date** | **Version** | **Changes** |
| 16/01/2012 | 1 | First issue. |
| 4/08/2014 | 2 | Introduction updated to reflect name change of CHC to CMA. |
| 25/06/2018 | 3 | Name Change.  Revision to reflect the TGO 92 and associated guidance (Version 1.1) including changes to Risk Analysis Key.  Removal of most ingredients not included in legislation.  Division into allergens and other substances of concern. |