



Nestlé Australia Ltd Submission

Increased online access to ingredient information – consultation paper

Response – 19th September 2019

Nestlé Submission

Consultation paper - Increased online access to ingredient information

Nestlé welcomes the opportunity to provide comments in response to TGA's proposal to publish the names of excipient ingredients in the public summaries of the ARTG.

Nestlé has no objection to the names of excipient ingredients of products being published in the public summary of the ARTG.

Consumers are increasingly looking for more information on the ingredients in food and medicine products that they consume and publishing excipient information on the ARTG will provide some increased level of information to consumers. No single solution will give every consumer all the information that they are looking for. Food manufacturers, where the ingredients list of the products are printed on labels, still receive a constant stream of questions from consumers about the product.

If the names of excipient ingredients are to be published on the ARTG records Nestlé would prefer and recommend the adoption of option 1B and the option that all proprietary ingredients are included in the public summary by their purpose only.

Reasons to not publish the ingredients of a Proprietary Ingredient

- Manufacturers of proprietary ingredients have provided the information about ingredients and formulation of the proprietary ingredient to TGA confidentially. The ingredients list of proprietary ingredients may be commercially confidential information and making the information publically available may have legal implications.
- Compound ingredients in foods are defined as an ingredient of a food that is itself made from two or more ingredients. Therefore Compound ingredients in foods could be considered to be similar to proprietary ingredients in therapeutic goods.

In the labelling of food ingredients, if a compound ingredient is added to a food at up to 5% of the final food, the ingredients of that compound ingredient are not required to be included on the ingredients list of the product (in this case only allergens or a food additive that performs a technical function in the final food need to be declared).

As the ingredients in compound ingredients of foods are in many cases not required to be declared it would be broadly consistent with the information consumers see on food labels if the ingredients of proprietary ingredients were not published in the public summary of the ARTG.

- A proprietary ingredient may contain an allergen substance and that allergen may not be included as any specific ingredient name.

- The ingredient names for excipients on the ARTG will be the Australian approved name. The names of ingredients may be different to names of ingredients that consumers are used to seeing on foods and cosmetics. These may be names that people are not familiar with and some names that may cause some alarm to consumers.

Reasons not to publish Proprietary Ingredient names

- Some proprietary ingredient names contain claims or implied claims. These include 'natural', 'nature identical', 'artificial', 'preservative free', 'lactose free', 'vegetarian', 'bovine', and 'halal'. Sponsor of products have no control over the name of the proprietary ingredient and if they are not making a claim on their product sponsors will not have substantiated a claim or implied claim that is in the name of a proprietary ingredient.

If the names of proprietary ingredients are published on the public summary of the ARTG record the issue of how any claims or implied claims in the proprietary ingredient name are verified to be true and not misleading will need to be addressed. As the sponsor would not be making the claim TGA would have to assume the responsibility for ensuring any published claims are accurate and not misleading.

An ingredient name in the ARTG that includes the claim of natural or vegetarian may lead the consumer to believe that the entire product is natural or vegetarian when this may not be the case.

- In most cases the name of the proprietary ingredient does not provide information that the consumer is looking for, does not provide any helpful information about allergens that may be present in the ingredient and there is no benefit in the consumer seeing the proprietary ingredient name.
- If the names of proprietary ingredients were included on the public summary of the ARTG and a sponsor submitted a grouping application to change a flavour, fragrance, or printing ink then there would be a period of time prior to the product formulation actually changing and a period of time where both the old and new formulation were on the market. Some way of how to have the correct excipient names during a grouping change would need to be implemented.

Proposed format for proprietary ingredients in the excipient list of the ARTG.

For all proprietary ingredients Nestlé proposes that the proprietary ingredient should be published on the ARTG by purpose only. There is no risk to the consumer in not knowing the proprietary ingredient name and no benefit to the consumer in knowing the proprietary ingredient name.

The table below gives some examples of what might be published on the ARTG record if the Proprietary Ingredient purpose or name was published.

Recommended Published by purpose	Not Recommended published by name
Flavour	(PF72) N&A Orange Tangerine FL SD#21816
Coating solution	OPADRY complete film coating system YS-1-12843-A Yellow
Capsule formulation	Empty Hard Gelatin Capsule Shell (LU01379) Cap & Body Bright Yellow Opaque & White Opaque Size 3
Colour	OPACOLOR liquid coloring system OD-11009 GREEN
Ink	No-Tox Flexographic Ink FGN-7214 NT20 Brown-465
Preservative mixes	Bactericide MB 2/500030

The proprietary ingredient purpose is concise and describes what the ingredient is used for. The proprietary ingredient names can be long and in most cases do not provide consumers with helpful information. For this reason Nestlé recommends that all proprietary ingredient excipients are published on the ARTG record by purpose only and not by name.

Commercial Impacts on sponsor – especially of some listed and OTC medicines

For some listed and OTC medicines the flavour of the product is a very important product attribute and a reason that a consumer may choose one product over another. Sponsors can spend a lot of time developing the flavour profile of a product to aim to have a product that is preferred by consumers. Products where flavour is a very important attribute and can be a determining factor in which product a consumer selects includes products such as cough syrups, medicated lozenges, chewable tablets, suspensions and elixirs.

If the proprietary ingredient flavour names are published on the ARTG then it would be easy for a potential competitor to source the same flavours and easily develop a competing product that looks and tastes almost exactly the same as a market leading product.

This would potentially commercially disadvantage the sponsor who went to the cost to develop the original product if that product can be easily copied.

For this reason we request that for flavour and colour proprietary ingredients the proprietary ingredient name is not published on the ARTG but only the purpose of the proprietary ingredient.

There is no risk to the consumer in not knowing the flavour or colour proprietary ingredient name and no benefit to the consumer in knowing the proprietary ingredient name.

Some points to consider if excipient names are included on the public summary of the ARTG.

- Product labels will declare the presence of substances as required by TGO 92. This includes substances such and other ingredient as milk, soy, nuts, gluten, lactose, sulphites, benzoates, sorbic acid, egg, pollen etc. The presence of these substances may not be obvious or included in the ingredients list published on the ARTG and consumers will need to be aware of this. Consumers will need to be advised to also read the product label and not just rely on the ARTG record.
- The ingredient names for excipients on the ARTG will be the Australian approved name. The names of ingredients may be different to names of ingredients that consumers are used to seeing on foods and cosmetics. Consumers who view the ARTG record will need to know this.
- For some products there are different formulations on the ARTG, some of which may no longer be supplied. If a consumer does not know the AUST R or AUST L number of the product that they are trying to find information for it may be very difficult for them to find the correct product record on the ARTG.
- Some Ingredients are present at insignificant levels in the final product but may still appear as an ingredient on the excipients list as an excipient. This is different to foods where ingredients at insignificant levels that are not intentionally added to a food product in order to perform some technological function are not likely to appear on the ingredients list. Consumers who view an ingredients list on the ARTG will need to be aware of this so that they do not automatically assume that an ingredient will be present at significant levels.
- Consumers are used to ingredients on food labels being in descending order of amount added. Consumers will need to be aware that excipients listed in the ARTG record are in alphabetical order not from highest to lowest amount.