

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	354468	NUTRA-LIFE PROBIOTICA KID'S DAILY	
ARTG entry for	Medicine Listed		
Sponsor	Vitaco Health Australia Pty Ltd		
Postal Address	PO Box 399, NORTH RYDE BC, NSW, 1670 Australia		
ARTG Start Date	8/02/2021		
Product Category	Medicine		
Status	Active		
Approval Area	Listed Medicines		
• III			

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . NUTRA-LIFE PROBIOTICA KID'S DAILY					
Product Type	Single Medicine Product	Effective Date	8/02/2021		
Permitted Indication	ons				
Maintain/support ge	eneral health and wellbeing				
Maintain/support int	testinal health				
Maintain/support int	estinal good/beneficial/friendly flora				
Maintain/support small intestine good/beneficial/friendly flora					
Maintain/support gastrointestinal system health					
Maintain/support gastrointestinal mucosal membrane health					
Maintain/support immune system health					
Maintain/support healthy immune system function					
Maintain/support healthy gastrointestinal immune function					
Indication Require	ments				
Product presentation	on must not imply or refer to serious immunolo	gical diseases.			
Standard Indicatio	ns				
No Standard Indica	tions included on Record				
Specific Indication	IS				
No Specific Indications included on Record					
Warnings					
(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].					
Additional Produc	t information				
Pack Size/Poison i	information				
Pack Size		Poison Schedule			
Components					
1. Formulation '	1				
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Dosage Form Tablet, chewable Route of Administration Oral Visual Identification **Active Ingredients** Bifidobacterium bifidum Bifidobacterium longum Lactobacillus gasseri Other Ingredients (Excipients) calcium carbonate dextrin Flavour fructose magnesium stearate maize starch

.125 billion CFU .125 billion CFU .75 billion CFU

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