



ORIGINAL DOCUMENT
Kayla Baumgart

Certificate of Analysis

CERT-27-OCT-2021-69882
Created: 13-OCT-2021

Material Description	ENFABEBE PREMATURES PWD 363G (6CAN) AR
SAP Material Number	2044019
Item	0019-85
Inventory Batch	ZP1HUV
Disposition	Accepted
Disposition Version	1
Manufacture Date	26-AUG-2021
Expiry Date	01-MAR-2023

<u>Test Name</u>	<u>Sample Type</u>	<u>Blend - Variable Specification No.</u>	<u>Results</u>	<u>UoM</u>	<u>Result Code</u>
Release Check	SUMMARY	0 Acceptable	Acceptable		A
Record Review	SUMMARY	0 Pass	Pass		A
Release Check for Relabeled Product	SUMMARY	0 Pass	Pass		A

This batch was relabeled from Enfabebe Prematures Powder, 2044073, batch 0615950. All analytical testing was completed on the original batch. The COA for the original batch is attached.

Reviewed by:

Gary Egli
Gary Egli
MJN SOP Administrator

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Certificate of Analysis

CERT-27-OCT-2021-69883
Created: 26-AUG-2021

Material Description	ENFABEBE PREMATUROS PWD 363G (6CAN) ARG
SAP Material Number	2044073
Formulation	IF00000968
Item	0019-86
Inventory Batch	0615950
Regulatory Batch	ZP1HUV
Disposition	Accepted
Disposition Version	1
Manufacture Date	26-AUG-2021
Expiry Date	01-MAR-2023

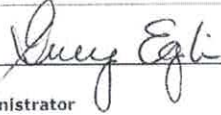
<u>Test Name</u>	<u>Sample Type</u>	<u>Blend - Variable Specification No.</u>	<u>Results</u>	<u>UoM</u>	<u>Result Code</u>
Release Check	SUMMARY	0	Acceptable	Acceptable	A
Loss on Drying	COMPOSITE	0	<=3.0	2.5	g/100g A
Fat	COMPOSITE	0	23.7 - 28.9	26.3	g/100g A
Protein	COMPOSITE	0	12.5 - 14.9	13.9	g/100g A
C18:2 Linoleic Acid	COMPOSITE	0	688 - 1200	907	mg/100cal A
C18:3 Linolenic Acid	COMPOSITE	0	69 - 150	120	mg/100cal A
C20:4 Arachidonic Acid	COMPOSITE	0	30.6 - 39.0	36.3	mg/100cal A
C22:6 Docosahexaenoic Acid	COMPOSITE	0	15.3 - 23.8	17.1	mg/100cal A
Carbohydrate	COMPOSITE	0	47.6 - 56.5	53.4	g/100g A
Vitamin B12	COMPOSITE	0	0.27 - 1.10	0.44	mcg/100cal A
Pantothenic Acid	COMPOSITE	0	765 - 1750	1102	mcg/100cal A
Vitamin E	COMPOSITE	0	3.6 - 7.0	5.1	IU/100cal A
Riboflavin	COMPOSITE	0	180 - 500	281	mcg/100cal A
Vitamin C	BLEND_EACH	3	14.4 - 59.0	29.6	mg/100cal A
Vitamin C	BLEND_EACH	2	14.4 - 59.0	31.8	mg/100cal A
Vitamin C	BLEND_EACH	1	14.4 - 59.0	30.4	mg/100cal A
Vitamin C	SINGLE	0	14.4 - 59.0	28.2	mg/100cal A
Vitamin C	SINGLE	0	14.4 - 59.0	30.1	mg/100cal A
Vitamin A	COMPOSITE	0	405 - 655	517	IU/100cal A
Thiamine HCl	COMPOSITE	0	163 - 360	232	mcg/100cal A
Vitamin C Average across all blends	SUMMARY	0	14.4 - 59.0	30.6	mg/100cal A
Vitamin C Maximum across all blends	SUMMARY	0	14.4 - 59.0	31.8	mg/100cal A
Vitamin C Minimum across all blends	SUMMARY	0	14.4 - 59.0	29.6	mg/100cal A
Calcium	BLEND_EACH	3	110 - 140	130	mg/100cal A
Calcium	BLEND_EACH	2	110 - 140	128	mg/100cal A
Calcium	BLEND_EACH	1	110 - 140	129	mg/100cal A
Calcium Average across all blends	SUMMARY	0	110 - 140	129	mg/100cal A
Calcium Maximum across all blends	SUMMARY	0	110 - 140	130	mg/100cal A
Calcium Minimum across all blends	SUMMARY	0	110 - 140	128	mg/100cal A
Phosphorus Minimum across all blends	SUMMARY	0	60 - 90	77	mg/100cal A
Selenium	COMPOSITE	0	2.5 - 7.0	5.1	mcg/100cal A
Chloride	COMPOSITE	0	70.2 - 117.0	85.3	mg/100cal A
Copper	BLEND_EACH	3	81 - 150	98	mcg/100cal A
Copper	BLEND_EACH	2	81 - 150	107	mcg/100cal A
Copper	BLEND_EACH	1	81 - 150	97	mcg/100cal A
Copper Average across all blends	SUMMARY	0	81 - 150	100	mcg/100cal A
Copper Maximum across all blends	SUMMARY	0	81 - 150	107	mcg/100cal A
Copper Minimum across all blends	SUMMARY	0	81 - 150	97	mcg/100cal A
Iron	BLEND_EACH	3	1.6 - 2.5	1.9	mg/100cal A
Iron	BLEND_EACH	2	1.6 - 2.5	1.9	mg/100cal A
Iron	BLEND_EACH	1	1.6 - 2.5	1.8	mg/100cal A
Iron Average across all blends	SUMMARY	0	1.6 - 2.5	1.9	mg/100cal A
Iron Maximum across all blends	SUMMARY	0	1.6 - 2.5	1.9	mg/100cal A
Iron Minimum across all blends	SUMMARY	0	1.6 - 2.5	1.8	mg/100cal A
Iodide	COMPOSITE	0	18.9 - 42.0	28.6	mcg/100cal A
Potassium	BLEND_EACH	3	95 - 180	168	mg/100cal A
Potassium	BLEND_EACH	2	95 - 180	167	mg/100cal A
Potassium	BLEND_EACH	1	95 - 180	171	mg/100cal A
Potassium Average across all blends	SUMMARY	0	95 - 180	168	mg/100cal A
Potassium Maximum across all blends	SUMMARY	0	95 - 180	171	mg/100cal A
Potassium Minimum across all blends	SUMMARY	0	95 - 180	167	mg/100cal A
Magnesium	BLEND_EACH	3	7.2 - 13.6	10.7	mg/100cal A
Magnesium	BLEND_EACH	2	7.2 - 13.6	10.8	mg/100cal A
Magnesium	BLEND_EACH	1	7.2 - 13.6	10.8	mg/100cal A
Magnesium Average across all blends	SUMMARY	0	7.2 - 13.6	10.8	mg/100cal A
Magnesium Maximum across all blends	SUMMARY	0	7.2 - 13.6	10.8	mg/100cal A
Magnesium Minimum across all blends	SUMMARY	0	7.2 - 13.6	10.7	mg/100cal A
Manganese	BLEND_EACH	3	13.5 - 30.0	20.7	mcg/100cal A

Manganese	BLEND_EACH	2	13.5 - 30.0	20.9	mcg/100cal	A
Manganese	BLEND_EACH	1	13.5 - 30.0	20.4	mcg/100cal	A
Manganese Average across all blends	SUMMARY	0	13.5 - 30.0	20.7	mcg/100cal	A
Manganese Maximum across all blends	SUMMARY	0	13.5 - 30.0	20.9	mcg/100cal	A
Manganese Minimum across all blends	SUMMARY	0	13.5 - 30.0	20.4	mcg/100cal	A
Sodium	BLEND_EACH	3	33.3 - 44.4	38.1	mg/100cal	A
Sodium	BLEND_EACH	2	33.3 - 44.4	37.9	mg/100cal	A
Sodium	BLEND_EACH	1	33.3 - 44.4	38.6	mg/100cal	A
Sodium Average across all blends	SUMMARY	0	33.3 - 44.4	38.2	mg/100cal	A
Sodium Maximum across all blends	SUMMARY	0	33.3 - 44.4	38.6	mg/100cal	A
Sodium Minimum across all blends	SUMMARY	0	33.3 - 44.4	37.9	mg/100cal	A
Phosphorus	BLEND_EACH	3	60 - 90	78	mg/100cal	A
Phosphorus	BLEND_EACH	2	60 - 90	77	mg/100cal	A
Phosphorus	BLEND_EACH	1	60 - 90	78	mg/100cal	A
Phosphorus Average across all blends	SUMMARY	0	60 - 90	77	mg/100cal	A
Phosphorus Maximum across all blends	SUMMARY	0	60 - 90	78	mg/100cal	A
Bacillus cereus	SINGLE	0	<=1000	<5	CFU/g	A
Bacillus cereus	SINGLE	0	<=1000	<5	CFU/g	A
Bacillus cereus	SINGLE	0	<=1000	<5	CFU/g	A
Bacillus cereus	SINGLE	0	<=1000	<5	CFU/g	A
Bacillus cereus	SINGLE	0	<=1000	<5	CFU/g	A
Bacillus cereus - Final Conclusion	SINGLE	0	Pass	Pass		A
Bacillus cereus - c value	SINGLE	0	<=1	0		A
Bacillus cereus - Final Conclusion	SINGLE	0	Pass	Pass		A
Bacillus cereus - c value	SINGLE	0	<=2	0		A
Bacillus cereus - Final Conclusion	SINGLE	0	Pass	Pass		A
Bacillus cereus - Final Conclusion	SINGLE	0	Pass	Pass		A
Bacillus cereus - Final conclusion	SINGLE	0	Pass	Pass		A
Fecal Coliform - c value	SINGLE	0	<=1	0		A
Fecal Coliform - Final Conclusion	SINGLE	0	Pass	Pass		A
Fecal Coliform - Final Conclusion	SINGLE	0	Pass	Pass		A
Coliforms - c value	SINGLE	0	<=2	0		A
Coliforms - Final conclusion	SINGLE	0	Pass	Pass		A
Coliforms - c value	SINGLE	0	<=1	0		A
Coliforms - Final conclusion	SINGLE	0	Pass	Pass		A
Coliforms - c value	SINGLE	0	<=2	0		A
Coliforms - Final conclusion	SINGLE	0	Pass	Pass		A
Coliforms	SINGLE	0	<=100	<3	CFU/g	A
Coliforms	SINGLE	0	<=100	<3	CFU/g	A
Coliforms	SINGLE	0	<=100	<3	CFU/g	A
Coliforms	SINGLE	0	<=100	<3	CFU/g	A
Coliforms	SINGLE	0	<=100	<3	CFU/g	A
Coliforms	SINGLE	0	<=100	<3	CFU/g	A
Fecal Coliforms	SINGLE	0	<3	<3	CFU/g	A
Fecal Coliforms	SINGLE	0	<3	<3	CFU/g	A
Fecal Coliforms	SINGLE	0	<3	<3	CFU/g	A
Fecal Coliforms	SINGLE	0	<3	<3	CFU/g	A
Fecal Coliforms	SINGLE	0	<3	<3	CFU/g	A
Cronobacter spp per 500g	COMPOSITE	0	Absent	Absent		A
Enterobacteriaceae	SINGLE	0	<0.0110	<0.0041	mpn/g	A
Enterobacteriaceae	SINGLE	0	<0.0110	<0.0041	mpn/g	A
Enterobacteriaceae	SINGLE	0	<0.0110	<0.0041	mpn/g	A
Enterobacteriaceae	SINGLE	0	<0.0110	<0.0041	mpn/g	A
Enterobacteriaceae	SINGLE	0	<0.0110	<0.0041	mpn/g	A
Enterobacteriaceae - FC	SINGLE	0	Pass	Pass		A
Enterobacteriaceae-Boolean	SINGLE	0	Pass	Pass		A
ENTEROBACTERIACEAE - FC	SINGLE	0	Pass	Pass		A
Enterobacteriaceae - FC	SINGLE	0	Pass	Pass		A
Enterobacteriaceae-FC	SINGLE	0	Pass	Pass		A
Enterobacteriaceae - FC	SINGLE	0	Pass	Pass		A
Enterobacteriaceae - FC	SINGLE	0	Pass	Pass		A
Listeria	SINGLE	0	Absent	Absent		A
Listeria	SINGLE	0	Absent	Absent		A
Listeria	SINGLE	0	Absent	Absent		A
Listeria	SINGLE	0	Absent	Absent		A
Listeria	SINGLE	0	Absent	Absent		A
Mold Count	SINGLE	0	<100	<10	CFU/g	A
Mold Count	SINGLE	0	<100	<10	CFU/g	A
Mold Count	SINGLE	0	<100	<10	CFU/g	A
Mold Count	SINGLE	0	<100	<10	CFU/g	A
Mold Count	SINGLE	0	<100	<10	CFU/g	A
Staphylococcus aureus	SINGLE	0		Absent		A
Staphylococcus aureus	SINGLE	0		Absent		A
Staphylococcus aureus	SINGLE	0		Absent		A
Staphylococcus aureus	SINGLE	0		Absent		A
Staphylococcus aureus	SINGLE	0		Absent		A
Salmonella per 1500g	COMPOSITE	0	Absent	Absent		A
S Aureus - Final Conclusion	SINGLE	0	Pass	Pass		A
Staphylococcus aureus - c value	SINGLE	0	<=2	0		A
Staphylococcus aureus - Final conclusion	SINGLE	0	Pass	Pass		A
Staphylococcus aureus - c value	SINGLE	0	<=1	0		A
Staphylococcus aureus - Final conclusion	SINGLE	0	Pass	Pass		A
Staphylococcus aureus - c value	SINGLE	0	<=1	0		A
Staphylococcus aureus - Final conclusion	SINGLE	0	Pass	Pass		A
Total Aerobic Plate Count	SINGLE	0	<=10000	80	CFU/g	A
Total Aerobic Plate Count	SINGLE	0	<=10000	120	CFU/g	A
Total Aerobic Plate Count	SINGLE	0	<=10000	90	CFU/g	A
Total Aerobic Plate Count	SINGLE	0	<=10000	50	CFU/g	A
Total Aerobic Plate Count	SINGLE	0	<=10000	130	CFU/g	A
Total Aerobic Plate Count - c value	SINGLE	0	<=2	0		A
Total Aerobic Plate Count - FC	SINGLE	0	Pass	Pass		A
Total Aerobic Plate Count - FC	SINGLE	0	Pass	Pass		A
Total Aerobic Plate Count - c value	SINGLE	0	<=1	0		A
Total Aerobic Plate Count - FC	SINGLE	0	Pass	Pass		A
Total Aerobic Plate Count - c value	SINGLE	0	<=2	0		A
Total Aerobic Plate Count - FC	SINGLE	0	Pass	Pass		A
Total Aerobic Plate Count - c value	SINGLE	0	<=2	0		A
Total Aerobic Plate Count - FC	SINGLE	0	Pass	Pass		A

Total Aerobic Plate Count - c value	SINGLE	0	<=2	0		A
Total Aerobic Plate Count - FC	SINGLE	0	Pass	Pass		A
Total Aerobic Plate Count - c value	SINGLE	0	<=2	0		A
Total Aerobic Plate Count - FC	SINGLE	0	Pass	Pass		A
75 Taps	COMPOSITE	0	0.53 - 0.61	0.58	g/ml	A
Measure Weight	COMPOSITE	0	27.9 - 32.3	31.3	g	A
Color	COMPOSITE	0	1.0 - 4.0	2.0		A
Mixability	COMPOSITE	0	0.0 - 1.0	0.7	g	A
Odor	COMPOSITE	0	1.0 - 4.0	2.0		A
pH	COMPOSITE	0	6.5 - 7.3	6.8		A
Scorched Particles	COMPOSITE	0	<=7.5	3.8	mg/100g	A
Sediment	COMPOSITE	0	<=0.3	0.0	mg/100g	A
Taste of solution	COMPOSITE	0	1.0 - 4.0	2.0		A

This batch was relabeled as Enfabebe Prematuros Powder, 2044019, ZP1HUV.

Reviewed by:



Gary Egli

MJN SOP Administrator

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