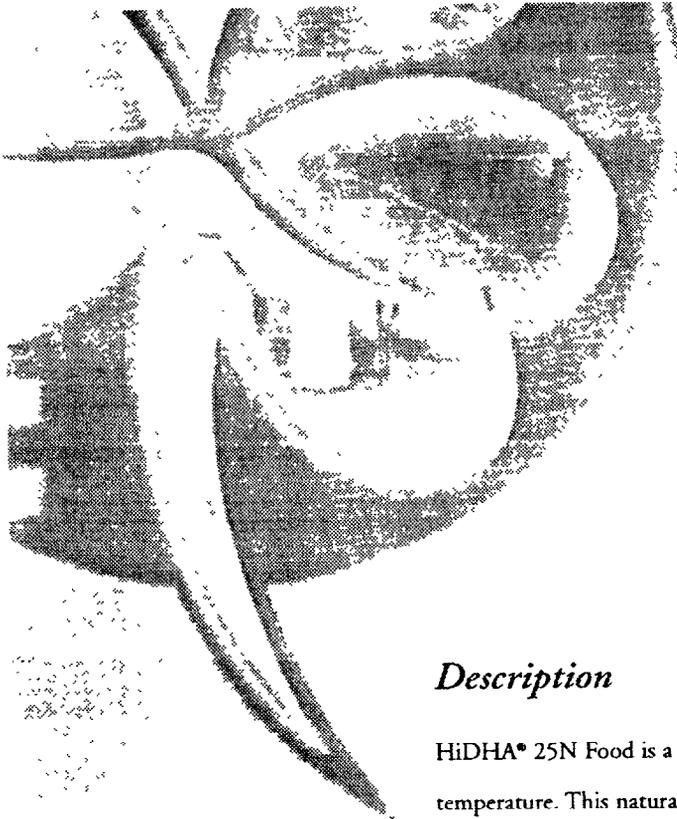


**Appendix II.**

**Product Data Sheets**



**PRODUCT DATA**

**HiDHA® 25N Food  
 7003**

*Description*

HiDHA® 25N Food is a refined non-winterised tuna oil. It is a cloudy oil at room temperature. This natural triglyceride contains approx. 25% DHA and 34% total omega-3 long chain polyunsaturated fatty acids present in the natural and bioactive all-cis form.

*Uses*

- For Food enrichment
- For Infant food enrichment

**PHYSICAL-CHEMICAL PROPERTIES**      **TYPICAL VALUE**

Docosahexaenoic acid (DHA)*	25 %
Eicosapentaenoic acid (EPA)*	6 %
Total Omega-3 Fatty Acid Content*	34 %
Acid Value	0.5 mg KOH/g
Peroxide Value	1.5 meq O <sub>2</sub> /kg
p-Anisidine Value	10
Colour	3 Gardner
Unsaponifiable Matter	2 %

**HEAVY METALS**

Lead	< 0.1 ppm
Mercury	< 0.1 ppm
Cadmium	< 0.1 ppm
Arsenic	< 0.1 ppm
Total Heavy Metals as Pb	< 2 ppm

\* GC analysis: Fatty acid composition expressed as percentage of fatty acid methyl esters.

## *Shelf Life & Storage*

HiDHA® oil is sensitive to air, light and extended periods at elevated temperatures. The product may be stored for 2 years from date of manufacture in the unopened original drum, in cool (10-25°C) dry conditions (relative humidity less than 75%). After opening contents should be used within a short period of time. To protect the oil from oxidation, after opening the original container the oil should be thoroughly flushed with an inert gas (nitrogen, argon, etc) and resealed under inert gas.

## *Packaging*

Standard 194 kg net drums.

HiDHA® 25N Food is a non-winterised tuna oil and at room temperature the solid material may settle out on the bottom of the drum. These solids will melt and become homogeneous on heating above 40°C.

## *General Handling*

Since the HiDHA® oil is sensitive to exposure to air and pro-oxidant materials, special handling instructions must be observed in addition to the standard health, safety and hygiene practices normally observed in the food and pharmaceutical industry. Ideally when opening the drum, the oil should be transferred in a closed system under inert gas. Only the following are suitable materials for equipment coming into contact with the oils: stainless steel, aluminium, glass, enamel or food-approved plastic.

## *Recommended Omega-3 Intake*

The role that DHA plays in both health and disease has become the focus of considerable research and is considered to be beneficial for the brain and eyes, heart and reducing inflammation.

DHA is a vital nutrient with particularly important roles in the structure and function of the brain, the eye and the nervous system and is considered essential for the optimum neurological development of the foetus and infant. Many national and international bodies strongly recommend that DHA should be added to infant formula and to infant weaning foods. There is also increasing support for the addition of DHA to the maternal diet.

A NIH working group recommended daily intakes of

- 650 mg per day of DHA plus EPA for adults
- 300mg of DHA for pregnant and breastfeeding women.

Further information is available upon request or visit [www.hi-dha.com](http://www.hi-dha.com)

## *Quality Assurance*

An intensive analytical program has established that the HiDHA® oil is substantially free of environmental contaminants including pesticide residues, PCBs/Dioxins, PAHs, heavy metals and microbial contaminants. Monitoring of the oils continues to ensure continued compliance with international standards such as those of Codex Alimentarius.

Analytical data to illustrate the high quality and purity of HiDHA® oil can be obtained upon request.

## *Manufacturing compliance*

The HiDHA® oil is produced in Australia in premises licenced by the Therapeutic Goods Administration in accordance with pharmaceutical standard GMP. The premises and the manufacturing processes have qualified for ISO 9002 and AQIS certification and operate under a strict EPA code.

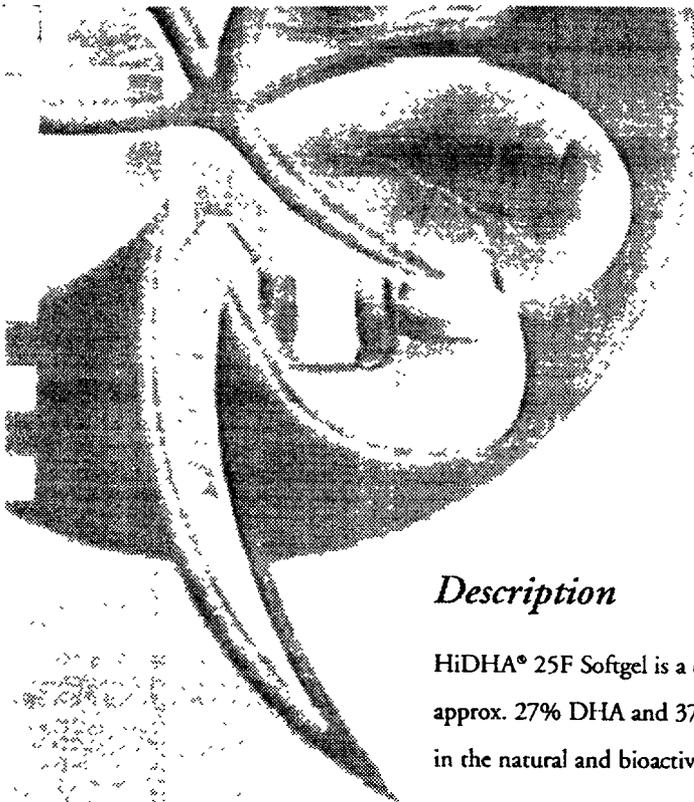
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**PRODUCT DATA**

**HiDHA® 25F SOFTGEL  
9004**

*Description*

HiDHA® 25F Softgel is a clear pale yellow tuna oil. This natural triglyceride contains approx. 27% DHA and 37% total omega-3 long chain polyunsaturated fatty acids present in the natural and bioactive all-cis form.

HiDHA® 25F Softgel is a refined tuna oil which has been clarified and enriched by full winterisation at 0°C to produce a bright, free-flowing, light yellow oil.

*Uses*

For softgel  
encapsulation

Nutritional Supplement

PHYSICAL-CHEMICAL PROPERTIES	TYPICAL VALUE
Docosahexaenoic acid (DHA)*	27 %
Eicosapentaenoic acid (EPA)*	6 %
Total Omega-3 Fatty Acid Content*	37 %
Acid Value	0.7 mg KOH/g
Peroxide Value	2.0 meq O <sub>2</sub> /kg
p-Anisidine Value	10
Colour	3 Gardner
Unsaponifiable Matter	2 %
Cold Test	passes, no haze at 3hrs at 0°C
HEAVY METALS	
Lead	< 0.1 ppm
Mercury	< 0.1 ppm
Cadmium	< 0.1 ppm
Arsenic	< 0.1 ppm
Total Heavy Metals as Pb	< 2 ppm

\*GC analysis: Fatty acid composition expressed as percentage of fatty acid methyl esters.

## *Shelf Life & Storage*

HiDHA® oil is sensitive to air, light and extended periods at elevated temperatures. The product may be stored for 2 years from date of manufacture in the unopened original drum, in cool (10-25°C) dry conditions (relative humidity less than 75%). After opening contents should be used within a short period of time. To protect the oil from oxidation, after opening the original container the oil should be thoroughly flushed with an inert gas (nitrogen, argon, etc) and resealed under inert gas.

## *Packaging*

Standard 194 kg net drums.

When the oil is exposed to very low temperatures during transportation or storage, a slight turbidity may form. This is a natural phase transition phenomenon and is completely reversed when heated to temperatures above 20°C.

## *General Handling*

Since the HiDHA® oil is sensitive to exposure to air and pro-oxidant materials, special handling instructions must be observed in addition to the standard health, safety and hygiene practices normally observed in the food and pharmaceutical industry. Ideally when opening the drum, the oil should be transferred in a closed system under inert gas. Only the following are suitable materials for equipment coming into contact with the oils: stainless steel, aluminium, glass, enamel or food-approved plastic.

## *Recommended Omega-3 Intake*

The role that DHA plays in both health and disease has become the focus of considerable research and is considered to be beneficial for the brain and eyes, heart and reducing inflammation.

DHA is a vital nutrient with particularly important roles in the structure and function of the brain, the eye and the nervous system and is considered essential for the optimum neurological development of the foetus and infant. Many national and international bodies strongly recommend that DHA should be added to infant formula and to infant weaning foods. There is also increasing support for the addition of DHA to the maternal diet.

A NIH working group recommended daily intakes of

- 650 mg per day of DHA plus EPA for adults
- 300mg of DHA for pregnant and breastfeeding women.

Further information is available upon request or visit [www.hi-dha.com](http://www.hi-dha.com)

## *Quality Assurance*

An intensive analytical program has established that the HiDHA® oil is substantially free of environmental contaminants including pesticide residues, PCBs/Dioxins, PAHs, heavy metals and microbial contaminants. Monitoring of the oils continues to ensure continued compliance with international standards such as those of Codex Alimentarius.

Analytical data to illustrate the high quality and purity of HiDHA® oil can be obtained upon request.

## *Manufacturing compliance*

The HiDHA® oil is produced in Australia in premises licenced by the Therapeutic Goods Administration in accordance with pharmaceutical standard GMP. The premises and the manufacturing processes have qualified for ISO 9002 and AQIS certification and operate under a strict EPA code.

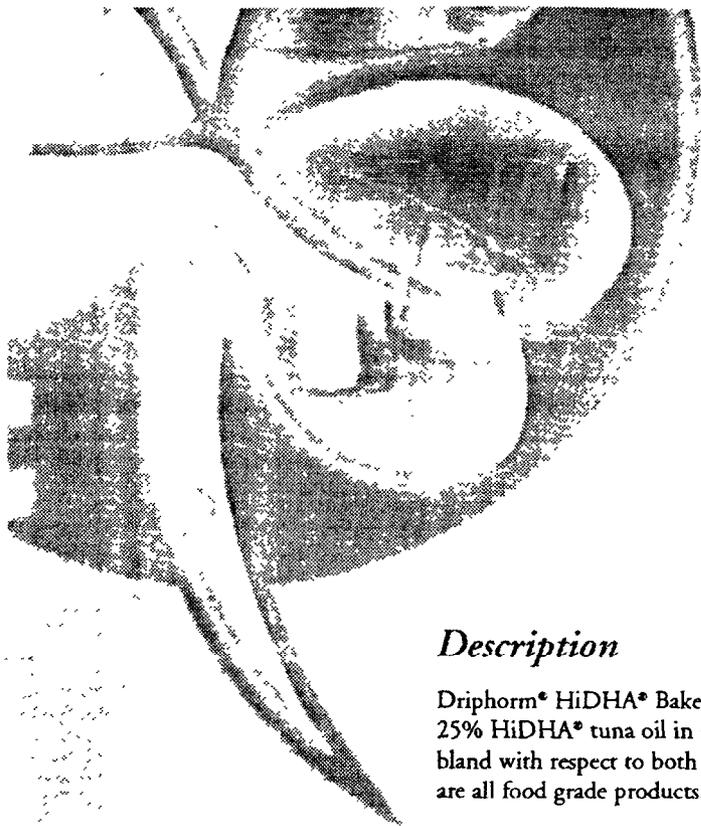
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**PRODUCT DATA**

**DRIPHORM®  
HiDHA® Bake  
D101**

*Description*

Driphorm® HiDHA® Bake is a fine, light beige, free-flowing, spray-dried powder containing 25% HiDHA® tuna oil in a stable and protected microencapsulated form. The powder is bland with respect to both taste and odour and the matrix materials and antioxidants used are all food grade products.

*Recommended Enrichment Levels*

Up to 2.0% in dry foods

DHA + EPA content in final product: 30-110 mg per serve

*Uses*

Recommended for DHA enrichment of bread premixes, bakery products, cereals, muesli, pasta, dehydrated products (soups, cooking sauces, instant potato powder, infant teething rusks, etc).

Details of how to use Driphorm® HiDHA® Bake can be obtained upon request.

PHYSICAL-CHEMICAL PROPERTIES	TYPICAL
Total Fat Content	27 %
Typical Fatty Acid Content per 1g of powder	
Docosahexaenoic acid (DHA)	56mg
Eicosapentaenoic acid (EPA)	13mg
Total Omega-3 Fatty Acid Content	74mg
Carbohydrate	approx. 54%
Protein	approx. 10%
Loss on Drying	max. 5%
Bulk density (100 taps)	0.45-0.65 g/ml
Particle Size	100-200 microns 100% through 20 mesh USP (850 µm) 95% through 40 mesh USP (425 µm) 4% through 325 mesh USP (45 µm)

MICROBIAL LIMITS	
Standard Aerobic Plate Count	max 1,000 cfu/g
Coliforms (37° C)	Not detected in 0.1g
Coagulase positive Staphylococci	Not detected in 0.01g
Salmonella spp.	Not detected in 25 g
Bacillus Cereus	Not detected in 0.01g

## *Stability*

Driphorm® HiDHA® Bake is sensitive to air, light and extended periods at elevated temperatures. Stability data in specific applications is available upon request.

## *Shelf Life & Storage*

The product may be stored for 18 months from date of manufacture in the unopened original package, in cool (10-25°C) dry conditions (relative humidity less than 75%). After opening contents should be used within a very short time period.

## *Packaging*

Laminated foil bag (sealed under nitrogen) in a cardboard box.  
Standard 1kg net.

## *General Handling*

Since the powder is sensitive to exposure to air and pro-oxidant materials, special handling instructions must be observed in addition to the standard health, safety and hygiene practices normally observed in the food industry. Transfer and weighing operations should be done as quickly as possible to minimise exposure to air. Only the following are suitable materials for equipment coming into contact with the powder: stainless steel, aluminium, glass, enamel or food-approved plastic.

## *Recommended Omega-3 Intake*

The role that DHA plays in both health and disease has become the focus of considerable research and is considered to be beneficial for the brain and eyes, heart and reducing inflammation.

DHA is a vital nutrient with particularly important roles in the structure and function of the brain, the eye and the nervous system and is considered essential for the optimum neurological development of the foetus and infant. Many national and international bodies strongly recommend that DHA should be added to infant formula and to infant weaning foods. There is also increasing support for the addition of DHA to the maternal diet.

A NIH working group recommended daily intakes of

- 650 mg per day of DHA plus EPA for adults
- 300mg of DHA for pregnant and breastfeeding women.

Further information is available upon request or visit [www.hi-dha.com](http://www.hi-dha.com)

## *Quality Assurance*

An intensive analytical program has established that the HiDHA® oil used in the manufacture of Driphorm® Bake is substantially free of environmental contaminants including pesticide residues, PCBs/Dioxins, PAHs, heavy metals and microbial contaminants. Monitoring of the oils continues to ensure continued compliance with international standards such as those of Codex Alimentarius.

Analytical data to illustrate the high quality and purity of Driphorm® HiDHA® Bake and HiDHA® oil can be obtained upon request.

## *Manufacturing compliance*

The HiDHA® oil used in Driphorm® HiDHA® Bake is produced in Australia in premises licenced by the Therapeutic Goods Administration in accordance with pharmaceutical standard GMP. The premises and the manufacturing processes have qualified for ISO 9002 and AQIS certification and operate under a strict EPA code.

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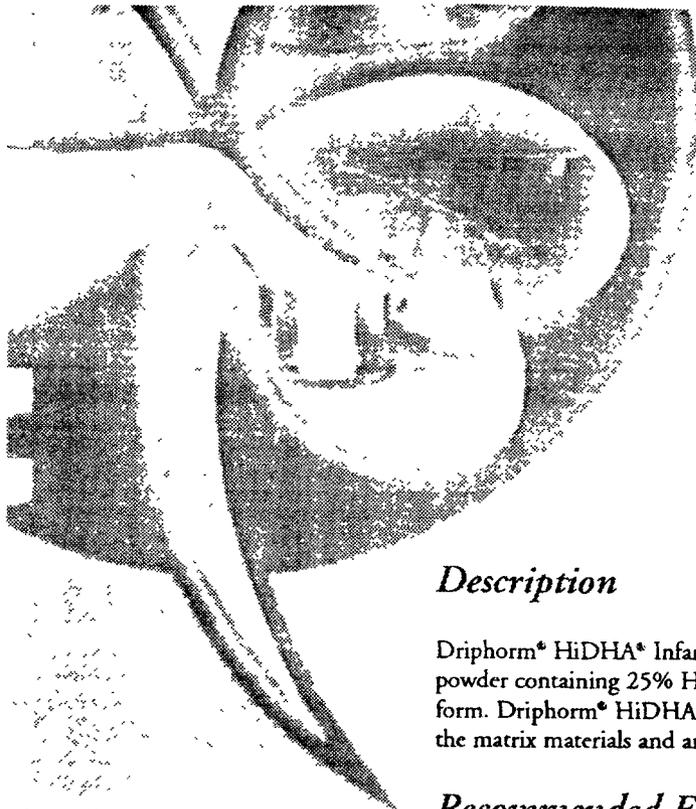
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**PRODUCT DATA**

**DRIPHORM®  
HiDHA® Infant  
D103**

*Description*

Driphorm® HiDHA® Infant is a fine white to light beige, free-flowing, spray-dried powder containing 25% HiDHA® tuna oil in a stable and protected microencapsulated form. Driphorm® HiDHA® Infant is bland with respect to both taste and odour and the matrix materials and antioxidants used are all food grade products.

*Recommended Enrichment Levels*

Up to 2.4 % in infant formula.

**Uses**

For addition to infant formula, weaning products and milk powder preparations for pregnant and lactating women.

Also for use in specialised nutritional products for the elderly and the infirm; slimming products and other products for those on restrictive diets; sports nutrition; and enteral clinical support nutrition.

Details of how to use Driphorm® can be obtained upon request.

PHYSICAL-CHEMICAL PROPERTIES	TYPICAL
Total Fat Content	26 %
Typical Fatty Acid Content per 1g of powder	
Docosahexaenoic acid (DHA)	54mg
Eicosapentaenoic acid (EPA)	12mg
Total Omega-3 Fatty Acid Content	70mg
Carbohydrate	approx. 47%
Protein	approx. 18%
Loss on Drying	max. 5%
Bulk density (100 taps)	0.55-0.70 g/ml
Particle Size	80-160 microns 100% through 20 mesh USP (850 µm) 95% through 40 mesh USP (425 µm) 3% through 325 mesh USP (45 µm)

MICROBIAL LIMITS	
Standard Aerobic Plate Count	max 1,000 cfu/g
Yeasts and Moulds	max. 50 cfu/g
Coliforms (37° C)	Not detected in 1.0 g
Coagulase positive Staphylococci	Not detected in 0.01g
Salmonella spp.	Not detected in 30x10 g
Bacillus Cereus	Not detected in 0.01g
Clostridium perfringens	Not detected in 0.01g
E. coli	Not detected in 25 g
Listeria spp.	Not detected in 2x25 g

## *Stability*

Driphorm® HiDHA® Infant is sensitive to air, light and extended periods at elevated temperatures. Stability data in specific applications is available upon request.

## *Shelf Life & Storage*

The product may be stored for 18 months from date of manufacture in the unopened original package, in cool (10-25°C) dry conditions (relative humidity less than 75%). After opening contents should be used within a very short time period.

## *Packaging*

Laminated foil bag (sealed under nitrogen) in a cardboard box. Standard 1kg net.

## *General Handling*

Since the powder is sensitive to exposure to air and pro-oxidant materials, special handling instructions must be observed in addition to the standard health, safety and hygiene practices normally observed in the food industry. Transfer and weighing operations should be done as quickly as possible to minimise exposure to air. Only the following are suitable materials for equipment coming into contact with the powder: stainless steel, aluminium, glass, enamel or food-approved plastic.

## *Recommended Omega-3 Intake*

The role that DHA plays in both health and disease has become the focus of considerable research and is considered to be beneficial for the brain and eyes, heart and reducing inflammation.

DHA is a vital nutrient with particularly important roles in the structure and function of the brain, the eye and the nervous system and is considered essential for the optimum neurological development of the foetus and infant. Many national and international bodies strongly recommend that DHA should be added to infant formula and to infant weaning foods. There is also increasing support for the addition of DHA to the maternal diet.

A NIH working group recommended daily intakes of

- 650 mg per day of DHA plus EPA for adults
- 300mg of DHA for pregnant and breastfeeding women.

Further information is available upon request or visit [www.hi-dha.com](http://www.hi-dha.com)

## *Quality Assurance*

An intensive analytical program has established that the HiDHA® oil used in the manufacture of Driphorm® HiDHA® Infant is substantially free of environmental contaminants including pesticide residues, PCBs/Dioxins, PAHs, heavy metals and microbial contaminants. Monitoring of the oils continues to ensure continued compliance with international standards such as those of Codex Alimentarius.

Analytical data to illustrate the high quality and purity of Driphorm® HiDHA® Infant powder and HiDHA® oil can be obtained upon request.

## *Manufacturing compliance*

The HiDHA® oil used in Driphorm® Infant is produced in Australia in premises licenced by the Therapeutic Goods Administration in accordance with pharmaceutical standard GMP. The premises and the manufacturing processes have qualified for ISO 9002 and AQIS certification and operate under a strict EPA code.

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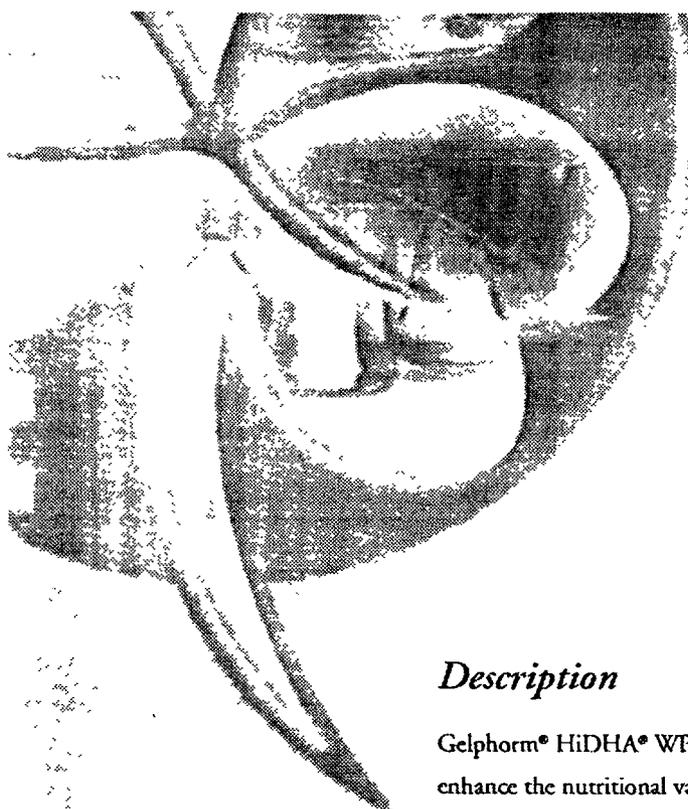
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**PRODUCT DATA**

**GELPHORM®  
HiDHA® WPI  
G001**

*Description*

Gelphorm® HiDHA® WPI is a stable liquid oil-in-water emulsion, which can be used to enhance the nutritional value of food products. The emulsion typically contains 25% of tuna fish oil and appears as an attractive smooth off-white liquid with excellent flow and dispersing properties. The emulsion is well stabilised in terms of aggregation, creaming and clarification reaction. Oil droplet size is below 0.5 micron in a very narrow particle size distribution. The product has been UHT treated. All the ingredients used in Gelphorm products comply with the Australian New Zealand Food Authorities (ANZFA) standards. Gelphorm® HiDHA® WPI is based on Whey Protein Isolate.

*Uses*

For Food enrichment

Suitable for adding to acidic food products such as yoghurts and mayonnaise

*Recommended Enrichment Levels*

Up to 1.2% in liquid foods

PHYSICAL-CHEMICAL PROPERTIES	TYPICAL
Total Fat Content	25 %
Protein	5 %
Carbohydrate	10 %
Typical Fatty Acid Content per 1g of emulsion	
Docosahexaenoic acid (DHA)	60mg
Eicosahexaenoic acid (EPA)	14mg
Total Omega-3 Fatty Acid Content	83mg
STABILITY	
Gelphorm® HiDHA® WPI is sensitive to microbial contamination, air, light and extended periods at high temperatures. It has been UHT treated.	

## *Storage*

Store in unopened original container. Treat as a UHT dairy product and refrigerate at +4°C after opening.

## *Packaging*

Laminated foil bag in a cardboard box. Standard 5 kg net.

## *Recommended Omega-3 Intake*

The role that DHA plays in both health and disease has become the focus of considerable research and is considered to be beneficial for the brain and eyes, heart and reducing inflammation.

DHA is a vital nutrient with particularly important roles in the structure and function of the brain, the eye and the nervous system and is considered essential for the optimum neurological development of the foetus and infant. Many national and international bodies strongly recommend that DHA should be added to infant formula and to infant weaning foods. There is also increasing support for the addition of DHA to the maternal diet.

A NIH working group recommended daily intakes of

- 650 mg per day of DHA plus EPA for adults
- 300mg of DHA for pregnant and breastfeeding women.

Further information is available upon request or visit [www.hi-dha.com](http://www.hi-dha.com)

**Gelphorm® HiDHA® WPI is intended for use in product incorporation trials only. ■**

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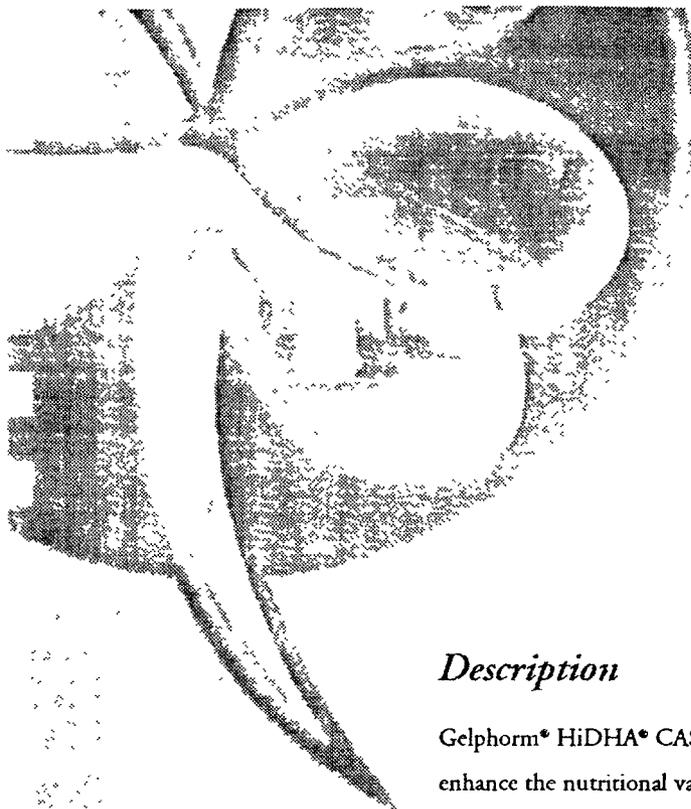
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## *PRODUCT DATA*

# **GELPHORM® HiDHA® CAS G002**

### *Description*

Gelphorm® HiDHA® CAS is a stable liquid oil-in-water emulsion, which can be used to enhance the nutritional value of food products. The emulsion typically contains 25% of tuna fish oil and appears as an attractive smooth off-white liquid with excellent flow and dispersing properties. The emulsion is well stabilised in terms of aggregation, creaming and clarification reaction. Oil droplet size is below 0.5 micron in a very narrow particle size distribution. The product has been UHT treated. All the ingredients used in Gelphorm products comply with the Australian New Zealand Food Authorities (ANZFA) standards. Gelphorm® HiDHA® CAS is based on Sodium Caseinate.

### *Uses*

For enrichment of dairy products

### *Recommended Enrichment Levels*

Up to 1.2% in liquid foods

PHYSICAL-CHEMICAL PROPERTIES	TYPICAL
Total Fat Content	25 %
Protein	5 %
Carbohydrate	12 %
Typical Fatty Acid Content per 1g of emulsion	
Docosahexaenoic acid (DHA)	60mg
Eicosahexaenoic acid (EPA)	14mg
Total Omega-3 Fatty Acid Content	83mg
STABILITY	
Gelphorm® HiDHA® CAS is sensitive to microbial contamination, air, light and extended periods at high temperatures. It has been UHT treated.	

## *Storage*

Store in unopened original container. Treat as a UHT dairy product and refrigerate at +4°C after opening.

## *Packaging*

Laminated foil bag in a cardboard box. Standard 5 kg net.

## *Recommended Omega-3 Intake*

The role that DHA plays in both health and disease has become the focus of considerable research and is considered to be beneficial for the brain and eyes, heart and reducing inflammation.

DHA is a vital nutrient with particularly important roles in the structure and function of the brain, the eye and the nervous system and is considered essential for the optimum neurological development of the foetus and infant. Many national and international bodies strongly recommend that DHA should be added to infant formula and to infant weaning foods. There is also increasing support for the addition of DHA to the maternal diet.

A NIH working group recommended daily intakes of

- 650 mg per day of DHA plus EPA for adults
- 300mg of DHA for pregnant and breastfeeding women.

Further information is available upon request or visit [www.hi-dha.com](http://www.hi-dha.com)

**Gelphorm® HiDHA® CAS is intended for use in product incorporation trials only.** ■

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