

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL:

USAN OMEGA-3-ACID ETHYL ESTERS

THERAPEUTIC CLAIM hypolipidemic

CHEMICAL DESCRIPTION

Omega-3-acid ethyl esters are obtained by esterification of the body oil of fat fish species coming from families such as *Engaulidae*, *Carangidae*, *Clupeidae*, *Osmeridae*, *Salmonidae*, and *Scrombroidae* and subsequent physico-chemical purification processes including urea fractionation followed by molecular distillation. The omega-3-acid ethyl esters are defined as the ethyl esters of alpha-linolenic acid, moroctic acid, eicosapentaenoic (timnodonic) acid, clupanodonic acid, and docosahexaenoic (cervonic) acid. The content of the total omega-3-acid ethyl esters is not less than 90 per cent. The content of the omega-3-acid ethyl esters eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) is not less than 80 per cent, with not less than 40 per cent of the EPA ethyl esters and not less than 34 per cent of DHA ethyl esters.

CHEMICAL NAMES

(See page 2 for the two main constituents, EPA and DHA ethyl esters)

STRUCTURAL FORMULA

(See page 2 for the two main constituents, EPA and DHA ethyl esters)

MOLECULAR FORMULA	EPA ethyl ester:	$C_{22}H_{34}O_2$
	DHA ethyl ester:	$C_{24}H_{36}O_2$

MOLECULAR WEIGHT	EPA ethyl ester:	330.51
	DHA ethyl ester:	356.55

TRADEMARK Omacor™

MANUFACTURER Pronova Biocare AS (Norway)

CODE DESIGNATION K85

<u>CAS</u> REGISTRY NUMBERS	EPA ethyl ester:	86227-47-6
	DHA ethyl ester:	81926-94-5

OMEGA-3-ACID ETHYL ESTERS

Page 2

CHEMICAL NAMES:

EPA ethyl ester:

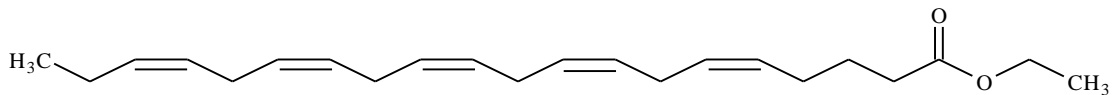
- 1) 5,8,11,14,17-eicosapentaenoic acid, ethyl ester, (all-*Z*)-
- 2) ethyl (5*Z*,8*Z*,11*Z*,14*Z*,17*Z*)-eicosa-5,8,11,14,17-pentaenoate

DHA ethyl ester:

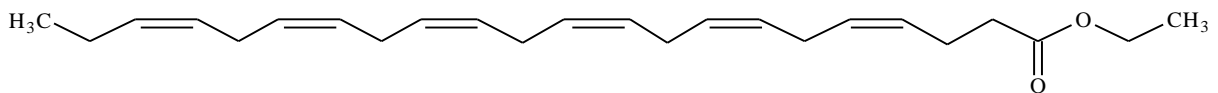
- 1) 4,7,10,13,16,19-docosahexaenoic acid, ethyl ester, (all-*Z*)-
- 2) ethyl (4*Z*,7*Z*,10*Z*,13*Z*,16*Z*,19*Z*)-docosa-4,7,10,13,16,19-hexaenoate

STRUCURAL FORMULA:

EPA ethyl ester



DHA ethyl ester



NOTE: The rINN for EPA is icosapent; the rINN for DHA is doconexent.