

PRODUIT DE SANTÉ NATUREL

PRODUITS D'HUILES FIXES - INGRÉDIENTS MULTIPLES – ORAL

- ▶ La présente monographie vise à servir de guide à l'industrie pour la préparation de demandes de licence de mise en marché (DLMM) et d'étiquettes dans le but d'obtenir une autorisation de mise en marché d'un produit de santé naturel (PSN) renfermant un ou plusieurs des ingrédients médicinaux indiqués au tableau 1. Elle ne vise pas à être une étude approfondie des ingrédients médicinaux.
- ▶ Les préparations d'huiles essentielles/volatiles (p.ex. celles préparées par distillation) dépassent le cadre de cette monographie.
- ▶ Les huiles hydrogénées et partiellement hydrogénées dépassent le cadre de cette monographie.

Nota

- ▶ Les parenthèses contiennent des éléments d'information facultatifs qui peuvent être inclus dans la DLMM ou sur l'étiquette du produit.
- ▶ La barre oblique (/) indique que les termes ou les énoncés sont synonymes. Le demandeur peut utiliser n'importe lequel des termes ou énoncés indiqués.

Date

7 janvier 2015

Nom(s) propre(s), Nom(s) commun(s) et Matière(s) d'origine

Tableau 1 : Nom(s) propre(s), Nom(s) commun(s) et Matière(s) d'origine des ingrédients médicinaux

Nom(s) propre(s) ¹	Nom(s) commun(s) ²	Matière(s) d'origine
<i>Borago officinalis</i>	Huile de bourrache	Graine (Martindale 2012; Hoffmann 2003)
<i>Brassica napus</i>	• Huile de canola • Huile de colza	Graine (FCC 2014)
<i>Brassica juncea</i>		
<i>Brassica rapa</i>		
<i>Camelina sativa</i>	Huile de caméline Huile de faux lin	Graine (Dubois <i>et al.</i> 2007)
<i>Cannabis sativa</i>	Huile de chanvre	Graine (Callaway <i>et al.</i> 2005)
<i>Carthamus tinctorius</i>	Huile de carthame	Graine (USP 37)
<i>Cocos nucifera</i>	Huile de noix de coco	Endosperme de la graine (FCC 2014)
Huile de foie de morue	Huile de foie de	Tel qu'indiqué dans la monographie Huile

	morue	de foie de morue de la DPSNSO
<i>Cucurbita pepo</i> var. <i>pepo</i>	Huile de graine de citrouille	Graine (Dubois <i>et al.</i> 2007)
Huile de poisson	Huile de poisson	Tel qu'indiqué dans la monographie Huile de poisson de la DPSNSO
<i>Helianthus annuus</i>	Huile de tournesol	Graine (FCC 2014)
<i>Hippophae rhamnoides</i>	Huile d'argousier	Graine (Yang <i>et al.</i> 1999)
Huile de krill	Huile de krill	Tel qu'indiqué dans la monographie Huile de krill de la DPSNSO
<i>Linum usitatissimum</i>	<ul style="list-style-type: none"> • Huile de lin • Huile de graine de lin 	Tel qu'indiqué dans la monographie Huile de lin de la DPSNSO
<i>Oenothera biennis</i>	Huile d'onagre	Tel qu'indiqué dans la monographie Huile d'onagre de la DPSNSO
<i>Olea europaea</i>	Huile d'olive	Fruit (NF 32)
<i>Prunus dulcis</i> var. <i>dulcis</i>	<ul style="list-style-type: none"> • Huile d'amande • Huile d'amande douce 	Noyau (NF 32)
<i>Ribes nigrum</i>	Huile de pépin de cassis	Graine (Linnamaa <i>et al.</i> 2010)
<i>Salvia hispanica</i>	Huile de graine de chia	Graine (Dubois <i>et al.</i> 2007)
<i>Schizochytrium</i> spp.	Huile de schizochytrium	<i>Schizochytrium</i> spp. (Yurko-Mauro <i>et al.</i> 2010)
Huile de phoque	Huile de phoque	Tel qu'indiqué sur la monographie Huile de phoque de la DPSNSO
Huile de calmar	Huile de calmar	<i>Todarodes pacificus</i> - entier (ITIS 2014) <i>Docidicus gigas</i> - entier (ITIS 2014) <i>Illex argentinus</i> - entier (ITIS 2014) <i>Illex illecebrosus</i> - entier (ITIS 2014)
<i>Triticum aestivum</i>	Huile de germe de blé	Germe (Ph.Eur 2013)
<i>Vitis vinifera</i>	Huile de pépin de raisin	Graine (Dubois <i>et al.</i> 2007)

^{1,2} Noms propres et noms communs : Base de données des ingrédients de produits de santé naturels (BDIPSN)

Voie(s) d'administration

Orale

Forme(s) posologique(s)



- ▶ Les formes posologiques pharmaceutiques acceptables comprennent, notamment les capsules, les formes posologiques à croquer (p. ex. les comprimés), les liquides, les poudres, les bandelettes ou les comprimés.
- ▶ Les aliments ou les formes posologiques semblables aux aliments, telles que les barres, les gommes à mâcher ou les breuvages, l'huile pour la cuisson et l'huile de table, sont exclus de cette monographie.

Usage(s) ou fin(s) recommandés

Énoncé(s) précisant ce qui suit

Tableau 2 : Usage(s) ou fin(s) recommandés selon les constituants d'acides gras

Constituants requis des acides gras ¹	Dose quotidienne minimale ² (mg par jour)	Usage(s) ou fin(s) recommandés
AL (Acide linoléique)	850	<ul style="list-style-type: none"> • Source d'acide linoléique (AL) pour le maintien d'une bonne santé • Source d'acide gras oméga-6 pour le maintien d'une bonne santé • Source d'acide gras essentiel pour le maintien d'une bonne santé
AAL (Acide alpha-linoléique)	80	<ul style="list-style-type: none"> • Source d'acide alpha-linoléique (AAL) pour le maintien d'une bonne santé • Source d'acide gras oméga-3 pour le maintien d'une bonne santé • Source d'acide gras essentiel pour le maintien d'une bonne santé
AL + AAL	850 AL + 80 AAL	Source d'acides gras essentiels pour le maintien d'une bonne santé
AEP + ADH + ADP (Acide eicosapentaénoïque + Acide docosahexaénoïque + Acide docosapentaénoïque (n-3))	100 AEP+ADH+ADP	Source d'acides gras oméga-3 pour le maintien d'une bonne santé
AEP	100	Source d'acide eicosapentaénoïque (AEP) pour le maintien d'une bonne santé
ADH	100	Source d'acide docosahexaénoïque (ADH) pour le maintien d'une bonne santé
	250	• Aide au soutien/maintien du fonctionnement des yeux



		<ul style="list-style-type: none"> • Aide au soutien/maintien de la santé oculaire • Aide au soutien/maintien des fonctions cérébrales normales
ADP	100	Source d'acide docosapentaénoïque (ADP) pour le maintien d'une bonne santé
AEP+ADH	250 AEP+ADH	Aide au soutien/maintien de la santé/des fonctions du cœur/cardiovasculaire(s) (normales)
	2000 AEP+ADH	Aide au soutien/maintien de niveaux normaux de triglycérides/triacylglycérols du sang/sérum
AGL (Acide gamma-linoléique)	100	Source d'acide gamma-linoléique
AO (Acide oléique)	100	Source d'acide oléique

¹Pour les produits proposant des allégations sur ce tableau, les activités doivent être indiquées pour les constituants d'acides gras correspondants. Consulter l'annexe I pour les activités des constituants et leurs pourcentages respectifs.

²Au moins une des références suivantes a été consultée pour les doses minimales et les usages ou fins recommandés : DPSNSO 2014; EFSA 2010a; EFSA 2010b; EFSA 2009; Simopolous 2007; IOM 2006; IOM 2002; Simopolous 1999;

Produits renfermant de l'huile de noix de coco, de l'huile d'olive et/ou de l'huile de germe de blé

Fournit/Source des antioxydants (Marina *et al.* 2009; Alessandri *et al.* 2006; Fito *et al.* 2005; Visioli *et al.* 2005; Marrugat *et al.* 2004; Weinbrenner *et al.* 2004)

Produits renfermant de l'huile de schizochytrium, de l'huile de bourrache, de l'huile de foie de morue, de l'huile de krill, de l'huile d'onagre, de l'huile de phoque et/ou produits pour fonctions cognitives

Les allégations permises sont celles indiquées dans les monographies respectives de la DPSNSO pour ces ingrédients. Les doses et les activités des monographies individuelles doivent être respectées.

Dose(s)

Sous-population(s)

Tous les produits

Adulte de 18 ans et plus

Produits renfermant de l'huile de poisson, de l'huile de lin, de l'huile de phoque et/ou de l'huile de foie de morue

Tel qu'indiqué dans les monographies de la DPSNSO respectives.

Preparations

Huile fixe; Huile fixe normalisée

Tableau 3 : Doses quotidiennes maximales des ingrédients médicinaux

Ingrédients médicinaux	Doses quotidiennes maximales (g par jour)
<i>Borago officinalis</i> /Huile de bourrache	Tel qu'indiqué dans la monographie Huile de bourrache de la DPSNSO
<i>Brassica napus</i> / <i>B. juncea</i> / <i>B. rapa</i> /Huile de canola	15,0 (DPSNSO 2014)
<i>Camelina sativa</i> /Huile de caméline	15,0 (DPSNSO 2014)
<i>Cannabis sativa</i> /Huile de chanvre	15,0 (DPSNSO 2014)
<i>Carthamus tinctorius</i> /Huile de carthame	15,0 (DPSNSO 2014)
<i>Cocos nucifera</i> /Huile de noix de coco	15,0 (DPSNSO 2014)
Huile de foie de morue	Tel qu'indiqué dans la monographie Huile de foie de morue de la DPSNSO
<i>Cucurbita pepo</i> var. <i>pepo</i> /Huile de graine de citrouille	15,0 (NNHPD 2014)
Huile de poisson	Tel qu'indiqué dans la monographie Huile de poisson de la DPSNSO
<i>Helianthus annuus</i> /Huile de tournesol	15,0 (DPSNSO 2014)
<i>Hippophae rhamnoides</i> /Huile d'argousier	5,0 (Yang <i>et al.</i> 1999)
Huile de krill	Tel qu'indiqué dans la monographie Huile de krill de la DPSNSO
<i>Linum usitatissimum</i> /Huile de lin	Tel qu'indiqué dans la monographie Huile de lin de la DPSNSO
<i>Oenothera biennis</i> /Huile d'onagre	Tel qu'indiqué dans la monographie Huile d'onagre de la DPSNSO
<i>Olea europaea</i> /Huile d'olive	15,0 (DPSNSO 2014)
<i>Prunus dulcis</i> var. <i>dulcis</i> /Huile d'amande	15,0 (DPSNSO 2014)
<i>Ribes nigrum</i> /Huile de pépin de cassis	10,5 (Leventhal <i>et al.</i> 1994)
<i>Salvia hispanica</i> /Huile de chia	4,5 (DPSNSO 2014)
<i>Schizochytrium</i> spp./Huile de schizochytrium	Quantité d'huile fournissant au plus 2000 mg ADH par jour (Quinn <i>et al.</i> 2010)
Huile de phoque	Tel qu'indiqué dans la monographie Huile de



	phoque de la DPSNSO
Huile de calmar	5,0 (DPSNSO 2014)
<i>Triticum aestivum</i> /Huile de germe de blé	15,0 (DPSNSO 2014)
<i>Vitis vinifera</i> /Huile de pépin de raisin	15,0 (DPSNSO 2014)

Mode(s) d'emploi

Énoncé non requis

Règles et restrictions pour les associations

Les ingrédients médicinaux inclus dans cette monographie peuvent être associés selon les restrictions suivantes :

- ▶ La dose quotidienne maximale d'un produit contenant des associations d'huiles ne doit pas dépasser 15,0 g par jour (DPSNSO 2014).
- ▶ Les doses quotidiennes maximales des ingrédients médicinaux individuels, indiquées au tableau 2, s'appliquent.
- ▶ La dose quotidienne maximale d'une association AEP+ADH+ADP dans un produit ne doit pas dépasser 5,0 g par jour (EFSA 2012).
- ▶ Les doses maximales pour AEP+ADH+ADP pour l'huile de schizochytrium s'appliquent.
- ▶ Les doses maximales pour AEP+ADH+ADP pour l'huile de krill, l'huile de poisson, et l'huile de phoque s'appliquent telles qu'indiquées dans les monographies individuelles respectives de la DPSNSO.
- ▶ Les doses maximales pour AEP+ADH et pour la vitamine A et D s'appliquent pour l'huile de foie de morue, telles qu'indiquées dans la monographie Huile de foie de morue de la DPSNSO.

Durée(s) d'utilisation

Énoncé non requis.

Mention(s) de risque Énoncé(s) précisant ce qui suit

Précaution(s) et mise(s) en garde

Produits renfermant de l'huile de chanvre, de l'huile d'argousier, de l'huile de krill, de l'huile de pépin de cassis et/ou de l'huile de calmar

Si vous êtes enceinte ou allaitez, consulter un praticien de soins de santé avant l'utilisation.

Contre-indications(s)

Énoncé non requis.

Réaction(s) indésirable(s) connue(s)

Produits renfermant de l'huile de krill et/ou de l'huile de calmar

Une hypersensibilité/allergie peut se manifester (lors de la consommation de crustacés et de mollusques); dans ce cas, cesser l'utilisation (Martindale 2012).

Ingrédients non médicinaux

Doivent être choisis parmi ceux de la version actuelle de la Base de données d'ingrédients de produits de santé naturels (BDIPSN) de la DPSNSO et respecter les restrictions mentionnées dans cette base de données.

Conditions d'entreposage

Tous les produits

Entreposer dans un contenant hermétique, dans un endroit frais et à l'abri de la lumière (Ph.Eur. 2012; USP 35).

Produits renfermant de l'huile de schizochytrium, de l'huile de caméline, de l'huile de chanvre, de l'huile de foie de morue, de l'huile de poisson, de l'huile d'argousier, de l'huile de krill, de l'huile de lin, de l'huile de pépin de cassis, de l'huile de chia, de l'huile de phoque et/ou de l'huile de calmar sauf les produits encapsulés

Réfrigérer après l'ouverture (Wille et Gonus 1989).

Spécifications

- ▶ Les spécifications du produit fini doivent être établies conformément aux exigences décrites dans le Guide de référence sur la qualité des produits de santé naturels de la DPSNSO. L'huile de foie de morue, l'huile de poisson, l'huile de krill, l'huile de phoque et l'huile de calmar sont des huiles marines et doivent respecter la section 3.3.8 Contaminants dans les huiles marines du Guide de référence sur la qualité des produits de santé naturels de la DPSNSO pour les produits renfermant ces ingrédients.
- ▶ Pour tous les produits renfermant un ou plusieurs ingrédients de cette monographie, la section 3.3.11 Résistance des huiles à l'oxydation du Guide de référence sur la qualité des produits de santé naturels de la DPSNSO doit être respectée.



- ▶ L'ingrédient médicinal doit être conforme aux exigences mentionnées dans la BDIPSN. De plus, l'ingrédient médicinal peut être conforme aux spécifications énoncées dans les pharmacopées américaines (USP), britanniques (BP) et/ou européennes (Ph.Eur.).
- ▶ Les produits renfermant de l'huile de chanvre ne doivent pas contenir plus de 10 ppm de delta-9-tétrahydro-cannabinol (THC) et leurs productions doivent respecter le *Règlement sur le chanvre industriel* (GC 2014).
- ▶ Pour tous les produits ayant une ou plusieurs des activités indiquées dans la section des doses, une analyse doit être faite afin de confirmer l'activité en question.
- ▶ Pour les ingrédients suivants, veuillez consulter les exigences supplémentaires concernant la qualité dans les monographies de la DPSNSO respectives : Huile de bourrache, Huile de foie de morue, Huile de poisson, Huile de krill, Huile de lin, Huile d'onagre, Huile de phoque.

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eicosanoids, arachidonic acid-derived mediators and pro-inflammatory cytokines (ID 520, 2914), and “immunomodulating agent” (4690) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). EFSA Journal 2010; 8(10):1796. [Internet] [Accessed 2014 September 26]. Available from: <http://www.efsa.europa.eu/en/efsajournal/doc/1796.pdf>.

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Annexe I

Tableau 1 Composition en acides gras des ingrédients médicinaux (%)^{1,2}

Ingrédient médicinal	Acide linoléique 18:2 (n-6) (AL)	Acide alpha-linolénique 18:3(n-3) (AAL)	Acide eicosapentaénoïque 20:5(n-3) (AEP)	Acide docosahexaénoïque 22:6(n-3) (ADH)	Acide docosapentaénoïque 22:5(n-3) (ADP)	Acide gammalinoléique 18:3(n-6) (AGL)	Acide oléique 18:1(n-9) (AO)
Huile de schizochytrium	--	--	Up to 3,9	22-55	--	--	--
Huile de bourrache	23-37	0,2-10	--	--	--	18-27	12-22
Huile de canola	16-40	6-14	--	--	--	--	50-67
Huile de caméline	15-25	29-40	--	--	--	--	11-36
Huile de chanvre	49-70	12-25	--	--	--	1-6	8-16
Huile de carthame	7-84	Up to 1,5	--	--	--	--	7-84
Huile de noix de coco	1-4	Up to 0,2	--	--	--	--	1-10
Huile de foie de morue	0.5-3	Up to 2	7-16	6-18	--	--	12-21
Huile de graine de citrouille	42-71	--	--	--	--	--	17-47
Huile de poisson	--	--	Minimum 4	Minimum 9	--	--	--
Huile de tournesol	20-75	Up to 0,5	--	--	--	--	14-65

Huile d'argousier	29-44	20-39	--	--	--	--	12-27
Huile de krill	1,4-3	0,5-3,5	14-22,1	7.5-13,2	Up to 0,7	--	7-14,5
Huile de lin	11-24	35-65	--	--	--	--	11-35
Huile d'onagre	65-85	Up to 0,5	--	--	--	7-14	5-12
Huile d'olive	3,5-20	Up to 1,2	--	--	--	--	56-85
Huile d'amande	10-30	Up to 0,4	--	--	--	--	59-86
Huile de pépin de cassis	30-49	11-34	--	--	--	11-23	11-15
Huile de chia	16-23	52-69	--	--	--	--	6-11
Huile de phoque	Up to 1,5	Up to 2,1	3-8	7-13	3-5	--	14-29
Huile de calmar	--	--	Minimum 5	Minimum 18	--	--	--
Huile de germe de blé	52-59	3-10	--	--	--	--	12-23
Huile de pépin de raisin	53-76	Up to 1,8	--	--	--	--	12-32

¹ Toutes les quantités d'activités acceptables des constituants sont indiquées pour chacun des ingrédients médicinaux (en pourcentages). Les plages de pourcentages sont indiquées en tant que référence uniquement et peuvent présenter des variations naturelles selon la matière d'origine utilisée et/ou la méthode de préparation.

² Au moins une des références suivantes a été utilisée pour les plages d'activités : FCC 2014; USP 37; Quinn *et al.* 2010; Arafles *et al.* 2011; BP 2014; Ph.Eur. 2013; Schirmer et Phinney 2007; Hoffman 2003; Takwale *et al.* 2003; van Gool *et al.* 2003; Ziboh *et al.* 2004; Mills et Bone 2005; WHO 2002; HC 2009; Cunnane *et al.* 1993; NF 32; Mansour *et al.* 2014; Hrastar *et al.* 2009; Kirkhus *et al.* 2013; Leizer *et al.* 2000; Bagci *et al.* 2002; Dubois *et al.* 2007; Laureles *et al.* 2002; Murkovic *et al.* 1996; Kirbaslar *et al.* 2012; Stevenson *et al.* 2007; Beveridge *et al.* 1999; Yang *et al.* 2001; Fatima *et al.* 2012; Kazantis *et al.* 2003; Soler *et al.* 1988; Ziboh et Fletcher, 1992; Ruiz del Castillo *et al.* 2002; Ixtaina *et al.* 2011; Segura-Campos *et al.* 2014; Ayerza, 2009; Grahl-Nielsen et Miaavtten, 1991; Gregersen *et al.* 2010; Bjorkkjaer *et al.* 2009; Mann *et al.* 2010; AU TGA 2013; Sabir *et al.* 2011; Lutterodt *et al.* 2011; Crews *et al.* 2006; Beveridge *et al.* 2005.