



NATURAL HEALTH PRODUCT

FLOWER ESSENCES

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredients.

Notes

- ▶ By submitting a PLA referencing this monograph, the applicant is attesting that the product will comply fully with the recommended conditions of use outlined in this monograph. The conditions of use include methods of preparations, source materials, doses, durations of use, combinations of medicinal ingredients, and risk statements.
- ▶ Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- ▶ The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant.
- ▶ The use of the electronic Product License Application form (ePLA) is not possible for products associated with this monograph.

Date

June 24, 2013

Proper name(s), Common name(s), and Source material(s)

Table 1 Products may contain one or more of the following ingredients

Proper name(s)	Common name(s)	Source material(s)
<i>Aesculus carnea</i>	Red Horse chestnut	Twigs with flowering pyramids and young leaves.
<i>Aesculus hippocastanum</i>	Horse chestnut	Buds and twigs
<i>Aesculus hippocastanum</i>	Horse chestnut	Flowers
<i>Agrimonia eupatoria</i>	Agrimony	Flower
Aqua petra	Rock water	Well or spring water
<i>Bromus ramosus</i>	Wild oat	Flowering spikelets
<i>Calluna vulgaris</i>	Heather	Flowering sprays and leaves
<i>Carpinus betulus</i>	Hornbeam	Young twigs with leaves, and flowers
<i>Castanea sativa</i>	Sweet chestnut	Young twigs with leaves, and flowers
<i>Centaureum umbellatum</i>	Centaury	Flower
<i>Ceratostigma willmottianum</i>	Cerato	Flower
<i>Cichorium intybus</i>	Chicory	Flower
<i>Clematis vitalba</i>	Clematis	Flower
<i>Fagus sylvatica</i>	Beech	Flower
<i>Gentianella amarella</i>	Gentian	Flower



Proper name(s)	Common name(s)	Source material(s)
<i>Helianthemum nummularium</i>	Rock rose	Flower
<i>Hottonia palustris</i>	Water violet	Flower
<i>Ilex aquifolium</i>	Holly	Flowering twigs
<i>Impatiens glandulifera</i>	Impatiens	Flower
<i>Juglans regia</i>	Walnut	Young shoots, leaves and flowers
<i>Larix decidua</i>	Larch	Twigs with the young green leaf-tufts, and flowers
<i>Lonicera caprifolium</i>	Honeysuckle	Flowering clusters with stalk and leaves
<i>Malus pumila</i>	Crab apple	Leaves and flower clusters
<i>Mimulus guttatus</i>	Mimulus	Flower
<i>Olea europaea</i>	Olive	Flower clusters
<i>Ornithogalum umbellatum</i>	Star of Bethlehem	Flowering clusters
<i>Pinus sylvestris</i>	Pine	Young shoots with flowers
<i>Populus tremula</i>	Aspen	Catkins
<i>Prunus cerasifera</i>	Cherry plum	Flowering twigs
<i>Quercus robur</i>	Oak	Catkins
<i>Rosa canina</i>	Wild rose/Dog rose	Flowers and leaves
<i>Salix vitellina</i>	Willow	Catkins
<i>Scleranthus annuus</i>	Scleranthus	Flowering stems and leaves
<i>Sinapis arvensis</i>	Mustard	Flower-heads and seed pods
<i>Ulex europaeus</i>	Gorse	Flowers
<i>Ulmus procera</i>	Elm	Twigs with flower clusters
<i>Verbena officinalis</i>	Vervain	Flower
<i>Vitis vinifera</i>	Vine	Flowering clusters

Route(s) of administration

- ▶ Oral
- ▶ Topical

Dosage form(s)

- ▶ The acceptable pharmaceutical oral dosage forms include, but are not limited to granules, liquids or lozenges.
- ▶ The acceptable pharmaceutical topical dosage forms include, but are not limited to creams, ointments or liquids.
- ▶ This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s) Statement(s) to the effect of
Flower Essence preparation/remedy/medicine

Dose Statement(s) to the effect of

Subpopulation(s)

Adults (≥ 18 years)

Potency

The dilution for each medicinal ingredient must be equivalent to 5X.

Method of preparation

The method of preparation must be one of the following:

- ▶ BHomP Method Br 9
- ▶ BHomP Method Br 10

Directions for use

All products

Take as directed by a health care practitioner.

Specific products

Liquids:

2 drops in water and sip at intervals throughout the day or as directed by a health care practitioner.

Granules:

5 granules, twice per day, before lunch and evening meal or as directed by a health care practitioner.

Lozenges:

1 or 2 lozenges, twice per day or as directed by a health care practitioner.

Cream/ointment:

Clean affected area and then apply cream/ointment to area thoroughly. Cover with a bandage if necessary.

Duration of use

No statement required.

Risk information

Statement(s) to the effect of

Cautions and warnings

- ▶ If symptoms persist or worsen, consult a health care practitioner.
- ▶ If you are pregnant or breastfeeding, consult a health care practitioner prior to use.

Contraindications

No statement required.

Known adverse reactions

No statement required.

Non-medicinal ingredients

Must be chosen from the current NHPD *Natural Health Products Ingredients Database* (NHPID) and must meet the limitations outlined in the database.

Specifications

- ▶ The finished product specifications must be established in accordance with the requirements described in the NHPD *Quality of Natural Health Products Guide*.
- ▶ The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).

References reviewed

Bach E. *The Twelve Healers and Other Remedies*. Saffron Walden (GB): The C.W. Daniel Company Ltd, 1999.

BHomP 1999: *British Homoeopathic Pharmacopoeia*. London (GB): British Association of Homoeopathic Manufacturers, 1999.

Justice Canada. *Food and Drug Regulations* (C.R.C., c. 870) [Internet]. Ottawa (ON): Justice Canada. [Current: 2013 May 20; Last amended: 2013 March 21; Accessed 2013 May 29]. Available from: http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html

Ramsell J. *Questions and Answers: Explaining the Basic Principles and Standards of The Bach Flower Remedies*. Saffron Walden (GB): The C.W. Daniel Company Ltd, 1996.

Scheffer M. *Bach Flower Therapy: Theory and Practice*. Rochester (VT): Healing Arts Press, 1998.

Weeks N, Bullen V. *The Bach Flower Remedies: Illustrations and Preparations*. Saffron Walden (GB): The C.W. Daniel Company Ltd, 1998.

Wheeler FJ. *The Bach Remedies Repertory*. Saffron Walden (GB): The C.W. Daniel Company Ltd, 1996.