

on Adulteration of *Arnica montana*

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Goal: The goal of this bulletin is to provide timely information and/or updates on issues of adulteration of *Arnica montana* flower to the international herbal products industry and extended natural products community in general. It is intended to present the available data on the occurrence of adulteration, the market situation, and consequences for the consumer and the industry.

1 General Information

1.1 Common name: Arnica¹

1.2 Other common names:

English: Leopard's bane, European arnica, mountain tobacco, wolfsbane^{2†}

Chinese: *S han jin hua* (山金花)³

French: Arnica, arnique, bétoine des montagnes, herbe aux chutes, souci des alpes, tabac des Vosges²

German: Arnika, Berg-Wohlverleih, Engeltrank, Fallkraut, Wohlverleih, Wolfsblume²

Italian: Arnica²

Spanish: Arnica, tabaco de montana²

1.3 Accepted Latin binomial: *Arnica montana*¹

1.4 Botanical family: Asteraceae

1.5 Plant part and form: Arnica bulk raw material is usually sold as dried whole flowers, or in the form of dried flower extracts. Arnica tinctures (usually made with 50-70% aqueous ethanol) are sold for external use or as dietary supplements, although arnica is not recommended for oral use according to the *American Herbal Products Association's Botanical Safety Handbook*, 2nd. ed., the European Medicines Agency's (EMA) draft Community Herbal Monograph, and the monographs on Arnica Flower by the European Scientific Cooperative on Phytotherapy (ESCOP) and the German Commission E.⁴⁻⁷ An exception is the use of arnica flower preparations in homeopathy, where highly diluted arnica tinctures in liquid form or tablets are popular. The predominant galenic form for arnica is as an ointment or a gel made with vari-

[†]The occasional common name 'wolfsbane' for arnica in some locations should not be confused with the more widespread use of the common name wolfsbane to refer to the toxic plants in the genus *Aconitum* (Ranunculaceae).



Arnica *Arnica montana*
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ous concentrations of arnica tincture. Arnica ointments are sold mainly as homeopathic remedies (although in most preparations, the arnica tincture is undiluted[‡]), or as herbal ointments in combination with other ingredients. Arnica is also a popular ingredient in massage oils and in cosmetic preparations.

1.6 General use(s): Traditionally, arnica tinctures, gels, creams, and ointments containing arnica oil, tinctures, or liquid extracts (liquid extracts are made using a 1:20 ratio of fresh flowers to 50% aqueous ethanol) are used topically for the relief of bruises, sprains, and localized muscular pain.⁶ The World Health Organization monograph lists the treatment of pain and inflammation (bruises and other types of injuries leading to hematomas [localized bleeds visible under the surface of the skin]) resulting from minor injuries and accidents, and the treatment of inflammation of the oral mucous membranes, insect bites, and superficial phlebitis as indications for arnica.⁸ The essential oil, flower water, or extracts of arnica are used in the cosmetic industry as a fragrance, or as a skin-conditioning agent.⁹

2 Market

2.1 Importance in the trade: The use of arnica as an ingredient in dietary supplements is not extensive, as it is not recommended for internal use.^{4,5} Ingestion of non-homeopathic arnica preparations can result in cardiac, pulmonary, and uterine toxicity (see section 3.5 below), and can cause gastrointestinal disorders.^{5,10} However, the herb

is popular as an ingredient in ointments and gels. According to the market research company SPINS, sales of arnica in the herbal category (according to SPINS, herbal tinctures, e.g., arnica tinctures labeled “for external use only”, and loose herbs do not have to bear a dietary supplement statement on their labels to be captured under the herbal category) have been increasing between 2012 and 2014 (Table 1), with ca. 65–75% of sales in the Mainstream Multi-Outlet retail channel in the United States, where arnica ranked between #83 and #113. (T. Smith [American Botanical Council] e-mail, September 2, 2015 and September 3, 2015). Sales of topical arnica ointments and gels were in the range of US \$15–25 million in the years 2013–2015 (Table 2), with a healthy year-to-year sales increase (K. Kawa [SPINS] e-mail, February 25, 2016 and February 29, 2016). The ranking of topical arnica preparations compared to other homeopathic products is not available.

2.2 Supply sources: *Arnica montana* is native to Europe; its range extends from Scandinavia across central Europe to Spain and Portugal, and eastward to the Balkan peninsula, Poland, Romania, Ukraine, and southern Russia. A report from 1998 suggests that Europe alone uses ca. 50 metric tons of dried arnica flowers (equivalent to 250–350 tons of fresh flowers) per year.¹¹ The same harvest volume is also cited in 2010 by Cropwatch, an independent organization assessing the status of threatened medicinal and aromatic plants.¹² Most commercial material is obtained from collections in the wild in Romania, Spain, and countries of the

[‡]Such undiluted tinctures in homeopathy are referred to as a ‘mother tincture’ and must conform to specifications for raw material and method of preparation found in officially recognized homeopathic pharmacopeias.

Table 1: Sales data for arnica (including bulk herbs and tinctures) in the herbal category in the United States from 2012-2014.

Channel	2012		2013		2014	
	Rank	Sales [US\$]	Rank	Sales [US\$]	Rank	Sales [US\$]
Natural ^a	189	59,044	182	85,813	176	125,246
Mainstream Multi-Outlet ^b	102	135,583	113	161,936	83	384,485

Table 2: Sales [in US\$] data for topical arnica preparations (sold as homeopathic remedies) in the United States from 2012-2015.

Channel	2012	2013	2014	2015
Natural ^a	3,814,350	4,112,825	4,257,750	4,184,862
Mainstream Multi-Outlet ^b	n/a	12,281,389	16,770,345	18,710,056

^a According to SPINS (SPINS does not track sales at Whole Foods Market, which is a major natural products retailer in the US, health professionals, or other outlets without scanners)

^b According to SPINS (the Mainstream Multi-Outlet channel was formerly known as food, drug and mass market channel [FDM], exclusive of sales at Walmart) n/a: not available

Source: T. Smith (American Botanical Council) e-mail, September 2, 2015 and September 3, 2015; K. Kawa (SPINS) e-mail, February 25, 2016 and February 29, 2016.

western Balkans.^{13,14} Cultivation is possible, but is difficult and more costly than collection in the wild.¹⁴ Results of an assessment of the arnica supply chain, commissioned by the World Wildlife Fund, were published in 2006. According to these data, harvesters received €0.28/kg (1€ was equivalent to US \$1.18-1.32 in 2006) for fresh arnica flowers, while intermediary collectors obtained €0.38/kg. After drying, arnica flowers were sold for ca. €10/kg to wholesale manufacturers. Prices at wholesale reached €25-28/kg, depending on the market (domestic versus export).¹⁵ These prices are in line with wholesale prices in 2006 from Australia, where material sold for US \$28-40/kg. In the past years, prices for sustainably wildcrafted bulk arnica flowers (minimum quantity of 500 kg) varied from €20 to €40/kg (US\$22.5 to \$45/kg based on the exchange rate on June 15, 2016) for Central European material and from €30 to €50/kg (US\$34 to \$57/kg) for Spanish material, depending on year and supplier (K.W. Quirin [Flavex] e-mail communication, May 25, 2016).

2.3 Raw material forms: Bulk arnica raw material is sold mainly as whole dried flowers. Other plant parts, e.g., the whole herb and the roots, are also sold. However, whole arnica herb or roots are not within the scope of this document.

2.4 Market dynamics: According to sales data of the past four years (Tables 1 and 2), there has been a steady increase in sales of arnica-based products in the United States. Sales data from other countries are not available. Pricing for the consumer is in the range of US \$99-216/kg for whole dried arnica flowers, according to an informal survey of smaller companies in the United States and Germany that had pricing listed on the internet, conducted for this Bulletin (SG). Dried whole flowers of *A. chamissonis* and false, or Mexican, arnica (*Heterotheca inuloides*, Asteraceae), were listed at US \$74-117/kg and US \$18-37/kg, respectively.

3 Adulteration

3.1 Known adulterants: Currently, *A. montana* is the only official species listed in the European Pharmacopoeia.¹⁶ However, other *Arnica* species, i.e., *A. angustifolia*, *A. chamissonis*, *A. chamissonis* subsp. *foliosa*, *A. cordifolia*, *A. latifolia*, and *A. sororia*, may legally be sold in the United States under the Standardized Common Name of “arnica”, according to the second edition of the *American Herbal Products Association’s Herbs of Commerce*.¹⁵ North America has the greatest natural diversity of *Arnica* species with 26 of 29 species within the genus.¹⁷ The most common adulteration-related issue in the arnica trade is the replacement of arnica flowers with flowers of so-called “Mexican arnica” (predominantly *Heterotheca* spp.). In addition, other species known as “arnica”, especially in the Southern United States and Mexico, are offered on the market. These species include members of the Asteraceae (*Gaillardia* spp., *Grindelia* spp., *Helenium mexicanum*, *Heterotheca leptoglossa*, *H.*

subaxillaris, *Jefea pringlei*, *Neurolaena lobata*, *Pseudogynoxys* spp., *Tithonia diversifolia*, *Trixis angustifolia*, *T. inula*, *T. radialis*, *Verbesina crocata*, *V. pinnatifida*), and Loasaceae (*Mentzelia conzattii*).^{18,19} Adulteration with other yellow-flowering species of the Asteraceae (*Calendula officinalis*, *Cota tinctoria*, *Doronicum pardalianches*, and *Inula britannica*) is reported in older textbooks, but a mixture of these species with arnica flowers has not been reported in the current market.²⁰

3.2 Sources of information supporting confirmation

of adulteration: Adulteration of arnica with *H. inuloides* was noted in mid-twentieth-century pharmacognostic literature.²¹ European literature states that it had been frequent in the 1990s.²²⁻²⁴ A 2012 study of bulk herbs sold by online retailers and two stores in the St. Louis, Missouri area reported that of 11 samples of unprocessed whole “arnica flower” obtained from US-based vendors of bulk herbs, six were *Heterotheca* rather than genuine arnica.²⁵

3.3 Accidental or intentional adulteration: Due to overharvesting, arnica has been protected in a number of European countries, but populations are still in decline.^{26,27} The relatively high price of *A. montana* flowers, compared to *H. inuloides*, has provided an incentive for economically-motivated adulteration. At the same time, other species of *Arnica*, or members of the family Asteraceae colloquially known as arnica, are interchangeably used by local herbalists for the same benefits as *A. montana*. In addition, *A. chamissonis* subsp. *foliosa* was approved by the German Commission E in 1984 as a substitute for *A. montana* for external use in preparations for treating muscle and joint injuries, and for inflammation of the oral cavity and the throat.⁵ However, the species *A. chamissonis* subsp. *foliosa* is currently not included in the European Pharmacopoeia.¹⁶

3.4 Frequency of occurrence: There is no comprehensive published study on the frequency of arnica adulteration, but information from limited publications to date indicates that adulteration is common.

3.5 Possible safety/therapeutic issues: Adulteration of arnica with *H. inuloides* is economic in nature and creates no apparent safety concern. Traditional uses of the latter are similar to those of the former. However, *H. inuloides* is also used internally without the cautions regarding toxicity that are usually expressed for arnica,^{28,29} which is contraindicated for ingestion.^{4,30}

Heterotheca inuloides contains cytotoxic compounds, but a recent study reported that a dose of 2,000 mg/kg of the predominant sesquiterpene, 7-hydroxy-3,4-dihydrocadalene, was required to produce evidence of acute toxicity in mice.³¹ The occurrence of allergic reactions and contact dermatitis after topical administration of arnica is well documented,^{4,32} but a comprehensive literature search has not revealed any such adverse event description for *H. inuloides*.

[§]The first edition of the *American Herbal Products Association’s Herbs of Commerce* lists *A. montana* and *A. latifolia* as the only species in commerce with arnica as the common name. The first edition of *Herbs of Commerce* was incorporated by reference in the U.S. Food and Drug Administration’s (FDA) rules for labeling dietary supplements in 1997. This regulation was codified at 21 CFR 101.4 (h), but codification has not been updated to include the second edition of *Herbs of Commerce*.

3.6 Analytical methods to detect adulteration: When present as whole dried flower, *A. montana* is readily distinguished from *H. inuloides* and *C. officinalis* using morphological characteristics.^{24,25} Arnica and calendula can also be differentiated using botanical microscopy.^{33,34} In addition, microscopic features to distinguish between *A. montana* and *H. inuloides* flowers have been detailed by Saukel.³⁵ However, a literature search has not located a comparison of the microscopic characteristics of the various other *Arnica* spp. The HPTLC Association has published a high-performance thin-layer chromatography (HPTLC) method with criteria to distinguish *A. montana* from *A. chamissonis*, *C. officinalis*, and *H. inuloides*.³⁶ A TLC method using the same solvent system is described in the European Pharmacopoeia.¹⁶ Chemical distinction among *A. montana*, *A. chamissonis*, and *H. inuloides* has also been achieved by Schröder and Merfort (1991) using high-performance liquid chromatography combined with mass spectrometry (HPLC-MS),³⁷ although more recent liquid chromatography methods to analyze flavonoids, caffeoylquinic acids, and sesquiterpene lactones are available.^{16,38-40} The sesquiterpene composition reportedly depends on the geographical origin of the flowers, with materials from Central Europe predominantly containing helenalin esters while flowers from Spain are characterized by the abundance of 11 α ,13-dihydrohelenalin esters.^{24,41} Finally, DNA barcoding using the *matK* and *rbcL* sequences was performed to authenticate four dried crude materials labeled as “arnica” sold in *yerberías* and supermarkets in the Rio Grande Valley in Texas. The method could successfully distinguish authentic *A. montana* from the commercial samples, which were identified as *Grindelia* spp., *Heterotheca subaxillaris*, *Pseudogynoxys* spp., and *Trixis inula*.¹⁹

4 Conclusions

Economic adulteration of arnica with less costly species, especially *H. inuloides*, remains an occurrence of which purchasers must be aware. Adulteration of arnica with *H. inuloides* is readily detected using macroscopic, microscopic, chemical analysis, and/or DNA analysis.

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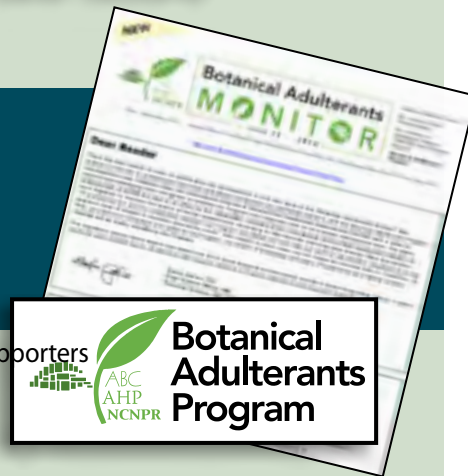
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Version 1, S. Gafner new	n/a	n/a	none