

TOX/2024/43 Annex B

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Table 8a: Combined acute consumption scenarios for 4-5 products of *Echinacea* (as dried root/herb) during pregnancy.

Estimated consumption of Echinacea (mg/day)	Estimated consumption of Echinacea (mg/day)	Estimated consumption of Echinacea (mg/day)	Estimated consumption of Echinacea (mg/day)	Estimated consumption of Echinacea (mg/day)	Estimated consumption of Echinacea (mg/day)
Tea	Honey	Lozenges	Tablets/capsules	Oral liquids	Total consumed per day

860 - 6,000	19 - 100	40	400 - 3,600	600 - 3,000	1,900 - 13,000
N/A	19 - 100	40	400 - 3,600	600 - 3,000	1,100 - 6,700
860 - 6,000	N/A	40	400 - 3,600	600 - 3,000	1,900 - 13,000
860 - 6,000	19 - 100	N/A	400 - 3,600	600 - 3,000	1,900 - 13,000
860 - 6,000	19 - 100	40	N/A	600 - 3,000	1,500 - 9,100
860 - 6,000	19 - 100	40	400 - 3,600	N/A	1,300 - 9,700

*Rounded to 2 significant figures.

Table 8b: Combined acute consumption scenarios for 3 products of *Echinacea* (as dried root/herb) during pregnancy.

Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)
Tea	Honey	Lozenges	Tablets/capsules	Oral liquids	Total consumed per day
860 - 6,000	19 - 100	40	N/A	N/A	920 - 6,100
860 - 6,000	19 - 100	N/A	400 - 3,600	N/A	1,300 - 9,700
860 - 6,000	19 - 100	N/A	N/A	600 - 3,000	1,500 - 9,100

860 - 6,000	N/A	N/A	400 - 3,600	600 - 3,000	1,900 - 13,000
860 - 6,000	N/A	40	400 - 3,600	N/A	1,300 - 9,600
860 - 6,000	N/A	40	N/A	600 - 3,000	1,500 - 9,000
N/A	N/A	40	400 - 3,600	600 - 3,000	1,000 - 6,700
N/A	19 - 100	N/A	400 - 3,600	600 - 3,000	1,000 - 6,700
N/A	19 - 100	40	400 - 3,600	N/A	460 - 3,700
N/A	19 - 100	40	N/A	600 - 3,000	660 - 3,100

*Rounded to 2 significant figures.

Table 8c: Combined acute consumption scenarios for 2 products of *Echinacea* (as dried root/herb) during pregnancy.

Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)
Tea	Honey	Lozenges	Tablets/capsules	Oral liquids	Total consumed per day
860 - 6,000	19 - 100	N/A	N/A	N/A	900 - 6,100
860 - 6,000	N/A	40	N/A	N/A	900 - 6,000

860 - 6,000	N/A	N/A	400 - 3,600	N/A	1,300 - 9,600
860 - 6,000	N/A	N/A	N/A	600 - 3,000	1,500 - 9,600
N/A	19 - 100	40	N/A	N/A	60 - 140
N/A	19 - 100	N/A	400 - 3,600	N/A	420 - 3,700
N/A	19 - 100	N/A	N/A	600 - 3,000	620 - 3,100
N/A	N/A	40	400 - 3,600	N/A	440 - 3,600
N/A	N/A	40	N/A	600 - 3,000	640 - 3,000
N/A	N/A	N/A	400 - 3,600	600 - 3,000	1,000 - 6,600

*Rounded to 2 significant figures.

Table 9a: Combined chronic consumption scenarios for 4-5 products of *Echinacea* (as dried root/herb) during pregnancy.

Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)
Tea	Honey	Lozenges	Tablets/capsules	Oral liquids	Total consumed per day
580 - 4,000	10-53	40	400 - 3,600	600 - 3,000	1,600 - 11,000

N/A	10-53	40	400 - 3,600	600 - 3,000	1,100 - 6,700
580 - 4,000	N/A	40	400 - 3,600	600 - 3,000	1,600 - 11,000
580 - 4,000	10-53	N/A	400 - 3,600	600 - 3,000	1,600 - 11,000
580 - 4,000	10-53	40	N/A	600 - 3,000	1,200 - 7,100
580 - 4,000	10-53	40	400 - 3,600	N/A	1,000 - 7,700

*Rounded to 2 significant figures.

Table 9b: Combined chronic consumption scenarios for 3 products of *Echinacea* (as dried root/herb) during pregnancy.

Estimated consumption of Echinacea (mg/day)	Estimated consumption of Echinacea (mg/day)	Estimated consumption of Echinacea (mg/day)	Estimated consumption of Echinacea (mg/day)	Estimated consumption of Echinacea (mg/day)	Estimated consumption of Echinacea (mg/day)
Tea	Honey	Lozenges	Tablets/capsules	Oral liquids	Total consumed per day
580 - 4,000	10-53	40	N/A	N/A	600 - 4,100
580 - 4,000	10-53	N/A	400 - 3,600	N/A	1,000 - 7,700
580 - 4,000	10-53	N/A	N/A	600 - 3,000	1,200 - 7,100
580 - 4,000	N/A	N/A	400 - 3,600	600 - 3,000	1,600 - 11,000

580 - 4,000	N/A	40	400 - 3,600	N/A	1,000 - 7,600
580 - 4,000	N/A	40	N/A	600 - 3,000	1,200 - 7,000
N/A	N/A	40	400 - 3,600	600 - 3,000	1,000 - 6,600
N/A	10 - 53	N/A	400 - 3,600	600 - 3,000	1,000 - 6,700
N/A	10 - 53	40	400 - 3,600	N/A	450-3,700
N/A	10 - 53	40	N/A	600 - 3,000	650-3,100

*Rounded to 2 significant figures.

Table 9c: Combined chronic consumption scenarios for 2 products of *Echinacea* (as dried root/herb) during pregnancy.

Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)	Estimated consumption of <i>Echinacea</i> (mg/day)
Tea	Honey	Lozenges	Tablets/capsules	Oral liquids	Total consumed per day
580 - 4,000	10-53	N/A	N/A	N/A	600 - 4,100
580 - 4,000	N/A	40	N/A	N/A	620 - 4,000
580 - 4,000	N/A	N/A	400 - 3,600	N/A	1,000 - 7,600
580 - 4,000	N/A	N/A	N/A	600 - 3,000	1,200 - 7,000

N/A	10-53	40	N/A	N/A	50 - 93
N/A	10-53	N/A	400 - 3,600	N/A	410 - 3,700
N/A	10-53	N/A	N/A	600 - 3,000	610 - 3,100
N/A	N/A	40	400 - 3,600	N/A	440 - 3,600
N/A	N/A	40	N/A	600 - 3,000	640 - 3,000
N/A	N/A	N/A	400 - 3,600	600 - 3,000	1,000 - 6,600

*Rounded to 2 significant figures.

Table 10: *Echinacea* products (oral dosage forms) with THR in the UK.

Product name	Dosage form	<i>Echinacea</i> species and plant part	Composition	Directions for use	Daily dose <i>Echinacea</i> (mg)
Echinaflu Soft Capsules.	Capsules.	<i>Echinacea purpurea</i> (L.) Moench herb.	176 mg of dried pressed juice from fresh flowering herb equivalent to 3.5-4.9 g of fresh herb (DER 20-28:1).	1-2 capsules daily for no longer than 10 days.	176 - 352 mg dried pressed juice equivalent to 3.5 - 9.8 g fresh herb.

Echinacea Cold and Flu Capsules.	Capsules.	<i>Echinacea purpurea</i> (L.) Moench) root.	140 mg dry extract from root equivalent to 838 - 1117 mg root (DER 6-8:1).	1 capsule twice a day.	280 mg dry root extract equivalent to 1,676- 2,234 mg root.
Ekinalife.	Capsules.	<i>Echinacea pallida</i> (Nutt.) Nutt. root and <i>Echinacea purpurea</i> (L.) Moench root.	200mg of <i>Echinacea pallida</i> . Nutt. and 200mg of <i>Echinacea purpurea</i> (L.) Moench powdered root.	1 capsule twice a day for no longer than 10 days.	400 mg <i>E. pallida</i> powdered root and 400 mg <i>E. purpurea</i> powdered root. Total of 1,600 mg powdered root.
Solgar Echinacea Cold and Flu Capsules.	Capsules.	<i>Echinacea purpurea</i> (L.) Moench root.	140 mg dry extract from root equivalent to 838 - 1117 mg root (DER 6-8:1).	1 capsule twice a day for no longer than 10 days.	280 mg dry root extract equivalent to 1,676- 2,234 mg root.
Phytocold.	Capsules.	<i>Echinacea purpurea</i> (L.) Moench root.	250 mg powdered root.	1-2 capsules three times a day fo no longer than 10 days.	750 - 1,500 mg powdered root.

Echinaflu Effervescent Tablets.	Effervescent Tablets.	<i>Echinacea purpurea</i> (L.) Moench herb.	176 mg of dried pressed juice from fresh flowering herb equivalent to 3.5-4.9 g of fresh herb (DER 20-28:1).	1-2 tablets daily for no longer than 10 days.	176 - 352 mg dried pressed juice equivalent to 3.5 - 9.8 g fresh herb.
Echineeze.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	70 mg dry extract from root equivalent to 460 - 530 mg root (DER 6.5-7.5:1).	1 tablet 3 times a day for no longer than 10 days.	210 mg dry root extract equivalent to 1,380 - 1,590 mg root.
Echinaforce Forte Cold & Flu Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench herb and root.	1,140 mg dry extract from fresh herb (DER 1:12) and 60 mg (DER 1:11) dry extract from fresh root.	1 tablet two to three times a day for no longer than 10 days.	2,280 - 3,420 mg dry herb extract and 120-180 mg dry root extract.
Herbal Cold And Flu Relief Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	71.5 mg dry extract from root equivalent to 429 - 500 mg root (DER 6-7:1).	1-2 tablets twice daily for no longer than 10 days.	143-286 mg dry root extract equivalent to 858 - 2,000 mg root.

High Strength Herbal Cold And Flu Relief Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	143 mg dry extract from root equivalent to 858 - 1000 mg root (DER 6-7:1).	1 tablet three times a day for no longer than 10 days.	429 mg dry root extract equivalent to 2,574 - 3,000 mg root.
Echinacea Skin Care Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	71.5 mg dry extract from root equivalent to 429 - 500 mg root (DER 6-7:1).	1-2 tablets three times a day for no longer than 10 days.	143-286 mg dry root extract equivalent to 858 - 2,000 mg root.
Herbal Classics Echinacea Cold Relief Film-Coated Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	40 mg dry extract from root equivalent to 260 mg root (DER 6.5:1).	2-3 tablets three times a day.	240-360 mg dry root extract equivalent to 1,560 - 2,340 mg root.
HRI Cold And Flu Echinacea Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	56 mg dry extract from root equivalent to 338 - 450 mg root (DER 6-8:1).	1-2 tablets twice daily.	112-224 mg dry root extract equivalent to 676-1,800 mg root.

Echinapret Coated Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench herb.	175 mg of dried pressed juice from fresh flowering herb equivalent to 6.7 - 9.8 g fresh herb (DER 38 - 56:1).	1 tablet three times a day for no longer than 10 days.	525 mg dried pressed juice equivalent to 18.4 - 29.4 mg fresh herb.
Thompson and Capper Echinacea Cold-n-Flu-Eze.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	105 mg dry extract from root equivalent to 630 - 840 mg root (DER 6-8:1).	1 tablet twice a day for no longer than 10 days.	210 mg dry root extract equivalent to 1,260 - 1,680 mg root.
Fuerte Tablets.	Tablets.	Wild indigo root (<i>Baptisia tinctoria</i> (L.) R.Br.), <i>Echinacea purpurea</i> root (<i>Echinacea purpurea</i> (L.) Moench), <i>Echinacea pallida</i> root (<i>Echinacea pallida</i> (Nutt.) Nutt.) , White cedar tips and leaves (<i>Thuja occidentalis</i> L.).	3.2 mg dry root extract (DER 4-9:1) from Wild indigo root, <i>E. purpurea</i> root, <i>E. pallida</i> root and Wild cedar tips and leaves (4.92:1.85:1.85:1).	5 tablets three times a day for no longer than 10 days.	9.2 mg <i>E. pallida</i> and 9.2 mg <i>E. purpurea</i> dry root extract. Total 18.4 mg dry root extract equivalent to 73.6-165.6 mg root.

Healthsense Echinashield Cold and Flu Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	70 mg dry extract from root equivalent to 420 - 560 mg root (DER 6-8:1).	1 tablet three times a day for no longer than 10 days.	210 mg dry root extract equivalent to 1,260 - 1,680 mg root.
Lamberts Echinacea Cold & Flu relief tablets Nature's Best Echinacea Cold & Flu Relief tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	105 mg dry extract from root equivalent to 630 - 840 mg root (DER 6-8:1).	1 tablet twice a day for no longer than 10 days.	210 mg dry root extract equivalent to 1,260 - 1,680 mg root.
Vitabiotics Echinacea Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	200 mg dry extract from root equivalent to 1200 - 1600 mg root (DER 6-8:1).	1 tablet twice a day for no longer than 10 days.	400 mg dry root extract equivalent to 2,400 - 3,200 mg root.
Potter's Skin Clear Tablets.	Tablets.	<i>Echinacea angustifolia</i> (D.C) root.	110 mg dry extract from root equivalent to 500 mg root (DER 4.5:1).	2 tablets three times a day for no longer than 10 days.	660 mg dry root extract equivalent to 2,970 mg root.

EKINACLEAR. Tablets.		<i>Echinacea purpurea</i> (L.) Moench root.	50 mg dry extract from root equivalent to 300 - 400 mg root (DER 6-8:1).	1-2 tablets three times a day for no longer than 10 days.	150-300 mg dry root extract equivalent to 900-2,400 mg root.
Lifeplan Echinacea Cold and Flu Relief Tablets.	Tablets.	<i>Echinacea purpurea</i> (L.) Moench root.	140 mg dry extract from root equivalent to 840 - 1120 mg root (DER 6-8:1).	1 tablet twice a day for no longer than 10 days.	150-300 mg dry root extract equivalent to 900-2,400 mg root.
Echinaforce Chewable Cold & Flu Tablets.	Chewable tablets.	<i>Echinacea purpurea</i> (L.) Moench herb and root.	380 mg dry extract from fresh herb (DER 1:12) and 20 mg dry extract (DER 1:11) from fresh root.	2 tablets two to three times a day for no longer than 10 days.	1,520 - 2,280 mg dry herb extract and 80-120 mg dry root extract.
Herbal Cold And Flu Sachets.	Sachets.	<i>Echinacea purpurea</i> (L.) Moench root.	71.5 mg dry extract from root equivalent to 429 - 500 mg root (DER 6-7:1).	1 sachet three times a day for no longer than 10 days.	214.5 mg dry root extract equivalent to 1,287-1,500 mg root.

Cystorelief Cystitis Uva- ursi & Echinacea oral drops ^a .	Tincture.	<i>Echinacea purpurea</i> (L.) Moench herb, Uva-ursi herb (<i>Arctostaphylos</i> <i>uva-ursi</i> (L.) Spreng, Herb).	240 mg of tincture from fresh herb (DER 1:12) per 1	15 drops in a little water 2-5 times daily. 1mL is equivalent to 30 drops.	240-600 mg of tincture from fresh herb.
Potter's Elixir of Echinacea Plus/Napiers Elixir of Echinacea Complex ^b .	Oral solution.	<i>Echinacea angustifolia</i> (D.C) root, Wild Indigo root, Fumitory herb.	0.64 mL liquid extract from root equivalent to 640 mg root per 5 mL (DER 1:1).	5 mL three times a day for no longer than 10 days.	1.92 mL liquid root extract equivalent to 1.92 g root.
Echinacin Juice MADAUS.	Oral solution.	<i>Echinacea purpurea</i> (L.) Moench) herb.	117 mg of dried pressed juice from fresh flowering herb equivalent to 3.7 - 6.3 g of fresh herb per 5 mL (DER 31.5-53.6:1).	5 mL three times a day for no longer than 10 days.	351 mg dried pressed juice equivalent to 11.1 - 18.9 g fresh herb.
Echinacin Liquidum MADAUS ^c .	Oral solution.	<i>Echinacea purpurea</i> (L.) Moench) herb.	1.99 g of pressed juice from fresh flowering herb equivalent to 3.4 - 5 g of fresh herb per 2.5 mL (DER 1.7-2.5:1).	2.5 mL three times a day for no longer than 10 days.	5,970 mg pressed juice equivalent to 10.2-15 g fresh herb.

Echinaforce hot drink cold & flu echinacea concentrate for oral solution.	Tincture.	<i>Echinacea purpurea</i> (L.) Moench herb and root.	1,140 mg extract (as tincture) from fresh herb (DER 1:12-13) and 60 mg extract (as tincture) from fresh root (DER 1:11-12) per 5 ml.	Days 1-3: Take 5 ml diluted in hot water five times daily. Days 4-10: Take 5 ml diluted in hot water three times daily.	3,420 - 5,700 mg herb extract (tincture) and 180-300 mg root extract (tincture).
Echinaforce Sore Throat Spray ^d .	Oromucosal spray.	<i>Echinacea purpurea</i> (L.) Moench herb and root, Sage leaves, (<i>Salvia officinalis</i> L. <i>folium</i>).	863.3 mg tincture from fresh herb (DER 1:12) and 45.5 mg tincture from fresh root (DER 1:11) per 1 mL.	1 spray (0.22 mL) six to ten times a day for no more than 7 days.	1,147 - 1,910 mg herb tincture and 60 - 100 mg root tincture.
Duchy Herbals Echina-Relief Tincture ^e .	Tincture.	<i>Echinacea purpurea</i> (L.) Moench root.	1mL of tincture from dried root (1:3) (equivalent to 33 mg dried root) per 1 mL tincture.	2.5 ml of tincture, in water, two or three times daily for no longer than 10 days.	5-7.5 mL tincture equivalent to 165 - 248 mg dried root.

a 1 mL contains 426 mg ethanol equivalent to 10.8 mL beer or 4.5 mL wine (43% v/v ethanol content).

b 5 mL contains 760 mg ethanol equivalent to 19 mL beer or 7.9 mL wine (19 % v/v ethanol content).

c 1 mL contains 179 mg ethanol equivalent to 4 mL beer or 1.6 mL wine (18% v/v ethanol content).

d 1 mL contains 370 mg ethanol equivalent to 8.4 mL beer or 3.4 mL wine (38-42% v/v ethanol content).

e 2.5 mL contains 900 mg ethanol equivalent to 23 mL beer or 10 mL wine (38-45% v/v ethanol content).

Table 11: Summary of doses and preparations of THR products in the UK and EMA monographs.

Echinacea species	Daily dose THR products UK	EMA monographs daily doses
	Pressed juice from herb (DER 1.7-2.5:1): 5,970 mg (equivalent to 10.2-15 g fresh herb).	Pressed juice from herb (DER 1.5-2.5:1): 6 - 9 g (equivalent to 9 - 22.5 g fresh herb.).
<i>Echinacea purpurea.</i>	Dried pressed juice from herb (DER 20-28:1): 176-352 mg (equivalent to 3.5 - 9.8 g fresh herb)	Dried pressed juice: Corresponding to the expressed juice above. (EMA monograph, 2014).
	Dry root extract (DER 6-7:1): 143 - 429 mg (equivalent to 858 - 3,000 mg root)	Dry root extract (DER 5.5-7.5:1): 360 mg (equivalent to 1,980 - 2,700 mg root).
	Powdered root: 250 -1500 mg.	 (EMA monograph, 2017).

*Echinacea
angustifolia.*

Dry root extract (DER

4.5:1):

660 mg equivalent to 2,970 mg root.

Liquid root extract (DER

1:1):

1.92 mL (equivalent to 1,920 mg root).

Powdered root:

500-1,500 mg.

Liquid root extract (DER 1:1):

0.75 - 3 mL (equivalent to 750 -3,000 mg root).

Tincture (DER 5:1):

3-6 mL (equivalent to 1,500 - 3,000 mg root).

(EMA monograph 2018).

*Echinacea
pallida.*

Dry root extract (DER 4-

9:1):

9.2 mg *E. pallida* and 9.2 mg *E. purpurea* (equivalent to 36.8-82.8 mg root).

Dry root extract (DER 4-8:1):

90-96 mg (equivalent to 360 - 786 mg root).

Powdered root:

400 mg *E. pallida* and 400 mg *E. purpurea*.

(EMA monograph 2012).