

**CALLOUSED-** allium sativum, anacardium orientale, calendula officinalis, capsicum annuum, ceanothus americanus, chamomilla, chelidonium majus, conium maculatum, kali carbonicum, lobelia cardinalis, mancinella, myristica sebifera, pinus sylvestris, flos, stigmata maidis, sepia, taraxacum officinale, thea sinensis liquid  
King Bio Inc.

*Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.*

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**Calloused™**

**Drug Facts**

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**HPUS active ingredients:** Allium sativum, Anacardium orientale, Calendula officinalis, Capsicum annuum, Ceanothus americanus, Chamomilla, Chelidonium majus, Conium maculatum, Kali carbonicum, Lobelia cardinalis, Mancinella, Myristica sebifera, Pinus sylvestris, flos, Stigmata maidis, Sepia, Taraxacum officinale, Thea sinensis. Equal volumes of each ingredient in 10X, 30X, 100X, LM1, LM2, LM3, LM5 potencies.

**Uses** for temporary relief of: hard-heartedness, fear of losing control. indifference, coldness toward others.

**Inactive Ingredients:**

Bio-Energetically Enhanced™ pure water, citric acid and potassium sorbate.

**Warnings**

- **Stop use and ask your doctor** if symptoms persist or worsen.
- **If pregnant or breast-feeding**, take only on advice of a healthcare professional.
- **Keep out of reach of children**

**Directions**

- Initially, depress pump until primed.
- Spray one dose directly into mouth.
- **Adults: 3 sprays 3 times per day.**
- **Children 2 - 12: 2 sprays 3 times per day.**
- Use additionally as needed, up to 6 times per day.

**Tamper resistant for your protection.** Use only if safety seal is intact.

**Uses** for temporary relief of:

- hard-heartedness
- fear of losing control
- indifference
- coldness toward others

**Drug Facts (continued)**

**Warnings**

■ Stop use and ask your doctor if symptoms persist or worsen. ■ If pregnant or breast-feeding, take only on advice of a healthcare professional. ■ Keep out of reach of children.

**Directions**

■ Initially, depress pump until primed. ■ Spray one dose directly into mouth. ■ Adults: 3 sprays 3 times per day. ■ Children 2-12 years: 2 sprays 3 times per day. ■ Use additionally as needed, up to 6 times per day.

Tamper resistant for your protection. Use only if safety seal is intact.

King Bio, Inc. - FDA Reg. #1053442  
3 Westside Dr. Asheville, NC 28806 USA  
Questions? Call (800) 543-3245

NDC# 57955-2311-2

**SafeCareRx**

**Calloused™**

**Mind & Body**

High Potency Homeopathic Formula for Professional Use Only

2 fl oz (59 mL)

Exp. 03/17  
Lot # 032614

**Drug Facts**

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**CALLOUSED**

allium sativum, anacardium orientale, calendula officinalis, capsicum annuum, ceanothus americanus, chamomilla,

chelidonium majus, conium maculatum, kali carbonicum, lobelia cardinalis, mancinella, myristica sebifera, pinus sylvestris, flos, stigmata maidis, sepia, taraxacum officinale, thea sinensis liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57955-2311
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GARLIC</b> (UNII: V1V998DC17) (GARLIC - UNII:V1V998DC17)	GARLIC	10 [hp_X] in 59 mL
<b>SEMECARPUS ANACARDIUM JUICE</b> (UNII: Y0F0BU8RDU) (SEMECARPUS ANACARDIUM JUICE - UNII:Y0F0BU8RDU)	SEMECARPUS ANACARDIUM JUICE	10 [hp_X] in 59 mL
<b>CALENDULA OFFICINALIS FLOWERING TOP</b> (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	10 [hp_X] in 59 mL
<b>CAPSICUM</b> (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)	CAPSICUM	10 [hp_X] in 59 mL
<b>CEANOOTHUS AMERICANUS LEAF</b> (UNII: 25B1Y14T8N) (CEANOOTHUS AMERICANUS LEAF - UNII:25B1Y14T8N)	CEANOOTHUS AMERICANUS LEAF	10 [hp_X] in 59 mL
<b>MATRICARIA RECUTITA</b> (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	10 [hp_X] in 59 mL
<b>CHELIDONIUM MAJUS</b> (UNII: 7E889U5RNN) (CHELIDONIUM MAJUS - UNII:7E889U5RNN)	CHELIDONIUM MAJUS	10 [hp_X] in 59 mL
<b>CONIUM MACULATUM FLOWERING TOP</b> (UNII: Q28R5GF371) (CONIUM MACULATUM FLOWERING TOP - UNII:Q28R5GF371)	CONIUM MACULATUM FLOWERING TOP	10 [hp_X] in 59 mL
<b>POTASSIUM CARBONATE</b> (UNII: BQN1B9B9HA) (CARBONATE ION - UNII:7UJQ5OPE7D)	POTASSIUM CARBONATE	10 [hp_X] in 59 mL
<b>LOBELIA CARDINALIS</b> (UNII: GT0PJ8MB5R) (LOBELIA CARDINALIS - UNII:GT0PJ8MB5R)	LOBELIA CARDINALIS	10 [hp_X] in 59 mL
<b>HIPPOMANE MANCINELLA FRUITING LEAFY TWIG</b> (UNII: HU6EY211W) (HIPPOMANE MANCINELLA FRUITING LEAFY TWIG - UNII:HU6EY211W)	HIPPOMANE MANCINELLA FRUITING LEAFY TWIG	10 [hp_X] in 59 mL
<b>VIROLA SEBIFERA RESIN</b> (UNII: GHJ5XX5SGS) (VIROLA SEBIFERA RESIN - UNII:GHJ5XX5SGS)	VIROLA SEBIFERA RESIN	10 [hp_X] in 59 mL
<b>PINUS SYLVESTRIS FLOWERING TOP</b> (UNII: 2HEM73YI9I) (PINUS SYLVESTRIS FLOWERING TOP - UNII:2HEM73YI9I)	PINUS SYLVESTRIS FLOWERING TOP	10 [hp_X] in 59 mL
<b>CORN SILK</b> (UNII: 7D3VB244UX) (CORN SILK - UNII:7D3VB244UX)	CORN SILK	10 [hp_X] in 59 mL
<b>SEPIA OFFICINALIS JUICE</b> (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2)	SEPIA OFFICINALIS JUICE	10 [hp_X] in 59 mL
<b>TARAXACUM OFFICINALE</b> (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	10 [hp_X] in 59 mL
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0) (GREEN TEA LEAF - UNII:W2ZU1RY8B0)	GREEN TEA LEAF	10 [hp_X] in 59 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CITRIC ACID MONO HYDRATE</b> (UNII: 2968PHW8QP)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57955-2311-2	59 mL in 1 BOTTLE, SPRAY		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/17/2014	

**Registrant** - King Bio Inc. (617901350)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
King Bio Inc.		617901350	manufacture(57955-2311)

Revised: 4/2014

King Bio Inc.