Rutland Biodynamics Ltd (Herbal Medicines)
Town Park Farm, Brooke, Rutland, LE15 8DG, UK
UK Dept of Health MHRA cGMP MIA number 28255
www.rutlandbio.com

Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company / undertaking

1.1. Product identifiers:

   (a) Product name: Carduus marianus fluid extract 1:1 25% ethanol
   (b) Product Number: 0014
   (c) Brand: None
   (d) Index-No.: not applicable
   (e) REACH No.: not applicable
   (f) CAS-No.: not applicable

1.2. Relevant identified uses of the substance or mixture and uses advised against:

   Herbal medicinal product

1.3. Details of the supplier of the safety data sheet:

   Rutland Biodynamics Ltd, Town Park Farm, Brooke, Rutland, LE158DG.

1.4. Emergency telephone number:

   +44(0) 1572 757440

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture:

   Flammable liquids, Category 3

2.2. Label elements:

   Hazard pictograms

(a) Hazards statements:

   • H320: Causes eye irritation
• H226: Flammable liquid

(b) Precautionary statements

• Keep away from heat, hot surfaces and other ignition sources.

SECTION 3: Composition / information on ingredients

3.1. Substances Synonyms:

Milk thistle, Silybum

3.2. Chemical Description:

an aqueous ethanolic extraction of herbal material

3.3. Ingredients:

Carduus marianus, Ethanol, Purified Water BP.

SECTION 4: First aid measures

4.1. General information:

When in doubt or if symptoms are observed, get medical advice. If unconscious place in recovery position and seek medical advice. Never give anything by mouth to an unconscious person or a person with cramps. Change contaminated, saturated clothing. Do not leave affected person unattended.

(a) After inhalation:

Remove casualty to fresh air and keep warm and at rest. If breathing is irregular or stopped, administer artificial respiration. In case of respiratory tract irritation, consult a physician.

(b) After eye contact:

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist. Protect uninjured eye. Remove contact lenses, if present and easy to do. Continue rinsing.

(c) In case of Skin contact:

Remove contaminated clothing wash the affected area thoroughly with soap and water. If discomfort persists seek medical attention.

(d) In case of Ingestion:

DO NOT INDUCE VOMITING. In case of spontaneous vomiting, ensure vomit can drain freely to prevent danger of suffocation. Never give anything by mouth to an unconscious person when conscious, rinse mouth with 500ml water. If there is difficulty in breathing give
oxygen. If breathing stops or shows signs of failing, apply artificial respiration. Obtain medical attention should symptoms persist.

4.2. Most important symptoms and effects, both acute and delayed:
No data available

4.3. Indication of any immediate medical attention and special treatment needed:
No data available

4.4. Self-protection of the first aider:
First aider: Pay attention to self-protection!

4.5. Information to physician:
No data available

SECTION 5: Firefighting measures

5.1. Extinguishing media:
(a) Suitable extinguishing media:
Water spray ABC-powder Carbon dioxide (CO2) Nitrogen
(b) Extinguishing media which must not be used for safety reasons:
No restriction

5.2. Special hazards arising from the substance or mixture:
In case of fire may be liberated: Carbon dioxide (CO2) Carbon monoxide

5.3. Advice for firefighters:
DO NOT fight fire when fire reaches explosives. In case of fire: Wear self-contained breathing apparatus.

5.4. Additional information:
Do not allow run-off from fire-fighting to enter drains or water courses. Do not inhale explosion and combustion gases. Use caution when applying carbon dioxide in confined spaces. Carbon dioxide can displace oxygen. Use water spray jet to protect personnel and to cool endangered containers.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:
Avoid generation of dust. Do not breathe dust/fume/gas/mist/vapours/spray. Provide adequate ventilation. Avoid contact with skin, eyes and clothes.

6.2. Environmental precautions:

Prevent contamination of soils, drains and surface water

6.3. Methods and materials for containment and cleaning up:

Spilled product must never be returned to the original container for recycling sweep up or absorb material, then place into a suitable clean dry, closed container for disposal. Wash area with detergent and water.

6.4. Additional information:

Clear spills immediately

SECTION 7: Handling and storage

7.1. Precautions for safe handling:

Product should be handled according to good industrial practice. Use in well ventilated area avoid inhaling vapour. Avoid contact with eyes, skin, and clothing. Keeping container tightly closed when not in use. Keep away from sources of ignition. - No smoking. Usual measures for fire prevention. slight dehydrating effect (hygroscopic).

7.2. Conditions for safe storage:

(a) storage temperature:

15-25 °C

(b) Storage class:

3

(c) storage area:

should be cool, well ventilated. Store away form sources of heat an ignition. Storage ans transfer should be adequately earthed and bounded to the accumulation of static charge

7.3. Specific end use(s):

no data available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters:

no data available
8.2.  Exposure controls:

(a)  Appropriate engineering controls:

Technical measures and the application of suitable work processes have priority over personal protection equipment

(b)  Personal protection equipment:

• Wear suitable protective clothing. When handling with chemical substances, protective clothing with CE-labels including the four control digits must be worn. For the protection against direct skin contact, body protective clothing is essential (in addition to the usual working clothes).

• Eye/face protection

• Eye glasses with side protection DIN-/EN-Norms: DIN EN 166

• Skin protection

• When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. Recommended glove articles DIN-/EN-Norms: DIN EN 374 In the case of wanting to use the gloves again, clean them before taking off and air them well.

(c)  Environmental exposure controls:

no data available

SECTION 9:  Physical and chemical properties

9.1.  Information on basic physical and chemical properties:

(a)  Appearance:  A brown mobile liquid

(b)  Odour:  Characteristic

(c)  Odour Threshold:  no data available

(d)  PH:  no data available

(e)  Melting point/freezing point Melting point/range:  no data available

(f)  Initial boiling point and boiling range:  no data available

(g)  Flash point:  no data available

(h)  Evaporation rate:  no data available

(i)  Flammability (solid, gas):  no data available
(j) Upper/lower flammability or explosive limits: no data available
  • Lower explosion limit:
  • Upper explosion limit:

(k) Vapour pressure: no data available

(l) Vapour density: no data available

(m) Relative density: no data available

(n) Solubility(ies):
  • at 20°C:
  • Soluble (g/L) in:

(o) Partition coefficient: n-octanol/water: no data available

(p) Auto-ignition temperature: no data available

(q) Decomposition temperature: no data available

(r) Viscosity: no data available
  • Kinematic viscosity:
  • Dynamic viscosity:

(s) Explosive properties: no data available

(t) Oxidizing properties: no data available

(u) Ethanol Content: 23 - 27 % (v/v)

9.2. Other safety information:

(a) Bulk density: no data available

(b) Refraction index: no data available

(c) Dissociation constant: no data available
(d) **Surface tension:**
no data available

(e) **Henry constant:**
no data available

**SECTION 10: Stability and reactivity**

10.1. **Reactivity:**
no data available

10.2. **Chemical stability:**
stable at storage temperature

10.3. **Possibility of hazardous reactions:**
no data available

10.4. **Conditions to avoid:**
no data available

10.5. **Incompatible materials:**
strong oxidizer. Nitric acid

10.6. **Hazardous decomposition products:**
no data available

10.7. **Additional information:**
no data available

**SECTION 11: Toxicological information**

11.1. **Information on toxicological effects:**

(a) **Acute effects**

- *Acute oral toxicity:* LD50 (oral. Rat): 6200 mg/kg (CHP) (Ethanol)
- *Acute dermal toxicity:* LD50 (dermal. Rabbit): >20000 mg/kg (CHP) (Ethanol)
- *Acute inhalation toxicity:* LC50 (inhalative. Rat. 4h): >8000 mg/l (CHP) (Ethanol)
(b) Irritant and corrosive effects:

• Primary irritation to the skin: not applicable
• Irritation to eyes: not applicable
• Irritation to respiratory tract: not applicable

(c) Respiratory or skin sensitisation:

in case of skin contact: not sensitising After inhalation: not sensitising

(d) STOT-single exposure:

not applicable

(e) STOT-repeated exposure:

not applicable

(f) CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):

• Carcinogenicity:
  no indication of human carcinogenicity.

• Germ cell mutagenicity:
  no indications of human germ cell mutagenicity exist.

• Reproductive toxicity:
  for ethanol components of preparation, adverse effects on male reproductive systems have been reported in laboratory animals on prolonged exposure

• Aspiration hazard:
  not applicable

• Other adverse effects:
  no data available

• Additional information:
  no data available

SECTION 12: Ecological information

12.1. Ecotoxicity
Safety Data Sheet

(a) **Acute (short-term) fish toxicity:**
   no data available

(b) **Chronic (long-term) fish toxicity:**
   no data available

(c) **Acute (short-term) daphnia toxicity:**
   no data available

(d) **Chronic (long-term) daphnia toxicity:**
   no data available

(e) **Acute (short-term) algae toxicity:**
   no data available

(f) **Chronic (long-term) algae toxicity:**
   no data available

12.2. **Persistence and degradability:**
   no data available

12.3. **Bioaccumulative potential:**
   Partition coefficient: n-octanol/water: no data available

12.4. **Mobility in soil:**
   no data available

12.5. **Results of PBT/vPvB assessment:**
   no data available

12.6. **Other adverse effects:**
   no data available

**SECTION 13: Disposal considerations**

13.1. **Waste treatment methods:**

(a) **Appropriate disposal / Product:**
Dispose according to local legislation:
Consult the appropriate local waste disposal expert about waste disposal.

Waste code product:
no data available

(b) Appropriate disposal / Package:
Dispose according to local legislation. Handle contaminated packages in the same way as the substance itself.

(c) Additional information:
This material must be disposed of as hazardous waste according to special waste regulations 1996 or according to local regulations, in compliance with duty of care regulations and special waste regulations as waste from manufacturing, supply and use of pharmaceuticals.

SECTION 14: Transport information

14.1. Land transport (ADR/RID)

(a) UN number: 1293 (tincture, medicinal)
(b) UN proper shipping name: Ethanolic solution
(c) Classification: R10 Flammable liquid
(d) Transport hazard class(es): 3
(e) Packaging group: III
(f) Environmental hazards: No
(g) Special precautions for user:
   - Hazard identification number (kemler No.): no data available
   - Tunnel restriction code: no data available

14.2. Sea transport (IMDG)

(a) UN number: 1293 (tincture, medicinal)
(b) UN proper shipping name: Ethanolic solution
(c) Classification: R10 Flammable liquid
(d) Transport hazard class(es): 3
(e) Packaging group: III
(f) Environmental hazards: No
   • Marine pollutant: No
(g) Special precautions for user: no data available
(h) Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not relevant

14.3. Air transport (ICAO-TI / IATA-DGR)
(a) UN number: 1293 (tincture, medicinal)
(b) UN proper shipping name: Ethanolic solution
(c) Classification: R10 Flammable liquid
(d) Transport hazard class(es): 3
(e) Packaging group: III
(f) Special precautions for user: Not relevant

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
(a) General rules:
   • Water hazard class (WGK): slightly hazardous to water (WGK 1)
15.2. **Chemical Safety Assessment:**

no data available

**SECTION 16: Other information**

16.1. **Abbreviations and acronyms:**

   (a) **ACGIH** - American Conference of Governmental Industrial Hygiensts
   
   (b) **ADR** - European Agreement concerning the International Carriage of Dangerous Goods by Road
   
   (c) **AGS** - Committee on Hazardous Substances (Ausschuss für Gefahrstoffe)
   
   (d) **CLP** - Regulation on Classification, Labelling and Packaging of Substances and Mixtures
   
   (e) **DFG** - German Research Foundation (Deutsche Forschungsgemeinschaft)
   
   (f) **Gestis** - Information system on hazardous substances of the German Social Accident Insurance (Gefahrstoffinformationssystem der Deutschen Gesetzlichen Unfallversicherung)
   
   (g) **IATA-DGR** - International Air Transport Association-Dangerous Goods Regulations
   
   (h) **ICAO-TI** - International Civil Aviation Organization-Technical Instructions
   
   (i) **IMDG** - International Maritime Code for Dangerous Goods
   
   (j) **LTV** - Long Term Value
   
   (k) **NIOSH** - National Institute for Occupational Safety and Health
   
   (l) **OSHA** - Occupational Safety & Health Administration
   
   (m)**PBT** - Persistent, Bioaccumulative and Toxic
   
   (n) **RID** - Regulation concerning the International Carriage of Dangerous Goods by Rail
   
   (o) **STV** - Short Term Value
   
   (p) **SVHC** - Substances of Very High Concern
   
   (q) **vPvB** - very Persistent, very Bioaccumulative
16.2. Additional information:

No date available

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.