1 Identification

Product identifier
Trade name: Tagitol V
Article number: 8140

Application of the substance / the mixture:
Radiopaque contrast media for diagnostic imaging of the gastrointestinal tract
Smooth off-white free-flowing liquid with apple aroma
Route of Administration: Oral

Details of the supplier of the safety data sheet
Manufacturer/Supplier:
E-Z-EM Canada Inc.
11065 boulevard L-H. Lafontaine
Montréal, QC, Canada
H1J 2Z4
tel: (514) 353-5820

Information department:
B-Lands Consulting
WTC, 5 Place Robert Schuman, BP 1516
38025 Grenoble, FRANCE
Tel: +33 476 295 869
Fax: +33 476 295 870
Email: clients@reachteam.eu
www.reachteam.eu

Emergency telephone number:
EMERGENCY CONTACT:
Health: 1-800-257-5181
U.S. Transport - Chemtrec: 1-800-424-9300
International Transport - Chemtrec: 1-703-527-3887

2 Hazard(s) identification

Classification of the substance or mixture
The product is not classified according to the Globally Harmonized System (GHS).

Label elements
GHS label elements Not applicable.
Hazard pictograms Not applicable.
Signal word Not applicable.
Hazard statements Not applicable.

Additional Information:
WHMIS-symbols:
Not Hazardous.
Not controlled under WHIMS (Canada).

Classification system:
NFPA ratings (scale 0 - 4)

<table>
<thead>
<tr>
<th>Health</th>
<th>Fire</th>
<th>Reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS-ratings (scale 0 - 4)

<table>
<thead>
<tr>
<th>Health</th>
<th>Fire</th>
<th>Reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixture: consisting of the following components.

Hazardous Components:

<table>
<thead>
<tr>
<th>Component Code</th>
<th>Component</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>7727-43-7</td>
<td>Barium sulphate</td>
<td>30.0% w/w</td>
</tr>
<tr>
<td>56-81-5</td>
<td>Glycerol</td>
<td>5.25% w/w</td>
</tr>
</tbody>
</table>

Information on components:

<table>
<thead>
<tr>
<th>Component Code</th>
<th>Component</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>7727-43-7</td>
<td>Barium sulphate</td>
<td>30.0% w/w</td>
</tr>
</tbody>
</table>

4 First-aid measures

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.

After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing: Do not induce vomiting; immediately call for medical help.

Most important symptoms and effects, both acute and delayed
No further relevant information available.

Indication of any immediate medical attention and special treatment needed
No further relevant information available.

5 Fire-fighting measures

Extinguishing media

Suitable extinguishing agents:

Use extinguishing measures appropriate to local circumstances and the environment. CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Special hazards arising from the substance or mixture
No further relevant information available.

Advice for firefighters

Protective equipment:

Firefighters should wear adequate personal protective equipment with protection of respiratory tract (self-contained breathing apparatus) (SCBA). In addition, firefighters should wear flame and chemicals resistant clothing, boots and gloves.

Additional information

Move containers from fire area if safe to do so. Cool closed containers exposed to fire with water spray. Do not allow run off from fire fighting to enter drains or water courses. Dike for water control. Evacuate personnel to an upwind direction. Remove unneeded material.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away. Remove persons from danger area.

Environmental precautions:

Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system.
Methods and material for containment and cleaning up:
Dispose of the collected material according to regulations.
Ventilate area of release.
Stop spill or leak at source if safely possible.
Contain and absorb spilled liquid with non-combustible, inert absorbent material (e.g. sand), then place
absorbent material into a container for later disposal (see Section 13).
Notify the appropriate authorities as required.

Reference to other sections
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

Precautions for safe handling
Ensure good ventilation/exhaustion at the workplace.
Avoid contact with the eyes and skin.

Information about protection against explosions and fires: No special measures required.

Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptacles:
Store in a cool, dry place in tightly closed receptacles.

Information about storage in one common storage facility: Not required.

Further information about storage conditions:
Storage area should be clearly identified, clear of obstruction and accessible only to trained and authorized
personnel.
Protect against physical damage

Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

Control parameters

<table>
<thead>
<tr>
<th>Components with limit values that require monitoring at the workplace:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>7727-43-7 Barium sulphate</strong></td>
</tr>
<tr>
<td>CAD AB OEL (Canada)</td>
</tr>
<tr>
<td>CAD BC OEL (Canada)</td>
</tr>
<tr>
<td>*: Respirable Fraction; **: Total Dust</td>
</tr>
<tr>
<td>CAD MB OEL (Canada)</td>
</tr>
<tr>
<td>CAD ON OEL (Canada)</td>
</tr>
<tr>
<td>OEL (QUE) (Canada)</td>
</tr>
<tr>
<td>*: Respirable Fraction; **: Total Dust</td>
</tr>
<tr>
<td>ACGIH (USA)</td>
</tr>
<tr>
<td>ACGIH 2014 TLV (USA)</td>
</tr>
<tr>
<td>Total Dust, no asbestos and &lt;1% crystalline silica</td>
</tr>
<tr>
<td>CAL/OSHA PEL (USA)</td>
</tr>
<tr>
<td>*:Respirable Fraction; **:Total Dust</td>
</tr>
<tr>
<td>NIOSH/GUIDE - REL (USA)</td>
</tr>
<tr>
<td>*: Respirable Fraction; **: Total Dust</td>
</tr>
<tr>
<td>OSHA PEL₁ (USA)</td>
</tr>
<tr>
<td>*: Respirable Fraction; **:Total Dust</td>
</tr>
</tbody>
</table>
Safety Data Sheet
acc. to OSHA HCS

Trade name: Tagitol V

| 56-81-5 glycerol | Long-term value: 10 mg/m³
| CAD AB OEL (Canada) | Mist
| CAD BC OEL (Canada) | Long-term value: 10*, 3** mg/m³
| CAD ON OEL (Canada ENG BRACCO) | Long-term value: 10 mg/m³
| Mist | *: Mist; **: Respirable Mist
| OEL (QUE) (Canada ENG BRACCO) | Long-term value: 10 mg/m³
| CAL/OSHA PEL (1 ; 2) (USA) | Long-term value: 10* ; 5** mg/m³
| *: Total Dust (Mist) ; **: Respirable Fraction
| CAL/OSHA PEL (1) (USA) | Long-term value: 10* ; 5** (2) mg/m³
| *: Total Dust (Mist) ; **: Respirable Fraction
| PEL (USA) | Long-term value: 15* ; 5** mg/m³
| *: Total Dust ; **: Respirable Fraction

Additional information: The lists that were valid during the creation were used as basis.

Exposure controls

Personal protective equipment

General protective and hygienic measures:
The usual precautionary measures for handling chemicals should be followed.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Do not eat, drink, smoke or sniff while working.

Breathing equipment:
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

Protection of hands:

Protective gloves

The glove material must be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection: Goggles recommended during refilling.

Body protection: Protective work clothing
9 Physical and chemical properties

Information on basic physical and chemical properties

General Information

Appearance:
  Form: Liquid.
  Color: Whitish

Odor:
  Apple Like
Odor threshold:
  Not determined.

pH-value:
  Not determined.

Melting point/Melting range:
  Not determined.

Boiling point/Boiling range:
  Not determined.

Flash point:
  Not determined.

Flammability (solid, gaseous):
  Not determined.

Ignition temperature:
  400 °C

Decomposition temperature:
  Not determined.

Danger of explosion:
  Product does not present an explosion hazard.

Flammability Limits:
  Lower: Not Determined.
  Upper: Not Determined.

Explosion limits:
  Lower: Not determined.
  Upper: Not determined.

Oxidizing properties
  Not determined.

Vapor pressure:
  Not determined.

Density:
  Not determined.

Relative density
  Not determined.

Vapor density
  Not determined.

Evaporation rate
  Not determined.

Solubility in / Miscibility with
  Water:
  Not determined.

Partition coefficient (n-octanol/water):
  Not determined.

Viscosity:
  Dynamic: 250-650 cPs
  Kinematic: Not determined.
  Solids content: 80.0 %

Other information
  No further relevant information available.

10 Stability and reactivity

Reactivity
  No further relevant information available.

Chemical stability

Thermal decomposition / conditions to be avoided:
  No decomposition if used according to specifications.

Possibility of hazardous reactions
  No dangerous reactions known.
Conditions to avoid: No further relevant information available.

Incompatible materials: Reactive metals

Hazardous decomposition products:
- Sulfur oxides (SOx)
- Carbon monoxide and carbon dioxide
- Barium Oxide (BaO)
- Other unidentified organic compounds.

11 Toxicological information

Information on toxicological effects

Acute toxicity:

<table>
<thead>
<tr>
<th>LD/LC50 values that are relevant for classification:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>7727-43-7 Barium sulphate</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>LD50</td>
</tr>
<tr>
<td><strong>56-81-5 glycerol</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>LD50</td>
</tr>
<tr>
<td>Dermal</td>
<td>LD50</td>
</tr>
<tr>
<td><strong>87-99-0 xylitol</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>LD50</td>
</tr>
<tr>
<td><strong>11138-66-2 Xanthan gum</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>LD50</td>
</tr>
<tr>
<td><strong>590-00-1 Potassium sorbate</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>LD50</td>
</tr>
<tr>
<td>Dermal</td>
<td>LD50</td>
</tr>
<tr>
<td><strong>9004-32-4 Sodium carboxymethyl cellulose</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>LD50</td>
</tr>
<tr>
<td>Dermal</td>
<td>LD50</td>
</tr>
<tr>
<td>Inhalative</td>
<td>LC50/4h</td>
</tr>
<tr>
<td><strong>6132-04-3 Trisodium citrate dihydrate</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>LD50</td>
</tr>
<tr>
<td>LD50 iv</td>
<td>170 mg/kg (Mouse)</td>
</tr>
<tr>
<td>LD50 ip</td>
<td>449 mg/kg (Rabbit)</td>
</tr>
<tr>
<td></td>
<td>1364 mg/Kg (Mouse)</td>
</tr>
<tr>
<td></td>
<td>1548 mg/Kg (Rat)</td>
</tr>
<tr>
<td><strong>77-92-9 Citric Acid, Anhydrous</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>LD50</td>
</tr>
<tr>
<td></td>
<td>3000 mg/kg (Rat) (RTEC)</td>
</tr>
<tr>
<td><strong>532-32-1 Sodium Benzoate</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>LD50</td>
</tr>
</tbody>
</table>

Primary irritant effect:
- on the skin: No irritant effect.
- on the eye: No irritating effect.

Sensitization: No sensitizing effects known.

Additional toxicological information:
The product is not subject to classification according to internally approved calculation methods for preparations.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

**Carcinogenic categories**

<table>
<thead>
<tr>
<th>Agency</th>
<th>Substance</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>IARC (International Agency for Research on Cancer)</td>
<td>Saccharin Sodium dihydrate</td>
<td>Yes: Carc. 3</td>
</tr>
<tr>
<td>NTP (National Toxicology Program)</td>
<td>Saccharin Sodium dihydrate</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Silica gel</td>
<td>K</td>
</tr>
</tbody>
</table>

**12 Ecological information**

**Toxicity**

**Aquatic toxicity:**

*7727-43-7 Barium sulphate*

EC50/48h: 32 mg/L (Daphnia Magna)

*56-81-5 glycerol*

IC5/7d: > 10000 mg/L (Scenedesmus Quadricauda) (Literature)

EC5/72h: 3200 mg/L (Echinodontium Sulcatum) (Literature)

EC50/24h: > 10000 mg/L (Daphnia Magna) (IUCLID)

LC50/24h: > 5000 mg/L (Carassius Auratus) (Literature)

*11138-66-2 Xanthan gum*

LC50/96h: 490 mg/L (Rainbow Trout)

LC50/48h: 980 mg/L (Daphnia Magna)

LC50/96h: > 5000 ppm (Mysis Shrimp) (Suspended Particulate (2 lb./bbl of Xanthan Gum))

*6132-04-3 Trisodium citrate dihydrate*

LC50/96h: > 18000 - 32000 mg/L (Poecilia Reticulata) (IUCLID - Anhydrous substance)

IC5/96h: > 18000 - 32000 mg/L (Chlorella Vulgaris) (IUCLID - Anhydrous substance)

EC50/8h: > 1800 - 3200 mg/L (Pseudomonas Fluorescens) (IUCLID - Anhydrous substance)

EC50/48h: 5600 - 10000 mg/L (Daphnia Magna) (IUCLID - Anhydrous substance)

*77-92-9 Citric Acid, Anhydrous*

LC50/96h: 440 - 760 mg/L (Leuciscus Idus) (IUCLID)

LC50: 440-706 mg/L (Fish)

IC5/7d: 640 mg/L (Scenedesmus Quadricauda) (Literature) (Max. Permissible Toxic Concentration)

EC5/72h: 485 mg/L (Echinodontium Sulcatum) (Literature)

IC5/8d: 80 mg/L (Microcystis Aeruginosa) (Literature) (Max. Permissible Toxic Concentration)

EC5/16h: > 10000 mg/L (Pseudomonas Putida) (Literature) (Max. Permissible Toxic Concentration)

EC50/72h: ca. 120 mg/L (Daphnia Magna) (IUCLID)

*532-32-1 Sodium Benzoate*

LC50: 460 mg/L (Leuciscus Idus) (ECOTOX Database)

EC0: 1000 mg/L (Bacteria) (Exernal SDS)

IC50/72h: > 10 mg/L (Algae) (Exernal SDS)

EC50/48h: > 100 mg/L (Daphnia) (Exernal SDS)

**Persistence and degradability** No further relevant information available.

**Bioaccumulative potential** No further relevant information available.

**Mobility in soil** No further relevant information available.

**Additional ecological information**

Use according to the good working practice. Avoid transfer into the environment.
General notes: Generally not hazardous for water

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

Other adverse effects No further relevant information available.

13 Disposal considerations

Waste treatment methods
The information presented only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Disposal should be in accordance with applicable regional, national and local laws and regulations.

Recommendation: Reutilise if possible or contact a waste processor for recycling or safe disposal

Waste disposal key:
If this product, as supplied, becomes a waste in the United States, it may meet the criteria of a hazardous waste as defined under RCRA, Title 40 CFR 261. It is the responsibility of the waste generator to determine the proper waste identification and disposal method. For disposal of unused or waste material, check with local, state and federal environmental agencies.

Uncleaned packagings:

Recommendation:
Disposal must be made according to official regulations.
Packagings that cannot be cleansed are to be disposed of in the same manner as the product.

14 Transport information

UN-Number
DOT
TDG, ADN, IMDG, IATA

UN proper shipping name
DOT, TDG, ADN, IMDG, IATA

Transport hazard class(es)
DOT, TDG, ADN, IMDG, IATA
Class

Packing group
DOT, TDG, IMDG, IATA

Environmental hazards:
Marine pollutant:

Special precautions for user
Not applicable.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Not applicable.
15 Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture
Sara

Section 355 (extremely hazardous substances):
None of the ingredients is listed.

Section 313 (Specific toxic chemical listings):
None of the ingredients is listed.

Canadian Ingredient Disclosure list (limit 0.1%)
None of the ingredients is listed.

Canadian Ingredient Disclosure list (limit 1%)
None of the ingredients is listed.

GHS label elements Not applicable.
Hazard pictograms Not applicable.
Signal word Not applicable.
Hazard statements Not applicable.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Date of preparation / last revision 10/31/2019

Abbreviations and acronyms:
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
WHMIS: Workplace Hazardous Materials Information System (Canada)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent