

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/31/2019

Version 4

Reviewed on 10/31/2019

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:

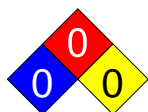
WHMIS-symbols:

Not Hazardous.

Not controlled under WHIMS (Canada).

Classification system:

NFPA ratings (scale 0 - 4)



Health = 0

Fire = 0

Reactivity = 0

HMIS-ratings (scale 0 - 4)



HEALTH 0 Health = 0

FIRE 0 Fire = 0

REACTIVITY 0 Reactivity = 0

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3 Composition/information on ingredients

Chemical characterization: Mixtures**Description:** Mixture: consisting of the following components.**Hazardous Components:**

7727-43-7	Barium sulphate	30.0% w/w
56-81-5	glycerol	5.25% w/w

Information on components:

7727-43-7	Barium sulphate	30.0% w/w
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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 personell to an upwind direction. Remove unneeded material.

6 Accidental release measures

Personal precautions, protective equipment and emergency proceduresWear 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.

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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

Components with limit values that require monitoring at the workplace:

7727-43-7 Barium sulphate

CAD AB OEL (Canada)	Long-term value: 10 mg/m ³
CAD BC OEL (Canada)	Long-term value: 3* ; 10** mg/m ³ *: Respirable Fraction; **: Total Dust
CAD MB OEL (Canada)	Long-term value: 10 mg/m ³
CAD ON OEL (Canada)	Long-term value: 10 mg/m ³
OEL (QUE) (Canada)	Long-term value: 5* ; 10** mg/m ³ *: Respirable Fraction; **: Total Dust
ACGIH (USA)	Long-term value: 10 mg/m ³
ACGIH 2014 TLV (USA)	Long-term value: 5 mg/m ³ Total Dust, no asbestos and <1% crystalline silica
CAL/OSHA PEL (USA)	Long-term value: 5* ; 10** mg/m ³ *:Respirable Fraction; **:Total Dust
NIOSH/GUIDE - REL (USA)	Long-term value: 5* ; 10** mg/m ³ *: Respirable Fraction; **: TotalDust
OSHA PEL ₁ (USA)	Long-term value: 5* ; 15** mg/m ³ *: Respirable Fraction; **:Total Dust

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56-81-5 glycerol	
CAD AB OEL (Canada)	Long-term value: 10 mg/m ³ Mist
CAD BC OEL (Canada)	Long-term value: 10*, 3** mg/m ³ *: Mist; **: Respirable Mist
CAD ON OEL (Canada ENG BRACCO)	Long-term value: 10 mg/m ³ Mist
OEL (QUE) (Canada ENG BRACCO)	Long-term value: 10 mg/m ³ Mist
ACGIH - TLV (USA)	TLV withdrawn-insufficient data human occup. exp.
CAL/OSHA PEL (1 ; 2) (USA)	Long-term value: 10* ; 5** mg/m ³ *: Total Dust (Mist) ; **: Respirable Fraction
CAL/OSHA PEL (1) (USA)	Long-term value: 10* ; 5** (2) mg/m ³ *: Total Dust (Mist) ; **: Respirable Fraction
PEL (USA)	Long-term value: 15* ; 5** mg/m ³ *: 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

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Trade name: Tagitol V**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.

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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:

LD/LC50 values that are relevant for classification:		
7727-43-7 Barium sulphate		
Oral	LD50	> 20000 mg/kg (Rat) (External SDS)
56-81-5 glycerol		
Oral	LD50	12600 mg/kg (Rat)
Dermal	LD50	> 18700 mg/kg (Rabbit)
87-99-0 xylitol		
Oral	LD50	17300 mg/kg (Rat)
11138-66-2 Xanthan gum		
Oral	LD50	> 5000 mg/kg (Rat)
590-00-1 Potassium sorbate		
Oral	LD50	>2000 mg/kg (unknown)
Dermal	LD50	>2000 mg/kg (unknown)
9004-32-4 Sodium carboxymethyl cellulose		
Oral	LD50	27000 mg/kg (Rat) (RTEC)
Dermal	LD50	> 2000 mg/kg (Rabbit) (External SDS)
Inhalative	LC50/4h	> 5800 mg/L (Rat) (RTEC)
6132-04-3 Trisodium citrate dihydrate		
Oral	LD50	> 8000 mg/kg (Rat) (IUCLID - Anhydrous substance)
	LD50 iv	170 mg/kg (Mouse)
		449 mg/kg (Rabbit)
	LD50 ip	1364 mg/Kg (Mouse)
		1548 mg/Kg (Rat)
77-92-9 Citric Acid, Anhydrous		
Oral	LD50	5040 mg/kg (Mouse)
		3000 mg/kg (Rat) (RTEC)
532-32-1 Sodium Benzoate		
Oral	LD50	3140 mg/kg (Rat) (External SDS)

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.

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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

IARC (International Agency for Research on Cancer)		
6155-57-3	Saccharin Sodium dihydrate	Yes: Carc. 3
NTP (National Toxicology Program)		
6155-57-3	Saccharin Sodium dihydrate	YES
63231-67-4	Silica gel	K

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	> 50000 ppm (Mysid 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)
IC50/96h	> 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) (External SDS)
IC50/72h	> 10 mg/L (Algae) (External SDS)
EC50/48h	> 100 mg/L (Daphnia) (External 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.

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Trade name: Tagitol V**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 processors 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 Void

TDG, ADN, IMDG, IATA

Void

UN proper shipping name

DOT, TDG, ADN, IMDG, IATA Void

Transport hazard class(es)

DOT, TDG, ADN, IMDG, IATA

Class Void

Packing group

DOT, TDG, IMDG, IATA Void

Environmental hazards:**Marine pollutant:** No**Special precautions for user**

Not applicable.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

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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