

According to SOR/2015-17 Hazardous Product Regulation

Printing date: 01/05/2023 Reviewed on: 01/05/2023 Version 6

1 Identification

Product identifier

Trade name: EZ-Paque

Article number: 747(INT), 750, 750(CAN), 750(INT), 7772

Application of the substance / the mixture: E-Z-Paque is indicated for use as a positive contrast medium for radiographic visualisation of the gastro-intestinal tract. 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

Email: <u>HSE@bracco.com</u> (responsible for the SDS)

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

Classification system: NFPA ratings (scale 0 - 4)



HMIS-ratings (scale 0 - 4)



Other hazards:

Results of PBT and vPvB assessment

PBT: Not applicable **vPvB:** Not applicable



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3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixtures consisting of the following components:

Hazardous Components: Not applicable

Non-Hazardous Components			
	CAS No.	Name	Qty.
	7727-43-7	Barium sulphate	96.31% w/w

Information on components		
CAS No.	Name	Qty.
7727-43-7	Barium sulphate	96.31% w/w

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

Inhalation: If dusts are formed, inhalation may cause adverse lung effects.

Eyes: Inert particles may cause mechanical irritation of the eyes, including scratches. Symptoms may include stinging and tearing.

Ingestion: Ingestion of large amounts may cause stomach irritation

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.

Unsuitable extinguishing agents:

None in particular.

Special hazards arising from the substance or mixture

Not flammable under normal conditions of use. Fine dust dispersed in air may ignite.

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.

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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 firefighting 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. Avoid formation of dust.

Environmental precautions:

Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage

Methods and material for containment and cleaning up:

- Dispose of the collected material according to regulations.
- Eliminate all ignition sources.
- Pick up mechanically.
- Clean the affected area carefully.
- Suitable cleaner is: water.
- Send for recovery or disposal in suitable receptacles.
- Ensure adequate ventilation.

Special spill response procedures:

FOR USA: If a spill/release in excess of the EPA reportable quantity is made into the environment, immediately notify the national response center in the United States (phone: 1-800-424-8002). US CERCLA Reportable quantity (RQ): None reported.

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

Do not inhale dust / smoke / mist.

Provide suction extractors if dust is formed.

Ensure good ventilation/exhaustion a the workplace.

Avoid contact with the eyes and skin.

Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.

Avoid accumulation of static charges, by means of adequate grounded electrical connection.

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.



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8 Exposure controls/personal protection

Control parameters

Components with limit values that require monitoring at the workplace:

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7727-43-7 Barium sulphate	e	
CAD AB OEL (Canada)	Long-term value: 10 mg/m³	
CAD BC OEL (Canada)	Long-term value: 3*; 10** mg/m³ *: Respirable Fraction; **: Total Dust	
CAD MB OEL (Canada)	Long-term value: 10 mg/m³	
CAD ON OEL (Canada)	Long-term value: 10 mg/m³	
OEL (QUE) (Canada)	Long-term value: 5*; 10** mg/m³ *: Respirable Fraction; **: Total Dust	
ACGIH (USA)	Long-term value: 10 mg/m³	
ACGIH TLV (USA)	Long-term value: 5 mg/m³ Total Dust, no asbestos and <1% crystalline silica	
CAL/OSHA PEL (USA)	Long-term value: 5*; 10** mg/m³ *:Respirable Fraction; **:Total Dust	
NIOSH – REL (USA)	Long-term value: 5*; 10** mg/m³ *:Respirable Fraction; **:Total Dust	
OSHA PEL (USA)	Long-term value: 5*; 15** mg/m³ *:Respirable Fraction; **:Total Dust	

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. Filter P2

Protection of hands:



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 aloves:

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 cannot 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

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gloves and has to be observed.

Eye protection: Goggles recommended during refiling

Body protection: Protective work clothing

9 Physical and chemical properties

Information on basic physical and chemical properties

General Information:

Appearance

Powder Form: Color: White

Odor: Characteristics Odor threshold: Not determined pH - Value: Not applicable Melting point/Melting range: Not determined Boiling point/Boiling range: Not determined Flash point: Not determined Flammability (Solid, Gaseous): Not determined Ignition temperature:

Danger of explosion: The product does not present an expl. Hazard

Not determined

Flammability Limits:

Not determined Lower: Not determined **Upper:**

Explosion Limits:

Not determined Lower: **Upper:** Not determined Oxidizing properties: Not determined Not determined Vapor pressure: Density: 4.2 - 4.5 g/cm³ Relativity density at 20 °C (68 °F): Not determined Vapor Density at 20 °C (68 °F): Not determined **Evaporation rate:** Not determined

Solubility in / Miscibility with

Water: Insoluble

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

Viscosity:

Dynamic: Not determined **Kinematic:** Not determined Water: Not determined



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VOC Content: Not determined

Solid content: 80.0 %

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 reaction known.

Conditions to avoid

Avoid all sources of ignition: Heat, sparks, Open flames

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:

	7.66.6 167.66.7		
LD/LC50 v	LD/LC50 values that are relevant for classification:		
7727-43-7	7727-43-7 Barium sulphate		
Oral	LD50	> 20000 mg/kg (Rat) (External SDS)	
50-70-4 D	-glucitol		
Oral	LD50	15900 mg/kg (Rat)	
6132-04-3	Trisodium	citrate dihydrate	
	LD50	> 8000 mg/kg (Rat) (IUCLID - Anhydrous substance)	
	LD50 iv	170 mg/kg (Mouse)	
Oral		449 mg/kg (Rabbit)	
	LD50 ip	1364 mg/Kg (Mouse)	
		1548 mg/Kg (Rat)	
9000-07-1 Carrageenan			
Oral	LD50	> 5000 mg/kg (Rat)	
Dermal	LD50	> 2000 mg/kg (Rabbit)	
Inhalative	LC50/4h	> 0.93 mg/L (Rat) (Maximum attainable concentration - zero mortality)	
77-92-9 C	77-92-9 Citric Acid, Anhydrous		
Oral	LD50	5040 mg/kg (Mouse)	
Oldi		3000 mg/kg (Rat) (RTEC)	



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9000-65-1	9000-65-1 Gum tragacanth		
Oral	LD50	10200 mg/kg (Rat) (RTEC)	
Oldi	LD50	7200 mg/Kg bw (Rabbit)	
63148-62-	9 Polydim	ethylsiloxane	
Oral	LD50	> 15400 mg/kg (Rat)	
Dermal	LD50	> 2000 mg/kg (Rabbit)	
11138-66-	11138-66-2 Xanthan gum		
Oral	LD50	> 5000 mg/kg (Rat)	
6155-57-3	6155-57-3 Saccharin Sodium dihydrate		
Oral	LD50	> 14200 mg/kg (Rat) (anydrous substance - RTEC)	
57-55-6 p	57-55-6 propane-1,2-diol		
Oral	LD50	19400 - 36000 mg/kg (Rat) (Literature)	
Dermal	LD50	20800 mg/kg (Rabbit) (Literature)	

Primary irritant effect:

on the skin: No irritating effect on the eye: No irritating effect

Sensitization: No sensitizing effects known.

Other information (about experimental toxicology):

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

1/	IARC (International Agency for Research on Cancer)		
900	00-07-1	Carrageenan	3
61.	55-57-3	Saccharin sodium dihydrate	Carc 2B
NTP (National Toxicology Program)			
6	155-57-3	Saccharin sodium dihydrate	Yes

12 Ecological information

Toxicity

Aquatic to	Aquatic toxicity:		
7727-43-7 I	7727-43-7 Barium sulphate		
EC50/48h	32 mg/L (Daphnia Magna)		
6132-04-3 1	risodium 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		
EC50/48h	substance) 5600 - 10000 mg/L (Daphnia Magna) (IUCLID - Anhydrous		
	substance)		



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77-92-9 Cit	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		
EC5/72h	Concentration) 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		
EC50/72h	Concentration) ca. 120 mg/L (Daphnia Magna) (IUCLID)		
63148-62-9	Polydimethylsiloxane		
EC50/48h	> 200 mg/L (Daphnia)		
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))		
57-55-6 pro	57-55-6 propane-1,2-diol		
LC50/96h	51600 mg/L (Onchorhyncus Mykiss) (External SDS)		
IC50/96h	19000 mg/L (Pseudokirchneriella Subcapitata) (External SDS)		
EC50/3h	> 1000 mg/L (Activated Sludge)		
EC50/48h	(Literature) 34400 mg/L (Daphnia		
	Magna) (Literature)		

Persistence and degradability

No further relevant information available

Bio accumulative potential

No further relevant information available

Mobility in soil

No further relevant information available

Additional ecological information

General notes: Use according to the good working practice. Avoid transfer into the environment. 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

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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 packaging:

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, ADR, ADN, IMDG, IATA Void

UN proper shipping name:

DOT, ADR, ADN, IMDG, IATA Void

Transport hazard class(es)

DOT, ADR, ADN, IMDG, IATA Void

Class:

Packing Group

DOT, ADR, IMDG, IATA Void

Environmental Hazards:

Marine pollutant: Void

Special precautions for user

Void

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

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 (S	Section 313 (Specific toxic chemical listings):		
None of the in	None of the ingredients is listed.		
Canadian Ing	Canadian Ingredient Disclosure list (limit 0.1%)		
9000-65-1	Gum tragacanth		
Canadian Ingredient Disclosure list (limit 1%)			
None of the ingredients is listed.			



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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. Training Hints: All persons handling this product should be informed on the existence of the hazard, on any possible risk they might be subjected to and about all required protective measures to prevent such a damage or to reduce the exposition.

Contact:

E-Z-EM Canada Inc.1065 Boulevard L-H. Lafontaine Montréal, QC, Canada H1J 2Z4

Date of preparation / last revision: 01/05/2023, revision 6 **Changes:** General revision of the entire document

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

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

ACGIH: American Conference of Governmental Industrial Hygienists 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)

VOC: Volatile Organic Compounds (USA, EU) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent

Acute Tox. 3: Acute toxicity – Category 3