

# Safety Data Sheet

acc. to OSHA HCS

Printing date 01/20/2021

Version 2

Reviewed on 01/20/2021

## 1 Identification

### Product identifier

**Trade name:** NeuLumEx

**Article number:** 450702, 9260, 705699

### Application of the substance / the mixture:

Radiopaque contrast media for diagnostic imaging of the gastrointestinal tract

Low viscosity opalescent liquid with a berry odor and no grittiness.

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](mailto:clients@reachteam.eu)

[www.reachteam.eu](http://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:

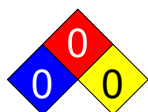
#### WHMIS-symbols:

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

Fire = 0

Reactivity = 0

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## 3 Composition/information on ingredients

**Chemical characterization:** Mixtures

**Description:** Mixture: consisting of the following components.

**Hazardous Components:** Not applicable.

**Information on components:**

50-70-4   D-glucitol	2.002% 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.  
CO<sub>2</sub>, 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 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.

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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:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

**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

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## 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:** Opalescent

**Odor:** Berry odor  
**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:** Not determined.

**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:** 50-200 cPs  
**Kinematic:** Not determined.

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**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:**

Formation of toxic gases is possible during heating or in case of fire.

## 11 Toxicological information

**Information on toxicological effects**

**Acute toxicity:**

**LD/LC50 values that are relevant for classification:**

**50-70-4 D-glucitol**

Oral	LD50	15900 mg/kg (Rat)
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**590-00-1 Potassium sorbate**

Oral	LD50	>2000 mg/kg (unknown)
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Dermal	LD50	>2000 mg/kg (unknown)
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**11138-66-2 Xanthan gum**

Oral	LD50	> 5000 mg/kg (Rat)
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**7727-43-7 Barium sulphate**

Oral	LD50	> 20000 mg/kg (Rat) (External SDS)
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**65-85-0 Benzoic acid**

Oral	LD50	1700 mg/kg (Rat)
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**532-32-1 Sodium Benzoate**

Oral	LD50	3140 mg/kg (Rat) (External SDS)
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**6155-57-3 Saccharin Sodium dihydrate**

Oral	LD50	> 14200 mg/kg (Rat) (anhydrous substance - RTEC)
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**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**

**IARC (International Agency for Research on Cancer)**

6155-57-3	Saccharin Sodium dihydrate
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Yes: Carc. 3
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NTP (National Toxicology Program)		
63231-67-4	Silica gel	K
6155-57-3	Saccharin Sodium dihydrate	YES

### 12 Ecological information

#### Toxicity

Aquatic toxicity:	
<b>11138-66-2 Xanthan gum</b>	
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))
<b>7727-43-7 Barium sulphate</b>	
EC50/48h	32 mg/L (Daphnia Magna)
<b>532-32-1 Sodium Benzoate</b>	
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.

**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.

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## 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.

## 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** 01/20/2021**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

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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