Safety Data Sheet – Canada

Acc. To OSHA HCS

Printing date 2024/09/30 Version 1 Reviewed on 2024/09/30
Trade name: SmoothHD

Note to practitioners: In Canada, the Voyageur SmoothLD barium sulfate oral suspension is regulated by the Natural and Non-prescription Health Products Directorate of Health Canada. For the convenience of practitioners familiar with contrast agents that are regulated as drugs, this information is provided in the typical Safety Data Sheet format.

1 Identification

Product identifier

Trade name: Voyageur SmoothHD

Article number: 10202090

Application of the substance / the mixture:
Radiopaque contrast media for diagnostic imaging of the gastrointestinal tract
White suspension with a sweet vanilla odor and no grittiness.

Route of Administration: Oral

Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Voyageur Pharmaceuticals Ltd.
4103B Centre Street NW
Calgary, AB Canada
Tel: 1-877-398-6866

Information department:
Voyageur Pharmaceuticals Ltd.
4103B Centre Street NW
Calgary, AB Canada
Tel: 1-877-398-6866
Email: info@vpharma.ca

Emergency telephone number:
Tel: 1-877-398-6866

2 Hazards 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.

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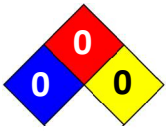
Additional Information:
WHMIS-symbols:
Not Hazardous.
Not controlled under WHIMS (Canada).

Classification system:
NFPA ratings (scale 0 - 4)



Health = 0
Fire = 0
Reactivity = 0

HMIS-ratings (scale 0 - 4)

HEALTH	0
FIRE	0
REACTIVITY	0

Health = 0
Fire = 0
Reactivity = 0

3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixture: consisting of the following components.

Hazardous Components:
7727-43-7 Barium sulphate 58.0% w/w
Information on components:
7727-43-7 Barium sulphate 58.0% 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
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.

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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:
None.
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/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 2014 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/GUIDE - REL (USA)	Long-term value: 5* ; 10** mg/m³ *: Respirable Fraction; **: Total Dust
OSHA PEL_1 (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.

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: Suspension
Color: White

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Odor:	Vanilla
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:	150 °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:	450-750 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)
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	307,000 mg/kg (OECD Test Guideline 401)
50-70-4 D-Sorbitol		
Oral	LD50	15900 mg/kg (Rat) RTECS
6132-04-03	**Sodium Citrate**	
Oral	LD50	5400 mg/kg (Mouse)
Dermal	LD50	> 2,000 mg/kg (Rat)
60616-95-7	**Sodium Carrageenan**	
Oral	LD50	5400 mg/kg (Mouse)
Dermal	LD50	> 2,000 mg/kg (Rat)
128-44-9	**Sodium Saccharin**	
Oral	LD50	> 14,200 mg/kg (Rat)
11138-66-2 Xanthan gum		
Oral	LD50	> 5000 mg/kg (Rat)
5949-29-1	**Citric Acid**	
Oral	LD50	5400 mg/kg (Mouse)
Dermal	LD50	> 2,000 mg/kg (Rat)
9000-01-05	**Gum Arabic / Acacia**	
Oral	LD50	> 16,000 mg/kg (Rat) RTECS
532-32-1 Sodium Benzoate		
Oral	LD50	2,140 mg/kg (Rat)
24634-61-5 Potassium sorbate		
Oral	LD50	> 10,500 mg/kg (Rat)
Dermal	LD50	>2000 mg/kg (Rat)

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

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC,HA, NTP, ACGIH.

12 Ecological information

Toxicity

Aquatic toxicity:	
7727-43-7 Barium sulphate	
LC50	Danio rerio (zebra fish) - > 174 mg/l - 96 h
ErC50	Pseudokirchneriella subcapitata (green algae) - > 100 mg/l - 72 h
6132-04-03 Sodium Citrate	
LC50	Poecilia reticulata (guppy) - > 18,000 - 32,000 mg/l - 96 h
EC50	Daphnia magna (Water flea) - 5,600 - 10,000 mg/l - 48 h
11138-66-2 Xanthan gum	
LC50 EC50	Oncorhynchus mykiss (rainbow trout) - 420 mg/l - 96 h Daphnia magna (Water flea) - 700 mg/l - 24 h
5949-29-1 Citric Acid	
LC50 IC5	Leuciscus idus (Golden orfe) - 440 - 760 mg/l - 96 h Scenedesmus quadricauda (Green algae) - 640 mg/l - 7 d
532-32-1 Sodium Benzoate	
LC50 LC50 ErC50 LC50	Pimephales promelas (fathead minnow) - 484 mg/l - 96 h Daphnia magna (Water flea) - > 100 mg/l - 96 h Pseudokirchneriella subcapitata (green algae) - >100 mg/l - 72 h LC50 - Danio rerio (zebra fish) - 1,400 - 1,500 mg/l- 24 h
24634-61-5 Potassium Sorbate	
LC50 EC50 ErC50	Danio rerio (zebra fish) - > 1,000 mg/l - 96 h Daphnia magna (Water flea) - 982 mg/l - 48 h Pseudokirchneriella subcapitata - 77 mg/l - 72 h

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.

14 Transport information

UN-Number
DOT Void

TDG, ADN, IMDG, IATA Void

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

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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 2023/04/17

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

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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