1 IDENTIFICATION

1.1 PRODUCT IDENTIFIER

Trade name: Voyageur SmoothX

Article number: 10101090

Application of the substance / the mixture
Radiopaque contrast media for diagnostic imaging of the gastrointestinal tract. Low viscosity, white colored liquid with a sweet vanilla odor and no grittiness.
Route of Administration: Oral

1.2 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 HAZARD(S) IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

The product is not classified according to the Globally Harmonized System (GHS).

2.2 LABEL ELEMENTS

GHS label elements Not applicable.

Hazard pictograms Not applicable.

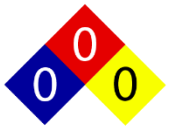
Signal word Not applicable.

Hazard statements Not applicable.

2.3 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

3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 CHEMICAL CHARACTERIZATION: MIXTURES

Description: Mixture consisting of the following components

Hazardous components
7727-43-7 Barium sulphate 2.0% w/v

Information on components
50-70-4 D-glucitol 2.507 w/v

4 FIRST-AID MEASURES

4.1 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

5.1 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.

5.2 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

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

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

6.2 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.

6.3 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.

6.4 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

7.1 PRECAUTIONS FOR SAFE HANDLING

Ensure good ventilation/exhaustion at the workplace.
Avoid contact with the eyes and skin.

7.2 INFORMATION ABOUT PROTECTION AGAINST EXPLOSIONS AND FIRES: NO SPECIAL MEASURES REQUIRED.

7.3 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES.

7.3.1 Requirements to be met by storerooms and receptacles

Store in a cool, dry place in tightly closed receptacles.

7.3.2 Information about storage in one common storage facility:

Not required.

7.3.3 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.

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

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Components with limit values that require monitoring at the workplace	
7727-43-7 Barium sulphate	
CAD AB OEL (Canada) CAD BC OEL (Canada)	Long-term value: 10 mg/m³ Long-term value: 3* ; 10** mg/m³ *: Respirable Fraction; **: Total Dust
CAD MB OEL (Canada) CAD ON OEL (Canada) OEL (QUE) (Canada)	Long-term value: 10 mg/m³ Long-term value: 10 mg/m³ Long-term value: 5* ; 10** mg/m³ *: Respirable Fraction; **: Total Dust
ACGIH (USA) ACGIH 2014 TLV (USA)	Long-term value: 10 mg/m³ 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 (USA)	Long-term value: 5* ; 15** mg/m³ *: Respirable Fraction; **: Total Dust

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

8.2 EXPOSURE CONTROLS

8.2.1 Personal protective equipment

8.2.1.1 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.

8.2.1.2 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.

8.2.1.3 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

8.2.1.4 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.

8.2.1.5 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.

8.2.1.6 Eye protection

Goggles recommended during refilling.

8.2.1.7 Body protection

Protective work clothing

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION OF BASIC PHYSICAL AND CHEMICAL PROPERTIES

Appearance	
Form	Suspension
Color	White
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	Not determined
Danger of explosion	Product does not present an explosion hazard
Flammability limits	
Upper	Not determined
Lower	Not determined
Explosion limits	
Upper	Not determined
Lower	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)	
Viscosity	
Dynamic	600 – 1100 cPs
Kinematic	Not determined
Water	0.1%
Solids content	80.0%

10 STABILITY AND REACTIVITY

10.1 REACTIVITY

No further relevant information available.

10.2 CHEMICAL STABILITY

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

10.2.2 Possibility of hazardous reactions No dangerous reactions known.

10.2.3 Conditions to avoid No further relevant information available.

10.2.4 Incompatible materials: Reactive metals

10.2.5 Hazardous decomposition products:
Formation of toxic gases is possible during heating or in case of fire.

11 TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

11.1.1 Acute Toxicity

LD/LC50 values that are relevant for classification:		
50-70-4 D-glucitol		
Oral	LD50	15900 mg/kg (Rat)
7727-43-7 Barium sulphate		
Oral	LD50	> 20000 mg/kg (Rat) (External SDS)
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)
532-32-1 Sodium Benzoate		
Oral	LD50	3140 mg/kg (Rat) (External SDS)
5989-27-5 (R)-p-mentha-1,8-diene		
Oral	LD50	4400 mg/kg (Rat)
77-92-9 Citric Acid, Anhydrous		
Oral	LD50	5040 mg/kg (Mouse) 3000 mg/kg (Rat) (RTEC)

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

11.1.3 Sensitization: No sensitizing effects known.

11.1.4 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.

11.1.5 Carcinogenic categories

IARC (International Agency for Research on Cancer)		
5989-27-5	(R)-p-mentha-1,8-diene	3
6155-57-3	Saccharin Sodium dihydrate	Yes: Carc. 3
NTP (National Toxicology Program)		
63231-67-4	Silica gel	K
6155-57-3	Saccharin Sodium dihydrate	YES

12 ECOLOGICAL INFORMATION

12.1 TOXICITY

Aquatic toxicity:	
7727-43-7 Barium sulphate	
EC50/48h	32 mg/L (Daphnia Magna)
11138-66-2 Xanthan gum	
LC50/96h LC50/48h LC50/96h	490 mg/L (Rainbow Trout) 980 mg/L (Daphnia Magna) > 50000 ppm (Mysid Shrimp) (Suspended Particulate (2 lb./bbl of Xanthan Gum))
532-32-1 Sodium Benzoate	
LC50 EC0 IC50/72h EC50/48h	460 mg/L (Leuciscus Idus) (ECOTOX Database) 1000 mg/L (Bacteria) (Exernal SDS) > 10 mg/L (Algae) (Exernal SDS) > 100 mg/L (Daphnia) (Exernal SDS)
5989-27-5 (R)-p-mentha-1,8-diene	
LC50/96h EC50/48h	1 mg/L (Fish) 70 mg/L (Daphnia)
77-92-9 Citric Acid, Anhydrous	
LC50/96h LC50 IC5/7d EC5/72h	440 - 760 mg/L (Leuciscus Idus) (IUCLID) 440-706 mg/L (Fish) 640 mg/L (Scenedesmus Quadricauda) (Literature)(Max. Permissible Toxic Concentration) 485 mg/L (Echinodontium Sulcatum) (Literature)

12.1.1 Persistence and degradability
No further relevant information available.

12.1.2 Bioaccumulative potential
No further relevant information available.

12.1.3 Mobility in soil
No further relevant information available.

12.1.4 Additional ecological information
Use according to the good working practice. Avoid transfer into the environment.

12.1.5 General notes
Generally, not hazardous for water

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

12.1.7 Other adverse effects No further relevant information available.

13 DISPOSAL CONSIDERATIONS

13.1 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.

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

13.2 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.

13.3 UNCLEANED PACKAGINGS
13.3.1 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

14.1 UN-NUMBER

14.1.1 DOT	Void
14.1.2 TDG, ADN, IMDG, IATA	Void

14.2 UN proper shipping name

14.2.1 DOT, TDG, ADN, IMDG, IATA	Void

14.3 TRANSPORT HAZARD CLASS(ES)

14.3.1 DOT, TDG, ADN, IMDG, IATA Class	Void

14.4 PACKING GROUP

DOT, TDG, IMDG, IATA	Void

14.5 ENVIRONMENTAL HAZARDS

14.5.1 Marine pollutant:	No
14.5.2 Special precautions for user	Not applicable
14.5.3 Transport in bulk according to Annex II Of MARPOL73/78 and the IBC Code	Not applicable

15 REGULATORY INFORMATION

15.1 SAFETY, HEALTH, AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

15.1.1 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.

15.1.2 GHS label elements Not applicable.
15.1.3 Hazard pictograms Not applicable.
15.1.4 Signal word Not applicable.
15.1.5 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.

This safety data sheet conforms to the U.S. OSHA Hazard Communication 29 CFR 1910.1200(g).

Date of preparation / last revision 2023/04/21

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