



# US - OSHA SAFETY DATA SHEET

Issue Date 30-July-2024

Revision Date NA

Version 1

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### Product identifier

**Product Name** GaviLyte™-N with Flavor Pack

### Other means of identification

**Product Code** Not available.

**Synonyms** None known.

### Recommended use of the chemical and restrictions on use

**Recommended Use** Laxative, Hyperosmotic

**Uses advised against** Not available.

### Details of the supplier of the safety data sheet

#### Supplier address

Lupin Somerset, LLC  
400 Campus Drive  
Somerset, NJ 08873

### Emergency telephone number

**Company Phone Number** 908-603-6066

**24 Hour Emergency Phone Number** 908-603-6029

## 2. HAZARDS IDENTIFICATION

### Classification

#### **Health Hazards**

Not classified.

#### **Physical Hazards**

Not classified.

### Label elements

#### **Emergency Overview**

Normal precautions common to safe manufacturing practice should be followed in handling and storage.

**Appearance** Crystalline

**Physical state** Solid

**Odor** Not available.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Weight-% **
Polyethylene glycol	25322-68-3	94-96
Sodium Bicarbonate	144-55-8	1-2
Sodium Chloride	7647-14-5	2-3
Potassium chloride	7447-40-7	<1

\*\*The exact percentage of the components in this product is withheld as a trade secret and is described as a range.

## 4. FIRST AID MEASURES

### Description of first aid measures

<b>Eye Contact</b>	In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
<b>Skin Contact</b>	In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.
<b>Inhalation</b>	In case of inhalation, remove to fresh air. If not breathing, call 911 and provide artificial respiration. Do not use mouth-to-mouth method; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device if breathing is difficult. Seek emergency medical attention immediately.
<b>Ingestion</b>	In case of accidental ingestion, wash out mouth with copious amounts of water. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

### Most important symptoms and effects, both acute and delayed

<b>Symptoms</b>	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.
-----------------	--

### Indication of any immediate medical attention and special treatment needed

<b>Note to Physicians</b>	Treat symptomatically.
---------------------------	------------------------

## 5. FIRE-FIGHTING MEASURES

### Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable Extinguishing Media** Caution: Use of water spray when fighting fire may be inefficient as the burning material may be spread.

### Specific hazards arising from the chemical

Not applicable.

#### Explosion data

**Sensitivity to Mechanical Impact** None known.

**Sensitivity to Static Discharge** None known.

### Protective equipment and precautions for firefighters

Wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

<b>Personal Precautions</b>	Not applicable to consumer use. In an industrial setting, ventilate area of leak or spill. Remove all sources of ignition. Wear appropriate personal protective equipment as specified in Section 8 and follow handling guidance appropriate for the compound (see Section 7). Isolate hazard area. Keep unnecessary and unprotected personnel from entering.
-----------------------------	---

**Environmental precautions** See Section 12 for additional ecological information.

**Methods and material for containment and cleaning up**

**Methods for Containment** Prevent further leakage or spillage if safe to do so.

**Methods for Cleaning Up** Pick up and transfer to properly labeled containers. Package all material in appropriate container for disposal.

## 7. HANDLING AND STORAGE

**Precautions for safe handling**

**Advice on Safe Handling** Handle in accordance with good industrial hygiene and safety practice. Take off contaminated clothing and wash it before reuse. Wash hands after handling.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place.

**Incompatible Materials** None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Control parameters**

**Exposure Guidelines** This product, as supplied, does not contain any hazardous materials with Occupational Exposure Limits (OEL) established by the region-specific regulatory bodies.

**Appropriate engineering controls**

**Engineering Controls** Emergency Showers  
Eyewash Stations  
Ventilation Systems

**Individual protection measures, such as personal protective equipment**

**Eye/Face Protection** None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full-face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

**Skin and Body Protection** None required for consumer use. In laboratory, medical or industrial settings, wear impervious fire-resistant protective clothing, including boots, gloves, lab coat, apron or coveralls, as appropriate, to prevent skin contact.

**Respiratory Protection** None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below exposure levels that cause respiratory irritation. Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

**General Hygiene Considerations** Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

Physical state	Solid	Odor	Not available.
Appearance	Crystalline	Odor Threshold	Not available.
Color	Not available.		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	No information available	
Melting point/freezing point	No information available	
Boiling point/boiling range	No information available	
Flash point	No information available	
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability Limit in Air		
Upper flammability limit:	No information available	
Lower flammability limit:	No information available	
Vapor pressure	Not available.	
Vapor density	No information available	
Specific Gravity	Not available.	
Water solubility	Not available.	
Solubility in other solvents	Not available.	
Partition coefficient	Not available.	
Autoignition temperature	No information available	
Hyphen	Not available.	
Kinematic viscosity	Not available.	
Dynamic viscosity	Not available.	
Explosive Properties	Not available.	
Oxidizing Properties	Not available.	
 <u>Other information</u>		
Softening point	Not available.	
Molecular weight	Not available.	
VOC Content (%)	No information available	
Density	Not available.	
Bulk density	Not available.	

## 10. STABILITY AND REACTIVITY

### Reactivity

No data available

### Chemical stability

Stable under recommended handling and storage conditions.

### Possibility of hazardous reactions

None under normal processing.

### Conditions to Avoid

Extremes of temperature and direct sunlight.

### Incompatible materials

None known.

### Hazardous decomposition products

None known.

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Product Information** Product does not present an acute toxicity hazard based on known or supplied information

#### Acute Toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Sodium Bicarbonate 144-55-8	= 4,220 mg/kg ( Rat )	-	-	-
Sodium Chloride 7647-14-5	= 3 g/kg ( Rat )	-	> 42 g/m <sup>3</sup> ( Rat ) 1 h	-
Potassium chloride 7447-40-7	= 2,600 mg/kg ( Rat )	-	-	-
Polyethylene glycol 25322-68-3	= 22 g/kg ( Rat )	> 20 g/kg ( Rabbit )	-	-

### Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** Ingestion may cause nausea, abdominal fullness, bloating, cramps, and anal irritation. These adverse reactions are transient and subside rapidly. Isolated cases of urticaria, rhinorrhea, dermatitis and (rarely) anaphylactic reaction have been reported which may represent allergic reactions. Published literature contains isolated reports of serious adverse reactions following the administrations of polyethylene glycol products in patients over 60 years of age. These adverse events include upper GI bleeding from Mallory-Weiss Tear, esophageal perforation, asystole, sudden dyspnea with pulmonary edema, and “butterfly-like” infiltrate on chest X-ray after vomiting and aspirating polyethylene glycol.

### Delayed and immediate effects as well as chronic effects from short- and long-term exposure

**Skin/Eye Irritation** Product dust or powder may cause mechanical eye irritation.

**Sensitization** This product is not classified as a respiratory or skin sensitizer.

**Germ Cell Mutagenicity** This product is not classified as a mutagenic hazard.

**Carcinogenicity** This product is not classified as a carcinogen.

**Reproductive Toxicity** This product is not classified as a reproductive hazard.

**STOT - Single Exposure** This product is not classified as a STOT Single Exposure.

**STOT - Repeated Exposure** This product is not classified as a STOT Single Exposure.

**Aspiration Hazard** This product is not classified as an aspiration hazard.

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium Bicarbonate 144-55-8		8,250 – 9,000: 96 h Lepomis macrochirus mg/L LC50 static		2,350: 48 h Daphnia magna mg/L EC50
Sodium Chloride 7647-14-5		4,747 – 7,824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 6,020 – 7,070: 96 h Pimephales promelas mg/L LC50 static 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 12,946: 96 h Lepomis macrochirus mg/L LC50 static 7,050: 96 h Pimephales promelas mg/L LC50 semi-static		340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static 1,000: 48 h Daphnia magna mg/L EC50
Potassium chloride 7447-40-7	2500: 72 h Desmodesmus subspicatus mg/L EC50	750 – 1,020: 96 h Pimephales promelas mg/L LC50 static 1,060: 96 h Lepomis macrochirus mg/L LC50 static		825: 48 h Daphnia magna mg/L EC50 83: 48 h Daphnia magna mg/L EC50 Static

### Persistence and degradability

No information available.

### Bioaccumulation

No information available.

### Other adverse effects

No information available

## 13. DISPOSAL CONSIDERATIONS

### Waste treatment methods

#### **Disposal of Wastes**

Disposal should be in accordance with applicable regional, national and local laws and regulations. Offer surplus and non-recyclable product to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Observe all federal, state, and local environmental regulations. This product does not contain any substance that is listed with the State of California as hazardous waste.

#### **Contaminated Packaging**

Do not reuse container/vial.

## 14. TRANSPORT INFORMATION

<b>DOT</b>	Not regulated
<b>TDG</b>	Not regulated
<b>MEX</b>	Not regulated
<b>IATA</b>	Not regulated.
<b>IMDG</b>	Not regulated.

## 15. REGULATORY INFORMATION

### International Inventories

<b>TSCA</b>	Does not apply
<b>DSL/NDSL</b>	Complies
<b>EINECS/ELINCS</b>	Complies
<b>ENCS</b>	Does not apply
<b>IECSC</b>	Does not apply
<b>KECL</b>	Does not apply
<b>PICCS</b>	Does not apply
<b>AICS</b>	Does not apply

### Legend:

- TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory
- DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List
- EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
- ENCS** - Japan Existing and New Chemical Substances
- IECSC** - China Inventory of Existing Chemical Substances
- KECL** - Korean Existing and Evaluated Chemical Substances
- PICCS** - Philippines Inventory of Chemicals and Chemical Substances
- AICS** - Australian Inventory of Chemical Substances

### US Federal Regulations

#### SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### SARA 311/312 Hazard Categories

<b>Acute health hazard</b>	No
<b>Chronic Health Hazard</b>	No
<b>Fire hazard</b>	No
<b>Sudden Release of Pressure Hazard</b>	No
<b>Reactive Hazard</b>	No

#### CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355).

### US State Regulations

#### California Proposition 65

This product does not contain any chemicals regulated by California Proposition 65.

**U.S. State Right-to-Know Regulations**

This product does not contain any chemicals regulated by U.S. State Right-to-Know Regulations.

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable.

<b>16. OTHER INFORMATION</b>
------------------------------

<b>Issue Date</b>	30-July-2024
<b>Revision Date</b>	NA
<b>Revision Note</b>	New SDS.

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**