

SAFETY DATA SHEET

Issuing Date 11-Jul-2016

Revision Date 11-Jul-2016

Revision Number 2



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

Product identifier

Product Name Bisacodyl 5mg E.C. Sugar Coated Orange Tablets

Other means of identification

Synonyms 44-327

Recommended use of the chemical and restrictions on use

Recommended Use Medicinal products

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier Name LNK International Inc.

Supplier Address 22 Arkay Drive
Hauppauge
New York
11788
US

Supplier Phone Number Phone:631-435-3500
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Emergency telephone number 1-800-426-9381

2. HAZARDS IDENTIFICATION

Classification

Over-the-counter drugs in their final form as sold to the consumer are exempt from regulation under the OSHA Hazard Communication Standard, 29 CFR 1910.1200. Thus, no SDS is required for this product. The information provided below is a composite of the safety data sheets for the active ingredients and is not intended to comply with any regulatory requirement. It is provided in the form of an SDS at the request of the purchaser.



GHS Label elements, including precautionary statements**Emergency Overview**

This product contains an active pharmaceutical ingredient(s): Bisacodyl. Please refer to the product labeling and packaging for information about appropriate use. The following is a summary of the information contained in the product labeling and packaging.

May cause eye irritation

May be harmful if swallowed in amounts above the therapeutic dose.

Consumers: Refer to the label or packaging for consumer-specific information about the directional use and effects of this product.

Only information about the ingredients that are expected to contribute to the potential health effects of the product are included in this SDS.

Do not use if package is open or torn.

Appearance Orange

Physical state Solid/Powder Solid

Odor Odorless

Precautionary Statements - Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Use personal protective equipment as required

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

Precautionary Statements - Storage

Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children.

Ingestion

IF SWALLOWED ABOVE THERAPEUTIC DOSE: Call a POISON CENTER or doctor/physician if you feel ill.

Rinse mouth

Precautionary Statements - Disposal

Dispose of in accordance with local regulations.

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity

31.05 % of the mixture consists of ingredient(s) of unknown toxicity

Other information

No information available

Interactions with Other Chemicals

No information available.



3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	CAS No	Weight-%	Trade Secret
Sucrose	57-50-1	15 - 40	*
Lactose	63-42-3	15 - 40	*
Maize starch	9005-25-8	10 - 30	*
Polyvinyl acetate phthalate	34481-48-6	10 - 30	*
Bisacodyl	603-50-9	5 - 15	*
Talc	14807-96-6	1 - 5	*
Calcium carbonate	471-34-1	1 - 5	*
Magnesium stearate	557-04-0	1 - 5	*
Acacia	9000-01-5	1 - 5	*
Povidone	9003-39-8	1 - 5	*
Propylene glycol	25322-68-3	1 - 5	*
Titanium dioxide	13463-67-7	0.1 - 1	*
Methylparaben	99-76-3	0.1 - 1	*
Hypromellose	9004-65-3	0.1 - 1	*
Polydextrose	68424-04-4	0.1 - 1	*
Polyethylene glycol	25322-68-3	0.1 - 1	*
Propylparaben	94-13-3	0.1 - 1	*
Sodium bicarbonate	144-55-8	0.1 - 1	*
Triacetin	102-76-1	0.1 - 1	*
Sodium benzoate	532-32-1	0.1 - 1	*
Sodium alginate	9005-38-3	0.1 - 1	*
D&C yellow #10 aluminum lake	68814-04-0	0.1 - 1	*
FD&C yellow #6 aluminum lake	15790-07-5	0.1 - 1	*
Silica	112945-52-5	0.1 - 1	*
Simethicone	8050-81-5	0.1 - 1	*
Stearic acid	57-11-4	0.1 - 1	*
Triethyl citrate	77-93-0	0.1 - 1	*
Ammonium hydroxide	1336-21-6	0.01 - 1	*
Carnauba wax	8015-86-9	0.01 - 1	*
Iron oxide black	12227-89-3	0.01 - 1	*
Shellac	9000-59-3	0.01 - 1	*

*The exact percentage (concentration) of composition has been withheld as a trade secret

4. FIRST AID MEASURES

First aid measures

General advice

Refer to information on package labeling and packaging. In case of overdose, get medical help or contact a Poison Control Center right away. Immediate medical attention is required.

Eye contact

Rinse thoroughly with plenty of water, also under the eyelids. If symptoms persist, call a physician.

Skin contact

Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.

Inhalation

Remove to fresh air. If symptoms persist, call a physician.



Ingestion If swallowed above therapeutic dose: Rinse mouth. Drink plenty of water. Do NOT induce vomiting. If symptoms persist, call a physician. If large quantities of this material are swallowed, call a physician immediately.

Most important symptoms and effects, both acute and delayed

Most Important Symptoms and Effects No information available.

Indication of any immediate medical attention and special treatment needed

Notes to Physician 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.

Specific hazards arising from the chemical

No information available.

Explosion Data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

<u>NFPA</u>	Health Hazard 1	Flammability 0	Stability 0	Physical and Chemical Hazards -
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6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with eyes.

Environmental precautions

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.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Storage Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children. Store in original container.

Incompatible Products None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines The following addresses exposure to some of the ingredients of Bisacodyl 5mg E.C. Sugar Coated Orange Tablets, not exposure to the product. For information regarding appropriate use of the product, review the labeling and packaging material.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sucrose 57-50-1	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust
Maize starch 9005-25-8	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust

Talc 14807-96-6	TWA: 2 mg/m ³	(vacated) TWA: 2 mg/m ³	IDLH: 1000 mg/m ³ containing no asbestos and <1% quartz TWA: 2 mg/m ³
Calcium carbonate 471-34-1	-	TWA: 15 mg/m ³ TWA: 5 mg/m ³ (vacated) TWA: 15 mg/m ³ (vacated) TWA: 5 mg/m ³	TWA: 5 mg/m ³ respirable dust TWA: 10 mg/m ³ total dust
Magnesium stearate 557-04-0	TWA: 10 mg/m ³	-	
Titanium dioxide 13463-67-7	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust (vacated) TWA: 10 mg/m ³ total dust	IDLH: 5000 mg/m ³

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits NIOSH IDLH Immediately Dangerous to Life or Health

Other Exposure Guidelines Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992)

Appropriate engineering controls

Engineering Measures Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Skin and body protection No special protective equipment required.

Respiratory protection If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical state	Solid/Powder, Solid	Odor	Odorless
Appearance	Varies	Odor Threshold	No information available
Color	No information available		

<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>Method</u>
pH	UNKNOWN	None known	
Melting / freezing point	No data available	None known	
Boiling point / boiling range	No data available	None known	
Flash Point	No data available	None known	
Evaporation Rate	No data available	None known	
Flammability (solid, gas)	No data available	None known	
Flammability Limit in Air			
Upper flammability limit	No data available		
Lower flammability limit	No data available		
Vapor pressure	No data available	None known	
Vapor density	No data available	None known	

Specific Gravity	No data available	None known
Water Solubility	Soluble in hot water	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water		None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity		None known
Explosive properties	No data available	
Oxidizing properties	No data available	

Other Information

Softening Point	No data available
VOC Content (%)	No data available
Particle Size	No data available
Particle Size Distribution	

10. STABILITY AND REACTIVITY**Reactivity**

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Conditions to avoid

None known based on information supplied.

Incompatible materials

None known based on information supplied.

Hazardous Decomposition Products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure****Product Information**

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.

Ingestion

Specific test data for the substance or mixture is not available.

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose 57-50-1	= 29700 mg/kg (Rat)	-	-
Calcium carbonate 471-34-1	= 6450 mg/kg (Rat)	-	-
Titanium dioxide 13463-67-7	> 10000 mg/kg (Rat)	-	-

Information on toxicological effects**Symptoms**

No information available.

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

No information available.

Mutagenic Effects

No information available.

Carcinogenicity

The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains titanium dioxide in a non-respirable form. Inhalation of titanium dioxide is unlikely to occur from exposure to this product.

Chemical name	ACGIH	IARC	NTP	OSHA
Talc 14807-96-6		Group 3		X
Titanium dioxide 13463-67-7		Group 2B		X

IARC (International Agency for Research on Cancer)*Group 2B - Possibly Carcinogenic to Humans**Group 3 - Not Classifiable as to Carcinogenicity in Humans***OSHA (Occupational Safety and Health Administration of the US Department of Labor)***X - Present***Reproductive toxicity**

No information available.

STOT - single exposure

No information available.

STOT - repeated exposure

No information available.

Chronic Toxicity

No known effect based on information supplied.

Target Organ Effects

Respiratory system. Eyes. Skin. Gastrointestinal tract (GI). Central Vascular System (CVS).

Aspiration Hazard

No information available.

Numerical measures of toxicity Product Information

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)

38,343.00 mg/kg

ATEmix (dermal)

1,434,160.00

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Chemical name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Talc 14807-96-6		96h LC50: > 100 g/L (Brachydanio rerio)		

Persistence and Degradability

No information available.

Bioaccumulation

No information available

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal methods

This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging

Dispose of contents/containers in accordance with local regulations.

California Hazardous Waste Codes 311

14. TRANSPORT INFORMATION

<u>DOT</u>	NOT REGULATED
Proper Shipping Name	NON REGULATED
Hazard Class	N/A

<u>TDG</u>	Not regulated
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<u>MEX</u>	Not regulated
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<u>ICAO</u>	Not regulated
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<u>IATA</u>	Not regulated
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Proper Shipping Name	NON REGULATED
Hazard Class	N/A
IMDG/IMO	Not regulated
Hazard Class	N/A
RID	Not regulated
ADR	Not regulated
ADN	Not regulated

15. REGULATORY INFORMATION

Regulatory status

Over-the-counter drugs in their final form as sold to the consumer are exempt from regulation under the OSHA Hazard Communication Standard, 29 CFR 1910.1200. Thus, no SDS is required for this product. The information provided below is a composite of the SD sheets for the active ingredients and is not intended to comply with any regulatory requirement. It is provided in the form of an SDS at the request of the purchaser.

International Inventories

TSCA	Complies
DSL	Exempt

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

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 which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	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). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals.



Chemical name	California Proposition 65
Titanium dioxide - 13463-67-7	Carcinogen

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Maize starch 9005-25-8		X	X		
Calcium carbonate 471-34-1	X				
Talc 14807-96-6	X	X	X		

International Regulations**Mexico****National occupational exposure limits**

Chemical name	Carcinogen Status	Exposure Limits
Sucrose		Mexico: TWA 10 mg/m ³ Mexico: STEL 20 mg/m ³
Talc		Mexico: TWA= 2 mg/m ³
Calcium carbonate		Mexico: TWA 10 mg/m ³ Mexico: STEL 20 mg/m ³
Titanium dioxide		Mexico: TWA= 10 mg/m ³ Mexico: STEL= 20 mg/m ³

*Mexico - Occupational Exposure Limits - Carcinogens***Canada****WHMIS Hazard Class**

Not determined

16. OTHER INFORMATION

NFPA	Health Hazards 1	Flammability 0	Instability 0	Physical and Chemical Hazards -
HMIS	Health Hazards 1	Flammability 0	Physical Hazard 0	Personal Protection X

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Issuing Date 11-Jul-2016
Revision Date 11-Jul-2016
Revision Note No information available

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 a 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