SAFETY DATA SHEET

1. Identification

Product identifier **Unisom Sleep Gels**

Other means of identification None.

Recommended use Nighttime Sleep Aid OTC Drug

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Company name Chattem, Inc.

Address 1715 West 38th Street
Chattanooga, TN 37409

Telephone 1-800-366-6077

E-mail consumer.affairs@chattem.com

Emergency phone number (800) 366-6833

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Reproductive toxicity	Effects on or via lactation
Specific target organ toxicity, single exposure	Category 3 narcotic effects

OSHA defined hazards

This mixture is a product regulated by the FDA and is not considered a hazard when used in a manner consistent with the labeled directions.

Label elements



Signal word Warning

Hazard statement May cause drowsiness or dizziness. May cause harm to breast-fed children.

Precautionary statement

Prevention Obtain special instructions before use. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact during pregnancy/while nursing. Wash thoroughly after handling. Do not eat, drink or smoke when using this product.

Response If inhaled: Remove person to fresh air and keep comfortable for breathing. If exposed or concerned: Get medical advice/attention. Call a poison center/doctor if you feel unwell.

Storage Store in a well-ventilated place. Keep container tightly closed.

Disposal Product is a consumer commodity. Empty containers may be disposed of as refuse.

Hazard(s) not otherwise classified (HNOC) None known.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Diphenhydramine Hydrochloride	147-24-0	<10

4. First-aid measures

Inhalation Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.

Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact	Do not rub eyes.
Ingestion	Seek medical attention, or call a poison control center immediately if overdosed.
Most important symptoms/effects, acute and delayed	May cause drowsiness and dizziness. Headache. Nausea, vomiting. Dusts may irritate the respiratory tract, skin and eyes.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Powder. Foam. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Applies only to the product when used in an industrial setting. Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Industrial: Wipe up with absorbent material. Collect and place in a suitable disposal container. This material is not known to possess additional hazards when spilled, beyond those of other non-hazardous solids. Household: Product used in household may be disposed of in refuse or sewer.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Applies only to the product when used in an industrial setting. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Provide adequate ventilation. Avoid prolonged exposure. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Applies only to the product when used in an industrial setting. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection	Applies only to the product when used in an industrial setting. If contact is likely, safety glasses with side shields are recommended.

Skin protection	
Hand protection	Applies only to the product when used in an industrial setting. Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.
Other	Use of an impervious apron is recommended.
Respiratory protection	Applies only to the product when used in an industrial setting. In case of insufficient ventilation, wear suitable respiratory equipment.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	When using, do not eat, drink or smoke. 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 to remove contaminants.

9. Physical and chemical properties

Appearance	Soft gel.
Physical state	Solid.
Form	Solid.
Color	Blue.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.

Hazardous decomposition products Carbon oxides. Decomposition may yield acrolein.

11. Toxicological information

Information on likely routes of exposure

Inhalation May cause drowsiness and dizziness.

Skin contact Not likely, due to the form of the product.

Eye contact Not likely, due to the form of the product.

Ingestion May be harmful if swallowed. May be absorbed in the body and cause dizziness, nausea and vomiting.

Symptoms related to the physical, chemical and toxicological characteristics Headache. May cause drowsiness and dizziness. Nausea, vomiting.

Information on toxicological effects

Acute toxicity Narcotic effects.

Components	Species	Test Results
Diphenhydramine Hydrochloride (CAS 147-24-0)		
Acute		
Oral		
LD50	Rat	500 mg/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity May cause harm to breastfed babies.

Specific target organ toxicity - single exposure May cause drowsiness and dizziness.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Applies only to the product when used in an industrial setting.

Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company. Material is not a RCRA hazardous D001 waste as generated per 40 CFR 261.2(a)(1).

Waste from residues / unused products	For bulk quantities: Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Product is a consumer commodity. Empty containers may be disposed of in refuse.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

15. Regulatory information

US federal regulations	This mixture is a product regulated by the FDA and is not considered a hazard when used in a manner consistent with the labeled directions.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	Yes

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)	Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 28-June-2015

Revision date 06-November-2016

Version # 02

HMIS® ratings Health: 2*
Flammability: 0
Physical hazard: 0

Disclaimer Chattem, Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.