

SAFETY DATA SHEET

4API Night Time (Night Cold, Flu, Cough and Allergy) Liquid Gels



HEALTH • HYGIENE • HOME

1. Product and company identification

Product name	4API Night Time (Night Cold, Flu, Cough and Allergy) Liquid Gels
Distributed by	: Reckitt Benckiser LLC. Morris Corporate Center IV 399 Interpace Parkway (P.O. Box 225) Parsippany, New Jersey 07054-0225 +1 973 404 2600
Emergency telephone number (Medical)	: 1-800-338-6167
Emergency telephone number (Transport)	: 1-800-424-9300 (U.S. & Canada) CHEMTREC Outside U.S. and Canada (North America), call Chemtrec:703-527-3887
Website:	: http://www.rbnainfo.com

Product use : Analgesic, Cough Suppressant and Expectorants.

This SDS is designed for workplace employees, emergency personnel and for other conditions and situations where there is greater potential for large-scale or prolonged exposure, in accordance with the requirements of USDOL Occupational Safety and Health Administration.

This SDS is not applicable for consumer use of our products. For consumer use, all precautionary and first aid language is provided on the product label in accordance with the applicable government regulations, and shown in Section 15 of this SDS.

SDS #	: D8222850 v2.0
Formulation #:	: 3015611 v1.0
UPC Code / Sizes	: LDPE bags

2. Hazards identification

Classification of the substance or mixture : SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2B

GHS label elements

Hazard pictograms	: Not applicable.
Signal word	: Warning
Hazard statements	: Causes eye irritation.
<u>Precautionary statements</u>	
General	: Read label before use. Keep out of reach of children.
Prevention	: Wear eye or face protection. Wash hands thoroughly after handling.
Response	: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.
Storage	: Not applicable.

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2. Hazards identification

- Disposal** : Not applicable.
- Supplemental label elements** : None known.
- Hazards not otherwise classified** : None known.

3. Composition/information on ingredients

- Substance/mixture** : Mixture Contains Inactive ingredients: FD&C Yellow#10, FD&C Blue #1, gelatin, glycerin, polyethylene glycol400, Povidone(K-12), propylene glycol, purified water, sorbitol sorbitan solution76%, and white edible ink.

Ingredient name	%	CAS number
Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy- Ethane-1,2-diol, ethoxylated	30 - 60	25322-68-3
paracetamol	15 - 30	103-90-2
dextromethorphan	1 - 2.5	125-71-3
phenylephrine hydrochloride	0.1 - 1.0	61-76-7
doxylamine hydrogen succinate	0.1 - 1.0	562-10-7

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

4. First aid measures

Description of necessary first aid measures

- Eye contact** : In case of contact with eyes, rinse immediately with plenty of water. If irritation persists, get medical attention.
- Inhalation** : In the event of any complaints or symptoms, avoid further exposure. Maintain an open airway. Get medical attention if adverse health effects persist or are severe.
- Skin contact** : In the event of any complaints or symptoms, avoid further exposure. Rinse skin with water. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. Get medical attention if adverse health effects persist or are severe. Do not induce vomiting. If affected person is conscious, give plenty of water to drink.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : Causes eye irritation.
- Inhalation** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : May be irritating to mouth, throat and stomach.

Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:
irritation
watering
redness
- Inhalation** : No specific data.
- Skin contact** : No specific data.
- Ingestion** : No specific data.

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4. First aid measures

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
 carbon dioxide
 carbon monoxide
 nitrogen oxides
 sulfur oxides
 metal oxide/oxides

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

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6. Accidental release measures

- Small spill** : Stop leak if without risk. Move containers from spill area. Vacuum or sweep up material and place in a designated, labeled waste container.
- Large spill** : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.
 See Section 1 for emergency contact information.
 See Section 8 for information on appropriate personal protective equipment.
 See section 13 for waste disposal information.

7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Avoid contact with eyes, skin and clothing. Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

- Conditions for safe storage, including any incompatibilities** : Store between the following temperatures: 15 to 25°C (59 to 77°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

8. Exposure controls/personal protection

Control

Occupational exposure limits

Ingredient name	Exposure limits
Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy- Ethane-1,2-diol, ethoxylated	AIHA WEEL (United States, 10/2011). TWA: 10 mg/m ³ 8 hours. Form: Aerosol

- Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.
- Individual protection measures**
- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : If operating conditions cause high dust concentrations to be produced, use dust goggles.
- Skin protection**

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8. Exposure controls/personal protection

- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : None required. However, use of adequate ventilation is good industrial practice.

9. Physical and chemical properties

Appearance

- Physical state** : Solid. [Gel]
- Color** : Green.
- Odor** : Characteristic.
- Odor threshold** : Not available.
- pH** : Not available.
- Melting point** : Not available.
- Boiling point** : Not available.
- Flash point** : Not available.
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not available.
- Lower and upper explosive (flammable) limits** : Not available.
- Vapor pressure** : Not available.
- Vapor density** : Not available.
- Relative density** : Not available.
- Solubility** : Not available.
- Partition coefficient: n-octanol/water** : Not available.
- Auto-ignition temperature** : Not available.
- Decomposition temperature** : Not available.
- Viscosity** : Not available.

10. Stability and reactivity

- Reactivity** : No specific test data related to reactivity available for this product or its ingredients.
- Chemical stability** : The product is stable.
- Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.
- Conditions to avoid** : No specific data.
- Incompatible materials** : Do not use with other products.
- Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

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11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
paracetamol	LD50 Oral	Rat	1944 mg/kg	-
C.I. Acid Yellow 3	LD50 Oral	Rat	2 g/kg	-
dextromethorphan	LD50 Oral	Rat	116 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy- Ethane-1,2-diol, ethoxylated	Eyes - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
	Eyes - Mild irritant	Rabbit	-	500 milligrams	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
	Skin - Mild irritant	Rabbit	-	500 milligrams	-

Conclusion/Summary

Eyes : Irritating to eyes.

Sensitization

Not available.

Mutagenicity

Not available.

Carcinogenicity

Not available.

Classification

Product/ingredient name	OSHA	IARC	NTP
paracetamol	-	3	-

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure : Not available.

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11. Toxicological information

Potential acute health effects

- Eye contact** : Causes eye irritation.
- Inhalation** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : May be irritating to mouth, throat and stomach.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : Adverse symptoms may include the following:
irritation
watering
redness
- Inhalation** : No specific data.
- Skin contact** : No specific data.
- Ingestion** : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

Long term exposure

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

Potential chronic health effects

Not available.

- General** : No known significant effects or critical hazards.
- Carcinogenicity** : No known significant effects or critical hazards.
- Mutagenicity** : No known significant effects or critical hazards.
- Teratogenicity** : No known significant effects or critical hazards.
- Developmental effects** : No known significant effects or critical hazards.
- Fertility effects** : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	3058.3 mg/kg

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12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy- Ethane-1,2-diol, ethoxylated paracetamol	Acute LC50 >1000000 μ g/l Fresh water	Fish - Salmo salar - Parr	96 hours
	Acute LC50 32 μ g/l Fresh water	Daphnia - Daphnia magna - Neonate	48 hours
	Acute LC50 160 mg/l Fresh water	Fish - Oryzias latipes	96 hours

Persistence and degradability

Not available.

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy- Ethane-1,2-diol, ethoxylated paracetamol	-	3.2	low
	0.4	3.162	low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

14. Transport information

Not a DOT controlled material (United States). Not a TDG-controlled material. This preparation is not classified as dangerous according to international transport regulations (ADR/RID, IMDG or ICAO/IATA).

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15. Regulatory information

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined
 United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Immediate (acute) health hazard

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy- Ethane-1,2-diol, ethoxylated	30 - 60	No.	No.	No.	Yes.	No.
paracetamol	15 - 30	Yes.	No.	No.	Yes.	No.
C.I. Acid Yellow 3	1 - 2.5	No.	No.	No.	Yes.	No.
dextromethorphan	1 - 2.5	No.	No.	No.	Yes.	No.

State regulations

Massachusetts : The following components are listed: GLYCERINE MIST; C.I. ACID BLUE 9, DISODIUM SALT

New York : None of the components are listed.

New Jersey : The following components are listed: GLYCERIN; 1,2,3-PROPANETRIOL; PROPYLENE GLYCOL; 1,2-PROPANEDIOL

Pennsylvania : The following components are listed: 1,2,3-PROPANETRIOL; 1,2-PROPANEDIOL

Label elements

Precautionary measures : Read label before use.
 Avoid contact with eyes.
 Keep out of reach of children.

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16. Other information

Hazardous Material Information System (U.S.A.) :

Health	1
Flammability	0
Physical hazards	0
Personal protection	B

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings are not required on MSDSs under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

National Fire Protection Association (U.S.A.) :



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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

Key to abbreviations :

- ATE = Acute Toxicity Estimate
- BCF = Bioconcentration Factor
- GHS = Globally Harmonized System of Classification and Labelling of Chemicals
- IATA = International Air Transport Association
- IBC = Intermediate Bulk Container
- IMDG = International Maritime Dangerous Goods
- LogPow = logarithm of the octanol/water partition coefficient
- MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
- UN = United Nations

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16. Other information

Revision comments : Addition of composition percentage information

☑ Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.



RB is a member of the CSPA Product Care Product Stewardship Program.