Material Safety Data Sheet
ANSI Format

Dristan Solid Products

Preparation Date 19-Sep-2007 **Revision Date** 31-Mar-2008 **Revision Number** 4

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name	Dristan Solid Products
Common Name	Not available
Chemical Name	Not applicable
Synonyms	Dristan Caplets, Dristan Non-Drowsy Caplets, Dristan Tablets, Dristan Multi-Symptom Cold Tablets, Dristan Sinus Caplets, Dristan Extra Strength, Dristan Extra Strength Non-Drowsy
Product Use	Pharmaceutical product
Classification	Fever Reducer, Nasal Decongestant, Antihistamine
Supplier	Wyeth P.O. Box 8299 Philadelphia, PA 19101 USA. Telephone: 1-610-688-4400
Emergency Telephone Number	Chemtrec USA, Puerto Rico, Canada 1-800-424-9300 Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Pharmaceutical Tablet or Caplet **Physical State** Solid **Odor** Odorless

Potential Physical Hazards Powders and solids are presumed to be combustible.

Potential Health Effects

Eyes	Not available
Skin	Not available
Inhalation	Not available
Ingestion	The most common effects may include sleep disturbances, drowsiness, dizziness and excitability. May impair ability when driving a motor vehicle or operating machinery. May cause harm to the unborn child. Please see Patient Package Insert for further information.
Therapeutic Target Organ(s)	Central nervous system
	Not listed by OSHA, NTP or IARC.

Potential Environmental Effects See Section 12.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Acetylsalicylate Acid	50-78-2	0-325 mg/tablet
Acetaminophen	103-90-2	0-500 mg/tablet
Ibuprofen	15687-27-1	0-200 mg/tablet
Pseudoephedrine HCl	345-78-8	0-30 mg/tablet
Phenylephrine HCl	61-76-7	0-5 mg/tablet
Chlorpheniramine Maleate	113-92-8	0-2 mg/tablet
Inactive Ingredients	Not applicable	Remainder
Caffeine	58-08-2	0-16.2 mg/tablet

4. FIRST AID MEASURES

Eye Contact In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.

Skin Contact Take off contaminated clothing and shoes immediately Wash off immediately with soap and plenty of water If skin irritation persists, call a physician

Inhalation Move to fresh air Artificial respiration and/or oxygen may be necessary If symptoms persist, call a physician

Ingestion If symptoms persist, call a physician Do not induce vomiting without medical advice Never give anything by mouth to an unconscious person

Aggravated Medical Conditions Not available

5. FIRE-FIGHTING MEASURES

Flammable Properties Presumed to be a combustible particulate solid.

Extinguishing Media

Suitable Extinguishing Media Use water spray, foam, dry chemical or carbon dioxide.

Unsuitable Extinguishing Media Do NOT use water jet.

Fire Fighting Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes. Cool closed containers exposed to fire with water spray In the event of fire and/or explosion do not breathe fumes

Hazardous Combustion Products Carbon oxides nitrogen oxides

Protective Equipment and Precautions for Firefighters In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions Prevent product from entering drains Local authorities should be advised if a significant spill cannot be contained

Methods for Containment Not available

Methods for Cleaning up Take up mechanically and collect in suitable container for disposal Clean contaminated surface thoroughly Avoid formation of dust and aerosols

7. HANDLING AND STORAGE

Handling For personal protection see Section 8 Handle in accordance with good industrial hygiene and safety practice Skin should be washed after contact Avoid formation of dust and aerosols

Storage No special safety precautions required Keep container tightly closed

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name	Exposure Guideline
Acetylsalicylate Acid	750 mcg/m^3
Acetaminophen	2000 mcg/m^3
Ibuprofen	2000 mcg/m^3
Pseudoephedrine HCl	200 mcg/m^3
Caffeine	500 mcg/m^3
Phenylephrine HCl	40 mcg/m^3
Chlorpheniramine Maleate	10 mcg/m^3

Engineering Controls Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.

Personal Protective Equipment

Eye/face Protection Provide eye protection based on risk assessment.

Skin Protection Wear nitrile or latex gloves. Wear protective garment.

Respiratory Protection Base respirator selection on a risk assessment.

General Hygiene Considerations When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.

Other Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Pharmaceutical Tablet or Caplet	**Physical State**	Solid
Color	Various	**Odor**	Odorless
Odor Threshold	Not available		
pH	Not available		
Specific Gravity	Not applicable	**Water Solubility**	Not available
Solubility	Not applicable	**Evaporation Rate**	Not applicable
Partition Coefficient (n-octanol/water)	Not available	**Vapor Pressure**	Not applicable

Boiling Point	Not available	**Autoignition Temperature**	Not available
Flash Point	Not available	**Method**	None
Melting Point	Not available		
Flammability Limits in Air	**Upper** Not applicable	**Lower** Not applicable	
Explosion Limits	**Upper** Not applicable	**Lower** Not applicable	

10. STABILITY AND REACTIVITY

Chemical Stability Stable at room temperature.

Conditions to Avoid No data available

Materials to Avoid No materials to be especially mentioned.

Hazardous Decomposition Products None under normal use.

Possibility of Hazardous Reactions None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Acetylsalicylate Acid

LD50 Oral	1460 mg/kg rats, 1100 mg/kg mice, 1010 mg/kg rabbits
Acute Dermal Irritation	7940 mg/kg rabbits, slightly irritating to rabbit skin.
Primary Eye Irritation	Irritating to rabbit eyes.
Sensitization	Not a dermal sensitizer in guinea pigs.

Acetaminophen

LD50 Oral	2404 mg/kg rats
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available

Ibuprofen

LD50 Oral	625 mg/kg rats
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available

Pseudoephedrine HCl

LD50 Oral	371 mg/kg mice
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available

Caffeine

LD50 Oral	192 mg/kg rats, 125 mg/kg mice
Acute Dermal Irritation	> 2000 mg/kg rats

Primary Eye Irritation	Not irritating to rabbit eyes.
Sensitization	No data available

Phenylephrine HCl

LD50 Oral	350 mg/kg rats, 1400 mg/kg mice
Acute Dermal Irritation	Not irritating to rabbit skin.
Primary Eye Irritation	No data available
Sensitization	No data available

Chlorpheniramine Maleate

LD50 Oral	118-680 mg/kg rats, 121 mg/kg mice
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available

Multiple Dose Toxicity

Acetylsalicylate Acid

No Toxicologic Effect Dose/Species/Study Length:	See Carcinogenicity

Ibuprofen

No Toxicologic Effect Dose/Species/Study Length:	Not available

Pseudoephedrine HCl

No Toxicologic Effect Dose/Species/Study Length:	No data available

Caffeine

No Toxicologic Effect Dose/Species/Study Length:	See Carcinogenicity

Chlorpheniramine Maleate

No Toxicologic Effect Dose/Species/Study Length:	This compound was well tolerated in rats and mice in repeat-dose toxicity studies for 13 weeks. There was a reduction of body weight gain and reduced survival at higher doses.

Maximum Tolerated Dose (MTD), Oral

Acetylsalicylate Acid

Carcinogenicity	Long-term studies in rats revealed no evidence of carcinogenicity.
Genetic Toxicity	AMES Test :Negative- Nonmutagenic Positive in the *in vivo* chromosome aberration assay in cultured fibroblasts.
Reproductive Toxicity	See Developmental Toxicity.
Developmental Toxicity	Fetotoxin and a teratogen in rats, mice, dogs, cats and monkeys at high doses.

Acetaminophen

Carcinogenicity	Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of carcinogenic activity in male rats or mice. Equivocal evidence was seen in female rats. IARC Category 3.
Genetic Toxicity	Not mutagenic in AMES Test. Induced sister chromatid exchanges and chromosomal aberrations in cytogenetic tests using Chinese hamster ovary cells.
Reproductive Toxicity	Testicular atrophy and inhibition of spermatogenesis was seen in animal studies at high dose levels. Relevance to humans is not known.
Developmental Toxicity	See Reproductive Toxicity

Ibuprofen

Carcinogenicity	Carcinogenic studies in mice and rats were negative.
Genetic Toxicity	Non-mutagenic in *in vivo* studies.
Reproductive Toxicity	Reproduction studies in rats and mice did not reveal any evidence of impaired fertility or embryotoxicity.
Developmental Toxicity	Reproduction studies in rats and mice did not reveal any teratogenic effects.

Pseudoephedrine HCl

Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available

Caffeine

Carcinogenicity	In a 2-year study in rats and mice, no evidence of carcinogenic potential was observed.
Genetic Toxicity	Evidence of Genotoxicity was observed in a battery of studies.
Reproductive Toxicity	Studies in monkeys have resulted in reduced fetal weight, stillbirths, and miscarriages.
Developmental Toxicity	Teratogenic effects were reported in both rats and mice at high doses (> 40 mg/kg/day). Digital defects, cleft palate, extra embryonic structures, and urogenital and musculosketal abnormalities were induced. Other findings in animal studies include inhibition of neurogenesis in the mouse embryo; reduced cerebral weight and cardiovascular, lens and thymic changes in rats.

Phenylephrine HCl

Carcinogenicity	Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of Carcinogenicity activity in male or female rats or mice.
Genetic Toxicity	No evidence of mutagenicity was observed in a battery of *in vitro* and *in vivo* assays.
Reproductive Toxicity	No data available
Developmental Toxicity	No data available

Chlorpheniramine Maleate

Carcinogenicity	Under the conditions of the National Toxicology Program (NTP) studies, there was no evidence of Carcinogenicity activity in male or female rats or mice.
Genetic Toxicity	No evidence of mutagenicity was observed in a battery of *in vitro* and *in vivo* assays.
Reproductive Toxicity	Animal studies to evaluate effects on fertility have not been conducted.
Developmental Toxicity	No teratogenic effects were observed in mice.

Acetylsalicylate Acid

Target Organ(s) of Toxicity No data available

Acetaminophen

Target Organ(s) of Toxicity No data available

Ibuprofen

Target Organ(s) of Toxicity No data available

Pseudoephedrine HCl

Target Organ(s) of Toxicity No data available

Caffeine

Target Organ(s) of Toxicity No data available

Phenylephrine HCl

Target Organ(s) of Toxicity No data available

Chlorpheniramine Maleate

Target Organ(s) of Toxicity No data available

12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information

Acetylsalicylate Acid

Mobility	Not available
Biodegradability	Readily biodegradable.
Stability in Water	Not available
Bioaccumulation	Bioaccumulation is unlikely.

Acetaminophen

Mobility	Not available
Biodegradability	Not available
Stability in Water	Not available
Bioaccumulation	Not available

Ibuprofen

Mobility	Not available
Biodegradability	Not available
Stability in Water	Not available
Bioaccumulation	Not available

Pseudoephedrine HCl

Mobility	Not available
Biodegradability	Moderately biodegradable.
Stability in Water	Not available
Bioaccumulation	Not available

Caffeine

Mobility	Not available
Biodegradability	Readily biodegradable.
Stability in Water	Not available
Bioaccumulation	Bioaccumulation is unlikely.

Phenylephrine HCl

Mobility	Not available
Biodegradability	Not available
Stability in Water	Not available
Bioaccumulation	Not available

Chlorpheniramine Maleate

Mobility	Not available
Biodegradability	Not available
Stability in Water	Not available
Bioaccumulation	Not available

Ecotoxicity

Acetylsalicylate Acid

Microorganisms	Not available

Algae	Not available
Daphnia	EC50/48h/daphnia = 330 mg/l
Fish	Not available

Acetaminophen

Microorganisms	Not available
Algae	Not available
Daphnia	Not available
Fish	Not available

Ibuprofen

Microorganisms	Not available
Algae	Not available
Daphnia	Not available
Fish	Not available

Pseudoephedrine HCl

Microorganisms	Not available
Algae	Not available
Daphnia	Not available
Fish	LC50/96h/golden orfe = 460-1000 mg/l

Caffeine

Microorganisms	EC50/17h/bacteria = 3490 mg/l
Algae	EC50/72h/green algae > 100 mg/l
Daphnia	EC50/48h/daphnia = 182 mg/l
Fish	LC50/96h/golden orfe = 87 mg/l

Phenylephrine HCl

Microorganisms	Not available
Algae	Not available
Daphnia	Not available
Fish	Not available

Chlorpheniramine Maleate

Microorganisms	Not available
Algae	Not available
Daphnia	Not available
Fish	Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

U.S. Department of Transport (DOT)	Not regulated
Canadian Transport of Dangerous Goods (TDG)	Not regulated
International Civil Aviation Organization (ICAO)	Not regulated
International Air Transport Association (IATA)	Not regulated
International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)	Not regulated

Transport of Dangerous Goods by Rail (RID)	Not regulated
Transport of Dangerous Goods by Road (ADR)	Not regulated
Transportation of Dangerous Goods via Inland Waterways (ADN)	Not regulated

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status
This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

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 40n of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazardous Categorization

Acute Health Hazard	No
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

This product does not contain any HAPs.

State Regulations

California Proposition 65
This product contains the following Proposition 65 chemicals:

Common Name	CAS-No	Type
Acetylsalicylate Acid	50-78-2	Developmental Female Reproductive

Canada

Not classified

WHMIS Hazard Class
Non-controlled

European Union
In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. OTHER INFORMATION

Prepared By	Wyeth Department of Environment, Health & Safety
Format	This MSDS was prepared in accordance with ANSI Z400.1-2004.
List of References	Product Profiles
Revision Summary	Changes to 8.

Disclaimer:

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End of MSDS