MATERIAL SAFETY DATA SHEET

1. Product and Company Identification

Material name **BC HEADACHE POWDER**

Version # 08

Revision date 04-27-2012

Product use Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Synonym(s) BC HEADACHE POWDER (US) * FORMULA NO. B0006 * BC ANALGESIC POWDER * ASPIRIN, CAFFEINE AND SALICYLAMIDE, FORMULATED PRODUCT

Manufacturer

Medtech Products Inc.
A Prestige Brands Company
90 North Broadway
Irvington, NY 10533

Contact Phone Number: 1-877-274-1787

2. Hazards Identification

Emergency overview Assume that this product is capable of sustaining combustion.
Eye irritant.
Health effects information is based on hazards of components.
No information is available about the potential of this product to produce adverse environmental effects.

OSHA regulatory status Exempt when packaged for sale to consumers in a retail establishment.

Potential health effects

Eyes Direct contact may occur. Irritation might occur following direct contact with eyes.

Skin Direct contact may occur. Irritation might occur following direct contact.

Inhalation Exposure from inhalation may occur.

Ingestion Exposure from ingestion may occur. Toxicity might occur following ingestion.

Signs and symptoms The possible consequences of overexposure include: impaired blood coagulation; symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing); abdominal discomfort.

3. Composition / Information on Ingredients

Components	CAS #	Percent
ASPIRIN	50-78-2	56
SALICYLAMIDE	65-45-2	17
CAFFEINE	58-08-2	<3.0

Components	CAS #	Percent
FUMARIC ACID	110-17-8	<3.0
Other components below reportable levels		23

4. First Aid Measures

First aid procedures

Eye contact Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

Skin contact Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.

Inhalation Using appropriate personal protective equipment, move exposed subject to fresh air. If breathing is difficult or ceases, ensure and maintain ventilation. Give oxygen as appropriate. The exposed subject should be kept warm and at rest. Obtain medical attention in cases of known or possible over exposure, or with symptoms including chest pain, difficulty breathing, loss of consciousness or other adverse effects, which may be delayed.

Ingestion Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

Notes to physician No specific antidotes are recommended. Medical treatment in cases of overexposure should be treated as an overdose of aspirin . Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

General advice Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. Fire Fighting Measures

Extinguishing media

Suitable extinguishing media Water, dry powder or foam extinguishers are recommended.

Unsuitable extinguishing media Carbon dioxide extinguishers may be ineffective.

Protection of firefighters

Specific hazards arising from the chemical Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

Protective equipment and precautions for firefighters Since toxic, corrosive or flammable vapours might be evolved from fires involving this material, self contained breathing apparatus and full protective equipment are recommended for firefighters.

Fire fighting equipment/instructions For single units (packages): No special requirements needed.
For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters.
If possible, contain and collect firefighting water for later disposal.

6. Accidental Release Measures

Personal precautions Wear protective clothing and equipment consistent with the degree of hazard.

Environmental precautions For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Methods for containment Collect and place it in a suitable, properly labelled container for recovery or disposal.

Methods for cleaning up No specific decontamination or detoxification procedures have been identified for this product.

7. Handling and Storage

Handling Normal room ventilation is expected to be adequate for routine handling of this product.

Storage No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. Exposure Controls / Personal Protection

Occupational exposure limits

GSK

Components	Type	Value
ASPIRIN (50-78-2)	8 HR TWA	3000 mcg/m3
	OHC	1
CAFFEINE (58-08-2)	8 HR TWA	200 mcg/m3
	OHC	2
FUMARIC ACID (110-17-8)	-	5000 mcg/m3
	OHC	1

ACGIH

Components	Type	Value
ASPIRIN (50-78-2)	TWA	5 mg/m3

U.S. - OSHA

Components	Type	Value
ASPIRIN (50-78-2)	TWA	5 mg/m3

Personal protective equipment

Eye / face protection	Wear approved safety glasses with side shields if eye contact is possible.
General hygiene considerations	None required for normal handling. Wash hands and arms thoroughly after handling.

9. Physical & Chemical Properties

Appearance	
Physical state	Solid.
Form	Glassine envelopes. Powder.
Color	White.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not available.
Solubility (water)	Not available.
Specific gravity	Not available.
Relative density	Not available.
Flash point	Not available.
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.
Auto-ignition temperature	Not available.

10. Chemical Stability & Reactivity Information

Chemical stability	This product is expected to be stable.
Conditions to avoid	None for normal handling of this product.
Incompatible materials	Not available.
Hazardous decomposition products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.
Possibility of hazardous reactions	Not available.

11. Toxicological Information

Toxicological data

Components	Species	Test Results
ASPIRIN (50-78-2)		
Acute		
Oral		
LD50	Rat	200 mg/kg
CAFFEINE (58-08-2)		
Acute		
Oral		
LD50	Rat	192 mg/kg

Sensitization Symptoms of hypersensitivity may include skin rash, hives, itching, and/or difficulty breathing.

Acute effects Toxicity might occur following ingestion.

Carcinogenicity No studies have been conducted. Not expected to produce cancer in humans under occupational exposure conditions.

IARC Monographs. Overall Evaluation of Carcinogenicity

CAFFEINE (CAS 58-08-2) 3 Not classifiable as to carcinogenicity to humans.

Skin corrosion/irritation No studies have been conducted. Irritation might occur following direct contact.

Serious eye damage/eye irritation No studies have been conducted. Irritation might occur following direct contact with eyes.

Mutagenicity Not expected to be genotoxic under occupational exposure conditions. Assessment based upon information from human exposure.

Reproductive effects Effects seen at therapeutic or higher doses are likely not relevant to occupational hazard estimation. The ingredient aspirin has caused adverse effects on the development of unborn offspring in animal studies. The ingredient aspirin has caused adverse effects on lactation in humans. The ingredient aspirin has caused adverse effects to fertility in animal studies. Clinical use of this active ingredient during pregnancy has resulted in reversible, adverse drug effects in infants. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

Symptoms and target organs The possible symptoms of overexposure include: impaired blood coagulation; symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing); abdominal discomfort.

Further information This product contains active ingredient(s) with the following activity: a non-steroidal anti-inflammatory substance.

12. Ecological Information

Ecotoxicological data

Components		Species	Test Results
ASPIRIN (50-78-2)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Activated sludge	> 100 mg/l, 3 hours, Nominal
	NOEC	Activated sludge	100
Algae	EC50	Green algae (Selenastrum capricornutum)	27 mg/l, 72 hours, Nominal
	NOEC	Algae	< 7.5 mg/l
Crustacea	EC50	Water flea (Daphnia magna)	168 mg/l, 24 hours
Fish	EC50	Golden ide/orfe (Adult Leuciscus idus)	> 1000 mg/l, 48 hours
Microtox	EC50	Microtox	26 mg/l, 5 minutes

Components		Species	Test Results
CAFFEINE (58-08-2)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Activated sludge	> 1000 mg/l, 3 hours, Nominal
	NOEC	Activated sludge	1000
Algae	EC50	Green algae (Scenedesmus subspicatus)	> 100 mg/l, 72 hours, Measured
	NOEC	Algae	100 mg/l
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	151 mg/l, 96 hours
		Golden ide/orfe (Adult Leuciscus idus)	87 mg/l, 96 hours
Microtox	EC50	Microtox	733 mg/l, 5 minutes

Ecotoxicity This material contains an active ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release.

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

ASPIRIN	19.8 Days Estimated
CAFFEINE	2.5 Hours Estimated

UV/visible spectrum wavelength

CAFFEINE	227 nm

Hydrolysis

Half-life (Hydrolysis-acidic)

ASPIRIN	12.5 Days Measured

Half-life (Hydrolysis-basic)

ASPIRIN	1.2 Hours Measured

Half-life (Hydrolysis-neutral)

ASPIRIN	6.3 Days Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

FUMARIC ACID	61 % BOD5

Percent degradation (Anaerobic biodegradation)

ASPIRIN	90 %, 56 days

Bioaccumulation / Accumulation

Bioaccumulative potential

Bioconcentration factor

CAFFEINE	0.52 - 2.25 Estimated
ASPIRIN	4.7 - 5.4 Calculated

Adsorption

Soil/sediment sorption - log Koc

CAFFEINE	1.25 - 1.34 Estimated
ASPIRIN	1.6 - 2 Calculated

Volatility

Henry's law

ASPIRIN	0 atm m^3/mol Calculated, 25 C
CAFFEINE	0 atm m^3/mol Estimated

13. Disposal Considerations

Disposal instructions Observe all local and national regulations when disposing of this product. Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

14. Transport Information

General The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations

Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2)

Not regulated.

DEA Essential Chemical Code Number

Not regulated.

Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))

Not regulated.

DEA Exempt Chemical Mixtures Code Number

Not regulated.

CERCLA (Superfund) reportable quantity

FUMARIC ACID: 5000

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
Section 302 extremely hazardous substance	No
Section 311 hazardous chemical	No

Inventory status

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)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

State regulations

US - California Proposition 65 - CRT: Listed date/Developmental toxin

ASPIRIN (CAS 50-78-2) Listed: July 1, 1990 Developmental toxin.

US - California Proposition 65 - CRT: Listed date/Female reproductive toxin

ASPIRIN (CAS 50-78-2)	Listed: July 1, 1990 Female reproductive toxin.

US - New Jersey RTK - Substances: Listed substance

FUMARIC ACID (CAS 110-17-8)	Listed.

US - Pennsylvania RTK - Hazardous Substances: Listed substance

ASPIRIN (CAS 50-78-2)	Listed.
FUMARIC ACID (CAS 110-17-8)	Listed.

16. Other Information

Recommended restrictions	No other uses are advised.
Further information	This material has not been assessed for HMIS or NFPA ratings. HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: Flammability: Physical hazard:
NFPA ratings	Health: Flammability: Instability:
Disclaimer	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.
Issue date	06-12-2002
This data sheet contains changes from the previous version in section(s):	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Reports Transport Information: Regulatory Information: United States