

SAFETY DATA SHEETS

This SDS packet was issued with item:

078914436

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078398137

West-Ward Pharmaceuticals

THIS CONTROLLED DRUG MUST BE UNDER CONSTANT SUPERVISION WHILE ACTUALLY IN-PROCESS AND LOCKED IN A SECURE AREA AT ALL OTHER TIMES.

MATERIAL SAFETY DATA SHEET

FMOM No.: 1785-2.5MM-1.09

DATE: 10/17/05

PRODUCT NAME: Butalbital/Aspirin/Caffeine Tablets

POTENCY: 50/325/40 mg

BATCH SIZE: 2,500,000 Tablets

Butalbital: CAS #77-26-9

Signs and Symptoms

of Overexposure: [TDL0: 3 mg/kg oral-human (psychotropic effects);
LD₅₀: 160 mg/kg subcutaneous-rat;
LD₅₀: 75 mg/kg oral-pigeon;
LD₅₀: 237 mg/kg oral-duck;
LD₅₀: 100 mg/kg oral-bird]

Possible allergic reaction to dust if inhaled, ingested or in contact with skin.
Sedation, hypnosis, coma depending upon amount ingested.

Acute: Eye, skin and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Emergency and First Aid Procedures:

Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity reactions must receive immediate medical attention. Upon eye or skin contact, flush affected area with copious quantities of water. Obtain medical attention. Treatment of overdosage consists of emptying the stomach via induction or gastric lavage, administration or activated charcoal and supportive/symptomatic treatment. Keep warm. Give stimulants. Maintain respiration.

1. Inhalation May cause irritation of respiratory tract. Avoid inhalation. Remove to fresh air.
2. Eyes May cause irritation. Flush with copious quantities of water.
3. Skin May cause irritation. Flush with copious quantities of water.
4. Ingestion: May cause irritation. Flush out mouth with water.

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CAFFEINE: CAS #58-08-2

Signs and Symptoms
Of Overexposure:

1. Inhalation Irritation of nasal, pharyngeal and tracheal mucous membranes, cough irritation.
2. Ingestion Only large amounts cause hypersensitivity reactions, muscle tremor, tachycardia, increased blood pressure, convulsions, hallucinations. Symptoms may persist for hours.
3. Skin Slight dermal irritation.
4. Eyes Severe irritation, burning, lacrimation.

Emergency and First
Aid Procedures:

Should product come into contact with the eyes, immediately rinse with plenty of water. Seek medical help should any symptoms occur attributable to inhalation, ingestion and contact with skin or eyes.

STARCH 1500: CAS #9005-25-8

Signs and Symptoms
of Overexposure:

Minimal – Dust may be irritating to nose and eyes.

Primary Route(s)
Of Entry:

Inhalation.

Emergency and First
Aid Procedures:

Unlikely to be necessary. Flush eyes with water. Remove to fresh air.

STEROTEX: CAS #68334-00-9

Threshold Limit Value: Unknown

Effects of
Overexposure:

None known to Karlshamns.

Emergency and First
Aid Procedures:

1. Skin Wash with soap and water.
2. Eyes Flush with low pressure water.
3. Ingestion Food Grade Product.

THIS CONTROLLED DRUG MUST BE UNDER CONSTANT SUPERVISION WHILE ACTUALLY IN-PROCESS AND LOCKED IN A SECURE AREA AT ALL OTHER TIMES.

ASPIRIN 10% STARCH; CAS #50-78-2

Signs and Symptoms
of Overexposure:

1. Inhalation Excessive exposure may cause irritation to upper respiratory tract. May cause respiratory sensitization to susceptible individuals.
2. Eyes May cause slight temporary eye irritation.
3. Skin Prolonged or repeated contact with the dust may irritate the skin.
4. Ingestion Single dose toxicity is low to moderate. Ingestion of large amounts could cause gastrointestinal irritation and interfere with normal blood clotting mechanism.

Chronic Effects of
Exposure:

Repeated exposures (Typically by Ingestion) may cause gastrointestinal irritation. Toxic or high doses may cause ringing in the ears, nausea, vomiting, metabolic disturbances and possible kidney damage. Has caused birth defects in laboratory animals only at doses toxic to the mother.

Medical Conditions
Generally Aggravated
by Exposure:

None reported.

Emergency and First
Aid Procedures:

1. Inhalation Remove to fresh air. Give artificial respiration if not breathing. Get medical attention.
2. Eyes Immediately flush eyes with lots of running water for 5 minutes, lifting the upper and lower eyelids occasionally. Get immediate medical attention.
3. Skin Immediately wash skin with lots of soap and water. Remove contaminated clothing and shoes. Wash before reuse. Get medical attention if irritation persists after washing.
4. Ingestion If conscious, immediately induce vomiting by giving 2 glasses of water and sticking a finger down the throat. Get immediate medical attention. Do not give anything to an unconscious or convulsing person.

THIS CONTROLLED DRUG MUST BE UNDER CONSTANT SUPERVISION WHILE ACTUALLY IN-PROCESS AND LOCKED IN A SECURE AREA AT ALL OTHER TIMES.

AVICEL: CAS #9004-34-6

Route(s) of Exposure:

1. Inhalation No significant hazard. No mortality in rats at maximum attainable concentration. 4 Hour LC₅₀ > 5.05 – 5.49 mg/l. FMC Study Numbers 182-622 and 182-627 (1983).
2. Skin Contact Nonirritant. Primary Irritation Index (Rabbit) = 0/8.0. FMC Study Number 182-625 (1982).
3. Eyes Minimally irritating (Rabbit). FMC Study Numbers 182-621 and 182-626 (1982).
4. Skin Absorption No significant hazard. Dermal LD₅₀ (Rabbit) > 2 g/kg. FMC Study Number 182-620 and 182-624 (1982).
5. Ingestion No Significant hazard. Oral LD₅₀ (Rat) > 5 g/kg. FMC Study Number 182-623 (1982).

Signs and Symptoms of Overexposure

No significant hazard in animal toxicity tests. No adverse human effects known.

Emergency and First Aid Procedures:

1. Eyes Flush with clean water for at least fifteen minutes. If irritation occurs and persists, obtain medical attention.
2. Skin Wash with soap and water. If irritation occurs and persists, obtain medical attention.
3. Inhalation Remove victim to fresh air. If breathing is difficult or if any discomfort persists, obtain medical attention.
4. Ingestion Drink plenty of water. If any discomfort persists, obtain medical attention.

TALC: CAS #14807-96-6

Signs and Symptoms of Overexposure:

May cause mechanical irritation to eyes and respiratory tract.

Emergency and First Aid Procedures:

Wash dust from skin with soap and water. Flush out eyes with generous amounts of water for at least 15 minutes. See a physician if irritation persists.

THIS CONTROLLED DRUG MUST BE UNDER CONSTANT SUPERVISION WHILE ACTUALLY IN-PROCESS AND LOCKED IN A SECURE AREA AT ALL OTHER TIMES.

SODIUM STARCH GLYCOLATE (Primojel): CAS #9063-38-1

Signs and Symptoms

Of Overexposure: Not a health hazard.

Special Fire

Fighting Procedures: Use health protection because poisonous gas will be formed when burning.

SAFETY DATA SHEET

Acetaminophen, Butalbital, and Caffeine Tablets, 325/50/40mg



Section 1. Identification

GHS product identifier	: Acetaminophen, Butalbital, and Caffeine Tablets, 325/50/40mg
Chemical name	: Acetaminophen: 4'-Hydroxyacetanilide Butalbital: 5-Allyl-5-isobutylbarbituric acid Caffeine: 1,3,7,-Trimethylxanthine
Synonyms	: ABC Blue.
Product code	: Not available.
Chemical family	: Not available.
Product type	: Regulated prescription drug.
Container information	: Not available.

Identified uses

For the relief of the symptom complex of tension (or muscle contraction) headache.

Supplier's details	: West-Ward Pharmaceutical Corp. 465 Industrial Way West Eatontown NJ 07724 USA
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Emergency telephone number (with hours of operation)	: CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887 24/7
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Section 2. Hazards identification

OSHA/HCS status	: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
Classification of the substance or mixture	: ACUTE TOXICITY (oral) - Category 4 SKIN SENSITIZATION - Category 1 Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 10%

GHS label elements

Hazard pictograms



Signal word	: Warning
Hazard statements	: Harmful if swallowed. May cause an allergic skin reaction.

Precautionary statements

Prevention	: Wear protective gloves. Avoid breathing dust. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace.
Response	: IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell. Rinse mouth. IF ON SKIN: Wash with plenty of soap and water. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention.



Section 2. Hazards identification

- Storage** : Not applicable.
- Disposal** : Dispose of contents and container in accordance with all local, regional, national and international regulations.
- Hazards not otherwise classified** : None known.

Section 3. Composition/information on ingredients

- Substance/mixture** : Mixture
- Chemical name** : Acetaminophen: 4'-Hydroxyacetanilide
Butalbital: 5-Allyl-5-isobutylbarbituric acid
Caffeine: 1,3,7,-Trimethylxanthine
- Other means of identification** : ABC Blue.

CAS number/other identifiers

- CAS number** : Not applicable.
- Product code** : Not available.

Ingredient name	%	CAS number
Paracetamol	60 - 100	103-90-2
Butalbital	10 - 30	77-26-9
Caffeine	5 - 10	58-08-2
Cellulose	10 - 30	9004-34-6
Starch, carboxymethyl ether, sodium salt	5 - 10	9063-38-1
Magnesium distearate	1 - 5	557-04-0
Silicon dioxide	0.1 - 1	7631-86-9
Dihydrogen (ethyl)[4-[[4-[ethyl(3-sulphonatobenzyl)amino]phenyl](2-sulphonatophenyl)methylene]cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl)Ammonium, Aluminium Salt	0.1 - 1	68921-42-6

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

There are no 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.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. 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.
- Skin contact** : Wash with plenty of soap and water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Section 4. First aid measures

- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Skin contact** : May cause an allergic skin reaction.
- Ingestion** : Harmful if swallowed.

Over-exposure signs/symptoms

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No known significant effects or critical hazards.

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. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 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.

Section 5. Fire-fighting measures

- 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** : No special measures are required.
- 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.

Section 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. 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 specialized 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

- Spill** : Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : 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. See also Section 8 for additional information on hygiene measures. Remove contaminated clothing and protective equipment before entering eating areas.

Section 7. Handling and storage

Conditions for safe storage, including any incompatibilities : 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.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Dihydrogen (ethyl)[4-[[4-[ethyl(3-sulphonatobenzyl)amino]phenyl](2-sulphonatophenyl)methylene]cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl)Ammonium, Aluminium Salt	OSHA PEL 1989 (United States, 3/1989). TWA: 2 mg/m ³ , (as Al) 8 hours. NIOSH REL (United States, 4/2013). TWA: 2 mg/m ³ , (as Al) 10 hours.

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.

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. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin 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. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

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 : Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Section 9. Physical and chemical properties

Appearance

Physical state	: Solid. [Round, unscored, compressed tablet; Debossed "West-ward 787".]
Color	: Blue.
Odor	: Odorless to faint odor.
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.

Section 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	: Reactive or incompatible with the following materials: oxidizing materials.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Paracetamol	LD50 Oral	Rat	1944 mg/kg	-
Caffeine	LD50 Oral	Rat	192 mg/kg	-

Section 11. Toxicological information

Irritation/Corrosion

There is no data available.

Sensitization

There is no data available.

Carcinogenicity

Classification

Product/ingredient name	OSHA	IARC	NTP
Paracetamol	-	3	-
Caffeine	-	3	-

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Skin contact** : May cause an allergic skin reaction.
- Ingestion** : Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No known significant effects or critical hazards.

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

Short term exposure

- Potential immediate effects** : No known significant effects or critical hazards.
- Potential delayed effects** : No known significant effects or critical hazards.

Long term exposure

- Potential immediate effects** : No known significant effects or critical hazards.
- Potential delayed effects** : No known significant effects or critical hazards.

Potential chronic health effects

- General** : Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.
- Carcinogenicity** : No known significant effects or critical hazards.



Section 11. Toxicological information

- 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	770.9 mg/kg

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Paracetamol	Acute LC50 32 µg/l Fresh water Acute LC50 160 mg/L Fresh water	Daphnia - Daphnia magna - Neonate Fish - Oryzias latipes	48 hours 96 hours

Persistence and degradability

There is no data available.

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Paracetamol	0.4	3.162	low
Caffeine	-0.091	-	low
Dihydrogen (ethyl)[4-[[4-[ethyl (3-sulphonatobenzyl)amino]phenyl] (2-sulphonatophenyl)methylene] cyclohexa-2,5-dien-1-ylidene] (3-sulphonatobenzyl)Ammonium, Aluminium Salt	1.25	3.2	low

Mobility in soil

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

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

Section 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 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 empty 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





Section 13. Disposal considerations

sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

AERG : Not applicable.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

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

Section 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.





Section 15. Regulatory information

SARA 304 RQ : Not applicable.

SARA 311/312

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Paracetamol	60 - 100	No.	No.	No.	Yes.	No.
Butalbital	10 - 30	No.	No.	No.	Yes.	No.
Caffeine	5 - 10	No.	No.	No.	Yes.	No.

State regulations

Massachusetts : The following components are listed: Cellulose; Silicon dioxide

New York : None of the components are listed.

New Jersey : The following components are listed: Cellulose

Pennsylvania : The following components are listed: Cellulose; Silicon dioxide; Dihydrogen (ethyl)[4-[[4-[ethyl(3-sulphonatobenzyl)amino]phenyl](2-sulphonatophenyl)methylene]cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl)Ammonium, Aluminium Salt

California Prop. 65

No products were found.

International regulations

International lists :

- Australia inventory (AICS)**: All components are listed or exempted.
- China inventory (IECSC)**: Not determined.
- Japan inventory**: All components are listed or exempted.
- Korea inventory**: Not determined.
- Malaysia Inventory (EHS Register)**: Not determined.
- New Zealand Inventory of Chemicals (NZIoC)**: All components are listed or exempted.
- Philippines inventory (PICCS)**: Not determined.
- Taiwan inventory (CSNN)**: Not determined.

Chemical Weapons Convention List Schedule I Chemicals : Not listed

Chemical Weapons Convention List Schedule II Chemicals : Not listed

Chemical Weapons Convention List Schedule III Chemicals : Not listed

Section 16. Other information

History

Date of issue mm/dd/yyyy : 02/15/2014

Version : 1

Revised Section(s) : Not applicable.

Prepared by : KMK Regulatory Services Inc.

Section 16. Other information

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

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.