SAFETY DATA SHEET

1. Identification

Product identifier **AUGMENTIN VIALS**

Other means of identification Not available.

Synonym(s) AUGMENTIN INTRAVENOUS 275 MG * AUGMENTIN INTRAVENOUS 550 MG * AUGMENTIN INTRAVENOUS 600 MG * AUGMENTIN INTRAVENOUS 1.1 GRAM * AUGMENTIN IV 1.2 GRAM * AUGMENTIN IV 2.2 GRAM * AUGMENTIN 5:1 INJECTION * AUGMENTIN 10:1 INJECTION * AUGMENTAN INFANT INJECTION 275 MG * AUGMENTAN IV 600 MG * AUGMENTAN IV 1.2 G * AUGMENTAN IV 2.2 G * CLAVULOX INJECTION * CLAVULIN INJECTION * PENILAN INJECTION * AMOXYCILLIN SODIUM AND POTASSIUM CLAVULANATE, FORMULATED PRODUCT

Recommended 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.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
AMOXYCILLIN SODIUM	AMOXICILLIN SODIUM SODIUM AMOXYCILLIN SODIUM [2S-[2.ALPHA.,5.ALPHA.,6.BETA.(S*)]]-6-[[AMINO(4-HYDROXYPHENYL)ACETYL]AMINO]-3,3-DIMETHYL-7-OXO-4-THIA-1-AZABICYCLO[3.2.0]HEPTANE-2-CARBOXYLATE (S*) MONOSODIUM [2S-[2.ALPHA.,5.ALPHA.,6.BETA.(S*)]]-6-[[AMINO(4-HYDROXYPHENYL)ACETYL]AMINO]-3,3-DIMETHYL-7-OXO-4-THIA-1-AZABICYCLO[3.2.0]HEPTAN-2-CARBOXYLATE	34642-77-8	83
POTASSIUM CLAVULANATE	POTASSIUM CLAVULANATE (STERILE) SKF-85472-Y BRL-14151MM-F ITEM NUMBER 8104750	61177-45-5	17

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation
If dust from the material is inhaled, remove the affected person immediately to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Skin contact
Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. For minor skin contact, avoid spreading material on unaffected skin.

Eye contact
Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.

Ingestion
Call a POISON CENTER or doctor/physician if you feel unwell.

Most important symptoms/effects, acute and delayed
Dusts may irritate the respiratory tract, skin and eyes. May cause an allergic skin reaction. Dermatitis. Rash. May cause allergic respiratory reaction.

Indication of immediate medical attention and special treatment needed
Provide general supportive measures and treat symptomatically. Symptoms may be delayed. Medical treatment in cases of overexposure should be treated as an overdose of penicillin antibiotic. In allergic individuals, exposure to this material may require treatment for initial or delayed allergic symptoms and signs. This may include immediate and/or delayed treatment of anaphylactic reactions. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre. This material may cause or aggravate allergy to penicillin antibiotics. The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should receive health surveillance focused on detecting respiratory symptoms and including respiratory function testing.
In the event of overexposure, individuals should receive post exposure health surveillance focused on detecting respiratory conditions and other allergy symptoms. Ocular symptoms may be indicative of allergic reaction. Pulmonary symptoms may indicate allergic reaction or asthma.

General information
In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media
Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media
None known.

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
Assume that this product is capable of sustaining combustion.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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
Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

Environmental precautions
Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling
Avoid contact with skin. Avoid contact with eyes. Avoid prolonged exposure. Avoid contact with clothing. Provide adequate ventilation. 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

GSK

Components	Type	Value	Note
AMOXYCILLIN SODIUM (CAS 34642-77-8)	15 MIN STEL	100 mcg/m3	
	OHC	3	SKIN SENSITISER
		3	RESPIRATORY SENSITISER
POTASSIUM CLAVULANATE (CAS 61177-45-5)	8 HR TWA	5000 mcg/m3	
	OHC	1	

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls 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. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed.

Hand protection The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

Other Not normally needed.

Respiratory protection When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state Solid.

Form Vial.

Color Not available.

Odor Not available.

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) 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	Not available.
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	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Expected to be a low ingestion hazard.
Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact	May cause an allergic skin reaction.
Eye contact	Direct contact with eyes may cause temporary irritation.
Symptoms related to the physical, chemical and toxicological characteristics	Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing), nausea, gastrointestinal distress, diarrhoea, dry mouth.

Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.

Components	Species	Test Results
POTASSIUM CLAVULANATE (CAS 61177-45-5)		
Acute		
Oral		
LD	Rat	> 5000 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Corrosivity

POTASSIUM CLAVULANATE	OECD 404 Result: Non-irritant

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.

Eye

POTASSIUM CLAVULANATE	OECD 405 Result: Non-Irritating

Respiratory or skin sensitization

Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitization May cause an allergic skin reaction.

Sensitization

AMOXYCILLIN SODIUM	Epidemiology Result: Positive Species: Human
POTASSIUM CLAVULANATE	Maximisation assay (Magnusson and Kligman) Result: Negative Species: Guinea pig SAR Result: No structural alerts identified.

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

Mutagenicity

POTASSIUM CLAVULANATE	Ames Result: Negative

Mutagenicity

POTASSIUM CLAVULANATE	Mouse Lymphoma Cell Assay Result: Negative SAR Result: No structural alerts identified.

Carcinogenicity Health injuries are not known or expected under normal use.

POTASSIUM CLAVULANATE	SAR Result: No structual alerts identified.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Health injuries are not known or expected under normal use.

Reproductivity

POTASSIUM CLAVULANATE	Fertility (IV) Result: Reproductive and developmental NOAEL 75 mg/kg/day Species: Rat Reproduction/Fertility Study (IV) Result: Reproductive performance NOAEL 150 mg/kg/day Species: Rabbit Reproduction/Fertility Study (IV) Result: Teratogenic and embryotoxic NOAEL 150 mg/kg/day Species: Rat

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Not likely, due to the form of the product.

Chronic effects Prolonged inhalation may be harmful.

Further information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity No information is available about the potential of this product to produce adverse environmental effects.

Components		Species	Test Results
AMOXYCILLIN SODIUM (CAS 34642-77-8)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	581 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	489 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 2123 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	2123 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	> 858 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	> 923 mg/l, 96 hours Static test
	NOEC	Bluegill sunfish (Adult Lepomis macrochirus)	858 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	923 mg/l, 96 hours Static test
POTASSIUM CLAVULANATE (CAS 61177-45-5)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	56 mg/L, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	9.4 mg/L, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	1610 mg/L, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	530 mg/L, 48 hours Static test

Components		Species	Test Results
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	> 790 mg/L, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	> 960 mg/L, 96 hours Static test
	NOEC	Bluegill sunfish (Adult Lepomis macrochirus)	790 mg/L, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	960 mg/L, 96 hours Static test

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Hydrolysis

Half-life (Hydrolysis-acidic)

POTASSIUM CLAVULANATE 11.9 Hours Measured

Half-life (Hydrolysis-basic)

POTASSIUM CLAVULANATE 9.92 Hours Measured

Half-life (Hydrolysis-neutral)

AMOXYCILLIN SODIUM 50 - 113 Days Measured

POTASSIUM CLAVULANATE 28.3 Hours Measured

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

POTASSIUM CLAVULANATE -5.8 (Estimated).

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

AMOXYCILLIN SODIUM -0.17 Estimated

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations. Dispose in accordance with all applicable regulations.

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.

Waste from residues / unused products 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 Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a dangerous good.

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 One or more components are not listed on TSCA.

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

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 No

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 regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

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)	No
Canada	Domestic Substances List (DSL)	No
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)	Yes
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)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply 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 05-30-2014

Revision date 05-30-2014

Version # 17

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings Health: 2*
Flammability: 1

NFPA ratings	Health: 2 Flammability: 1 Instability:
References	GSK Hazard Determination
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.
Revision Information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Transport Information: Material Transportation Information Regulatory Information: United States GHS: Classification