



SAFETY DATA SHEET

1. Identification

Product identifier	MenB VACCINE (RECONSTITUTED)
Other means of identification	
Product code	PENMENVY VACCINE
Synonyms	MenACWY AND MenB COMBINATION VACCINE * PENMENVY COMBINATION VACCINE * PENTA COMBINATION VACCINE * PENTA COMPONENT 2 of 2 * PENMENVY COMPONENT 2 of 2 * NDC 58160-750-03 LIQUID MenB * MenB, 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	

COMPANY NAME	GSK
Address:	410 Blackwell Street Durham, NC, 27701
Telephone:	+1-888-825-5249 (GSK General Inquiries) +1-877-844-8872 (ViiV General Inquiries)
Email:	msds@gsk.com
Website:	www.gsk.com

EMERGENCY CONTACTS

	3E GLOBAL INCIDENT RESPONSE
Telephone:	+(1) 760 476 3971 (In country) +(1) 760 476 3962 or +(1) 866 519 4752 (International) 24/7; multi-language response
Contract Number:	334878

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials.

Disposal	Dispose of waste and residues in accordance with local authority requirements.
Hazard(s) not otherwise classified (HNOC)	Caution - Pharmaceutical agent. See section 11 of the SDS for additional information on health hazards.
Supplemental information	2% of the mixture consists of component(s) of unknown acute dermal toxicity. 2% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 2% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
SUCROSE	SUGAR CANE SUGAR BEET SUGAR CONFECTIONER'S SUGAR ALPHA-D-GLUCOPYRANOSIDE, BETA-D-FRUCTOFURANOSYL GRANULATED SUGAR SUCRALOX	57-50-1	2
SODIUM CHLORIDE	COMMON SALT ROCK SALT SODIUM MONOCHLORIDE SALT SEA SALT TABLE SALT SALT, WHITE CRYSTALS, SOLAR	7647-14-5	0.625
ALUMINIUM HYDROXIDE	ALUMIGEL ALUMINA HYDRATED ALUMINA TRIHYDRATE ALPHA-ALUMINA TRIHYDRATE ALUMINIC ACID ALUMINIUM HYDROXIDE ALUMINUM HYDRATE ALUMINUM(III) HYDROXIDE ALUMINUM HYDROXIDE GEL ALUMINUM OXIDE TRIHYDRATE ALUMINUM TRIHYDRATE ALUMINUM TRIHYDROXIDE	21645-51-2	0.3
MenB287-953	RECOMBINANT NEISSERIA MENINGITIDIS SEROGROUP B NHBA (NEISSERIA HEPARIN BINDING ANTIGEN) FUSION PROTEIN RP287-953	NOT ASSIGNED	0.01
MenB936-741	RECOMBINANT NEISSERIA MENINGITIDIS SEROGROUP B fHBP (FACTOR H BINDING PROTEIN) FUSION PROTEIN RP936-741	NOT ASSIGNED	0.01
MENB961C	RECOMBINANT NEISSERIA MENINGITIDIS SEROGROUP B NadA (NEISSERIA ADHESIN A) PROTEIN RP961C	NOT ASSIGNED	0.01
SODIUM DESOXYCHOLATE	CHOLAN-24-OIC ACID, 3,12-DIHYDROXY-, MONOSODIUM SALT, (3.ALPHA.,5ß,12.ALPHA.)-	302-95-4	0
TRIS BUFFER	TRIS(HYDROXYMETHYL)AMINOMETHAN E 2- AMINO-2- (HYDROXYMETHYL) -1,3- PROPANEDIOL AMINOTRIMETHYLOLMETHANE AMINOTRIS(HYDROXYMETHYL)METHAN E TRIS (BUFFERING AGENT) 2-AMINO-2-HYDROXYMETHYL-1,3-PROP ANEDIOL TROMETAMOL	77-86-1	0

Chemical name	Common name and synonyms	CAS number	%
ETHYLENEDIAMINETETRAACETIC ACID	N,N'-1,2-ETHANEDIYLBIS(N-(CARBOXYMETHYL)GLYCINE (ETHYLENEDINITRILO)TETRAACETIC ACID VERSENE ACID EDTA ETHYLENEDIAMINE-TETRAACETIC ACID (EDTA) Edetic acid ETHYLENEDIAMINETETRAACETIC ACID AND SELECTED SALTS EDTA AND SALTS THEREOF	60-00-4	0
Other components below reportable levels			97.045

4. First-aid measures

Inhalation	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if irritation develops and persists.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Get medical attention if irritation develops and persists.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation.
Indication of immediate medical attention and special treatment needed	Treat symptomatically. No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water. 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. Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. 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. 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 prolonged exposure. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

GSK

Components	Type	Value	Form
ETHYLENEDIAMINETETRA ACETIC ACID (CAS 60-00-4)	8 HR TWA	3000 mcg/m3	
	OHC	1	
MenB287-953	OHC	3	>10 - <=100 mcg/m3 PROVISIONAL
MenB936-741	OHC	3	>10 - <= 100 mcg/m3 PROVISIONAL
MENB961C	OHC	3	>10 - <=100 mcg/m3 PROVISIONAL
SODIUM CHLORIDE (CAS 7647-14-5)	OHC	1	
SODIUM DESOXYCHOLATE (CAS 302-95-4)	OHC	2	>100 - <=1000 mcg/m3 PROVISIONAL
TRIS BUFFER (CAS 77-86-1)	OHC	1	>1000 - <=5000 mcg/m3 PROVISIONAL

US. OSHA Table Z-1 Permissible Exposure Limits (PEL) for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
SUCROSE (CAS 57-50-1)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. OSHA Table Z-3 Permissible Exposure Limits (PEL) for Mineral Dusts (29 CFR 1910.1000)

Components	Type	Value	Form
ALUMINIUM HYDROXIDE (CAS 21645-51-2)	TWA	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values (TLV)

Components	Type	Value	Form
ALUMINIUM HYDROXIDE (CAS 21645-51-2)	TWA	1 mg/m3	Respirable fraction.
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3	

US. NIOSH: Pocket Guide to Chemical Hazards Recommended Exposure Limits (REL)

Components	Type	Value	Form
SUCROSE (CAS 57-50-1)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

Biological limit values

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

Exposure guidelines

Appropriate engineering controls

Good general ventilation 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. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection

Not normally needed. Wear safety glasses with side shields (or goggles). Eye wash fountain is recommended.

Skin protection

Hand protection

Not normally needed. Wear appropriate chemical resistant gloves.

Other	Not normally needed. Wear suitable protective clothing.
Respiratory protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
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

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.
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Decomposition temperature	Not available.
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Viscosity	Not available.
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Other information

Explosive properties	Not established.
Oxidizing properties	Not established.
Percent volatile	96.9 % estimated

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
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Chemical stability	Material is stable under normal conditions.
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Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
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Conditions to avoid	Contact with incompatible materials.
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Incompatible materials	Strong oxidizing agents.
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Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. No hazardous decomposition products are known.
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11. Toxicological information

Information on likely routes of exposure

Inhalation	Prolonged inhalation may be harmful.
Skin contact	Prolonged skin contact may cause temporary irritation.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation.

Information on toxicological effects

Acute toxicity Not known.

Components	Species	Test Results
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SODIUM CHLORIDE (CAS 7647-14-5)

Acute

Oral

LD50	Rat	3000 mg/kg
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TRIS BUFFER (CAS 77-86-1)

Acute

Oral

LD50	Rat	5900 mg/kg
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Skin corrosion/irritation Due to partial or complete lack of data the classification is not possible.

Corrosivity

TRIS BUFFER

OECD 404
Result: Non-irritant
Species: Rabbit

Serious eye damage/eye irritation Due to partial or complete lack of data the classification is not possible.

Eye

TRIS BUFFER

OECD 405
Result: Non-irritant
Species: Rabbit

Respiratory or skin sensitization Due to partial or complete lack of data the classification is not possible.

Respiratory sensitization Due to partial or complete lack of data the classification is not possible.

Skin sensitization Due to partial or complete lack of data the classification is not possible.

Sensitization

TRIS BUFFER

OECD 406
Result: Negative
Species: Guinea pig

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

Mutagenicity

TRIS BUFFER

Ames Assay
Result: Negative
QSAR, Leadscope
Result: Negative

Carcinogenicity No data available to indicate product or any components present at greater than 0.1% are carcinogenic.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity	Due to partial or complete lack of data the classification is not possible.
Specific target organ toxicity - single exposure	Not assigned. Based on available data, the classification criteria are not met.
Specific target organ toxicity - repeated exposure	Not assigned. Based on available data, the classification criteria are not met.
Aspiration hazard	Due to partial or complete lack of data the classification is not possible.
Chronic effects	Prolonged inhalation may be harmful.
Further information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components	Species	Test Results
ALUMINIUM HYDROXIDE (CAS 21645-51-2)		
Aquatic		
<i>Acute</i>		
Algae	NOEC	Green algae (Selenastrum capricornutum) > 100 mg/l, 72 hours
Crustacea	NOEC	Water flea (Daphnia magna) > 100 mg/l, 48 hours
Fish	NOEC	Brown trout (Adult Salmo trutta) > 100 mg/l, 96 hours Static renewal test
ETHYLENEDIAMINETETRAACETIC ACID (CAS 60-00-4)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) 17 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna) 3.2 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus) 41.3 mg/l, 96 hours Static test
		Channel catfish (Adult Ictalurus punctatus) 129 mg/l, 96 hours Static test
		Fathead minnow (Adult Pimephales promelas) 59.8 mg/l, 96 hours Static test
SODIUM CHLORIDE (CAS 7647-14-5)		
Aquatic		
<i>Acute</i>		
Algae	EC50	Algae (Nitscheria linearis) 2430 mg/l, 5 days
Crustacea	EC50	Water flea (Daphnia magna) 3310 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Juvenile Lepomis macrochirus) 1295 mg/l, 96 hours Static test
		Fathead minnow (Juvenile Pimephales promelas) 6390 mg/l, 96 hours Static test
		Goldfish (Adult Carassius auratus) 7000 mg/l, 96 hours
		Mosquito fish (Adult Gambusia affinis) 17550 mg/l, 96 hours Static test

Persistence and degradability No data is available on the degradability of this product.

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ETHYLENEDIAMINETETRAACETIC ACID 37 %, 14 days Zahn-Wellens, Activated sludge
SUCROSE 69 % BOD5

Percent degradation (Aerobic biodegradation-ready)

ETHYLENEDIAMINETETRAACETIC ACID 28 %, 28 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

ETHYLENEDIAMINETETRAACETIC ACID 13 - 45 %, 15 weeks

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

ETHYLENEDIAMINETETRAACETIC ACID -3.86
SUCROSE -3

Bioconcentration factor (BCF)
ETHYLENEDIAMINETETRAACETIC ACID

0.8 - 1.8 Measured, Lepomis macrochirus, bluegill sunfish

Mobility in soil No data available.

Mobility in general

Volatility

Henry's law

ETHYLENEDIAMINETETRAACETIC ACID

< 0 Estimated

SUCROSE

< 0 atm m³/mol Estimated

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. 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). Avoid discharge into water courses or onto the ground.

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as a dangerous good.

Read safety instructions, SDS and emergency procedures before handling. Not available.

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 This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No (Exempt)

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**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. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	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)	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)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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** 11-17-2021**Revision date** 12-11-2024**Version #** 03**HMIS® ratings**
Health: 1
Flammability: 0
Physical hazard: 0**NFPA ratings**
Health: 1
Flammability: 0
Instability: 0**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: Synonyms
Exposure controls/personal protection: Eye/face protection
Toxicological information: Acute toxicity
Toxicological information: Aspiration hazard
Toxicological information: Corrosivity
Toxicological information: Eye contact
Toxicological information: Mutagenicity
Toxicological information: Reproductivity
Toxicological information: Respiratory or skin sensitization
Toxicological information: Respiratory sensitization
Toxicological information: Ingestion
Toxicological information: Inhalation
Toxicological information: Skin contact
Toxicological information: Skin contact