1. Identification

Product identifier: Q-QIV+ QUADRIVALENT VACCINE

Other means of identification: Not available.

Synonym(s): QUADRIVALENT INFLUENZA VACCINE WITH THIMEROSAL * FLULAVAL QUADRIVALENT * INFLUENZA VIRUS HEMAGGLUTININ

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
4. First-aid measures

Inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.

Skin contact

Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion

Rinse mouth thoroughly. Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Most important symptoms/effects, acute and delayed

The following adverse effects have been noted with therapeutic use of this material: anorexia; irritability; drowsiness; headache; sweating; joint pain; fatigue; shivering; sore throat; coughing; malaise.

Indication of immediate medical attention and special treatment needed

No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

General information

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

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

Move containers from fire area if you can do so without risk.

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 personal protective equipment. 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 MSDS.

Methods and materials for containment and cleaning up

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills in original containers for re-use. Water can be used for clean-up and decontamination operations. Sodium hypochlorite (bleach) or other strong oxidizers can be used in clean-up decontamination operations. Contaminated surfaces should be washed with water, then bleach or other oxidizing solution, followed by another water wash. For waste disposal, see section 13 of the MSDS.

Environmental precautions

Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS). Store at 2 to 8 °C (36 to 46 °F). Do not freeze. Dispose of properly if frozen.

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Not established

US. OSHA Table Z-2 (29 CFR 1910.1000)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)</td>
<td>Ceiling</td>
<td>0.04 mg/m³</td>
</tr>
<tr>
<td>ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)</td>
<td>TWA</td>
<td>0.01 mg/m³</td>
</tr>
</tbody>
</table>

US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)</td>
<td>STEL</td>
<td>0.03 mg/m³</td>
</tr>
</tbody>
</table>

US. NIOSH: Pocket Guide to Chemical Hazards

<table>
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<td>TWA</td>
<td>0.01 mg/m³</td>
</tr>
</tbody>
</table>

Biological limit values

<table>
<thead>
<tr>
<th>ACGIH Biological Exposure Indices</th>
<th>Value</th>
<th>Determinant</th>
<th>Specimen</th>
<th>Sampling Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)</td>
<td>35 µg/g</td>
<td>Total inorganic mercury</td>
<td>Creatinine in urine</td>
<td>*</td>
</tr>
<tr>
<td>ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)</td>
<td>15 micrograms/liter</td>
<td>Total inorganic mercury</td>
<td>Blood</td>
<td>*</td>
</tr>
</tbody>
</table>

* - For sampling details, please see the source document.
Exposure guidelines

US - Tennesse OELs: Skin designation
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT Can be absorbed through the skin.
(CAS 54-64-8)

US NIOSH Pocket Guide to Chemical Hazards: Skin designation
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT Can be absorbed through the skin.
(CAS 54-64-8)

Appropriate engineering controls
No particular ventilation requirements.

Individual protection measures, such as personal protective equipment

Eye/face protection
If contact is likely, safety glasses with side shields are recommended.

Hand protection
Use personal protective equipment as required. 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.

Respiratory protection
Not available.

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.

9. Physical and chemical properties

Appearance

Physical state
Liquid.

Form
Vaccine.

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)
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
The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability
Material is stable under normal conditions. DO NOT FREEZE - dispose of properly if frozen.
Possibility of hazardous reactions

Hazardous polymerization does not occur.

Conditions to avoid

Contact with incompatible materials.

Incompatible materials

Strong oxidizing agents.

Hazardous decomposition products

No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

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

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

Skin contact
Health injuries are not known or expected under normal use.

Eye contact
Health injuries are not known or expected under normal use.

Symptoms related to the physical, chemical and toxicological characteristics

The following adverse effects have been noted with therapeutic use of this material: anorexia; irritability; drowsiness; headache; sweating; fatigue; joint pain; shivering; sore throat; coughing; malaise.

Information on toxicological effects

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

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

Serious eye damage/eye irritation
Health injuries are not known or expected under normal use.

Respiratory sensitization
None known.

Skin sensitization
Not available.

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

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

Reproductive toxicity
This product is not expected to cause reproductive or developmental effects. Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

Specific target organ toxicity - single exposure
None known.

Specific target organ toxicity - repeated exposure
None known.

Aspiration hazard
None known.

Chronic effects
None known.

Further information
Caution - Pharmaceutical agent.

12. Ecological information

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

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

Bioaccumulative potential
No data available.

Mobility in soil
No data available.

Mobility in general
Not available.

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. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

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 a dangerous good.

IMDG
Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not listed.

SARA 304 Emergency release notification
Not regulated.

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

SARA 302 Extremely hazardous substance
No

SARA 311/312 Hazardous chemical
No

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA)
Not regulated.

Food and Drug Administration (FDA)
Not regulated.

US state regulations

US. Massachusetts RTK - Substance List
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

US. New Jersey Worker and Community Right-to-Know Act
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT 500 lbs (CAS 54-64-8)

US. Pennsylvania RTK - Hazardous Substances
Not regulated.

US. Rhode Island RTK
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

US. California Proposition 65
WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Developmental toxin
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT Listed: July 1, 1990 (CAS 54-64-8)

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
## Country(s) or region | Inventory name | On inventory (yes/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
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 | 10-31-2013 |
| Version # | 01 |
| Further information | This material has not been assessed for HMIS or NFPA ratings. |
| 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. |