

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Trade name or designation of the mixture FLULAVAL

Registration number -

Synonyms FLULAVAL (INFLUENZA VIRUS VACCINE) INTRAMUSCULAR INJECTION * VACCIN FLUVIRAL * GRIPLAVAL * INFLUENZA VIRUS VACCINE, TRIVALENT, INACTIVATED

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1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses 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.

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Directive 67/548/EEC or 1999/45/EC as amended**

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements**Label according to Regulation (EC) No. 1272/2008 as amended**

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

2.3. Other hazards

Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients**3.2. Mixtures**

General information

| Chemical name | % | CAS-No. / EC No. | REACH Registration No. | INDEX No. | Notes |
|--|-------------|--|------------------------|--------------|-------|
| ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT | < 0.1 | 54-64-8 200-210-4 | - | 080-004-00-7 | |
| Classification: | DSD: | T+;R26/27/28, R33, N;R50/53 | | | A,1 |
| | CLP: | Acute Tox. 2;H300, Acute Tox. 1;H310, STOT RE 2;H373, Aquatic Acute 1;H400, Aquatic Chronic 1;H410 | | | 1,A |
| INACTIVATED MONOVALENT SPLIT-VIRION DRUG SUBSTANCE, A/H1N1 | < 0.1 | | - | - | |
| Classification: | DSD: | - | | | |
| | CLP: | - | | | |
| INACTIVATED MONOVALENT SPLIT-VIRION DRUG SUBSTANCE, A/H3N2 | < 0.1 | | - | - | |
| Classification: | DSD: | - | | | |
| | CLP: | - | | | |
| INACTIVATED MONOVALENT SPLIT-VIRION DRUG SUBSTANCE, B STRAIN | < 0.1 | | - | - | |
| Classification: | DSD: | - | | | |
| | CLP: | - | | | |

Other components below reportable levels >99.0

List of abbreviations and symbols that may be used above

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

Composition comments

The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures**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.

4.1. Description of 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 symptoms occur.

Eye contact

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

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 centre immediately. Do not induce vomiting without advice from poison control center.

4.2. Most important symptoms and effects, both acute and delayed

The following adverse effects have been noted with therapeutic use of this material: headache; fatigue; fever; malaise.

4.3. Indication of any immediate medical attention and special treatment needed

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 centre.

SECTION 5: Firefighting measures

| | |
|---|---|
| General fire hazards | No unusual fire or explosion hazards noted. |
| 5.1. Extinguishing media | |
| Suitable extinguishing media | Water. Foam. Dry chemical powder. Carbon dioxide (CO2). |
| Unsuitable extinguishing media | None known. |
| 5.2. Special hazards arising from the substance or mixture | During fire, gases hazardous to health may be formed. |
| 5.3. Advice for firefighters | |
| Special protective equipment for firefighters | Self-contained breathing apparatus and full protective clothing must be worn in case of fire. |
| Special fire fighting procedures | 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. |

SECTION 6: Accidental release measures

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|---|---|
| 6.1. Personal precautions, protective equipment and emergency procedures | |
| For non-emergency personnel | Keep unnecessary personnel away. For personal protection, see section 8. |
| For emergency responders | Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS. |
| 6.2. Environmental precautions | Avoid discharge into drains, water courses or onto the ground. |
| 6.3. Methods and material for containment and cleaning up | <p>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. Following product recovery, flush area with water.</p> <p>Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.</p> <p>Never return spills to original containers for re-use.</p> |
| 6.4. Reference to other sections | For personal protection, see section 8. For waste disposal, see section 13 of the SDS. |

SECTION 7: Handling and storage

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|--|---|
| 7.1. Precautions for safe handling | Observe good industrial hygiene practices. |
| 7.2. Conditions for safe storage, including any incompatibilities | Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). |
| 7.3. Specific end use(s) | Medicinal Product. |

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Not established

Ireland. Occupational Exposure Limits

| Components | Type | Value |
|--|------|--|
| ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8) | STEL | 0.03 mg/m ³ |
| | TWA | 0.01 mg/m ³ |
| Biological limit values | | No biological exposure limits noted for the ingredient(s). |
| Recommended monitoring procedures | | Follow standard monitoring procedures. |
| Derived no-effect level (DNEL) | | Not available. |
| Predicted no effect concentrations (PNECs) | | Not available. |

Exposure guidelines

Ireland Exposure Limit Values: Skin designation

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT Can be absorbed through the skin.
(CAS 54-64-8)

8.2. Exposure controls

Appropriate engineering controls General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

| | |
|-------------------------------|---|
| General information | Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace. |
| Eye/face protection | If contact is likely, safety glasses with side shields are recommended. (e.g. EN 166). Not normally needed. |
| Skin protection | |
| - Hand protection | For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time). Not normally needed. |
| - Other | Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust). Not normally needed. |
| Respiratory protection | When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387). No personal respiratory protective equipment normally required. |
| Thermal hazards | Wear appropriate thermal protective clothing, when necessary. |
| Hygiene measures | 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. |

Environmental exposure controls

Hazard guidance and control recommendations Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

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|--|----------------|
| Physical state | Liquid. |
| Form | Vaccine. |
| Colour | Not available. |
| Odour | Not available. |
| Odour threshold | Not available. |
| pH | 7.1 |
| 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. |
| Vapour pressure | Not available |
| Vapour density | Not available |
| Relative density | Not available. |
| Solubility(ies) | |
| Solubility (water) | Not available. |
| Solubility (other) | Not available. |

| | |
|--|---|
| Partition coefficient (n-octanol/water) | Not available. |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available |
| Explosive properties | Not available. |
| Oxidizing properties | Not available. |
| 9.2. Other information | No relevant additional information available. |

SECTION 10: Stability and reactivity

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|---|--|
| 10.1. Reactivity | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| 10.2. Chemical stability | Material is stable under normal conditions. |
| 10.3. Possibility of hazardous reactions | No dangerous reaction known under conditions of normal use. |
| 10.4. Conditions to avoid | Contact with incompatible materials. |
| 10.5. Incompatible materials | Strong oxidising agents. |
| 10.6. Hazardous decomposition products | None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. |

SECTION 11: Toxicological information

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|----------------------------|--|
| General information | Occupational exposure to the substance or mixture may cause adverse effects. |
|----------------------------|--|

Information on likely routes of exposure

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|---------------------|---|
| Inhalation | Under normal conditions of intended use, this material is not expected to be an inhalation hazard. |
| Skin contact | Health injuries are not known or expected under normal use. |
| Eye contact | Health injuries are not known or expected under normal use. |
| Ingestion | Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure. |
| Symptoms | The following adverse effects have been noted with therapeutic use of this material: headache; fatigue; fever; malaise. |

11.1. Information on toxicological effects

| | |
|---|---|
| Acute toxicity | Expected to be a low hazard for usual industrial or commercial handling by trained personnel. |
| 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 sensitisation | No studies have been conducted. |
| Skin sensitisation | 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 | Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure. |
| Reproductive toxicity | Contains no ingredient listed as toxic to reproduction |
| 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. |
| Mixture versus substance information | No information available. |
| Other information | Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects. |

SECTION 12: Ecological information

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|--|--|
| 12.1. Toxicity | Not expected to be harmful to aquatic organisms. |
| 12.2. Persistence and degradability | Not available. |
| 12.3. Bioaccumulative potential | Not available. |
| Partition coefficient n-octanol/water (log Kow) | Not available. |

| | |
|---|----------------|
| Bioconcentration factor (BCF) | Not available. |
| 12.4. Mobility in soil | Not available. |
| Mobility in general | Not available. |
| 12.5. Results of PBT and vPvB assessment | Not available. |
| 12.6. Other adverse effects | Not available. |

SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|-------------------------------------|---|
| Residual waste | 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 | 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. |
| EU waste code | The Waste code should be assigned in discussion between the user, the producer and the waste disposal company. |
| Disposal methods/information | 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. |
| Special precautions | Dispose in accordance with all applicable regulations. |

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

| | |
|--|---|
| 14.7. Transport in bulk according to Annex II of MARPOL73/78 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. |
|--|---|

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

Directive 94/33/EC on the protection of young people at work

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws.
This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

Not available.

References

GSK Hazard Determination

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R26/27/28 Very toxic by inhalation, in contact with skin and if swallowed.
R33 Danger of cumulative effects.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
H300 Fatal if swallowed.
H310 Fatal in contact with skin.
H373 May cause damage to organs through prolonged or repeated exposure.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Revision information

Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Undisclosed Ingredient Statement
Physical & Chemical Properties:
Regulatory Information: United States
GHS: Classification

Training information

Follow training instructions when handling this material.

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.