SAFETY DATA SHEET

1. Identification

Product identifier **FLUTICASONE FUROATE/ VILANTEROL DRY POWDER INHALER**

Other means of identification

Synonyms RELVAR ELLIPTA * BREO ELLIPTA * REVINTY ELLIPTA * REVINTY ELLIPTA 184/22 MCG POLVO INH * FLUTICASONE FUROATE/VILANTEROL ELLIPTA * FLUTICASONE FUROATE/VILANTEROL INHALATION POWDER * FLUTICASONE FUROATE/VILANTEROL INHALATION POWDER (50/25MCG) * FLUTICASONE FUROATE/VILANTEROL INHALATION POWDER (100/25MCG) * FLUTICASONE FUROATE/ VILANTEROL TRIPHENYLACETIC ACID SALT, 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 GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

Telephone: +1-888-825-5249 (General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

VERISK 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

Reproductive toxicity	Category 1B
Specific target organ toxicity, repeated exposure	Category 2 (Adrenal, bone, eye, immune system)

Environmental hazards

Hazardous to the aquatic environment, long-term hazard	Category 2

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement May damage fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure. Toxic to aquatic life with long lasting effects.

Precautionary statement

Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If exposed or concerned: Get medical advice/attention. Collect spillage.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	Caution - Pharmaceutical agent. See section 11 of the SDS for additional information on health hazards.
Supplemental information	100% of the mixture consists of component(s) of unknown acute dermal toxicity. 100% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
LACTOSE, MONOHYDRATE	D-LACTOSE LACTOSE MONOHYDRATE NF ALPHA-LACTOSE A-LACTOSE MILK SUGAR LACTOHALE 200 ALPHA-LACTOSE MONOHYDRATE	64044-51-5	98 - < 100
FLUTICASONE FUROATE	GW685698X FURAN-2-CARBOXYLIC ACID 6,9-DIFLUORO-17-FLUOROMETHYLSULFANYLCARBONYL-11-HYDROXY-10,13,16-TRIMETHYL-3-OXO-6,7,8,9,10,11,12,13,14,15,16,17-DODECAHYDRO-3H-CYCLOPENTA(A)PHENANTHREN-17-YL ESTER (6ALPHA,11BETA,16ALPHA,17ALPHA)-6,9-DIFLUORO-17-{[(FLUOROMETHYL)THIO]CARBONYL}-11-HYDROXY-16-METHYL-3-OXOANDROSTA-1,4-DIEN-17-YL 2-FURANCARBOXYLATE	397864-44-7	0.4 - 3.2
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE	557-04-0	1
VILANTEROL TRIPHENYLACETIC ACID SALT	VILANTEROL TRIFENATATE (ALPHA1-R)-ALPHA1-[[[6-[2-[(2,6-DICHLOROPHENYL)METHOXY]ETHOXY] HEXYL] AMINO]METHYL]-4-HYDROXY-1,3-BENZENEDIMETHANOL, TRIPHENYLACETIC ACID SALT GW642444 TRIPHENYLACETIC ACID SALT GW642444M	503070-58-4	0.1 - 0.4

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

Most important symptoms/effects, acute and delayed	The following adverse effects have been noted with therapeutic use of this material: increased susceptibility to infection; headache; back pain; altered heart rate and pulse;; Coughing.
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 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.
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. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. 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	This material is classified as a water pollutant under the Clean Water Act and should be prevented from contaminating soil or from entering sewage and drainage systems which lead to waterways. 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 release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid prolonged exposure. Avoid release to the environment.
Conditions for safe storage, including any incompatibilities	Store in 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
FLUTICASONE FUROATE (CAS 397864-44-7)	8 HR TWA	2 mcg/m3	SKIN
	OHC	4	SKIN
LACTOSE, MONOHYDRATE (CAS 64044-51-5)	OHC	1	>1000 - </=5000 mcg/m3 PROVISIONAL
VILANTEROL TRIPHENYLACETIC ACID SALT (CAS 503070-58-4)	15 MIN STEL	20 mcg/m3	
	8 HR TWA	2 mcg/m3	
	OHC	4	

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.

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

Exposure guidelines

Appropriate engineering controls General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Other Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

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 Solid.

Form Powder.Inhaler.

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.

Other information

Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

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 related to the physical, chemical and toxicological characteristics	The following adverse effects have been noted with therapeutic use of this material:; headache; back pain; altered heart rate and pulse; pain;.

Information on toxicological effects

Acute toxicity

Product	Species	Test Results
FLUTICASONE FUROATE/ VILANTEROL DRY POWDER INHALER		
Subchronic		
Inhalation		
NOEL	Dog	2388 mcg/kg/day, 39 weeks estimated
		2325 mcg/kg/day, 13 weeks estimated
	Mouse	14750 mcg/kg/day, 13 weeks estimated
	Rat	14500 mcg/kg/day, 26 weeks estimated
		14000 mcg/kg/day, 13 weeks estimated

Components	Species	Test Results
FLUTICASONE FUROATE (CAS 397864-44-7)		
Acute		
Inhalation		
LCLo	Rat	> 0.133 mg/l
Oral		
LD50	Mouse	> 2000 mg/kg
	Rat	> 2000 mg/kg
Subacute		
Inhalation		
LOEL	Dog	<= 9 mg/kg/day, 4 weeks Pharmacological effects
	Rat	<= 6.9 mg/kg/day, 4 weeks Pharmacological effects

Components	Species	Test Results
Subchronic		
Inhalation		
LOEL	Dog	<= 13 mcg/kg/day, 39 weeks Pharmacological effects
	Rat	<= 20 mcg/kg/day, 26 weeks Pharmacological effects
LACTOSE, MONOHYDRATE (CAS 64044-51-5)		
Acute		
Oral		
LD50	Rat	> 10 g/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
VILANTEROL TRIPHENYLACETIC ACID SALT (CAS 503070-58-4)		
Acute		
Oral		
LD		> 300 mg/kg
Subchronic		
Inhalation		
NOAEL	Dog	62.5 mcg/kg/day, 39 weeks heart, respiratory tract irritation
		9.3 mcg/kg/day, 13 weeks heart, respiratory tract irritation
	Mouse	38200 mcg/kg/day, 13 weeks clinical signs, mortality
	Rat	658 mcg/kg/day, 13 weeks respiratory tract irritation
		58 mcg/kg/day, 26 weeks respiratory tract irritation
NOEL	Dog	< 9.3 mcg/kg/day, 13 weeks adrenergic effects
		< 9.55 mcg/kg/day, 39 weeks adrenergic effects
	Mouse	< 59 mcg/kg/day, 13 weeks adrenergic effects
	Rat	< 56 mcg/kg/day, 13 weeks adrenergic effects
		< 58 mcg/kg/day, 26 weeks adrenergic effects

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

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

FLUTICASONE FUROATE	OECD 404 Result: Negative Species: Rabbit
VILANTEROL TRIPHENYLACETIC ACID SALT	Reconstituted Human Epidermis Result: Negative

Irritation Corrosion - Skin: P.I.I. value

MAGNESIUM STEARATE	0

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye

FLUTICASONE FUROATE	0.05 % Acute Occular irritation Result: Negative Species: Rabbit Read across, Read across, Fluticasone propionate Result: Negative Species: Rabbit
VILANTEROL TRIPHENYLACETIC ACID SALT	Reconstituted Human Corneal Epithelium (HCE) Result: Negative

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE	4 Recovery Period: 2 days

Respiratory or skin sensitization

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

Skin sensitization This product is not expected to cause skin sensitization.

Sensitization

VILANTEROL TRIPHENYLACETIC ACID SALT	50 % OECD 429, Vehicle - Dimethyl formamide Result: Negative
FLUTICASONE FUROATE	Read across, Fluticasone propionate 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

FLUTICASONE FUROATE	Ames Result: Negative
VILANTEROL TRIPHENYLACETIC ACID SALT	Ames Result: Negative bacterial mutation assay (high throughput fluctuation test), GW642444H Result: Negative
FLUTICASONE FUROATE	Chromosomal aberration assay Result: Negative
VILANTEROL TRIPHENYLACETIC ACID SALT	L5178Y mouse lymphoma thymidine kinase locus assay, GW642444H Result: Negative L5178Y mouse lymphoma thymidine kinase locus assay, GW642444H, DNA damage occurred only at cytotoxic concentrations. Result: Positive Micronucleus Assay Result: Negative
FLUTICASONE FUROATE	Mouse Lymphoma Cell (L5178Y) Assay Result: Negative Rat Micronucleus Assay Result: Negative
VILANTEROL TRIPHENYLACETIC ACID SALT	Rat UDS assay, GW642444H Result: Negative Syrian Hamster Embryo (SHE) cell transformation assay, GW642444H Result: Negative

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure.

VILANTEROL TRIPHENYLACETIC ACID SALT	> 10.5 mcg/kg/day ICH S1B - Inhalation, NOAEL Result: Negative Species: Rat Test Duration: 104 weeks > 6.4 mcg/kg/day ICH S1B - Inhalation, NOAEL Result: Negative Species: Mouse Test Duration: 104 weeks

Carcinogenicity

VILANTEROL TRIPHENYLACETIC ACID SALT	> 62 mcg/kg/day ICH S1B - Inhalation, Species-specific Result: Positive Species: Mouse Organ: Uterus/ Ovary Test Duration: 104 weeks > 84.4 mcg/kg/day ICH S1B - Inhalation, Species-specific Result: Positive Species: Rat Organ: Pituitary/ Ovary Test Duration: 104 weeks
FLUTICASONE FUROATE	ICH S1B - Inhalation Result: Negative Species: Mouse ICH S1B - Inhalation Result: Negative Species: Rat

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 Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

Reproductivity

VILANTEROL TRIPHENYLACETIC ACID SALT	> 33700 mcg/kg/day Embryo-foetal development Species: Rat
FLUTICASONE FUROATE	>= 47 mcg/kg/day Embryofetal Development Result: Maternal weight loss/ Foetal abortion Species: Rabbit
VILANTEROL TRIPHENYLACETIC ACID SALT	10000 mcg/kg/day Pre- and Post-natal development Result: No developmental effects observed. Species: Rat
FLUTICASONE FUROATE	23 mcg/kg/day Embryofetal Development Result: NOAEL Species: Rat
VILANTEROL TRIPHENYLACETIC ACID SALT	30 mcg/kg/day Embryo-foetal development, sub-cutaneous administration Result: NOAEL Species: Rabbit 300 mcg/kg/day Embryo-foetal development, sub-cutaneous administration Species: Rabbit Organ: open eye 300 mcg/kg/day Embryo-foetal development, sub-cutaneous administration Species: Rabbit Organ: Skeletal effects 33700 mcg/kg/day Fertility, Male Result: No adverse effects on fertility. Species: Rat 37112 mcg/kg/day Fertility, Female Result: No adverse effects on fertility. Species: Rat
FLUTICASONE FUROATE	8 mcg/kg/day Embryofetal Development Result: NOAEL Species: Rabbit 91 mcg/kg/day Female Fertility / Early Embryonic Development Result: reduced foetal bodyweight, minor skeletal variations Species: Rat Male Fertility Result: No effect Species: Rat

Specific target organ toxicity - single exposure Not assigned.

Specific target organ toxicity - repeated exposure May cause damage to organs through prolonged or repeated exposure.

FLUTICASONE FUROATE — Read across, Glucocorticoid
Organ: Adrenals, Immune system, Bone, Eyes

Aspiration hazard Due to partial or complete lack of data the classification is not possible.

Chronic effects Prolonged inhalation may be harmful. May cause damage to organs through prolonged or repeated exposure.

Further information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity Contains a substance which causes risk of hazardous effects to the environment. Toxic to aquatic life with long lasting effects.

Components		Species	Test Results
FLUTICASONE FUROATE (CAS 397864-44-7)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 1000 mg/l, 3 hours Nominal, OECD 209
	NOEC	Residential sludge	1000, 3 hours Nominal
Crustacea	EC50	Water flea (Daphnia magna)	> 4.2 mg/l, 48 hours Static renewal test, OECD 202
	NOEC	Water flea (Daphnia magna)	4.2 mg/l, 48 hours Static renewal test
Chronic			
Fish	Growth test LOEC	Fathead minnow (Juvenile Pimephales promelas)	> 0.0006 mg/l, 118 days Measured, OECD 210/234
	Growth test NOEC	Fathead minnow (Juvenile Pimephales promelas)	0.0006 mg/l, 118 days
Terrestrial			
Acute			
Earthworm	EC50	Manure worm (Eisenia foetida)	> 1000 mg/kg, 14 days Measured, OECD 207
	NOEC	Manure worm (Eisenia foetida)	1000 mg/kg, 14 days
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
VILANTEROL TRIPHENYLACETIC ACID SALT (CAS 503070-58-4)			
Aquatic			
Acute			
Algae	EC50	Green algae (Pseudokirchnereilla subcapitata)	1.33 mg/l, 72 hours Nominal
	NOEC	Green algae (Pseudokirchnereilla subcapitata)	0.139 mg/l, 72 hours
Chronic			
Crustacea	LOEC	Water flea (Daphnia magna)	18.25 mg/l, 21 days semi-static test conditions
	NOEC	Water flea (Daphnia magna)	9.125 mg/l, 21 days
Fish	Growth test LOEC	Fathead minnow (Juvenile Pimephales promelas)	1.62 mg/l, 28 days Nominal
	Growth test NOEC	Fathead minnow (Adult Pimephales promelas)	0.54 mg/l, 28 days

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE	17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE	210 nm

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

FLUTICASONE FUROATE	0 %, 28 days Modified MITI (II) Test., Activated sludge
MAGNESIUM STEARATE	77 %, 28 days BOD

Percent degradation (Aerobic biodegradation-ready)

MAGNESIUM STEARATE	95 %, 22 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

FLUTICASONE FUROATE	2 - 3 %, 64 days, Soil
MAGNESIUM STEARATE	50 %, 13 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

FLUTICASONE FUROATE	2.61 (Measured).
VILANTEROL TRIPHENYLACETIC ACID SALT	1.39

Bioconcentration factor (BCF)

MAGNESIUM STEARATE	> 9999 Estimated

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

FLUTICASONE FUROATE	3.6 - 4.2 Measured
LACTOSE, MONOHYDRATE	1 Calculated
MAGNESIUM STEARATE	5.86 Estimated

Mobility in general Not available.

Volatility

Henry's law

LACTOSE, MONOHYDRATE	< 0 atm m3/mol Calculated

Distribution

Octanol/water distribution coefficient log DOW

VILANTEROL TRIPHENYLACETIC ACID SALT	0.09 Measured., pH 5 1.35 Measured., pH 7 1.39 Measured., pH 9

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.

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

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 Yes

Classified hazard categories Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

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.

16. Other information, including date of preparation or last revision

Issue date	05-15-2013
Revision date	09-15-2021
Version #	07
HMIS® ratings	Health: 2* Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 2 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 Hazard(s) identification: Disposal Composition / Information on Ingredients: Disclosure Overrides First-aid measures: Most important symptoms/effects, acute and delayed Handling and storage: Conditions for safe storage, including any incompatibilities Toxicological information: Symptoms related to the physical, chemical and toxicological characteristics