SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	TRELEGY ELLIPTA
Registration number	-
Synonyms	ELEBRATO ELLIPTA * FLUTICASONE FUROATE, UMECLIDINIUM BROMIDE, AND VILANTEROL TRIFENATATE, FORMULATED PRODUCT
Issue date	03-April-2018
Version number	01

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

Company name	GlaxoSmithKline UK
Address:	980 Great West Road Brentford, Middlesex TW8 9GS UK
Telephone:	+44-20-8047-5000 (General Inquiries)
Email:	msds@gsk.com
Website:	www.gsk.com

EMERGENCY CONTACTS

	CHEMTREC EMERGENCY NUMBERS
Telephone:	+(44)-870-8200418 (In country) +(1) 703 527 3887 (International) 24/7; multi-language response
Contract Number:	CCN9484
	VERISK 3E GLOBAL INCIDENT RESPONSE
Telephone:	+(44) 20 35147487 or 0 800 680 0425 (In country) +(1) 760 476 3961 (International) 24/7; multi-language response
Contract Number:	334878

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 of the SDS 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
FLUTICASONE FUROATE	< 1	397864-44-7 -	-	-	
Classification:	Repr. 1B;H360Df, Repr. 2;H361, STOT RE 2;H373, Aquatic Chronic 1;H410				
MAGNESIUM STEARATE	< 1	557-04-0 209-150-3	-	-	
Classification:	-				
UMECLIDINIUM BROMIDE	< 1	869113-09-7 -	-	-	
Classification:	Acute Tox. 4;H302, Acute Tox. 4;H332, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				
VILANTEROL TRIPHENYLACETIC ACID SALT	< 1	503070-58-4 -	-	-	
Classification:	STOT RE 2;H373, Aquatic Chronic 2;H411				

Other components below reportable levels 90 - 100

List of abbreviations and symbols that may be used above

#: This substance has been assigned Union workplace exposure limit(s).
M: M-factor
PBT: persistent, bioaccumulative and toxic substance.
vPvB: very persistent and very bioaccumulative substance.
All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments The full text for all H-statements 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. Diarrhoea. back pain, gastrointestinal distress. Coughing.

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

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel 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.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. 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.

6.3. Methods and material for containment and cleaning up Avoid the generation of dusts during clean-up. Collect dust using a vacuum cleaner equipped with HEPA filter. Prevent product from entering drains. Stop the flow of material, if this is without risk.

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal.

6.4. Reference to other sections For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Minimise dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Avoid prolonged exposure. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

7.2. 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).

7.3. Specific end use(s) Medicinal Product.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value	Note
FLUTICASONE FUROATE (CAS 397864-44-7)	8 HR TWA	6 mcg/m3	REPRODUCTIVE HAZARD, SKIN
	OHC	4	REPRODUCTIVE HAZARD, SKIN
	PDE	20 µg/day	(50kg person)
LACTOSE, MONOHYDRATE (CAS 64044-51-5)	OHC	1	>1000 - </=5000 mcg/m3 PROVISIONAL
UMECLIDINIUM BROMIDE (CAS 869113-09-7)	8 HR TWA	2 mcg/m3	
	Environmental PDE	100 µg/day	
	OHC	4	
	PDE	20 µg/day	(50kg person)
VILANTEROL TRIPHENYLACETIC ACID SALT (CAS 503070-58-4)	15 MIN STEL	20 mcg/m3	
	8 HR TWA	2 mcg/m3	
	OHC	4	
	PDE	5 µg/day	(50kg person)

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

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no effect levels (DNELs) Not available.

Predicted no effect concentrations (PNECs) Not available.

Exposure guidelines

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	Not normally needed. If contact is likely, safety glasses with side shields are recommended. (e.g. EN 166).
Skin protection	
- Hand protection	Not normally needed. 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).
- Other	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust).
Respiratory protection	No personal respiratory protective equipment normally required. 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).
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	Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Solid.
Form	Powder.Inhaler.Coiled blister strip.
Colour	Not available.
Odour	Not available.
Odour 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.
Vapour pressure	Not available.
Vapour 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.
Explosive properties	Not explosive.

Oxidising properties	Not oxidising.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

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

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

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.
Symptoms	The following adverse effects have been noted with therapeutic use of this material: Headache. back pain, gastrointestinal distress. Diarrhoea. Coughing.

11.1. Information on toxicological effects

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

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
Subchronic		
Inhalation		
LOEL	Dog	<= 13 mcg/kg/day, 39 weeks Pharmacological effects
	Rat	<= 20 mcg/kg/day, 26 weeks Pharmacological effects
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
UMECLIDINIUM BROMIDE (CAS 869113-09-7)		
Acute		
Oral		
LD	Mouse	1000 mg/kg, 3 Day
Subacute		
Oral		
LD	Rat	> 300 mg/kg/day, 14 Day
NOAEL	Rat	> 100 mg/kg/day, 14 Day

Components	Species	Test results
Subchronic		
Inhalation		
NOAEL	Dog	109 mcg/kg/day, 39 weeks
	Mouse	5 mcg/L/day, 13 weeks
	Rat	87.1 mcg/kg/day, 26 weeks
Oral		
NOAEL	Mouse	3 mg/kg/day, 13 weeks
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 Health injuries are not known or expected under normal use.

Corrosivity

FLUTICASONE FUROATE	OECD 404 Result: negative Species: Rabbit
UMECLIDINIUM BROMIDE	Reconstituted Human Epidermis Result: Mild
VILANTEROL TRIPHENYLACETIC ACID SALT	Reconstituted Human Epidermis Result: negative

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

MAGNESIUM STEARATE	0

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

Eye

FLUTICASONE FUROATE	0.05 % Acute Occular irritation Result: negative Species: Rabbit Read across, Read across, Fluticasone propionate Result: negative Species: Rabbit
UMECLIDINIUM BROMIDE	Reconstituted Human Corneal Epithelium (HCE) Result: Mild
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 sensitisation Health injuries are not known or expected under normal use.

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

Sensitisation

VILANTEROL TRIPHENYLACETIC ACID SALT	50 % OECD 429, Vehicle - Dimethyl formamide Result: negative
UMECLIDINIUM BROMIDE	Local lymph node assay, Vehicle - Propylene glycol Result: negative Species: Mouse
FLUTICASONE FUROATE	Read across, Fluticasone propionate Result: negative Species: Guinea pig

Germ cell mutagenicity Health injuries are not known or expected under normal use.

Mutagenicity

FLUTICASONE FUROATE	Ames Result: negative
UMECLIDINIUM BROMIDE	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
UMECLIDINIUM BROMIDE	L5178Y mouse lymphoma thymidine kinase locus 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
UMECLIDINIUM BROMIDE	Mouse micronucleus test Result: negative
FLUTICASONE FUROATE	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 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 > 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

Carcinogenicity

UMECLIDINIUM BROMIDE	ICH S1B - Inhalation Result: negative Species: Mouse Test Duration: 104 weeks
FLUTICASONE FUROATE	ICH S1B - Inhalation Result: negative Species: Rat
UMECLIDINIUM BROMIDE	ICH S1B - Inhalation Result: negative Species: Rat Test Duration: 104 weeks

Reproductive toxicity Health injuries are not known or expected under normal use. Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

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
UMECLIDINIUM BROMIDE	278 mcg/kg/day S5(R2) - Inhalation, NOAEL Result: negative 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
UMECLIDINIUM BROMIDE	306 mcg/kg/day S5(R2) - Inhalation, NOAEL Result: negative Species: Rabbit
VILANTEROL TRIPHENYLACETIC ACID SALT	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 Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure Not assigned.

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

Aspiration hazard Not an aspiration hazard.

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

12.1. Toxicity Contains a substance which causes risk of hazardous effects to the environment.

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
UMECLIDINIUM BROMIDE (CAS 869113-09-7)			
Aquatic			
Acute			
Algae	EC50	Green algae (Pseudokirchnereilla subcapitata)	0.3 mg/l, 72 hours Nominal
	NOEC	Green algae (Pseudokirchnereilla subcapitata)	0.074 mg/l, 72 hours
Chronic			
Crustacea	LOEC	Water flea (Daphnia magna)	11.86 mg/l, 21 days nominal
	NOEC	Water flea (Daphnia magna)	3.8 mg/l, 21 days
Fish	Growth test LOEC	Fathead minnow (Juvenile Pimephales promelas)	1.11 mg/l, 28 days Nominal
	Growth test NOEC	Fathead minnow (Juvenile Pimephales promelas)	0.37 mg/l, 28 days
VILANTEROL TRIPHENYLACETIC ACID SALT (CAS 503070-58-4)			
Aquatic			
Acute			
Algae	EC50	Green algae (Pseudokirchnereilla subcapitata)	1.33 mg/l, 72 hours Nominal
	NOEC	Algae	0.139 mg/l, 72 hours
Chronic			
Crustacea	LOEC	Water flea (Daphnia magna)	18.25 mg/l, 21 days semi-static test conditions
	NOEC	Daphnia	9.125 mg/l, 21 days
Fish	Growth test LOEC	Fathead minnow (Juvenile Pimephales promelas)	1.62 mg/l, 28 days Nominal

Components	Species	Test results
Growth test NOEC	Fish	0.54 mg/l, 28 days

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

12.2. 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

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

FLUTICASONE FUROATE	2.61 (Measured).
UMECLIDINIUM BROMIDE	1.26 (measured)
VILANTEROL TRIPHENYLACETIC ACID SALT	1.39

Bioconcentration factor (BCF)

MAGNESIUM STEARATE	> 9999 Estimated

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

FLUTICASONE FUROATE	3.6 - 4.2 Measured
MAGNESIUM STEARATE	5.86 Estimated

Mobility in general

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

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 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.

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

14.1. - 14.6.: Not regulated as dangerous goods.

RID

14.1. - 14.6.: Not regulated as dangerous goods.

ADN

14.1. - 14.6.: Not regulated as dangerous goods.

IATA

14.1. - 14.6.: Not regulated as dangerous goods.

IMDG

14.1. - 14.6.: Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

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 and II, as amended

Not listed.

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

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 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, as amended

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, as amended.

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Not listed.

Other regulations Pregnant women should not work with the product, if there is the least risk of exposure. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended. The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. Additional information is given in the Safety Data Sheet.

National regulations Follow national regulation for work with chemical agents. Young people under 18 years old are not allowed to work with this product according to EU Directive 94/33/EC on the protection of young people at work, as amended.

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 H-statements not written out in full under Sections 2 to 15	H302 Harmful if swallowed. H332 Harmful if inhaled. H360Df May damage the unborn child. Suspected of damaging fertility. H361 Suspected of damaging fertility. 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. H411 Toxic to aquatic life with long lasting effects.
Revision information	None.
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.