SAFETY DATA SHEET



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

1.1. Product identifier

Trade name or designation

RELVAR (ROW)/ BREO (US) ELLIPTA

of the mixture

Registration number

Synonyms RELVAR ELLIPTA * BREO ELLIPTA * FLUTICASONE FUROATE/VILANTEROL ELLIPTA *

> FLUTICASONE FUROATE/VILANTEROL INHALATION POWDER * FLUTICASONE FUROATE/VILANTEROL INHALATION POWDER (50/25MCG) * FLUTICASONE

FUROATE/VILANTEROL INHALATION POWDER (100/25MCG)

Issue date 15-May-2013

Version number 02

Revision date 15-May-2013

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 (by country / geographic region):

Africa / EU / Israel / Middle East

(English / European languages): +44 (0) 1235 239 670 Asia Pacific (except China): +65 3158 1074 China: +86 10 5100 3039 Middle East / Africa (Arabic-speaking countries): +44 (0) 1235 239 671

+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.

Supplemental label information None.

2.3. Other hazards Caution - Pharmaceutical agent.

This product is expected to be combustible, based on components present.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Material name: RELVAR (ROW)/ BREO (US) ELLIPTA SDS UK **General information**

Chemical name CAS-No. / EC No. REACH Registration No. INDEX No. **Notes**

FLUTICASONE FUROATE 0.4 - 3.2397864-44-7

Classification: **DSD:** Repr. Cat. 2;R61, Repr. Cat. 3;R62, Xn;R48/20/21

Repr. 1B;H360, Repr. 1B;H360D, Repr. 2;H361, Repr. 2;H361f, STOT RE 2;H373

MAGNESIUM STEARATE 1 557-04-0

209-150-3

Classification: **DSD:** Xi;R36/37/38

CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335

VILANTEROL 503070-58-4 0.1 - 0.4

DSD: N;R51/53 Classification:

CLP: STOT RE 2;H373, Aquatic Chronic 2;H411

Other components below reportable levels >95.0

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).

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

SECTION 4: First aid measures

General information If you feel unwell, seek medical advice (show the label where possible).

4.1. Description of first aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Get medical attention if symptoms occur.

4.2. Most important symptoms and effects, both acute and

delayed

The following adverse effects have been noted with therapeutic use of this material: increased susceptibility to infection; changes in clinical chemistry parameters; headache; inflamed nasal cavity; back pain; changes in blood pressure; altered heart rate and pulse; pain; coughing.

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

SECTION 5: Firefighting measures

General fire hazards This material is expected to be combustible.

5.1. Extinguishing media

Suitable extinguishing

Water fog. Foam. Dry chemical powder.

media

Unsuitable extinguishing

media

Carbon dioxide (CO2).

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

In the event of fire, cool tanks with water spray.

SECTION 6: Accidental release measures

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

MSDS.

6.2. Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Stop the flow of material, if this is without risk. Following product recovery, flush area with water.

6.4. Reference to other

sections

For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe

handling

Avoid prolonged exposure. Use care in handling/storage.

7.2. Conditions for safe storage, including any incompatibilities

Store in accordance with local/regional/national/international regulation. Store away from

incompatible materials (see Section 10 of the MSDS).

7.3. Specific end use(s) Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK Components	Туре	Value	Note
FLUTICASONE FUROATE (CAS 397864-44-7)	8 HR TWA	6 mcg/m3	
,	OHC	4	Reproductive hazard
		4	Skin
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
VILANTEROL (CAS 503070-58-4)	15 MIN STEL	20 mcg/m3	
	8 HR TWA	2 mcg/m3	
	ADE	5 μg/day	
	OHC	4	

Biological limit values

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

Recommended monitoring

procedures

Follow standard monitoring procedures.

Derived No Effect Level (DNEL)

Predicted no effect concentrations (PNECs)

Not available.

8.2. Exposure controls

Appropriate engineering

controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

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.

Eye/face protection Skin protection If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

- Hand protection For prolonged or repeated skin contact use suitable protective gloves. The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and

specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Glove selection must take into account any solvents and other hazards present. Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6

(>480min permeation time).

- Other Wear suitable protective clothing. (EN 14605 for splashes, EN ISO 13982 for dust)

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).

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Material name: RELVAR (ROW)/ BREO (US) ELLIPTA

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.

Environmental exposure controls

Hazard guidance and control recommendations Not available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state Solid.

Form Dry powder.Inhaler.

Colour Not available. Odour Not available. Not available. **Odour threshold** Not available. pН Not available. Melting point/freezing point

Initial boiling point and boiling range

Not available.

Not available. Flash point **Evaporation rate** Not available. Not available. Flammability (solid, gas) Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

(%)

Not available.

Not available. Vapour pressure Vapour density Not available. Not available. Relative density Not available. Solubility(ies)

Partition coefficient (n-octanol/water)

Not available.

Auto-ignition temperature Decomposition temperature Not available. Not available. Not available.

Viscosity Explosive properties Not available. Oxidizing properties Not available

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

10.6. Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

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

adverse effects.

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.

Material name: RELVAR (ROW)/ BREO (US) ELLIPTA

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

Eye contact

The following adverse effects have been noted with therapeutic use of this material: increased susceptibility to infection; changes in clinical chemistry parameters; headache; inflamed nasal cavity; back pain; changes in blood pressure; altered heart rate and pulse; pain; coughing.

11.1. Information on toxicological effects

Symptoms

Acute toxicity Health injur	es are not known or expected under normal use.
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Acute toxicity	Health injuries are not known or expected under no	
Components	Species	Test results
FLUTICASONE FUROATE (CAS 39	97864-44-7)	
Acute		
Inhalation		
LCLo	Rat	> 0.133 mg/l
Oral		
LD50	Mouse	> 2000 mg/kg
	Rat	> 2000 mg/kg
Subacute		
Inhalation		
LOEL	Dog	<= 10.4 mg/kg/day, 4 weeks, Pharmacological effects
		<= 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
		<= 11 mcg/kg/day, 13 weeks, Pharmacological effects
	Mouse	<= 7 mcg/kg/day, 13 weeks, Pharmacological effects
	Rat	<= 24 mcg/kg/day, 13 weeks, Pharmacological effects
		<= 20 mcg/kg/day, 26 weeks, Pharmacological effects
MAGNESIUM STEARATE (CAS 55	7-04-0)	· ·
Acute	,	
Oral		
LD50	Rat	> 2000 mg/kg
VILANTEROL (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

Material name: RELVAR (ROW)/ BREO (US) ELLIPTA

 Components
 Test results

 < 9.55 mcg/kg/day, 39 weeks, adrenergic effects</td>

 Mouse
 < 59 mcg/kg/day, 13 weeks, adrenergic effects</td>

 Rat
 < 56 mcg/kg/day, 13 weeks, adrenergic effects</td>

 < 58 mcg/kg/day, 26 weeks, adrenergic</td>

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

Corrosivity

FLUTICASONE FUROATE OECD 404

Result: negative Species: Rabbit

VILANTEROL Reconstituted Human Epidermis

Result: negative

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

MAGNESIUM STEARATE 0

Serious eye damage/eye irritation

Eve

FLUTICASONE FUROATE 0.05 % Acute Occular irritation

Result: negative Species: Rabbit

Read across, Read across, Fluticasone propionate

effects

Result: negative Species: Rabbit

VILANTEROL Reconstituted Human Corneal Epithelium (HCE)

Result: negative

Respiratory sensitisation Due to lack of data the classification is not possible.

Skin sensitisation

Sensitisation

VILANTEROL 50 % OECD 429, Vehicle - Dimethyl formamide

Result: negative

FLUTICASONE FUROATE Read across, Fluticasone propionate

Result: negative Species: Guinea pig

Germ cell mutagenicityNo data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Germ cell mutagenicity

Germ cell mutagenicity: Ames test

VILANTEROL ICH S 2 (R1)

Result: negative

Germ cell mutagenicity: Micronucleus

VILANTEROL ICH S 2 (R1)

Result: negative

Mutagenicity

FLUTICASONE FUROATE Ames

Result: negative

Chromosomal aberration assay

Result: negative

VILANTEROL 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

FLUTICASONE FUROATE Mouse Lymphoma Cell (L5178Y) Assay

Result: negative Rat Micronucleus Assay Result: negative

VILANTEROL Rat UDS assay, GW642444H

Result: negative

Material name: RELVAR (ROW)/ BREO (US) ELLIPTA

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

Mutagenicity

VILANTEROL Syrian Hamster Embryo (SHE) cell transformation assay,

GW642444H Result: negative

bacterial mutation assay (high throughput fluctuation test),

GW642444H Result: negative

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Not Carcinogenicity

classifiable as to carcinogenicity to humans.

> 10.5 mcg/kg/day ICH S1B - Inhalation, NOAEL **VILANTEROL**

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 ICH S1B - Inhalation Result: negative Species: Mouse

ICH S1B - Inhalation Result: negative Species: Rat

FLUTICASONE FUROATE

Reproductive toxicity

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

laboratory animals.

Reproductive toxicity

Developmental effects

VILANTEROL 30 mcg/kg/day S5(R2) Sub-cutaneous, NOAEL

> Result: negative Species: Rabbit

300 mcg/kg/day S5(R2) Sub-cutaneous

Result: positive Species: Rabbit Organ: Eye

300 mcg/kg/day S5(R2) Sub-cutaneous

Result: positive Species: Rabbit Organ: Skeleton

> 33700 mcg/kg/day S5(R2)

Result: negative Species: Rat

Fertility effects - Females

VILANTEROL > 10000 mcg/kg/day ICH S5(R2) Pre- and post-natal, oral

Result: negative Species: Rat

> 37112 mcg/kg/day ICH S5(R2), Inhalation

Result: negative Species: Rat

Fertility effects - Males

VILANTEROL > 33700 mcg/kg/day ICH S5(R2), Inhalation

Result: negative Species: Rat

Reproductivity

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

Material name: RELVAR (ROW)/ BREO (US) ELLIPTA

Reproductivity

FLUTICASONE FUROATE

>= 47 mcg/kg/day Embryofetal Development Result: Maternal weight loss/ Foetal abortion

> 1000 mg/l, 3 hours, Nominal

Species: Rabbit Male Fertility Result: No effect Species: Rat

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

Specific target organ toxicity -

single exposure

Heart.

Specific target organ toxicity -

repeated exposure

Immune system. Adrenal glands. Bone tissue.

Aspiration hazard

Due to lack of data the classification is not possible.

Mixture versus substance

information

12.1. Toxicity

Not available.

Other information Caution - Pharmaceutical agent.

IC50

SECTION 12: Ecological information

Components	Species	lest results
FLUTICASONE FUROATE (CAS 397864-44-7)		
Acute		
NOEC	Activated sludge	1000, 3 hours, Nominal

domestic sewage

Acute

Other

Crustacea EC50 Water flea (Daphnia magna) > 4.2 mg/l, 48 hours, Static renewal test **NOEC** Water flea (Daphnia magna) 4.2 mg/l, 48 hours, Static renewal test

Activated sludge of a predominantly

Terrestrial

Acute

Earthworm EC50 Manure worm (Eisenia foetida) > 1000 mg/kg, 14 days, Measured

> **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 130 mg/l, 96 hours latipes)

FC50 Microtox Microtox 12.5 mg/l, 15 minutes

VILANTEROL (CAS 503070-58-4)

Aquatic

Acute

Algae	EC50	Green algae (Pseudokirchnereilla	1.33 mg/l, 72 hours, Nominal
		subcapitata)	

NOEC Algae 0.139 mg/l, 72 hours

Chronic

LOEC Crustacea 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 1.62 mg/l, 28 days, Nominal

Fathead minnow (Juvenile Pimephales LOEC promelas)

Growth test Fish 0.54 mg/l, 28 days

NOEC

12.2. Persistence and

No data is available on the degradability of this product.

degradability

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

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

UV/visible spectrum wavelength

210 nm MAGNESIUM STEARATE

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)

95 %, 22 days Sturm test MAGNESIUM STEARATE

Percent degradation (Aerobic biodegradation-soil)

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

12.3. Bioaccumulative potential No data available for this product.

Partition coefficient n-octanol/water (log Kow)

> FLUTICASONE FUROATE 2.61 (Measured).

VILANTEROL 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 0.09 Measured., pH 5

1.35 Measured., pH 7 1.39 Measured., pH 9

Not available. 12.5. Results of PBT

and vPvB assessment

Not available. 12.6. Other adverse effects

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).

Contaminated packaging 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.

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 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. according to Annex II of

MARPOL73/78 and the IBC Code

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

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

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

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(1) 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

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

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

Not listed.

Other EU regulations

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

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

Always applicable.

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

Not regulated.

This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. Pregnant women should not work with the product, if there is the least risk of exposure.

The product is classified and labelled in accordance with EC directives or respective national laws.

National regulations Young people under 18 years old are not allow to work with this product according to the EU

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

15.2. Chemical safety

Other regulations

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

R36/37/38 Irritating to eyes, respiratory system and skin.

R48/20/21 Harmful: danger of serious damage to health by prolonged exposure through inhalation

and in contact with skin.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic

environment.

R61 May cause harm to the unborn child. R62 Possible risk of impaired fertility.

H315 Causes skin irritation.

Material name: RELVAR (ROW)/ BREO (US) ELLIPTA

H319 Causes serious eye irritation. H335 May cause respiratory irritation. H360 May damage the unborn child. H360D May damage the unborn child. H361 Suspected of damaging fertility. H361f Suspected of damaging fertility.

H373 May cause damage to organs through prolonged or repeated exposure.

H411 Toxic to aquatic life with long lasting effects.

Revision information Product and Company Identification: Synonyms

Composition / Information on Ingredients: Disclosure Overrides SECTION 9: Physical and chemical properties: <INDENT>Form

Regulatory Information: United States

Training information

Disclaimer

Follow training instructions when handling this material.

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.