SAFETY DATA SHEET

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

1.1. Product identifier

Name of the substance	DUTASTERIDE
Identification number	164656-23-9 (CAS number)
Registration number	-
Synonyms	GI198745X * 4A, 6A, 8-TRIMETHYL-2-OXO-2, 4A, 4B, 5, 6, 6A, 7, 8, 9, 9A, 10, 11, 11A-TETRADECAHYDRO-1H-INDENO(5,4-F)QUINOLINE-7-CARBOX YLIC ACID(2,5-BIS-TRIFLUOROMETHYLPHENYL)-AMIDE * 5-ARI * GG745
Issue date	18-December-2014
Version number	27
Revision date	02-February-2017
Supersedes date	18-December-2014

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

Identified uses	Active Pharmaceutical 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

Emai: Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

CHEMTREC TRANSPORT EMERGENCIES:
Customer Number: CCN9484
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

The substance has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

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

Health hazards		
Reproductive toxicity (the unborn child)	Category 1B	H360D - May damage the unborn child.
Reproductive toxicity (fertility)	Category 2	H361f - Suspected of damaging fertility.
Environmental hazards		
Hazardous to the aquatic environment, long-term aquatic hazard	Category 1	H410 - Very toxic to aquatic life with long lasting effects.

Hazard summary Caution - Pharmaceutical agent. May cause harm to the unborn child. Possible risk of impaired fertility. See section 11 for additional information on health hazards.
This material will support combustion. May form combustible dust concentrations in air.

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

2.2. Label elements

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

Contains: DUTASTERIDE

Hazard pictograms

Signal word Danger

Hazard statements

H360Df	May damage the unborn child. Suspected of damaging fertility.
H410	Very toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
Response	
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P391	Collect spillage.
Storage	
P405	Store locked up.
Disposal	
P501	Dispose of contents/container (in accordance with related regulations).

Supplemental label information None.

2.3. Other hazards This material will support combustion.
Ignition of dust clouds can produce explosions.
Caution - Pharmaceutical agent. See section 11 for additional information on health hazards. Dust clouds are very sensitive to electrostatic ignition.

SECTION 3: Composition/information on ingredients

3.1. Substances

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
DUTASTERIDE	90 - 100	164656-23-9 -	-	-	
Classification:	Repr. 1B;H360Df, Aquatic Chronic 1;H410				

List of abbreviations and symbols that may be used above

DSD: Directive 67/548/EEC.
CLP: Regulation No. 1272/2008.
#: This substance has been assigned Union workplace exposure limit(s).
#: This substance has been assigned Community 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 R- and H-phrases is displayed in section 16. The full text for all H-statements is displayed in section 16.

SECTION 4: First aid measures

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

4.1. Description of first aid measures

Inhalation	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, trained personnel should give oxygen. Get medical attention immediately.
Skin contact	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person.

4.2. Most important symptoms and effects, both acute and delayed Dusts may irritate the respiratory tract, skin and eyes. Rash.

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 This material will support combustion.

5.1. Extinguishing media

Suitable extinguishing media Water. Foam. Dry chemical powder. Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.

Unsuitable extinguishing media Carbon dioxide (CO_2).

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 case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers. Water runoff can cause environmental damage. Apply extinguishing media carefully to avoid creating airborne dust.

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. Use only non-sparking tools. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.

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. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Collect dust using a vacuum cleaner equipped with HEPA filter. Prevent entry into waterways, sewer, basements or confined areas.

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

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

7.1. Precautions for safe handling Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Minimise dust generation and accumulation. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Explosion-proof general and local exhaust ventilation. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Do not taste or swallow. Avoid prolonged exposure. When using, do not eat, drink or smoke. Should be handled in closed systems, if possible. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Do not empty into drains. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities Store in a cool, dry place out of direct sunlight. Keep away from heat, sparks and open flame. Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

7.3. Specific end use(s) Active Pharmaceutical Ingredient

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Material	Type	Value	Form
DUTASTERIDE (CAS 164656-23-9)	OHC	5	REPRODUCTIVE HAZARD, SKIN
		3 mcg/m3	REPRODUCTIVE HAZARD, SKIN

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.

8.2. Exposure controls

Appropriate engineering controls An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. It is strongly advised that dedicated areas and containment, such as glove boxes, isolators, and enclosed material transfer systems be used to prevent personnel exposure and spread of contamination. Explosion-proof general and local exhaust ventilation. If engineering measures are not sufficient to maintain concentrations of dust particulates below the OEL (occupational exposure limit), suitable respiratory protection must be worn.

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 Wear safety glasses with side shields (or goggles). (e.g. EN 166). Eye wash fountain is recommended.

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). The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Suitable gloves can be recommended by the glove supplier. Glove selection must take into account any solvents and other hazards present.

- Other Wear appropriate chemical resistant clothing. (EN 14605 for splashes, EN ISO 13982 for dust).

Respiratory protection If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. 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 Observe any medical surveillance requirements. When using, do not eat, drink or smoke. An occupational/industrial hygiene monitoring method has been developed for this material. 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. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

Environmental exposure controls

GSK environmental hazard category 4

Hazard guidance and control recommendations Contain spills and prevent releases and observe national regulations on emissions. Ensure discharge to the aquatic environment does not exceed the EHAC for this material.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Solid.
Form	Powder.
Colour	Pale Yellow.
Odour	Not available.
Odour threshold	Not available.
pH	5.2 - 5.9 (10 % suspension, 21 °C (69.8 °F))
Melting point/freezing point	249 °C (480.2 °F)
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	1.00E-08 Pa (25 °C (77 °F))
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	0.026 g/l (6 pH, Insoluble.)
Solubility (other)	chloroform, dimethyl sulphoxide, ethanol, ethyl acetate, tetrahydrofuran, methylene trichloride, methanol Insoluble in; ether, hexane.
Partition coefficient (n-octanol/water)	3.87 (6 pH)
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.
9.2. Other information	
Dissociation constant	> 13
Dust explosion properties	
Group	A
Pmax	8 bar
dP/dT	976 bar/s
Kst	265 bar.m/s
St class	2 (Tested at particle size < 75 micron)
Limiting Oxygen Concentration (LOC)	12 % v/v
Minimum explosible concentration (MEC)	60 g/m3
Minimum Ignition Energy (MIE) - dust cloud	10 - 13 mJ (Tested at particle size < 75 micron)
Minimum Ignition Temperature (MIT) - dust cloud	420 °C (788 °F)
Minimum Ignition Temperature (MIT) - dust layer	No ignition or exotherm observed up to 400 °C.

Electrostatic properties	
Charge relaxation time at ambient humidity	18455 s (50 %, 22 °C (71.6 °F))
Charge relaxation time at low humidity	1237854 s (15 %, 22 °C (71.6 °F))
Resistivity at ambient humidity	5.71E+14 ohm.m (50 %, 22 °C (71.6 °F))
Resistivity at low humidity	2.00E+15 ohm.m (15 %, 22 °C (71.6 °F))
Molecular formula	C27-H30-F6-N2-O2
Molecular weight	528.52
Oxygen balance	-203 (This material is considered to be of low energy hazard potential).
Temperature rating (T-rating)	
IEC	T3
USA	T2 A
Train fire	Non-combustible. (Supports localised combustion).

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. Avoid dispersion as a dust cloud. Keep away from heat, sparks and open flame. Heat, flames and sparks. Minimise dust generation and accumulation.
10.5. Incompatible materials	None known.
10.6. Hazardous decomposition products	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	May cause irritation to the respiratory system. Prolonged inhalation may be harmful.
Skin contact	Dust or powder may irritate the skin.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	May be harmful if swallowed.
Symptoms	Direct contact with eyes may cause temporary irritation. Dusts may irritate the respiratory tract, skin and eyes. Rash.

11.1. Information on toxicological effects

Acute toxicity May be harmful if swallowed.

Product	Species	Test results
DUTASTERIDE (CAS 164656-23-9)		
Acute		
Dermal		
MLD	Rabbit	> 2000 mg/kg
Oral		
MLD	Mouse	> 2000 mg/kg
Subacute		
Oral		
NOAEL	Rat	< 2 mg/kg, 30 days female
		2 mg/kg, 30 days male

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

Skin corrosion/irritation

Irritation Corrosion - Skin
Acute dermal irritation; OECD 404, Primary dermal irritation index = 0.1
Result: Slightly irritating
Species: Rabbit

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Eye
Acute ocular irritation; OECD 405
Result: Slight to moderate conjunctival irritation; some iridial involvement
Species: Rabbit

Respiratory sensitisation No studies have been conducted. Due to partial or complete lack of data the classification is not possible.

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

Sensitisation
Buehler assay
Result: negative
Species: Guinea pig

Germ cell mutagenicity Not expected to be genotoxic under occupational exposure conditions.

Mutagenicity
Ames Assay, GLP assay
Result: negative
Chromosomal Aberration Assay In Vitro, CHO cells
Result: negative
Micronucleus Test, GLP assay; maximum dose = 1500 mg/kg Result: negative
Species: Rat

Carcinogenicity Based on available data, the classification criteria are not met. Not expected to produce cancer in humans under occupational exposure conditions.

2 year bioassay
Result: negative
Species: Mouse
2 year bioassay, Female
Result: negative
Species: Rat
2 year bioassay, Male
Result: Increase in benign testicular interstitial cell tumours; high dose only (equivalent of 158X human therapeutic dose)
Species: Rat

Reproductive toxicity Suspected of damaging fertility. May damage the unborn child.

Reproductivity
Embryo-foetal development - Oral
Result: Evidence of feminisation of male foetuses with 0.05 mg/kg/day or more; maternal and foetal toxicity with 2.5 mg/kg/day or more
Species: Rat
Embryo-foetal development - Oral
Result: No maternal toxicity with doses </= 200 mg/kg/day; evidence of feminisation of male foetuses with doses >/= 0.05 mg/kg/day
Species: Rabbit
Female Fertility / Early Embryonic Development
Result: Maternal and foetal toxicity (increased foetal resorptions, decreased foeta weight, feminisation of male foetuses) with doses of 2.5 mg/kg/day or more
Species: Rat
Fertility, Male
Result: Decreased fertility with doses of 0.05 mg/kg/day for up to 31weeks
Species: Rat
Pre- and Post-natal development
Result: Maternal toxicty (reduced weight and lengthened gestation) at 2.5 mg/kg/day or more; no toxic effect dose in male offspring (feminisation) <0.05 mg/kg/day; no toxic effect dose in female offspring = 0.05 mg/kg/day with adverse effects at 2.5 mg/kg/day or
Species: Rat

Specific target organ toxicity - single exposure Due to partial or complete lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure Due to partial or complete lack of data the classification is not possible.

Aspiration hazard No studies have been conducted. 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

12.1. Toxicity Very toxic to aquatic life with long lasting effects. This material may have reproductive or developmental effects on environmental organisms.

Product		Species	Test results
DUTASTERIDE (CAS 164656-23-9)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 1000 mg/l, 3 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 1 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna)	> 1 mg/l, 48 hours
Chronic			
Fish	Growth test LOEC	Fathead minnow (Juvenile Pimephales promelas)	0.079 mg/l, 101 days Flow-through test, extended OECD 210
	Growth test NOEC	Fathead minnow (Juvenile Pimephales promelas)	0.021 mg/l, 101 days
Terrestrial			
Acute			
Earthworm	EC50	Manure worm (Eisenia foetida)	1010 mg/kg, 28 days
	NOEC	Manure worm (Eisenia foetida)	1010 mg/kg, 28 days

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

12.2. Persistence and degradability

Photolysis
UV/visible spectrum wavelength
300, pH 2-11

Biodegradability
Percent degradation (Aerobic biodegradation-ready)
< 1 %, 28 days Modified Sturm test
Percent degradation (Aerobic biodegradation-soil)
< 2.3 %, 64 days
Percent degradation (Anaerobic biodegradation)
12 %, 56 days

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)
3.87

12.4. Mobility in soil No data available.

Mobility in general

Volatility
Henry's law
0 atm m^3/mol Calculated, 25 C

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Potential for endocrine disruption in exposed organisms.

12.7. Additional information

GSK Environmental Hazard Assessment Concentration

Water: 2.1 µg/L

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	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. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. UN number	UN3077
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (DUTASTERIDE)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
Hazard No. (ADR)	90
Tunnel code	Not available.
14.4. Packing group	III
14.5. Environmental hazards	No.
14.6. Special precautions for user	Not available.

IATA

14.1. UN number	UN3077
14.2. UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (DUTASTERIDE)
14.3. Transport hazard class(es)	9
Subsidiary class(es)	-
14.4. Packing group	III
14.5. Environmental hazards	No.
Labels required	9
ERG Code	9L
14.6. Special precautions for user	Not available.
Other information	
Cargo aircraft only	Allowed with restrictions.
Additional Information:	
Passenger & cargo	Allowed with restrictions.

IMDG

14.1. UN number	UN3077
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (DUTASTERIDE), MARINE POLLUTANT
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
14.4. Packing group	III
14.5. Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F

14.6. Special precautions for user	Not available.
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.

ADR; IATA; IMDG

Marine pollutant

General information	Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

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.

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

Not listed.

Other EU regulations

Directive 2012/18/EU on 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, as amended

Not listed.

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

Not listed.

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, as amended.
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	Not applicable.
Full text of any H-statements not written out in full under Sections 2 to 15	H360Df May damage the unborn child. Suspected of damaging fertility. H410 Very toxic to aquatic life with long lasting effects.
Revision information	This document has undergone significant changes and should be reviewed in its entirety.
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.