



SAFETY DATA SHEET

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

1.1. Product identifier

Name of the substance	ANILINE ESA SALT
Identification number	-
Registration number	-
Synonyms	TERT-BUTYL (S)-3-(4-AMINOPHENYL)PIPERIDINE-1-CARBOXYLATE, ETHANE SULPHONIC ACID SALT * C12110912-H
Issue date	04-December-2020
Version number	01

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

Identified uses	Isolated Chemical Intermediate.
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

Telephone:	VERISK 3E GLOBAL INCIDENT RESPONSE +(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

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

Hazard summary	This material will support combustion. Caution - Pharmaceutical agent. See section 11 of the SDS for additional information on health hazards.
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2.2. Label elements

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

Contains:	ANILINE ESA SALT
Hazard pictograms	None.
Signal word	None.
Hazard statements	The substance does not meet the criteria for classification.

Precautionary statements

Prevention	Not available.
Response	Not available.
Storage	Not available.
Disposal	Not available.

Supplemental label information	100% of the substance consists of component(s) of unknown acute oral toxicity. 100% of the substance consists of component(s) of unknown acute dermal toxicity. 100% of the substance consists of component(s) of unknown acute inhalation toxicity. 100% of the substance consists of component(s) of unknown acute hazards to the aquatic environment. 100% of the substance consists of component(s) of unknown long-term hazards to the aquatic environment.
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2.3. Other hazards

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

SECTION 3: Composition/information on ingredients

3.1. Substances

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	Index No.	Notes
ANILINE ESA SALT	100	Unassigned	-	-	
Classification:	-				

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.

SECTION 4: First aid measures

General information

IF exposed or concerned: Get medical advice/attention. 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 If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop. If breathing is difficult, trained personnel should give oxygen.

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: immediately call a poison centre or doctor/physician. Do not induce vomiting without advice from poison control center.

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

Dusts may irritate the respiratory tract, skin and eyes. Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).

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.

Unsuitable extinguishing media Carbon dioxide (CO₂).

5.2. Special hazards arising from the substance or mixture

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. 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. 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 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 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. 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.
- Never return spills to original containers for re-use.
- 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. 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. Ground/bond container and receiving equipment. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Explosion-proof general and local exhaust ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
- 7.2. Conditions for safe storage, including any incompatibilities** 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)** Isolated Chemical Intermediate.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK Material	Type	Value	Note
ANILINE ESA SALT	OHC	3	>10 - ≤100 mcg/m ³ PROVISIONAL

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 Ventilate as needed to control airborne dust. Use explosion-proof ventilation equipment if airborne dust levels are high. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. 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** Use personal protective equipment as required. 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** 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.
 - **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	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	Good general ventilation 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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Solid.
Form	Powder.
Colour	Off-white.
Odour	Not available.
Odour threshold	Not available.
pH	2.4 - 2.5 (10 % solution, 20 °C (68 °F))
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	149 °C (300.2 °F)
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.

9.2. Other information

Dust explosion properties

Group	A
Pmax	8.7 bar
dP/dT	819 bar/s
Kst	222 bar.m/s
St class	2 (Tested at particle size < 75 micron)
Limiting Oxygen Concentration (LOC)	11 % v/v

Minimum explosible concentration (MEC)	60 g/m ³
Minimum Ignition Energy (MIE) - dust cloud	6 - 7 mJ (Tested at particle size < 75 micron)
Minimum Ignition Temperature (MIT) - dust cloud	460 °C (860 °F)
Minimum Ignition Temperature (MIT) - dust layer	No ignition or exotherm observed up to 400 °C.
Electrostatic properties	
Charge relaxation time at ambient humidity	281 s (50 %, 23 °C (73.4 °F))
Charge relaxation time at low humidity	17306 s (15 %, 23 °C (73.4 °F))
Resistivity at ambient humidity	6.30E+12 ohm.m (50 %, 23 °C (73.4 °F))
Resistivity at low humidity	3.10E+14 ohm.m (15 %, 23 °C (73.4 °F))
Molecular formula	C18-H30-N2-O5-S
Molecular weight	386.51
Oxygen balance	-190 (This material is considered to be of low energy hazard potential).
Temperature rating (T-rating)	
IEC	T2
USA	T2
Train fire	53 - 78 s

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	Keep away from heat, sparks and open flame. Contact with incompatible materials. Minimise dust generation and accumulation.
10.5. Incompatible materials	Strong oxidising agents.
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.
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Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system.
Skin contact	Dust or powder may irritate the skin.
Eye contact	Dust may irritate the eyes.
Ingestion	May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms	Dusts may irritate the respiratory tract, skin and eyes. Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).
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11.1. Information on toxicological effects

Acute toxicity	Due to partial or complete lack of data the classification is not possible.
Skin corrosion/irritation	Due to partial or complete lack of data the classification is not possible.
Serious eye damage/eye irritation	Due to partial or complete lack of data the classification is not possible.
Respiratory sensitisation	Due to partial or complete lack of data the classification is not possible.
Skin sensitisation	Due to partial or complete lack of data the classification is not possible.

Sensitisation

SAR, DEREK, Lhasa, UK
Result: Positive

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Mutagenicity

Ames
Result: Negative
Mouse Lymphoma Cell Assay
Result: Negative
SAR, DEREK, Lhasa, UK
Result: Negative

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

SAR, DEREK, Lhasa, UK
Result: Negative

Reproductive toxicity Due to partial or complete lack of data the classification is not possible.

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

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 The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

12.2. Persistence and degradability Not available.

12.3. Bioaccumulative potential No data available.

Partition coefficient n-octanol/water (log Kow) Not available.

Bioconcentration factor (BCF) Not available.

12.4. Mobility in soil No data available.

Mobility in general Not available.

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

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 Not applicable.

**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 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

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. 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 in accordance with Directive 98/24/EC, 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

None.

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.