

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

1.1. Product identifier

Trade name or designation of the mixture SENSODYNE MULTIACTION ISOACTIVE FOAM

Registration number -

Synonyms REINDEER BRIDGE * SENSODYNE BLACK REINDEER * MFC 02387 * SENSODYNE PRONAMEL AEROSOL * SENSODYNE PRONAMEL ACTIVE TOOTHGEL * MFC 02439 * SODIUM FLUORIDE AND POTASSIUM NITRATE, FORMULATED PRODUCT

Issue date 19-September-2014

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

Identified uses Oral Care

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::
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

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

Aerosol containers may violently rupture when exposed to the heat of fire.
Based on the ingredients and the result of the Foam Flammability Test, this product is unlikely to be considered a fire hazard.
See section 11 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
SIDENT	5 - < 10	7631-86-9 231-545-4	-	-	
Classification:	DSD: Xi;R36/37				
	CLP: Eye Irrit. 2;H319, STOT SE 3;H335				

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
ISOPENTANE	1 - < 3	78-78-4 201-142-8	-	601-085-00-2	#
Classification:	DSD: F+;R12, Xn;R65, R66-67, N;R51/53				C
	CLP: Flam. Liq. 1;H224, Asp. Tox. 1;H304, STOT SE 3;H336, Aquatic Chronic 2;H411				
TEGO BETAIN CK D	1 - < 3	61789-40-0 263-058-8	-	-	
Classification:	DSD: N;R50-51/53				
	CLP: Aquatic Acute 1;H400, Aquatic Chronic 2;H411				
CARVONE	< 1	2244-16-8 218-827-2	-	-	
Classification:	DSD: Xn;R22, R43				
	CLP: Acute Tox. 4;H302, Skin Sens. 1;H317				
XANTHAN GUM	< 1	11138-66-2 234-394-2	-	-	
Classification:	DSD: -				
	CLP: -				

Other components below reportable levels 80 - < 90

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).

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

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	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).

4.2. Most important symptoms and effects, both acute and delayed Direct contact with eyes may cause temporary irritation.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards Aerosol containers may violently rupture when exposed to the heat of fire. This product will support combustion.

5.1. Extinguishing media

Suitable extinguishing media	Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Water.

5.2. Special hazards arising from the substance or mixture Contents under pressure. Pressurised container may explode when exposed to heat or flame.

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	Containers should be cooled with water to prevent vapor pressure build up.
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. 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 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 Pressurised container: Do not pierce or burn, even after use. Do not use if spray button is missing or defective. Do not spray on a naked flame or any other incandescent material. Do not smoke while using or until sprayed surface is thoroughly dry. Do not cut, weld, solder, drill, grind, or expose containers to heat, flame, sparks, or other sources of ignition. Do not re-use empty containers. Avoid prolonged exposure. Use only in well-ventilated areas.

7.2. Conditions for safe storage, including any incompatibilities Level 1 Aerosol.
Contents under pressure. Do not expose to heat or store at temperatures above 120°F/49°C as can may burst. Do not puncture, incinerate or crush. Do not handle or store near an open flame, heat or other sources of ignition. Store away from incompatible materials (see Section 10 of the SDS).

7.3. Specific end use(s) Oral Care

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK Components	Type	Value
D-SORBITOL (CAS 50-70-4)	OHC	1
PEG 6 (CAS 2615-15-8)	OHC	2
XANTHAN GUM (CAS 11138-66-2)	OHC	1

Malta. OELs. Occupational Exposure Limit Values (L.N. 227. of Occupational Health and Safety Authority Act (CAP. 424), Schedules I and V)

Components	Type	Value
ISOPENTANE (CAS 78-78-4)	TWA	3000 mg/m3 1000 ppm

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU

Components	Type	Value
ISOPENTANE (CAS 78-78-4)	TWA	3000 mg/m3 1000 ppm

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	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	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.
Eye/face protection	Wear safety glasses with side shields (or goggles). (eg. EN 166)
Skin protection	
- 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 degradation that may occur under the circumstances of use. 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	In case of insufficient ventilation, wear suitable respiratory equipment. 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.
Environmental exposure controls	
Hazard guidance and control recommendations	Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Liquid.
Form	Aerosol Foam.
Colour	Light green.
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	25 °C (77 °F) Closed cup
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.
Solubility (other)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.

9.2. Other information

Aerosol foam

Flame duration	0 s
Flame height	0 cm
Percent volatile	52,7 % estimated

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. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
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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. 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	Direct contact with eyes may cause temporary irritation.
Symptoms	Direct contact with eyes may cause temporary irritation.

11.1. Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use.
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Components	Species	Test results
CARVONE (CAS 2244-16-8)		
Acute		
Oral		
LD50	Rat	1640 mg/kg
XANTHAN GUM (CAS 11138-66-2)		
Acute		
Inhalation		
LC50	Rat	> 21 mg/l, 1 hour exposure
Oral		
LD50	Rat	> 5000 mg/kg

* 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.
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.
Respiratory sensitisation	Not available.
Skin sensitisation	Health injuries are not known or expected under normal use.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	Health injuries are not known or expected under normal use. Not classifiable as to carcinogenicity to humans.

IARC Monographs. Overall Evaluation of Carcinogenicity

SIDENT (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.
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Reproductive toxicity	Health injuries are not known or expected under normal use. Contains no ingredient listed as toxic to reproduction
Specific target organ toxicity - single exposure	None known.
Specific target organ toxicity - repeated exposure	None known.

Aspiration hazard	Not available.
Mixture versus substance information	No information available.
Other information	Not available.

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.

Components		Species	Test results
SIDENT (CAS 7631-86-9)			
Aquatic			
<i>Acute</i>			
Crustacea	NOEC	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours
Fish	NOEC	Zebra fish (Adult Brachydanio rerio)	> 10000 mg/l, 96 hours
TEGO BETAIN CK D (CAS 61789-40-0)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Scenedesmus subspicatus)	0,55 mg/l, 96 hours
	NOEC	Green algae (Scenedesmus subspicatus)	0,09 mg/l, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	6,5 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna)	1,6 mg/l, 48 hours
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	2 mg/l, 96 hours semi-static test conditions
	NOEC	Zebra fish (Adult Brachydanio rerio)	1,7 mg/l, 96 hours semi-static test conditions
Microtox	MIC	Pseudomonas	> 3000 mg/l, 16 hours
<i>Chronic</i>			
Crustacea	LOEC	Water flea (Daphnia magna)	3,6 mg/l, 21 days
	NOEC	Water flea (Daphnia magna)	0,9 mg/l, 21 days
XANTHAN GUM (CAS 11138-66-2)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	420 mg/l, 96 hours Static test

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

12.2. Persistence and degradability No data is available on the degradability of this product.

Photolysis

Half-life (Photolysis-atmospheric)

CARVONE 2,7 Hours Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

TEGO BETAIN CK D 97 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge
99 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge

Percent degradation (Aerobic biodegradation-ready)

TEGO BETAIN CK D 100 %, 20 Days Modified Sturm test., Activated sludge
84 %, 30 days Closed Bottle test, Activated sludge

12.3. Bioaccumulative potential No data available.

Partition coefficient n-octanol/water (log Kow)

ISOPENTANE 3,27

Bioconcentration factor (BCF)

CARVONE 11 Estimated

12.4. Mobility in soil No data available.

Adsorption	
Soil/sediment sorption - log Koc	
CARVONE	1,93 Estimated
Mobility in general	Not available.
Volatility	
Henry's law	
CARVONE	0,000077 atm m ³ /mol Estimated
12.5. Results of PBT and vPvB assessment	Not available.
12.6. Other adverse effects	None known.

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. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
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. 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

General	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.
ADR	
14.1. UN number	UN1950
14.2. UN proper shipping name	Aerosols, non-flammable, (each not exceeding 1 L capacity)
14.3. Transport hazard class(es)	
Class	2.2
Subsidiary risk	-
Label(s)	2.2
Hazard No. (ADR)	Not available.
Tunnel code	Not available.
14.4. Packing group	Not applicable.
14.5. Environmental hazards	No.
14.6. Special precautions for user	Not available.
IATA	
14.1. UN number	UN1950
14.2. UN proper shipping name	Aerosols, non-flammable
14.3. Transport hazard class(es)	2.2
Subsidiary class(es)	-
14.4. Packing group	Not available.
Labels required	2
14.5. Environmental hazards	No.
ERG Code	2L
14.6. Special precautions for user	Not available.
Other information	
Cargo aircraft only	Allowed.
Additional Information:	
Passenger & cargo	Allowed.

IMDG

14.1. UN number	UN1950
14.2. UN proper shipping name	AEROSOLS, asphyxiant
14.3. Transport hazard class(es)	
Class	2
Subsidiary risk	5A
Label(s)	2
14.4. Packing group	Not applicable.
14.5. Environmental hazards	
Marine pollutant	No.
EmS	Not available.
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



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

Not listed.

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

Not listed.

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

Not listed.

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

Not listed.

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

ISOPENTANE (CAS 78-78-4)

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

ISOPENTANE (CAS 78-78-4)

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of 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

ISOPENTANE (CAS 78-78-4)

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

ISOPENTANE (CAS 78-78-4)

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.

National regulations

Follow national regulation for work with chemical agents.

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 statements or R-phrases and H-statements under Sections 2 to 15

R10 Flammable.
R12 Extremely flammable.
R22 Harmful if swallowed.
R36/37 Irritating to eyes and respiratory system.
R43 May cause sensitization by skin contact.
R50 Very toxic to aquatic organisms.
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R65 Harmful: may cause lung damage if swallowed.
R66 Repeated exposure may cause skin dryness or cracking.
R67 Vapours may cause drowsiness and dizziness.
H224 Extremely flammable liquid and vapour.
H302 Harmful if swallowed.
H304 May be fatal if swallowed and enters airways.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.

Revision information

Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Transport Information: Material Transportation Information
Regulatory Information: United States
GHS: Classification

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.